

#### **EUROPEAN COMMISSION**

Consumers, Health, Agriculture and Food Executive Agency

#### **GRANT AGREEMENT**

#### NUMBER — 761296 — EU-JAMRAI

This **Agreement** ('the Agreement') is **between** the following parties: **on the one part,** 

the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

represented for the purposes of signature of this Agreement by Veronique WASBAUER, Director, or his duly authorised representative,

#### and

# on the other part,

1. 'the coordinator':

**INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**, 180036048, established in RUE DE TOLBIAC 101, PARIS 75654, France, FR31180036048 represented for the purposes of signing the Agreement by Regional representative, Armelle BARELLI

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 40):

- 2. **MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE (MoH-FR)**, N/A, established in AVENUE DUQUESNE 14, PARIS CEDEX 75350, France, N/A
- 3. **GESUNDHEIT ÖSTERREICH GMBH (GÖG)** GMBH, FN281909Y, established in STUBENRING 6, WIEN 1010, Austria, ATU62777178
- 4. SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT (FPS HFCSE), N/A, established in SQUARE VICTOR HORTA 40 BUR 1D 1G, BRUSSELS 1060, Belgium, N/A
- 5. NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES (NCIPD ), 000662721, established in blvd. Yanko Sakazov 26, SOFIA 1504, Bulgaria
- 6. **HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH)**, 080407487, established in ROCKEFELLEROVA 7, ZAGREB 10000, Croatia, HR75297532041
- 7. **STATNI ZDRAVOTNI USTAV (NIPH)**, 75010330, established in Srobarova 48, PRAHA 10 10042, Czech Republic

- Associated with document Ref. Ares(2017)4194538 28/08/2017
- 8. **STATENS SERUM INSTITUT (SSI)**, 46837428, established in ARTILLERIVEJ 5, KOBENHAVN S 2300, Denmark, DK46837428
- 9. **TERVISEAMET (TA)**, 70008799, established in PALDISKI MNT 81, TALLINN 10617, Estonia, EE101339803
- 10. **ROBERT KOCH-INSTITUT (RKI)**, n/a, established in Nordufer 20, Berlin 13353, Germany
- 11. **KENTRO ELENCHOU & PROLIPSIS NOSIMATON (HCDCP)** GR8, 2071, established in AGRAFON STREET 3-5, MAROUSI 15123, Greece, EL090193594
- 12. **ETHNIKI SCHOLI DIMOSIAS YGEIAS (ESDY-NSPH)**, 2194, established in 196 ALEXANDRAS AVENUE, ATHINA 11521, Greece, EL099017070
- 13. **DIOIKHSH YGEIONOMIKHS PERIFEREIAS KRHTHS (7HC)**, ., established in 3RD KM NATIONAL ROAD HERAKLION MOIRES, HERAKLION 71500, Greece, EL999161778
- 14. UNIVERSITA DEGLI STUDI DI FOGGIA (UNIFG), CF94045260711, established in VIA GRAMSCI 89/91, FOGGIA 71122, Italy, IT03016180717
- 15. **ISTITUTO SUPERIORE DI SANITA (ISS)**, 80211730587, established in Viale Regina Elena 299, ROMA 00161, Italy
- 16. **PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA (PSKUS)** SIA, 40003457109, established in PILSONU IELA 13, RIGA 1002, Latvia, LV40003457109
- 17. **LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS (LSMULKK)** LT3, 135163499, established in EIVENIU 2, KAUNAS 50009, Lithuania, LT351634917
- 18. **VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS (VULSK)** LT3, 124364561, established in SANTARISKIU G 2, VILNIUS 08661, Lithuania, LT243645610
- 19. **HIGIENOS INSTITUTAS (HI)**, 111958286, established in DIDZIOJI STREET 22, VILNIUS LT-01128, Lithuania
- 20. NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS (NVSC), 291349070, established in KALVARIJU 153, VILNIUS LT-08221, Lithuania
- 21. **MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT (VWS)**, N/A, established in PARNASSUSPLEIN 5, DEN HAAG 2500 EJ, Netherlands
- 22. **HELSEDIREKTORATE (HdiR)**, 983544622, established in UNIVERSITETSGATA 2, OSLO 0164, Norway
- 23. **FOLKEHELSEINSTITUTTET (FHI)**, 983744516, established in LOVISENBERGGATA 8, OSLO 0456, Norway, NO983744516MVA
- 24. **VETERINAERINSTITUTTET NORWEGIAN VETERINARY INSTITUTE (NVI)**, 970955623, established in ULLEVALSVEIEN 68, OSLO 0454, Norway
- 25. NARODOWY INSTYTUT LEKOW (NMI), 015244176, established in ULICA CHELMSKA 30/34, WARSZAWA 00 725, Poland, PL5213212384

- Associated with document Ref. Ares(2017)4194538 28/08/2017
- 26. MINISTERIO DA SAUDE REPUBLICA PORTUGUESA (DGS), Decreto-Lei n.º 212/2006, de 27 de Outubro, established in Av. João Crisóstomo, 9, LISBOA 1049-062, Portugal
- 27. UNIVERSITATEA DE MEDICINA SI FARMACIE IULIU HATIEGANU CLUJ-NAPOCA (UMPIH), 263327, established in Emil Isac Street 13, Cluj-Napoca 400023, Romania, RO4288047
- 28. NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ) SI2, 6462642000, established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia, SI44724535
- 29. AGENCIA ESPANOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS), established in c/ Campezo Edificio 8 1, MADRID 28022, Spain, ESQ2827023I
- 30. **DEPARTAMENT DE SALUT GENERALITAT DE CATALUNYA (GENCAT)**, established in Trav. de les Corts (Pavelló Ave Maria) 131-159, BARCELONA 08028, Spain
- 31. **CONSELLERIA DE SALUD (IdISBa)** ES8, established in PLAZA DE ESPANA 9, PALMA DE MALLORCA 07002, Spain, ESS0711001H
- 32. FUNDACION PARA LA FORMACION E INVESTIGACION SANITARIAS DE LA REGION DE MURCIA (FFIS) ES3, 92, established in CALLE LUIS FONTES PAGAN 9 EDIF EMI HOSPITAL REINA SOFIA, MURCIA 30003, Spain, ESG73338857
- 33. **FUNDACION PUBLICA MIGUEL SERVET (FMS)** ES3, 406, established in CALLE IRUNLARREA 3 CENTRO INVESTIGACION BIOMEDICA RECINTO COMPLEJO HOSPITALARIO DE NAVARRA, PAMPLONA 31008, Spain, ESG31187420
- 34. **SERVICIO ANDALUZ DE SALUD (SAS)**, not applicable, established in AVENIDA DE LA CONSTITUCION 18, SEVILLA 41071, Spain, ESQ9150013B
- 35. **INSTITUTO DE SALUD CARLOS III (ISCIII)**, established in MONFORTE DE LEMOS 5, MADRID 28029, Spain, ESQ2827015E
- 36. **SERVICIO MADRILENO DE SALUD (SERMAS)**, 142005, established in PLAZA CARLOS TRIAS BERTRAN 7, MADRID 28020, Spain, ESQ2801221I
- 37. **FOLKHALSOMYNDIGHETEN (FoHM)**, 2021006545, established in NOBELS VAG 18, SOLNA 171 82, Sweden, SE202100654501
- 38. **SOCIALSTYRELSEN** (**SoS**), 2021000555, established in RALAMBSVAGEN 3, STOCKHOLM 106 30, Sweden, SE202100055501
- 39. **STATENS JORDBRUKSVERK (SBA)**, 2021004151, established in JONKOPING, JONKOPING 551 82, Sweden, SE202100415101
- 40. **LIVSMEDELS VERKET (NFA)**, 202100-1850, established in Hamnesplanaden 5, UPPSALA 751 26, Sweden
- 41. **STATENS VETERINAERMEDICINSKA ANSTALT (SVA)**, 2021001868, established in Ulls Vaeg 2B, UPPSALA 75189, Sweden
- 42. **VETENSKAPSRADET SWEDISH RESEARCH COUNCIL (SRC)**, 2021005208, established in VASTRA JARNVAGSGATAN 3, STOCKHOLM 111 64, Sweden
- 43. **UPPSALA LANS LANDSTING (UAS)**, 2321000024, established in PO BOX 602, UPPSALA 751 25, Sweden, SE232100002401

# 44. AGENCE NATIONALE DE LA SECURITE SANITAIRE DE L'ALIMENTATION DE L'ENVIRONNEMENT ET DU TRAVAIL (ANSES), 130012024, established in 14 RUE PIERRE ET MARIE CURIE, MAISONS ALFORT 94700, France, FR54130012024

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

By signing the Agreement or the Accession Form, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

Model for the certificate on the financial statements (CFS)

The Agreement is composed of:

#### Terms and Conditions

Annex 5

Annex 1	Description of the action
Annex 2	Estimated budget for the action
Annex 3	Accession Forms
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# **TERMS AND CONDITIONS**

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# CHAPTER 1 GENERAL

#### ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

#### **CHAPTER 2 ACTION**

#### ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled 'European Joint Action on antimicrobial resistance and associated infections — EU-JAMRAI' ('action'), as described in Annex 1.

#### ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be 36 months as of 01/09/2017 ('starting date of the action').

#### ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

#### 4.1 Estimated budget

The 'estimated budget' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary (and affiliated entity) and budget category (see Articles 5, 6).

#### 4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 39, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 10.

#### **CHAPTER 3 GRANT**

# ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

# 5.1 Maximum grant amount

The 'maximum grant amount' is EUR 4,178,162.75 (four million one hundred and seventy eight thousand one hundred and sixty two EURO and seventy five eurocents).

# 5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses 60% of the action's eligible costs (see Article 6) ('reimbursement of eligible costs grant') (see Annex 2).

The estimated eligible costs of the action are EUR **6,963,604.61** (six million nine hundred and sixty three thousand six hundred and four EURO and sixty one eurocents).

Eligible costs (see Article 6) must be declared under the following forms ('forms of costs' or 'costs forms'):

- (a) for direct personnel costs: as actually incurred costs (actual costs);
- (b) for direct costs of subcontracting: as actually incurred costs (actual costs);
- (c) for other direct costs: as actually incurred costs (actual costs);
- (d) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2.D ('flat-rate costs');

#### 5.3 Final grant amount — Calculation

The 'final grant amount' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the Agency — when the payment of the balance is made — in the following steps:

- Step 1 Application of the reimbursement rate to the eligible costs
- Step 2 Limit to the maximum grant amount
- Step 3 Reduction due to the no-profit rule
- Step 4 Reduction due to improper implementation or breach of other obligations

#### 5.3.1 Step 1 — Application of the reimbursement rate to the eligible costs

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries *and affiliated entities* (see Article 15) and approved by the Agency (see Article 16).

### 5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

# 5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

**'Profit'** means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The 'action's total eligible costs' are the consolidated total eligible costs approved by the Agency.

The 'action's total receipts' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

- (a) income generated by the action;
- (b) financial contributions given by third parties to the beneficiary or to an affiliated entity specifically to be used for costs that are eligible under the action.

The following are however **not** considered receipts:

- (a) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);
- (b) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted in proportion to the final rate of reimbursement of the eligible actual costs approved by the Agency (as compared to the amount calculated following Steps 1 and 2).

# 5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 27), the Agency will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 27.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or
- the reduced grant amount following Step 4.

# 5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 17) — the Agency rejects costs (see Article 26) or reduces the grant (see Article 27), it will calculate the 'revised final grant amount' for the action.

This amount is calculated by the Agency on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the Agency for the action, limiting it to the maximum grant amount and making a reduction if there is a profit (see Article 5.3);
- in case of **reduction of the grant**: by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 27.2) from the maximum grant amount set out in Article 5.1.

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the action will be the lower of the two amounts above.

#### ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

# 6.1 General conditions for costs to be eligible

'Eligible costs' are costs that meet the following criteria:

# (a) for actual costs:

- (i) they must be actually incurred by the beneficiary;
- (ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 15);
- (iii) they must be indicated in the estimated budget set out in Annex 2;
- (iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;
- (v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;
- (vi) they must comply with the applicable national law on taxes, labour and social security, and
- (vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;

#### (b) for flat-rate costs:

- (i) they must be calculated by applying the flat-rate set out in Annex 2, and
- (ii) the costs (actual costs) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

# 6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below, for each of the following budget categories:

- A. direct personnel costs;
- B. direct costs of subcontracting;
- C. other direct costs;
- D. indirect costs;

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point D below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

## A. Direct personnel costs

### Types of eligible personnel costs

A.1 Personnel costs are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action ('costs for employees (or equivalent)'). They must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

They may also include **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

- (a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;
- (b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.
- A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract or seconded by a third party against payment are eligible personnel costs, if:
  - (a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;
  - (b) the result of the work carried out belongs to the beneficiary, and
  - (c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

#### Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{hourly rate multiplied by the number of actual hours worked on the action}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 13).

The total number of hours declared in EU or Euratom grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate. Therefore, the maximum number of hours that can be declared for the grant are:

(the number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary, for that person for that year, for other EU or Euratom grants}.

The 'hourly rate' is the amount calculated as follows:

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{actual annual personnel costs for the person divided by number of annual productive hours}.
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The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

- (i) 'fixed number of hours': 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);
- (ii) 'individual annual productive hours': the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable collective labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) 'standard annual productive hours': the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

**B. Direct costs of subcontracting** (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if the conditions in Article 10.1.1 are met.

#### C. Other direct costs

- C.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible if they are in line with the beneficiary's usual practices on travel.
- C.2 The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 9.1.1 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

C.3 Costs of other goods and services (including related duties, taxes and charges, such as non-deductible value added tax (VAT) paid by beneficiaries that are not public bodies acting as public authority) are eligible, if they are purchased specifically for the action and in accordance with Article 9.1.1.

Such goods and services include, for instance, consumables and supplies, dissemination, protection of results, certificates on the financial statements (if they are required by the Agreement), translations and publications.

#### **D.** Indirect costs

**Indirect costs** are eligible if they are declared on the basis of the flat-rate of 7% of the eligible direct costs (see Article 5.2 and Points A to C above).

Beneficiaries receiving an operating grant<sup>1</sup> financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

### 6.3 Conditions for costs of affiliated entities to be eligible

Costs incurred by affiliated entities are eligible if they fulfil — mutatis mutandis — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 11.1.1.

<sup>&</sup>lt;sup>1</sup> For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('Financial Regulation No 966/2012'): 'operating grant' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

# 6.4 Ineligible costs

# 'Ineligible costs' are:

- (a) costs that do not comply with the conditions set out above (Article 6.1 to 6.3), in particular:
  - (i) costs related to return on capital;
  - (ii) debt and debt service charges;
  - (iii) provisions for future losses or debts;
  - (iv) interest owed;
  - (v) doubtful debts;
  - (vi) currency exchange losses;
  - (vii) bank costs charged by the beneficiary's bank for transfers from the Agency;
  - (viii) excessive or reckless expenditure;
  - (ix) deductible VAT;
  - (x) costs incurred during suspension of the implementation of the action (see Article 33);
  - (xi) in-kind contributions provided by third parties;
- (b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

# 6.5 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 26).

This may also lead to any of the other measures described in Chapter 6.

#### CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

# SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

#### ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

# 7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

### 7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

# ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION — THIRD PARTIES INVOLVED IN THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 9);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 10);
- call upon affiliated entities to implement action tasks described in Annex 1 (see Article 11).

In these cases, the beneficiaries retain sole responsibility towards the Agency and the other beneficiaries for implementing the action.

# ARTICLE 9 — PURCHASE OF GOODS, WORKS OR SERVICES

# 9.1 Rules for purchasing goods, works or services

9.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 20).

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their contractors.

9.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC<sup>2</sup> or 'contracting entities' within the meaning of Directive 2004/17/EC<sup>3</sup> must comply with the applicable national law on public procurement.

<sup>&</sup>lt;sup>2</sup> Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

# 9.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 9.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

If a beneficiary breaches any of its obligations under Article 9.1.2, the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### ARTICLE 10 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

# 10.1 Rules for subcontracting action tasks

10.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 20).

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The Agency may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 39), if:

- they are specifically justified in the periodic technical report and
- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their subcontractors.

10.1.2 The beneficiaries must ensure that their obligations under Articles 20, 21, 22 and 30 also apply to the subcontractors.

Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC or 'contracting entities' within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

# 10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 26).

<sup>&</sup>lt;sup>3</sup> Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### ARTICLE 11 — IMPLEMENTATION OF ACTION TASKS BY AFFILIATED ENTITIES

# 11.1 Rules for calling upon affiliated entities to implement part of the action

11.1.1 The following **affiliated entities**<sup>4</sup> may implement the action tasks attributed to them in Annex 1:

- Centre hospitalier universitaire de Limoges (CHU Limoges), affiliated or linked to INSERM
- UNIVERSITE DE LIMOGES (UL), affiliated or linked to INSERM
- University General Hospital of Heraklion General Hospital "Venizelei" o (GH Heraklion), affiliated or linked to 7HC
- Consejería de Salud-Región de Murcia (DGPIFAC), affiliated or linked to FFIS
- SERVICIO MURCIANO DE SALUD (SMS), affiliated or linked to FFIS
- FUNDACION PUBLICA ANDALUZA PARA LAGESTION DE LA INVESTIGACION EN SALUD DE SEVILLA (FISEVI), affiliated or linked to SAS
- FUNDACIÓN PARA LA INVESTIGACIÓN E INNOVACIÓN BIOMÉDICA DE ATENCIÓN PRIMARIA (FBRIPC), affiliated or linked to SERMAS

The affiliated entities may declare as eligible the costs they incur for implementing the action tasks in accordance with Article 6.3.

The beneficiaries must ensure that the Agency, the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) can exercise their rights under Articles 17 and 18 also towards their affiliated entities.

11.1.2 The beneficiaries must ensure that their obligations under Articles 13, 15, 20, 21 and 22 also apply to their affiliated entities.

#### 11.2 Consequences of non-compliance

If any obligation under Article 11.1.1 is breached, the costs of the affiliated entity will be ineligible (see Article 6) and will be rejected (see Article 26).

If any obligation under Article 11.1.2 is breached, the grant may be reduced (see Article 27).

<sup>&</sup>lt;sup>4</sup> For the definition, see Article 122 of the Financial Regulation (EU, Euratom) No 966/2012: **entities** affiliated **to the beneficiary** are:

<sup>(</sup>a) entities that form a 'sole beneficiary' (i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant);

<sup>(</sup>b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 131(4) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

Such breaches may also lead to any of the other measures described in Chapter 6.

# SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATIONFR

#### ARTICLE 12 — GENERAL OBLIGATION TO INFORM

# 12.1 General obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards and in accordance with Article 25.2 — any information requested in order to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

# 12.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (via the electronic exchange system; see Article 36) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the Agency and the other beneficiaries — of any of the following:

- (a) **events** which are likely to affect significantly or delay the implementation of the action or the EU's financial interests, in particular:
  - (i) changes in its legal, financial, technical, organisational or ownership situation *or those* of its affiliated entities and
  - (ii) changes in the name, address, legal form, organisation type of its affiliated entities;

# (b) circumstances affecting:

- (i) the decision to award the grant or
- (ii) compliance with requirements under the Agreement.

# 12.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### ARTICLE 13 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

# 13.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *three* years after the payment of the balance — keep records and other supporting documentation, in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 12) or in the context of checks, reviews, audits or investigations (see Article 17).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 17), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Agency may accept non-original documents if it considers that they offer a comparable level of assurance.

# 13.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on the technical implementation of the action, in line with the accepted standards in the respective field.

# 13.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

- (a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;
- (b) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate

In addition, for **personnel costs** (declared as actual costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *Agency* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

For costs declared by affiliated entities (see Article 11), it is the beneficiary that must keep the originals of the financial statements and the certificates on the financial statements of the affiliated entities.

# 13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 26), and the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### ARTICLE 14 — SUBMISSION OF DELIVERABLES

#### 14.1 Obligation to submit deliverables

The coordinator must submit the 'deliverables' identified in Annex 1 (if any), in accordance with the timing and conditions set out in it.

#### 14.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

#### ARTICLE 15 — REPORTING — PAYMENT REQUESTS

## 15.1 Obligation to submit reports

The coordinator must submit to the Agency (see Article 36) the technical and financial reports set out in this Article. These reports include the requests for payment and must be drawn up using the forms and templates provided in the electronic exchange system (see Article 36).

# 15.2 Reporting periods

The action is divided into the following 'reporting periods':

- RP1: from month 1 to month 18
- RP2: from month 19 to month 36

#### 15.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

#### (a) a 'periodic technical report' containing:

- (i) an **explanation of the work carried out** by the beneficiaries;
- (ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;

- (iii) a summary for publication by the Agency;
- (iv) the answers to the 'questionnaire', covering issues related to the action implementation and its impact, if required in Annex 1;

# (b) a 'periodic financial report' containing:

(i) an 'individual financial statement' (see Annex 4) from each beneficiary and from each affiliated entity, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries *and affiliated entities* must declare all eligible costs, even if — for actual costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the Agency.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary and each affiliated entity must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 13) that will be produced upon request (see Article 12) or in the context of checks, reviews, audits and investigations (see Article 17), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);
- (ii) an **explanation of the use of resources** and the information on subcontracting (see Article 10) from each beneficiary *and from each affiliated entity*, for the reporting period concerned;
- (iii) not applicable;
- (iv) a 'periodic summary financial statement' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including except for the last reporting period the request for interim payment.

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- (v) a 'certificate on the financial statements' (drawn up in accordance with Annex 5) for each beneficiary and for each affiliated entity, if:
  - the (cumulative) amount of payments it requests as reimbursement of actual costs (and for which no certificate has yet been submitted) is EUR 325 000 or more and
  - the maximum grant amount indicated, for that beneficiary *or affiliated entity*, in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.

# 15.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

- (a) a 'final technical report' with a summary for publication containing:
  - (i) an overview of the results and their dissemination;
  - (ii) the conclusions on the action and
  - (iii) the impact of the action;
- (b) a 'final financial report' containing:
  - (i) a 'final summary financial statement' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance and
  - (ii) a 'certificate on the financial statements' (drawn up in accordance with Annex 5) for each beneficiary *and for each affiliated entity*, if:
    - the cumulative amount of payments it requests as reimbursement of actual costs (and for which no certificate has been submitted) is EUR 325 000 or more and
    - the maximum grant amount indicated, for that beneficiary *or affiliated entity*, in the estimated budget (see Annex 2) as reimbursement of actual costs is EUR 750 000 or more.

# 15.5 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries and affiliated entities with accounting established in a currency other than the euro must convert the costs recorded in their accounts into euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries *and affiliated entities* with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

# 15.6 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

# 15.7 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the Agency may suspend the payment deadline (see Article 31) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the Agency, the Agreement may be terminated (see Article 34).

#### ARTICLE 16 — PAYMENTS AND PAYMENT ARRANGEMENTS

# 16.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;
- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 15), and
- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 15).

# 16.2 Pre-financing payment — Amount

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the EU until the payment of the balance.

The amount of the pre-financing payment will be EUR **1,253,448.83** (one million two hundred and fifty three thousand four hundred and forty eight EURO and eighty three eurocents).

The Agency will — except if Article 32 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 42) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

#### 16.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The Agency will pay to the coordinator the amount due as interim payment within 60 days from receiving the periodic report (see Article 15.3), except if Articles 31 or 32 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the Agency in the following steps:

```
Step 1 – Application of the reimbursement rate
```

Step 2 – Limit to 90% of the maximum grant amount

### 16.3.1 Step 1 — Application of the reimbursement rate

The reimbursement rate (see Article 5.2) is applied to the eligible costs (actual costs and flat-rate costs; see Article 6) declared by the beneficiaries *and the affiliated entities* (see Article 15) and approved by the Agency (see above) for the concerned reporting period.

# 16.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

```
{90% of the maximum grant amount (see Article 5.1) minus {pre-financing and previous interim payments}}.
```

### 16.4 Payment of the balance — Amount — Calculation

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 28).

If the total amount of earlier payments is lower than the final grant amount, the Agency will pay the balance within 60 days from receiving the final report (see Article 15.4), except if Articles 31 or 32 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the Agency by deducting the total amount of prefinancing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

```
{final grant amount (see Article 5.3)
minus
{pre-financing and interim payments (if any) made}}.
```

If the balance is positive, it will be paid to the coordinator.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed by a beneficiary to the Agency, the Commission or another executive agency (under the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

If the balance is negative, it will be recovered.

#### 16.5 Notification of amounts due

When making payments, the Agency will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 27 and 28.

#### 16.6 Currency for payments

The Agency will make all payments in euro.

# 16.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the Agency from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

- (a) if 90% of the beneficiaries have acceded to the Agreement (see Article 40) and
- (b) to beneficiaries that have acceded to the Agreement (see Article 40).

#### 16.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: TRESOR PUBLIC

Address of branch: PL OCCITANE TOULOUSE, France

Full name of the account holder: AGENT COMPTABLE SECONDAIREDE L INSERM

Full account number (including bank codes): IBAN code: FR7610071310000000100135407

#### 16.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the Agency bears the cost of transfers charged by its bank;

- the beneficiary bears the cost of transfers charged by its bank;
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

#### 16.10 Date of payment

Payments by the Agency are considered to have been carried out on the date when they are debited to its account.

# 16.11 Consequences of non-compliance

16.11.1 If the Agency does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 31 and 32) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

16.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or the participation of the coordinator may be terminated (see Article 34).

Such breaches may also lead to any of the other measures described in Chapter 6.

# ARTICLE 17 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

#### 17.1 Checks, reviews and audits by the Agency and the Commission

#### 17.1.1 Right to carry out checks

The Agency or the Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose, the Agency or the Commission may be assisted by external persons or bodies.

The Agency or the Commission may also request additional information in accordance with Article 12. The Agency or the Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

# 17.1.2 Right to carry out reviews

The Agency or the Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports) and compliance with the obligations under the Agreement.

Reviews may be started **up to** *three* **years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 9, 10, 11), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Agency or the Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a 'review report' will be drawn up.

The Agency or the Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('contradictory review procedure').

Reviews (including review reports) are in the language of the Agreement.

#### 17.1.3 Right to carry out audits

The Agency or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to** *three* **years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification

If the audit is carried out on a third party (see Articles 9, 10, 11), the beneficiary concerned must inform the third party.

The Agency or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Agency or the Commission may request beneficiaries to provide such information to it directly.

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a 'draft audit report' will be drawn up.

The Agency or the Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('contradictory audit procedure'). This period may be extended by the Agency or the Commission in justified cases.

The 'final audit report' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Agency or the Commission may also access the beneficiaries' statutory records for the periodical assessment of flat-rate amounts.

#### 17.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013<sup>5</sup> and No 2185/96<sup>6</sup> (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

<sup>&</sup>lt;sup>5</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 232, 18.09.2013, p. 1).

<sup>&</sup>lt;sup>6</sup> Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

#### 17.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 161 of the Financial Regulation No 966/2012<sup>7</sup>, the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

17.4 Checks, reviews, audits and investigations for international organisations

Not applicable

# 17.5 Consequences of findings in checks, reviews, audits and investigations —Extension of findings

#### 17.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 39).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('extension of findings from this grant to other grants').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

#### 17.5.2 Findings in other grants

The Agency or the Commission may extend findings from other grants to this grant ('extension of findings from other grants to this grant'), if:

- (a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and
- (b) those findings are formally notified to the beneficiary concerned together with the list of grants affected by the findings no later than three years after the payment of the balance of this grant.

<sup>&</sup>lt;sup>7</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ('Financial Regulation No 966/2012') (OJ L 298, 26.10.2012, p. 1).

The extension of findings may lead to the rejection of costs (see Article 26), reduction of the grant (see Article 27), recovery of undue amounts (see Article 28), suspension of payments (see Article 32), suspension of the action implementation (see Article 33) or termination (see Article 34).

#### 17.5.3 Procedure

The Agency or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

- 17.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:
  - (a) an invitation to submit observations on the list of grants affected by the findings;
  - (b) the request to submit revised financial statements for all grants affected;
  - (c) the **correction rate for extrapolation** established by the Agency or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected, if the beneficiary concerned:
    - (i) considers that the submission of revised financial statements is not possible or practicable or
    - (ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Agency or the Commission in justified cases.

The Agency or the Commission may then start a rejection procedure in accordance with the procedure set out in Article 26, either on the basis of the revised financial statements or the rate announced.

- 17.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:
  - (a) an invitation to submit observations on the list of grants affected by the findings and
  - (b) the flat-rate the Agency or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The Agency or the Commission may then start a reduction procedure in accordance with the procedure set out in Article 27, either on the basis of the alternative flat-rate or the flat-rate announced.

# 17.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 26).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### ARTICLE 18 — EVALUATION OF THE IMPACT OF THE ACTION

#### 18.1 Right to evaluate the impact of the action

The Agency or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the EU programme.

Evaluations may be started during implementation of the action and **up to** *three* **years after the payment of the balance**. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Agency or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

### 18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Agency may apply the measures described in Chapter 6.

#### **SECTION 3 OTHER RIGHTS AND OBLIGATIONS**

# ARTICLE 19 — PRE-EXISTING RIGHTS AND OWNERSHIP OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

# 19.1 Pre-existing rights and access rights to pre-existing rights

Where industrial and intellectual property rights (including rights of third parties) exist prior to the Agreement, the beneficiaries must establish a list of these pre-existing industrial and intellectual property rights, specifying the owner and any persons that have a right of use.

The coordinator must — before starting the action — submit this list to the Agency.

The beneficiaries must give each other (and their affiliated entities) access to any pre-existing industrial and intellectual property rights needed for the implementation of the action and compliance with the obligations under the Agreement.

# 19.2 Ownership of results and rights of use

The results of the action (including the reports and other documents relating to it) are owned by the beneficiaries.

The beneficiaries must give the Agency and the Commission the right to use the results for their communication activities under Article 22.

#### 19.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

Such a breach may also lead to any of the other measures described in Chapter 6.

#### **ARTICLE 20 — CONFLICT OF INTERESTS**

# 20.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests').

They must formally notify to the Agency without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The Agency may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

### 20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27) and the Agreement or participation of the beneficiary may be terminated (see Article 34).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### **ARTICLE 21 — CONFIDENTIALITY**

### 21.1 General obligation to maintain confidentiality

During implementation of the action and for **five years after the payment of the balance**, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed (**'confidential information'**).

They may use confidential information to implement the Agreement.

The confidentiality obligations no longer apply if:

- (a) the disclosing party agrees to release the other party;
- (b) the information becomes generally and publicly available, without breaching any confidentiality obligation;
- (c) the disclosure of the confidential information is required by EU or national law.

# 21.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

# ARTICLE 22 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

#### 22.1 Communication activities by the beneficiaries

#### 22.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results.

# 22.1.2 Information on EU funding — Obligation and right to use of the EU emblem

Unless the Agency requests or agrees otherwise, any communication activity related to the action (including at conferences, seminars, in information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via social media, etc.) and any infrastructure, equipment or major results funded by the grant must:

- (a) display the EU emblem and
- (b) include the following text:

"This [insert appropriate description, e.g. report, publication, conference, infrastructure, equipment, insert type of result, etc.] is part of the project / joint action '761296 / EU-JAMRAI' which has received funding from the European Union's Health Programme (2014-2020)."

When displayed in association with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

#### 22.1.3 Disclaimer excluding Agency/Commission responsibility

Any communication activity related to the action must indicate the following disclaimer:

"The content of this [insert appropriate description, e.g. report, publication, conference, etc.] represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains."

#### 22.2 Communication activities by the Agency

# 22.2.1 Right to use the beneficiaries' materials, documents or information

The Agency may use information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 21, which still apply.

The right to use the beneficiary's materials, documents and information includes:

- (a) **use for its own purposes** (in particular, making them available to persons working for the Agency or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);
- (b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);
- (c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);
- (d) translation;
- (e) giving access in response to individual requests under Regulation No 1049/2001<sup>8</sup>, without the right to reproduce or exploit;
- (f) **storage** in paper, electronic or other form;
- (g) archiving, in line with applicable document-management rules, and
- (h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the Agency.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiary), the Agency will insert the following information:

"©-[year]-[name of the copyright owner]. All rights reserved. Licensed to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) under conditions."

#### 22.3 Consequences of non-compliance

If the beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 27).

Such breaches may also lead to any of the other measures described in Chapter 6.

#### ARTICLE 23 — PROCESSING OF PERSONAL DATA

Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

#### 23.1 Processing of personal data by the Agency and the Commission

Any personal data under the Agreement will be processed by the Agency or the Commission under Regulation No 23/2001<sup>9</sup> and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Agency or the Commission (publicly accessible in the DPO register).

Such data will be processed by the 'data controller' of the Agency or the Commission, for the purposes of implementing, managing and monitoring the Agreement or protecting the financial interests of the EU or Euratom (including checks, reviews, audits and investigations; see Article 17).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) on the Agency and Commission websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

#### 23.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the Agency or the Commission. For this purpose, they must provide them with the privacy statement(s) (see above), before transmitting their data to the Agency or the Commission.

#### 23.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 23.2, the Agency may apply any of the measures described in Chapter 6.

#### ARTICLE 24 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE AGENCY

The beneficiaries may not assign any of their claims for payment against the Agency to any third party, except if approved by the Agency on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the Agency has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the Agency.

<sup>&</sup>lt;sup>9</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

#### CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

#### ARTICLE 25 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

#### 25.1 Roles and responsibilities towards the Agency

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Agency expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 28, 29 and 30.

#### 25.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

#### (a) Each beneficiary must:

- (i) keep information stored in the 'Beneficiary Register' (via the electronic exchange system) up to date (see Article 12);
- (ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 12);
- (iii) submit to the coordinator in good time:
  - individual financial statements for itself *and its affiliated entities* and, if required, certificates on the financial statements (see Article 15);
  - the data needed to draw up the technical reports (see Article 15);
  - any other documents or information required by the Agency or the Commission under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the Agency or the Commission.

#### (b) The **coordinator** must:

- (i) monitor that the action is implemented properly (see Article 7);
- (ii) act as the intermediary for all communications between the beneficiaries and the Agency (in particular, providing the Agency with the information described in Article 12), unless the Agreement specifies otherwise;
- (iii) provide a pre-financing guarantee if requested by the Agency (see Article 16.2);

- (iv) request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;
- (v) submit the deliverables and reports to the Agency (see Articles 14 and 15);
- (vi) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 16).

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

#### 25.3 Internal arrangements between beneficiaries — Consortium agreement

The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written 'consortium agreement' between the beneficiaries, which may cover:

- internal organisation of the consortium;
- management of access to the electronic exchange system;
- distribution of EU funding;
- additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3 of Chapter 4);
- settlement of internal disputes;
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The consortium agreement must not contain any provision contrary to the Agreement.

# <u>CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE</u>

# SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

#### ARTICLE 26 — REJECTION OF INELIGIBLE COSTS

#### **26.1 Conditions**

26.1.1 The Agency will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 17).

26.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 17.5.2.

#### 26.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the Agency rejects costs without reduction of the grant (see Article 27) or recovery of undue amounts (see Article 28), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 16.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the Agency of its disagreement and the reasons why.

If the Agency rejects costs with reduction of the grant or recovery of undue amounts, it will formally notify the rejection in the 'pre-information letter' on reduction or recovery set out in Articles 27 and 28.

#### 26.3 Effects

If the Agency rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement (see Articles 15.3 and 15.4). It will then calculate the interim payment or payment of the balance as set out in Articles 16.3 or 16.4.

If the Agency — after an interim payment but before the payment of the balance — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 16.3 or 16.4.

If the Agency rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

#### ARTICLE 27 — REDUCTION OF THE GRANT

#### **27.1 Conditions**

- 27.1.1 The Agency may at the payment of the balance or afterward reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 to the Specific Agreement concerned or another obligation under the Agreement has been breached.
- 27.1.2 The Agency may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 17.5.2.

#### 27.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the Agency will formally notify a 'pre-information letter' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 16).

#### 27.3 Effects

If the Agency reduces the grant at the time of the payment of the balance, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Article 5.3.4 and Article 16.4).

If the Agency reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount (see Article 5.4). If the revised final grant amount is lower than the final grant amount, the Agency will recover the difference (see Article 28).

#### ARTICLE 28 — RECOVERY OF UNDUE AMOUNTS

#### 28.1 Amount to be recovered — Calculation — Procedure

The Agency will — at the payment of the balance or afterwards — claim back amount that was paid but is not due under the Agreement.

The coordinator is fully liable for repaying debts of the consortium (under the Agreement) even if it has not been the final recipient of those amounts.

In addition, the beneficiaries (including the coordinator) are jointly and severally liable for repaying any unpaid debts under the Agreement (due by the consortium or any beneficiary, including late-payment interest) — up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2).

Undue amounts paid by the Agency for costs declared by an affiliated entity will be considered as amounts unduly paid to the beneficiary.

#### 28.1.1 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 16.4), the Agency will formally notify a 'pre-information letter' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why and
- inviting the coordinator to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator a **debit note** with the terms and the date for payment (together with the notification of amounts due; see Article 16.5).

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

(a) by 'offsetting' it — without the coordinator's consent — against any amounts owed to the coordinator by the Agency, Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;

- (b) not applicable;
- (c) by holding the other beneficiaries jointly and severally liable up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2);
- (d) by taking legal action (see Article 41) or by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

#### 28.1.2 Recovery of amounts after payment of the balance

If — after the payment of the balance — the Agency revised the final grant amount for the action (see Article 5.4), due to a rejection of costs or reduction of the grant, and the revised final grant amount is lower than the final grant amount (see Article 5.3), the Agency will:

- if the rejection or reduction does *not* concern a specific beneficiary (or its affiliated entities): claim back the difference from the coordinator (even if it has not been the final recipient of the amount in question)

or

- otherwise: claim back the difference from the beneficiary concerned.

The Agency will formally notify a **pre-information letter** to the coordinator or beneficiary concerned:

- informing it of its intention to recover, the amount to be repaid and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the Agency decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the coordinator or beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission will **recover** the amount:

- (a) by 'offsetting' it without the coordinator's or beneficiary's consent against any amounts owed to the coordinator or beneficiary by the Agency, Commission or another executive agency (from the EU or Euratom budget).
  - In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date specified in the debit note;
- (b) by holding the other beneficiaries jointly and severally liable, up to the maximum EU contribution indicated, for each beneficiary, in the estimated budget (as last amended; see Annex 2);
- (c) by taking legal action (see Article 41) or by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 16.11, from the day following the date for payment in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

#### ARTICLE 29 — ADMINISTRATIVE AND FINANCIAL PENALTIES

#### 29.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the Agency may impose administrative and financial penalties if a beneficiary:

- (a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or
- (b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the Agency or the Commission may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

#### 29.2 Duration — Amount of penalty — Calculation

**Administrative penalties** exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the Agency.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may extend the exclusion period up to 10 years.

**Financial penalties** will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the Agency may increase the rate of financial penalties to between 4% and 20%.

#### 29.3 Procedure

Before applying a penalty, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission may **recover** the amount:

- (a) by **offsetting** it without the beneficiary's consent against any amounts owed to the beneficiary concerned by the Agency, Commission or another executive agency (from the EU or Euratom budget).
  - In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;
- (b) by taking legal action (see Article 41) or by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 79(2) of the Financial Regulation No 966/2012.

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

#### **SECTION 2 LIABILITY FOR DAMAGES**

#### ARTICLE 30 — LIABILITY FOR DAMAGES

#### 30.1 Liability of the Agency

The Agency cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The Agency cannot be held liable for any damage caused by any beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

#### 30.2 Liability of the beneficiaries

#### 30.2.1 Conditions

Except in case of force majeure (see Article 35), the beneficiaries must compensate the Agency for any damage it sustains as a result of the implementation of the actione or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

#### 30.2.2 Amount of damages - Calculation

The amount the Agency can claim from a beneficiary will correspond to the damage caused by that beneficiary.

#### 30.2.3 Procedure

Before claiming damages, the Agency will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the Agency does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the Agency or the Commission may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the Agency, Commission or another executive agency (from the EU or Euratom budget).

In exceptional circumstances, to safeguard the EU's financial interests, the Agency may offset before the payment date in the debit note;

(b) by taking legal action (see Article 41) or by adopting an enforceable decision under Article 79(2) of the Financial Regulation No 966/2012 and Article 299 of the Treaty on the Functioning of the EU (TFEU).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 16.11, from the day following the payment date in the debit note, up to and including the date the Agency or the Commission receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

#### **SECTION 3 SUSPENSION AND TERMINATION**

#### ARTICLE 31 — SUSPENSION OF PAYMENT DEADLINE

#### 31.1 Conditions

The Agency may — at any moment — suspend the payment deadline (see Article 16.2 to 16.4) if a request for payment (see Article 15) cannot be approved because:

- (a) it does not comply with the provisions of the Agreement (see Article 15);
- (b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or
- (c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

#### 31.2 Procedure

The Agency will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the Agency (see Article 36).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the Agency if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 15) and the revised report or statement is not submitted or was submitted but is also rejected, the Agency may also terminate the Agreement or the participation of the beneficiary (see Article 34.3.1).

#### **ARTICLE 32 — SUSPENSION OF PAYMENTS**

#### 32.1 Conditions

The Agency may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

- (a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or
- (b) has committed in other EU or Euratom grants awarded to it under similar conditions systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 17.5.2).

#### 32.2 Procedure

Before suspending payments, the Agency will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will take effect the day the confirmation notification is sent by the Agency.

If the conditions for resuming payments are met, the suspension will be lifted. The Agency will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 15.3) must not contain any individual financial statements from the beneficiary concerned *and its affiliated entities*. When the Agency resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 33.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 34.1 and 34.2).

#### ARTICLE 33 — SUSPENSION OF THE ACTION IMPLEMENTATION

#### 33.1 Suspension of the action implementation, by the beneficiaries

#### 33.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 35) — make implementation impossible or excessively difficult.

#### 33.1.2 Procedure

The coordinator must immediately formally notify to the Agency the suspension (see Article 36), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the Agency.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the Agency and request an **amendment** of the Agreement, to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 34).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

#### 33.2 Suspension of the action implementation, by the Agency

#### 33.2.1 Conditions

The Agency may suspend implementation of the action or any part of it:

- (a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or
- (b) if a beneficiary has committed in other EU or Euratom grants awarded to it under similar conditions systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 17.5.2).

#### 33.2.2 Procedure

Before suspending implementation of the action, the Agency will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be **amended**, to set the date on which the action will be resumed, extend the duration of the action and make other changes

necessary to adapt the action to the new situation (see Article 39) — unless the Agreement has already been terminated (see Article 34).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the Agency (see Article 30).

Suspension of the action implementation does not affect the Agency's right to terminate the Agreement or participation of a beneficiary (see Article 34), reduce the grant or recover amounts unduly paid (see Articles 27 and 28).

# ARTICLE 34 — TERMINATION OF THE AGREEMENT OR OF THE PARTICIPATION OF ONE OR MORE BENEFICIARIES

#### 34.1 Termination of the Agreement, by the beneficiaries

#### 34.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the Agency (see Article 36), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the Agency the Agreement will be considered to have been 'terminated improperly'.

The termination will **take effect** on the day specified in the notification.

#### **34.1.2** Effects

The coordinator must — within 60 days from when termination takes effect — submit:

- (i) a periodic report (for the open reporting period until termination; see Article 15.3) and
- (ii) the final report (see Article 15.4).

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 27).

After termination, the beneficiaries' obligations (in particular, Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

#### 34.2 Termination of the Specific Agreement, by the Agency

#### 34.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the Agency (see Article 36) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 39), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 40). If termination takes effect after the period set out in Article 3, no request for amendment must be included, unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the Agency considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

#### **34.2.2 Effects**

The beneficiary concerned must submit to the coordinator:

- (i) a technical report and
- (ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in the periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is amended to introduce the necessary changes (see Article 39).

Improper termination may lead to a reduction of the grant (see Article 27) or termination of the Agreement (see Article 34).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

# 34.3 Termination of the Agreement or of the participation of one or more beneficiaries, by the Agency

#### 34.3.1 Conditions

The Agency may terminate the Agreement or the participation of one or more beneficiaries, if:

- (a) one or more beneficiaries do not accede to the Agreement (see Article 40);
- (b) a change to their legal, financial, technical, organisational or ownership situation (or those of its affiliated entities) is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;
- (c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 39);
- (d) implementation of the action is prevented by force majeure (see Article 35) or suspended by the coordinator (see Article 33.1) and either:
  - (i) resumption is impossible, or
  - (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;
- (e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;
- (f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;
- (g) a beneficiary does not comply with the applicable national law on taxes and social security;
- (h) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the EU's financial interests;
- (i) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has in the award procedure or under the Agreement committed:
  - (i) substantial errors, irregularities, fraud or
  - (ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(j) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('extension of findings from other grants to this grant').

#### 34.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the Agency will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and
- inviting it, within 30 days of receiving notification, to submit observations and in case of Point (i.ii) above to inform the Agency of the measures to ensure compliance with the obligations under the Agreement.

If the Agency does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

#### The termination will take effect:

- for terminations under Points (b), (c), (e), (g) and (i.ii) above: on the day specified in the notification of the confirmation (see above);
- for terminations under Points (a), (d), (f), (h), (i.i) and (j) above: on the day after the notification of the confirmation is received by the coordinator.

#### **34.3.3** Effects

#### (a) for termination of the Agreement:

The coordinator must — within 60 days from when termination takes effect — submit:

- (i) a periodic report (for the last open reporting period until termination; see Article 15.3) and
- (ii) a final report (see Article 15.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 15.7 and 34.3.1), the coordinator may not submit any reports after termination.

If the Agency does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The Agency will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 16.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the Agency's right to reduce the grant (see Article 27) or to impose administrative and financial penalties (Article 29).

The beneficiaries may not claim damages due to termination by the Agency (see Article 30).

After termination, the beneficiaries' obligations (in particular Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

#### (b) for termination of the participation of one or more beneficiaries:

The coordinator must — within 60 days from when termination takes effect — submit a request for amendment (see Article 39), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 40). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator.

The beneficiary concerned must submit to the coordinator:

- (i) a technical report and
- (ii) a financial statement covering the period from the end of the last reporting period to the date when termination takes effect.

This information must be included by the coordinator in the periodic report for the next reporting period (see Article 15.3).

If the request for amendment is rejected by the Agency (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the Agreement may be terminated according to Article 34.3.1(c).

If the request for amendment is accepted by the Agency, the Agreement is **amended** to introduce the necessary changes (see Article 39).

After termination, the concerned beneficiary's obligations (in particular Articles 15, 17, 18, Section 3 of Chapter 4, 21, 22 and 24) continue to apply.

#### **SECTION 4 FORCE MAJEURE**

#### ARTICLE 35 — FORCE MAJEURE

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and

- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

#### **CHAPTER 7 FINAL PROVISIONS**

#### ARTICLE 36 — COMMUNICATION BETWEEN THE PARTIES

#### 36.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

**Until the payment of the balance**: all communication must be made through the electronic exchange system and using the forms and templates provided there.

**After the payment of the balance**: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, the partner must have designated—before the signature of the Framework Partnership Agreement—a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Agency and Commission websites.

#### 36.2 Date of communication

**Communications** are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

**Formal notifications** through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by **registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

#### 36.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

https://ec.europa.eu/research/participants/portal/desktop/en/projects/

The Agency will formally notify the coordinator and beneficiaries in advance any changes to this URL.

**Formal notifications on paper** (only after the payment of the balance) addressed **to the Agency** must be sent to the following address:

Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)
Health Unit Health Unit
Drosbach Building
L-2920 Luxembourg

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the 'Beneficiary Register'.

#### ARTICLE 37 — INTERPRETATION OF THE AGREEMENT

#### 37.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

Annex 2 takes precedence over Annex 1.

#### 37.2 Privileges and immunities

Not applicable

#### ARTICLE 38 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71<sup>10</sup>, periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

#### ARTICLE 39 — AMENDMENTS TO THE AGREEMENT

#### 39.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

#### 39.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 36).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents, and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The Agency may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the Agency has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

#### ARTICLE 40 — ACCESSION TO THE AGREEMENT

<sup>&</sup>lt;sup>10</sup> Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8/6/1971, p. 1).

#### 40.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 36) within 30 days after its entry into force (see Article 42).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 42).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the Agency's right to terminate the Agreement (see Article 34).

#### 40.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 39. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 36).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

#### ARTICLE 41 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

#### 41.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

#### 41.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

As an exception, if such a dispute is between the Agency and 'HELSEDIREKTORATE', 'FOLKEHELSEINSTITUTTET', 'VETERINAERINSTITUTTET' - NORWEGIAN VETERINARY INSTITUTE', the competent Belgian courts have sole jurisdiction.

If a dispute concerns administrative or financial penalties, offsetting or an enforceable decision under Article 79(2) of the Financial Regulation No 966/2012 and Article 299 TFEU (see Articles 28, 29 and 30), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU. Actions against enforceable decisions must be brought against the Commission (not against the Agency).

#### ARTICLE 42 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the Agency or the coordinator, depending on which is later.

#### **SIGNATURES**

For the coordinator

For the Agency

Armelle BARELLI with ECAS id nbarelar signed in the Participant Portal on 28/08/2017 at 09:45:44 (transaction id Sigld-2706-KIStvOeh6ZZLdYNvTbf2RaNo2IzMdUAQSk8ZjeS6YZTvqfl498swlbFQTd97zTSkXqosvMpmcKwBQfhJj6c9Q7-Jj71zxYb8yrN6HT4pVHCoC- Signed by Jacques REMACLE with ECAS id remacjs as an authorised representative on 28-08-2017 18:01:56 (transaction id Sigld-9702-tEBk21LFkzl2MEyB56Rv1xH7KzqKULP3zGzmzQX8azQuWmw5t6LNzYcKbZXrrVu1wIR6PcPYBzsykV5AQHVu6ZWT-Jj71zxYb8yrN6HT4pVHCoC-



#### **EUROPEAN COMMISSION**

Consumers, Health, Agriculture and Food Executive Agency Health Unit

ANNEX 1 (part A)

**Project** 

NUMBER - 761296 - EU-JAMRAI

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### 1.1. The project summary

Project Number <sup>1</sup>	761296	Project Acronym <sup>2</sup>	EU-JAMRAI

	One form per project				
	General information				
Project title <sup>3</sup>	European Joint Action on antimicrobial resistance and associated infections				
Starting date <sup>4</sup>	01/09/2017				
Duration in months 5	36				
Call (part) identifier <sup>6</sup>	HP-JA-2016				
Торіс	HP-JA-04-2016 Antimicrobial resistance and Health Care Associated Infections				
Fixed EC Keywords					
Free keywords  Antimicrobial resistance, Health-Care Associated Infections, One Health, Public Health Policies, Research					
Abstract 7					

Antimicrobial resistance (AMR) is a serious public health threat that is gaining swift ground. The increase of multiresistant bacteria associated to the lack of new antibiotics represents a threat to global health. Some patients are faced with no therapeutic solutions as some bacteria resist to all antibiotics. Moreover, "old" antibiotics and to some extent more "recent" ones are gradually removed from the market because they are not economically sustainable, albeit being still possibly efficient. The issue of antimicrobial resistance is a real challenge that decision-makers are well aware of and has gained a high priority among public health challenges.

A closely related challenge is the issue of Healthcare Associated Infections that shall not be considered separately. In fact, infection prevention and control strategies should go hand in hand with i) prudent use of antibiotics ii) appropriate tools for monitoring and surveillance and iii) accurate diagnostic tests to decide on the right therapy. The various national, European and international initiatives that have emerged over the last decade have shown a great commitment to actively tackle these issues. It is essential that all actors in the field of AMR join forces so as to avoid duplication of efforts and ensure greater coherence. Moreover, it is essential that the strategies adopted extend beyond the sole human health domain and bring a global One Health response.

The overall objective of the AMR-HCAI JA is to ensure that policies for control of AMR and HCAI are adopted and implemented across EU MS in a coordinated way, ensuring national specificities are accounted for, in line with the ECDC and WHO guidelines and recommendations, and in conjunction with other European initiatives. This will be made possible by bringing together different networks of policy makers, experts and organizations on AMR and HCAI working in different European and International initiatives and projects relevant for policy decision.

### 1.2. List of Beneficiaries

Project Number <sup>1</sup>	761296	Project Acronym <sup>2</sup>	EU-JAMRAI
3			

#### List of Beneficiaries

1	No	Name	Short name	Country	Project entry month <sup>8</sup>	Project exit month
2	1		INSERM	France	1	36
SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT  NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES  RATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES  REVICE PUBLIC PROFITE OF INFECTIOUS AND PARASITIC DISEASES  REVICE PUBLIC PROFITE OF INFECTIOUS AND PARASITIC DISEASES  NCIPD  Bulgaria  1 36  REVICE PUBLIC PROFITE OF INFECTIOUS AND PARASITIC DISEASES  NCIPD  Bulgaria  1 36  REVICE PUBLIC PROFITE OF INFECTIOUS AND PARASITIC DISEASES  NCIPD  Bulgaria  1 36  REVID  Croatia  1 36  REVID  TOTALIA  STATINI ZDRAVOTNI USTAV  NIPH  Czech Republic  1 36  PERVISEAMET  TA Estonia  1 36  RESTATENS SERUM INSTITUT  REVID  RESTONIA  REVID  RESTONIA  1 36  RENTIC  Germany  1 36  REDCP  Greece  1 36  REDCP  Greece  1 36  DIOIKHSH YGEIONOMIKHS PERIFEREIAS KRHTHS  PERIFEREIAS KRHTHS  PERIFEREIAS KRHTHS  PERIFEREIAS REVIDI DI FOGGIA  UNIFG  Italy  1 36  Italy  1 36  Italy  1 36  Italy  1 36  Italy  ILIETUVOS SVEIKATOS MOKSLU UNIVERSITATES SLIMNICA  PSKUS  Latvia  1 36  LETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS  LETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS  HIGIENOS INSTITUTAS  HI  LITHUANIA  LITHUANIA  1 36  NACIONALINIS VISUOMENES NVSC  Lithuania  1 36  NACIONALINIS VISUOMENES NVSC  Lithuania  1 36  NEDD  REPRIFEREIAS  REPRIFEREIAS  REPRIFERENTE OLIGONINE SANTAROS APSAUGOS MINISTERIJOS NVSC  Lithuania  1 36  NACIONALINIS VISUOMENES NVSC  Lithuania  1 36  NETHORITORION OLIVERS SEVEIKATOS APSAUGOS MINISTERIJOS NVSC  Lithuania  1 36  NETHORITORION OLIVERS SEVEIKATOS APSAUGOS MINISTERIJOS NVSC  LITHUANIA NCHERITARION OLIVERS SEVEIKATOS APSAUGOS MINISTERIJOS NVSC  NETHORITORION OLIVERS  REVIEW  REVIEW  REVIEW  1 36  REVIEW  REVIEW  REVIEW  1 36  REDCECH REPUBLIC  REVIEW  REVIEW  1 36  REDGEMENTE OLIGONINE SANTAROS REVIEW  REVIEW  REVIEW  REVIEW  1 36  REDCECH REPUBLIC  REVIEW  REVIEW  REVIEW  1 36  REDCECH REPUBLIC  REVERSITATO  REVIEW  REVIEW  1 36  REDCECH REPUBLIC  REVIEW  REVIEW  1 36  REDCECH REVIEW  REVIEW  1 36  REDCECH REPUBLIC  REVERSITATON  R	2		MoH-FR	France	1	36
4 PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT 5 NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES 6 HRVATSKI ZAVOD ZA JAVNO CIPH Croatia 1 36 7 STATNI ZDRAVOTNI USTAV NIPH Czech Republic 1 36 8 STATENS SERUM INSTITUT SSI Denmark 1 36 9 TERVISEAMET TA Estonia 1 36 10 ROBERT KOCH-INSTITUT RKI Germany 1 36 11 KENTRO ELENCHOU & PROLIPSIS NOSIMATON Greece 1 36 12 ETHNIKI SCHOLI DIMOSIAS YGEIAS EDY-NSPH Greece 1 36 13 POIOIKHSH YGEIONOMIKHS PRIFEREIAS KRHTHS 711C Greece 1 36 14 UNIVERSITA DEGLI STUDI DI FOGGIA UNIFG Italy 1 36 15 ISTITUTO SUPERIORE DI SANITA ISS Italy 1 36 16 PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA PSKUS Latvia 1 36 17 LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS UNIVERSITETO LIGONINE KAUNO KLINIKOS UNIVERSITETO LIGONINE SANTAROS KLINIKOS Lithuania 1 36 20 SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS NVSC Lithuania 1 36 21 MINISTERIE VAN VOLKSGEZONDHEID, WWS Netherlands 1 36	3	GESUNDHEIT ÖSTERREICH GMBH	GÖG	Austria	1	36
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5 ZDRAVSTVO CIPH COMBAN CIPH COMBAN C	5		NCIPD	Bulgaria	1	36
8         STATENS SERUM INSTITUT         SSI         Denmark         1         36           9         TERVISEAMET         TA         Estonia         1         36           10         ROBERT KOCH-INSTITUT         RKI         Germany         1         36           11         KENTRO ELENCHOU & PROLIPSIS NOSIMATON         HCDCP         Greece         1         36           12         ETHNIKI SCHOLI DIMOSIAS YGEIAS         ESDY-NSPH         Greece         1         36           12         ETHNIKI SCHOLI DIMOSIAS YGEIAS         ESDY-NSPH         Greece         1         36           13         DIOIKHSH YGEIONOMIKHS PERIFEREIAS KRHTHS         7HC         Greece         1         36           14         UNIVERSITA DEGLI STUDI DI FOGGIA         UNIFG         Italy         1         36           15         ISTITUTO SUPERIORE DI SANITA         ISS         Italy         1         36           16         PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA         PSKUS         Latvia         1         36           17         UNIVERSITETO LIGONINE KAUNO KLINIKK         Lithuania         1         36           18         UNIVERSITETO LIGONINE SANTAROS KLINIKOS         VULSK         Lithuania         1         <	6		СІРН	Croatia	1	36
9         TERVISEAMET         TA         Estonia         1         36           10         ROBERT KOCH-INSTITUT         RKI         Germany         1         36           11         KENTRO ELENCHOU & PROLIPSIS NOSIMATON         HCDCP         Greece         1         36           12         ETHNIKI SCHOLI DIMOSIAS YGEIAS         ESDY-NSPH         Greece         1         36           13         DIOIKHSH YGEIONOMIKHS PERIFEREIAS KRHTHS         7HC         Greece         1         36           14         UNIVERSITA DEGLI STUDI DI FOGGIA         UNIFG         Italy         1         36           15         ISTITUTO SUPERIORE DI SANITA         ISS         Italy         1         36           16         PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA         PSKUS         Latvia         1         36           16         PAULA STRADINA KLINISKA UNIVERSITETO LIGONINE KAUNO KLINIKOS         LISMULKK         Lithuania         1         36           17         VIESOJI ISTAIGA VILNIAUS VULSK         Lithuania         1         36           18         UNIVERSITETO LIGONINE SANTAROS KLINIKOS         VULSK         Lithuania         1         36           19         HIGIENOS INSTITUTAS         HI         Lithuania	7	STATNI ZDRAVOTNI USTAV	NIPH	Czech Republic	1	36
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11 KENTRO ELENCHOU & PROLIPSIS NOSIMATON  12 ETHNIKI SCHOLI DIMOSIAS YGEIAS 13 DIOIKHSH YGEIONOMIKHS PERIFEREIAS KRHTHS  14 UNIVERSITA DEGLI STUDI DI FOGGIA 15 ISTITUTO SUPERIORE DI SANITA 16 PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA  17 LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS  18 VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS  19 HIGIENOS INSTITUTAS  HI LIETUVAS IN	9	TERVISEAMET	TA	Estonia	1	36
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15 ISTITUTO SUPERIORE DI SANITA ISS Italy 1 36  16 PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA PSKUS Latvia 1 36  17 LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS LISMULKK Lithuania 1 36  18 VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS LITHUANIA 1 36  19 HIGIENOS INSTITUTAS HI Lithuania 1 36  NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS NVSC Lithuania 1 36  20 MINISTERIE VAN VOLKSGEZONDHEID, WWS Netherlands 1 36	13		7HC	Greece	1	36
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17 UNIVERSITETO LIGONINE KAUNO KLINIKOS  LITHUANIA  18 UNIVERSITETO LIGONINE SANTAROS KLINIKOS  UNIVERSITETO LIGONINE SANTAROS KLINIKOS  HI LITHUANIA  1 36  NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS  MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT  VWS  Netherlands  1 36	16		PSKUS	Latvia	1	36
18       UNIVERSITETO LIGONINE SANTAROS KLINIKOS       VULSK       Lithuania       1       36         19       HIGIENOS INSTITUTAS       HI       Lithuania       1       36         20       NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS       NVSC       Lithuania       1       36         21       MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT       VWS       Netherlands       1       36	17	UNIVERSITETO LIGONINE KAUNO	LSMULKK	Lithuania	1	36
NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS  NVSC  Lithuania  1 36  MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT  Vws  Netherlands  1 36	18	UNIVERSITETO LIGONINE SANTAROS	VULSK	Lithuania	1	36
20 SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS  21 MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT  NVSC Lithuania 1 36  Netherlands 1 36	19	HIGIENOS INSTITUTAS	н	Lithuania	1	36
WELZIJN EN SPORT VWS Netherlands 1 36	20	SVEIKATOS CENTRAS PRIE SVEIKATOS	NVSC	Lithuania	1	36
22 HELSEDIREKTORATE HdiR Norway 1 36	21		VWS	Netherlands	1	36
	22	HELSEDIREKTORATE	HdiR	Norway	1	36

# 1.2. List of Beneficiaries

No	Name	Short name	Country	Project entry month <sup>8</sup>	Project exit month
23	FOLKEHELSEINSTITUTTET	FHI	Norway	1	36
24	VETERINAERINSTITUTTET - NORWEGIAN VETERINARY INSTITUTE	NVI	Norway	1	36
25	NARODOWY INSTYTUT LEKOW	NMI	Poland	1	36
26	MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	DGS	Portugal	1	36
27	UNIVERSITATEA DE MEDICINA SI FARMACIE IULIU HATIEGANU CLUJ- NAPOCA	UMPIH	Romania	1	36
28	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	NIJZ	Slovenia	1	36
29	AGENCIA ESPANOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS	AEMPS	Spain	1	36
30	DEPARTAMENT DE SALUT - GENERALITAT DE CATALUNYA	GENCAT	Spain	1	36
31	CONSELLERIA DE SALUD	IdISBa	Spain	1	36
32	FUNDACION PARA LA FORMACION E INVESTIGACION SANITARIAS DE LA REGION DE MURCIA	FFIS	Spain	1	36
33	FUNDACION PUBLICA MIGUEL SERVET	FMS	Spain	1	36
34	SERVICIO ANDALUZ DE SALUD	SAS	Spain	1	36
35	INSTITUTO DE SALUD CARLOS III	ISCIII	Spain	1	36
36	SERVICIO MADRILENO DE SALUD	SERMAS	Spain	1	36
37	FOLKHALSOMYNDIGHETEN	FoHM	Sweden	1	36
38	SOCIALSTYRELSEN	SoS	Sweden	1	36
39	STATENS JORDBRUKSVERK	SBA	Sweden	1	36
40	LIVSMEDELS VERKET	NFA	Sweden	1	36
41	STATENS VETERINAERMEDICINSKA ANSTALT	SVA	Sweden	1	36
42	VETENSKAPSRADET - SWEDISH RESEARCH COUNCIL	SRC	Sweden	1	36
43	UPPSALA LANS LANDSTING	UAS	Sweden	1	36
44	AGENCE NATIONALE DE LA SECURITE SANITAIRE DE L ALIMENTATION DE L ENVIRONNEMENT ET DU TRAVAIL	ANSES	France	1	36

# 1.3. Workplan Tables - Detaile implementation

# 1.3.1. WT1 List of work packages

WP Number <sup>9</sup>	WP Title	Lead beneficiary 10	Person- months <sup>11</sup>	Start month 12	End month <sup>13</sup>
WP1	Coordination	1 - INSERM	54.20	1	36
WP2	Dissemination	29 - AEMPS	70.60	1	36
WP3	Evaluation of the project	15 - ISS	22.00	1	36
WP4	Integration into national policies and sustainability	2 - MoH-FR	16.40	3	36
WP5	Implementation of One Health national strategies and National Action Plans for AMR	21 - VWS	132.60	1	36
WP6	Policies for prevention of Health- Care-Associated Infections and their implementation	37 - FoHM	341.40	1	36
WP7	Appropriate use of antimicrobials in human and animals	23 - FHI	334.60	1	36
WP8	Awareness raising and Communication	29 - AEMPS	91.60	1	36
WP9	Prioritizing and implementing research and innovation for public health needs	1 - INSERM	84.30	1	36
		Total	1,147.70		

### 1.3.2. WT2 list of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	WP number <sup>9</sup>	Lead beneficiary	Type 15	Dissemination level <sup>16</sup>	Due Date (in months) 17
D1.1	Interim reports	WP1	1 - INSERM	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D1.2	Final report	WP1	1 - INSERM	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D2.1	Dissemination plan	WP2	29 - AEMPS	Report	Public	10
D2.2	Layman report	WP2	29 - AEMPS	Report	Public	33
D2.3	Final conference on dissemination	WP2	29 - AEMPS	Report	Public	36
D3.1	Evaluation plan	WP3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	4
D3.2	Validation of the evaluation tools	WP3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D3.3	Progress monitoring and quality assessment of JA documentation and deliverables Y1	WP3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D3.4	Progress monitoring and quality assessment of JA documentation and deliverables Y2	WP3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.5	Progress monitoring and quality assessment of JA documentation and deliverables Y3	WP3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	36

Deliverable Number 14	Deliverable Title	WP number <sup>9</sup>	Lead beneficiary	Type 15	Dissemination level <sup>16</sup>	Due Date (in months) 17
D3.6	Report on stakeholders evaluation and on JA impact in Europe	WP3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D4.1	Integration plan and sustainability Strategy	WP4	2 - MoH-FR	Report	Public	30
D4.2	Report on integration plan	WP4	2 - MoH-FR	Report	Public	30
D4.3	Updated report on integration plan	WP4	2 - MoH-FR	Report	Public	36
D4.4	Report on sustainability plan	WP4	2 - MoH-FR	Report	Public	36
D5.1	Tool for country self-assessments	WP5	21 - VWS	Report	Public	6
D5.2	Summary Country-to- country assessments	WP5	21 - VWS	Report	Public	36
D5.3	Overview enforcement and recommendations to be presented to the One Health Network	WP5	21 - VWS	Report	Public	36
D5.4	Assessment of the cost-benefit for the implementation of an infection control program	WP5	11 - HCDCP	Report	Public	36
D6.1	Revised guidelines for the implementation of infection control program in healthcare settings	WP6	11 - HCDCP	Report	Public	13
D6.2	An Universal Infection Control framework with specific roles, priorities, resources and interventions for the implementation of an infection control plan in healthcare settings	WP6	11 - HCDCP	Report	Public	36
D6.3	Report on experience from country teams of introducing and working with the implementation model	WP6	37 - FoHM	Report	Public	18

Deliverable Number <sup>14</sup>	Deliverable Title	WP number <sup>9</sup>	Lead beneficiary	Type 15	Dissemination level <sup>16</sup>	Due Date (in months) 17
D6.4	Updated report on experience from country teams of introducing and working with the implementation model	WP6	37 - FоНМ	Report	Public	36
D6.5	Experience from non-EU country teams of introducing implementation model	WP6	37 - FоНМ	Report	Public	36
D7.1	Website with evaluated tools and information	WP7	23 - FHI	Websites, patents filling, etc.	Public	12
D7.2	Report on workshop of models for implementation of stewarship tools	WP7	23 - FHI	Report	Public	13
D7.3	Indicators used for monitoring antibiotic use and resistance in humans and animals	WP7	23 - FHI	Report	Public	36
D7.4	Surveillance of antimicrobial use and resistance in human	WP7	34 - SAS	Report	Public	36
D7.5	Surveillance of antimicrobial use and resistance in animal	WP7	44 - ANSES	Report	Public	36
D8.1	Awareness and Communication Plan	WP8	29 - AEMPS	Report	Public	10
D8.2	European Prize: better journalism report or better video about antibiotics	WP8	29 - AEMPS	Report	Public	27
D8.3	European competition with High Schools students	WP8	29 - AEMPS	Report	Public	32
D8.4	Awareness and Communication High Level Meeting	WP8	29 - AEMPS	Report	Public	34
D9.1	National priority- setting best practices	WP9	1 - INSERM	Report	Public	34
D9.2	Implementation strategy for EU collaboration	WP9	23 - FHI	Report	Public	36
D9.3	Dissemination strategies	WP9	1 - INSERM	Report	Public	36

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#### 1.3.3. WT3 Work package descriptions

Work package number 9	WP1	Lead beneficiary 10	1 - INSERM
Work package title	Coordination		
Start month	1	End month	36

#### Objectives

The main objective of this WP is to set up an effective management framework and ensure the smooth management and coordination of the project towards the planned objectives through effective internal communication.

The specific objectives of this WP are three-fold:

- 1. At the strategic level, to ensure that the project reaches its objectives;
- 2. At the managerial level, to put in place the procedures and tools needed to ensure that the project progresses in conformity with the work plan and produces timely and quality results as well as overseeing conformity of all activities to EC rules and the Consortium agreement;
- 3. At the administrative level, to organise project meetings, prepare project reports, manage the project budget and payments.

#### Description of work and role of partners

WP1 - Coordination [Months: 1-36]

INSERM, MoH-FR

Task 1.1: Strategic steering

Leader: INSERM / Contributors: Governance bodies / Start date: M1 End date: M36

Task description: this task involves setting up and managing the relevant steering and management bodies described fully in section:

- General Assembly: deciding board made up of one representative per associated partner
- Executive Board: operational body made up of WP leaders
- Steering Committee: composed of one representative (competent authority) from each Member State. The members will be nominated at the start of the project.
- Stakeholders Forum: composed of external experts from international organizations such as WHO, ECDC, OECD, EFSA, OIE, FAO and other representatives from healthcare professionals' organizations and of patients (see section 9 for details). The members will be nominated at the start of the project.

This governance structure will ensure the relevance of the JA AMR HCAI activities in line with the work plan and national and European strategies.

Task 1.2: Contractual and financial management

Leader: INSERM / Contributors: WP Leaders / Start date: M1 End date: M36

Task description: this task will be coordinated by the Joint Action Secretariat (JAS) that will be responsible for the day-to-day management. It is composed of the project coordinator (Marie-Cécile Ploy, INSERM) assisted by resources including a project manager based at INSERM. The JAS will be in charge of:

- Preparation of the Consortium Agreement to be signed by all beneficiaries at the start of the project
- Appraisal and monitoring of the project costs in order to oversee and check the overall costs incurred per work package and per participant
- Management and distribution of EC payments
- Assistance to individual project partners on specific administrative and financial issues

The PMT will meet monthly and will hold every 4 months teleconferences with the Executive Board to share updates on progress of the WPs.

Task 1.3: Periodic reporting

Leader: INSERM / Contributors: Executive Board (technical), All partners (financial reporting) / Start date: M1 End date: M36

Task description: this task will:

- Monitor the progress of the project in terms of deliverables, milestones, etc., using dedicated project management tools;
- Identify and monitor risks and propose appropriate mitigation measures to the General Assembly and the Steering Committee;
- Prepare periodic and final reporting to ensure timely and efficient submission to the EC

Task 1.4: Communication: internal and with CHAFEA / DG SANTE

Leader: INSERM; Participants: MoH-FR / Start date: M1 End date: M36

Task description: the following activities will be carried out:

- To use the project website to be set up in WP2. It will act as a platform to share internal project documents;
- Regular web/audio conferences to support WP collaboration and interactions;
- Every 4 months, activity reports updating all project collaborators on the project activities;

The project coordinator will act as the official representative towards the CHAFEA and DG SANTE. The project coordinator will provide those two interims and a final report, assisted by the JAS (composed of a project manager at Inserm and an assistant manager at MoH-FR).

#### Participation per Partner

Partner number and short name	WP1 effort
1 - INSERM	46.00
2 - MoH-FR	8.20
Total	54.20

#### List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D1.1	Interim reports	1 - INSERM	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D1.2	Final report	1 - INSERM	Report	Confidential, only for members of the consortium (including the Commission Services)	36

#### Description of deliverables

#### D1.1 : Interim reports [18]

This report describes the activities carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes.

#### D1.2: Final report [36]

This report describes the project implementation and the results achieved. The deliverables are annexed.

#### Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS1	Kick-off meeting	1 - INSERM	1	Organisation of the kick- off meeting completed

### Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				(meeting, agenda & preparatory documents)
MS2	The Steering committee and Advisory Boards Forum are set up	1 - INSERM	2	The Steering committee and Advisory Boards Forum are set up
MS3	First annual meeting	1 - INSERM	10	Organisation of First annual meeting completed (meeting, agenda & preparatory documents)
MS4	Second annual meeting	1 - INSERM	22	Organisation of second annual meeting completed (meeting, agenda & preparatory documents)

Work package number 9	WP2	Lead beneficiary 10	29 - AEMPS
Work package title	Dissemination		
Start month	1	End month	36

#### Objectives

The main objective of this WP is to ensure correct dissemination on high quality information on JA deliverables and progress among targeted groups through organised dissemination activities, which in turn will allow for sustainability beyond the project end. The specific objectives of this WP are to:

- Develop an internal communication strategy to ensure back and forth communication amongst WPs to build on the work coming from all the different WPs within the JA.
- Develop external communication strategies to disseminate information on JA both to general public and stakeholders as well as ensuring the promotion of the project outcomes and results amongst the targeted public and stakeholders.
- To widely and effectively coordinate and disseminate research outcomes and results through various channels, including online dissemination channels (website; twitter; Facebook; newsletter) so that we can actively engage all partners and stakeholders throughout the course of the project to ensure applicable and appropriate results to the targeted public and partners.

#### Description of work and role of partners

#### WP2 - Dissemination [Months: 1-36]

**AEMPS**, INSERM, MoH-FR, GÖG, FPS HFCSE, NCIPD, CIPH, NIPH, SSI, TA, RKI, HCDCP, ESDY-NSPH, UNIFG, ISS, PSKUS, LSMULKK, VULSK, HI, NVSC, VWS, HdiR, FHI, DGS, UMPIH, NIJZ, FFIS, FMS, SAS, ISCIII, FoHM, SRC, ANSES

WP Methodology

In order to meet the main objectives, WP2 will pay special attention to both, its internal and external communication and will line up a qualified team for its development. A wide variety of dissemination methods and tools to inform, engage and promote the outcomes of the JA will be put in place.

To start with, all WPs will designate a contact person to collaborate with WP2 for all matters related to dissemination activities (events, articles, reports...). Communication between the WP2 leader and each WP contact person (informing WP leaders and also the coordinator) will be carried out via email on regular basis, and also via TLC, depending on the project's needs.

WP2 facilitates coherent and sustainable external communication of the JA and ensures that its objectives, activities, results, and deliverables are known. In order to do so, AEMPS will develop a dissemination plan that is planned to cover relevant stakeholders and identify the appropriate timing of release of interim and final results through appropriate and effective dissemination activities such as conferences, congresses or publications so that widespread dissemination is achieved. This plan will be a living document and will be monitored and adapted to reflect progress and changes.

The main dissemination tools (website, leaflet, layman report...) and materials will be produced in English. There will be the option to send the same material translated into different languages (translated by the country itself), however, that would depend on the tool or activity (relevance) and the resources of the country to carry out this translation and work. Each participant will ensure language is appropriate for the audiences addressed. This WP will ensure the quality of the website and tools as well as engage with other WP leaders and partners so as to ensure the appropriate level of dissemination for each of the WP outputs, services, tools, events, etc.

#### Task 2.1: Design of a dissemination plan

Leader: AEMPS / Start date: M1 End date: M10

The main principles in order to elaborate the dissemination plan will be: Defining key messages, establishing target audiences and selecting the appropriate tools and activities so that we can achieve the following aims of this task:

- To ensure that the results and deliverables are known to all partners and available to all key audiences and target groups
- To bring knowledge, experience and best practice together in order to achieve the objectives, activities, results and deliverables are known to all identified stakeholders and wider audience on EU and national / regional levels.
- Assist different WPs in their communicational needs. Thus, active and collaborating partners will be able to ask for support for any sort of dissemination event or activity related to their own aims, as well as any advice to develop any of their initiatives. This assistance will strengthen the dissemination and make it more effective.

• Creation of an official website with the aim of gathering and collecting a group of useful reference tools that could be progressively updated.

#### Task 2.2: Communication tool-kit (visual identity)

All the dissemination related material, such as project logo, templates for internal and public documents, leaflet format, etc., will be defined at the very beginning of the project in order to establish the project image as soon as possible. The corporate identity and communication tools will be developed for the project in line with what will be developed by JA to ensure consistency.

Leader: AEMPS / Start date: M1 End date: M12

Task description: a tool-kit will be developed, including

- Logo and claim: they should incorporate the project mission into one single graphic along with a catchy slogan/claim able to engage with the target audience. Logo will indicate co-foundation as do other materials.
- Web banner design as an extra tool, complementary one, for all the others (logo etc. ).-
- Develop Templates: Word, Power point
- Leaflets and Factsheet: Editing, publication and distribution of promotional leaflet for broad public with focus on the promotion of JA objectives and planned activities that constitutes Leaflet will contain also logo JA visual identity and distribution will be realized according stakeholder analysis within the first period of the dissemination plan. This tool will be targeted at all stakeholders through online dissemination channel website, e mail. Two "official" leaflets will be produced during the JA. One first hand-out disseminated at an early stage of the JA to inform people about the project, and which would include a general description of the project goals, aimed at informing the target groups about the project existence and the planned activities. The second leaflet to be issued in the later stages of the JA when the results are more visible and tangible. Special leaflet can also be created for promotional purposed for a special Conference where our Joint Action can be represented and promoted.
- Distribution List
- Newsletter sent to different countries and different stakeholders, produced 3-monthly (M 1,4, 7,10,13,16, 19, 22, 25, 28, 31, 34). The exact timing could be adapted according to JA events and meetings, milestones, political occasions or presidency activity. Dissemination channel used: website, e mail, social media. Newsletter will be free to view and download on our website.
- Social media communications strategy will be an essential component of the overall communications strategy of the JA (Dissemination through twitter and facebook of all events/results related to JA)
- Website is the main tool where all the outcomes will be collected. (see task 2.4)

Task 2.3: Identification of the relevant target audiences and their expectations from the JA

Leader: AEMPS; Start date:M1 End date:M36

Task description: to design a plan that allows for dissemination strategies, it will be necessary to build a consistent strategy based on a stakeholder analysis that has carefully planned to cover different target groups to allow maximizing the impact of the efforts. The first step will be the identification of the relevant target audiences by a stakeholder analysis looking at the different users of the JA relevant information and their needs in regards with this output at EU level and within MSs. This analysis will include 4 target groups i.e. citizens (that includes patients and the mass media), healthcare professionals (HCP, managers, veterinarians), industries (agribusiness, livestock farming), and authorities (governments, regulators, public health and food safety agencies). This work will be conducted with the support of the stakeholder forum. Regular updates will be conducted since new target audiences might arise regularly

In order to analyze the target audience/stakeholders involvement on AMR and HCAI, it would be possible to use social networks analysis tool.

Regular updates will be conducted since new target audiences might arise regularly

Task 2.4: Web site Design: Internal and external use

Leader: AEMPS; Contributors: UMPIH/ Start date:M1 End date:36

Task description: A website as central hub for internal communication as well as main platform to communicate outputs and disseminate the information to the targeted audiences. This task is one of the most important dissemination tools for the second JA period (2nd and 3rd year) and will aim to:

- Design a sharing platform (see task 2.4) as for internal communication.
- Design and Implementation of a web platform (use of English for all dissemination activities) as for external dissemination. We believe the JA would benefit from easy to use software that will enable correct classification, efficient search and interactive collaboration.
- Used of the web banner designed (see task 2.1) on the webs of beneficiaries and collaborative partners. This banner will boost the JA visibility and will lead other websites' visitors to get to JA website

The first part of this task will involve the development of an interactive file-sharing platform where all partners can interact and share relevant information. This platform will have private access for the partners and the capacity of store the information.

The informative content of the website whose access is opened to all public, will consist partly of the information of the project (each WP will have a section etc.) and also a section to publish project news, events and all relevant information. This website activity will be regularly monitored through feedback via public tools (Google analytics) and internal methods (internal communications working groups, surveys, etc)

The benefit of developing this website in a way that best suits the needs of the project will ensure the key role of WP2 as the coordinating body of the dissemination activities for the project and make sure that results and relevant information produced over the lifetime of the project will not be lost and can continue to be a crucial part of JA products and services well into the future. It will include conferences and materials produced for each WP and websites of interest that can be shared as a tool for people to access relevant information about the JA and the topic.

Task 2.5: Implement the Dissemination Plan

Leader: AEMPS; Contributors: UMPIH/ Start date:M1 End date:36

Task description:

The main principles in order to ensure the implementation of the dissemination plan will be:

- Implementation of contents related to the JA: reports, interviews to key spokesperson within the JA and general information about AMR and HCAI. Video interviews will allow us to edit the clips or promos that will energize the website. For example, animated infographics videos will also contribute to get some more attention into the project.
- Encourage the participation of all partners in international seminars and conferences to promote the project. WP leaders/co-leaders will be responsible for writing at least one (informative) editorial related to the JA specific results and send it to the WP2 leader/co-leader. This editorial will be then disseminated by each partner through their networks/ social media channels and to any known relevant organization and/or person of interest they may consider. On the other hand, all these editorials will be gathered on the main website of the JA and maybe, as an idea, also the summaries of those articles could be gathered on a wordpress/blog to help disseminate and engage more public.
- To develop one promotional online campaign (competition or game, at European level) in the 2nd and 3rd years to attract general public to the website (campaign non-related to promote communication materials). For example in a previous JA, that WP2 prepared a Facebook competition and games to attract public, offering certain limited number of T-Shirts designed and signed by one celebrity and with a message related to antibiotic use. Also, another example would be a photography contest related to the overuse of medicines or something similar to get people thinking about the topic in their day-to-day life. This might be used at European level.
- To plan press releases informing about newsworthy outcomes and activities. Newsletters.
- Layman report: At the end of the project, beneficiaries should produce a Layman's report, a comprehensive information brochure targeted at a non-specialist audience. It serves to inform decision makers and non-technical parties of the project objectives and results with a full overview of the project outcomes.
- To organise a final Dissemination Conference (3° year). A final Conference will be organized at the end of the project to disseminate the project results. This Conference will target at researchers, clinicians and general practitioners, professional associations, mass media, patient organizations, etc., and also participate some representatives of the JA active partners.
- To be able to verify if the strategy was well chosen and well implemented through an evaluation component (in collaboration with WP3) into all dissemination activities to monitor the quality and to verify whether they have achieved their aim.

## Participation per Partner

Partner number and short name	WP2 effort
1 - INSERM	4.00
2 - MoH-FR	1.70
3 - GÖG	0.10
4 - FPS HFCSE	0.50
5 - NCIPD	0.70
6 - CIPH	0.20

Partner number and short name	WP2 effort
7 - NIPH	0.50
8 - SSI	0.50
9 - TA	2.00
10 - RKI	0.10
11 - HCDCP	1.00
12 - ESDY-NSPH	1.00
14 - UNIFG	0.40
15 - ISS	1.00
16 - PSKUS	1.00
17 - LSMULKK	1.00
18 - VULSK	1.00
19 - HI	0.50
20 - NVSC	0.10
21 - VWS	2.00
22 - HdiR	0.10
23 - FHI	1.50
26 - DGS	1.00
27 - UMPIH	2.50
28 - NIJZ	1.50
29 - AEMPS	39.00
32 - FFIS	1.00
33 - FMS	0.50
34 - SAS	1.00
35 - ISCIII	0.80
37 - FoHM	1.00
42 - SRC	0.40
44 - ANSES	1.00
	<b>Total</b> 70.60

# List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D2.1	Dissemination plan	29 - AEMPS	Report	Public	10
D2.2	Layman report	29 - AEMPS	Report	Public	33
D2.3	Final conference on dissemination	29 - AEMPS	Report	Public	36

## Description of deliverables

A dissemination plan, a layman report and a final conference on dissemination will be delivered in WP2.

D2.1: Dissemination plan [10]

Dissemination plan report

D2.2 : Layman report [33]

Layman report

D2.3: Final conference on dissemination [36]

Conference event agenda and minutes

## Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS5	Communication tool-kit	29 - AEMPS	6	Communication tool-kit
MS6	Dissemination Plan: intermediate control point	29 - AEMPS	7	Dissemination Plan: intermediate control point
MS7	Layman report	29 - AEMPS	30	Layman report: intermediate control point about document design and draft
MS8	Final Conference on dissemination	29 - AEMPS	30	Final Conference on dissemination: intermediary control point

Work package number 9	WP3	Lead beneficiary 10	15 - ISS		
Work package title	Evaluation of the project				
Start month	1	End month	36		

#### Objectives

The main objectives of this WP are:

- (i) to assess the achievement of the project objectives;
- (ii) to assess whether the outcomes meet the needs of the target groups.

The specific objectives of WP3 are:

- 1. Develop, share and disseminate an Evaluation Plan (EP);
- 2. Develop Evaluation Tools (ETs) for data collection according to the EP;
- 3. Perform interim and final evaluation;
- 4. Develop quality assessment and report it as a specific paragraph/chapter in JA deliverables and documentation;
- 5. Report and share the evaluation results to participants and relevant stakeholders;
- 6. Evaluate the impact of JA in Europe (MS and regional governments).

## Description of work and role of partners

WP3 - Evaluation of the project [Months: 1-36]

**ISS**, INSERM, MoH-FR, HCDCP, UNIFG, VWS, FHI, AEMPS, FFIS, FoHM WP Methodology

The evaluation process will include two major issues:

- i) Progress and results evaluation (Internal evaluation);
- ii) Quality evaluation (External evaluation).

The details of the evaluation process will be included in the Evaluation Plan (EP).

Relevant stakeholders will be engaged in the different phases of the evaluation process:

- one or more delegates for every WP and ECDC (due to its experience in infection prevention and control) for Internal evaluation (progress and results evaluation);
- Institutions at national (e.g. representatives of Ministry of Health, Agriculture, Environment, Research) and regional/local level, Policy-makers, Industries, Patients Association, Healthcare professionals Association, Scientific Societies (ECDC, EPHA), International Organizations (WHO Europe, OECD, FAO) for External evaluation (quality evaluation).

In order to reach the main objective (i) (progress and results evaluation), for every single JA objective and milestone process, output and outcome will be explored through specific indicators, defined and shared with WPs' leaders and relevant stakeholders.

These indicators will help evaluating the project progress, outcomes, impact and expected and unexpected development.

#### Tools

- i. Surveys through on-line questionnaires designed to be completed through self-assessment at country level by project participants and internal stakeholders;
- ii. Recording data out of routine documentation of WPs and pre-release deliverables (data from internal WP surveys, training materials, developed guidelines, operations manual, recommendations, results of pilot projects, questionnaire exploring: the carrying out and accomplishments of general and technical meetings, characteristics of participants, outcomes emerged and appreciation degree);
- iii. Meetings (on-line or face to face) to agree the Evaluation Plan, agree and share Evaluation Tools and share reports (interim and final) results with participant representatives of all JA WPs.

In order to reach the main objective (ii) (quality evaluation), the evaluation plan will be based on comments, suggestions and/or recommendation made by the Steering Committee and the Stakeholders Forum, which will give their contribution to assess:

- accuracy of Evaluation Plan in all its phases and efficacy and usefulness of Evaluation tools;
- relevance of JA AMR and HAI issues perceived at different level (institutional, academic and operational level);
- reproducibility, truthfulness and completeness of data provided by WPs' leaders and partners (e.g. through surveys' questionnaires) through National and Regional health institutions web-sites consultation, requests for integrations/clarifications, dispatch of additional documentation, etc.;

- comprehensiveness and accessibility of contents of deliverables and documentation released (e.g. clarity and realistic nature of conclusion and proposal);
- representativeness and relevance of stakeholders engaged and experts involved and of their performance;
- satisfaction degree about JA strategies, actions, tools and outcomes by policy makers, HCWs, Patients Associations and other stakeholders.

#### Tools

- i. Surveys through on-line questionnaires designed to be completed through self-assessment at country level;
- ii. Consultations involving different participants and stakeholders (WP leaders and partners, external stakeholders...) experts in HAI prevention and AMR;
- iii. Meetings (on-line or face to face) to share reports (interim and final) with external stakeholders.
- iv. EU MS National and Regional health institutions web-sites consultation for the availability of official data.

Progress and results evaluation and Quality evaluation will be included in interim and final reports, which will be shared with both internal and external stakeholders.

The team of evaluators will be composed by several professionals from Institutions/University with expertise in "projects evaluation" and previously engaged in similar experiences, both from Institution participating in the JA or subcontracted. Task descriptions

Task 3.1: Definition of the evaluation plan (EP)

Leader: ISS; Contributors: DGPIFAC / Start date: M1 End date: M4

Task description: EP, specifying evaluation activities, will be developed by the WP3 leader based on the set of defined indicators and reviewed by collaborating with representatives of all relevant JA WPs. The evaluation activities will include data recording out of routine documentation of WPs and pre-release deliverables, surveys (conducted through web-based questionnaires) and consultations involving different participants and stakeholders, and monitoring with a calendar of JA milestones. For each of these activities the evaluation plan will identify specific responsibilities, time for completion and mode of data collection for evaluation.

Revision of the EP will be carried out during the project, if necessary.

Specific and well-defined actions:

- i. assessment of the achievement of every single WP tasks and outputs;
- ii. the respect of the defined timeline and deadlines for WPs activities and outputs;
- iii. assessment of the correct development of general and technical meetings;
- iv. monitoring (support, early reaction, securing data) of the calendar of JA milestones;
- v. engagement of every single WPs leader and associated partner who contribute to the development of WP3 by providing evaluation information on their own activities, attended events (meetings, conferences, etc.) and deliverables.

## Task 3.2: Development of evaluation tools.

Leader: ISS (subcontracting); Contributors: DGPIFAC / Start date: M1 End date: M36

Task description: Based on the definition of the EP, ETs will be developed to collect all information that is not easily accessible by data recording out of routine documentation of WPs and pre-release deliverables and require instead surveys and consultations involving different participants and stakeholders. This task will include the definition and implementation of web based tools to facilitate data collection and surveys conduction. Prior to use, ETs will be reviewed by all relevant stakeholders included the participants of the Stakeholders forum, this will maximise evaluation response rate and avoid issues during data collection activities, thus minimising risks for the task. All ETs will be tested and piloted before their use and they will be revised during the project, if necessary.

## Task 3.3: Conduct interim and final evaluation.

Leader: DGPIFAC; Contributors: UNIFG, ISS / Start date: M5 End date: M36

Task description: based on the EP, interim and final evaluation activities will be carried out to monitor the implementation process for WPs activities and assessment of achievement of JA specific objectives. Evaluation activities (as described in the EP, see task 3.1) will provide information on WPs progress and timely attainment of the milestones, deliverables together with assessment of pilot projects. In case of issues in carrying out the evaluation activities, direct consultations will be performed with relevant partners and/or stakeholders (e.g. reminders to partners not responding surveys, communication with WP leaders and partners in case of delays with deliverables/activities, etc.).

## Task 3.4: Quality Assessment.

Leader: DGPIFAC; Contributors: UNIFG, ISS / Start date: M1 End date: M36

Task description: WP3 leader, in collaboration with the leaders of others WP, will support the quality assessment of JA documentation and deliverables and report it as a specific paragraph/chapter in JA deliverables and documentation. Deliverables and documentation will be assessed for quality aspects (e.g. comprehensibility, completeness, etc.) by the WP3 leader, who will coordinate the evaluation involving relevant internal and external stakeholders.

## Task 3.5: Report of evaluation results to relevant stakeholders

Leader: ISS (subcontracting); Contributors: UNIFG / Start date: M18 End date: M36

Task description: based on results from evaluation activities, the WP3 leader will produce an interim and a final report including all collected information and indicators. Reports will be shared with internal and external stakeholders, including the Steering Committee and the Stakeholders forum. This will ensure that quality of JA output is always a top priority to the management bodies.

The final evaluation report will be focused on the positive and negative aspects of the impact of the action and the reached aims (as a result of task 3.3); it will also evaluate usability and comprehensibility of JA results and deliverables in the target population (as a result of task 3.4).

## Task 3.6: Evaluation of the JA impact in Europe

Leader: ISS (subcontracting); Contributors: UNIFG / Start date: M18 End date: M36

Task description: A final evaluation of the JA impact in Europe will be performed (M36). The first positive results (if any) will be assessed, as well as possible barriers/room for improvements.

The impact will be evaluated at different levels:

- increase in number of professionals with skills on HAI prevention and AMR;
- availability of guidelines;
- increase in training initiatives for professionals.

According to the actions effectively adopted and the goals achieved by the Joint Action, also the following items will be assessed:

- decrease in HAI prevalence rate in MS participating to JA;
- decrease in prescriptions/consumption of antibiotics (overall and of one or more classes);
- lower rate of AMR in human and veterinary areas for one or more target microorganism;

To reach the objectives two main actions will be adopted:

- Questionnaires to national, regional and local authorities as well as to professionals and citizens associations on the main topics of the project; opinions will be collected about the first results of the JA;
- EU MS national and subnational web-site consultation for the availability of official data.

#### Participation per Partner

Partner number and short name	WP3 effort
1 - INSERM	3.50
2 - MoH-FR	0.60
11 - HCDCP	1.00
14 - UNIFG	2.50
15 - ISS	6.00
21 - VWS	1.00
23 - FHI	0.40
29 - AEMPS	1.00
32 - FFIS	5.00
37 - FoHM	1.00
Total	22.00

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D3.1	Evaluation plan	15 - ISS	Report	Confidential, only for members of	4

## List of deliverables

Deliverable Number 14	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
				the consortium (including the Commission Services)	
D3.2	Validation of the evaluation tools	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D3.3	Progress monitoring and quality assessment of JA documentation and deliverables Y1	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D3.4	Progress monitoring and quality assessment of JA documentation and deliverables Y2	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.5	Progress monitoring and quality assessment of JA documentation and deliverables Y3	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D3.6	Report on stakeholders evaluation and on JA impact in Europe	15 - ISS	Report	Confidential, only for members of the consortium (including the Commission Services)	36

## Description of deliverables

D3.1: Evaluation plan [4]

Release of the evaluation plan

D3.2 : Validation of the evaluation tools [12]

Report on the evaluation tools. All processes reported on a yearly basis.

D3.3: Progress monitoring and quality assessment of JA documentation and deliverables Y1 [12]

Reports on actions and initiatives to support teams responsible for the release of deliverables and documents. Interim and final evaluation reports based on the EP

D3.4: Progress monitoring and quality assessment of JA documentation and deliverables Y2 [24]

Reports on actions and initiatives to support teams responsible for the release of deliverables and documents. Interim and final evaluation reports based on the EP

D3.5: Progress monitoring and quality assessment of JA documentation and deliverables Y3 [36]

Reports on actions and initiatives to support teams responsible for the release of deliverables and documents. Interim and final evaluation reports based on the EP

D3.6: Report on stakeholders evaluation and on JA impact in Europe [36]

Report on the evaluation of the actions and documents released by the different WPs by relevant stakeholders. Report on the impact of actions and documents on MS at national and subnational level

## Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS9	Agreement on ETs plan	15 - ISS	5	Agreement on ETs plan
MS10	Availability of the web platform with tools to support the monitoring	15 - ISS	7	Availability of the web platform with tools to support the monitoring
MS11	Periodic check 1	15 - ISS	6	Periodic (every six months) check of correspondence between planned activities and timetable
MS12	Periodic check 2	15 - ISS	12	Periodic (every six months) check of correspondence between planned activities and timetable
MS13	Periodic check 3	15 - ISS	18	Periodic (every six months) check of correspondence between planned activities and timetable
MS14	Periodic check 5	15 - ISS	30	Periodic (every six months) check of correspondence between planned activities and timetable
MS15	Periodic check 6	15 - ISS	36	Periodic (every six months) check of correspondence between planned activities and timetable
MS16	Identification of interested stakeholders	15 - ISS	6	Identification of interested stakeholders
MS17	Quality meeting report 1	15 - ISS	2	Report on quality of the meetings within two months after their conclusion
MS18	Quality meeting report 2	15 - ISS	13	Report on quality of the meetings within

# Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				two months after their conclusion
MS19	Quality meeting report 3	15 - ISS	25	Report on quality of the meetings within two months after their conclusion
MS20	Quality meeting report 4	15 - ISS	36	Report on quality of the meetings within two months after their conclusion
MS21	Interim evaluation of JA	15 - ISS	19	Interim evaluation of JA
MS22	Final report on JA impact in Europe	15 - ISS	36	Final report on JA impact in Europe

Work package number 9	WP4	Lead beneficiary 10	2 - MoH-FR			
Work package title	Integration into national policies and sustainability					
Start month	3	End month	36			

#### Objectives

This overarching task of WP4 is to foster the integration into national policies of the recommendations issued by the consortium and/or ECDC and encourage healthcare workers and policy makers to expand and maintain their implementation in their respective countries when and where needed.

Since this JA involves 47 partners from 28 countries, one goal of WP4 is to secure the contribution of all participants to the JA (i.e associate and collaborative partners), and other bodies and institutions at the national and EU level, beyond the participating institutions. Specifically, the ECDC, FAO, OIE, WHO Europe and the European Commission will be involved to contribute to and support the sustainability of actions proposed within WP4.

The general approach taken within this WP is to build upon the work done in the JA WPs, especially guidelines, recommendations and tools for implementation. Since the scope of these studies will be rather limited within the time-frame of the JA, the task of planning the scaling-up of the results obtained when needed and obtaining adhesion to best practices from other institutions, partners, and MS relies on this WP. Support from the ECDC to address a specific problem through adapting guidelines or recommendation will be sought.

Several actions will need to be carried forward beyond the 3-year JA duration to ensure sustainability of results and actions initiated during the JA. The first task of WP4 will be to design an integration and sustainability strategy and plan based on the expected outputs from the JA. The strategy will account for potential differences in identified priorities based on public health organisation, geographical area and epidemiology, and also define potential indicators for follow-up of actions undertaken. As action on AMR and HCAI implies multilevel, multi-actor and multi-sectoral approach, the WP will provide for tailored recommendation to JA partners and groups targeted, associated with clear and measurable goals.

The specific objectives of this WP will include:

- 1. Developing an integration and sustainability plan
- 2. Ensuring integration of preventive strategies for AMR and HCAI into national policies
- 3. Fostering sustainability of core actions engaged by the JA WPs

## Description of work and role of partners

#### WP4 - Integration into national policies and sustainability [Months: 3-36]

## MoH-FR, AEMPS

WP Methodology

In general, the approach taken in WP4 will be through workshops and consultation of stakeholders, policy makers and competent authorities represented in the Steering Committee, and partners.

Given the specific role of this WP in terms of extension/dissemination of actions and implementation of sustainability strategies within Europe, it is clearly of importance that a maximum possible of MS, and whenever possible associated states and non-EU members contribute or be associated with the steps taken within this WP.

Task descriptions

Task 4.1: Integration plan and sustainability strategy

Leader: MoH-FR; Contributors: NMI, AEMPS / Start date: M3; End date: M30

Task description: the integration plan and sustainability strategy will propose, within the remit of the priorities identified by the WP and validated by Member States, an implementation plan on AMR and HCAI, compliant with EU Action plan as well as WHO Global action plan. It will identify for each actor, from patient groups to international organisations, achievable and realistic actions that are "game-changer". Based on the gap analysis performed within WP5, and a SWOT analysis of national strategies, the integration plan will propose specific roadmap for national competent authorities to adapt their national strategy to identified priority areas for intervention. Being focused on achieving reasonable and concrete objectives, the JA will share the best practice and deliverables it has produce with key players.

The WP will ensure that all core WPs (5,6,7,8,9) take into account the sustainability of their action within their work and reports. Close cooperation during the JA lifespan will ensure that from the beginning, sustainability and integration into national policies are carefully considered. WP4 leaders will therefore closely follow-up and contribute to the work done by other WPs through participation at meetings, iterative process of deliverables, observation and guidance on other WP's outputs.

4.1.1: Identify outputs from the JA which will should be widely disseminated and integrated into national strategies for control of AMR and HCAI.

This preliminary step aims to analyse the expected outputs from the JA in terms of guidelines, recommendations or implementation tools which are planned to be available by the end of the 3-year duration of the JA, and would need to be promoted at the regional/ national/ EU level. This analysis will be based on the compilation of objectives and deliverables from the JA WPs, and timing of availability of these outputs. After having analysed the MS priorities with regard to prevention and control of AMR and HCAI through a survey of Stakeholders and competent authorities as well as integrating information from gap analyses performed within WP5,6 and 7, these outputs will be put in perspective with MS priorities and existing reference documents (e.g., from ECDC, WHO,...) and analysed for their added value and potential for integration into national policies and action plans. This will form the basis for a draft version of the integration & sustainability plan. This draft version will be made available of the JA website (with WP2) for all JA partners and advisory bodies to comment and provide input on the draft plan.

## 4.1.2. Produce a sustainability plan

From the analysis performed in 4.1.1., priority areas for improvement will be discussed with the stakeholders forum and incorporated into a development program for prevention of AMR and HCAI, which will form the final version of the integration plan and sustainability strategy, produced by M30. This task will be coordinated by MoH-FR with the contribution of all partners. Representatives of Member States will be consulted regularly during the process of developing the plan to ensure that priority goals match the national agendas on AMR and HCAI.

A workshop with SC members will be organised to consolidate the recommendations included in the plan, and obtain commitment of MS on adopting the plan.

Task 4.2: Integrating preventive strategies within national policies

 $Leader: MoH\text{-}FR\ ; Contributors:\ NMI,\ AEMPS\ /\ Start\ date:\ M12\ End\ date:\ M36$ 

Task description:

After identification of gaps and proposed priority goals resulting from surveys and/or pilot studies performed within WP5, 6, 7, 8, the strengths and weaknesses of NAP will be assessed. The WP will elaborate concrete recommendations targeting those gaps and adapted to various contexts and problems (e.g., countries with high antibiotic consumption, countries with high levels of resistance, ...). It will propose a set of measures to be implemented, based on available recommendations and best practices identified, and include indicators for each group of actors to measure progress. Strong interaction with WP5 will be maintained, especially with regard to action within the OneHealth network and the supervising bodies network as supporting bodies following-up the adoption of actions proposed.

The actions, recommendations and tools selected for integration within the NAP and programs, as well as means for dissemination will be described in a report available within the last 6 months of the JA. Policy briefs will be used for dissemination to competent authorities. The integration task will require support and engagement of stakeholders and support from implementation science experts for communication of recommendations to public health levels.

Indicators suggested for this task include the number of policy briefs endorsed by national competent authorities

## Task 4.3: Fostering sustainability

Leader: MoH-FR; Contributors: NMI, AEMPS / Start date: M30 End date: M36

Task description: besides integration into MS' NAP of specific actions promoted within the JA WPs, some other outcomes or actions will need tailored actions to be undertaken to ensure their sustainability. The strategy used for this, involving national competent authorities and stakeholders as well as EU bodies, will be described in task 4.1 (DEL4.2). Sustainability of JA recommendations does not solely rely on international organisations or policy makers. Each stakeholder is part of the solution to tackle AMR. In this regard, the input received from the Stakeholder forum will be taken into consideration and specific recommendation for each target group will be included. For instance, representatives of patient associations will be able to take the recommendation of JA to their constituency.

Depending on the actions selected in 4.1.1, recommendations or practice guidelines will be elaborated. These will entail soliciting either institutions (eg, ECDC, WHO) or professional societies (eg, ESCMID). The guidelines will propose indicators allowing follow-up of progresses made toward reaching the objectives set up in the recommendations.

The country-to-country assessment method and tool tested within WP5 could be proposed for endorsement by WHO Europe and promoted among other MS not participating into WP5 for further joint assessment. Besides, the findings from these and recommendation discussed with the supervisory network should be integrated in the national supervision plans and procedures.

Likewise, the material produced and validated within WP6.1 and WP6.2 during pilot studies of implementing preventive strategies for designated HCAI, notably the improvement model and approach taken will need to be expanded to other settings and networks within EU MS and outside; this uptake could be promoted through two channels: the supervising bodies network convened within WP5 (Del 5.5) for EU MS and/or the professional bodies within the stakeholder forum; in addition, cooperation with WHO Europe will be needed to expand the approach to non-EU member states. Likewise, the model for implementation of the antimicrobial stewardship program and short-lagged

resistance surveillance designed within WP7 and pilot-tested will need, if successful, to be expanded to other settings and networks.

In addition, reference documents produced during the JA, such as the review of guidelines for prudent use of antibiotics (WP 7.1), best practices for promoting awareness and communication on AMR (WP8.1), or recommendation to ensure that MS use best procedures to improve their input into the EU research agenda (WP9.1) will need to be endorsed by external bodies and maintained /updated for example on the ECDC website. Indicators suggested for this action include recommendations endorsed by ECDC and made available on its website, as well as the number of MS countries adopting the implementation models and tools promoted by the JA.

Components of the JA included in the sustainability plan and specific processes used for their implementation will be described in the final report.

# Participation per Partner Partner number and short name 2 - MoH-FR 29 - AEMPS Total Total

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D4.1	Integration plan and sustainability Strategy	2 - MoH-FR	Report	Public	30
D4.2	Report on integration plan	2 - MoH-FR	Report	Public	30
D4.3	Updated report on integration plan	2 - MoH-FR	Report	Public	36
D4.4	Report on sustainability plan	2 - MoH-FR	Report	Public	36

## Description of deliverables

D4.1: Integration plan and sustainability Strategy [30]

Report on the implementation plan for integration of key actions into national policies and strategy for sustainability of JA outputs

D4.2 : Report on integration plan [30]

Specific measures for prevention and control of AMR and HCAI to be integrated in national action plans

D4.3: Updated report on integration plan [36]

Specific measures for prevention and control of AMR and HCAI to be integrated in national action plans

D4.4 : Report on sustainability plan [36]

Specific measures for prevention and control of AMR and HCAI to be sustained beyond the JA

# Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS23	Survey of MS priorities	2 - MoH-FR	12	Survey of MS priorities
MS24	Workshop with SC members	15 - ISS	24	Workshop with SC members on priority goals and integration of JA key actions into national AMR-HCAI plans

Work package number 9	WP5	Lead beneficiary 10	21 - VWS	
Work package title	Implementation of One Health national strategies and National Action Plans for AMR			
Start month	1	End month	36	

#### Objectives

The main objective of this WP is to support MSs (and other participant countries) on the implementation of some of the provisions laid down in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance (2016/C 269/05) unanimously adopted by the Council of the European Union in June 2016.

The specific objectives of this WP are to:

- 1) Support MSs in the development and implementation of national strategies and national action plans based on the One Health approach and in line with the WHO Global Action Plan (GAP) on AMR and the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance especially by:
- a) the development of a self-assessment tool to monitor country progress and identify gaps and shortcomings on the implementation of national strategies and national action plans;
- b) the setting up of a country-to-country peer review system to evaluate each other's national action plans and reflect about policy options;
- c) the establishment of a network of supervisory bodies to discuss different approaches on the way supervision, inspection and enforcement in the Member States is organized and on how the level of compliance with legislation, national (professional) guidelines, standards and recommendations relevant to AMR can be improved in the Member States.
- 2) Report regularly and discuss within the One Health Network described in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance on the outcome of the activities of WP5.

## Description of work and role of partners

WP5 - Implementation of One Health national strategies and National Action Plans for AMR [Months: 1-36] VWS, INSERM, MoH-FR, FPS HFCSE, NCIPD, NIPH, RKI, ESDY-NSPH, UNIFG, LSMULKK, HI, NMI, UMPIH, NIJZ, AEMPS, FoHM, SBA, NFA, SVA, ANSES

WP Methodology

The methodology used in this WP is in line with WHO approach to move from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts and the WHO framework for the monitoring and evaluation of the implementation of the Global Action Plan on AMR, based on the tripartite self-assessment and the performance of the Joint External Evaluation.

All activities described in this WP are based on the implementation of the One Health approach. The representatives of the WP5 participating countries are responsible for the engagement of the relevant sectors, including the formation of team of policy makers and experts from both the human and veterinary domain and the other relevant areas (e.g. agriculture, environment) within the country.

Workshops, electronic and physical meetings, tele/videoconferences, (self)-assessments, reports, literature/review, presentations at the One Health Network, etc.

Task descriptions

Task 5.1: Mapping and self-assessment of National Action Plans and strategies

Leader: VWS (NL) Contributors: all WP5 participating countries / Start date: M1 End date: M12

Task description:

In order to support MSs in the development of national strategies and NAP on AMR, the WP5 participating countries will:

- Map existing NAP and national strategies in the participating countries and in the rest of the EU, including, where relevant, the elements of the GAP on AMR and the Council Conclusions (One Health approach, overview of measurable goals, enforcement by competent authorities or national supervisory bodies, etc.).
- The mapping will be developed by the participant countries (at least one representative of each WP5 participating country) and will be based on publicly available information (e.g. internet site of ECDC, European Commission, Member State) and on direct information collected by the competent authorities in the MSs.
- Countries not participating in WP5 will be asked (thought the collaborative partners or partners involved in other WP of this Joint Action) to voluntarily provide the same information about existing NAP and national strategies in their countries in order to be able to also map the situation in these Member States.

- This mapping will provide an overview of the situation in the Member States and a view of the areas of concern and will be used for the development of the self-assessment tool.
- Develop a tool for the self-assessment of national strategies and NAP, including the One Health approach. The tool will be developed on the basis of the WHO (tripartite) tool "Global Monitoring of Country Progress on AMR: country self-assessment questionnaire" (or similar tool developed/revised in the future by WHO), by extending it to the situation in the EU, adding the specific requirements of the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance and the other requirements laid down in relevant EU legislation, recommendations, guidelines, etc. The self assessment tool will allow for the analysis of the strengths and weaknesses in the Member States.
- The tool will be developed by the WP5 participating countries (at least one representative of each country), with the assistance of collaborating stakeholders: EU agencies (ECDC, EMA, EFSA) and Directorate on Health and Food Audits and Analysis of the European Commission, WHO-EURO, WHO-HQ and OIE.
- For the development of the tool, several electronic working groups or tele/video conferences and also a physical meeting (workshop) will be organized. The tool will be presented to the participating countries. During the meeting participating countries will receive the instructions for the capture of data in the tool.
- In preparation of the country-to-country assessment (Task 2 see below), each of the participating countries will perform the self-assessment using the tool described in this task. Each participating country will analyze the results of its own self-assessment, in order to identify gaps in the NAP, evaluate the national strategy, etc. and will discuss at the national (or where relevant regional) level how to address gaps and improve the national situation. This analysis will preferably be SWOT-based in order to allow for the analysis of the strengths and weaknesses, identification of the opportunities and threats to face.
- Each participating country will provide the results of the findings of the self-assessment and the outcome of the own analysis to the WP5 leader.
- All participating countries will present, discuss and analyse together the report of the outcome of the self-assessments during several electronic working groups and/or video/teleconferences and also a physical meeting (workshop).
- The results of the self-assessments and the discussions during the workshop will be presented and discussed within the One Health Network.

NB: all WP5 participating countries will perform both Task 1 and Task 2. The performance of Task 1, the self-assessment, is a preparatory work for Task 2 (country-to-country assessment). At least one of the contributors from each participating country will be involved in the mapping task. The representatives of the WP5 participating countries will organize a team of policy makers and experts from both the human and veterinary domain and the other relevant areas (e.g. agriculture, environment) within the country to carry-out the self-assessments. These representatives are also responsible for involvement of the relevant (competent) authorities in their own Member State in the discussion of the outcome of the self-assessment.

## Task 5.2: Country-to-country assessments

Leader: VWS (NL) Contributors: all WP5 participating countries / Start date: M4 End date: M36 Task description:

A country-to-country peer review/assessment system will be set up, as described in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance. The country-to-country assessment will allow representatives of one or several WP5 participating countries to evaluate each other's national action plans and One Health strategies, reflect about policy options and provide recommendations to support countries on the development and implementation of the NAP and the measures taken.

The following actions will be performed:

- Development of the methodology and the tools to be used for the country-to country assessments. This activity will be performed by a (multidisciplinary) group of representatives of the WP5 participating countries, in close collaboration with the collaborating stakeholders: e.g. ECDC, the Directorate on Health and Food Audits and Analysis of the European Commission and where relevant international institutions (e.g. WHO-EURO).
- The tool for the country-to-country assessments will be developed and based on the self-assessment tool from Task 1 and taking into consideration the experience of the performance of the self-assessments.
- Performance of 3 pilot "country-to-country" assessments in countries that have already performed a self-assessment on NAP and have provided the summary of the findings and discussed them in the workshop.
- The 3 pilot countries will be chosen by the participating countries and will reflect, as much as possible, different situations in Europe. For this selection, the geographical distribution, division of responsibilities within the Member State (national vs regional), level of development and implementation of the NAP, etc. will be considered. All 3 selected countries must have already performed the self-assessment as described in Task 5.1.
- The country-to-country pilot assessments will be performed by a (multidisciplinary) team of one or more representatives of the WP5 participating countries. The team will consist of policy makers and experts and may include representatives from the relevant collaborating stakeholders: ECDC, EMA, EFSA, Directorate on Health and Food

Audits and Analysis of the European Commission, WHO-Euro or other international organizations. The team will visit a country, for example for 5 days (to be determined), in order to evaluate its national action plan, reflect about policy options and provide recommendations to support and improve measures taken. The team will make use of the already performed country self-assessment (see task 5.1) and where possible other existing assessment or audit activities (e.g. ECDC, Directorate on Health and Food Audits and Analysis or WHO) in order to avoid overlap or get additional information. At the end of the visit, the team will hold a wrap-up meeting with the relevant national competent authorities to present the preliminary outcome of the assessment.

- The countries assessed will further discuss internally at country level and also in the context of the One Health Network, the outcome of the country-to-country assessments and to follow up on identified shortcomings and gaps and address them and sustain this action.
- The representatives in WP5 of the country assessed are responsible for the involvement of the relevant (competent) authorities in their own Member State in the performance and the discussion of the outcome of the country-to-country assessment. The representatives of WP5 participating countries will organise a team of policy makers and experts from both the human and veterinary domain within the country to participate in the country assessment.
- The results of the 3 pilots will be discussed and the methodology and tool used for the country-to-country assessment will be revised based on the experience of the 3 pilot country-to-country assessments. For this purpose, several electronic working groups and/or video/teleconferences and a physical meeting (workshop) will be organized.
- The results of the 3 pilot country-to-country assessments will be presented and discussed at the One Health Network.
- Perform "country-to-country" assessments for the other countries in the WP that have already performed a self-assessment on NAP and provide a summary on the findings, based on the revised tool and methodology and report and discuss the results within the One Health Network.

NB: all WP5 participating countries will perform and participate in the country-to-country assessments. At least one of the contributors of each Member State will be involved in the development and revision of the country-to-country assessment. The representatives of the WP5 participating countries will organize a team of policy makers and experts from both the human and veterinary domain and the other relevant areas (e.g. agriculture, environment) within the country to participate in the country-assessment. They are also responsible for involvement of the relevant (competent) authorities in their own Member State in the performance and the discussion of the outcome of the country-assessment. Additional country-to-country assessments can be performed in additional countries not actively participating in WP5 provided that these countries have performed Task 5.1, the country-to-country assessment is supported, organized and self-funded by a collaborative partner in this Member State and based on the agenda and resources, including availability of the representatives of WP5.

#### Task 5.3: Strengthening supervision

Leader: VWS (NL) Contributors all WP5 participating countries / Start date: M2 End date: M36 Task description:

Control activities (supervision, inspection) and enforcement by the competent authority or a (delegated) supervisory body (including professional associations), provides information about the level of implementation of national policies, the level of compliance with legislation and the adherence to guidelines and recommendations. Furthermore, it is a tool to assess the execution of the NAP, to identify areas where action or improvement is needed, to assess the reasons why compliance is not met and may help parties to comply or better abide by existing rules (legislation, guidelines, recommendations).

For example, to achieve policy goals such as improvement of prudent use of antibiotics, strict adherence to the guidelines for antibiotic use is necessary and inspections and strict enforcement may discourage activities such as over the counter sales of antimicrobials.

However, these activities are organized in different ways in the different countries depending on the healthcare system, national legislation and distribution of competences and responsibilities within the country. Additionally, competent authorities and supervisory bodies may be responsible for the control of many different topics related to healthcare, and AMR is either not always on the agendas of all supervisory bodies in all European countries, or not considered a priority. To facilitate collaboration between supervisory bodies in the Member States, to facilitate control activities and enforcement of national policies related to AMR and on the implementation of the NAPs, Task 3 will include the following actions:

- Set up a voluntary network of national supervisory bodies in Europe and discuss methods of integrated supervision, best practices, exchange of experiences, etc. For this purpose, all participating countries in WP5 will identify the relevant supervisory bodies in their own country. A first meeting (workshop) will take place to establish the network, to learn about the different situations in the EU and to discuss further work. Representatives of the relevant collaborating stakeholders will be invited.
- The network will identify common white spots and shortcomings in the implementation of national strategies and discuss possible solutions and recommendations to improve the situation and the work of supervisory bodies. The

network will discuss the outcome of this work on a workshop and will present the results of this work to the One Health Network.

NB: all in WP5 participating countries will participate in the task of identification of the supervisory bodies in own country. At least one of the contributors of each member state will be involved in this task. All participating countries will be requested to participate in the network.

Participation per Partner				
Partner number and short name	WP5 effort			
1 - INSERM	9.00			
2 - MoH-FR	4.00			
4 - FPS HFCSE	4.00			
5 - NCIPD	6.70			
7 - NIPH	4.30			
10 - RKI	5.40			
12 - ESDY-NSPH	8.20			
14 - UNIFG	6.00			
17 - LSMULKK	6.50			
19 - HI	12.00			
21 - VWS	29.00			
25 - NMI	7.00			
27 - UMPIH	5.50			
28 - NIJZ	10.00			
29 - AEMPS	3.00			
37 - FoHM	3.00			
39 - SBA	0.80			
40 - NFA	1.50			
41 - SVA	0.70			
44 - ANSES	6.00			
Total	132.60			

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D5.1	Tool for country self-assessments	21 - VWS	Report	Public	6
D5.2	Summary Country- to-country assessments	21 - VWS	Report	Public	36
D5.3	Overview enforcement and	21 - VWS	Report	Public	36

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## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
	recommendations to be presented to the One Health Network				
D5.4	Assessment of the cost-benefit for the implementation of an infection control program	11 - HCDCP	Report	Public	36

## Description of deliverables

D5.1: Tool for country self-assessments [6]

Availability of the tool for the country (self) assessment based on the WHO-tool and adapted to the EU situation (Council Conclusions): summary of the questionnaire.

D5.2 : Summary Country-to-country assessments [36]

Performance of the country-to-country assessments

D5.3: Overview enforcement and recommendations to be presented to the One Health Network [36]

Report about white spots, shortcomings in the implementation of national strategies and discuss possible solutions and recommendations and preparation to present to the One Health Network.

D5.4 : Assessment of the cost-benefit for the implementation of an infection control program [36] Report

#### Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS25	Workshop	21 - VWS	10	Presentation, discussion and analysis of the outcome of the self- assessments (workshop)
MS26	Workshop WP5 2	21 - VWS	18	Workshop on the outcome of the 3 pilot country-to-country assessment and revision of the tool and methods.
MS27	Invitational workshop	21 - VWS	18	Invitational workshop for the establishment of the network of supervisory bodies

Work package number 9	WP6	Lead beneficiary 10	37 - FoHM		
Work package title	Policies for pr	es for prevention of Health-Care-Associated Infections and their implementation			
Start month	1	End month	36		

#### Objectives

In line with the EU action plan COM (2011) 748 - WP6 objectives are to ensure that guidance on infection prevention and control is developed, surveillance of HCAI is strengthened and that proper education and training of health-care workers is organised - this work will support the establishment of efficient and feasible infection control programs through the effective implementation of agreed key components for guidelines and/or other tools at national, regional and local level to prevent infections and thereby limit the use of antibiotics and spread of resistant bacteria in health-care settings. Two complementary objectives will be developed in this WP:

- I. Promoting a top-down approach for preventing HCAI through the implementation of agreed infection control programs and institutional behavior change.
- II. Promoting a bottom-up approach from clinical practice to policy level by implementing evidence-based guidelines and existing policies using a structured implementation model and working in country teams.

Patients and other relevant stakeholders must be involved in the improvement work concerning infection prevention and control measures. Participating MSs should involve relevant stakeholders in this work including patients, health-care professionals, infection prevention and control professionals, patient safety professionals, clinic management, hospital management, regional health-care management, national health authorities, existing European associations and networks within the field of infection prevention and control (IFIC, ESCMID, EUCIC, UMEMS, ESGNI, ISC and EUNETIPS).

The two objectives of WP6 will have strong interaction between each other in order to secure tight links to reach overall objective of WP6 - prevention of HCAI and also avoiding overlap in content.

#### Description of work and role of partners

WP6 - Policies for prevention of Health-Care-Associated Infections and their implementation [Months: 1-36] FoHM, INSERM, GÖG, FPS HFCSE, NIPH, TA, HCDCP, ESDY-NSPH, 7HC, UNIFG, ISS, PSKUS, LSMULKK, VULSK, HI, NVSC, VWS, DGS, NIJZ, AEMPS, GENCAT, IdISBa, FFIS, ISCIII, SoS, UAS WP Methodology

Objective 6.I: top-down approach: Policies for preventing health-care associated infections through the implementation of agreed infection control programs and institutional behavior change

The specific goals are to:

- 1. Determine the necessary institutional structures and resources for the implementation of infection control programs and promote adequate hospital organization, management and structure for the prevention of HCAI.
- 2. Incorporate Infection control programs into clinical practice for the improvement of health professionals' compliance with infection control routine using the institutional behaviour change as a tool to accomplish it.
- 3. Develop the tools for increasing awareness and improving the training of health professionals to infection control and prevention.

Given the differences in the AMR context in European countries, the aim of the objective 6.1 is to fill the gap between policy and practice of infection control in healthcare facilities based on evidence based practices and the national experience of participating partners for elaborating a concrete, implementable and reasonable Infection Control Plan for the prevention of HCAIs. The WP will contribute to improve the infection control capacity within health-care through institutional awareness using identified key components and specific interventions which will be adapted to the real needs, resources and priorities of the national health systems. The project will use the JA web-based platform for developing common protocols and sharing documents.

Objective 6.I will be divided into three main tasks which are a sequence of activities aimed at the development of a Universal Infection Control Framework (UICFW) for health professionals according to which roles, responsibilities and accountability will promote teamwork strengthening towards improved health professionals compliance and, consequently, patient safety. Ideally, the same partner-countries will be involved in all three tasks.

This methodology will follow four phases: plan, action, evaluation and improvement. The plan will be based on evidence-based practices and surveys, and action on the implementation of the infection control framework. Surveys will address all European Union member-states targeting to increase our knowledge regarding the current situation and the barriers that limit health system to restrict HCAIs. The implementation of the Universal Infection Control Framework (UICF) will be performed in the selected hospitals of the participants aiming to estimate the gap between policy and

practice. Each country should take advantage of the results of the surveys and the UICF implementation for improving its capability to develop HCAIs prevention policies at local and national level. For that reason the active contribution of national representatives is crucial for the collection of reliable data, the dissemination of the results, the feedback of stakeholders and the sustainability of this venture.

Task 6.1.1. Determine the necessary institutional structures and resources for the implementation of infection control programs and promote adequate hospital organization, management and structure for the prevention of HCAIs, according to the EU Action Plan.

Leader: HCDCP; Contributors: GOG; NIPH; 7HRC; NCE; UNIFG; ISS; DGS; CCS; AEMPS; GENCAT; Illas Baleares; DGPIFAC/SMS/FFIS; ISCII; FOHM / Start date: M1 End date: M36

Task description: the aim of this task is the determination of the necessary institutional structure and resources for the implementation of efficient and feasible infection control programs in healthcare according to the standards and requirements of the EU Action Plan for AMR.

This objective will be achieved through the following activities:

- 6.1.1.1- Survey for the key components of an infection control program based on the ECDC guidance (survey A in the table above) and the requirements of the updated EU Action Plan for AMR regarding the hospital sector. The questionnaire will be disseminated to all EU countries and will address public health organizations, relevant national scientific committees, hospital Infection Control Committees and hospital managers. The participating healthcare facilities to the survey will be determined from the partners depending on the health care structure in the country, with a strong focus on acute care and long-term settings. Regarding the EU member states that are not participating in the task the questionnaire will be disseminated with the contribution of the respective national public health organizations. The aim of this extensive survey is to have the clearest picture of the reality associated with the capability of each country to implement ICP policies. Finally, a workshop will be organized at the end of the survey by each participating country at local or/and national level for feedback on the survey's results, for raising the awareness of the contributors and the determination of the real needs and priorities of each country. (M1 M7)
- 6.1.1.2 Review of the guidelines for the implementation of ICPs and their applicability to clinical reality based on the result of the survey and the requirements of AMR action plans of WHO and EU. (M8 M13)
- 6.1.1.3. Assessment of cost-benefit for the development and implementation of an infection control program. It is of crucial importance to persuade the hospital managers and the politicians that the prevention of HAIs is saving lives and resources. It will be a supportive element to the organization behaviour change bundle. Intensive efforts for controlling AMR and HCAIs are costly and the cost-effectiveness of these efforts at the hospital or national level has not been defined. The initial plan of the assessment will be based on the existing literature and the revised guidelines. Its final formulation will be resulted from the implementation of the Universal Infection Control Framework in participating countries. Once the core components of an infection control program have been determined, assessment of their simultaneous impact on epidemiological, clinical and economic levels will follow on the basis of respective indicators that will have been chosen. The aim is to assess the implementation of an infection control program within the specific financial circumstances of each country so that the data produced can be totally compehensible and usable by professionals, who are mainly hospital administrators. This venture is ambitious and demands the development of broad collaborations among the participating countries, even at the level of health finances (M10- M36)
- Task 6.1.2: Incorporation of infection control programs to clinical practice for the improvement of health professionals' compliance with infection control routine using the institutional behaviour change as a tool to accomplish it.

Leader: HCDCP; Contributors: GOG; NIPH; 7HRC; NCE; UNIFG; ISS; DGS; CCS; AEMPS; GENCAT; Illas Baleares; DGPIFAC/SMS/FFIS; ISCII; FOHM / Start date: M1 End date: M36

Task description: the aim of this task is to fill the gap between policy and practice of infection control in healthcare facilities in European countries and evaluate the impact of the institutional behavior change on improving the HCWs compliance with infection control and prevention measures.

This aim will be achieved through the following activities:

- 6.1.2.1. Survey of the infection control policies at hospital level (Survey B, Table above). The aim of this survey is to examine and analyse barriers (attitudes, level of training, lack of awareness, etc) to an effective implementation of an infection control program in clinical reality, which are mainly linked to the institutional policy and organizational behavior. The survey will be based on common axes for all the participants, accounting for the peculiarity of each country's health system in which it will be performed for ensuring the sustainability of the project. A questionnaire will be disseminated to the participating EU countries and will be conducted through interviews of hospital administrations, Infection Control Committees, clinical department leaders, doctors and nurses at European level. The results of the survey will be evaluated at national and European level. (M1 M8)
- 6.1.2.2. A framework with specific roles, priorities and necessary interventions for implementing an infection control program (Universal Infection Control Framework –UICF)in healthcare facilities will be based on the results of the

two first ongoing tasks and feedback from governments, public health organizations, scientific committees and health professionals. (M8-M36)

6.1.2.3. Pilot testing of the Universal Infection Control Framework (UICF) in European hospitals. The aim of this testing is to estimate its impact on routine clinical practice and the behavioural change of clinicians on infection control. A limited number of healthcare facilities (at least two healthcare facilities) will be selected from partners to participate for a year in the pilot framework implementation study. The implementation of the plan will be based on intervention without additional costs and it will be modified in accordance to the operation, structure and resources of the hospitals. Hospitals will adapt the UIC framework to their needs and priorities adopting and performing the appropriate interventions. The final proposed UICF will be finalized with the incorporation of the pilot study results and it will be introduced at national and EU level.

The UICF impact will be assessed by the repetition of the initial survey using the following indicators:

- 1. The number of the key components of the proposed plan which were performed by hospitals (structure and process indicators
- 2. The cost-benefit assessment of the programme's implementation
- 3. The response (positive/negative) of stakeholders regarding the implementation of the infection control framework to the repetition of the survey
- 4. Additional outcome and process indicators (AMR and AB consumption rates, HCAIs incidence, hand hygiene compliance) will be used despite the fact that the time frame of this pilot testing is very limited to produce significant results. (M14 M32)

Task 6.1.3: Development of tools for increasing awareness and improving the training of health professionals in infection control and prevention.

Leader: HCDCP; Contributors: GOG; NIPH; 7HRC; NCE; UNIFG; ISS; DGS; CCS; AEMPS; GENCAT; Illas Baleares; DGPIFAC/SMS/FFIS; ISCIII; FOHM / Start date: M7 End date: M36

Task description: the objective of this task is to develop tools based on the results of the previous surveys on supporting the framework of hospital administrations and ICs regarding the implementation of an ICP and improving HCWs compliance with infectious control measures.

The objective of this task will be achieved through the following activities: development of tools will be mainly web-based and will aim at increasing professionals' awareness and strengthen infection control training schedules for prevention of HCAI and of the spread of multidrug resistant bacteria in hospital environment. The development of these tools will be based on previous surveys and they will be improved through the pilot testing.

OBJECTIVE 6.2: BOTTOM-UP APPROACH: PROMOTING A BOTTOM-UP APPROACH FROM CLINICAL PRACTICE TO POLICY LEVEL BY IMPLEMENTING EVIDENCE BASED GUIDELINES AND EXISTING POLICIES USING AN ESTABLISHED IMPLEMENTATION MODEL AND WORKING IN COUNTRY TEAMS.

This objective will be focused on adaption and implementation of existing policies (national/regional/ local) and evidence-based guidelines and on improving the infection control capacity within health-care. The improvement work will be performed using the "The Breakthrough Series Model" as advocated by the Institute of Healthcare Improvement (US). Thus another overarching objective is capacity building through education of the participants in this particular improvement model and in adapting existing guidelines to country requirements.

The specific objectives of this part are to: (i) introduce an evidence-based implementation model which ensures cooperation between key levels (national/regional/local) and stakeholders and (ii) promote that similar working routines are implemented in EU and non-EU countries across Europe

#### Task descriptions

Task 6.2.1. Introduce an evidence-based implementation model

Leader: FOHM; Contributors: FPS HFCSE; NIPH; TA; HCDCP; PSCUH; LSMULKK; VULSK; NVSC; HI; VWS; NIJZ; SoS; UAS / Start date: M1 End date: M36

Task description:

We will implement existing policies and evidence-based guidelines (see list below) with the aim to produce routines that can be implemented nationally. The Breakthrough Model from the Institute for Health-Care Improvement will be used. This model has been used and documented in numerous successful improvement projects within health-care (http://www.ihi.org/resources/pages/ihiwhitepapers/thebreakthroughseriesihiscollaborativemodelforachievingbreakthroughimprovement.aspx). The model will initiate cooperation between the levels represented (national/regional/hospital) depending on the health care structure in the country, as they will participate as a 'country team' in the workshops and in line with the national activities planned in between the workshops.

This objective will be achieved through the following activities:

6.2.1.1. Selecting topics and participants, development of a framework and proposed changes. According to the model "learning sessions", called workshops in this task, are then alternated with "action periods", called national activity periods in this project. During the action periods the participants use iterative P-D-S-A (Plan-Do-Study-Act)-cycles to test and finally implement small changes, which gradually leads to the goal of full implementation. In this work process both discussion of current practices, development of implementation tools, barriers to change (e.g. difficulties concerning behaviour change or administrative barriers), and adapting towards common policies and guidelines will be included. The experience and expertise of participants from hospitals, regions and nations will be used when the countries implement the changes nationwide as a continuation of the project.

The core components for infection prevention and control identified by WHO in 2009 and revised in 2016 will be used for strengthening the capacity on both the national and local (health-care facilities) levels for the prevention of HCAI and to prepare an efficient response to outbreaks of resistant bacteria. The WHO core components address key factors such as the organisation of infection and prevention programmes at the hospital level, the development of technical guidelines, training for health-care staff and specialised training of infection control professionals, surveillance of infections and pathogens and several other key factors for a comprehensive infection prevention programme. The same key factors and other complementary factors for the organization, management and structure for prevention of HCAI were recently compiled in a review and expert consensus by Zingg and others published in 2015 and will be used in this WP. The paper identified crucial elements for the organisation of effective infection-prevention programmes including ward occupancy and staff workload, access to materials and equipment (i. e hand rub), the development of multimodal strategies and tools and identification and engagement of strategy champions and creating a positive organisational culture. Assessment of competencies and training of health-care staff and infection control professionals will use the ECDC core competencies for infection control and hospital professionals in the European Union (2013) as a template.

6.2.1.2 Focus on specific topics. In addition to working with infection prevention and control policies general guidelines, the countries will choose to work with one or several of the following specific topics: catheter-associated urinary tract infection, hand hygiene, surgical site infections, and/or central line-associated blood stream infections. There are several well established, international guidelines available for these, and they are suitable for a multi-modal or bundle approach. Evidence-based guidelines are available for all these areas, and these will be provided to the participants as a basis for development and adaption of local implementation tools. The aim is to compile the evidence to improve compliance with routines. Based on the evidence the participants will agree on a model for improvement of compliance. After an initial phase of testing the model in 1-2 wards using the Model for Improvement, the model will possibly be revised and then implemented in several wards in the same hospital.

This task aims to engage key levels (national, regional, hospital) in participating MS in collaborative work to both start implementation of general policies/guidelines and to start implementation in specific areas (e.g. hand hygiene, catheter related UTI). For a sustained impact these teams are planned to continue the work towards nationwide implementation after the Joint Action, a so called "full" participation. MS/partners involved in the Joint Action who lack capacity for implementation at hospital level, may express interest in participating with one or two persons (who must be partners) at those WP6 workshops that will be held in conjunction to other Joint Action meetings (as appropriate), to build capacity on implementation in those countries and partner organisations, a so called "light-track" participation.

Criteria for taking part in this task

- The participating country needs to appoint one individual as country team coordinator and also appoint representatives for relevant levels, e.g., national/regional/hospital levels
- The national level will select one or two hospitals that has designated professionals for infection control The hospital management supports the project and is willing to actively support nation-wide implementation

Task 6.2.2: Promote that similar working routines are implemented in non-EU countries in Europe

Leader: FOHM; Contributors: FPS HFCSE; NIPH; TA; HCDCP; PSCUH; LSMULKK; VULSK; NVSC; HI; VWS; NIJZ; SoS; UAS / Start date: M1 End date: M36

Task description: the aim of the task is to engage European countries, other than MS, Norway, Iceland and Serbia by involving existing and well established networks of professionals. The goal is to promote that the same guidelines and methods are implemented throughout Europe. An implicit part of the chosen method is capacity-building, where the participating organisations may be strengthened through education, by independently adapting published guidelines and by practical improvement work.

The working model will be that participants in task 6.2.2 work closely and follow the model and participate in chosen activities – with MS partners in task 6.2.1 to safeguard a wider spread and transfer of knowledge. Some of the countries in task 6.2.2 can share their experiences with implementing the model and continue to carry out their own implementation efforts.

One example of a network is the Baltic Antibiotic Resistance collaborative Network (BARN), which is a grass root network for action against antibiotic resistance, with a focus on raising awareness and exchanging knowledge and

experience among practitioners on effective interventions in health-care settings. The network has three focus areas: Infection prevention and control; antibiotic stewardship and laboratory diagnosis and surveillance of resistant bacteria. The network has active members in Belarus, Estonia, Georgia, Latvia, Lithuania, Moldova, Poland, Russia, Sweden and Ukraine. It is a true multidisciplinary network: health-care personnel on all levels, microbiologists, infection control specialists, pharmacists, governmental workers and more.

Other relevant networks should also be engaged in this task, depending on which partner organisations will participate in Task 6.2.1. (both as full and light track participant).

Participation pe	r Partner
Partner number and short name	WP6 effort
1 - INSERM	12.00
3 - GÖG	6.00
4 - FPS HFCSE	8.30
7 - NIPH	24.50
9 - TA	5.00
11 - HCDCP	85.00
12 - ESDY-NSPH	2.00
13 - 7HC	11.50
14 - UNIFG	7.00
15 - ISS	7.00
16 - PSKUS	11.00
17 - LSMULKK	12.00
18 - VULSK	12.00
19 - HI	18.00
20 - NVSC	6.00
21 - VWS	7.00
26 - DGS	10.00
28 - NIJZ	11.00
29 - AEMPS	12.00
30 - GENCAT	12.00
31 - IdISBa	2.90
32 - FFIS	12.00
35 - ISCIII	4.00
37 - FoHM	41.20
38 - SoS	1.00
43 - UAS	1.00
	otal 341.40

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D6.1	Revised guidelines for the implementation of infection control program in healthcare settings	11 - HCDCP	Report	Public	13
D6.2	An Universal Infection Control framework with specific roles, priorities, resources and interventions for the implementation of an infection control plan in healthcare settings	11 - HCDCP	Report	Public	36
D6.3	Report on experience from country teams of introducing and working with the implementation model	37 - FoHM	Report	Public	18
D6.4	Updated report on experience from country teams of introducing and working with the implementation model	37 - FoHM	Report	Public	36
D6.5	Experience from non-EU country teams of introducing implementation model	37 - FоНМ	Report	Public	36

## Description of deliverables

D6.1 : Revised guidelines for the implementation of infection control program in healthcare settings [13] Report

D6.2: An Universal Infection Control framework with specific roles, priorities, resources and interventions for the implementation of an infection control plan in healthcare settings [36]

Report

D6.3 : Report on experience from country teams of introducing and working with the implementation model [18] Progress report

D6.4 : Updated report on experience from country teams of introducing and working with the implementation model [36]

# Progress report

 $D6.5: Experience \ from \ non-EU \ country \ teams \ of \ introducing \ implementation \ model \ [36]$  Report

## Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS28	Results of survey A	11 - HCDCP	8	Results of survey A (national-hospital policy)
MS29	Assessment of cost- benefit study	11 - HCDCP	12	Assessment of cost- benefit study
MS30	Results of survey B	11 - HCDCP	8	Results of survey B (barriers for an effective implementation of an ICP)
MS31	Initial proposed of UICFW	11 - HCDCP	14	Initial proposed of UICFW
MS32	Evaluation of the UICFW implementation	11 - HCDCP	32	Evaluation of the UICFW implementation
MS33	Initial presentation of the training tools	11 - HCDCP	12	Initial presentation of the training tools
MS34	Participating hospitals and topics selected per country	37 - FоНМ	12	Participating hospitals and topics selected per country
MS35	Selected IPC- guidelines and plan for implementation for participating hospital(s) in line with national plans.	37 - FоНМ	30	Selected IPC- guidelines and plan for implementation for participating hospital(s) in line with national plans.
MS36	Implementation work at hospitals established.	37 - FoHM	36	Implementation work at hospitals established.

Work package number 9	WP7	Lead beneficiary 10	23 - FHI	
Work package title	Appropriate use of antimicrobials in human and animals			
Start month	1	End month	36	

#### Objectives

The major objective of this WP is to collate and organise into a useable database the current guidelines for antibiotic stewardship at all levels of the European health system and selected animal (food and companion) species, and to establish workable tools for evaluating the implementation of antibiotic stewardship in all EU member states.

The specific objectives of this WP are to:

- 1. Identify and review existing guidelines, tools (including quality indicators) and importantly, implementation methods in the human sector (by level-of-care, hospital, long-term care facility and community setting) and the animal sector (diseased food and companion animals) and to summarize available information on the ECDC website
- 2. To use the results of objective 1 to guide a workshop with all the interested partners looking at barriers, opportunities and successful strategies for implementation at the three levels of care and the animal sector in order to evaluate possible options for the implementation of the work.
- 3. To report the level of implementation and level of acceptance of antibiotic stewardship strategies at different levels of care, in food and companion animals in different countries, including both indicators for consumption of antibiotics by humans and animals.
- 4. To design and run pilot projects looking at effective implementation (as defined by the previous two activities) of antibiotic stewardship by introducing a simple surveillance system of antibiotic consumption and resistance, including feedback mechanisms for a shorter time-lag than present alternatives. This would be done in parallel projects in settings with differing resources in human and animals and focusing on different levels of care.

We envisage a high degree of synergy between WP7 and WP6 and suggest close cooperation between the two packages.

#### Description of work and role of partners

WP7 - Appropriate use of antimicrobials in human and animals [Months: 1-36]

**FHI**, GÖG, FPS HFCSE, NCIPD, CIPH, NIPH, SSI, TA, RKI, HCDCP, ESDY-NSPH, UNIFG, ISS, LSMULKK, HI, NVSC, VWS, Hdir, NVI, NMI, DGS, UMPIH, AEMPS, GENCAT, IdISBa, FFIS, FMS, SAS, SERMAS, FoHM, ANSES

Task 7.1: Identify and review existing guidelines, tools and importantly, implementation methods for antibiotic stewardship by level-of-care (hospital, long-term care facility and community setting) and in food and companion animals and to summarize available information on the ECDC website

Leader: FHI; Contributors: HDir; AEMPS; DG de Planificación, Evaluación y Farmacia.- Consejería Salud Comunidad Autónoma Illes Balears; NMI; UNIFG; VWS; SSI; UMPIH; RKI; GOG; ISS; ANSES; CIPH HZJZ; LSMULKK; NVSC / Start date: M2 End date: M11

Collaborating with: ECDC dept. for antimicrobial resistance and Healthcare Associated Infections and OIE. ECDC would be asked to host the information made available through this project on their website.

Task description:

- Review material from ECDC, EFSA and EMA and other actors such as OIE, FAO, WHO, GHSA, website, other initiatives such as the ARNA project, the OECD report, the STRAMA network, and published literature
- Questionnaire to member states on current, past and proposed activities including receiving copies of tools and guidelines with weight given to the level of implementation of antibiotic stewardship plans, reason for choice of tool/guideline and implementation plan, "partners" in charge of work, success stories and the barriers that have hindered implementation of this work. This will expand on work already conducted by the OECD

The aim will be to update and expand the information available on the ECDC website to include information on existing guidelines, implementation methodology and work at different levels of the healthcare system. This will include strategies aimed at different settings and the existence of national or local indicators (including structural, process and outcome indicators of quality).

Task 7.2. Workshop involving all the registered partners to discuss models of implementation

Leader: FHI; Contributors: Hdir; AEMPS; GOG; NMI; NIJZ; VWS; SSI; UMPIH; RKI; GOG; ISS; ANSES; LSMULKK; NVSC / Start date: M11 End Date: M12, EFSA

Collaborating with: ECDC dept. for antimicrobial resistance and Healthcare Associated Infections: TBC Task description:

- Identify experts and organize expert group meetings (virtual and at least one face-to-face) to evaluate findings from task 7.1, identifying key tools and implementation mechanisms (expert group around 10 people) in both the human and animal sectors.
- Organize workshop to share experiences between countries and comment on expert group's findings, with a focus on barriers for implementation. Interest from Austria to help organize meeting (workshop about 40-60 people at end of year 1)
- Discuss suitability to different settings (cultural, epidemiological and financial)

Task 7.3 Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals, in different country settings. This will focus on identifying and establishing success factors and barriers.

Leader: FHI; Contributors: HDir; SAS; FFIS; GENCAT; SERMAS; Illes Balears; NMI; FOHM; UNIFG; NPIH; SSI; UMPIH; RKI; GOG; ISS; ANSES; LSMULKK; NVSC / Start date: M2 End date: M36 Task description:

- Follow-up questionnaire to active partners, which will be further disseminated in each member state or region. This will include structured questions and oral interviews. The aim of this activity will be to collate information about attitudes to stewardship methodologies and campaigns in order to determine both factors for success and barriers to acceptance.
- Evaluation and publication of recommendations on core components needed for implementation that can be used by member states when planning their own programs based on the information from tasks 7.1, 7.2 and 7.4.
- We will deliver a report on which indicators of antibiotic use and resistance are available in each country in human (for each level of care) and animals and, including for animal husbandry (as an indicator of the antibiotic burden in the environment).

Task 7.4.1 Develop and test near real time surveillance of antimicrobials and multidrug resistant bacteria Task description:

Current surveillance networks are informative and concise. However, there is a long delay in the data reported and some countries do not have data. Therefore, there is a need for reinforcing current surveillance systems. Surveillance networks need to be adapted to work in conjunction to provide a simple surveillance system of antibiotic use and resistance. This subject is essential to guide the fight against the antimicrobial resistance (AMR) and to improve the results by means of feedback and benchmarking. In addition, this system must work and data must be available in a shorter time-lag than present alternatives.

Subtask 7.4.1. Surveillance in human medicines - consumption of antimicrobials and AMR

Leader: SAS; Contributors: AEMPS; FFIS; GENCAT; SERMAS; Illes Balers; FMS; FHI; UMPIH; NMI; FPS HFCSE; UNIFG; ESDY-NSPH; NIPH; SSI; RKI; GOG; ISS; NVSC; LSMULKK / Start date: M2 End date: M36

- Select basic indicators for surveillance system of antimicrobial consumption: : DDD/1000 stays (in hospital settings) or inhabitants (in primary care settings) of:
- -. Overall antimicrobial drugs consumption
- -. Carbapenems, piperacillin-tazobactam, amoxicillin-clavulanate, aminoglycosides, quinolones, 3rd and 4th gen cephalosporins, vancomycin and colistin (in hospitals)
- -. Amoxicillin-clavulanate, 3rd gen cephalosporins, quinolones and macrolides (in primary care)
- Select basic indicators for surveillance system of antimicrobial resistance: Number of isolates in clinical samples per patient/1000 stays (in hospital) or inhabitants (primary care) of of the following pathogens:
- -. Carbapenemase-Producing Enterobacteriaceae, ESBL E. coli, ESBL K. pneumoniae, MDR A. baumannii, MDR P. aeruginosa and methicillin-resistant S. aureus (MRSA), ), vancomycin resistant enterococci (E. faecalis and E. faecium) in hospital settings.
- -. Carbapenemase-Producing Enterobacteriaceae, ESBL E. coli, ESBL K. pneumoniae, methicillin-resistant S. aureus (MRSA), in primary care area.
- Reinforce already existing local surveillance systems in order to have the available data as soon as possible.
- Select pilot sites that will represent the three levels of healthcare named above and to cover countries with different resources available including regular meetings, follow-up and support.
- Frequency: quarterly. Data managers will have a two-month period after the end of each trimester to upload data onto the website software.
- Collaborations with existing networks. Potential connections with EARS-net and ESAC: the project leader will have periodical meetings with with ECDC networks EARS and ESAC to share the project status and outcomes, so that it could be of interest for future collaborations.
- Quality of data: Indicators definitions and data management will be explained carefully in guidelines. A website with data management software will be developed specifically. Data will be entered by each participating hospital/primary

care area/region/country in the form of numbers (two figures per each indicator). The accuracy of data will be under each national coordinator's responsibility.

Regional data could be cumulative (sum of hospitals data / primary care areas data) or directly entered specifically by a designated responsible person.

Country data could be cumulative (sum of regional data) or directly entered specifically by a designated responsible person.

Calculations will be carried out by the software to minimize human error. Prior to validate entered data, a technician will supervise them quarterly in order to find out any possible outliers and take the measures to correct them. Besides, the task leader will carry out random audits to any participating country.

#### Subtask 7.4.2. Surveillance of AMR in animals

Leader: ANSES and ISS; Contributors: NVI, ESDY, SSI, AEMPS / Start date: M2 End date: M36

AMR surveillance in animals will be conducted to evaluate the correlation between AMR spread in humans and animals. Thus, antimicrobial-resistant bacteria that will be surveyed will be mainly the same in a One Health strategy. Numerous issues in the veterinary sector have already been covered by EU and/or MS initiatives sustained by scientific advice from EFSA. It is particularly the case for AMR surveillance under EC directives in healthy food animals and antibiotic consumption under ESVAC. On the contrary, the project will fill the gaps by focusing on the uncovered domain of AMR surveillance in diseased animals in the EU. Thus, the objectives will be to:

- Assess the surveillance systems in place on AMR in animal pathogens in MS
- Identify the main gaps and appropriate strategies for AMR surveillance in diseased animals in Europe depending on MS specificities towards their diversity in animal species and diseases
- Select appropriate AMR indicators in diseased animals in coherence with human ones, including carbapenemase-producing Enterobacteriaceae, ESBL E. coli, ESBL K. pneumoniae, MDR P. aeruginosa, MDR A. baumannii, methicillin-resistant S. aureus (MRSA), methicillin-resistant S. pseudintermedius (MRSP), colistin-resistant Enterobacteriaceae, vancomycin resistant enterococci (E. faecalis and E. faecium). The choice of these indicators will allow to correlate the animal data with the human data from subtask 7.4.1
- Identify laboratory and technical capacities in MS for potential establishment of a molecular-based AMR national surveillance of relevant resistant pathogens, to be further compared with human counterparts
- Assess the opportunities to combine MS surveillance systems into a pilot EU network for the surveillance of AMR in clinical animal isolates, covering prioritized animal species and relevant pathogens, based on existing networks in place at national levels (RESAPATH, VetPath, ...), and including common reporting and communication issues
- Draw guidelines for uploading, validation and management of the data, with particular emphasis on accuracy and types of the data (per animal species, pathogen and disease) under each national coordinator's responsibility.
- Provide global and specific recommendations to EU to build a European network covering AMR surveillance in diseased animals, including interface with AMR surveillance in human medicine

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Partner number and short name	WP7 effort
3 - GÖG	5.30
4 - FPS HFCSE	2.50
5 - NCIPD	11.00
6 - CIPH	10.70
7 - NIPH	5.30
8 - SSI	12.00
9 - TA	5.00
10 - RKI	5.90
11 - HCDCP	12.00
12 - ESDY-NSPH	38.00
14 - UNIFG	6.00

Partner number and short name	WP7 effort
15 - ISS	12.00
17 - LSMULKK	7.00
19 - HI	9.00
20 - NVSC	2.70
21 - VWS	2.00
22 - HdiR	3.80
23 - FHI	33.20
24 - NVI	6.00
25 - NMI	6.00
26 - DGS	5.00
27 - UMPIH	4.50
29 - AEMPS	18.00
30 - GENCAT	12.00
31 - IdISBa	7.30
32 - FFIS	4.80
33 - FMS	5.00
34 - SAS	17.10
36 - SERMAS	28.00
37 - FoHM	2.00
44 - ANSES	35.50
	<b>Total</b> 334.60

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D7.1	Website with evaluated tools and information	23 - FHI	Websites, patents filling, etc.	Public	12
D7.2	Report on workshop of models for implementation of stewarship tools	23 - FHI	Report	Public	13
D7.3	Indicators used for monitoring antibiotic use and resistance in humans and animals	23 - FHI	Report	Public	36

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D7.4	Surveillance of antimicrobial use and resistance in human	34 - SAS	Report	Public	36
D7.5	Surveillance of antimicrobial use and resistance in animal	44 - ANSES	Report	Public	36

## Description of deliverables

D7.1: Website with evaluated tools and information [12]

Website hosted by ECDC organised by level of care

D7.2: Report on workshop of models for implementation of stewarship tools [13]

Report on antibiotic stewardship implementation models

D7.3: Indicators used for monitoring antibiotic use and resistance in humans and animals [36]

Report

D7.4: Surveillance of antimicrobial use and resistance in human [36]

Results of pilot study from indicators selected to monitor antibiotic use and resistance in humans

D7.5 : Surveillance of antimicrobial use and resistance in animal [36]

Feasibility report for surveillance system in animals

## Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS37	Progress check of review procedure	23 - FHI	4	Progress check of review procedure
MS38	Progress check in terms of website	23 - FHI	12	Progress check in terms of website
MS39	Progress check of implementation of stewardship tools	23 - FHI	24	Progress check of implementation of stewardship tools
MS40	Progress check surveillance system	29 - AEMPS	15	Progress check surveillance system

Work package number 9	WP8	Lead beneficiary 10	29 - AEMPS
Work package title	Awareness raising and Communication		
Start month	1	End month	36

#### Objectives

Despite the European Commission and the Member States having developed and implemented strategies and action plans at national level to control the development of antimicrobial resistance, figures show that efforts should continue to keep on fighting against the development and propagation of antimicrobial resistance.

The main objective of this WP is increasing Awareness and optimizing Communication strategies on antibiotic use and AMR and prevention of Healthcare associated infections with the aim of promoting the responsible use of these medicines and encouraging best practices among the general public and healthcare professionals and through dialogue with young population and mass media.

The specific objectives of this WP are to:

- 1. Define best practices on Communication and Awareness: state-of-the-art as a guide for new or updated communication strategies.
- 2. Reach different targets using different strategies: Develop a Communication and Awareness Plan that will address these targets.
- 3. Use the website developed by WP2 as a key tool for promoting communication and interacting with social networks and traditional media to guarantee reaching the general public, specific groups of society and professionals subgroups. This website will work as a unifying platform that will collect all the contents created within the project, so it is a tool to ensure both, correct dissemination on high quality information on JA deliverables and awareness raising on AMR and HCAI issues. As for these contents, they will all be designed according to the different targets and properly updated as the project moves forward.
- 4. Support coordination about World Week and the European Day of Appropriate Use of Antibiotics. Establish dialogue with other initiatives and actors related to antibiotic use and antimicrobial resistance.

## Description of work and role of partners

#### WP8 - Awareness raising and Communication [Months: 1-36]

**AEMPS**, INSERM, MoH-FR, CIPH, NIPH, SSI, TA, RKI, HCDCP, ESDY-NSPH, UNIFG, LSMULKK, HI, NVSC, VWS, HdiR, DGS, NIJZ, GENCAT, IdISBa, FFIS, FMS, ISCIII, SERMAS

WP Methodology

The following tasks have been designed and planned in order to promote the responsible use of antibiotics by highlighting the importance of appropriate prescribing and use as well as informing about the risks associated with overuse and misuse of these medicines. Thus, this WP is intended to change minds and behaviors regarding antibiotics use and the threat of increasing AMR and HCAI.

WP8 strategy will be designed and carried out by a team that will consist of health communication specialists with relevant professional experience within this field. Communication between the Communication Officer in charge of WP8 and each country's contact person will be carried out via email on a monthly basis or more frequently if it is needed or via TLC depending on the project's dynamics. These active partners will maintain dialogue with its country's contact person for informing about relevant events, news, and other material related to awareness and communication.

## Task descriptions

Task 8.1: Data Collection to define best practices in Awareness and Communication Plans Leader: AEMPS; Contributors: TA and all WP8 participating partners / Start date: M1 End date: M12 8.1.1.

- Data collection on previous strategies, activities and materials targeting professionals in the fields of public health, animal health and the environment (one health approach), the general public and other specific population groups such as youth, medical students, caretakers or elderly. The objective is to collect and analyze all these materials to avoid efforts duplication, share good practices and offer ideas to MSs for building further new awareness and communication plans.
- The analysis of the mentioned materials will help to implement new awareness and communication plans to reach the following objectives:
- o Increase awareness on the importance and consequences of the inappropriate use of antibiotics in human and animal sector.

- o Optimize Compliance with treatment regimens of prescribed antibiotics.
- o Avoid the use of antibiotics when they are not indicated.
- o Avoid the storage and consumption of leftover antibiotics (self-medication).
- o Strengthen the position of professionals in public and animal health, to make them feel less pressured to prescribe and dispense antibiotics.
- o Encourage Health professionals to undertake Continuing Professional Development activities (i.e e-learning, webinars, live educational events)
- Selection of some efficient and innovative communication strategies and activities that have been performed in previous years, regardless their relation to antibiotic use. Search for some relevant and successful cases to take advantage of them.
- Analyze and evaluate previous awareness and communication materials and/or strategies.
- Prepare a report about Communication Good Practices as a guide or reference tool when designing new strategies. 8.1.2.

Analyze the use of the theme "antibiotic" in social networks and Internet. A pilot study will be conducted to analyze how the theme "antibiotic" is approached by the society in the social networks. Different periods of time in each year will be targeted to identify the key themes arising in relation to antibiotics (ie. April, October and January). A web-based tool will be used to detect daily occurrences of the word 'antibiotic' and other related terms during the chosen time period in Tweets. How the society dialogue about antibiotics as well as activity peaks (message frequency over three times that of baseline) will be analyzed to identify key issues and events that need to be considered in future awareness and communication campaigns. In that way, findings could determine the best period for launching campaigns in addition to negative attitudes or perceptions that should be considered to better address overuse and misuse. For the data collection, staff members will retrospectively analyze the selected periods.

8.1.3.

Identify some efficient and innovative educational strategies and activities performed in Europe focusing on prudent use of antibiotic in both High School and Universities.

A content analysis of teaching materials will be conducted to explore and identify innovative strategies and activities performed in the secondary high schools and universities. The project will organize strategies to share these activities and motivate all MSs to implement them, for example, by promoting the use of the e-bug platform, and its adaptation, or other similar initiatives.

Task 8.2: Design and Implementation of Awareness and Communication Plan

Leader: AEMPS; Contributors: VWS and all WP8 participating partners / Start date:M1 End date:M8

Task description: To design Awareness and Communication strategies targeting governments and stakeholders.

- 8.2.1. Prepare the Awareness and Communication Plan
- Definition of the objectives and identification of the relevant target audiences. Both WP8 and WP2 share target audiences (general media and health-specialized journalists, general public -specially considering caretakers for elderly and children-, healthcare professionals in both human and animal health, medical and veterinary students, human and animal health industries, key decision makers) but differ in goals since WP8 is intended to change minds and behaviors toward antibiotics by raising awareness of the dangers of AMR whereas WP2 is intended to disseminate outcomes and deliverables produced by the JA that could lead to this change.
- Definition of basic key messages to be communicated to the general public, health professionals and specific target audiences, along the same lines as ECDC's messages through the activities included within WP8. Messages targeted at general public:
- Antibiotic misuse and overuse creates antibiotic-resistant germs that could lead us to a scenario where antibiotics no longer work.
- Antibiotics are effective only against bacterial infections. Taking them for wrong reasons, such as against colds or flue, has no benefit for you.
- Antibiotics often give you side effects such as diarrhea. Always seek your doctor's advice before taking them.

Messages targeted at health professionals (physicians and veterinarians, pharmacists, nurses, specialist nurses, ...):

- Antibiotic resistance is an increasingly serious public health problem all over the world.
- While the number of infections due to antibiotic-resistant bacteria is growing, the pipeline of new antibiotics is unpromising, thus presenting a bleak outlook on availability of effective antibiotic treatment in the future.
- Unnecessary antibiotic prescribing could boost the emergence and selection of antibiotic-resistant bacteria.

More specific messages targeted at more specific audiences according to each country will be designed as the project moves forward, as well as the tools and the schedule to better spread them.

• Description of the issues to be tackled and identification of good practices and specific tools to be used or developed in order to support effective actions.

- 8.2.2. Implementation of some of the following proposed activities. Depending on budget, some pilot activities could be carried out in some countries or could be removed, if necessary. First working meetings will clarify each participant contribution so this schedule can be set up:
- Database design including European Science and Health Communication researchers. Organize 1 European webinar/year during the 2nd and 3rd years (mass media, other communicators, etc). Trying to generate a starting point for a network of communicators about increasing antibiotic use and antimicrobial resistance.
- Carry out 1 or 2conferences (similar to TED Conferences; maybe a pilot activity in some countries) in the second-third years of the JA, one with scientific communicators, and another conference with High School and university students as speakers. The conference with students will be organized with the aim of encouraging them to improve their public speaking skills as well as spreading our key messages among youth. Each country will determine criteria and rules for speakers' selection. For instance, invitations to participate in this programme could be sent to the regional or local authorities or to largest high schools in each region or the top-rated medical schools. A jury will select the best talk in each region and those students will take part of a national competition. Each country winner will eventually compete in a final contest that will take place in Brussels or in a Spanish city.
- High Level Awareness and Communication Meeting (included as activity developed in task 8.4): One High Level European Meeting in the last year focusing on governments (relevant institutional organizations at the regional (e.g. Health Authorities), national (MoH)) and stakeholder's (Industry) awareness with the attendance of international organizations (e.g. EIP, DG SANCO, OECD, WHO, JPI AMR, etc.). This High Level European Meeting could be organized within the context of the ECDC's European Antibiotic Awareness Day at the European Parliament or in a Spanish city chosen to host it. As speakers we might invite scientific and healthcare professional communicators or maybe some JA representatives (WPleaders). Organized as a workshop aimed to communicate the risks of misusing antibiotics and the need for commitment to fight AMR coming from different stakeholders. Thus, topics included will focus on highlighting the danger of not facing this problem from several perspectives (political, scientific and economical) in order to change different behaviors. This meeting is intended to set up a conclusion document that could work as a road map/call to action to be signed (supported) by different stakeholders (e.g. http://www.who.int/globalchange/global-campaign/call-for-action/en/). In any case, specific details will be decided by participants involved in WP8 at this work package's kick-off meeting.
- Training webinars on AMR lead by physicians and veterinarians that will be targeted at general media and health-specialized journalists. One purpose of these webinars is to provide clear and accurate scientific information about this problem so journalists are able to correctly inform the audience about AMR consequences. Furthermore, physicians and veterinarians will be asked to undertake Continuing Professional Development (CPD) activities on AMR. National accreditation authorities will be asked to require their doctors to do that. All of these activities will be carried out in close collaboration with different work packages involving interactions with physicians and veterinarians, so webinars and CPD activities' materials will be designed according to achievements that are being made.

Task 8.3: Tools for Awareness and Communication (probable interaction with WP2)
Leader: AEMPS; Contributors: UNIFG and all WP8 participating partners / Start date:M1 End date:36
Task description:

- Use of the web platform for promoting awareness and communication campaigns/materials or events carried out by WP8. The exclusive use of English would undermine effective communication and devalue the funding efforts made by all partners. Thus, our proposal would consider different versions in English, French and Spanish, as well as partial translations (i.e. objectives, news or blogs) to each MS language.
- Creation and implementation of a (or some) relevant blog(s) and performing an active search for contents within the website: news, podcast, reports, scientific papers, interviews, and general information about antimicrobial resistance. As previously mentioned, each active country should have one contact person for communication activities. All Work Packages leaders will notify any event, communications, news related to Awareness and Communication produced during WP development.
- Social media promotion:
- o Create profiles in Facebook, Twitter and Youtube, and make sure to update the content of these profiles on a regular basis (daily and weekly updating). Contents will spread initiatives related to our goals that are being carried out all over Europe and will also consider the organization of Twitter chats with healthcare professionals and contests that will boost engagement (e.g. online quizzes or sharing experiences related to the use of antibiotics).
- o Carry out 3 social media promotion actions per year in the 2nd and 3rd years to attract internet traffic to the website (at European level) for example by JA-blog Promotion (promote communication and awareness materials) in the social media. Paid media in Facebook or Twitter will create more exposure and will drive searchers to our website, to help increase not just traffic but also conversations. Thus, tools such as advertising or collaboration with influencers will impact the reach of our key messages.

o Use of a social networks analysis tool to measure the impact of the promotion actions and to get a deeper knowledge of the flow of information based on complex networks techniques and the topology of the network (Analytics, online reputation, etc).

#### · Awards

- o Award for the best European article or best video about antibiotic use. This award will be granted to the journalist whose article/video presents the clearest, informative and scientifically-based piece of work. Articles/videos to be considered will be chosen from the most read newspapers and top television news services.
- o Award for a European competition with University students (High School students should be also considered if it does not provoke legal difficulties in audio-visuals activities related to the use of underage images) presenting a video work about antibiotic use and increasing AMR. The competition "Eurovision Antibiotic Contest" will grant the most creative piece of work (a music video, a short film, a monologue, using their own language) explaining how we should use antibiotics and how we actually use them. Just like in "Eurovision Song Contest" each country will select a winner that will compete in a final contest. The winner will get a study-abroad grant. The organization of this contest could work as an inter-university competition leaded by selected professors within each university (e.g. https://www.consumerclassroom.eu/consumer-classroom-inter-school-competition-2016-2017). This competition will permit future sustainability of this type of health competition and working closely with CHAFEA could also be the opportunity to implement later a "Health classroom" within their "consumer classroom".
- This social campaign will be designed in order to address general public and healthcare professionals in both human and animal health, according to the One Health approach. Audiovisual materials will be created to be posted at social networks profiles and leaflets/posters will be distributed among hospitals and medical centers and in professional congress. Cited examples in the Luxembourg meeting were: use Term antibiotic in the box. Cooperation with the industry. Or TV France example "antibiotic is not automatic anymore" or "proper prescribing", Maybe use an ethical message about a good prescription.
- Interview management with key national spokesperson in the top general and health-specialized media. Each partner should contact the most relevant national media to offer an interview with the selected national spokesperson, who will highlight the project's key messages during the interview. National spokesperson should be selected according to their authority, expertise, communication skills and interview background.

Task 8.4: Support coordination about World Week and the European Day of Appropriate Use of Antibiotics. Establish dialogue with other initiatives and actors.

Leader: AEMPS; Contributors: NIJZ and all WP8 participating partners / Start date:M1 End date:36 Task description:

- Following ECDC's line of work, meetings with AMR JPI, IMI JU consortium working on antibiotics, WHO/Europe and other initiatives will be held in order to share ideas and jointly collaborate in campaigns.
- Meetings with National Action Plan Coordinators to share best awareness practices.
- Coordination meetings on European Antibiotic Awareness Day. WP8 Communication team will be able to offer any support and help in order to face any need and contribute to implementing any proposed activity.
- High Level Awareness and Communication Meeting (explained previously in subtask 8.2.2.3.)

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Partici	nation	ner	Partner
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Partner number and short name	WP8 effort
1 - INSERM	7.50
2 - MoH-FR	1.00
6 - CIPH	0.50
7 - NIPH	0.50
8 - SSI	0.50
9 - TA	5.00
10 - RKI	0.10
11 - HCDCP	1.00
12 - ESDY-NSPH	1.00

Partner number and short name	WP8 effort
14 - UNIFG	1.90
17 - LSMULKK	0.50
19 - НІ	0.50
20 - NVSC	2.50
21 - VWS	2.00
22 - HdiR	0.10
26 - DGS	2.50
28 - NIJZ	3.50
29 - AEMPS	49.00
30 - GENCAT	4.00
31 - IdISBa	3.10
32 - FFIS	1.00
33 - FMS	0.50
35 - ISCIII	0.40
36 - SERMAS	3.00
	<b>Total</b> 91.60

## List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D8.1	Awareness and Communication Plan	29 - AEMPS	Report	Public	10
D8.2	European Prize: better journalism report or better video about antibiotics	29 - AEMPS	Report	Public	27
D8.3	European competition with High Schools students	29 - AEMPS	Report	Public	32
D8.4	Awareness and Communication High Level Meeting	29 - AEMPS	Report	Public	34

# Description of deliverables

D8.1: Awareness and Communication Plan [10]

Report

D8.2 : European Prize: better journalism report or better video about antibiotics [27]

Report: list of competitors, agenda of the event, report of the prices and winners, report of the applicants considered and a short brief of their applications.

D8.3 : European competition with High Schools students [32]

Report: list of competitors, agenda of the event, report of the winners, report of the applicants considered and a short brief of their applications.

D8.4: Awareness and Communication High Level Meeting [34]

Report on road map for stakeholders with minutes and videos available

# Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS41	Awareness and Communication Plan	29 - AEMPS	7	Awareness and Communication Plan
MS42	Database control check	29 - AEMPS	7	Database control check
MS43	European Webinar and of Science and Health Communication researchers	29 - AEMPS	14	European Webinar and of Science and Health Communication researchers (Mass media): control point
MS44	Design of promotion activities related to better journalism report or better video about antibiotics	29 - AEMPS	14	Design of promotion activities related to better journalism report or better video about antibiotics
MS45	European competition with High Schools students: starting control point	29 - AEMPS	12	European competition with High Schools students: starting control point
MS46	European competition with High Schools students: intermediate control point	29 - AEMPS	24	European competition with High Schools students: intermediate control point
MS47	Awareness and Communication High Level Meeting: starting control point	29 - AEMPS	16	Awareness and Communication High Level Meeting: starting control point
MS48	Awareness and Communication High Level Meeting: intermediate 1 control point	29 - AEMPS	24	Awareness and Communication High Level Meeting: intermediate 1 control point
MS49	Awareness and Communication High Level Meeting: intermediate 2 control point	29 - AEMPS	30	Awareness and Communication High Level Meeting: intermediate 2 control point

Work package number 9	WP9	Lead beneficiary 10	1 - INSERM		
Work package title	Prioritizing and implementing research and innovation for public health needs				
Start month	1	End month	36		

#### Objectives

The main objective of this WP is to contribute to a coordinated European response in regards to prioritizing and assisting in the implementation of research and innovation expected to help achieve public health-related AMR and HCAI goals and objectives. (This WP will not fund any research or innovation projects.) The three specific objectives of this WP each corresponding to a dedicated task are to:

- 1. Work with Member States to ensure that national processes for research and innovation priority-setting are grounded in a broad One Health approach and that both Member State research priorities and knowledge gaps are addressed in the development of the update of the JPIAMR SRA (Strategic Research Agenda.
- 2. Explore and detail European strategies to implement mechanisms to increase innovation and other means to fight against AMR and HCAI
- 3. Contribute to ensuring that evidence-informed public health policies and practices related to combatting AMR and HCAI are implemented

#### Description of work and role of partners

# **WP9 - Prioritizing and implementing research and innovation for public health needs** [Months: 1-36] **INSERM**, 7HC, ISS, VWS, FHI, NVI, NIJZ, IdISBa, SERMAS, SRC

Task 9.1: Work with Member States to ensure that national processes for research and innovation priority-setting are grounded in a broad One Health approach and that both Member State research priorities and knowledge gaps are addressed in the development of the update of the JPIAMR SRA.

Leader: INSERM Main contributors: FHI, SRC; Other contributors: 7HRC; ISS; VWS; NVI; NIJZ; Balearic Isles, SERMAS / Start date: M1 End date: M36

Task description:

The aim of this task is to contribute to a strengthened process for European-wide and internationally acknowledged agreement on research and innovation priorities to meet the public health goals related to AMR and HCAI in a broad One Health approach.

The European Union Member States in 2016 through the Council Conclusions, particularly §22.8, expressed their will to align strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostic, and set priorities based on societal needs in the field of public health, animal health and the environment, taking into account gaps analysis in this domain.

Significant efforts led by JPIAMR in collaboration with the EU and IMI have already been established in regards to AMR research and innovation priority-setting. Its Strategic Research Agenda (SRA) outlines key, neglected areas to tackle, which guides JPIAMR and others to shape cohesive and coordinated AMR funding and research actions to maximise on resources and reduce duplication of research. The SRA is scheduled to be updated in 2017. About half of EU members, but also other countries, participate in JPIAMR.

This process can be expanded upon by working directly with Member States in preparation of their participation in priority-setting activities with JPIAMR. Member States need to ensure that their national processes include: (1) a One Health focus including not only the Ministry of Health but also Ministries of Agriculture, Fisheries, and Environment; (2) ensure that the special needs of HCAI are also included; (3) ensure that an appropriate breadth of research fields is considered including social sciences; and (4) consider where research syntheses are needed in order to inform policies. Social sciences are an often forgotten aspect of research priorities but can have major impact on achieving stewardship and infection control goals. Member States should also ensure that their own national research agendas are in line and fill the identified gaps with the priorities set out by JPIAMR and other related initiatives like the international clinical trial networks. Member States not participating in JPIAMR should be encouraged to share their priority research and innovation topics with JPIAMR. Links to Horizon 2020 will also be evaluated.

Member State priority-setting for AMR and HCAI research and innovation in line with public health needs

- Gather national approaches to participation and input into the SRA update to assess best practices and gaps (INSERM, FHI, SRC)
- Work with Member States to provide best practices and routines that can assist them with identifying national research and innovation priorities to be communicated into the SRA process (INSERM, FHI, SRC)

• Provide feedback to JPIAMR and potentially Horizon 2020 and others about perceived gaps and potential procedural improvements to SRA update process (INSERM, FHI, SRC in conjunction with WP4 Implementation)

Task 9.2: Explore and detail European strategies to implement mechanisms to foster antimicrobial innovation and other means to fight against AMR and HCAI

Leader: FHI Main contributor: INSERM; Other contributors: SRC; 7HRC; ISS; VWS; NVI; NIJZ; Balearic Isles, SERMAS / Start date: M1 End date: M36

The aim of this task is to act upon recommendations for stimulating greater innovation (including medicines, vaccines, diagnostics, and medical devices – for both human and animal health) to combat AMR and HCAI. Innovation has been acknowledged to be dangerously lacking for the past decades. Yet this is not to say that this type of innovation has been determined to be more impactful than other types of research and innovation. Significant funds have recently been invested in projects, like the UK's AMR Review and IMI's DRIVE-AB, to explore new economic models and strategies to stimulate innovation. It is timely now to react to the results of these initiatives and assist Member States with implementation.

Since the cost of developing some products, like a new antibiotic, may be large, the financing for stimulating innovation is also large, requiring coordination across countries. Other processes, like joint procurement mechanisms, new regulatory classifications, and regulatory harmonization, can also be impactful and require collaboration. UK's AMR Review delivered its final report in May 2016 which included recommendations to stimulate both antibacterial innovation for human and animal use as well as diagnostic innovation. DRIVE-AB will deliver its final recommendations in September 2017.

Assist with EU-wide implementation of incentives to stimulate antimicrobial, diagnostic and other innovations for fighting AMR and HCAI

- Hold a meeting where AMR Review, DRIVE-AB, and other potential actors present their recommendations to Member States and non-Member States regarding the need for multi-country collaboration in order to stimulate the innovation of antimicrobials (for both human and animal health) as well as diagnostics and other innovations, including an opportunity for governments to ask questions and provide feedback (FHI, INSERM)
- Perform a gap analysis for any missing incentives with a special focus on how to align and/or differentiate what is needed for AMR on the one side and HCAI on the other (FHI, INSERM)
- Hold follow-up meetings with about ten Member States and 3-5 non-Member States to gather direct feedback on the recommendations and options for implementation; request written feedback from the remaining Member States (FHI, INSERM)
- Develop an implementation strategy aligned with feedback from Member States (FHI, INSERM in conjunction with WP4)
- Request that all Member States formally respond to the implementation strategy with firm commitments (FHI, INSERM)

Task 9.3: Contribute to ensuring that evidence-informed public health policies and practices related to combatting AMR and HCAI are implemented

Leader: FHI / INSERM; Main contributor: SRC; Other contributors: 7HRC; ISS; VWS; NVI; NIJZ; Balearic Isles, SERMAS / Start date: M1 End date: M36

The aim of this task is to ensure that national procedures are in place to translate research findings (including those from the social sciences) into public health policies and practices. Since the quality, certainty, and strength of recommendations can vary for individual studies, it is important to first synthesize the existing evidence through a systematic review where the evidence is graded and then summarize the findings in plain language for policymakers. SURE Policy Briefs are a tested format that can be used to convey evidence to policymakers. This task will require support of and engagement in fora for communication of research findings to public health implementation levels, including the exchange of good practices as a procedure to reinforce implementation. A particular attention will be paid to establish functional links with WP2, WP4 and WP8 in that regard.

Assist with evidence-informed policymaking.

- Evaluate existing tools for evidence-informed policymaking, like policy briefs, and modes of dissemination and sharing, as well as implementation good practices (FHI)
- Recommend national dissemination and sharing strategies for policy briefs or other tools (FHI, SRC)
- Gather feedback on recommendations and update recommendations appropriately (INSERM)
- Request EU to agree to and publish the recommendations (INSERM)

Partner number and short name	WP9 effort
1 - INSERM	31.00
13 - 7HC	1.50
15 - ISS	3.00
21 - VWS	4.00
23 - FHI	32.50
24 - NVI	1.00
28 - NIJZ	1.00
31 - IdISBa	2.40
36 - SERMAS	3.30
42 - SRC	4.60
Total	84.30

# List of deliverables

Deliverable Number <sup>14</sup>	Deliverable Title	Lead beneficiary	Type 15	Dissemination level	Due Date (in months) 17
D9.1	National priority- setting best practices	1 - INSERM	Report	Public	34
D9.2	Implementation strategy for EU collaboration	23 - FHI	Report	Public	36
D9.3	Dissemination strategies	1 - INSERM	Report	Public	36

# Description of deliverables

D9.1: National priority-setting best practices [34]

Best practices and routines that can be implemented by Member States to improve the input that they send to SRA regarding research and innovation priorities

D9.2: Implementation strategy for EU collaboration [36]

A concrete strategy for implementing multi-country incentives to stimulate antimicrobial and diagnostic innovation

D9.3 : Dissemination strategies [36]

Policy briefs or other tools publicly available

# Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS50	Gathering of national approaches to providing input to	1 - INSERM	18	Gathering of national approaches to providing input to SRA from at least five countries

# Schedule of relevant Milestones

Milestone number 18	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
	SRA from at least five countries			
MS51	Inter-governmental meeting to discuss DRIVE-AB and AMR Review recommendations with regards to AMR and HCAI	23 - FHI	6	Inter-governmental meeting to discuss DRIVE-AB and AMR Review recommendations with regards to AMR and HCAI
MS52	Recommendation for dissemination of policy briefs or other tools sent to Member States for review	1 - INSERM	24	Recommendation for dissemination of policy briefs or other tools sent to Member States for review

# 1.3.4. WT4 List of milestones

Milestone number 18	Milestone title	WP number 9	Lead beneficiary	Due Date (in months) 17	Means of verification
MS1	Kick-off meeting	WP1	1 - INSERM	1	Organisation of the kick- off meeting completed (meeting, agenda & preparatory documents)
MS2	The Steering committee and Advisory Boards Forum are set up	WP1	1 - INSERM	2	The Steering committee and Advisory Boards Forum are set up
MS3	First annual meeting	WP1	1 - INSERM	10	Organisation of First annual meeting completed (meeting, agenda & preparatory documents)
MS4	Second annual meeting	WP1	1 - INSERM	22	Organisation of second annual meeting completed (meeting, agenda & preparatory documents)
MS5	Communication tool-kit	WP2	29 - AEMPS	6	Communication tool-kit
MS6	Dissemination Plan: intermediate control point	WP2	29 - AEMPS	7	Dissemination Plan: intermediate control point
MS7	Layman report	WP2	29 - AEMPS	30	Layman report: intermediate control point about document design and draft
MS8	Final Conference on dissemination	WP2	29 - AEMPS	30	Final Conference on dissemination: intermediary control point
MS9	Agreement on ETs plan	WP3	15 - ISS	5	Agreement on ETs plan
MS10	Availability of the web platform with tools to support the monitoring	WP3	15 - ISS	7	Availability of the web platform with tools to support the monitoring
MS11	Periodic check 1	WP3	15 - ISS	6	Periodic (every six months) check of correspondence between planned activities and timetable
MS12	Periodic check 2	WP3	15 - ISS	12	Periodic (every six months) check of correspondence between planned activities and timetable
MS13	Periodic check 3	WP3	15 - ISS	18	Periodic (every six months) check of correspondence between planned activities and timetable

Milestone number 18	Milestone title	WP number 9	Lead beneficiary	Due Date (in months) 17	Means of verification
MS14	Periodic check 5	WP3	15 - ISS	30	Periodic (every six months) check of correspondence between planned activities and timetable
MS15	Periodic check 6	WP3	15 - ISS	36	Periodic (every six months) check of correspondence between planned activities and timetable
MS16	Identification of interested stakeholders	WP3	15 - ISS	6	Identification of interested stakeholders
MS17	Quality meeting report 1	WP3	15 - ISS	2	Report on quality of the meetings within two months after their conclusion
MS18	Quality meeting report 2	WP3	15 - ISS	13	Report on quality of the meetings within two months after their conclusion
MS19	Quality meeting report 3	WP3	15 - ISS	25	Report on quality of the meetings within two months after their conclusion
MS20	Quality meeting report 4	WP3	15 - ISS	36	Report on quality of the meetings within two months after their conclusion
MS21	Interim evaluation of JA	WP3	15 - ISS	19	Interim evaluation of JA
MS22	Final report on JA impact in Europe	WP3	15 - ISS	36	Final report on JA impact in Europe
MS23	Survey of MS priorities	WP4	2 - MoH-FR	12	Survey of MS priorities
MS24	Workshop with SC members	WP4	15 - ISS	24	Workshop with SC members on priority goals and integration of JA key actions into national AMR- HCAI plans
MS25	Workshop	WP5	21 - VWS	10	Presentation, discussion and analysis of the outcome of the self-assessments (workshop)
MS26	Workshop WP5 2	WP5	21 - VWS	18	Workshop on the outcome of the 3 pilot country-to-country assessment and revision of the tool and methods.
MS27	Invitational workshop	WP5	21 - VWS	18	Invitational workshop for the establishment of the network of supervisory bodies

Milestone number <sup>18</sup>	Milestone title	WP number 9	Lead beneficiary	Due Date (in months) 17	Means of verification
MS28	Results of survey A	WP6	11 - HCDCP	8	Results of survey A (national-hospital policy)
MS29	Assessment of cost-benefit study	WP6	11 - HCDCP	12	Assessment of cost-benefit study
MS30	Results of survey	WP6	11 - HCDCP	8	Results of survey B (barriers for an effective implementation of an ICP)
MS31	Initial proposed of UICFW	WP6	11 - HCDCP	14	Initial proposed of UICFW
MS32	Evaluation of the UICFW implementation	WP6	11 - HCDCP	32	Evaluation of the UICFW implementation
MS33	Initial presentation of the training tools	WP6	11 - HCDCP	12	Initial presentation of the training tools
MS34	Participating hospitals and topics selected per country	WP6	37 - FoHM	12	Participating hospitals and topics selected per country
MS35	Selected IPC- guidelines and plan for implementation for participating hospital(s) in line with national plans.	WP6	37 - FoHM	30	Selected IPC-guidelines and plan for implementation for participating hospital(s) in line with national plans.
MS36	Implementation work at hospitals established.	WP6	37 - FоНМ	36	Implementation work at hospitals established.
MS37	Progress check of review procedure	WP7	23 - FHI	4	Progress check of review procedure
MS38	Progress check in terms of website	WP7	23 - FHI	12	Progress check in terms of website
MS39	Progress check of implementation of stewardship tools	WP7	23 - FHI	24	Progress check of implementation of stewardship tools
MS40	Progress check surveillance system	WP7	29 - AEMPS	15	Progress check surveillance system
MS41	Awareness and Communication Plan	WP8	29 - AEMPS	7	Awareness and Communication Plan
MS42	Database control check	WP8	29 - AEMPS	7	Database control check
MS43	European Webinar and of Science and Health	WP8	29 - AEMPS	14	European Webinar and of Science and Health

Milestone number 18	Milestone title	WP number 9	Lead beneficiary	Due Date (in months) 17	Means of verification
	Communication researchers				Communication researchers (Mass media): control point
MS44	Design of promotion activities related to better journalism report or better video about antibiotics	WP8	29 - AEMPS	14	Design of promotion activities related to better journalism report or better video about antibiotics
MS45	European competition with High Schools students: starting control point	WP8	29 - AEMPS	12	European competition with High Schools students: starting control point
MS46	European competition with High Schools students: intermediate control point	WP8	29 - AEMPS	24	European competition with High Schools students: intermediate control point
MS47	Awareness and Communication High Level Meeting: starting control point	WP8	29 - AEMPS	16	Awareness and Communication High Level Meeting: starting control point
MS48	Awareness and Communication High Level Meeting: intermediate 1 control point	WP8	29 - AEMPS	24	Awareness and Communication High Level Meeting: intermediate 1 control point
MS49	Awareness and Communication High Level Meeting: intermediate 2 control point	WP8	29 - AEMPS	30	Awareness and Communication High Level Meeting: intermediate 2 control point
MS50	Gathering of national approaches to providing input to SRA from at least five countries	WP9	1 - INSERM	18	Gathering of national approaches to providing input to SRA from at least five countries
MS51	Inter-governmental meeting to discuss DRIVE-AB and AMR Review recommendations with regards to AMR and HCAI	WP9	23 - FHI	6	Inter-governmental meeting to discuss DRIVE-AB and AMR Review recommendations with regards to AMR and HCAI

Milestone number <sup>18</sup>	Milestone title	WP number 9	Lead beneficiary	Due Date (in months) 17	Means of verification
MS52	Recommendation for dissemination of policy briefs or other tools sent to Member States for review	WP9	1 - INSERM	24	Recommendation for dissemination of policy briefs or other tools sent to Member States for review

# 1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	Overspending	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Appropriate financial control: Reporting throughout project
2	Subcontractor fails to deliver	WP2, WP8	Contractual agreement with subcontractor to cover implication of non-delivery
3	Partners' commitment declines	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Efficient internal communication tools and close follow-up by WP leaders
4	Staff turnover	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Project status meetings at WP level to identify issues on the horizon
5	Different level of understanding and sharing due to heterogeneity in native languages	WP3	Adopt English as official language. Content revision by MS representatives Evaluation surveys about the understanding of released documentation
6	Differences in JA partners compliance/collaboration to evaluation activities	WP3	Monitoring of the timeline of activities within WP 3. ETs will be reviewed by partners involved in the evaluation prior their use. Reminders will be sent to non-respondents. Communication with management bodies asking for direct actions on partners.
7	Lack of essential results/ information in the provided documents	WP3	Support by SC and Stakeholders Forum in reviewing documents - Communication with management bodies asking for direct actions on partners.
8	Differences / non homogeneity among indicators adopted by different Work Packages and for evaluation purposes	WP3	.Dissemination and review of the EP (at the beginning of the JA) and the ETs (during the whole JA lifetime) will provide a common and shared set of measures for indicatorsRevision of the EP/ETs will be carried out if necessary to avoid differences among indicators usedConsultation with SC and Stakeholders Forum on the harmonization of indicators proposed
9	Lack of coordination / synchrony amongst related activities from different WPs	WP3	.Promoting continuous communication among WPs leadersMonitoring every six months of the activities with respect to expected results and timelines .Sharing information and data on a common web based platform
10	Lack of information on national measures	WP5	Leader will use its network to verify information from partners of the project and double check information received
11	No consensus on the priority goals	WP5	Leader will ensure that all partners are satisfied with priority goals proposed. Delphi process will help to reach consensus
12	Link/overlap with WP6 and WP7 (WP5 target group is	WP5	We will ask WP6 leaders to develop or remark on the HCAI aspects to be developed in the self-

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
	national policy level. WP6 and WP7 target groups are professionals/local level).		assessment tool. Equally we will ask WP7 leaders to do this for prudent use aspects.
13	Link/overlap with WP4	WP5	Coordination with WP4 and EU agencies/ institutions needed to ensure continuity of the actions
14	Low engagement in the self- and country-to-country assessments: - Not all MS participate -No involvement of all relevant authorities -Disparity between supervisory bodies	WP5	Engagement of countries by informing/reporting to the One Health Network on the activities of WP5
15	No reporting to the One Health Network	WP5	Until now, the One Health Network has met only once and it's not clear which will be the frequency of the meetings, etc. Contact with EC to ask for frequent, regular meetings of the One Health Network.
16	Lack of appropriate monitoring of the implementation of the ICP in the hospitals	WP6	The hospitals will chose the core components they will perform regarding their priorities and needs, so the hospital managers support is necessary.
17	The impact of the implementation of this WP depends on the active participation of the partners at local and national level.	WP6	The scope and the aim of the project must be clarified from the begging and the partners should be encouraged continuously from the WP leader and the coordinator team
18	Objectives and tasks for WP 6 might be too ambitious and might run the risk of not being manageable within the time and resources allocated.	WP6	Actions within this WP focus on supporting implementation and setting realistic goals.
19	Difficulties in having hospitals joining actions.	WP6	Good preparatory work and contacts in order to explain the actions and also the added value of these actions
20	Time constraints.	WP6	Realistic time schedule and regularly monitor progress.
21	Lack of funding in pilot states	WP7	.Restrict participants number .Encourage co- funding by MS
22	Lack of infrastructure	WP7	Pilot only in countries that can deliver data
23	Lack of acceptance and cooperation from ECDC	WP7	Early dialogue with ECDC as soon as WP agreed
24	Disagreement regarding scope of priorities between MS and JPIAMR	WP9	Define this early in the process to ensure that JPIAMR's mandate is well understood
25	Lack of description of the differences and	WP9	Firmly engage all stakeholders to participate in this mapping

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
	communalities between the needs for AMR and HCAI.		
26	Lack of interest to align public health priorities	WP9	Engage countries from the start regarding the importance and cost savings potential of alignment
27	Cost of stimulating greater antibiotic innovation can be significant	WP9	Work with DRIVE-AB and AMR Review to understand the counterfactual cost and different methods of financing

# 1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person/Months per Participant
1 - INSERM	46	4	3.50	0	9	12	0	7.50	31	113
· CHU Limoges	0	0	0	0	0	0	0	0	0	0
· UL	0	0	0	0	0	0	0	0	0	0
2 - MoH-FR	8.20	1.70	0.60	14.40	4	0	0	1	0	29.90
3 - GÖG	0	0.10	0	0	0	6	5.30	0	0	11.40
4 - FPS HFCSE	0	0.50	0	0	4	8.30	2.50	0	0	15.30
5 - NCIPD	0	0.70	0	0	6.70	0	11	0	0	18.40
6 - CIPH	0	0.20	0	0	0	0	10.70	0.50	0	11.40
7 - NIPH	0	0.50	0	0	4.30	24.50	5.30	0.50	0	35.10
8 - SSI	0	0.50	0	0	0	0	12	0.50	0	13
9 - TA	0	2	0	0	0	5	5	5	0	17
10 - RKI	0	0.10	0	0	5.40	0	5.90	0.10	0	11.50
11 - HCDCP	0	1	1	0	0	85	12	1	0	100
12 - ESDY-NSPH	0	1	0	0	8.20	2	38	1	0	50.20
13 - 7HC	0	0	0	0	0	11.50	0	0	1.50	13
· GH Heraklion	0	0	0	0	0	0	0	0	0	0
14 - UNIFG	0	0.40	2.50	0	6	7	6	1.90	0	23.80
15 - ISS	0	1	6	0	0	7	12	0	3	29
16 - PSKUS	0	1	0	0	0	11	0	0	0	12
17 - LSMULKK	0	1	0	0	6.50	12	7	0.50	0	27
18 - VULSK	0	1	0	0	0	12	0	0	0	13
19 - HI	0	0.50	0	0	12	18	9	0.50	0	40
20 - NVSC	0	0.10	0	0	0	6	2.70	2.50	0	11.30

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person/Months per Participant
21 - VWS	0	2	1	0	29	7	2	2	4	47
22 - HdiR	0	0.10	0	0	0	0	3.80	0.10	0	4
23 - FHI	0	1.50	0.40	0	0	0	33.20	0	32.50	67.60
24 - NVI	0	0	0	0	0	0	6	0	1	7
25 - NMI	0	0	0	0	7	0	6	0	0	13
26 - DGS	0	1	0	0	0	10	5	2.50	0	18.50
27 - UMPIH	0	2.50	0	0	5.50	0	4.50	0	0	12.50
28 - NIJZ	0	1.50	0	0	10	11	0	3.50	1	27
29 - AEMPS	0	39	1	2	3	12	18	49	0	124
30 - GENCAT	0	0	0	0	0	12	12	4	0	28
31 - IdISBa	0	0	0	0	0	2.90	7.30	3.10	2.40	15.70
32 - FFIS	0	1	5	0	0	12	4.80	1	0	23.80
· DGPIFAC	0	0	0	0	0	0	0	0	0	0
· SMS	0	0	0	0	0	0	0	0	0	0
33 - FMS	0	0.50	0	0	0	0	5	0.50	0	6
34 - SAS	0	1	0	0	0	0	17.10	0	0	18.10
· FISEVI	0	0	0	0	0	0	0	0	0	0
35 - ISCIII	0	0.80	0	0	0	4	0	0.40	0	5.20
36 - SERMAS	0	0	0	0	0	0	28	3	3.30	34.30
· FBRIPC	0	0	0	0	0	0	0	0	0	0
37 - FoHM	0	1	1	0	3	41.20	2	0	0	48.20
38 - SoS	0	0	0	0	0	1	0	0	0	1
39 - SBA	0	0	0	0	0.80	0	0	0	0	0.80
40 - NFA	0	0	0	0	1.50	0	0	0	0	1.50
41 - SVA	0	0	0	0	0.70	0	0	0	0	0.70
42 - SRC	0	0.40	0	0	0	0	0	0	4.60	5

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	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person/Months per Participant
43 - UAS	0	0	0	0	0	1	0	0	0	1
44 - ANSES	0	1	0	0	6	0	35.50	0	0	42.50
Total Person/Months	54.20	70.60	22	16.40	132.60	341.40	334.60	91.60	84.30	1147.70

# 1.3.7. WT7 Tentative schedule of project reviews

Review number 19	Tentative timing	Planned venue of review	Comments, if any
RV1	20	in Chafea or over the phone	If deemed necessary by PO
RV2	36	in Chafea or over the phone	If deemed necessary by PO

# 1.4. Ethics Requirements

No ethics requirements indicated

#### 1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

#### 2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should** appear on each page of the grant agreement preparation documents (part A and part B) to prevent errors during its handling.

#### 3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

#### 4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB: entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

#### 5. Duration

Insert the duration of the project in full months.

#### 6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

#### 7. Abstract

#### 8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

#### 9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

#### 10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

#### 11. Person-months per work package

The total number of person-months allocated to each work package.

### 12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

#### 13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

#### 14. Deliverable number

Deliverable numbers: D1 - Dn

#### 15. Type

Please indicate the type of the deliverable using one of the following codes:

R Document, report

DEM Demonstrator, pilot, prototype
DEC Websites, patent fillings, videos, etc.

**OTHER** 

ETHICS Ethics requirement

ORDP Open Research Data Pilot

#### 16. Dissemination level

Please indicate the dissemination level using one of the following codes:

PU Public

CO Confidential, only for members of the consortium (including the Commission Services)

EU-RES Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)

EU-CON Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)

EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

#### 17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

#### 18. Milestone number

Milestone number: MS1, MS2, ..., MSn

#### 19. Review number

Review number: RV1, RV2, ..., RVn

#### 20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

#### 21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

#### 22. Type of access

VA if virtual access,

TA-uc if trans-national access with access costs declared on the basis of unit cost,

TA-ac if trans-national access with access costs declared as actual costs, and

TA-cb if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

#### 23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

Associated with document Ref. Ares(2017)4194538 - 28/08/2017

# 1. TITLE OF PROPOSAL: EUROPEAN JOINT ACTION ON ANTIMICROBIAL RESISTANCE AND HEALTHCAREASSOCIATED INFECTIONS (EU-JAMRAI)

Comments from the ESR	Answer	Reference in the proposal
"The One Health approach should have a much stronger focus on specific activities and indicators oriented towards impact, than is suggested in the current proposal as this would increase the added value to public health."	The revised version focuses on more concrete actions and identifies specific indicators.	Section 2
чише 10 рионе нешт.	Revision and refinement of 'Methods and means"	Section 5
The outcome indicators for SO 1, 5, 6, 7 are in fact output indicators.	The specific objectives outcomes have been revised	Section 2
"Cost-effectiveness of preventing infections and resistance should be addressed more clearly in the proposal."	A paragraph describing this task has been added in WP6 (6.1.1.3)	Section 7 WP6
"Evidence base is missing in an in-depth problem analysis. Although the problem of AMR is well known, it would be appropriate to include key references. Burden of AMR has been well described by O'Neil; https://amr-review.org/"	Section 1 "Problem analysis including evidence base" has been revised.	Section 1
"Actions with respect to capacity building and training (workshops) are not addressed."	The revised version has included capacity building as one of the expected outcomes	Section 6
"There is massive overlap between activities of WP2 and WP8."	WP2 and WP8 have been revised accordingly to distinguish precisely dissemination from communication activities.	Section 7
"All partners should be included in WP2-3 for dissemination and evaluation activities to ensure contributions to the dissemination and evaluation activities (for instance 0,1 person-month per partner)."	Almost all partners will dedicate at least 0.1 PM to the WP2 and all Work Package leaders will dedicate at least 1 PM to this WP	Section 7
WP3: "The external evaluation strategy will be developed and refined in a later stage (task 3.1) and some indicators are provided only as an example – by the time of the submission the evaluation strategy needs to be finished and refined. Evaluation strategy is organised within the partnership to keep track of the achievements, to support the coordinator and other WP activities, and ensure that the project reaches the objectives. An interim and final evaluation report are suggested. Task 3.4. quality assessment is unclear and should be explained more carefully."	WP3 has been revised accordingly.	Section 7, WP3
"It would be strongly suggested to include (sub-contract) an evaluation expert to advise on the impact assessment as the suggested method is not appropriate and to prepare the evaluation strategy. »		
WP4: "evidence based tools will be made available but the interaction with HCPs seems to be missing, although the proposal outlines that MS representatives will be consulted regularly during the process of developing the plan). WP4 misses the target specified in the description "Integration into national policies and sustainability" - the activities included are only support measures: sustainability strategy, guidelines, recommendations, proposal for endorsement. There are no actual integration activities. The JA should focus specifically in adjusting policies and focusing more on implementation science. To ensure sustainability a bottom-up approach is essential as well as a SWOT analysis; in that regard, a good collaboration with WP5 will be necessary. Mapping of NAP through self-assessment is included in	WP4 has been revised accordingly.	Section 7, WP4

both SO 3 and 6; why is this separated and how is this included WPs?	Associated with document Ref. Ares(2017)41	94538 - 28/08/201
WP5: "All countries need to be involved in the mapping of the NAP development progress, self-assessment and country-to-country review. This WP should be open to additional countries joining. Consider to add the initiation of NAP implementation in several countries and to document the improvement in NAP progress during the course of JA. In Europe, 15 countries have already developed an NAP. These countries are most likely engaged in the implementation process, what kind of support is envisioned for those countries? It is unclear whether a situational analysis will be part of the self-assessment. JA needs to be aware that WHO has developed a tool for self-assessment which is most likely going to be adapted. WHO is planning a follow-up on NAP to monitor the progress (globally) - this should be discussed and reviewed to avoid overlap. ECDC and WHO Euro have developed a template for country missions AMR/HCAI assessment. JA should liaise to ensure that no overlap will exist in tools and activities (complimentary). WP5, Part C on strengthening the supervisory functionality is very good and innovative as it will encourage countries to discuss, review and improve their regularity systems. Here, the animal and food sectors should be included as well. This is not clear from the description of activities."	WP5 has been revised accordingly	Section 7, WP5
WP7: "The proposal should include a stronger component addressing animal health, veterinary sector and AB use in the environment, food sector, []"  WP 7: includes the development of real-time-surveillance of AMR. It should be explained more carefully how this will be developed and implemented with respect to quality of data, selection of pathogens and timeliness in reporting and how this must be seen in connection to the existing European AMR Resistance Surveillance network	WP7 has been revised accordingly reflecting the animal sector  An additional partner has been involved in the project: ANSES to address the animal and food sector  Participation of veterinarian partners has been strengthened and thus increased the total budget.	Section 7, WP7
(EARSNET).  WP 7: monitoring AB use: it would be a missed opportunity to not include animal health. With respect to actions, there is no specific project which includes animal health. Also, explain carefully how this connects with the activities of the European Surveillance of Antimicrobial Consumption network (ESAC).	Task 7.4.1.has been refined and an Additional task 7.4.2. about animal surveillance has been added	
WP8 "is underestimated in the current proposal and should be upgraded as a core activity of the JA. Consider to include a health communication specialist."	The person-months for the communication specialist of the WP8 leader (AEMPS) has been upgraded, increasing the AEMPS budget, as suggested (reshuffling of a decrease of another partner).	Section , WP8
WP9: Some of the activities seem to overlap with WP4, could be integrated (strategies to implement). A rationale should be given for this WP as an important activity to contribute to the research agenda including social sciences.	WP9 has been revised accordingly.	Section 7, WP9
"Additional collaborative stakeholders should be invited to cover the multisector approach. »	OIE, EFSA, FAO as well as other healthcare professionals have been contacted.	Appendix 1
"[] hygienist specialists and coordinators as well as hygiene teams at hospital level should be targeted. »	Healthcare professionals have been contacted to join stakeholder Forum. In WP6, hygiene team at hospital will be involved.	Appendix 1 Section 7, WP6
All partners should give justification of detailed person months per	This has been done	Section 10
activity.  All partners should be included in WP2-3 for dissemination and evaluation activities to ensure contributions to the dissemination and evaluation activities (for instance 0,1 person-month per partner).	This has been done	

Associated with document Ref. Ares(2017)4194538 - 28/08/2017

# History of changes

Date	Section and page	Changes
29/05/2017	Section 2, page 5	Revision of the specific objectives outcomes
	Section 5, pages 9 - 11	Revision and refinement of methods and means
	Section 6, page 11	Addition of capacity building as one of the expected outcomes
	Section 7, pages 12 - 46	Changes in WP2, WP3, WP4, WP5, WP6, WP7, WP8 and WP9
	Section 8, pages 47 – 51	Revision of deliverables and milestones accordingly with changes in Work Packages
	Section 9, page 66	Presentation of the additional partner, n°47: ANSES
	Section 10, pages 69 - 126 Appendix 1, page 127	Revision and detailed information about each partner budget
		Detailed list of international organisation willing to contribute to the Joint Action
16/06/2017	Whole text	Change of the name partner n°32
	Section 2, page 4	Minor changes in the main objective description
	Section 5, page 10	Revision of the number of partners and countries (withdrawal of Hungarian partners)
	Section 7, pages 25, 35 - 37	Changes in WP5 and WP7
	Section 10, pages 70-71 page 72	Table of direct costs per partner per WP updated Revision about INSERM budget (taking in charge Hungarian partners budget)
	page 74	Precision about other direct costs for partner n°2 (in charge of the Kick-off Meeting organisation)
	page 107	AEMPS will have an affiliated entity
	page 113 page 115	SAS will have an affiliated entity SERMAS will have an affiliated entity
12/07/02/7	Appendix 1, page 129	Updated list of stakeholders
12/07/2017	Title	Add "Healthcare" to the title
	List of applicants	Change of the name of the partner 18: VILNIUS UNIVERSITY HOSPITAL SANTAROS KLINIKOS
		Change of the partner 33: Fundación para la Formación e
		Investigacion Sanitarias de la Región de Murcia instead of Dirección General de Planificación, Investigación, Farmacia y Atención al
		Ciudadano. Servicio Murciano de Salud
		P28-CCS become collaborating partner and change of partner numbering
	Section 5, page 13	Updated number of partners
	Section 7, page 16	Description of WP1 Task1.3 : one interim report and not two
	Section 9, page 60 page 63	P18-VULSK: additional information about project manager P28-CCS become collaborating partner
	1.00	Removal of the description of capacity staff of partner CCS

	Section 10, page 70	Updated table of summary of staff effort
	page 72	Updated table of all direct costs per WP per partners
	page 74	P01-INSERM: revised budget and explanations
	page 91	P15-ISS: details about subcontracting and other goods and services
		items
	page 105	P26-DGS: details about travel expenses items
	page 108	P29-AEMPS: details about the budget of subcontracting items
	page 112	P32-FFIS: reshuffling of budget between beneficiary and affiliated entities
	page 118	P37-FOHM: details about other goods and services items
	page 125	P44-ANSES: details about travel expenses items
	page 126	Additional table about subcontracting costs
	Section 14, page 130	Adding CCS as a collaborating partner
	Appendix 1, page 134	Updated list of stakeholders
24/07/2017	Section 7, page 44	Additional details in WP8, task 8.3
	Section 8, page 17	Adding tangibility of deliverables of WP2, WP5 and WP8.
07/08/2017	Section 7.2	Update of Inserm effort in the WP5 and WP6 description
	Section 10.2	Update of Inserm summary staff effort in the table
	Section 10.3	Details on WP5 and WP6 costs in Inserm's budget.
09/08/2017	Appendix 1, page 137	Updated list of stakeholders

# **LIST OF APPLICANTS**

Applicant No*	Applicant organisation name	Country
FR-1	Institut National de la santé et la recherche médicale	France
FR-2	Ministry of Social Affairs and health	France
AT-3	Austrian Public Health Institute	Austria
BE-4	Federal Public Service Health, Food Chain Safety and Environment	Belgium
BG-5	National Center of Infectious and Parasitic Diseases	Bulgaria
HR-6	Croatian Institute of Public Health	Croatia
CZ-7	The National Institute of Public Health	Czech Republic
DK-8	Statens Serum Institut	Denmark
EE-9	Terviseamet (Health board)	Estonia
DE-10	Robert Koch-Institute	Germany
GR-11	HELLENIC CENTER FOR DISEASE CONTROL & PREVENTION (HCDCP)	Greece
GR-12	ETHNIKI SCHOLI DIMOSIAS YGEIAS	Greece
GR-13	7th HEALTH REGION CRETE	Greece
IT-14	UNIVERSITY OF FOGGIA	Italy
IT-15	ISTITUTO SUPERIORE DI SANITA'	Italy
LV-16	Pauls Stradins Clinical University Hospital	Latvia
	THE HOSPITAL OF LITHUANIAN UNIVERSITY OF HEALTH SCIENCES KAUNO	Lithuania
LT-17	KLINIKOS	
LT-18	VILNIUS UNIVERSITY HOSPITAL SANTAROS KLINIKOS	Lithuania
LT-19	INSTITUTE OF HYGIENE	Lithuania
LT-20	NATIONAL PUBLIC HEALTH CENTRE	Lithuania
NL-21	Dutch Ministry of Health, Welfare and Sport	Netherlands
NO-22	Norwegian Directorate of Health	Norway
NO-23	Norwegian Institute of Public Health	Norway
NO-24	The Norwegian Veterinary Institute	Norway
PL-25	The National Medicines Institute	Poland
PT-26	Directorate-General of Health	Portugal
	UNIVERSITY OF MEDICINE AND PHARMACY "IULIU HATIEGANU"CLUJ-	Romania
RO-27	NAPOCA	
SI-28	National Institute of Public Health	Slovenia
SP-29	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS	Spain

	Dirección General de Ordenación Profesional y Regulación Sanitaria.	tet. Ares(2017)4194538 - 2   Spain
SP-30	Departamento de Salud de la Generalitat de Cataluña	•
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#### 2. PROBLEM ANALYSIS INCLUDING EVIDENCE BASE

Today, microbial resistance to antibiotics (antimicrobial resistance, AMR) is a serious public health threat that is gaining swift ground. The increase of multi-resistant bacteria associated to the lack of new antibiotics represents a threat to global health. Some patients are faced with no therapeutic solutions as some bacteria resist to all antibiotics. Moreover, "old" antibiotics and to sometimes more "recent" ones are gradually removed from the market because they are not economically sustainable, albeit being still effective. The issue of antimicrobial resistance is a major challenge that decision-makers are well aware of and has gained a high priority among public health challenges.

AMR is not confined to a geographical region or a Member State. In 2008, the ECDC estimated that 25.000 deaths and 2.5 million extra hospital days were caused annually by infections caused by multi-resistant bacteria across Europe, and associated with yearly societal costs of about €1.5 billion.¹ According to data provided by OECD, it is estimated that about 700 000 deaths may be caused globally each year by AMR. Despite action taken by, amongst others the World Health Organisation (WHO), the number of victims (mortality, morbidity) is steadily rising, and the outlook is increasingly bleak; according to the "Review of antimicrobial resistance" coordinated by J. O'Neill, antimicrobial resistance could become the #1 killer globally by 2050, if nothing is done.² With the pressing needs for infection prevention and prudent use of antibiotics, new therapies to be found, the efficacy of existing antibiotics to be preserved and the spread of resistance in the environment to be contained, many countries and international organizations have launched ambitious plans in the past few years.

The various national, European and international initiatives that have emerged over the last decade reflect the shared commitment to actively tackle this issue. It is essential that all actors in the field of AMR join forces so as to avoid duplication of efforts and ensure greater coherence in the global movement against AMR. In this sense, WHO in collaboration with FAO and OIE has elaborated a global action plan (GAP)<sup>3</sup>, after having reviewed the global burden of AMR.<sup>4</sup> The GAP sets 5 major goals and emphasizes the "OneHealth" approach, encompassing human, animal health and the environment. Countries have committed themselves to draft and implement national strategies aligned with the GAP by mid-2017. Moreover, the European Union has recently adopted ambitious Council conclusions on the *next steps* to tackle AMR, which includes setting up a OneHealth network across member states.<sup>5</sup> The European Commission and its agencies, as well as other International organizations or agencies (i.e. OECD, WHO Europe, ECDC, OIE, FAO) are best placed to support countries to implement national strategies for raising awareness on AMR and develop policies for controlling AMR in the human and veterinarian health sectors. Academia and industry are best placed to develop new drugs and alternatives approaches to therapy. National and international agencies are best placed to strengthen surveillance and develop indicators to monitor antibiotic use

<sup>&</sup>lt;sup>1</sup> ECDC/EMEA Technical report, 2009. The bacterial challenge: time to react.

http://ecdc.europa.eu/en/publications/Publications/0909\_TER\_The\_Bacterial\_Challenge\_Time\_to\_React.pdf

<sup>&</sup>lt;sup>2</sup> AMR Review: Tackling drug-resistant infections globally: Final report and recommendations. <a href="http://amr-review.org/sites/default/files/160518\_Final%20paper\_with%20cover.pdf">http://amr-review.org/sites/default/files/160518\_Final%20paper\_with%20cover.pdf</a>

<sup>&</sup>lt;sup>3</sup> World Health Organization 2015. Global action plan on antimicrobial resistance. http://www.who.int/antimicrobial-resistance/global-action-plan/en

<sup>&</sup>lt;sup>4</sup> WHO. AMR: Global report on surveillance, 2014. <a href="http://www.who.int/drugresistance/documents/surveillancereport/en/">http://www.who.int/drugresistance/documents/surveillancereport/en/</a>

<sup>&</sup>lt;sup>5</sup> Council of the European Union. June 17, 2016. *Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance*. http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-antimicrobial-resistance/

and resistance in the animal and human health sectors. Health are providers are best placed to ensure AVIR policies and infection control and prevention strategies are efficiently integrated in routine human and animal care. In this regard, controlling resistance and preserving the efficacy of antibiotics is the responsibility of everyone and can only result from joint efforts towards sustainable development of antimicrobials.

Although AMR and HCAI (Health-Care Associated Infections) are often considered separately, the relationships between AMR and HCAI are well established, and both are dealt with by the same bodies in many organizations. Infection prevention and control strategies (IPC stewardship) should go hand in hand with i) prudent use of antibiotics (antibiotic stewardship), ii) appropriate tools for monitoring and surveillance and iii) accurate diagnostic tests to decide on the right therapy (diagnostic stewardship).

As also mentioned in the recently adopted council conclusions on AMR, strengthening national and international health security initiatives against this public health challenge mandates a common European approach taking into account local features and existing initiatives. Although there are important differences in the epidemiology of AMR and organization of infection control activities across European countries, the principles underlying strategies to control AMR and prevent HCAI<sup>6</sup> are shared. However, these national specificities and various organizations and approaches to infection prevention and control and antibiotic stewardship must be taken into account by involving the many relevant stakeholders within the prioritization process of the JA actions.

This JA provides the opportunity to strengthen and coordinate efforts directed to both AMR and HCAI issues, following a One Health approach. Ensuring consistency of actions of key players at the various levels is essential to secure concrete outcomes.

#### 3. AIMS AND OBJECTIVES OF THE PROJECT

## 3.1. General objective of the project

In line with the EU Action plan and the Council Conclusions on AMR (adopted on 17 June 2016) and the tripartite GAP, the Joint Action on AMR and HCAI will build on existing works and initiatives by Member States as well as international organizations (OECD, ECDC, WHO Europe, OIE and FAO). It will propose concrete steps enabling European countries to strengthen the implementation of efficient and evidence-based measures to tackle AMR and HCAI, for the benefit of Member States and overall public health in Europe.

Therefore, the overarching objective of the AMR-HCAI Joint Action is to support EU Member States develop and implement effective one health policies to combat AMR and reduce healthcare-associated infections.

The Joint Action will therefore contribute to:

- Identifying and testing evidence-based measures to address AMR and HCAI in different contexts and, based
  on the outcome of these tests, support capacity-building and provide recommendations to policy-makers
  (WP6, WP7, WP4);
- Bringing together different networks of policy makers, experts and organizations on AMR and HCAI working
  in different European and International initiatives and projects relevant for policy decision (WP1, WP2,
  WP4, WP5, WP8);
- Promoting (i) the One Health approach through a closer collaboration, understanding and trust between the animal health and human health sector, accounting for environmental issues, and (ii) the "One Health in all policies" concept (health policies should have an intersectoral dimension) in addition to the "Health in all policies" concept (all policies should have a health dimension) (WP5, WP7);
- Increase awareness and understanding of AMR across European member states (WP2, WP8)
- Producing concrete recommendations for a European contribution to international initiatives such as WHO,
   GHSA, G7...(WP2, WP4, WP9)

# 3.2. Specific objective(s) of the project

Specific Objective N°1 Facilitate implementation of National Strategies for prevention of HCAI

<sup>&</sup>lt;sup>6</sup> Zingg W, Holmes A, Dettenkofer M, et al. Hospital organisation, management, and structure for prevention of health-care-associated infection: a systematic review and expert consensus. Lancet Infect Dis 2015; 15:212-24.

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	at the national and regional/local levels, including optimising the		
	implementation at national level of work done by the ECDC		
Process Indicator(s)	Target		
Development/implementation of an	Availability of an instrument for assessing the national/regional ICFW		
infection control framework (ICFW)			
Output Indicator(s)	Target		
Implementation of ICFW	Pilot testing of the UICFW in selected hospitals, using awareness and training tools		
Outcome/Impact Indicator(s)	Target		
Adoption of the ICFW at national or local level	80% of the partners involved in the WP6		
Adoption of working routines through the evidence-based implementation model	80% of the partners involved in the WP6		
Specific N°2 Objective	Develop efficient tools and guidelines to facilitate implementation of best practices for antimicrobial stewardship and surveillance of resistance in both human and animals		
Process Indicator(s)	Target		
Analysis of existing guidelines	Review of guidelines and recommendations performed in human and		
Antibiotic use in primary care and in animals tools available	animal health		
	Model for implementation of antibiotic use		
Output Indicator(s)	Target		
Summary available Implementation of antibiotic use in primary care	Best practices identified and summarized; policy briefs elaborated Pilot testing of antibiotic use in primary care and in animal health and surveillance implementation model in human and animal sectors		
Outcome/Impact Indicator(s)	Target		
Integration Antimicrobial use	Integration of best practices into NAP of 80% EU MS; Guidelines for antimicrobial use; Quarterly feedback on resistance trends in human and animal sectors.		
Specific N°3 Objective	Improve implementation of National Action Plans for AMR and HCAI		
Process Indicator(s)	Target		
Mapping of NAP	Gaps and barriers for implementation are identified		
Output Indicator(s)	Target		
Integration of best practices	Recommendations for implementation of AMR and HCAI best practices and improvement of the available programs		
Outcome/Impact Indicator(s)	Target		
Improvement of NAP for AMR and HCAI	All EU MS have an operational NAP for AMR and HCAI by the end of the JA		
Specific N°4 Objective	Ensure discussion among policy makers on the development and implementation of the National Action Plans and strategies, measures taken within member states and actions for improvement		
Process Indicator(s)	Target		
Involvement of policy makers in the improvement process of NAP	Planned workshops with the steering committee to review and discuss gaps and barriers to implementation of NAP on AMR and HCAI, and improvement strategies		
Output Indicator(s)	Target		
Plan for implementing measures	Integration and sustainability plan available		
Outcome/Impact Indicator(s)	Target		
Improvement of NAP	Uptake of key recommendations for integration into NAP by policy makers of 80% EU MS		
Specific N°5 Objective	Ensure consistency between national, European and Internationa research programmes identify gaps in knowledge and contributing to		

	ensure linkage between research on AMR/HCAI and Public Health Policies		
Process Indicator(s)	Target		
National priority-setting best practices	Best practices and routines that can be implemented by EU MS to improve the input that they send to SRA of the JPI AMR regarding research and innovation priorities		
Output Indicator(s)	Target		
Implementation strategy for EU collaboration	A concrete strategy for implementing multi-country incentives to stimulate antimicrobial and diagnostic innovation		
Outcome/Impact Indicator(s)	Target		
Translate research findings (including those from the social sciences) into public health policies and practices	SURE policy briefs or other tools made publicly available		
Specific N°6 Objective	Ensure that all Member States have an objective-driven national strategy consistent with their national context and with the One Health approach		
Process Indicator(s)	Target		
Mapping of AMR national action plans (NAP) to identify gaps	All MS have an operational NAP involving the human and animal health sector; self-assessment performed		
Output Indicator(s)	Target		
Country-to-country assessment based on a standardised evaluation tool	Pilot testing done; organisation and gap analyses is performed		
Outcome/Impact Indicator(s)	Target		
Develop and involve the one health network (OHN) in monitoring MS policies	Analysis of NAP and recommendation from the OHN or implementation and follow-up of the NAP. Achievement of >80% selected indicators fulfilled in the assessment tool		
Specific N°7 Objective	Strengthening awareness on AMR and HCAI of all stakeholders		
Process Indicator(s)	Target		
Mapping of existing strategies	Review of effective targeted strategies for raising awareness and improve communication on AMR available		
Output Indicator(s)	Target		
Effective communication and dissemination tools	Identify effective tools for awareness raising, adapted to relevant target audiences		
Outcome/Impact Indicator(s)	Target		
Integration	Incorporation of recommendations into NAP through mobilizing stakeholders		
Specific N°8 Objective	Ensure efficient dissemination of activities and outcomes from the JA and contribute to sustaining its results		
Process Indicator(s)	Target		
Develop an efficient communication tool for internal and external communication	JA website operational		
Output Indicator(s)	Target		
Communication on JA actions and outputs	Effective and timely dissemination of outputs (tools, guidelines recommendations)		
	·		
Outcome/Impact Indicator(s)	Target		

# 4. TARGET GROUPS

The JA aims at providing recommendations to a large variety of groups and key actors that are all affected in one way or another by the challenges of antimicrobial resistance and HCAI. To be efficient, an AMR policy has to be

applicable to several groups from patients to policy makers at regional/local, national and international levels. There is need for a consistent holistic approach through appropriate definition of the challenges to be addressed at various levels. The rationale is that each actor in the field of AMR and HCAI should focus on its main added value so as to avoid duplication of efforts and ensure greater coherence in the global movement against AMR.

The JA will notably target the following groups:

- Governments (Ministries of Health, Agriculture, Environment, Research...)
- Public Health and regulatory Agencies
- Local authorities
- Patients
- Healthcare providers (incl. healthcare professionals, hospital managers, etc)
- Industries
- Researchers and scientists
- International Organisations (OCDE, WHO, WHO Europe, European Union, OIE, FAO, ECDC)

The JA will contribute to shape tailored recommendations to each group taking into consideration each one's specificity and linkage between them, bearing in mind the need for concrete, pragmatic and realistic recommendations. It will ensure that consistency of recommendation is safeguarded and integrated into a comprehensive strategy thereby contributing to strengthen the EU action plan implementation.

#### 5. POLICY RELEVANCE

The JA aims to contribute to adapt public health policies to the current challenges in AMR and HCAI based on existing knowledge and initiatives. It aims to contribute to implementing European objectives as set out in the Council conclusions and the European Action plan on AMR and foster cooperation among partners to achieve concrete progress in line with WHO GAP. The JA management structure includes a Steering Committee, gathering representatives of MS competent authorities to be involved in the JA program and adopt the conclusions of the JA, adapting these to their specific context, thus contributing to the sustainability of the JA outcomes in their respective countries.

### 5.1. Contribution to meeting the objectives and priorities defined in the annual work programme

According to its founding treaties, the EU has to ensure that human health is protected as part of all its policies, and to work with the Member States to improve public health, prevent human illness and eliminate sources of danger to physical and mental health.

The third programme of the Union's action in the field of health (2014-2020)<sup>7</sup> seeks to promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle; protect Union citizens from serious cross-border health threats; contribute to innovative, efficient and sustainable health systems and, facilitate access to better and safer healthcare for Union citizens.

The 2017 annual work programme states that the "objective of this action co-financed with Member State authorities is to increase the level and effectiveness of activities at EU, national and local levels to improve EU health security by addressing the increasing threats to health from antimicrobial resistance (AMR) and the linked but separate issue of healthcare-associated infections (HCAI)."

In this regard, the AMR-HCAI Joint Action aims to:

- a. Support the development of national strategies and action plans on AMR;
- b. Support strategy development at national, local, and health-care setting level (hospital, long term care, community) in the field of HCAI, including optimising the implementation at national level of work done by the ECDC;
- c. Develop and enhance the implementation of evidence-based tools and capacity-building, and through training, organisational change and/or other methods to enable sustainable improvements in practice by health care staff and teams in hospitals, as well as in long term care and community settings;

<sup>&</sup>lt;sup>7</sup> REGULATION (EU) No 282/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2014. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0282&from=EN

- d. Strengthen the 'One Health' approach and coordination with relevant sectors including for AMR with animal health, food safety, agriculture, environmental and research and the Joint Programming Initiative (JPI) on AMR;
- e. Contribute to the implementation of relevant research findings and identify priorities for research;
- f. Promote awareness and commitment by governments and stakeholders.

Activities planned in this proposal have been shaped to address all the objectives set out in the annual work programme, as outlined in section 2.2.

#### 5.2. Added value at EU level in the field of public health

The Joint Action will enhance cooperation between Member States, the European Commission and its agencies and other international organisations and will enable each target group to contribute to address the issue of AMR and HCAI. Through appropriate involvement of each group within the different work packages, the JA will strengthen the existing public health policies both at the national or European level and contribute to achieve the objectives of the WHO Global Action plan on AMR, the Council conclusions on AMR and the EU plan on AMR.

The involvement of a large variety of actors (competent authorities, patients, industry, researchers, healthcare and infection control professionals ...) to elaborate concrete recommendations and implementable measures will foster synergies and imply cooperation among these. While each group is part of the solution to tackle AMR and HCAI, the Joint Action will demonstrate the added value of each group and provide tailored measures to implement national and EU action plans. Additionally, each group will disseminate the output of the Joint Action to its own network both during and after the Joint Action.

AMR and HCAI have no border and cannot be fully addressed at national level if not embedded into a larger and more comprehensive European action. In this sense, the Joint Action will capitalize on national best practices and current European projects while acknowledging countries specificities (i.e antibiotic consumption or resistance epidemiology may differ from one country to another, thereby justifying specific/tailored measures).

The JA will contribute to strengthen a European "One Health" strategy and propose actions for implementation through National Plans, in line with the recommendations of the Council Conclusion on AMR adopted by the EU Council on 17<sup>th</sup> June 2016. In this regard, it is expected that the work of the Joint action performed within WP5 with regard to the One Health approach will serve as basis for the Commission to strengthen the role and impact of the "One Health network" that will further continue the work done during the Joint Action.

The gap analysis of national action plans of European member states will contribute to orient decision-makers to address the challenges identified, discuss progress and implementation of National Action plans, using insights from the country-to-country assessments and best practices promoted through the JA.

#### 5.3. Pertinence of geographical coverage

The high number of participants of the Joint Action as well as their variety (Competent Authorities, Public Health institutes, Research institutes, Universities) will enable the Joint Action to cover the 28 EU countries. Additionally, thanks to the involvement of the EU agencies, WHO Europe and other international organisations (OECD, OIE and FAO), the geographical coverage and impact of the Joint Action will go beyond the borders of the EU. Being also involved in several international fora (such as G7, G20, UN, GHSA or WHO), the coordinator France will ensure consistency between JAMRAI's outputs and discussions in these institutions or initiatives.

In line with the objectives of the JA pertaining to the linkage to existing national, European and international policies and initiatives, it is expected that the JA output will extend and impact outside the EU's remit *stricto sensu*. AMR is a global challenge that needs a global action as outlined in the WHO GAP. The Joint Action will therefore be embedded into this international context and strives to be at the European level, an example of initiative focusing on achieving concrete results.

The burden of AMR varies across EU countries and even more so in neighbouring countries outside EU. Since AMR is a cross border health threat, measures taken within one Member State influence other Member States. Therefore AMR needs a coordinated response. Also, there are common issues and the recommended measures of the JA to a specific group of countries will also be applicable to non-EU countries. Specific work done within WP6 will include implementation of best practices and improvement in the prevention of HCAI within a European network outside of EU MSs. Building on this experience, the implementation model tested in WP6 will be proposed to other organisations or countries within WP4.

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# 5.4. Consideration of the social, cultural and political contex Associated with document Ref. Ares(2017)4194538 - 28/08/2017

The efficiency of any action addressing AMR and HCAI relies on involving different groups (see point 3) and on understanding the context of each of these. The rationale underpinning the international action on AMR has to be "Think global, act local". This means that for each group, one has to identify the driving forces and consider its social, cultural, economic and political environment.

For instance, as regards the public and patients, actions addressing AMR and HCAI targeted to this group within WP8 will focus on increasing public awareness and providing appropriate information through campaigns targeting the general public, general practitioners and healthcare professionals, insurances... It has to tailor the recommendation to the categories of public and patients through different channels and take into consideration their level of health literacy. Therefore, successful action towards patients will combine several complementary measures and altogether constitute an efficient action. Through cooperation with and involvement of professional organisations of the animal and human health sector and of patient groups within the JA stakeholders forum, the JA will identify the appropriate means to reach the different categories of public, patients and healthcare professionals.

#### 6. METHODS AND MEANS

The aim of this JA is to join forces to define European common policies to fight AMR and to control HCAI in line with ongoing EU and international policies. The JA will look over the best programmes in each country to get the best for this JA and see how cooperation at EU level can improve national AMR-related policies. In line with Council conclusion on AMR adopted on 17 June 2016, the JA will contribute to propose concrete steps to tackle AMR and HCAI, so the political intentions must lead to practical actions shared by MS involved in the JA. To efficiently implement concrete actions, the national specific political contexts of AMR and HCAI status (antibiotic prescription behaviour, AMR epidemiology, hygiene measures, variety of health-care systems, population size ...) will be taken into account in all WPs. The JA will ensure that the key component of the Knoster modal (vision, skills, incentives, ressources and action plan) are used to foster change and ensure implementation at local level of JA recommendation.

By involving key stakeholders (see point 3 target groups), the JA will capitalise on existing expertise derived from these various groups to elaborate and disseminate the JA outputs. Moreover, when appropriate, the stakeholders will be directly involved in the WPs. Besides stakeholders, HCW (general practitioners, hygienists, nurses,...), veterinarians and patient groups will be also highly involved. Only a coordinated action including all the partners at local and national levels and with a OneHealth approach will be decisive to successfully reduce AMR and prevent HCAI and have an impact on the overall public health in Europe.

Three main general objectives will be addressed, with concrete specific objectives involving the different JA partners in the WPs.

General objective 1: Identifying and testing evidence-based measures to address AMR and HCAI in different contexts and, based on the outcome of these tests, provide recommendations to policy-makers.

Specific objective 1: Facilitate implementation of National Strategies for prevention of HCAI at the national and regional/ local levels, including optimising the implementation at national level of work done by the ECDC (WP6)

In line with the EU action plan, the JA will support the establishment of efficient and feasible national infection control programmes through the effective implementation of agreed key components for guidelines and/or other tools at national, regional and local level to prevent infections and thereby limit the use of antibiotics and spread of resistant bacteria in health-care settings. This work will be based on available evidence-based guidelines and validated implementation strategies. Patient organizations and other relevant stakeholders (health-care professionals, infection prevention and control professionals, patient safety professionals, clinic management, hospital management, regional health-care management, and national health authorities) will be involved in the improvement work concerning infection prevention and control measures. This co-operation at different levels (national/regional/local) will depend on the health care structure in the country, and will be in line with the national activities planned during the JA. The methods used will include health-care and infection control professional education and training using the ECDC core competencies for infection control and hospital hygiene professionals

in the European Union (2013)<sup>8</sup> as a template and outcomes from the systematic review and evidence-based guidance on organization of hospital infection control programmes (SIGHT) study group.

Specific objective 2: Develop efficient tools and guidelines to facilitate implementation of best practices for antimicrobial stewardship and surveillance of resistance in human and in animals (WP7)

The objective is to collate and organise into a useable database current guidelines for antibiotic stewardship and to develop efficient tools for the implementation of guidelines for the proper use of antibiotics in all EU member states in primary care in human and in animals. The JA will identify and review existing guidelines, tools and implementation methods by level-of-care (hospital, long-term care facility and community setting) for human and in food and companion animals. The different available guidelines or reports from ECDC, WHO, OECD, EFSA, EMA, OIE, FAO ... will be analysed to guide a workshop looking at barriers, incentives and effective measures of implementation. Pilot projects will be performed, looking at effective implementation of guidelines in MS with differing resources and focusing on different levels of care for human health, and outcome measures (indicators) in both the human and animal sectors. Lastly, simple surveillance systems of antibiotic use and resistance in the different levels of healthcare and in animals will be tested, based on existing surveillance systems. Following the One Health strategy, antimicrobial-resistant bacteria surveyed will be essentially the same, in order to assess the relationships between AMR spread in humans and animals.

General objective 2: Bringing together different networks of policy makers, experts and organizations on AMR and HCAI working in different European and International initiatives and projects relevant for policy decision.

Specific objective 3: Identify the challenges faced by countries for implementation of National Action Plans for AMR and HCAI (WP 4, 5, 6 and 7)

Fighting AMR and HCAI will need a holistic approach taking into account the One Health approach to provide concrete coordinated actions. In all the core WPs (5, 6 and 7), the JA will take into account the specificities of each country (AMR epidemiology, health-care systems, population size, institutional behaviour). Work planned in the respective WPs will first identify potential barriers and gaps to the support and implementation of national action plans for controlling AMR and HCAI after the respective WP analyses of existing guidelines and recommendations, accounting for those from ECDC and the EC, ESCMID, or other institutions (eg, CDC, WHO Europe, OIE) or expert panel recommendations when necessary. Pilot studies will be conducted in WP5, 6, and 7, allowing to identify gaps and barriers to implementation of best practices, and then to provide tailored recommendations and guidelines to inform WP4. Within the latter, policy makers and relevant stakeholders will be involved to structure networks for a sustainable plan to fight AMR and HCAI (WP4).

Specific objective 4: Ensure discussion among policy makers on the development and implementation of the National Action Plans and strategies, measures taken within member states and actions for improvement (WP2, 3 and 4)

By involving policy makers and competent authorities, the JA will contribute to implement the EU action plan on AMR in the middle term and to ensure convergence of programs and actions of MS for prevention and control of AMR and HCAI. Since this JA involves 44 partners from 21 countries, these goals imply the contribution of all participants to the JA, and other bodies and institutions at the national and EU level, beyond the participating institutions. Specifically, the ECDC, WHO Europe and the European Commission will be approached to contribute to and support the sustainability of actions. The Steering Committee and the Stakeholder forum will be involved in the evaluation tasks for comments, suggestions and recommendations on final core WPs deliverables. Given the wide range of stakeholders involved in the JA, including National and Regional Governments, Patients' Associations and Scientific Societies (to be selected at the beginning of the project), their contribution in one or more phases of the evaluation process (e.g. surveys on specific topics to specific target population) will be guaranteed.

Specific objective 5: Ensure consistency between national, European and International research programmes, identify gaps in knowledge and contributing to ensure linkage between Research on AMR / HCAI and Public Health policies (WP9)

The JA will contribute to a coordinated European response in regards to prioritizing and assisting in the implementation of research and innovation expected to help achieve public health-related AMR and HCAI goals and objectives. Significant efforts led by JPIAMR in collaboration with the EU and IMI have already been established

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<sup>&</sup>lt;sup>8</sup> http://ecdc.europa.eu/en/publications/Publications/infection-control-core-competencies.pdf

in regards to AMR research and innovation priority-setting. Its Strategic Research Agenda (SRA) outlines key, neglected areas to tackle, which guides JPIAMR and others to shape cohesive and coordinated AMR funding and research actions to maximise on resources and reduce duplication of research. As the SRA is scheduled to be updated in 2017, it can be expanded upon via the JA by working directly with MS in preparation of their participation in priority-setting activities with JPIAMR. MS involved in the JA need to ensure that their national processes include: (1) a One Health focus; (2) the special needs of HCAI; (3) an appropriate breadth of research fields including social sciences; and (4) research policy briefs to inform policymakers. MS should also ensure that their own national research agendas are in line with the priorities set out by JPIAMR and other related initiatives like the international clinical trial networks.

General objective 3: Promoting (i) the One Health approach through a closer collaboration, understanding and trust between the animal health and human health sector, accounting for environmental issues, and (ii) the "One Health in all policies" concept (health policies should have an intersectoral dimension) in addition to the "Health in all policies" concept (all policies should have a health dimension).

Specific objective 6: Ensure that all Member States have a "One Health" objective-driven national strategy (WP 4 and 5).

The JA will support Member States (and other participant countries) on the implementation of some of the provisions laid down in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance (2016/C 269/05) unanimously adopted by the Council of the European Union in June 2016. The JA aims also to support Member States in the development and implementation of national strategies and national action plans on AMR in line with the tripartite (WHO, FAO, OIE) Global Action Plan (GAP) on AMR and to reinforce the collaboration between Member States, European Commission and other European and international organisations on the implementation of these strategies. To reach this objective, the JA will develop a self-assessment tool to monitor country progress and identify gaps and shortcomings on the implementation of national strategies and national action plans. The JA will set up a country-to-country peer review system to evaluate each other's national action plans and reflect about policy options. Furthermore, to ensure the sustainability of results and actions initiated during the JA beyond the 3-year JA duration, the JA work will report regularly and discuss within the One Health Network described in the Council Conclusions.

General objective 4: Producing concrete recommendations and promote awareness and commitment by governments and stakeholders for a European contribution to international initiatives such as WHO, GHSA, G7...

#### Specific objective 7: Strengthening awareness on AMR and HCAI (WP8)

The JA will aim at promoting the responsible use of antibiotics and encouraging best practices among the general public and healthcare professionals and through higher dialogue with young population and mass media. The objective is to change minds and behaviors toward antibiotics by raising awareness of the dangers of AMR. The JA will define basic key messages to be communicated to the general public, health professionals and specific target audiences using different tools (JA website, social and traditional media, specific groups of society and professionals subgroups). The JA will also have to foster the European Week initiatives by coordinating activities jointly with ECDC and MS. Furthermore, two types of conferences (similar to TED Conferences; maybe a pilot activity in some countries) will be carried out in the second-third years of the JA, one with scientific communicators, and another conference with High School and university students as speakers. One European Meeting in the last year focusing on increasing awareness among governments and stakeholders will be organized.

Specific objective 8: Ensure efficient dissemination of activities and outcomes from the JA and contribute to sustaining its results (WP2, 3 and 4)

Dissemination of actions and results as well as exchanges and dialogue within WPs and between the JA partners will be supported by a dedicated website (WP2). The JA will provide an integration plan for implementation of the JA results into national policies as well as a sustainability plan to prolong the JA efforts and actions beyond its duration. These plans will build on work done within the other WPs and the gap analyses performed within WP5, 6 and 7, and results of pilot studies conducted within these; the sustainability plan will also account for the evaluations performed within WP3. The plan will result from strong interaction with the Steering Committee and the stakeholder forum, including a dedicated workshop. Adoption of best practices for implementation of preventive measures for HCAI and AMR identified within WP6 and WP7 will be sought, accounting for the specific needs and context of the various MSs, and extension to existing networks and non-EU countries.

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#### 7. EXPECTED OUTCOMES

The overall expected outcome of this JA is the effective and sustainable implementation in MS of the Council recommendations in the field of AMR and HCAI and, in particular, provide concrete recommendations to policy makers to have a European strategy to tackle the threat of AMR and HCAI, taking a One Health approach.

#### This JA aims to:

- Support Member States in the development and implementation of national strategies and action plans on AMR and HCAI and ensure a common approach at European level on the implementation of the Global Action Plan.
- Produce guidance documents and tools allowing MS to improve the fight against AMR and the management of HCAI at national, local, and health-care setting level (hospital, long term care, community)
- Enhance the implementation of evidence-based tools and capacity-building, through training, organisational change and/or other methods to enable sustainable improvements in practice by health care professionals
- Strengthen the 'One Health' approach and coordination with relevant sectors including for AMR with animal health, food safety, agriculture, environmental and research and the Joint Programming Initiative (JPI) on AMR
- Promote awareness and commitment by governments and stakeholders.
- Foster a coordinated European response in regards to prioritizing and assisting in the implementation of research and innovation to help achieve public health-related AMR and HCAI goals and objectives

#### 8. WORK PACKAGES

#### 8.1. Overview on work packages

WP	Title	Description	
number			
1	Coordination of the project	Actions undertaken to manage the project and to make sure that it is implemented as planned	
2	Dissemination of the project	Actions undertaken to ensure that the results and deliverables of the project will be made available to the target groups	
3	Evaluation of the project	Actions undertaken to verify if the project is being implemented as planned and reaches its objectives	
4	Integration in National Policies and sustainability	Actions undertaken for integration of evidence-based policy initiatives and key recommendations issued from the JA into MSs policies, to support and improve national plans development, and to ensure the sustainability of the JA activities at national or on the local or regional level, based on the Knoster model.	
5	Implementation of One Health national strategies and National Action Plans for AMR	Actions to support Member States (and other participant countries) on the implementation of some of the provisions laid down in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance (2016/C 269/05) <sup>9</sup> .	
6	Policies for prevention of Health Care Associated Infections and their implementation	Actions to support the establishment of efficient and feasible infection control programs through the effective implementation of agreed key components for guidelines and/or other tools at national, regional and local level to prevent infections and thereby limit the use of antibiotics and spread of resistant bacteria in health-care settings.	
7	Appropriate use of antimicrobials in human and animals	Actions to collate and organise into a useable database current guidelines for antibiotic stewardship at all levels of the European health system and to develop efficient tools and checklists for the implementation of guidelines for the proper use of antibiotics in all EU member states.	

<sup>&</sup>lt;sup>9</sup> OJ C269, 23.7.2016, p. 26 (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C\_.2016.269.01.0026.01.ENG&toc=OJ:C:2016:269:TOC

8	Awareness raising and	Actions to promote the responsible use of antibiotics and encourage best	
	communication	practices among the general public and healthcare professionals and	
		through higher dialogue with young population and mass media.	
9	Prioritizing and	Actions to contribute to a coordinated European response in regards to	
	implementing research and	prioritizing and assisting in the implementation of research and	
	innovation for public	innovation expected to help achieve public health-related AMR and HCAI	
	health needs	goals and objectives.	

#### 8.2. Work package descriptions

St.	tart date or starting event		M1
Er	nd date		M36
Coordination			
INSERM			
INSERM	MOH-FR	Total	
FR-1	FR-2		
46	8.2	54.2	
	Coordination INSERM INSERM FR-1	Coordination INSERM INSERM FR-1 FR-2  End date  MOH-FR FR-2	Coordination INSERM INSERM FR-1 FR-2  End date  Total

#### **Objectives**

The main objective of this WP is to set up an effective management framework and ensure the smooth management and coordination of the project towards the planned objectives through effective internal communication.

The specific objectives of this WP are three-fold:

- 1. At the strategic level, to ensure that the project reaches its objectives;
- 2. At the managerial level, to put in place the procedures and tools needed to ensure that the project progresses in conformity with the work plan and produces timely and quality results as well as overseeing conformity of all activities to EC rules and the Consortium agreement;
- 3. At the administrative level, to organise project meetings, prepare project reports, manage the project budget and payments.

# Description of work, role of the participants and interactions

#### Task 1.1: Strategic steering

Leader: INSERM / Contributors: Governance bodies / Start date: M1 End date: M36

**Task description:** this task involves setting up and managing the relevant steering and management bodies described fully in section 9:

- General Assembly: deciding board made up of one representative per associated partner
- Executive Board: operational body made up of WP leaders
- Steering Committee: composed of one representative (competent authority) from each Member State. The members will be nominated at the start of the project.
- Stakeholders Forum: composed of external experts from international organizations such as WHO, ECDC, OECD, EFSA, OIE, FAO and other representatives from industries, healthcare professionals' organizations and of patients (see section 9 for details). The members will be nominated at the start of the project.

This governance structure will ensure the relevance of the JA AMR HCAI activities in line with the work plan and national and European strategies.

# Task 1.2: Contractual and financial management

Leader: INSERM / Contributors: WP Leaders / Start date: M1 End date: M36

**Task description:** this task will be coordinated by the Joint Action Secretariat (JAS) that will be responsible for the day-to-day management. It is composed of the project coordinator (Marie-Cécile Ploy, INSERM) assisted by resources including a project manager based at INSERM. The JAS will be in charge of:

- Preparation of the Consortium Agreement to be signed by all beneficiaries at the start of the project
- Appraisal and monitoring of the project costs in order to oversee and check the overall costs incurred per work package and per participant
- Management and distribution of EC payments
- Assistance to individual project partners on specific administrative and financial issues

The PMT will meet monthly and will hold every 4 months teleconferences with the Executive Board to share

updates on progress of the WPs.

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#### Task 1.3: Periodic reporting

Leader: INSERM / Contributors: Executive Board (technical), All partners (financial reporting) / Start date: M1 End

date: M36

Task description: this task will:

- Monitor the progress of the project in terms of deliverables, milestones, etc., using dedicated project management tools;
- Identify and monitor risks and propose appropriate mitigation measures to the General Assembly and the Steering Committee;
- Prepare periodic and final reporting to ensure timely and efficient submission to the EC

#### Task 1.4: Communication: internal and with CHAFEA / DG SANTE

Leader: INSERM; Participants: MoH-FR / Start date: M1 End date: M36

**Task description:** the following activities will be carried out:

- To use the project website to be set up in WP2. It will act as a platform to share internal project documents;
- Regular web/audio conferences to support WP collaboration and interactions;
- Every 4 months, activity reports updating all project collaborators on the project activities;

The project coordinator will act as the official representative towards the CHAFEA and DG SANTE. The project coordinator will provide the interim and final reports, assisted by the JAS (composed of a project manager at Inserm and an assistant manager at MoH-FR).

Work package	14/02		Start o	late or start	ing event			M1
number	WP2		End da	ite				M36
Work package title	Dissemina	ition						
<b>Leading participant</b>	AEMPS (SI	P)						
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8
Participant short name	INSERM	Moh	GOG	FCS	NCIPD	CIPH HZJZ	NIPH	SSI
Person-months per participant	4	1,7	0,1	0,5	0,7	0,2	0,5	0,5
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS
Person-months per participant	2	0,1	1	1	0	0,4	1	1
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	НІ	NVSC	VWS	HdiR	FHI	NVI
Person-months per participant	1	1	0,5	0,1	2	0,1	1,5	0
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS
Person-months per participant	0	1	2,5	1,5	39	0	0	1
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	0,5	1	0,8	0	1	0	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44		TO	TAL	•
Participant short	SVA	SRC	UAS	ANSES		10	IAL	

name				O As	sociated with document Ref. Ares(2017)4194538 - 28/08/201
Person-months per participant	0	0,4	0	1	70,6
Objectives					

The main objective of this WP is to ensure correct dissemination on high quality information on JA deliverables and progress among targeted groups through organised dissemination activities, which in turn will allow for sustainability beyond the project end. The specific objectives of this WP are to:

- Develop an internal communication strategy to ensure back and forth communication amongst WPs to build on the work coming from all the different WPs within the JA.
- Develop external communication strategies to disseminate information on JA both to general public and stakeholders as well as ensuring the promotion of the project outcomes and results amongst the targeted public and stakeholders.
- To widely and effectively coordinate and disseminate research outcomes and results through various channels, including online dissemination channels (website; twitter; Facebook; newsletter) so that we can actively engage all partners and stakeholders throughout the course of the project to ensure applicable and appropriate results to the targeted public and partners.

#### Description of work, role of the participants and interactions

#### WP Methodology

In order to meet the main objectives, WP2 will pay special attention to both its internal and external communication and will line up a qualified team for its development. A wide variety of dissemination methods and tools to inform, engage and promote the outcomes of the JA will be put in place.

To start with, all WPs will designate a contact person to collaborate with WP2 for all matters related to dissemination activities (events, articles, reports...). Communication between the WP2 leader and each WP contact person (informing WP leaders and also the coordinator) will be carried out via email on regular basis, and also via TLC, depending on the project's needs.

WP2 facilitates coherent and sustainable external communication of the JA and ensures that its objectives, activities, results, and deliverables are known. In order to do so, AEMPS will develop a dissemination plan that is planned to cover relevant stakeholders and identify the appropriate timing of release of interim and final results through appropriate and effective dissemination activities such as conferences, congresses or publications so that widespread dissemination is achieved. This plan will be a living document and will be monitored and adapted to reflect progress and changes.

The main dissemination tools (website, leaflet, layman report...) and materials will be produced in English. There will be the option to send the same material translated into different languages (translated by the country itself), however, that would depend on the tool or activity (relevance) and the resources of the country to carry out this translation and work. Each participant will ensure language is appropriate for the audiences addressed. This WP will ensure the quality of the website and tools as well as engage with other WP leaders and partners so as to ensure the appropriate level of dissemination for each of the WP outputs, services, tools, events, etc.

#### Task 2.1: Design of a dissemination plan

Leader: AEMPS / Start date: M1 End date: M10

The main principles in order to elaborate the dissemination plan will be: Defining key messages, establishing target audiences and selecting the appropriate tools and activities so that we can achieve the following aims of this task:

- To ensure that the results and deliverables are known to all partners and available to all key audiences and target groups
- To bring knowledge, experience and best practice together in order to achieve the objectives, activities, results and deliverables are known to all identified stakeholders and wider audience on EU and national / regional levels.
- Assist different WPs in their communicational needs. Thus, active and collaborating partners will be able
  to ask for support for any sort of dissemination event or activity related to their own aims, as well as any
  advice to develop any of their initiatives. This assistance will strengthen the dissemination and make it
  more effective.
- Creation of an official website with the aim of gathering and collecting a group of useful reference tools

that could be progressively updated.

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#### Task 2.2: Communication tool-kit (visual identity)

All the dissemination related material, such as project logo, templates for internal and public documents, leaflet format, etc., will be defined at the very beginning of the project in order to establish the project image as soon as possible. The corporate identity and communication tools will be developed for the project in line with what will be developed by JA to ensure consistency.

Leader: AEMPS / Start date: M1 End date: M12

Task description: a tool-kit will be developed, including

- Logo and claim: they should incorporate the project mission into one single graphic along with a catchy slogan/claim able to engage with the target audience. Logo will indicate co-foundation as do other materials.
- Web banner design as an extra tool, complementary one, for all the others (logo etc.).-
- Develop Templates: Word, Power point
- Leaflets and Factsheet: Editing, publication and distribution of promotional leaflet for broad public with focus on the promotion of JA objectives and planned activities that constitutes Leaflet will contain also logo JA visual identity and distribution will be realized according stakeholder analysis within the first period of the dissemination plan. This tool will be targeted at all stakeholders through online dissemination channel website, e mail. Two "official" leaflets will be produced during the JA. One first hand-out disseminated at an early stage of the JA to inform people about the project, and which would include a general description of the project goals, aimed at informing the target groups about the project existence and the planned activities. The second leaflet to be issued in the later stages of the JA when the results are more visible and tangible. Special leaflet can also be created for promotional purposed for a special Conference where our Joint Action can be represented and promoted.
- Distribution List
- Newsletter sent to different countries and different stakeholders, produced 3-monthly (M 1,4, 7,10,13,16, 19, 22, 25, 28, 31, 34). The exact timing could be adapted according to JA events and meetings, milestones, political occasions or presidency activity. Dissemination channel used: website, e mail, social media. Newsletter will be free to view and download on our website.
- Social media communications strategy will be an essential component of the overall communications strategy of the JA (Dissemination through twitter and facebook of all events/results related to JA)
- Website is the main tool where all the outcomes will be collected. (see task 2.4)

#### Task 2.3: Identification of the relevant target audiences and their expectations from the JA

Leader: AEMPS; Start date:M1 End date:M36

Task description: to design a plan that allows for dissemination strategies, it will be necessary to build a consistent strategy based on a stakeholder analysis that has carefully planned to cover different target groups to allow maximizing the impact of the efforts. The first step will be the identification of the relevant target audiences by a stakeholder analysis looking at the different users of the JA relevant information and their needs in regards with this output at EU level and within MSs. This analysis will include 4 target groups i.e. citizens (that includes patients and the mass media), healthcare professionals (HCP, managers, veterinarians), industries (agribusiness, livestock farming), and authorities (governments, regulators, public health and food safety agencies). This work will be conducted with the support of the stakeholder forum. Regular updates will be conducted since new target audiences might arise regularly

In order to analyze the target audience/stakeholders involvement on AMR and HCAI, it would be possible to use social networks analysis tool.

Regular updates will be conducted since new target audiences might arise regularly

#### Task 2.4: Web site Design: Internal and external use

Leader: AEMPS; Contributors: UMPIH / Start date:M1 End date:36

**Task description:** A website as central hub for internal communication as well as main platform to communicate outputs and disseminate the information to the targeted audiences. This task is one of the most important dissemination tools for the second JA period (2nd and 3rd year) and will aim to:

- Design a sharing platform (see task 2.4) as for internal communication.
- Design and Implementation of a web platform (use of English for all dissemination activities) as for

external dissemination. We believe the JA would benefit from easy to use software that will enable correct classification, efficient search and interactive collaboration.

• Used of the web banner designed (see task 2.1) on the webs of beneficiaries and collaborative partners. This banner will boost the JA visibility and will lead other websites' visitors to get to JA website

The first part of this task will involve the development of an interactive file-sharing platform where all partners can interact and share relevant information. This platform will have private access for the partners and the capacity of store the information.

The informative content of the external website with open access to all public, will consist partly of the information of the project (each WP will have a section etc.) and also a section to publish project news, events and all relevant information.

This website activity will be regularly monitored through feedback via public tools (Google analytics) and internal methods (internal communications working groups, surveys, etc)

The benefit of developing this website in a way that best suits the needs of the project will ensure the key role of WP2 as the coordinating body of the dissemination activities for the project and make sure that results and relevant information produced over the lifetime of the project will not be lost and can continue to be a crucial part of JA products and services well into the future. It will include conferences and materials produced for each WP and websites of interest that can be shared as a tool for people to access relevant information about the JA and the topic.

#### Task 2.5: Implement the Dissemination Plan

Leader: AEMPS; Contributors: UMPIH/ Start date:M1 End date:36

#### Task description:

The main principles in order to ensure the implementation of the dissemination plan will be:

- Implementation of contents related to the JA: reports, interviews to key spokesperson within the JA and general information about AMR and HCAI. Video interviews will allow us to edit the clips or promos that will energize the website. For example, animated infographics videos will also contribute to get some more attention into the project.
- Encourage the participation of all partners in international seminars and conferences to promote the project. WP leaders/co-leaders will be responsible for writing at least one (informative) editorial related to the JA specific results and send it to the WP2 leader/co-leader. This editorial will be then disseminated by each partner through their networks/ social media channels and to any known relevant organization and/or person of interest they may consider. On the other hand, all these editorials will be gathered on the main website of the JA and the summaries of those articles could be gathered on a wordpress/blog to help disseminate and engage more public.
- To develop one promotional online campaign (competition or game, at European level) in the 2<sup>nd</sup> and 3<sup>rd</sup> years to attract general public to the website (campaign non-related to promote communication materials). For example in a previous JA, that WP2 prepared a Facebook competition and games to attract public, offering certain limited number of T-Shirts designed and signed by one celebrity and with a message related to antibiotic use. Also, another example would be a photography contest related to the overuse of medicines or something similar to get people thinking about the topic in their day-to-day life. This might be used at European level.
- To plan press releases and Newsletters.informing about newsworthy outcomes and activities.
- Layman report: At the end of the project, beneficiaries should produce a Layman's report, a
  comprehensive information brochure targeted at a non-specialist audience. It serves to inform decision
  makers and non-technical parties of the project objectives and results with a full overview of the project
  outcomes.
- To organise a final Dissemination Conference (3º year). A final Conference will be organized at the end of the project to disseminate the project results. This Conference will target at researchers, clinicians and general practitioners, professional associations, mass media, patient organizations, etc., and also involve some representatives of the JA active partners.
- To be able to verify if the strategy was well chosen and well implemented through an evaluation

component (in collaboration with WP3) into all dissemination activities to monitor the quality and to verify whether they have achieved their aim.

Work package	WP3		Start date	or starting	event			M1
number	WP3		<b>End date</b>					M36
Work package title	Evaluation (	of the proje	ct					
Leading participant	ISS (IT)							
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8
Participant short name	INSERM	Moh	GOG	FPS HFCSE	NCIPD	CIPH HZJZ	NIPH	SSI
Person-months per participant	3,5	0,6	0	0	0	0	0	0
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS
Person-months per participant	0	0	1	0	0	2,5	6	0
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	ні	NVSC	VWS	HdiR	FHI	NVI
Person-months per participant	0	0	0	0	1	0	0,4	0
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	DGPIFA C
Person-months per participant	0	0	0	0	1	0	0	5
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	0	0	0	0	1	0	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES		TOT	AL	
Person-months per participant	0	0	0	0		22		

#### **Objectives**

The main objectives of this WP are:

- (i) to assess the achievement of the project objectives;
- (ii) to assess whether the outcomes meet the needs of the target groups.

The specific objectives of WP3 are:

- 1. Develop, share and disseminate an Evaluation Plan (EP);
- 2. Develop Evaluation Tools (ETs) for data collection according to the EP;
- 3. Perform interim and final evaluation;
- 4. Develop quality assessment and report it as a specific paragraph/chapter in JA deliverables and documentation;
- 5. Report and share the evaluation results to participants and relevant stakeholders;
- 6. Evaluate the impact of JA in Europe (MS and regional governments).

Description of work, role of the participants and interactions Associated with document Ref. Ares(2017)4194538 - 28/08/201

#### WP Methodology

The evaluation process will include two major issues:

- i) Progress and results evaluation (Internal evaluation);
- ii) Quality evaluation (External evaluation).

The details of the evaluation process will be included in the Evaluation Plan (EP).

Relevant stakeholders will be engaged in the different phases of the evaluation process:

- one or more delegates for every WP and ECDC (due to its experience in infection prevention and control) for Internal evaluation (progress and results evaluation);
- Institutions at national (e.g. representatives of Ministry of Health, Agriculture, Environment, Research) and regional/local level, Policy-makers, Industries, Patients Association, Healthcare professionals Association, Scientific Societies (ECDC, EPHA), International Organizations (WHO Europe, OECD, FAO) for External evaluation (quality evaluation).

In order to reach the main objective (i) (progress and results evaluation), for every single JA objective and milestone <u>process</u>, <u>output</u> and <u>outcome</u> will be explored through specific indicators, defined and shared with WPs' leaders and relevant stakeholders.

These indicators will help evaluating the project progress, outcomes, impact and expected and unexpected development.

#### **Tools**

- i. <u>Surveys</u> through on-line questionnaires designed to be completed through self-assessment at country level by project participants and internal stakeholders;
- ii. Recording data out of routine documentation of WPs and pre-release deliverables (data from internal WP surveys, training materials, developed guidelines, operations manual, recommendations, results of pilot projects, questionnaire exploring: the carrying out and accomplishments of general and technical meetings, characteristics of participants, outcomes emerged and appreciation degree);
- iii. <u>Meetings</u> (on-line or face to face) to agree the Evaluation Plan, agree and share Evaluation Tools and share reports (interim and final) results with participant representatives of all JA WPs.

In order to reach the main objective (ii) (quality evaluation), the evaluation plan will be based on comments, suggestions and/or recommendation made by the Steering Committee and the Stakeholders Forum, which will give their contribution to assess:

- accuracy of Evaluation Plan in all its phases and efficacy and usefulness of Evaluation tools;
- relevance of JA AMR and HAI issues perceived at different level (institutional, academic and operational level);
- reproducibility, truthfulness and completeness of data provided by WPs' leaders and partners (e.g. through surveys' questionnaires) through National and Regional health institutions web-sites consultation, requests for integrations/clarifications, dispatch of additional documentation, etc.;
- comprehensiveness and accessibility of contents of deliverables and documentation released (e.g. clarity and realistic nature of conclusion and proposal);
- representativeness and relevance of stakeholders engaged and experts involved and of their performance;
- satisfaction degree about JA strategies, actions, tools and outcomes by policy makers, HCWs, Patients Associations and other stakeholders.

**Tools** 

- i. <u>Surveys</u> through on-line questionnaires designed to be completed through self-assessment at country level;
- ii. <u>Consultations</u> involving different participants and stakeholders (WP leaders and partners, external stakeholders...) experts in HAI prevention and AMR;
- iii. <u>Meetings</u> (on-line or face to face) to share reports (interim and final) with external stakeholders.
- iv. <u>EU MS National and Regional health institutions web-sites consultation</u> for the availability of official data.

Progress and results evaluation and Quality evaluation will be included in interim and final reports, which will be shared with both internal and external stakeholders.

The team of evaluators will be composed by several professionals from Institutions/University with expertise in "projects evaluation" and previously engaged in similar experiences, both from Institution participating in the JA or subcontracted.

#### **Task descriptions**

#### Task 3.1: Definition of the evaluation plan (EP)

Leader: ISS; Contributors: FFIS / Start date: M1 End date: M4

**Task description:** EP, specifying evaluation activities, will be developed by the WP3 leader based on the set of defined indicators and reviewed by collaborating with representatives of all relevant JA WPs. The evaluation activities will include data recording out of routine documentation of WPs and pre-release deliverables, surveys (conducted through web-based questionnaires) and consultations involving different participants and stakeholders, and monitoring with a calendar of JA milestones. For each of these activities the evaluation plan will identify specific responsibilities, time for completion and mode of data collection for evaluation.

Revision of the EP will be carried out during the project, if necessary.

Specific and well-defined actions:

- i. assessment of the achievement of every single WP tasks and outputs;
- ii. the respect of the defined timeline and deadlines for WPs activities and outputs;
- iii. assessment of the correct development of general and technical meetings;
- iv. monitoring (support, early reaction, securing data) of the calendar of JA milestones;
- v. engagement of every single WPs leader and associated partner who contribute to the development of WP3 by providing evaluation information on their own activities, attended events (meetings, conferences, etc.) and deliverables.

#### Task 3.2: Development of evaluation tools.

Leader: ISS (subcontracting); Contributors: FFIS / Start date: M1 End date: M36

**Task description:** Based on the definition of the EP, ETs will be developed to collect all information that is not easily accessible by data recording out of routine documentation of WPs and pre-release deliverables and require instead surveys and consultations involving different participants and stakeholders. This task will include the definition and implementation of web based tools to facilitate data collection and surveys conduction. Prior to use, ETs will be reviewed by all relevant stakeholders included the participants of the Stakeholders forum, this will maximise evaluation response rate and avoid issues during data collection activities, thus minimising risks for the task. All ETs will be tested and piloted before their use and they will be revised during the project, if necessary.

#### Task 3.3: Conduct interim and final evaluation.

Leader: FFIS; Contributors: UNIFG, ISS / Start date: M5 End date: M36

**Task description:** based on the EP, interim and final evaluation activities will be carried out to monitor the implementation process for WPs activities and assessment of achievement of JA specific objectives. Evaluation activities (as described in the EP, see task 3.1) will provide information on WPs progress and timely attainment of the milestones, deliverables together with assessment of pilot projects. In case of issues in carrying out the evaluation activities, direct consultations will be performed with relevant partners and/or stakeholders (e.g. reminders to partners not responding surveys, communication with WP leaders and partners in case of delays with deliverables/activities, etc.).

Task 3.4: Quality Assessment.

Associated with document Ref. Ares(2017)4194538 - 28/08/201

Leader: FFIS; Contributors: UNIFG, ISS / Start date: M1 End date: M36

**Task description:** WP3 leader, in collaboration with the leaders of others WP, will support the quality assessment of JA documentation and deliverables and report it as a specific paragraph/chapter in JA deliverables and documentation.

Deliverables and documentation will be assessed for quality aspects (e.g. comprehensibility, completeness, etc.) by the WP3 leader, who will coordinate the evaluation involving relevant internal and external stakeholders.

#### Task 3.5: Report of evaluation results to relevant stakeholders

Leader: ISS (subcontracting); Contributors: UNIFG / Start date: M18 End date: M36

**Task description:** based on results from evaluation activities, the WP3 leader will produce an interim and a final report including all collected information and indicators. Reports will be shared with internal and external stakeholders, including the Steering Committee and the Stakeholders forum. This will ensure that quality of JA output is always a top priority to the management bodies.

The final evaluation report will be focused on the positive and negative aspects of the impact of the action and the reached aims (as a result of task 3.3); it will also evaluate usability and comprehensibility of JA results and deliverables in the target population (as a result of task 3.4).

#### Task 3.6: Evaluation of the JA impact in Europe

Leader: ISS (subcontracting); Contributors: UNIFG / Start date: M18 End date: M36

**Task description:** A final evaluation of the JA impact in Europe will be performed (M36). The first positive results (if any) will be assessed, as well as possible barriers/room for improvements.

The impact will be evaluated at different levels:

- increase in number of professionals with skills on HAI prevention and AMR;
- availability of guidelines;
- increase in training initiatives for professionals.

According to the actions effectively adopted and the goals achieved by the Joint Action, also the following items will be assessed:

- <u>decrease in HAI prevalence rate</u> in MS participating to JA;
- decrease in prescriptions/consumption of antibiotics (overall and of one or more classes);
- lower rate of AMR in human and veterinary areas for one or more target microorganism;

To reach the objectives two main actions will be adopted:

- Questionnaires to national, regional and local authorities as well as to professionals and citizens associations
  on the main topics of the project; opinions will be collected about the first results of the JA;
- EU MS national and subnational web-site consultation for the availability of official data.

Work package	WP	14	Start date o	r starting ev	ent			M3	
number	VVP	<b>'4</b>	End date					M36	
Work package title	Integration	into natio	nal policies	and sustain	ability				
Leading participant	MoH-FR								
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8	
Participant short name	INSERM	Moh	GOG	FCS	NCIPD	CIPH HZJZ	NIPH	SSI	
Person-months per participant	0	14,4	0	0	0	0	0	0	
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16	
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS	
Person-months per participant	0	0	0	0	0	0	0	0	
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24	
Participant short	LSMULKK	VULSK	HI	NVSC	VWS	HdiR	FHI	NVI	

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name				710	poolatoa witi a	Dournont Hor. 7	1100(2017)+10	1000 20/00/20
Person-months per participant	0	0	0	0	0	0	0	0
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS
Person-months per participant	0	0	0	0	2	0	0	0
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	0	0	0	0	0	0	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES	TOTAL			
Person-months per participant	0	0	0	0	16,4			

#### **Objectives**

This overarching task of WP4 is to foster the integration into national policies of the recommendations issued by the consortium and/or ECDC and encourage healthcare workers and policy makers to expand and maintain their implementation in their respective countries when and where needed.

Since this JA involves 44 partners from 21 countries, one goal of WP4 is to secure the contribution of all participants to the JA (i.e associate and collaborative partners), and other bodies and institutions at the national and EU level, beyond the participating institutions. Specifically, the ECDC, FAO, OIE, WHO Europe and the European Commission will be involved to contribute to and support the sustainability of actions proposed within WP4.

Since the scope of studies performed within the JA will be rather limited within its time-frame, the task of planning the scaling-up of the results obtained when needed and obtaining adhesion to best practices from other institutions, partners, and MS relies on this WP. Support from the ECDC to address a specific problem through adapting guidelines or recommendation will be sought.

Several actions will need to be carried forward beyond the 3-year JA duration to ensure sustainability of results and actions initiated during the JA. The first task of WP4 will be to design an integration and sustainability strategy and plan based on the expected outputs from the JA. The strategy will account for potential differences in identified priorities based on public health organisation, geographical area and epidemiology, and also define potential indicators for follow-up of actions undertaken. As action on AMR and HCAI implies multilevel, multi-actor and multi-sectoral approach, the WP will provide for tailored recommendation to JA partners and groups targeted, associated with clear and measurable goals.

The specific objectives of this WP will include:

- 1. Developing an integration and sustainability plan
- 2. Ensuring integration of preventive strategies for AMR and HCAI into national policies
- 3. Fostering sustainability of core actions engaged by the JA WPs and uptake at the national level.

#### Description of work, role of the participants and interactions

#### WP Methodology

In general, the approach taken in WP4 will follow the Knoster model for promoting cultural, behavioural and organisational change to further reduce the burden of AMR. This will be done through workshops and consultation of stakeholders, policy makers and competent authorities represented in the Steering Committee, and partners.

Given the specific role of this WP in terms of extension/dissemination of actions and implementation of sustainability strategies within Europe, it is clearly of importance that a maximum possible of MS, and whenever

possible associated states and non-EU members contribute of the associated with document Ref. Ares (2017) 4.194538, -.28/08/2017

#### **Task descriptions**

#### Task 4.1: Integration plan and sustainability strategy

Leader: MoH-FR; Contributors: AEMPS / Start date: M3; End date: M30

**Task description:** the integration plan and sustainability strategy will propose, within the remit of the priorities identified by the WP and validated by Member States, an implementation plan on AMR and HCAI, based on the Knoster model, compliant with EU Action plan as well as WHO Global action plan. It will identify for each actor, from patient groups to international organisations, achievable and realistic actions that are "game-changer". Based on the gap analysis performed within WP5, and a SWOT analysis of national strategies, the integration plan will propose specific roadmap for national competent authorities to adapt their national strategy to identified priority areas for intervention. Being focused on achieving reasonable and concrete objectives, the JA will share the best practice and deliverables it has produce with key players.

The WP will ensure that all core WPs (5,6,7,8,9) take into account the sustainability of their action within their work and reports. Close cooperation during the JA lifespan will ensure that from the beginning, sustainability and integration into national policies are carefully considered. WP4 leaders will therefore closely follow-up and contribute to the work done by other WPs through participation at meetings, iterative process of deliverables, observation and guidance on other WP's outputs.

## 4.1.1: Identify outputs from the JA which will should be widely disseminated and integrated into national strategies for control of AMR and HCAI.

This preliminary step aims to analyse the expected outputs from the JA in terms of guidelines, recommendations or implementation tools which are planned to be available by the end of the 3-year duration of the JA, and would need to be promoted at the regional/ national/ EU level. This analysis will be based on the compilation of objectives and deliverables from the JA WPs, and timing of availability of these outputs. After having analysed the MS priorities with regard to prevention and control of AMR and HCAI through a survey of Stakeholders and competent authorities as well as integrating information from gap analyses performed within WP5, 6 and 7, these outputs will be put in perspective with MS priorities and existing reference documents (e.g., from ECDC, WHO,...) and analysed for their added value and potential for integration into national policies and action plans. This will form the basis for a draft version of the integration & sustainability plan. This draft version will be made available of the JA website (with WP2) for all JA partners and advisory bodies to comment and provide input on the draft plan.

#### 4.1.2. Produce a sustainability plan

From the analysis performed in 4.1.1., priority areas for improvement will be discussed with the stakeholders' forum and incorporated into a development program for prevention of AMR and HCAI, which will form the final version of the integration plan and sustainability strategy, produced by M30. This task will be coordinated by MoH-FR with the contribution of all partners. Representatives of Member States will be consulted regularly during the process of developing the plan to ensure that priority goals match the national agendas on AMR and HCAI. A workshop with SC members will be organised to consolidate the recommendations included in the plan, and obtain commitment of MS on adopting the plan.

#### Task 4.2: Integrating preventive strategies within national policies

Leader: MoH-FR; Contributors: AEMPS / Start date: M12 End date: M36

#### Task description:

After identification of gaps and proposed priority goals resulting from surveys and/or pilot studies performed within WP5, 6, 7, 8, the strengths and weaknesses of NAP will be assessed. The WP will elaborate concrete recommendations targeting those gaps and adapted to various contexts and problems (e.g., countries with high antibiotic consumption, countries with high levels of resistance, ...). It will propose a set of measures to be implemented, based on available recommendations and best practices identified, and include indicators for each group of actors to measure progress. Strong interaction with WP5 will be maintained, especially with regard to action within the OneHealth network and the supervising bodies network as supporting bodies following-up the adoption of actions proposed.

The actions, recommendations and tools selected for integration within the NAP and programs, as well as means for dissemination will be described in a report available within the last 6 months of the JA. Policy briefs will be used for dissemination to competent authorities. The integration task will require support and engagement of

stakeholders and support from implementation science experts for communication of recommendations to public health levels.

Indicators suggested for this task include the number of policy briefs endorsed by national competent authorities

#### Task 4.3: Fostering sustainability

Leader: MoH-FR; Contributors: AEMPS / Start date: M30 End date: M36

**Task description:** besides integration into MS' NAP of specific actions promoted within the JA WPs, some other outcomes or actions will need tailored actions to be undertaken to ensure their sustainability. The strategy used for this, involving national competent authorities and stakeholders as well as EU bodies, will be described in task 4.1 (DEL4.2). Sustainability of JA recommendations does not solely rely on international organisations or policy makers. Each stakeholder is part of the solution to tackle AMR. In this regard, the input received from the Stakeholder forum will be taken into consideration and specific recommendation for each target group will be included. For instance, representatives of patient associations will be able to take the recommendation of JA to their constituency.

Depending on the actions selected in 4.1.1, recommendations or practice guidelines will be elaborated. These will entail soliciting either institutions (eg, ECDC, WHO) or professional societies (eg, ESCMID). The guidelines will propose indicators allowing follow-up of progresses made toward reaching the objectives set up in the recommendations.

The country-to-country assessment method and tool tested within WP5 could be proposed for endorsement by WHO Europe and promoted among other MS not participating into WP5 for further joint assessment. Besides, the findings from these and recommendation discussed with the supervisory network should be integrated in the national supervision plans and procedures.

Likewise, the material produced and validated within WP6.1 and WP6.2 during pilot studies of implementing preventive strategies for designated HCAI, notably the improvement model and approach taken will need to be expanded to other settings and networks within EU MS and outside; this uptake could be promoted through two channels: the supervising bodies network convened within WP5 (Del 5.5) for EU MS and/or the professional bodies within the stakeholder forum; in addition, cooperation with WHO Europe will be needed to expand the approach to non-EU member states. Likewise, the model for implementation of the antimicrobial stewardship program and short-lagged resistance surveillance designed within WP7 and pilot-tested will need, if successful, to be expanded to other settings and networks.

In addition, reference documents produced during the JA, such as the review of guidelines for prudent use of antibiotics (WP 7.1), best practices for promoting awareness and communication on AMR (WP8.1), or recommendation to ensure that MS use best procedures to improve their input into the EU research agenda (WP9.1) will need to be endorsed by external bodies and maintained /updated for example on the ECDC website. Indicators suggested for this action include recommendations endorsed by ECDC and made available on its website, as well as the number of MS countries adopting the implementation models and tools promoted by the JA.

Components of the JA included in the sustainability plan and specific processes used for their implementation will be described in the final report.

Work package number	WP5		Start dat	e or starting	g event			M01 M36
Work package title	Implement	ation of On			egies and N	lational Acti	ion Plans fo	
Leading participant	VWS (NL)							
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8
Participant short name	INSERM	Moh	GOG	FPS HFCSE	NCIPD	CIPH HZJZ	NIPH	SSI
Person-months per participant	9	4	0	4	6,7	0	4,3	0
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short	TA	RKI	HCDCP	ESDY	7HC	UNIFG	ISS	PSKUS

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name				NSPH			, ,	
Person-months per participant	0	5,4	0	8,2	0	6	0	0
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	НІ	NVSC	vws	HdiR	FHI	NVI
Person-months per participant	6,5	0	12	0	29	0	0	0
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS
Person-months per participant	7	0	5,5	10	3	0	0	0
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	0	0	0	0	3	0	0,8	1,5
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES	TOTAL			
Person-months per participant	0,7	0	0	6	131,6			

#### **Objectives**

The main objective of this WP is to support MSs (and other participant countries) on the implementation of some of the provisions laid down in the *Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance* (2016/C 269/05)<sup>10</sup> unanimously adopted by the Council of the European Union in June 2016. The Council Conclusions on AMR call upon a new EU Action Plan against AMR. This activity may also be included as an activity of the implementation of the new EU Action plan.

The specific objectives of this WP are to:

- 1) Support MSs in the development and implementation of national strategies and national action plans based on the One Health approach and in line with the WHO Global Action Plan (GAP) on AMR<sup>11</sup> and the *Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance* especially by:
  - a) the development of a self-assessment tool to monitor country progress and identify gaps and shortcomings on the implementation of national strategies and national action plans;
  - b) the setting up of a country-to-country peer review system to evaluate each other's national action plans and reflect about policy options;
  - c) the establishment of a network of supervisory bodies to discuss different approaches on the way supervision, inspection and enforcement in the Member States is organized and on how the level of compliance with legislation, national (professional) guidelines, standards and recommendations relevant to AMR can be improved in the Member States.
- Report regularly and discuss within the One Health Network described in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance on the outcome of the activities of WP5.

Description of work, role of the participants and interactions

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<sup>&</sup>lt;sup>10</sup> OJ C269, 23.7.2016, p. 26 (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C \_.2016.269.01.0026.01.ENG&toc=OJ:C:2016:269:TOC

<sup>11</sup>http://www.who.int/antimicrobial-resistance/global-action-plan/en

Confidential

#### **WP Methodology**

Associated with document Ref. Ares(2017)4194538 - 28/08/2017

The methodology used in this WP is in line with WHO approach to move from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts and the WHO framework for the monitoring and evaluation of the implementation of the Global Action Plan on AMR, based on the tripartite self-assessment and the performance of the Joint External Evaluation.

All activities described in this WP are based on the implementation of the One Health approach. The representatives of the WP5 participating countries are responsible for the engagement of the relevant sectors, including the formation of team of policy makers and experts from both the human and veterinary domain and the other relevant areas (e.g. agriculture, environment) within the country.

Workshops, electronic and physical meetings, tele/videoconferences, (self)-assessments, reports, literature/review, presentations at the One Health Network, etc.

#### Task descriptions

#### Task 5.1: Mapping and self-assessment of National Action Plans and strategies

Leader: VWS (NL) Contributors: all WP5 participating countries / Start date: M1 End date: M12

#### Task description:

In order to support MSs in the development of national strategies and NAP on AMR, the WP5 participating countries will:

- Map existing NAP and national strategies in the participating countries and in the rest of the EU, including, where relevant, the elements of the GAP on AMR and the Council Conclusions (One Health approach, overview of measurable goals, enforcement by competent authorities or national supervisory bodies, etc.).
- The mapping will be developed by the participant countries (at least one representative of each WP5 participating country) and will be based on publicly available information (e.g. internet site of ECDC, European Commission, Member State) and on direct information collected by the competent authorities in the MSs.
- Countries not participating in WP5 will be asked (thought the collaborative partners or partners involved in other WP of this Joint Action) to voluntarily provide the same information about existing NAP and national strategies in their countries in order to be able to also map the situation in these Member States.
- This mapping will provide an overview of the situation in the Member States and a view of the areas of concern and will be used for the development of the self-assessment tool.
- Develop a tool for the self-assessment of national strategies and NAP, including the One Health approach. The tool will be developed on the basis of the WHO (tripartite) tool "Global Monitoring of Country Progress on AMR: country self-assessment questionnaire" (or similar tool developed/revised in the future by WHO), by extending it to the situation in the EU, adding the specific requirements of the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance and the other requirements laid down in relevant EU legislation, recommendations, guidelines, etc. The self assessment tool will allow for the analysis of the strengths and weaknesses in the Member States.
- The tool will be developed by the WP5 participating countries (at least one representative of each country), with the assistance of collaborating stakeholders: EU agencies (ECDC, EMA, EFSA) and Directorate on Health and Food Audits and Analysis of the European Commission, WHO-EURO, WHO-HQ and OIE.
- For the development of the tool, several electronic working groups or tele/video conferences and also a physical meeting (workshop) will be organized. The tool will be presented to the participating countries. During the meeting participating countries will receive the instructions for the capture of data in the tool.
- In preparation of the country-to-country assessment (Task 2 see below), each of the participating countries will perform the self-assessment using the tool described in this task. Each participating country will analyze the results of its own self-assessment, in order to identify gaps in the NAP, evaluate the national strategy, etc. and will discuss at the national (or where relevant regional) level how to address gaps and improve the national situation. This analysis will preferably be SWOT-based in order to allow for the analysis of the strengths and weaknesses, identification of the opportunities and threats to face.
- Each participating country will provide the results of the findings of the self-assessment and the outcome of the own analysis to the WP5 leader.
- All participating countries will present, discuss and analyse together the report of the outcome of the selfassessments during several electronic working groups and/or video/teleconferences and also a physical meeting (workshop).
- The results of the self-assessments and the discussions during the workshop will be presented and discussed within the One Health Network.

NB: all WP5 participating countries will perform both Task T und Task 2. The performance of Task 1, the self-assessment, is a preparatory work for Task 2 (country-to-country assessment). At least one of the contributors from each participating country will be involved in the mapping task. The representatives of the WP5 participating countries will organize a team of policy makers and experts from both the human and veterinary domain and the other relevant areas (e.g. agriculture, environment) within the country to carry-out the self-assessments. These representatives are also responsible for involvement of the relevant (competent) authorities in their own Member State in the discussion of the outcome of the self-assessment.

#### Task 5.2: Country-to-country assessments

Leader: VWS (NL) Contributors: all WP5 participating countries / Start date: M4 End date: M36 Task description:

A country-to-country peer review/assessment system will be set up, as described in the *Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance*. The country-to-country assessment will allow representatives of one or several WP5 participating countries to evaluate each other's national action plans and One Health strategies, reflect about policy options and provide recommendations to support countries on the development and implementation of the NAP and the measures taken.

The following actions will be performed:

- Development of the methodology and the tools to be used for the country-to country assessments. This activity will be performed by a (multidisciplinary) group of representatives of the WP5 participating countries, in close collaboration with the collaborating stakeholders: e.g. ECDC, the Directorate on Health and Food Audits and Analysis of the European Commission and where relevant international institutions (e.g. WHO-EURO).
- The tool for the country-to-country assessments will be developed and based on the self-assessment tool from Task 1 and taking into consideration the experience of the performance of the self-assessments.
- Performance of 3 pilot "country-to-country" assessments in countries that have already performed a self-assessment on NAP and have provided the summary of the findings and discussed them in the workshop.
- The 3 pilot countries will be chosen by the participating countries and will reflect, as much as possible, different situations in Europe. For this selection, the geographical distribution, division of responsibilities within the Member State (national vs regional), level of development and implementation of the NAP, etc. will be considered. All 3 selected countries must have already performed the self-assessment as described in Task 5.1.
- The country-to-country pilot assessments will be performed by a (multidisciplinary) team of one or more representatives of the WP5 participating countries. The team will consist of policy makers and experts and may include representatives from the relevant collaborating stakeholders: ECDC, EMA, EFSA, Directorate on Health and Food Audits and Analysis of the European Commission, WHO-Euro or other international organizations. The team will visit a country, for example for 5 days (to be determined), in order to evaluate its national action plan, reflect about policy options and provide recommendations to support and improve measures taken. The team will make use of the already performed country self-assessment (see task 5.1) and where possible other existing assessment or audit activities (e.g. ECDC, Directorate on Health and Food Audits and Analysis or WHO) in order to avoid overlap or get additional information. At the end of the visit, the team will hold a wrap-up meeting with the relevant national competent authorities to present the preliminary outcome of the assessment.
- The countries assessed will further discuss internally at country level and also in the context of the One Health Network, the outcome of the country-to-country assessments and to follow up on identified shortcomings and gaps and address them and sustain this action.
- The representatives in WP5 of the country assessed are responsible for the involvement of the relevant (competent) authorities in their own Member State in the performance and the discussion of the outcome of the country-to-country assessment. The representatives of WP5 participating countries will organise a team of policy makers and experts from both the human and veterinary domain within the country to participate in the country assessment.
- The results of the 3 pilots will be discussed and the methodology and tool used for the country-to-country assessment will be revised based on the experience of the 3 pilot country-to-country assessments. For this purpose, several electronic working groups and/or video/teleconferences and a physical meeting (workshop) will be organized.

- The results of the 3 pilot country-to-country assessments will be presented and discussed at the One Health

  Network

  Network
- Perform "country-to-country" assessments for the other countries in the WP that have already performed a self-assessment on NAP and provide a summary on the findings, based on the revised tool and methodology and report and discuss the results within the One Health Network.

NB: all WP5 participating countries will perform and participate in the country-to-country assessments. At least one of the contributors of each Member State will be involved in the development and revision of the country-to-country assessment. The representatives of the WP5 participating countries will organize a team of policy makers and experts from both the human and veterinary domain and the other relevant areas (e.g. agriculture, environment) within the country to participate in the country-assessment. They are also responsible for involvement of the relevant (competent) authorities in their own Member State in the performance and the discussion of the outcome of the country-assessment.

Additional country-to-country assessments can be performed in additional countries not actively participating in WP5 provided that these countries have performed Task 5.1, the country-to-country assessment is supported, organized and self-funded by a collaborative partner in this Member State and based on the agenda and resources, including availability of the representatives of WP5.

#### Task 5.3: Strengthening supervision

**Leader:** VWS (NL) **Contributors** all WP5 participating countries / **Start date:** M2 **End date:** M36 **Task description:** 

Control activities (supervision, inspection) and enforcement by the competent authority or a (delegated) supervisory body (including professional associations), provides information about the level of implementation of national policies, the level of compliance with legislation and the adherence to guidelines and recommendations. Furthermore, it is a tool to assess the execution of the NAP, to identify areas where action or improvement is needed, to assess the reasons why compliance is not met and may help parties to comply or better abide by existing rules (legislation, guidelines, recommendations).

For example, to achieve policy goals such as improvement of prudent use of antibiotics, strict adherence to the guidelines for antibiotic use is necessary and inspections and strict enforcement may discourage activities such as over the counter sales of antimicrobials.

However, these activities are organized in different ways in the different countries depending on the healthcare system, national legislation and distribution of competences and responsibilities within the country. Additionally, competent authorities and supervisory bodies may be responsible for the control of many different topics related to healthcare, and AMR is either not always on the agendas of all supervisory bodies in all European countries, or not considered a priority.

To facilitate collaboration between supervisory bodies in the Member States, to facilitate control activities and enforcement of national policies related to AMR and on the implementation of the NAPs, Task 3 will include the following actions:

- Set up a voluntary network of national supervisory bodies in Europe and discuss methods of integrated supervision, best practices, exchange of experiences, etc. For this purpose, all participating countries in WP5 will identify the relevant supervisory bodies in their own country. A first meeting (workshop) will take place to establish the network, to learn about the different situations in the EU and to discuss further work. Representatives of the relevant collaborating stakeholders will be invited.
- The network will identify common white spots and shortcomings in the implementation of national strategies and discuss possible solutions and recommendations to improve the situation and the work of supervisory bodies. The network will discuss the outcome of this work on a workshop and will present the results of this work to the One Health Network.

NB: all in WP5 participating countries will participate in the task of identification of the supervisory bodies in own country. At least one of the contributors of each member state will be involved in this task. All participating countries will be requested to participate in the network.

Work	package	WP6 Start date or starting event End date  M01 M36  Policies for prevention of Health-Care-Associated Infections and their implementation	M01	
number			End date	M36
Work pack	age title	Policies for prevention	of Health-Care-Associated Infections and their im	plementation

Leading participants	HCDCP (GF	R) & FOHM	(SE)	○ AS	ssociated with	document Ref.	Ares(2017)4	194538 - 28/0
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8
Participant short name	INSERM	Moh	GOG	FPS HFCSE	NCIPD	CIPH HZJZ	NIPH	SSI
Person-months per participant	12	0	6	8,3	0	0	24,5	0
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS
Person-months per participant	5	0	85	2	11,5	7	7	11
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	н	NVSC	vws	HdiR	FHI	NVI
Person-months per participant	12	12	18	6	7	0	0	0
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS
Person-months per participant	0	10	0	11	12	12	3,5	12
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	0	0	4	0	41,2	1	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES	TOTAL			
Person-months per participant	0	0	1	0	329.4			

#### **Objectives**

In line with the EU action plan COM (2011) 748 - WP6 objectives are to ensure that guidance on infection prevention and control is developed, surveillance of HCAI is strengthened and that proper education and training of health-care workers is organised - this work will support the establishment of efficient and feasible infection control programs through the effective implementation of agreed key components for guidelines and/or other tools at national, regional and local level to prevent infections and thereby limit the use of antibiotics and spread of resistant bacteria in health-care settings.

Two complementary objectives will be developed in this WP:

- I. Promoting a top-down approach for preventing HCAI through the implementation of agreed infection control programs and institutional behavior change.
- II. Promoting a bottom-up approach from clinical practice to policy level by implementing evidencebased guidelines and existing policies using a structured implementation model and working in country teams.

Patients and other relevant stakeholders must be involved in the improvement work concerning infection prevention and control measures. Participating MSs should involve relevant stakeholders in this work including patients, health-care professionals, infection prevention and control professionals, patient safety professionals, clinic management, hospital management, regional health-care management, national health authorities,

existing European associations and networks within the field of infection prevention and control (IFIC, ESCMID, EUCIC, UMEMS, ESGNI, ISC and EUNETIPS).

The two objectives of WP6 will have strong interaction between each other in order to secure tight links to reach overall objective of WP6 - prevention of HCAI and also avoiding overlap in content.

#### Description of work, role of the participants and interactions

#### WP Methodology

Objective 6.I: top-down approach: Policies for preventing health-care associated infections through the implementation of agreed infection control programs and institutional behavior change

The specific goals are to:

- 1. Determine the necessary institutional structures and resources for the implementation of infection control programs and promote adequate hospital organization, management and structure for the prevention of HCAI.
- 2. Incorporate Infection control programs into clinical practice for the improvement of health professionals' compliance with infection control routine using the institutional behaviour change as a tool to accomplish it.
- **3.** Develop the tools for increasing awareness and improving the training of health professionals to infection control and prevention.

Given the differences in the AMR context in European countries, the aim of the objective 6.1 is to fill the gap between policy and practice of infection control in healthcare facilities based on evidence based practices and the national experience of participating partners for elaborating a concrete, implementable and reasonable Infection Control Plan for the prevention of HCAIs. The WP will contribute to improve the infection control capacity within health-care through institutional awareness using identified key components and specific interventions which will be adapted to the real needs, resources and priorities of the national health systems. The project will use the JA web-based platform for developing common protocols and sharing documents.

**Objective 6.1** will be divided into three main tasks which are a sequence of activities aimed at the development of a Universal Infection Control Framework (UICF) for health professionals according to which roles, responsibilities and accountability will promote teamwork strengthening towards improved health professionals compliance and, consequently, patient safety. Ideally, the same partner-countries will be involved in all three tasks.

This methodology will follow four phases: plan, action, evaluation and improvement. The plan will be based on evidence-based practices and surveys, and action on the implementation of the infection control framework. Surveys will address all European Union member-states targeting to increase our knowledge regarding the current situation and the barriers that limit health system to restrict HCAIs. The implementation of the *Universal Infection Control Framework (UICF)* will be performed in the selected hospitals of the participants aiming to estimate the gap between policy and practice. Each country should take advantage of the results of the surveys and the UICFW implementation for improving its capability to develop HCAIs prevention policies at local and national level. For that reason the active contribution of national representatives is crucial for the collection of reliable data, the dissemination of the results, the feedback of stakeholders and the sustainability of this venture.

Task 6.1.1. Determine the necessary institutional structures and resources for the implementation of infection control programs and promote adequate hospital organization, management and structure for the prevention of HCAIs, according to the EU Action Plan.

Leader: HCDCP; Contributors: GOG; NIPH; 7HRC; UNIFG; ISS; DGS; AEMPS; GENCAT; IdISBa; DGPIFAC/SMS/FFIS; ISCII; FOHM; Inserm / Start date: M1 End date: M36

**Task description:** the aim of this task is the determination of the necessary institutional structure and resources for the implementation of efficient and feasible infection control programs in healthcare according to the standards and requirements of the EU Action Plan for AMR.

This objective will be achieved through the following activities:

<u>6.1.1.1-</u> Survey for the key components of an infection control program based on the ECDC guidance (survey A in the table above) and the requirements of the updated EU Action Plan for AMR regarding the hospital sector. The questionnaire will be disseminated to all EU countries and will address public health organizations, relevant national scientific committees, hospital Infection Control Committees and hospital managers. The participating healthcare facilities to the survey will be determined from the partners depending on the health care structure in the country, with a strong focus on acute care and long-term settings. Regarding the EU member states that are not participating in the task the questionnaire will be disseminated with the contribution of the respective

national public health organizations. The aim of this extensive survey is to have the clearest picture of the reality associated with the capability of each country to implement ICP policies. Finally, a workshop will be organized at the end of the survey by each participating country at local or/and national level for feedback on the survey's results, for raising the awareness of the contributors and the determination of the real needs and priorities of each country. (M1 – M7)

<u>6.1.1.2</u> - Review of the guidelines for the implementation of ICPs and their applicability to clinical reality based on the result of the survey and the requirements of AMR action plans of WHO and EU. **(M8 – M13)** 

6.1.1.3. Assessment of cost-benefit for the development and implementation of an infection control program. It is of crucial importance to persuade the hospital managers and the politicians that the prevention of HAIs is saving lives and resources. It will be a supportive element to the organization behaviour change bundle. Intensive efforts for controlling AMR and HCAIs are costly and the cost-effectiveness of these efforts at the hospital or national level has not been defined. The initial plan of the assessment will be based on the existing literature and the revised guidelines. Its final formulation will be resulted from the implementation of the Universal Infection Control Framework in participating countries. Once the core components of an infection control program have been determined, assessment of their simultaneous impact on epidemiological, clinical and economic levels will follow on the basis of respective indicators that will have been chosen. The aim is to assess the implementation of an infection control program within the specific financial circumstances of each country so that the data produced can be totally compehensible and usable by professionals, who are mainly hospital administrators. This venture is ambitious and demands the development of broad collaborations among the participating countries, even at the level of health finances (M10- M36)

Task 6.1.2: Incorporation of infection control programs to clinical practice for the improvement of health professionals' compliance with infection control routine using the institutional behaviour change as a tool to accomplish it.

Leader: HCDCP; Contributors: GOG; NIPH; 7HRC; UNIFG; ISS; DGS; AEMPS; GENCAT; IdISBa; DGPIFAC/SMS/FFIS; ISCII; FOHM; Inserm / Start date: M1 End date: M36

**Task description**: the aim of this task is to fill the gap between policy and practice of infection control in healthcare facilities in European countries and evaluate the impact of the institutional behavior change on improving the HCWs compliance with infection control and prevention measures.

This aim will be achieved through the following activities:

- 6.1.2.1. Survey of the infection control policies at hospital level (Survey B, Table above). The aim of this survey is to examine and analyse barriers (attitudes, level of training, lack of awareness, etc) to an effective implementation of an infection control program in clinical reality, which are mainly linked to the institutional policy and organizational behavior. The survey will be based on common axes for all the participants, accounting for the peculiarity of each country's health system in which it will be performed for ensuring the sustainability of the project. A questionnaire will be disseminated to the participating EU countries and will be conducted through interviews of hospital administrations, Infection Control Committees, clinical department leaders, doctors and nurses at European level. The results of the survey will be evaluated at national and European level. (M1 M8)
- <u>6.1.2.2. A framework with specific roles</u>, priorities and necessary interventions for implementing an infection control program (<u>Universal Infection Control Framework</u> –UICF)in healthcare facilities will be based on the results of the two first ongoing tasks and feedback from governments, public health organizations, scientific committees and health professionals. (M8-M36)
- <u>6.1.2.3. Pilot testing of the Universal Infection Control Framework (UICF) in European hospitals.</u> The aim of this testing is to estimate its impact on routine clinical practice and the behavioural change of clinicians on infection control. A limited number of healthcare facilities (at least two healthcare facilities) will be selected from partners to participate for a year in the pilot framework implementation study. The implementation of the plan will be based on intervention without additional costs and it will be modified in accordance to the operation, structure and resources of the hospitals. Hospitals will adapt the UIC framework to their needs and priorities adopting and performing the appropriate interventions. The final proposed UICF will be finalized with the incorporation of the pilot study results and it will be introduced at national and EU level.

The UICF impact will be assessed by the repetition of the initial survey using the following indicators:

- **1.** The number of the key components of the proposed plan which were performed by hospitals (structure and process indicators
- 2. The cost-benefit assessment of the programme's implementation

- **3.** The response (positive/negative) of stakeholders regarding the implementation of the infection control framework to the repetition of the survey
- **4.** Additional outcome and process indicators (AMR and AB consumption rates, HCAIs incidence, hand hygiene compliance) will be used despite the fact that the time frame of this pilot testing is very limited to produce significant results. (M14 M32)

## Task 6.1.3: Development of tools for increasing awareness and improving the training of health professionals in infection control and prevention.

Leader: HCDCP; Contributors: GOG; NIPH; 7HRC; UNIFG; ISS; DGS; AEMPS; GENCAT; IdISBa; DGPIFAC/SMS/FFIS; ISCIII; FOHM; Inserm / Start date: M7 End date: M36

**Task description:** the objective of this task is to develop tools based on the results of the previous surveys on supporting the framework of hospital administrations and ICs regarding the implementation of an ICP and improving HCWs compliance with infectious control measures.

The objective of this task will be achieved through the following activities: development of tools will be mainly web-based and will aim at increasing professionals' awareness and strengthen infection control training schedules for prevention of HCAI and of the spread of multidrug resistant bacteria in hospital environment. The development of these tools will be based on previous surveys and they will be improved through the pilot testing.

# Objective 6.2: Bottom-up approach: Promoting a bottom-up approach from clinical practice to policy level by implementing evidence based guidelines and existing policies using an established implementation model and working in country teams.

This objective will be focused on adaption and implementation of existing policies (national/regional/ local) and evidence-based guidelines and on improving the infection control capacity within health-care. The improvement work will be performed using the "The Breakthrough Series Model" as advocated by the Institute of Healthcare Improvement (US). Thus another overarching objective is capacity building through education of the participants in this particular improvement model and in adapting existing guidelines to country requirements.

The specific objectives of this part are to: (i) introduce an evidence-based implementation model which ensures co-operation between key levels (national/regional/local) and stakeholders and (ii) promote that similar working routines are implemented in EU and non-EU countries across Europe

#### Description of work, role of the participants and interactions

#### **Task descriptions**

#### Task 6.2.1. Introduce an evidence-based implementation model<sup>12</sup>

Leader: FOHM; Contributors: FPS HFCSE; NIPH; TA; HCDCP; PSKUS; LSMULKK; VULSK; NVSC; HI; VWS; NIJZ;

SoS; UAS / Start date: M1 End date: M36

#### Task description:

We will implement existing policies and evidence-based guidelines (see list below) with the aim to produce routines that can be implemented nationally. The Breakthrough Model from the Institute for Health-Care Improvement will be used. This model has been used and documented in numerous successful improvement projects

within health-care

(http://www.ihi.org/resources/pages/ihiwhitepapers/thebreakthroughseriesihiscollaborativemodelforachievin gbreakthroughimprovement.aspx). The model will initiate co-operation between the levels represented (national/regional/hospital) depending on the health care structure in the country, as they will participate as a 'country team' in the workshops and in line with the national activities planned in between the workshops.

This objective will be achieved through the following activities:

6.2.1.1. Selecting topics and participants, development of a framework and proposed changes. According to the model "learning sessions", called workshops in this task, are then alternated with "action periods", called national activity periods in this project. During the action periods the participants use iterative P-D-S-A (Plan-Do-Study-Act)-cycles to test and finally implement small changes, which gradually leads to the goal of full implementation. In this work process both discussion of current practices, development of implementation tools, barriers to change (e.g. difficulties concerning behaviour change or administrative barriers), and adapting

towards common policies and guidelines will be included. The experience and expertise of participants from hospitals, regions and nations will be used when the countries implement the changes nationwide as a continuation of the project.

The core components for infection prevention and control identified by WHO in 2009 and revised in 2016 will be used for strengthening the capacity on both the national and local (health-care facilities) levels for the prevention of HCAI and to prepare an efficient response to outbreaks of resistant bacteria. The WHO core components address key factors such as the organisation of infection and prevention programmes at the hospital level, the development of technical guidelines, training for health-care staff and specialised training of infection control professionals, surveillance of infections and pathogens and several other key factors for a comprehensive infection prevention programme. The same key factors and other complementary factors for the organization, management and structure for prevention of HCAI were recently compiled in a review and expert consensus by Zingg and others published in 2015 and will be used in this WP. The paper identified crucial elements for the organisation of effective infection-prevention programmes including ward occupancy and staff workload, access to materials and equipment (i. e hand rub), the development of multimodal strategies and tools and identification and engagement of strategy champions and creating a positive organisational culture. Assessment of competencies and training of health-care staff and infection control professionals will use the ECDC core competencies for infection control and hospital professionals in the European Union (2013) as a template.

6.2.1.2 Focus on specific topics. In addition to working with infection prevention and control policies general guidelines, the countries will choose to work with one or several of the following specific topics: catheter-associated urinary tract infection, hand hygiene, surgical site infections, and/or central line-associated blood stream infections. There are several well established, international guidelines available for these, and they are suitable for a multi-modal or bundle approach. Evidence-based guidelines are available for all these areas, and these will be provided to the participants as a basis for development and adaption of local implementation tools. The aim is to compile the evidence to improve compliance with routines. Based on the evidence the participants will agree on a model for improvement of compliance. After an initial phase of testing the model in 1-2 wards using the Model for Improvement, the model will possibly be revised and then implemented in several wards in the same hospital.

This task aims to engage key levels (national, regional, hospital) in participating MS in collaborative work to both start implementation of general policies/guidelines and to start implementation in specific areas (e.g. hand hygiene, catheter related UTI). For a sustained impact these teams are planned to continue the work towards nationwide implementation after the Joint Action, a so called "full" participation. MS/partners involved in the Joint Action who lack capacity for implementation at hospital level, may express interest in participating with one or two persons (who must be partners) at those WP6 workshops that will be held in conjunction to other Joint Action meetings (as appropriate), to build capacity on implementation in those countries and partner organisations, a so called "light-track" participation.

#### Criteria for taking part in this task

- The participating country needs to appoint one individual as country team coordinator and also appoint representatives for relevant levels, e.g., national/regional/hospital levels
- The national level will select one or two hospitals that has designated professionals for infection control
  The hospital management supports the project and is willing to actively support nation-wide
  implementation

#### Task 6.2.2: Promote that similar working routines are implemented in non-EU countries in Europe

Leader: FOHM; Contributors: FPS HFCSE; NIPH; TA; HCDCP; PSKUS; LSMULKK; VULSK; NVSC; HI; VWS; NIJZ; SoS; UAS / Start date: M1 End date: M36

**Task description:** the aim of the task is to engage European countries, other than MS, Norway and Iceland by involving existing and well established networks of professionals. The goal is to promote that the same guidelines and methods are implemented throughout Europe. An implicit part of the chosen method is capacity-building, where the participating organisations may be strengthened through education, by independently adapting published guidelines and by practical improvement work.

The working model will be that participants in task 6.2.2 work closely and follow the model and participate in chosen activities – with MS partners in task 6.2.1 to safeguard a wider spread and transfer of knowledge. Some of the countries in task 6.2.2 can share their experiences with implementing the model and continue to carry

out their own implementation efforts.

Associated with document Ref. Ares(2017)4194538 - 28/08/2017

One example of a network is the Baltic Antibiotic Resistance collaborative Network (BARN), which is a grass root network for action against antibiotic resistance, with a focus on raising awareness and exchanging knowledge and experience among practitioners on effective interventions in health-care settings. The network has three focus areas: Infection prevention and control; antibiotic stewardship and laboratory diagnosis and surveillance of resistant bacteria.

The network has active members in Belarus, Estonia, Georgia, Latvia, Lithuania, Moldova, Poland, Russia, Sweden and Ukraine. It is a true multidisciplinary network: health-care personnel on all levels, microbiologists, infection control specialists, pharmacists, governmental workers and more.

Other relevant networks should also be engaged in this task, depending on which partner organisations will participate in Task 6.2.1. (both as full and light track participant).

Work package	WP7		Start date	or starting e	event			M1
number	VVP7		End date					M36
Work package title	Appropria <sup>-</sup>	te use of ar	timicrobial	s in human	and anima	ls		
Leading participant	FHI & AEM	IPS						
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8
Participant short name	INSERM	Moh	GOG	FPS HFCSE	NCIPD	CIPH HZJZ	NIPH	SSI
Person-months per participant	0	0	5,3	2,5	11	10,7	5,3	12
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS
Person-months per participant	5	5,9	12	38	0	6	11	0
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	ні	NVSC	vws	HdiR	FHI	NVI
Person-months per participant	7	0	9	2,7	2	3,8	33,2	6
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS
Person-months per participant	6	5	4,5	0	18	12	8,4	4,8
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	5	17,1	0	28	2	0	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES		тс	OTAL	
Person-months per participant	0	0	0	33		32	6.20	
Objectives								

The major objective of this WP is to collate and organise into a useable database the current guidelines for antibiotic stewardship at all levels of the European health system and selected animal (food and companion) species, and to establish workable tools for evaluating the implementation of antibiotic stewardship in all EU member states.

The specific objectives of this WP are to:

- 1. Identify and review existing guidelines, tools (including quality indicators) and importantly, implementation methods in the human sector (by level-of-care, hospital, long-term care facility and community setting) and the animal sector (diseased food and companion animals) and to summarize available information on the ECDC website
- 2. To use the results of objective 1 to guide a workshop with all the interested partners looking at barriers, opportunities and successful strategies for implementation at the three levels of care and the animal sector in order to evaluate possible options for the implementation of the work.
- 3. To report the level of implementation and level of acceptance of antibiotic stewardship strategies at different levels of care, in food and companion animals in different countries, including both indicators for consumption of antibiotics by humans and animals.
- 4. To design and run pilot projects looking at effective implementation (as defined by the previous two activities) of antibiotic stewardship by introducing a simple surveillance system of antibiotic consumption and resistance, including feedback mechanisms for a shorter time-lag than present alternatives. This would be done in parallel projects in settings with differing resources in human and animals and focusing on different levels of care. We envisage a high degree of synergy between WP7 and WP6 and suggest close cooperation between the two packages.

#### Description of work, role of the participants and interactions

Task 7.1: Identify and review existing guidelines, tools and importantly, implementation methods for antibiotic stewardship by level-of-care (hospital, long-term care facility and community setting) and in food and companion animals and to summarize available information on the ECDC website

**Leader:** FHI ; **Contributors**: HDir; AEMPS; DG de Planificación, Evaluación y Farmacia.- Consejería Salud Comunidad Autónoma Illes Balears; NMI; UNIFG; VWS; SSI; UMPIH; RKI; GOG; ISS; ANSES; CIPH HZJZ; LSMULKK; NVSC / **Start date:**M2 **End date:**M11

Collaborating with: ECDC dept. for antimicrobial resistance and Healthcare Associated Infections and OIE. ECDC would be asked to host the information made available through this project on their website.

#### Task description:

- Review material from ECDC, EFSA and EMA and other actors such as OIE, FAO, WHO, GHSA, website, other
  initiatives such as the ARNA project, the OECD report, the STRAMA network, and published literature
- Questionnaire to member states on current, past and proposed activities including receiving copies of tools
  and guidelines with weight given to the level of implementation of antibiotic stewardship plans, reason for
  choice of tool/guideline and implementation plan, "partners" in charge of work, success stories and the
  barriers that have hindered implementation of this work. This will expand on work already conducted by the

The aim will be to update and expand the information available on the ECDC website to include information on existing guidelines, implementation methodology and work at different levels of the healthcare system. This will include strategies aimed at different settings and the existence of national or local indicators (including structural, process and outcome indicators of quality).

#### Task 7.2. Workshop involving all the registered partners to discuss models of implementation

Leader: FHI; Contributors: Hdir; AEMPS; GOG; NMI; NIJZ; VWS; SSI; UMPIH; RKI; GOG; ISS; ANSES; LSMULKK; NVSC / Start date: M11 End Date: M12, EFSA

Collaborating with: ECDC dept. for antimicrobial resistance and Healthcare Associated Infections and OIE: TBC Task description:

Confidential

- Identify experts and organize expert group meetings (virtual and at least one face-to-face) to evaluate findings from task 7.1, identifying key tools and implementation mechanisms (expert group around 10 people) in both the human and animal sectors.
- Organize workshop to share experiences between countries and comment on expert group's findings, with
  a focus on barriers for implementation. Interest from Austria to help organize meeting (workshop about
  40-60 people at end of year 1)
- Discuss suitability to different settings (cultural, epidemiological and financial)

Task 7.3 Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals, in different country settings. This will focus on identifying and establishing success factors and barriers.

Leader: FHI; Contributors: HDir; SAS; FFIS; GENCAT; SERMAS; Illes Balears; NMI; FOHM; UNIFG; NPIH; SSI; UMPIH; RKI; GOG; ISS; ANSES; LSMULKK; NVSC / Start date: M2 End date: M36

#### Task description:

- Follow-up questionnaire to active partners, which will be further disseminated in each member state or region. This will include structured questions and oral interviews. The aim of this activity will be to collate information about attitudes to stewardship methodologies and campaigns in order to determine both factors for success and barriers to acceptance.
- Evaluation and publication of recommendations on core components needed for implementation that can be used by member states when planning their own programs based on the information from tasks 7.1, 7.2 and 7.4.
- We will deliver a report on which indicators of antibiotic use and resistance are available in each country in human (for each level of care) and animals (including for animal husbandry).

### Task 7.4.1 Develop and test near real time surveillance of antimicrobials and multidrug resistant bacteria Task description:

Current surveillance networks are informative and concise. However, there is a long delay in the data reported and some countries do not have data. Therefore, there is a need for reinforcing current surveillance systems. Surveillance networks need to be adapted to work in conjunction to provide a simple surveillance system of antibiotic use and resistance. This subject is essential to guide the fight against the antimicrobial resistance (AMR) and to improve the results by means of feedback and benchmarking. In addition, this system must work and data must be available in a shorter time-lag than present alternatives.

Subtask 7.4.1. Surveillance in human medicines - consumption of antimicrobials and AMR

Leader: SAS; Contributors: AEMPS; FFIS; GENCAT; SERMAS; Illes Balers; FMS; FHI; UMPIH; NMI; FPS HFCSE; UNIFG; ESDY-NSPH; NIPH; SSI; RKI; GOG; ISS; NVSC; LSMULKK / Start date: M2 End date: M36

- Select basic indicators for surveillance system of antimicrobial consumption: : DDD/1000 stays (in hospital settings) or inhabitants (in primary care settings) of:
  - -. Overall antimicrobial drugs consumption
  - -. Carbapenems, piperacillin-tazobactam, amoxicillin-clavulanate, aminoglycosides, quinolones, 3rd and 4th gen cephalosporins, vancomycin and colistin (in hospitals)
  - -. Amoxicillin-clavulanate, 3rd gen cephalosporins, quinolones and macrolides (in primary care)
- Select basic indicators for surveillance system of antimicrobial resistance: Number of isolates in clinical samples per patient/1000 stays (in hospital) or inhabitants (primary care) of of the following pathogens:
  - -. Carbapenemase-Producing Enterobacteriaceae, ESBL *E. coli*, ESBL K. *pneumoniae*, MDR *A. baumannii*, MDR *P. aeruginosa* and methicillin-resistant *S. aureus* (MRSA), ), vancomycin resistant enterococci (*E. faecalis* and *E. faecium*) in hospital settings.
  - -. Carbapenemase-Producing Enterobacteriaceae, ESBL *E. coli*, ESBL *K. pneumoniae*, methicillin-resistant *S. aureus* (MRSA), in primary care area.
- Reinforce already existing local surveillance systems in order to have the available data as soon as possible.
- Select pilot sites that will represent the three levels of healthcare named above and to cover countries with different resources available including regular meetings, follow-up and support.
- Frequency: quarterly. Data managers will have a two-month period after the end of each trimester to upload data onto the website software.

- Collaborations with existing networks. Potential commections with EARS-net and ESAC: the project leader will have periodical meetings with with ECDC networks EARS and ESAC to share the project status and outcomes, so that it could be of interest for future collaborations.
- Quality of data: Indicators definitions and data management will be explained carefully in guidelines. A website with data management software will be developed specifically. Data will be entered by each participating hospital/primary care area/region/country in the form of numbers (two figures per each indicator). The accuracy of data will be under each national coordinator's responsibility.
  - Regional data could be cumulative (sum of hospitals data / primary care areas data) or directly entered specifically by a designated responsible person.

Country data could be cumulative (sum of regional data) or directly entered specifically by a designated responsible person.

Calculations will be carried out by the software to minimize human error. Prior to validate entered data, a technician will supervise them quarterly in order to find out any possible outliers and take the measures to correct them. Besides, the task leader will carry out random audits to any participating country.

#### Subtask 7.4.2. Surveillance of AMR in animals

Leader: ANSES and ISS; Contributors: NVI, ESDY, SSI, AEMPS / Start date: M2 End date: M36

AMR surveillance in animals will be conducted to evaluate the correlation between AMR spread in humans and animals. Thus, antimicrobial-resistant bacteria that will be surveyed will be mainly the same in a One Health strategy. Numerous issues in the veterinary sector have already been covered by EU and/or MS initiatives sustained by scientific advice from EFSA. It is particularly the case for AMR surveillance under EC directives in healthy food animals and antibiotic consumption under ESVAC. On the contrary, the project will fill the gaps by focusing on the uncovered domain of AMR surveillance in diseased animals in the EU. Thus, the objectives will be to:

- Assess the surveillance systems in place on AMR in animal pathogens in MS
- Identify the main gaps and appropriate strategies for AMR surveillance in diseased animals in Europe depending on MS specificities towards their diversity in animal species and diseases
- Select appropriate AMR indicators in diseased animals in coherence with human ones, including carbapenemase-producing Enterobacteriaceae, ESBL E. coli, ESBL K. pneumoniae, MDR P. aeruginosa, MDR A. baumannii, methicillin-resistant S. aureus (MRSA), methicillin-resistant S. pseudintermedius (MRSP), colistin-resistant Enterobacteriaceae, vancomycin resistant enterococci (E. faecalis and E. faecium). The choice of these indicators will allow to correlate the animal data with the human data from subtask 7.4.1
- Identify laboratory and technical capacities in MS for potential establishment of a molecular-based AMR national surveillance of relevant resistant pathogens, to be further compared with human counterparts
- Assess the opportunities to combine MS surveillance systems into a pilot EU network for the surveillance
  of AMR in clinical animal isolates, covering prioritized animal species and relevant pathogens, based on
  existing networks in place at national levels (RESAPATH, VetPath, ...), and including common reporting
  and communication issues
- Draw guidelines for uploading, validation and management of the data, with particular emphasis on accuracy and types of the data (per animal species, pathogen and disease) under each national coordinator's responsibility.
- Provide global and specific recommendations to EU to build a European network covering AMR surveillance in diseased animals, including interface with AMR surveillance in human medicine

Work package	WP8		Start da	te or startii	ng event			M1	
number	VVFO		<b>End dat</b>	End date					
Work package title	Awarenes	s raising an	d Commun	ication					
Leading participant	AEMPS								
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8	
Participant short name	INSERM	Moh	GOG	FCS	NCIPD	CIPH HZJZ	NIPH	SSI	
Person-months per	7,5	1	0	0	0	0,5	0,5	0,5	

participant				O Ass	ociated with o	ocument Ref.	Ares(2017)41	94538 - 28/08
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS
Person-months per participant	5	0,5	1	1	0	1,9	0	0
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	ні	NVSC	vws	HdiR	FHI	NVI
Person-months per participant	0,5	0	0,5	2,5	2	0,1	0	0
Participant nr.	PL-25	PT-26	RO-27	SI-38	SP-29	SP-30	SP-31	SP-32
Participant short name	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS
Person-months per participant	0	2,5	0	3,5	49	4	03,1	1
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	FOHM	SoS	SBA	NFA
Person-months per participant	0,5	0	0,4	3	0	0	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES		то	TAL	
Person-months per participant	0	0	0	0	91.6			

#### **Objectives**

Despite the European Commission and the Member States having developed and implemented strategies and action plans at national level to control the development of antimicrobial resistance, figures show that efforts should continue to keep on fighting against the development and propagation of antimicrobial resistance.

The main objective of this WP is increasing Awareness and optimizing Communication strategies on antibiotic use and AMR and prevention of Healthcare associated infections with the aim of promoting the responsible use of these medicines and encouraging best practices among the general public and healthcare professionals and through dialogue with young population and mass media.

The specific objectives of this WP are to:

- 1. Define best practices on Communication and Awareness: state-of-the-art as a guide for new or updated communication strategies.
- 2. Reach different targets using different strategies: Develop a Communication and Awareness Plan that will address these targets.
- 3. Use the website developed by WP2 as a key tool for promoting communication and interacting with social networks and traditional media to guarantee reaching the general public, specific groups of society and professionals subgroups. This website will work as a unifying platform that will collect all the contents created within the project, so it is a tool to ensure both, correct dissemination on high quality information on JA deliverables and awareness raising on AMR and HCAI issues. As for these contents, they will all be designed according to the different targets and properly updated as the project moves forward.
- 4. Support coordination about World Week and the European Day of Appropriate Use of Antibiotics. Establish dialogue with other initiatives and actors related to antibiotic use and antimicrobial resistance.

#### Description of work, role of the participants and interactions

#### **WP Methodology**

The following tasks have been designed and planned in order to promote the responsible use of antibiotics by highlighting the importance of appropriate prescribing and use as well as informing about the risks associated

with overuse and misuse of these medicines. Thus, this WP is intended to change minds and behaviors regarding antibiotics use and the threat of increasing AMR and HCAI.

WP8 strategy will be designed and carried out by a team that will consist of health communication specialists with relevant professional experience within this field. Communication between the Communication Officer in charge of WP8 and each country's contact person will be carried out via email on a monthly basis or more frequently if it is needed or via TLC depending on the project's dynamics. These active partners will maintain dialogue with its country's contact person for informing about relevant events, news, and other material related to awareness and communication.

#### **Task descriptions**

Task 8.1: Data Collection to define best practices in Awareness and Communication Plans Leader: AEMPS; Contributors: TA and all WP8 participating partners / Start date: M1 End date: M12 8.1.1.

- Data collection on previous strategies, activities and materials targeting professionals in the fields of public
  health, animal health and the environment (one health approach), the general public and other specific
  population groups such as youth, medical students, caretakers or elderly. The objective is to collect and
  analyze all these materials to avoid efforts duplication, share good practices and offer ideas to MSs for
  building further new awareness and communication plans.
- The analysis of the mentioned materials will help to implement new awareness and communication plans to reach the following objectives:
  - Increase awareness on the importance and consequences of the inappropriate use of antibiotics in human and animal sector.
  - o Optimize Compliance with treatment regimens of prescribed antibiotics.
  - o Avoid the use of antibiotics when they are not indicated.
  - o Avoid the storage and consumption of leftover antibiotics (self-medication).
  - Strengthen the position of professionals in public and animal health, to make them feel less pressured to prescribe and dispense antibiotics.
  - Encourage Health professionals to undertake Continuing Professional Development activities (i.e elearning, webinars, live educational events)
- Selection of some efficient and innovative communication strategies and activities that have been
  performed in previous years, regardless their relation to antibiotic use. Search for some relevant and
  successful cases to take advantage of them.
- Analyze and evaluate previous awareness and communication materials and/or strategies.
- Prepare a report about Communication Good Practices as a guide or reference tool when designing new strategies.

#### 8.1.2.

Analyze the use of the theme "antibiotic" in social networks and Internet. A pilot study will be conducted to analyze how the theme "antibiotic" is approached by the society in the social networks. Different periods of time in each year will be targeted to identify the key themes arising in relation to antibiotics (ie. April, October and January). A web-based tool will be used to detect daily occurrences of the word 'antibiotic' and other related terms during the chosen time period in Tweets. How the society dialogue about antibiotics as well as activity peaks (message frequency over three times that of baseline) will be analyzed to identify key issues and events that need to be considered in future awareness and communication campaigns. In that way, findings could determine the best period for launching campaigns in addition to negative attitudes or perceptions that should be considered to better address overuse and misuse. For the data collection, staff members will retrospectively analyze the selected periods.

#### 8.1.3.

Identify some efficient and innovative educational strategies and activities performed in Europe focusing on prudent use of antibiotic in both High School and Universities.

A content analysis of teaching materials will be conducted to explore and identify innovative strategies and activities performed in the secondary high schools and universities. The project will organize strategies to share these activities and motivate all MSs to implement them, for example, by promoting the use of the e-bug platform, and its adaptation, or other similar initiatives.

Task 8.2: Design and Implementation of Awareness and Communication Plan

Leader: AEMPS; Contributors: VWS and all WP8 participating partners / Start date:M1 End date:M8

**Task description:** To design Awareness and Communication strategies targeting governments and stakeholders. **8.2.1.** Prepare the Awareness and Communication Plan

- Definition of the objectives and identification of the relevant target audiences. Both WP8 and WP2 share
  target audiences (general media and health-specialized journalists, general public -specially considering
  caretakers for elderly and children-, healthcare professionals in both human and animal health, medical and
  veterinary students, human and animal health industries, key decision makers) but differ in goals since WP8
  is intended to change minds and behaviors toward antibiotics by raising awareness of the dangers of AMR
  whereas WP2 is intended to disseminate outcomes and deliverables produced by the JA that could lead to
  this change.
- Definition of basic key messages to be communicated to the general public, health professionals and specific target audiences, along the same lines as ECDC's messages through the activities included within WP8.
   Messages targeted at general public:
  - Antibiotic misuse and overuse creates antibiotic-resistant germs that could lead us to a scenario where antibiotics no longer work.
  - Antibiotics are effective only against bacterial infections. Taking them for wrong reasons, such as against colds or flue, has no benefit for you.
  - Antibiotics often give you side effects such as diarrhea. Always seek your doctor's advice before taking them.

Messages targeted at health professionals (physicians and veterinarians, pharmacists, nurses, specialist nurses, ...):

- Antibiotic resistance is an increasingly serious public health problem all over the world.
- While the number of infections due to antibiotic-resistant bacteria is growing, the pipeline of new antibiotics is unpromising, thus presenting a bleak outlook on availability of effective antibiotic treatment in the future.
- Unnecessary antibiotic prescribing could boost the emergence and selection of antibiotic-resistant bacteria.

More specific messages targeted at more specific audiences according to each country will be designed as the project moves forward, as well as the tools and the schedule to better spread them.

- Description of the issues to be tackled and identification of good practices and specific tools to be used or developed in order to support effective actions.
- **8.2.2**. Implementation of some of the following proposed activities. Depending on budget, some pilot activities could be carried out in some countries or could be removed, if necessary. First working meetings will clarify each participant contribution so this schedule can be set up:
- Database design including European Science and Health Communication researchers. Organize 1 European webinar/year during the 2<sup>nd</sup> and 3<sup>rd</sup> years (mass media, other communicators, etc). Trying to generate a starting point for a network of communicators about increasing antibiotic use and antimicrobial resistance.
- Carry out 1 or 2conferences (similar to TED Conferences; maybe a pilot activity in some countries) in the second-third years of the JA, one with scientific communicators, and another conference with High School and university students as speakers. The conference with students will be organized with the aim of encouraging them to improve their public speaking skills as well as spreading our key messages among youth. Each country will determine criteria and rules for speakers' selection. For instance, invitations to participate in this programme could be sent to the regional or local authorities or to largest high schools in each region or the top-rated medical schools. A jury will select the best talk in each region and those students will take part of a national competition. Each country winner will eventually compete in a final contest that will take place in Brussels or in a Spanish city.
- High Level Awareness and Communication Meeting (included as activity developed in task 8.4): One High
  Level European Meeting in the last year focusing on governments (relevant institutional organizations at the
  regional (e.g. Health Authorities), national (MoH)) and stakeholder's (Industry) awareness with the
  attendance of international organizations (e.g. EIP, DG SANCO, OECD, WHO, JPI AMR, etc.). This High Level
  European Meeting could be organized within the context of the ECDC's European Antibiotic Awareness Day

at the European Parliament or in a Spanish city chosen to nost it. As speakers we might invite scientific and healthcare professional communicators or maybe some JA representatives (WPleaders). Organized as a workshop aimed to communicate the risks of misusing antibiotics and the need for commitment to fight AMR coming from different stakeholders. Thus, topics included will focus on highlighting the danger of not facing this problem from several perspectives (political, scientific and economical) in order to change different behaviors. This meeting is intended to set up a conclusion document that could work as a road map/call action be signed (supported) by different stakeholders to http://www.who.int/globalchange/global-campaign/call-for-action/en/). In any case, specific details will be decided by participants involved in WP8 at this work package's kick-off meeting.

• Training webinars on AMR lead by physicians and veterinarians that will be targeted at general media and health-specialized journalists. One purpose of these webinars is to provide clear and accurate scientific information about this problem so journalists are able to correctly inform the audience about AMR consequences. Furthermore, physicians and veterinarians will be asked to undertake Continuing Professional Development (CPD) activities on AMR. National accreditation authorities will be asked to require their doctors to do that. All of these activities will be carried out in close collaboration with different work packages involving interactions with physicians and veterinarians, so webinars and CPD activities' materials will be designed according to achievements that are being made.

# Task 8.3: Tools for Awareness and Communication (probable interaction with WP2) Leader: AEMPS; Contributors: UNIFG and all WP8 participating partners / Start date:M1 End date:36 Task description:

- Use of the web platform for promoting awareness and communication campaigns/materials or events carried out by WP8. The exclusive use of English would undermine effective communication and devalue the funding efforts made by all partners. Thus, our proposal would consider different versions in English, French and Spanish, as well as partial translations (i.e. objectives, news or blogs) to each MS language.
- Creation and implementation of a (or some) relevant blog(s) and performing an active search for contents
  within the website: news, podcast, reports, scientific papers, interviews, and general information about
  antimicrobial resistance. As previously mentioned, each active country should have one contact person for
  communication activities. All Work Packages leaders will notify any event, communications, news related to
  Awareness and Communication produced during WP development.
- Social media promotion:
  - Create profiles in Facebook, Twitter and Youtube, and make sure to update the content of these profiles on a regular basis (daily and weekly updating). Contents will spread initiatives related to our goals that are being carried out all over Europe and will also consider the organization of Twitter chats with healthcare professionals and contests that will boost engagement (e.g. online quizzes or sharing experiences related to the use of antibiotics).
  - Carry out 3 social media promotion actions per year in the 2<sup>nd</sup> and 3<sup>rd</sup> years to attract internet traffic to the website (at European level) for example by JA-blog Promotion (promote communication and awareness materials) in the social media. Paid media in Facebook or Twitter will create more exposure and will drive searchers to our website, to help increase not just traffic but also conversations. Thus, tools such as advertising or collaboration with influencers will impact the reach of our key messages.
  - Use of a social networks analysis tool to measure the impact of the promotion actions and to get a
    deeper knowledge of the flow of information based on complex networks techniques and the topology
    of the network (Analytics, online reputation, etc).

#### Awards

- Award for the best European article or best video about antibiotic use. This award will be granted to the
  journalist whose article/video presents the clearest, informative and scientifically-based piece of work.
  Articles/videos to be considered will be chosen from the most read newspapers and top television news
  services.
- O Award for a European competition with University students (High School students should be also considered if it does not provoke legal difficulties in audio-visuals activities related to the use of underage images) presenting a video work about antibiotic use and increasing AMR. The competition "Eurovision Antibiotic Contest" will grant the most creative piece of work (a music video, a short film, a monologue, using their own language) explaining how we should use antibiotics and how we actually use them. Just like in "Eurovision Song Contest" each country will select a winner that will compete in a

final contest. The winner will get a study-abroad grant. The organization of this contest could work as an inter-university competition leaded by selected professors within each university (e.g. <a href="https://www.consumerclassroom.eu/consumer-classroom-inter-school-competition-2016-2017">https://www.consumerclassroom.eu/consumer-classroom-inter-school-competition-2016-2017</a>). This competition will permit future sustainability of this type of health competition and working closely with CHAFEA could also be the opportunity to implement later a "Health classroom" within their "consumer classroom".

- This social campaign will be designed in order to address general public and healthcare professionals in both human and animal health, according to the One Health approach. Audiovisual materials will be created to be posted at social networks profiles and leaflets/posters will be distributed among hospitals and medical centers and in professional congress. Cited examples in the Luxembourg meeting were: use Term antibiotic in the box. Cooperation with the industry. Or TV France example "antibiotic is not automatic anymore" or "proper prescribing", Maybe use an ethical message about a good prescription.
- Interview management with key national spokesperson in the top general and health-specialized media.
   Each partner should contact the most relevant national media to offer an interview with the selected national spokesperson, who will highlight the project's key messages during the interview. National spokesperson should be selected according to their authority, expertise, communication skills and interview background.

## Task 8.4: Support coordination about World Week and the European Day of Appropriate Use of Antibiotics. Establish dialogue with other initiatives and actors.

**Leader:** AEMPS; **Contributors:** NIJZ and all WP8 participating partners / **Start date:**M1 **End date:**36 **Task description:** 

- Following ECDC's line of work, meetings with AMR JPI, IMI JU consortium working on antibiotics, WHO/Europe and other initiatives will be held in order to share ideas and jointly collaborate in campaigns.
- Meetings with National Action Plan Coordinators to share best awareness practices.
- Coordination meetings on European Antibiotic Awareness Day. WP8 Communication team will be able to
  offer any support and help in order to face any need and contribute to implementing any proposed activity.
- High Level Awareness and Communication Meeting (explained previously in subtask 8.2.2.3.)

Work package number	WP9			arting even	t			M1 M36
	Prioritizing and implementing research and innovation for public health needs							
Leading participants	FHI & INSE	FHI & INSERM						
Participant nr.	FR-1	FR-2	AT-3	BE-4	BG-5	HR-6	CZ-7	DK-8
Participant short name	INSERM	Moh	GOG	FPS HFCSE	NCIPD	CIPH HZJZ	NIPH	SSI
Person-months per participant	31	0	0	0	0	0	0	0
Participant nr.	EE-9	DE-10	GR-11	GR-12	GR-13	IT-14	IT-15	LV-16
Participant short name	TA	RKI	HCDCP	ESDY NSPH	7HC	UNIFG	ISS	PSKUS
Person-months per participant	0	0	0	0	1,5	0	3	0
Participant nr.	LT-17	LT-18	LT-19	LT-20	NL-21	NO-22	NO-23	NO-24
Participant short name	LSMULKK	VULSK	ні	NVSC	vws	HdiR	FHI	NVI
Person-months per participant	0	0	0	0	4	0	32,5	1
Participant nr.	PL-25	PT-26	RO-27	SI-28	SP-29	SP-30	SP-31	SP-32
Participant short	NMI	DGS	UMPIH	NIJZ	AEMPS	GENCAT	IdISBa	FFIS

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name				O A	ssociated with	document her	. Ares(2017)41	#4556 - 26/06/i
Person-months per participant	0	0	0	1	0	0	0,6	5
Participant nr.	SP-33	SP-34	SP-35	SP-36	SE-37	SE-38	SE-39	SE-40
Participant short name	FMS	SAS	ISCIII	SERMAS	гонм	SoS	SBA	NFA
Person-months per participant	0	0	0	3,3	0	0	0	0
Participant nr.	SE-41	SE-42	SE-43	FR-44				
Participant short name	SVA	SRC	UAS	ANSES	TOTAL			
Person-months per participant	0	4,6	0	0	82,5			

#### **Objectives**

The main objective of this WP is to contribute to a coordinated European response in regards to prioritizing and assisting in the implementation of research and innovation expected to help achieve public health-related AMR and HCAI goals and objectives. (This WP will <u>not</u> fund any research or innovation projects.) The three specific objectives of this WP each corresponding to a dedicated task are to:

- 1. Work with Member States to ensure that national processes for research and innovation priority-setting are grounded in a broad One Health approach and that both Member State research priorities and knowledge gaps are addressed in the development of the update of the JPIAMR SRA (Strategic Research Agenda.
- 2. Explore and detail European strategies to implement mechanisms to increase innovation and other means to fight against AMR and HCAI
- 3. Contribute to ensuring that evidence-informed public health policies and practices related to combatting AMR and HCAI are implemented

#### Description of work, role of the participants and interactions

Task 9.1: Work with Member States to ensure that national processes for research and innovation prioritysetting are grounded in a broad One Health approach and that both Member State research priorities and knowledge gaps are addressed in the development of the update of the JPIAMR SRA.

Leader: INSERM Main contributors: FHI, SRC; Other contributors: 7HRC; ISS; VWS; NVI; NIJZ; IdISBa, SERMAS / Start date: M1 End date: M36

#### Task description:

The aim of this task is to contribute to a strengthened process for European-wide and internationally acknowledged agreement on research and innovation priorities to meet the public health goals related to AMR and HCAI in a broad One Health approach.

The European Union Member States in 2016 through the Council Conclusions, particularly §22.8, expressed their will to align strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostic, and set priorities based on societal needs in the field of public health, animal health and the environment, taking into account gaps analysis in this domain.

Significant efforts led by JPIAMR in collaboration with the EU and IMI have already been established in regards to AMR research and innovation priority-setting. Its Strategic Research Agenda (SRA) outlines key, neglected areas to tackle, which guides JPIAMR and others to shape cohesive and coordinated AMR funding and research actions to maximise on resources and reduce duplication of research. The SRA is scheduled to be updated in 2017. About half of EU members, but also other countries, participate in JPIAMR.

This process can be expanded upon through the EU-JAMRAI by working directly with Member States in preparation of their participation in priority-setting activities with JPIAMR. Member States need to ensure that their national processes include: (1) a One Health focus including not only the Ministry of Health but also Ministries of Agriculture, Fisheries, and Environment; (2) ensure that the special needs of HCAI are also included; (3) ensure that an appropriate breadth of research fields is considered including social sciences; and (4) consider where research syntheses are needed in order to inform policies. Social sciences are an often forgotten aspect of research priorities but can have major impact on achieving stewardship and infection control goals. Member States should also ensure that their own national research agendas are in line and fill the identified gaps with the priorities set out by JPIAMR and other related initiatives like the international clinical trial networks. Member States not participating in JPIAMR should be encouraged to share their priority research and innovation topics

with JPIAMR. Links to Horizon 2020 will also be evaluated.

Associated with document Ref. Ares(2017)4194538 - 28/08/2017

Member State priority-setting for AMR and HCAI research and innovation in line with public health needs
 Gather national approaches to participation and input into the SRA update to assess best practices and gaps (INSERM, FHI, SRC)

- Work with Member States to provide best practices and routines that can assist them with identifying national research and innovation priorities to be communicated into the SRA process (INSERM, FHI, SRC)
- Provide feedback to JPIAMR and potentially Horizon 2020 and others about perceived gaps and potential
  procedural improvements to SRA update process (INSERM, FHI, SRC in conjunction with WP4
  Implementation)

## Task 9.2: Explore and detail European strategies to implement mechanisms to foster antimicrobial innovation and other means to fight against AMR and HCAI

Leader: FHI Main contributor: INSERM; Other contributors: SRC; 7HRC; ISS; VWS; NVI; NIJZ; IdISBa, SERMAS / Start date: M1 End date: M36

The aim of this task is to act upon recommendations for stimulating greater innovation (including medicines, vaccines, diagnostics, and medical devices – for both human and animal health) to combat AMR and HCAI. Innovation has been acknowledged to be dangerously lacking for the past decades. Yet this is not to say that this type of innovation has been determined to be more impactful than other types of research and innovation. Significant funds have recently been invested in projects, like the UK's AMR Review and IMI's DRIVE-AB, to explore new economic models and strategies to stimulate innovation. It is timely now to react to the results of these initiatives and assist Member States with implementation.

Since the cost of developing some products, like a new antibiotic, may be large, the financing for stimulating innovation is also large, requiring coordination across countries. Other processes, like joint procurement mechanisms, new regulatory classifications, and regulatory harmonization, can also be impactful and require collaboration. UK's AMR Review delivered its final report in May 2016 which included recommendations to stimulate both antibacterial innovation for human and animal use as well as diagnostic innovation. DRIVE-AB will deliver its final recommendations in September 2017.

Assist with EU-wide implementation of incentives to stimulate antimicrobial, diagnostic and other innovations for fighting AMR and HCAI

- Hold a meeting where AMR Review, DRIVE-AB, and other potential actors present their recommendations
  to Member States and non-Member States regarding the need for multi-country collaboration in order to
  stimulate the innovation of antimicrobials (for both human and animal health) as well as diagnostics and
  other innovations, including an opportunity for governments to ask questions and provide feedback (FHI,
  INSERM)
- Perform a gap analysis for any missing incentives with a special focus on how to align and/or differentiate what is needed for AMR on the one side and HCAI on the other (FHI, INSERM)
- Hold follow-up meetings with about ten Member States and 3-5 non-Member States to gather direct feedback on the recommendations and options for implementation; request written feedback from the remaining Member States (FHI, INSERM)
- Develop an implementation strategy aligned with feedback from Member States (FHI, INSERM in conjunction with WP4)
- Request that all Member States formally respond to the implementation strategy with firm commitments (FHI, INSERM)

## Task 9.3: Contribute to ensuring that evidence-informed public health policies and practices related to combatting AMR and HCAI are implemented

Leader: FHI / INSERM; Main contributor: SRC; Other contributors: 7HRC; ISS; VWS; NVI; NIJZ; IdISBa, SERMAS / Start date: M1 End date: M36

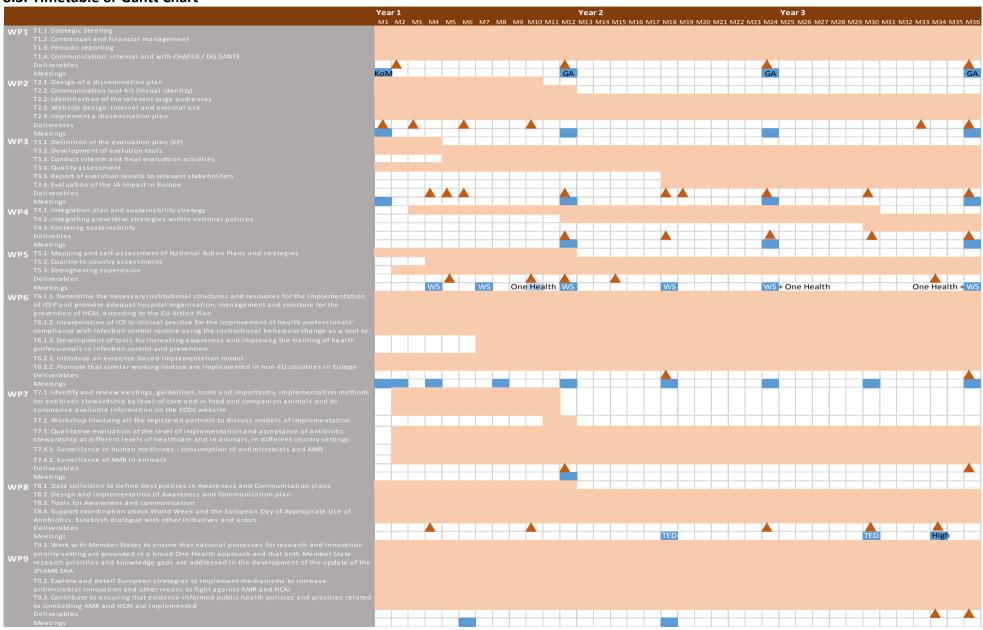
The aim of this task is to ensure that national procedures are in place to translate research findings (including those from the social sciences) into public health policies and practices. Since the quality, certainty, and strength of recommendations can vary for individual studies, it is important to first synthesize the existing evidence through a systematic review where the evidence is graded and then summarize the findings in plain language for policymakers. SURE Policy Briefs are a tested format that can be used to convey evidence to policymakers. This task will require support of and engagement in fora for communication of research findings to public health implementation levels, including the exchange of good practices as a procedure to reinforce implementation. A

particular attention will be paid to establish functional links with WP2, WP4 and WP8 in that regard.

#### Assist with evidence-informed policymaking.

- Evaluate existing tools for evidence-informed policymaking, like policy briefs, and modes of dissemination and sharing, as well as implementation good practices (FHI)
- Recommend national dissemination and sharing strategies for policy briefs or other tools (FHI, SRC)
- Gather feedback on recommendations and update recommendations appropriately (INSERM)
- Request EU to agree to and publish the recommendations (INSERM)

#### 8.3. Timetable or Gantt Chart



#### 9. MILESTONES AND DELIVERABLES

Del N°	Deliverable name	WP N°	Leader acronym	Content specification	Dissemi nation	Delive ry mo.
					leval	
D1.1	Interim reports	1	Inserm	This report describes the activities carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes.	со	M18
D1.2	Final report	1	Inserm	This report describes the project implementation and the results achieved. The deliverables are annexed.	СО	M36
D2.1	Dissemination Plan	2	AEMPS	Report	PU	M10
D2.2	Layman report	2	AEMPS	Report	PU	M33
D2.3	Final Conference on dissemination	2	AEMPS	Conference event agenda and minutes.	PU	M36
D3.1	Evaluation plan	3	ISS	Release of the evaluation plan	СО	M4
D3.2	Validation of the evaluation tools	3	ISS / FFIS	Report on the evaluation tools. All processes reported on a yearly basis.	СО	M12
D3.3	Progress monitoring and quality assessment of JA documentation and deliverables	3	ISS / FFIS	Reports on actions and initiatives to support teams responsible for the release of deliverables and documents. Interim and final evaluation reports based on the EP	со	M12; 24; 36
D3.4	Report on stakeholders evaluation and on JA impact in Europe	3	ISS	Report on the evaluation of the actions and documents released by the different WPs by relevant stakeholders. Report on the impact of actions and documents on MS at national and subnational level	со	36
D 4.1	Integration plan and sustainability Strategy	4	MoH-FR	Report on the implementation plan for integration of key actions into national policies and strategy for sustainability of JA outputs	PU	M30
D 4.2	Report on integration plan	4	MoH-FR	Specific measures for prevention and control of AMR and HCAI to be integrated in national action plans	PU	M30- 36
D 4.3	Report on sustainability plan	4	MoH-FR	Specific measures for prevention and control of AMR and HCAI to be sustained beyond the JA	PU	M36
D 5.1	Tool for country self- assessments	5	VWS	Availability of the tool for the country (self) assessment based on the WHO-tool and adapted to the EU situation (Council Conclusions): summary of the questionnaire.	PU	M06
D 5.2	Summary Country-to-	5	VWS	Performance of the country-to-	PU	M36
D 5.3	Overview enforcement and recommendations to be	5	VWS	country assessments  Report about white spots, shortcomings in the implementation of national	PU	M36

			I		T	I
	presented to the One Health Network			strategies and discuss possible solutions and recommendations and preparation to present to the One Health Network.		
D6.1.1	Revised guidelines for the implementation of infection control program in healthcare settings	6	HCDCP	Report	PU	M13
D6.1.2	Assessment of the cost- benefit for the implementation of an infection control program	6	HCDCP	Report	PU	M36
D6.1.3	An Universal Infection Control framework with specific roles, priorities, resources and interventions for the implementation of an infection control plan in healthcare settings	6	HCDCP	Report	PU	M36
D6.2.1	Report on experience from country teams of introducing and working with the implementation model	6	FOHM	Progress report	PU	M18; M36
D6.2.2.	Experience from non-EU country teams of introducing implementation model	6	FOHM	Report	PU	M36
D7.1	Website with evaluated tools and information	7	FHI	Website hosted by ECDC organised by level of care	PU	M12
D7.2	Report on workshop of models for implementation of stewarship tools (M12)	7	FHI/AEMP S	Report on antibiotic stewardship implementation models	PU	M13
D7.3	Indicators used for monitoring antibiotic use and resistance in humans and animals	7	FHI/AEMP S	Report	PU	M36
D7.4	Surveillance of antimicrobial use and resistance in human	7	SAS	Results of pilot study from indicators selected to monitor antibiotic use and resistance in humans	PU	M36
D7.5	Surveillance of antimicrobial use and resistance in animal	7	ANSES	Feasibility report for surveillance system in animals	PU	M36
D 8.1	Awareness and Communication Plan	8	AEMPS	Report	PU	M10
D 8.2	European Prize: better journalism report or better video about antibiotics	8	AEMPS	Report: list of competitors, agenda of the event, report of the prices and winners, report of the applicants considered and a short brief of their applications.	PU	M27
D 8.3	European competition with High Schools students	8	AEMPS	Report: list of competitors, agenda of the event, report of the winners, report of the applicants considered and a short brief of their applications.	PU	M32
D 8.4	Awareness and Communication High Level Meeting	1-2-8	AEMPS	Report on road map for stakeholders with minutes and videos available	PU	M34

D 9.1	National priority-setting best practices	9	INSERM	Best practices and routines that can be implemented by Member States to improve the input that they send to SRA regarding research and innovation priorities	PU	M34
D 9.2	Implementation strategy for EU collaboration	9	FHI	A concrete strategy for implementing multi-country incentives to stimulate antimicrobial and diagnostic innovation	PU	M36
D 9.3	Dissemination strategies WP4	9	INSERM / FHI	Policy briefs or other tools publicly available	PU	M36

Milestone number	Milestone name	Short name lead participant	Estimated date1
MS1.1	Kick-off meeting	INSERM	M2
MS1.2	The Steering committee and Advisory Boards Forum are set up	INSERM	M2
MS1.3	Organisation of meetings completed (meeting, agenda & preparatory documents)	INSERM	M10, M22
MS2.1	Communication tool-kit	AEMPS	M6
MS2.2	Dissemination Plan: intermediate control point	AEMPS	M7
MS2.3	Layman report: intermediate control point about document design and draft	AEMPS	M30
MS2.4	Final Conference on dissemination: intermediary control point	AEMPS	M30
MS3.1	Agreement on ETs plan	ISS	M 5
MS3.2	Availability of the web platform with tools to support the monitoring	ISS	M 7
MS3.3	Periodic (every six months) check of correspondence between planned activities and timetable	ISS	M 6, 12, 18, 24, 30, 36.
MS3.4	Identification of interested stakeholders	ISS	M 6
MS3.5	Report on quality of the meetings within two months after their conclusion	ISS	M2; 13; 25; 36
MS3.6	Interim evaluation of JA	ISS	M19

MS3.7	Final report on JA impact in Europe	ISS	M 36
MS4.1	Survey of MS priorities	MoH-FR	M12
MS4.2	Workshop with SC members on priority goals and integration of JA key actions into national AMR-HCAI plans	MoH-FR	M24
MS5.1	Presentation, discussion and analysis of the outcome of the self-assessments (workshop)	vws	M10
MS5.2	Workshop on the outcome of the 3 pilot country-to-country assessment and revision of the tool and methods.	VWS	M18
MS5.3	Invitational workshop for the establishment of the network of supervisory bodies	vws	M18
MS6.1.1.a	Results of survey A (national-hospital policy)	HCDCP	M8
MS6.1.1.b	Assessment of cost-benefit study	HCDCP	M12
MS6.1.2.a	Results of survey B (barriers for an effective implementation of an ICP)	HCDCP	M8
MS6.1.2.b	Initial proposed of UICFW	HCDCP	M14
MS6.1.2.c	Evaluation of the UICFW implementation	HCDCP	M32
MS6.1.3	Initial presentation of the training tools	HCDCP	M12
MS6.2.1.a	Participating hospitals and topics selected per country.	FOHM	M12
MS6.2.1.b	Selected IPC-guidelines and plan for implementation for participating hospital(s) in line with national plans.	FOHM	M30
MS6.2.1.c	Implementation work at hospitals established.	FOHM	M36
MS7.1	Progress check of review procedure	FHI	M4
MS7.2	Progress check in terms of website	FHI	M12
MS7.3	Progress check of implementation of stewardship tools	FHI /AEMPS	M24
MS7.4	Progress check surveillance system	AEMPS	M15

MS8.1	Awareness and Communication Plan	AEMPS	M7
MS8.2	Database // European Webinar and of Science and Health Communication researchers (Mass media): control point	AEMPS	M7/14
MS8.3	Design of promotion activities related to better journalism report or better video about antibiotics	AEMPS	M14
MS8.4	European competition with High Schools students: starting // intermediate control point	AEMPS	M12//M24
MS8.5	Awareness and Communication High Level Meeting: starting // intermediate 1 // intermediate 2 control points	AEMPS	M16//M24 //30
MS 9.1	Gathering of national approaches to providing input to SRA from at least five countries	INSERM	M18
MS 9.2	Inter-governmental meeting to discuss DRIVE-AB and AMR Review recommendations with regards to AMR and HCAI	FHI	M6
MS 9.3	Recommendation for dissemination of policy briefs or other tools sent to Member States for review	INSERM	M24

#### 10. PROJECT MANAGEMENT STRUCTURE

**10.1.** Management structure of the Joint Action (A detailed presentation of the management structure in appendix 1)

The management structure of **JA AMR HCAI** has been defined to:

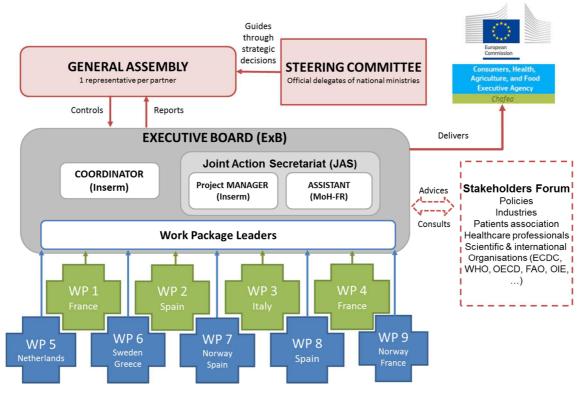
- Plan, organize and monitor the effort to achieve the **JA AMR HCAI**'s objectives within constraints of time schedule and budget.
- Define clearly the decision making procedures and bodies.
- Run performance control procedures leading to the expected quality of achievements and deliverables described in the work plan.
- Continually inform the partners on the project status and progress.
- Drive the project implementation in accordance with administrative, financial and legal issues defined by the European regulations and national peculiarities.
- Guarantee that the rights and obligations of the partners are kept compliant with the Grant Agreement signed with the Commission and the Consortium Agreement.

A <u>consortium agreement</u> will be signed between the partners to specify the project governance, the internal organization of the consortium, the management of the project and any other critical aspects such as liability and confidentiality.

The organisational structure of the consortium will be as follow:

- The Coordinator Marie-Cécile Ploy (INSERM) will monitor the compliance by the partners with their obligations under the Grant Agreement.
- Work package Leaders will be in charge of managing their Work Package resources and planning. They will form together the Executive Board (ExB) that provides assistance to the Coordinator for the monitoring of the action.
- The Joint Action Secretariat (JAS) will assist with the administrative and financial management of the action.
- The General Assembly (GA) will be responsible for the execution of the JA and will take major decisions with regards to its implementation.
- The Steering Committee (SC) will provide strategic guidance to the GA and the ExB and ensure adequacy between the JA activities and National Strategies.

To ensure engagement with relevant stakeholders, a **Stakeholders Forum** will be set up that will receive periodic update from the ExB on the Joint Action developments, as well as provide recommendations to the GA.



#### 10.2. Quality of the partnership

All the participants of the JA AMR HCAI have been nominated by the respective MS for their involvement in the field of AMR and/or HCAI and their capacity to run the activities foreseen in this joint action. The partners are not only from Ministries but also research institutes (such as INSERM), Clinical centres, Public Health agencies, Universities or else. This JA will cover all the national specificities of AMR and HCAI as it gathers all EU countries as beneficiaries or collaborating partners. Moreover, most of the participants have already successfully collaborated in former or ongoing projects around AMR and HCAI proving the excellence of the Consortium: MoH-FR and INSERM are involved in the national taskforce on AMR, INSERM is part of JPI AMR and IMI committees, In addition, several partners are involved in ongoing projects and actions related to the JA major themes. For example, Norway is cocoordinating the IMI funded DRIVE-AB project to define new approaches for research and development of antimicrobials; Sweden is currently leading the JPI-AMR board. Finally, some partners (French MoH, Austrian MoH, ...) already cooperate within the Health Security Committee (HSC), one priority of which is antimicrobial resistance.

#### 10.3. Capacity of the staff

#### 1. Coordinator: France - INSERM

The coordination institution is the French National Institute of Health and Medical Research (INSERM), founded in 1964, is a public scientific and technological institute which operates under the joint authority of the French Ministry of Health and French Ministry of Research

Research at Inserm covers all fields of health research, from basic research to applied research. It is central to the French health care and public health systems. Today, Inserm coordinates more than 300 research structures (research units, centres of clinical investigation (CIC)) throughout France and its overseas departments. Amongst the 13,000 researchers, engineers, technicians and administrative staff working in Inserm laboratories, 5,000 are permanent employees, more than 2,700 have contractual positions and almost 4,500 have positions in universities, teaching hospitals or other research organizations. As for results, Inserm is the leading health research institution in Europe in terms of publications, patent filings and participation in European research programs. Inserm is ranked 2nd amongst health research institutes in the world in publications (roughly 10,000) following the American NIH (National Institutes of Health). In addition, Inserm and Inserm Transfert are world leaders in innovation in the fields of life science and human health with good practice and results in terms of technology transfer. In the European

Patents Office's 2014 listings, Inserm ranks sixth overall among French patent submitters (all sectors). At national level, INSERM plays a key leadership role in the structuration as it pertains to ensuring greater alignment and cohesion between health research organizations and funding bodies, to ensure greater uptake and impact of France's investments in the health field.

In line with the evolution of antimicrobial resistance in the world, Inserm Institute has encouraged its fundamental and translational research teams to accelerate research innovation to implement prevention, diagnostic, research and innovation in the aim to fight AMR and HCAI. Beside, Inserm has organized meetings to favour the combination of synergistic scientific competences that are an essential factor to stimulate new strategies and perspectives to fight drug resistance in all its forms. Finally, Inserm has significantly contributed to the elaboration of the French national plan entitled "Propositions pour une politique de recherche et d'innovation dédiée à la lutte contre la résistance bactérienne aux antibiotiques ». This plan tackles the burden of antimicrobial resistance by identification of gaps and an effective proposal of major research and societal challenges in a "One Health" approach, with the following needs and priorities: improve the understanding of the mechanisms of resistance and transmission, accelerate the drug discovery, develop efficient diagnostics tools, reinforce information and education for a better use of antibiotics in human and animals and create a comprehensive network of surveillance system. Globally, the french national plan and the great expertise of Inserm to head interdisciplinarity program in the field of the health at national and European level are a roadbed to intend the JA AMR-HCAI actions.

The coordinator: Professor Marie-Cécile Ploy, PharmD, PhD, will coordinate the JA on AMR and HCAI scientific program. She is a medical microbiologist and head of the clinical microbiology department and infection control team in the Limoges teaching hospital in France. She also heads an Inserm research team on antimicrobial resistance. Her main research focuses on genetic elements involved in antimicrobial resistance dissemination and on biomarkers for early diagnostic of infections and AMR in Intensive Care. She works at the borders of AMR with a One Health approach. Indeed, she is involved in European/H2020 programs on antimicrobial resistance both in the environment (PILLS and no PILLS programs, Marie Curie) and in clinics through academic or industrial research programs, including IMI COMBACTE. In 2015, she was nominated by Inserm to co-lead the research and innovation group for the French taskforce on AMR. She was the vice-deputy of the Inserm Scientific Committee microbiologyimmunology (2013-2016). She is member of the Inserm institute "Immunology, inflammation, infectiology and microbiology", of the French committee for antibiogram and vice-deputy of the antimicrobials section of the French Society for Microbiology. She is also the coordinator of the French network on the surveillance of resistance and serotypes of Streptococcus pneumoniae (Observatoires Régionaux du Pneumocoque). She is expert for different national and international research programs (French expert for the 1st JPI AMR call on therapeutic innovations and member of the advisory board to elaborate the JPI AMR transmission call). She is the author of 111 peer-reviewed manuscripts in international journals.

### Key staff involved in parallel to the coordinator

Professor Antoine Andremont - M.D., Ph. D. is amongst the leading international experts in the field focused on the consequences of antimicrobial therapies on the evolution of bacterial resistance and on the occurrence of nosocomial infections. He is the author of over 140 international publications and has filed 5 patents dealing with mechanisms of resistance. He is also part of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and the EU Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) as an expert and a scientific advisor. Evelyne Jouvin Marche- Ph. D, director of research at Inserm, has developed a translational research focused on the role of the immune cells of the liver in patients infected with hepatitis virus and provided the root of two patents currently licensed to two companies. She is author of over 135 international publications and is a partner in European H2020-NMBP project. She is member of "Pôle Chimie, Biologie, Santé" at University Grenoble Alpes and director of fundation Finovi which supports research in respiratory diseases and nosocomial infections. At national level, she is deputy director of the thematic multi-organization institutes "Immunology, inflammation, infectiology and microbiology" which covers in particular, the emergence of new epidemics/pandemics and the evolution of antimicrobial resistance. Professor Jean-François Delfraissy - MD, PhD, is currently Director of the Institute of Immunology, Inflammation, Infectious Diseases and Microbiology (I3M) at Inserm/Aviesan. This institute brings together research teams working on immunology, inflammation, infectiology and microbiology. Its challenges are both cognitive and medical. The purpose is to develop multidisciplinary research combining the clinical approach, microbiology, genomics, molecular and human epidemiology,

entomology, mathematics and sociology across a broad range of diseases affecting both animals and humans that can interact in complex ways with ecosystems and social and medical practices. Pr Delfraissy is deeply involved in research in a range of programmes and therapeutic trials. Olivier Barraud- PharmD, PhD is clinical microbiologists working with the coordinator and involved in IMI programmes on AMR and HCAI. He develops a translational research on multidrug resistant bacteria and more specifically on their early diagnostic in critical care patients. Elodie Pfender – Pharm D, is project manager at the Limoges hospital, France. She is involved in the financial coordination of European IMI projects. She will guide the project manager who will be hired in WP1.

#### 2 France - MoH

**Participant's institution:** The Ministry of Health (MoH) is responsible for ensuring that the population's health is assured and protected. Within the MoH, the Directorate General for Health is responsible for the elaboration of Public Health policies. It elaborates national plans and monitors their implementation together with other competent bodies (i.e the National public health agencies, Regional health agencies), including the national plans on antibiotics (since 2001) and for prevention of healthcare associated infections.

Key staff: Prof. Christian Brun-Buisson is a medical doctor trained in Intensive Care. He has been appointed in February 2016 by Minister Touraine as Ministerial delegate on AMR to coordinate the action of key actors in the field of AMR. He has a long-standing experience in HCAI and antimicrobial resistance and has been involved in various European (FP6-FP7) and international projects. Dr Jean-Michel Azanowsky is medical doctor specialist in Public Health. He is responsible for the national action plan on antibiotics, its steering committee, and monitors its implementation since the first plan. He has excellent knowledge of the national AMR policy, its strengths and weaknesses. M. Jean-Baptiste Rouffet is Policy Advisor on European Affairs. Based on his solid experience of Joint Actions, he initiated the idea of France coordinating the Joint Action to share its experience and benefit from European cooperation. He is the French representative to the Health Programme Committee and contributed to a concept paper on AMR detailing the French views in this regard.

## 3 Austria – GÖG

Participant's institution: The Austrian Public Health Institute Gesundheit Österreich GmbH has one shareholder: the Austrian Federal Government, represented by the Federal Minister of Health and Women's Affairs. One of the core assets of GÖG is, due to its nature as a think-tank for health care topics, its strong network with both academic research institutions and public bodies. This is reflected by the fact that GÖG managed and has been managing several EU projects, some of them with participation from all Member States. We are involved in AMR- and HCAI-related activities for more than 15 years. GÖG is also involved in WHO or OECD activities.

**Key staff: Eva-Maria Kernstock** is head of the Austrian Federal Institute for Quality in Health Care (BIQG), a business unit of GÖG since 2006. She has extensive experience in the field of quality in healthcare, risk-management and management of patient safety programmes including prevention and control of healthcare-associated infections. **Anton Hlava**, who works as epidemiologist at GÖG since 2000, has been working on the issue of prevention and control of healthcare-associated infections (HCAI) for many years. He has been involved in writing national and regional health reports, in data management and project management and in projects concerning healthcare associated infections and antimicrobial resistances in the healthcare sector. **Vera Buhmann** is a professionally trained nurse and has studied Health Care Management. She has experience in field of project management of EU projects and has been working in projects to HCAI and antimicrobial resistances in the healthcare sector.

# 4 Belgium - FPS HFCSE

**Participant's institution:** The Belgian Federal Public Service Health, Food Chain Safety and Environment (FPS Health) is responsible for policy preparation and execution with a view to guarantee the public health, the safety of the food chain and a safe environment. Its healthcare department, including its service for patient safety and quality of care which is also responsible for work on antimicrobial resistance, falls under the responsibility of the Belgian federal minister for Health and Social Affairs Dr. Maggie De Block.

**Key staff: Dr. Greet Haelterman** (Federal Public Service Health, Food Chain Safety and Environment) is a medical doctor and head of the service for quality and patient safety in the Federal Public Service Health, Food Chain Safety and Environment. She is responsible for the Joint Action on AMR in Belgium. **Dr. Ann Versporten** is working for the Belgian Commission for the Coordination of Antibiotic Policy, a Commission which is hosted by the Federal Public Service Health, Food Chain Safety and Environment and in the past years she was in charge of the data management for several European projects on antimicrobial consumption. **Gilles Van Onacker** (Federal Public Service Health,

Food Chain Safety and Environment) studied history and EU-studies and is working as public health official on patient safety, quality management in healthcare and antimicrobial resistance. **Lieven De Raedt** (Federal Public Service Health, Food Chain Safety and Environment) studied political sciences and public management and has 10 years of experience in health policy with a focus on international health policy.

## 5 Bulgaria - NCIPD

**Participant's institution:** NCIPD is a national institution with the status of scientific organization under the Ministry of Health, which aims to develop the scientific foundations of the fight against infectious diseases and methods for its implementation. It is where all the specialized Reference Laboratories for diagnosis and management of viral, bacterial, fungal and parasitic infections are situated. The experts form NCIPD are nominated as focal points on various infections from the European Centre for Disease Control.

Key staff: Dr. Todor Kantardjiev, MD, DSc, Microbiologist/ Immunologist, President of NCIPD, National Consultant in Microbiology, exuberant experience with BSL3 pathogens, clinical microbiology and mycology, antibiotics and therapy of immunocompromised patients. Coordinator of the external quality assessment and surveillance of the national microbiological lab network. Ivan Ivanov, PhD, Molecular biologist (15 years' experience), Head of the Nat. Reference lab for AMR. Development and optimization of molecular techniques, DNA sequencing and bioinformatics in the field of AMR and HAI. Martyn Nedyalkov, MD, PhD, experience with pediatrics, allergology, microbiology, antibiotics and therapy.

# 6 Croatia - HZJZ/CIPH

Participant's institution: CROATIAN INSTITUTE OF PUBLIC HEALTH (CIPH) is Public health institute on national level with 120 years of tradition in public health. Its main missions are to maintain and promote health of Croatia's population, and promote Public Health Actions on national level. Also, CIPH has obligation to coordinate public health activities in network of County Institutes of Public Health in all country. Microbiology department in CIPH has specfic role in public health and performs microbiological activities at professional, scientific and educational level. Microbiology department is in constant cooperation with the World Health Organization (WHO), and also has 19 national reference centers for cooperation with the European Centre for Disease Control and Prevention (ECDC). Mycrobiology is organized into five departments: Department for tuberculose diagnostics, Department of Parasitology and Mycology, Department of Virology, Department of Bacteriology and Department of Molecular Diagnostics with the unit for intervent diagnostic of highly infectious agents.

**Key staff:** A microbiologist, medical doctor, with PhD thesis/field of quinolone resistance, 15 years of professional experience in microbiology, especially in bacteriology and in the antimicrobial resistance (AMR), abroad experience, fluent knowledge in English. Two **engineers of laboratory diagnostics**, with 15 years of professional experience in microbiology, especially in the AMR, and hospital infections, having also a high command of English, high IT knowledge in managing of applied microbiology in primary health care units (PHCU). **Financial officer** — with 4 years of experience in financial administration and preparation of financial reports, internal and external, experience in Co-ordination and project management tasks. **Administrative officer** — experience in administrative work on projects as support to project management staff, tasks implementation and coordination.

## 7 Czech Republic - NIPH

**Participant's institution:** NRC-HAI and NRL for ATB are core structures within CEM of the Czech NIPH (CCB for ECDC). NRC HAI is responsible for coordination of HAI surveillance, education and training of IC professionals, implementing hospital IC/ABS programmes and creating IC guidance at the nat. level. NRL for ATB concentrates on epidemiologic surveillance of AMR in national, and international projects, is responsible for a national coordination of EARS-Net and participate in Czech National Antibiotic Programme.

Key staff: Professional at clinical microbiology, antimicrobial stewardship, hospital epidemiology, infection prevention and control, experienced in EU projects (ABS International, IPSE), NFP for HAI (ECDC), recent activities focused on implementing hospital programmes on prevention and control of infections, local – national – European surveillance of HAI, training on IC/hospital hygiene professionals (European core competencies). Professional at hospital epidemiology, hospital hygiene, experienced in EU projects IPSE, TRICE-IS. Professional in medical microbiology with experience in surveillance of antibiotic resistance, in methods of detection of antibiotic resistance, and molecular epidemiology of antibiotic resistant bacteria. An applicant is in charge of Czech working Group on Monitoring Resistance, and is a national coordinator of EARS-Net (ECDC), is a member of EARS-Net Disease Network Coordination Committee, and Czech NFP for AMR (ECDC).

#### 8 Denmark - SSI

**Participant's institution:** Statens Serum Institut (SSI) is internationally recognised as the Danish National Public Health Institute for Infectious Diseases. SSI is responsible for research-based health surveillance and analysis, as well as the prevention and control of infectious diseases, biological threats and congenital disorders.

Key staff: Brian Kristensen, MD, PhD: Head of National Center for Infection Control, Denmark: a microbiologist with 20 years of professional experience within antibiotic use and infectious disease epidemiology. Ute Wolf Sönksen, MD: Project-manager of the Danish One-Health project, DanMap: microbiologist with 10 years of professional experience within antibiotic use and infectious disease epidemiology. Sissel Skovgaard, MD, PhD: Project-manager of the national Danish collaboration on surveillance of antibiotic-resistance (e-Res): microbiologist with 5 years of professional experience within antibiotic use and infectious disease epidemiology. Mikkel Lyndrup; Int. M.Sc. in Economics and Business Administration, part of SSI's Executive Office, which supports researchers with external funding issues and Grant Management. His role will be to support the allocated staff in Administrative matters.

#### 9 Estonia – TA

**Participant's institution:** Terviseamet (Health Board) is a governmental institution and the competent authority for surveillance, prevention, and control of communicable diseases, risk analysis in epidemiology.

Key staff: An infectionist with a university degree in medicine (residency -infection diseases) and 10 years experience in infection control (hospital level) incl. participation in international projects (HCAI, AMR, AB stewardship). 5 years experience at national level (HCAI in ICU, SSI, PPS). Excellent command of English. Project manager, university degree in chemistry, more than 15 years of experience of managerial work, national coordination of international projects (several Transition Facility projects, ENHIS-2, SINPHONIE, QUANDHIP, EMERGE). Excellent command of English.

### 10 Germany - RKI

**Participant's institution:** The Robert Koch-Institute (RKI) is the German federal institution for disease control and prevention, and provides national and European reference diagnostics, surveillance and management plans for communicable diseases. RKI runs national surveillance systems for antibiotic use and resistance, and hosts the Commission for Anti-Infective Drugs, Resistance and Therapy (ART), the Centre for the Prevention and Control of Antibiotic Resistance, and it is broadly linked to European and international health institutions.

**Key staff:** an **epidemiologist** with a university degree in medicine and more than 3 years of professional experience in infectious disease epidemiology

#### 11 Greece - HCDCP

**Participant's institution:** HAIs and Antimicrobial Resistance Office of HCDCP is responsible for the implementation of the national strategy for the fight against AMR in healthcare settings as also for the AB use in ambulatory sector (surveillance at national level, professionals training programs, research, guidelines, and national focal point in ECDC for HAIs and AB consumption). Additionally, HAIs/AMR Office has a key role in the formulation of the Greek national action plan for AMR according to EU and WHO requirements.

**Key staff:** The staff will participate in the performance of WP6 and WP7 includes professionals with the followings specialties: The scientific manager of the project is the head of HAIs and AMR Office-HCDCP, an **Infectious disease specialist (MD,PhD)** with specific experience in AMR issues at national and European level, responsible for the monitoring of the national surveillance, guidance and training of health professionals. The leading team includes also **infectious diseases and infection control specialists, infection control nurses** with significant experience in Infection Control Committees, intensivists specialized in infection control in ICUs. Additionally, there is an **epidemiologist** with at least 5 year professional experience in public health and also a biostatistician. The technical stuff includes a data manager and administrative support from professionals dedicated EU programs.

#### 12 Greece - ESDY- NSPH

**Participant's institution:** ESDY/NSPH has long experience in AR epidemiology including electronic surveillance (see <a href="https://www.mednet.gr/whonet">www.mednet.gr/whonet</a>), detecting newly-emerged resistant genes, and (molecular) typing. Also there is increasing experience in communication and collaboration with the veterinary institutions in Greece in setting up common databases and assessing the spread of (AR) bacteria among the two departments (human and veterinary).

Key staff: Our team include a medical microbiologist (MD PhD) with long (20 years) experience in AR epidemiology including setting up electronic surveillance systems international collaboration (WHO, EU), identifying new AR genes, and molecular typing. Also in setting up collaboration with veterinary institutions to follow AR in Greece. A Biologist (PhD) who plays a leading role in studying the molecular mechanisms of AR and the dissemination of resistant genes and bacteria in Greece for the last 15 years. A veterinarian (DVM, PhD) who has a leading role in Greece in implementing the One Health approach in relation to zoonotic diseases. All staff have experience in running FP7 project and a high command of English

#### 13 Greece - 7th HR CRETE

Participant's institution: The 7th Health Region Crete is the tactician vector control and management of the National Health System at the Region of Crete. The 7<sup>th</sup> HR will work in close cooperation with the Medical School of the University of Crete. The staff participating in the joint action on its behalf is highly qualified and experienced in administrative, scientific, technical and research terms, presenting active work in the international bibliography. **Key staff:** The project management will be carried out by a **project manager** with a relevant university degree and experience in managing projects at national or EU level, having also a high command of English. The team will also include highly qualified **infection control specialists** with at least 3 years of hospital experience, a **medical statistics** specialist with academic experience, a **molecular microbiologist** with academic experience and an **infectious diseases** specialist with additional expertise on infection control and more than 20 years of European experience, active bibliography and participation in projects.

## 14 Italy - UNIFG

**Participant's institution:** The Unit of Hygiene of the University of Foggia is taking part in drafting the Italian Plan on AMR, drawing the section on "awareness raising and communication". Close connected to the Italian Ministry of Health and the Istituto Superiore di Sanità, the Unifg team has participated in several national and European initiatives on HCAI and AMR surveillance, control, and prevention (e.g., ESAC-3 NH project 2008, HALT project 2009-2010, ECDC PPS-ICA 2016-2017).

Key staff: The head of the Unit is a medical doctor specialized in Public Health, epidemiologist, full professor of Hygiene, with approximately 20 years of professional experience in infectious disease and chronic disease epidemiology, leading a team of 12 persons, chief of a Public Health Department, managing most of the epidemiological activities at Apulia regional Health Authorities, with >15 years of experience in coordinating research projects in public health field, having a high command of English. The other key staff member is a medical doctor, specialized in Public Health, PhD in Oncology, epidemiologist, assistant professor of Hygiene, with 10 years of professional experience in infectious disease and chronic disease epidemiology, working in the same Public Health Department and serving as epidemiologist at the regional Public Health Authorities, with >5 years of experience in managing research projects, having high command of English.

### 15 Italy - ISS

**Participant's institution:** ISS is the leading technical and scientific body of the Italian National Health Service. Its activities include research, surveillance, training in public health, advice and consultation, with a special multidisciplinary approach and integration between the human and the veterinary field. ISS is engaged in several national and international projects including EU-funded projects and has a long standing experience in AMR, coordinating the national surveillance and research projects on this issue.

**Key staff: Annalisa Pantosti** a specialist in Infectious Diseases, and is in charge of the national program for the surveillance of antibiotic resistance and AMR Focal Point at ECDC. She leads a research group with expertise in antibiotic-resistance surveillance and molecular epidemiology. **Dr. Alessandra Carattoli**, **PhD**, Molecular Microbiologist, leads projects on innovative typing methods and genomics for detection and control of AMR bacteria. She served as Italian Member Board at the JPI-AMR. **Dr. Patrizio Pezzotti**, statistician and epidemiologist, has more than 25 years of experience in statistical analysis, infectious diseases epidemiology, surveillance and public health. **Dr. Luca Busani** is a veterinarian epidemiologist for the evaluation of public health priorities in regards to risk assessment and surveillance for zoonoses

#### 16 Latvia - PSKUS

**Participant's institution:** PSKUS is a leading terciary teaching hospital and leading biomedical research institution in Latvia. European antimicrobial resistance surveillance system (EARSS-Net) and European Surveillance of Antibiotic-Consumption (ESAC-Net) have been coordinated by the researchers from the PSKUS from the very start.

Hospital have also participated in European Comission supported intervention projects that all were focusing on the spread of multidrug resistant microorganisms in hospital setting.

Key staff: The research team in Latvia includes medical practitioners with a particular focus on infectious diseases and an extensive involvement in setting up local, national and international infection control policies. Uga Dumpis has been working in the field of antimicrobial resistance for more than 15 years with a particular interest in the spread of multidrug resistant microorganisms in the hospitals and antibiotic stewardship. He has lead Latvian Nosocomial infection study group, was the lead investigator in the Latvian study site for three multicentre intervention projects. Epidemiologist Elina Dimiṇa has completed her PhD in 2014 on point prevalence studies in Latvian Hospitals. Medical doctor Alise Grāmatniece has been working on A. baumannii spread and containment in neonatal intensive care unit. She will enter her PhD work during the project. Infection control nurse Jelena Urbena has been coordinating infection control activities in the PSKUS.

## 17 Lithuania - LSMULKK

Participant's institution: The Hospital of Lithuanian University of Health Sciences (LSMU) Kauno klinikos is the largest healthcare institution in Lithuania, it has 37 departments devoted to all medical and surgical specialties, 8 intensive care units, 2 300 hospital beds. We could contribute in WP6: implementation of the infection control policies at hospital level, expanding tasks to non-EU countries, improving the training of health professionals and WP7: to take part in developing and testing near real time surveillance of antimicrobials and multidrug resistant bacteria.

**Key staff: Astra Vitkauskiene – MD, PhD**, Professor, clinical microbiologist, the head of Laboratory Medicine Department, over 20 years of experience in consulting and forming politics of antimicrobial usage in tertiary health care hospital, the research field – multidrug resistant bacteria (Pseudomonas aeruginosa, Acinetobacter and ect.) **Asta Dambrauskiene – MD**, physician of Laboratory Medicine, PhD student, the head of Infection Control Service, 10 years of experience in clinical microbiology, the head of hospital infection control group in hospital. **Lukas Cemnalanskis – MD**, the resident of Laboratory Medicine, takes part in researches with multidrug resistant bacteria, risk factors and their impact on infection diseases.

### 18 Lithuania - VULSK

**Participant's institution:** VULSK is the biggest hospital in Lithuania with 1200 beds, 4 ICUs. Has experience in MDR infections. Hospital has capacity to work in several tasks of <u>WP6</u>: implementation of the infection control policies at hospital level, expanding tasks to non-EU countries, improving the training of health professionals, microbiological and molecular testing as part of epidemiologic surveillance organized by partner NVSC.

Key staff: Edita Kazenaite – MD, PhD, clinical pharmacologist, representative of the hospital administration, 15 years professional experience in regulating antimicrobials usage in the hospital. Silvija Kiveryte – MD, PhD, head of laboratory of microbiology, 15 years professional experience in clinical microbiology, molecular diagnostics of infectious agents, 10 years of pedagogical work with students and hospital staff. Ruta Ambrazaitiene – MD, senior physician of laboratory medicine, 20 years professional experience in diagnostic microbiology and MDR, HAI surveillance group in hospital. Asta Macioniene – MD, physician of laboratory medicine, 9 years professional experience in diagnostic microbiology, participation in AMR surveillance networks (EARS-Net, BARN). Kristina Marcinkeviciene - MD, physician of laboratory medicine, 8 years professional experience in diagnostic microbiology, participation in AMR surveillance networks (EARS-Net, BARN). Project manager - 5 years experience in managing different projects in hospital, will be a key staff member in WP2

# 19 Lithuania - HI

**Participant's institution:** Institute of Hygiene (HI) is responsible for planning, coordination and implementation of different activities related to antimicrobial resistance (AMR) and healthcare associated infections (HCAI) on national level: (i) coordinates national surveillance of antimicrobial consumption and HCAI and provides data to European Centre for Disease Prevention and Control networks ESAC-Net and HAI-Net; (ii) was responsible for elaboration and coordination of previous national HCAI and AMR programs and currently is involved in preparation of national AMR strategy; (iii) coordinates the activities of regional AMR management groups; (iv) organizes annual European Antibiotic Awareness events.

**Key staff:** An **epidemiologist with PHD** (in healthcare-associated infections) and more than 20 years professional experience in AMR management and healthcare-associated infections surveillance, experience in project management, participation in international and national projects, postgraduate training, national contact person

for AMR (ECDC). A **public health bachelor** (in healthcare-associated infections) and more than 5 years professional experience in antimicrobial consumption surveillance, national coordinator of regional antimicrobial resistance management groups, participation in international projects, national contact person for ESAC-Net (ECDC).

## 20 Lithuania - NVSC

**Participant's institution:** Lithuanian National Public Health Centre (NVSC), is institution that has 10 regional departments and is responsible for coordination of activities of antimicrobial resistance (AMR) management groups in every Lithuania's district. NPHC is responsible institution for identifying and dealing with antimicrobial resistance and antimicrobial agents' consumption problems in every district, submitting proposals to interested institutions about AMR monitoring and control.

Key staff: Designated Manager is administration staff with a Master university degree in public health and a half of year of experience in managing Joint Action at national level, having a high command of English. Other designated staff: a) 2 chief district epidemiologists, doctors of hygiene and epidemiology with a university degree in medicine and at least 20 years of professional experience in infectious disease epidemiology (at least 1 year in managing antimicrobial resistance (AMR) groups activities); b) doctor of hygiene and epidemiology with a university degree and at least 10 years of experience in public health inspections of health care institutions; c) public health specialist with a university degree, at least 3 years of professional experience in infectious disease epidemiology (at least 3 year in managing antimicrobial resistance (AMR) groups activities) and at least 5 years of experience in coordinating Joint Action at national level. All designated staff have also a high command of English.

## 21 Netherlands - VWS

Participant's institution: The Dutch Ministry of Health, Welfare and Sport is the national authority responsible for the coordination of the One Health AMR policy in the Netherlands, in close cooperation with the Dutch Ministry of Economic Affairs. International collaboration has been a priority in the Dutch approach. The Ministry of Health is involved in several international and bilateral initiatives related to AMR. The Health Care Inspectorate (IGZ) and the Dutch Institute for Public Health and Environment (RIVM) are part of Ministry of Health, Welfare and Sport. Key staff: The multidisciplinary team of the Dutch Min. of Health includes professionals from the departments of: International affairs (IZ): a coordinator/senior advisor AMR with degree on veterinary medicine, agricultural engineering and food technology and post-doc degree in veterinary public health, with 20 years' experience on the field of public health and food safety in 3 Member States and 4 years' experience at the EC as policy officer AMR/coordinator of the EU Action Plan against AMR (2011-15); Public Health (PG): 2 senior policy officers AMR with degree on public health and bioprocess technology, with international experience and responsible for the Dutch One Health National Action Plan on AMR (2015-20). Health Inspectorate (IGZ): a manager, trained as immunologist, responsible in NL of the supervision of infection prevention and control and AMR in all health care settings and member of the Dutch National Healthcare Council. NL National Institute for Public Health (RIVM): a biologist and clinical epidemiologist with specialisation in infectious diseases, policy advisor for AMR and coordinator of international AMR activities. Medicines and Medical Technology (GMT): a policy officer responsible for Innovation with a degree on biomedical Sciences. Communication (DCo): a project leader Communication, responsible for the communication strategy and multimedia communication campaigns in the Netherlands.

## 22 Norway - Hdir

**Participant's institution:** Executive agency and professional, regulatory and implementing authority under the Ministry of Health and Care services. Responsible for developing, revising and implementing clinical guidelines for use of antimicrobials in human health. Responsible for coordinating implementation of national action plan against antimicrobial resistance in Norwegian health care services.

**Key staff: Senior adviser, MD** from the University of Oslo (1982); **Specialist in General Practice** from 1990. Since 2012 responsible for infectious diseases at the department of Community Health Services and for the Norwegian guidelines for antibiotic use in General Practice at the Norwegian Directorate of Health. Senior adviser with MSc in pharmacy and MSc in Molecular biology of infectious diseases and 4 years of professional experience in implementing policies and interventions in health care services, including clinical guidelines and action plans against antimicrobial resistance.

#### 23 Norway - FHI

**Participant's institution:** The Norwegian Institute of Public Health (NIPH) is a subordinate institution to the Norwegian Ministry of Health and Care Services. NIPH acts as a national competence institution for governmental

authorities, the health service, the judiciary, prosecuting authorities, politicians, the media and the general public. The institute's responsibilities include infectious disease control and research.

**Key staff:** An **MD PhD** with experience working with AMR both in terms of control and interventions. An **MD** researching for her doctorate the impact of responsible use on antibacterial innovation and access. A **policy expert** with a university degree in business and doctorate focused on innovation models, experience working across healthcare sectors including national health services, industry, and more. A **pharmacist** with experience in multinational financing and coordination, currently researching policies to link antibacterial innovation to stewardship and access.

# 24 Norway - NVI

**Participant's institution:** NVI is a biomedical research institute with research, preparedness, diagnostics, surveillance, scientific advisory and risk assessment as the most important areas of operation. The institute is Norway's leading centre of expertise on antimicrobial resistance and usage within the veterinary sector, is designated as National Reference Laboratory for antimicrobial resistance and coordinates the Norwegian monitoring program for antimicrobial resistance in the veterinary sector (NORM-VET).

**Key staff:** The staff at the Norwegian Veterinary Institute (NVI) that will be involved in the action consist of **scientists** with various complementary backgrounds within veterinary antimicrobial usage and resistance, microbiology, bacteriology, molecular microbiology, epidemiology, bioinformatics, food safety, surveillance, method development, veterinary medicine and veterinary public health. These staff members have been active in development and implementation of the Norwegian strategy and action plan against AMR in the veterinary sector. Additionally, many of these staff members are part of the NVI AMR research group currently involved in several AMR research and development projects.

### 25 Poland - NMI

**Participant's institution:** National Medicines Institute located in Warsaw, Poland is involved in control, legislative and research activities. Department of Epidemiology and Clinical Microbiology who will be responsible for Joint Action on AMR and HCAI has long time experience in leading the National Program for Antibiotic Protection based on One Health concept and EU recommendations, and cooperate with ECDC in coordination of EARS-Net, ESAC-Net and part of HAI-Net in Poland.

Key staff: Clinical microbiologist with the professor title in medicine and more than 10 years' experience in leading the National Program for Antibiotic Protection and the main author and editor of the based on EBM national antibiotic treatment guidelines. Clinical microbiologists with the university degree in medicine or biological science and more than 5 years' experience in clinical microbiology, epidemiology and antimicrobial resistance surveillance or healthcare associated infections surveillance. Public health professionals with the university degree and more than 5 years professional experience and involvement in the tasks of the National Program for Antibiotic Protection, including antibiotic consumption surveillance and public campaigns on prudent use of antibiotics.

#### 26 Portugal - DGS

**Participant's institution:** The Directorate-General of Health (DGS) is a public body of the Portuguese Ministry of Health that positions itself as a reference for all those who think and operate in the healthcare field. Among its main areas of activity are to issue clinical and organizational guidelines and to guide and develop programs related to public health issues. PPCIRA is the DGS program for IPC & AMR, responsible for defining and implementing strategies and monitoring results in both fields of HAI and antibiotic use.

Key staff: Paulo André Fernandes – Physician, Intensivist, MasterD in HAI, director of national program for IPC &AMR; field work in ES, IPC & AMR. Carlos André Palos - Physician, Intensivist, member of IPC&AMR national program coordination, Postgraduate in HAI, university lecturer, field work in ES, IPC & AMR Pedro Pacheco – Physician, General Practicioner, member of IPC&AMR national program coordination, field work in ES, IPC,AMR. Ana Paula Cruz – RN Specialist, MasterD in HAI, member of IPC&AMR national program coordination, field work in ES, IPC&AMR. Margarida Valente - RN Pediatric Specialist, Postgraduate in HAI, member of IPC&AMR national program coordination, field work in ES, IPC&AMR. Isabel Neves - Physician, Infecciologist, member of IPC&AMR national program coordination, field work in ES, IPC, AMR.

#### 27 Romania – UMPIH

**Participant's institution:** The UMPIH is an educational health research unit operating with clinical settings, being one of the leading research institutions in Romania that also integrates educational programs. Our activities develop

mainly in clinical units and include, among others, clinical and experimental studies at a national and international level and active contribution to public health programs. The institution lead a JA project, conducting the Evaluation WP (CANCUN project).

Key staff: CR, MD, PhD from UMPIH has extensive experience in conducting clinical research projects in Romania. He won and lead 4 national projects regarding screening programs for malignancy and was also member in 6 others. MD, MD, PhD is the head of the department which provides clinical and experimental support for developing research projects. He has extensive experience in coordinating and managing public health research and capacity building projects. He coordinated 4 national and international projects with a strong focus on clinical aspects. IC, MD, PhD conducted several clinical studies and his focus is on developing international health networks and capacity building in Eastern Europe. MA, MD, PhD has experience in financial and technical reporting for research and will conduct financial management and prepare financial reports.

#### 28 Slovenia – NIJZ

**Participant's institution:** NIJZ is the central Slovenian institution for public health in the areas of communicable and non-communicable diseases, health promotion, health protection, health system research, national coordination of preventive programmes in primary health care and health statistics. NIJZ is organised as a central unit and nine regional units and employs over 400 staff members. NIJZ has participated in many international projects and successfully coordinated EPAAC JA, PARENT JA and CANCON JA.

Key staff: Marija Magajne (F) is medical doctor with specialization in epidemiology and master in management. She coordinated PARENT JA and has been actively involved in other JAs and projects. Jana Kolman (F) is a specialist in clinical microbiology with university degree in medicine, with professional experiences in AMR and HAI for more than 10 years — coordination of EARSS/EARS-Net in Slovenia from 2000 and active involvement in HAI prevention, control and epidemiology. Maja Šubelj (F) is a medical epidemiologist with a PhD in Biomedical Sciences and 6 years of professional experiences in Infectious Disease Epidemiology, with diploma in European Program for Intervention Epidemiology Training (EPIET) governed by the ECDC. Mojca Serdt (F) is a microbiologist with university degree and 5 years experiences in HCAI epidemiology, being partly involved in one JA (CanCon).

### 29 Spain – AEMPS

**Participant's institution:** Spanish Agency of Medicines and Medical Devices (AEMPS) mission is to give guarantees to the general public on quality, safety, efficacy and accurate information on medicines and medical devices from research to end use, to protect and promote health. AEMPS is leading and coordinating the National Action Plan on Antimicrobial Resistance (PRAN) together with the collaboration of six Ministries, all the Spanish autonomous communities, universities, and professional societies, associations and organizations.

Key staff: A Professional Expert\_with high knowledge about the JA matter. A WPs Manager with a relevant university degree, some knowledge in Public Health and antibiotic resistance, experience on managing projects including high English level. A Communication Officer with university degree and experience in developing international Conferences, social networks management, and interactions with international organizations and also experience in coordinating communication strategies and content generation. A Communication Officer with university degree and experience in European projects dissemination, meetings organization, online and traditional campaigns. A Webmaster with relevant experience in managing websites. A Managing Assistance with experience in information management with international organizations, budget coordinating and controlling, and supporting other managerial, administrative and financial services.

#### 30 Spain – GENCAT

**Participant's institution:** Departament de Salut (DS) – Generalitat de Catalunya has exclusive competences in the field of health in its region. Through a network of healthcare professionals (in all health system areas), DS has implement the "Best Practices" in Patient Safety.

We have wide experience in the coordination and implementation of different projects of prevention of HCAI-associated AMR, also in the appropriate use of antimicrobials in health care.

In addition, DS has been working for more than 10 years in the surveillance of organisms with specific AMR problems and develops a standardized monitoring of hospital antimicrobial consumption.

Key staff: The group is integrated of different discipline members: Medical Doctor, specialist in Preventive Medicine and Public Health, with experience in Healthcare Research and assessment of health services. Medical Doctor, specialist in Infectious Diseases, with experience in Clinical Research in Infectious Diseases and

Antimicrobial Therapy Antibiotic Stewardship. Medical Doctor, specialist in Preventive Medicine and Public Health and epidemiology, with experience in the field of patient safety. Medical Doctor, specialist in General Practitioner Medical, with experience in methodology in Expert Quality in Healthcare Quality and Policy. Pharmacists, with knowledge in appropriate use of antimicrobial, antimicrobial resistances, etc.

## 31 Spain - IdISBa

**Participant's institution:** Conselleria de Salud (Regional Ministry of Health) from the Government of the Balearic Islands has exclusive competences in the field of health in its region. It takes responsibility for the correct implementation and achievement of the JA activities and it delegates the financial management to the Health Research Foundation of the Balearic Islands Ramon Llull (FISIB).

**Key staff:** The current **General Manager** of "Planning, Evaluation and Pharmacy" with a degree in law, master degree in legal practice and nine years of professional experience in health management, having also a good command of English and French. An **Official** of Service of Health Planning of the Consejería de Salud. A **pediatrician** with a university degree in medicine. Master in economics of health and health management.

## 32 Spain -FFIS

Participant's institution: The Foundation for Health Research and Training in the Region of Murcia (FFIS) is a public nonprofit organization constituted by the Autonomous Community Region of Murcia. The General Direction of Planning, Research, Pharmacy and Care for Citizens (DGPIFAC) depend of the Regional Ministry of health is responsible for regional health planning of health services and management and development of pharmaceutical care in the law on Pharmacy of the Region of Murcia, planning and coordination of strategies for the development of a comprehensive drug policy. ServicioMurciano de Salud (SMS), depending directly on Ministry, is a public entity responsible for the provision of health care to citizens, in the different levels of care, Primary Health Care, Specialized Healthcare.

Key staff: PhD in Medicine. Primary Physician and Preventive Medicine and Public Health. Currently Director General of Planning, Research, Pharmacy and Citizen of the Ministry of Health of the Region of Murcia (Spain)/Bachelor of Pharmacy. Specialist in Clinical Analysis, Graduated in Tropical, Parasitic Diseases. Certificate of Business Management in Health organizations. current Deputy Director General of Pharmacy and Research/PhD Pharmacology PharmD, Health Inspector, Drug Information and Evaluation Centre, Pharmaceutical Management and Care Services/ Master Degree in Public Health, Project Manager in 4 European projects, Research in Health/BSc in Pharmacy, Senior technical research in strategic programs of Rational Use of Medicines for 8 years and Coordinator of the Program of Responsible Use of Antibiotics in Early Childhood at the Ministry of Health of the Region of Murcia/ Two Pediatrician advisers of the Program of Responsible Use of Antibiotics in Early Childhood in Primary Care and hospitals. Researchers in the area of biomedical data quality and construction standards. Experience in Hospital Management for 15 years, Master in Management of Health Services, Master in Health Law and Bioethics, an expert in High Direction/ Nursing BA in Anthropology. PhD in Health Sciences. Researcher on health Experience in early development and implementation of health programs and clinical guidelines and collaborator in Use of Antibiotics in Early Childhood.

## 33 Spain - FMS

**Participant's institution:** NavarraBiomed-Fundación Pública Miguel Servet, carries out research in health sciences in the framework of the objectives and priorities of the Health Department and the Health Plan of the region Navarre in Spain. Its objectives include promoting research through the creation and maintenance of human teams and stable lines of research, guaranteeing them basic equipment and adequate infrastructure. It also manages the banks of biological material of Navarre.

**Key staff:** The team consists of the following members: One **specialist in clinical microbiology**, with an university degree in medicine with over 15 years' experience in clinical microbiology, and specifically in the areas of antimicrobial resistance, tuberculosis, STD and primary care microbiology. One **specialist in clinical microbiology** with an university degree in medicine with specific training in infectious diseases for 5 years, with a doctorate in microbiology with professional experience of over 20 years in clinical microbiology and infectious diseases, specifically in the areas of bacteremia, infection control, antimicrobial resistance, molecular microbiology. Both are involved in national and European research projects on flu, pneumococcus, tuberculosis, fungal infections, and prosthetic joint infections.

## 34 Spain – SAS

Participant's institution: Servicio Andaluz de Salud or Andalusian Health Service (SAS) is an autonomous public body attached to the Ministry of Health from the Government of Andalusia. Its mission is to provide public health care to the citizens, seeking for quality and efficient use of resources. SAS has a network of integrated care services and is organized to ensure the accessibility of the population, including 1,491 primary care centers, 29 hospitals and 84.706 employees. Departments involved in the proposal include Infectious Diseases from Hospital Universitario Virgen del Rocio (HUVR). Besides, research at HUVR is managed by FISEVI foundation. FISEVI is a Foundation created in order to handle the administrative/financial tasks of the beneficiary. FISEVI is a legal entity which is in charge of the financial administration of the beneficiary.

Key staff: José Miguel Cisneros Herreros is Chief of the Infectious Diseases Department in Hospital Universitario Virgen del Rocio in Sevilla. He was the project coordinator of MagicBullet "Optimisation of treatment with off-patent antimicrobial agents of ventilator-associated pneumonia" (FP7-HEALTH-2011 - 278232) and is currently involved in COMBACTE-Care IMI project, as National coordinator for clinical studies (trial REJUVENATE). Jose Miguel Cisneros has conceived and implemented at regional level the institutional programm of the Andalusian Health Service approved in February 2013 called PIRASOA to better antibiotics use strategy.

## 35 Spain - ISCIII

**Participant's institution:** The Instituto de Salud Carlos III (ISCIII) is the national body offering technical and scientific support to the National Health System and public health. ISCIII hosts the national reference centres for public health, including inter alia microbiology and epidemiology. ISCIII also runs the national health research programme and is member of the Joint Programming Initiative on Antimicrobial Resistance. ISCIII coordinates the Joint Action CHRODIS and will coordinate the new JA on chronic diseases.

Key staff: Carlos Segovia is family physician and master of public health. He coordinates Joint Action CHRODIS. He is Chair of the Joint Programming Initiative on Antimicrobial Resistance, and has ten years of experience in European public health and research programmes, including three Joint Actions. María José González de Suso, MD, is Spanish National Focal Point for EU Health Programme, PhD on Medicine and Master on Research and Innovation on Health Sciences. She has been research team leader in different RTD departments in hospitals and pharmaceutical industries. José Campos is head of the reference antibiotic lab and Resistance programme of the National Centre for Microbiology. He is MD, clinical microbiologist, Spanish coordinator for EARSS and ESAC programmes of ECDC, and for TATFAR. Carmen Varela is epidemiologist working in the area of epidemiologic surveillance. She has been working for several years at the Public Health Capacity and Communication unit of ECDC.

#### 36 Spain - SERMAS

**Participant's institution:** Our institution, Assistant Direction of Pharmaceutical Management, is a public organization, part of the Health System of the region of Madrid, dedicated to the pharmaceutical management. Among its functions it is to promote the application of criteria for the rational use of medicines in primary care and hospitals and works in coordination with other organizational structures of the health system. It is the coordinator of the antibiotic's policy.

**Key staff:** Pharmacist with several years of experience as Assistant Director of pharmaceutical management. She is the president of the commission of Central antimicrobial policy. The **Director of the Foundation for Research and Biomedical Innovation Primary Care**. Two **Hospital pharmacists** who work in the Assistant Direction of Pharmaceutical Management with experience in the coordination work teams. One of them also worked for 5 years in primary care and was coordinator of a guideline of antimicrobial use.

#### 37 Sweden – FOHM

Participant's institution: In April 2016 the Unit for Antibiotics and Infection Control at the Public Health Agency of Sweden (PHAS) was designated as a WHO Collaborating Centre for Antimicrobial Resistance Containment that aims to develop the strategic direction of global AMR containment with focus on implementing surveillance. The unit has collaborations with India, China and the Baltic Sea region, and multilateral collaborations with European and international organisations, such as ECDC, WHO and ReAct. PHAS has a national responsibility for public health issues and works to ensure good public health. The agency also works to ensure that the population is protected against communicable diseases and other health threats.

Key staff: A project leader with a university degree in medicine or similar and 5 years of professional experience in infection control. Experience in international project management. A senior MD specialised in clinical microbiology with 15 years of professional experience with focus on AMR. 5 years' experience of leading

international multicentre improvement projects within the field of infection prevention and control. A **pharmacist with a PhD** in the area of antimicrobial resistance and 5 years professional experience of policy work within infection control and antibiotic stewardship.

#### 38 Sweden - SoS

**Participant's institution:** The National Board of Health and Welfare is a Swedish governmental institution responsible to produce and develop statistics, regulations and knowledge for the Government and those working within health and medical care and social service. Knowledge is produce in a number of areas such as patient safety which includes basic hygiene in the Swedish health service to prevent hospital acquired infections and thereby lower antibiotic consumption.

**Key staff:** From the National Board of Health and Welfare one senior employee with a PhD- degree in Clinical Bacteriology is going to participate in the Joint action project. The participant has professional experience in research related to AMR and infectious diseases both on a national and international level. Previous experience working on a three year EU finance project between Europe and India can be noteworthy. The participant has experience from pharmaceutical industry and 6 years' experience in public service.

## 39 Sweden - SBA

**Participant's institution:** The Swedish Board of Agriculture (SBA) is the Government's expert authority in matters of agri-food policy, and is responsible for the agricultural and horticultural sectors. SBA is a legislative authority and the risk manager regarding animal health including spread of AMR. SBA report sales statistics regarding veterinary drugs and manages the reporting framework regarding use of veterinary drugs. The SBA together with the Public Health Agency have since 2012 a government mandate to coordinate the work on containment of antimicrobial resistance.

Key staff: At the Swedish Board of Agriculture, the Department of Animal Welfare and Health there are about 100 persons employed and a majority of the staff have a university degree. There are for instance lawyers, economists, agronomists, biologists and about 30 veterinarians. Of these mainly 6-8 persons are involved in the work on AMR, all of those with university degree in veterinary medicine and with more than 5 years of professional experience of animal contagious disease control (including AMR) and epidemiology. Most involved are one person with 15 years professional experience related to veterinary drugs and AMR issues, one person with 8 years professional experience on AMR issues and one person with 30 years' experience from microbiology, veterinary public health and contagious disease control. At the SBA there are also competence in contingency planning and comprehensive investigations.

#### 40 Sweden – NFA

**Participant's institution:** The National Food Agency (NFA) is a Swedish national authority with the responsibility for safe and healthy food and drinking water. From a safe food perspective this includes chemical and biological hazards such as pharmaceutical residuals and antimicrobial resistance, which has been a prioritized area since the last five years.

**Key staff:** NFA has an internal working group on AMR including two **microbiologists**, three **risk assessors**, three **risk managers and a risk communicator**. The team members have a long experience working in the area of AMR and have participated in and coordinated national and international AMR projects. The main expert to be involved in JA AMR, WP5, is an associate **professor in infection biology** working as a risk assessor. He has been WP-leader in three EU projects and committee member in the action group of One Health Sweden.

## 41 Sweden - SVA

**Participant's institution:** The National Veterinary Institute (SVA) is a Swedish national authority whose most important role is to align the activities towards contagious and other serious infectious diseases of animals including diseases that can be transferred to humans, i.e., zoonoses. This includes antimicrobial resistance and SVA monitor the situation in bacteria from animals and food conducts research into this field. Thus, at SVA there is both expertize and laboratory capacity in the field of antimicrobial resistance.

**Key staff:** At SVA there are 7 senior **employees with PhD-degrees working in the field of antimicrobial resistance (AMR) in the veterinary sector.** Of these 6 have a university degree in veterinary medicine and 1 in microbiology. All 7 have more than 5 years professional experience of research in AMR on a national and international level. The employees also have large national as well as international networks within the field of AMR and are experienced in communicating issues related to AMR in scientific as well as to non-scientific contexts. The employees are also

experienced in policymaking, risk assessment and other tasks related to AMR at an expert governmental authority such as SVA. Two of the employees have more than 15 years' experience of working in this field and 1 employee more than 20 years' experience.

#### 42 Sweden - SRC

**Participant's institution:** The Swedish Research Council (SRC) is the leading government agency for funding and developing Swedish basic research of the highest academic quality within all areas of knowledge. The SRC is working to stimulate Swedish participation in international research cooperation and is the host of the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) Secretariat. SRC is also the coordinator of the ERA-Net Cofund JPI-EC-AMR and the CSA EXEDRA within JPIAMR.

Key staff: Dr. Jan-Ingvar Jönsson, Secretary-General for medicine and health at the SRC and vice-Chair of the JPIAMR. PhD in tumor immunology 1990. Professor of medical cell biology, Linköping Univeristy 2008. Member of HIROs (Head of International Research Organizations). Laura Marin, Project Manager of the JPIAMR. Previously responsible for Science Policy and Member Relations at the European Science Foundation. Dr. Patriq Fagerstedt, Senior Research Officer, JPIAMR Secretariat. MSc microbiology and biochemistry, PhD neuroscience 2000. Research experience from both academia and AstraZeneca. Dr Maria Starborg, Senior Research Officer, JPIAMR Secretariat, national expert in H2020 societal challenge Health, Demographic Change and well-being, PhD in molecular genetics 1995. Research experience from academia.

#### 43 Sweden – UAS

**Participant's institution:** Uppsala University Hospital (UUH) is a highly specialized public hospital responsible for a region of 3 million citizens. UUH has 5 intensive care units (burn's, neonatal, medical/surgery, thoracic and neurosurgical) and 8 operating theatres. UUH has approximately 50 wards and 1000 beds. The hospital collaborate closely with Uppsala University.

Key staff: A medical doctor, specialized in clinical microbiology and infection prevention and control with a PhD in medical sciences, with 10 years professional experience in infectious disease epidemiology and infection prevention and control having also a high command of the English language. 5 years' experience of leading international multicenter improvement projects within the field of infection prevention and control.

#### 44 France - ANSES

**Participant's institution:** Anses is a key partner of the One Health National Strategic Plan for AMR set up in France with specific duties on AMR in the non-human sector. Anses is the scientific body holding the national surveillance network for AMR in animals in France (Resapath) and is responsible for all issues dealing with antibiotic marketing authorizations, surveillance of antibiotic use, antibiotic stewardship and guidelines in veterinary medicine.

**Key staff:** Anses will include the contribution of 3 senior scientists (2 microbiologists and 1 epidemiologist) and four technical staff. All scientists are PhD with 10 years of professional experience in AMR and antibiotic use in animals, in relation with AMR and antibiotic use in humans. Two also are veterinary doctors. One of them, who will be the coordinator of the tasks, has over 10 years of experience in supervising, coordinating and managing activities on AMR, and particularly as National Supervisor on AMR issues at Anses within the One Health National Strategic Plan on AMR, including daily contacts with relevant stakeholders, professional bodies and national/EU authorities. The latter also has over 5 years of experience in coordinating workpackages in several EU or international scientific projects on AMR. The four technical staff have daily experience with managing the surveillance network of AMR and collecting antibiotic use in animals in France.

# 10.4. External and internal risk analysis and contingency planning

The JA Secretariat in collaboration with the ExB will put in place a risk management plan from the project start. This will include open communication about risk management process during the Kick off meeting, so that it becomes part of the JA's culture and that partners feel comfortable with notifying the WP leader or the Coordinator when a risk occurs.

During the course of the action, project partners and in particular WP leaders will be supported by the SC and the Stakeholder Forum in identifying risks, quantifying risks and developing appropriate responses to risk. The JAS will be responsible for the maintenance of a Risk Register containing a comprehensive listing of all risks

identified during the course of the project and the manner in which they are being addressed. This register will be reviewed periodically during ExB meetings, as part of the project risk management process.

The table below describes the critical risks already identified in relation to the action implementation and the associated measures that will be taken to mitigate them:

WP / Task	Identified Risk	Likeli- hood	Impact	Contingency planning
All WPs	Overspending	low	medium	Appropriate financial control: Reporting throughout project
WP2; WP8	Subcontractor fails to deliver	medium	medium	Contractual agreement with subcontractor to cover implication of non-delivery
All WPs	Partners' commitment declines	medium	low	Efficient internal communication tools and close follow-up by WP leaders
All WPs	Staff turnover	medium	low	Project status meetings at WP level to identify issues on the horizon
WP3 (tasks 3.3 & 3.4	Different level of understanding and sharing due to heterogeneity in native languages	high	medium	.Adopt English as official language.     .Content revision by MS representatives     .Evaluation surveys about the understanding of released documentation
WP3 (task 3.3)	Differences in JA partners compliance/collaboration to evaluation activities	medium	high	.Monitoring of the timeline of activities within WP 3. ETs will be reviewed by partners involved in the evaluation prior their useReminders will be sent to non-respondents. Communication with management bodies asking for direct actions on partners.
WP3 (task 3.4)	Lack of essential results/information in the provided documents	low	high	Support by SC and Stakeholders Forum in reviewing documents - Communication with management bodies asking for direct actions on partners.
WP3 (tasks 3.1 & 3.2	Differences / non homogeneity among indicators adopted by different Work Packages and for evaluation purposes	medium	medium	.Dissemination and review of the EP (at the beginning of the JA) and the ETs (during the whole JA lifetime) will provide a common and shared set of measures for indicators.  .Revision of the EP/ETs will be carried out if necessary to avoid differences among indicators used.  .Consultation with SC and Stakeholders Forum on the harmonization of indicators proposed
WP3 (tasks 3.3 & 3.5)	Lack of coordination / synchrony amongst related activities from different WPs	high	high	.Promoting continuous communication among WPs leadersMonitoring every six months of the activities with respect to expected results and timelines .Sharing information and data on a common web based platform
WP5	Lack of information on national measures	medium	high	Leader will use its network to verify information from partners of the project and double check information received
WP5	No consensus on the priority goals	medium	medium	Leader will ensure that all partners are satisfied with priority goals proposed. Delphi process will help to reach consensus
WP5	Link/overlap with WP6 and WP7 (WP5 target group is national policy level. WP6 and WP7 target groups are professionals/local level).	medium	low	We will ask WP6 leaders to develop or remark on the HCAI aspects to be developed in the self-assessment tool. Equally we will ask WP7 leaders to do this for prudent use aspects.
WP5	Link/overlap with WP4	low	high	Coordination with WP4 and EU agencies/institutions needed to ensure continuity of the actions

WP5	Low engagement in the self- and country-to-country	medium	high	Engagement of countries by informing/reporting to the One Health Network on the activities of WP5
	assessments: -Not all MS participate -No involvement of all relevant authorities -Disparity between supervisory bodies			
WP5	No reporting to the One Health Network	low	medium	Until now, the One Health Network has met only once and it's not clear which will be the frequency of the meetings, etc. Contact with EC to ask for frequent, regular meetings of the One Health Network.
WP61.2	Lack of appropriate monitoring of the implementation of the ICP in the hospitals	low	medium	The hospitals will chose the core components they will perform regarding their priorities and needs, so the hospital managers support is necessary.
WP61.1	The impact of the implementation of this WP depends on the active participation of the partners at local and national level.	low	medium	The scope and the aim of the project must be clarified from the begging and the partners should be encouraged continuously from the WP leader and the coordinator team
WP6.2	Objectives and tasks for WP 6 might be too ambitious and might run the risk of not being manageable within the time and resources allocated.	medium	high	Actions within this WP focus on supporting implementation and setting realistic goals.
WP6.2	Difficulties in having hospitals joining actions.	low	medium	Good preparatory work and contacts in order to explain the actions and also the added value of these actions
WP6	Time constraints.	medium	high	Realistic time schedule and regularly monitor progress.
WP7 Task7.2	Lack of funding in pilot states	medium	medium	.Restrict participants number .Encourage co-funding by MS
Task7.3	Lack of infrastructure	high	high	Pilot only in countries that can deliver data
WP7	Lack of acceptance and cooperation from ECDC	low	high	Early dialogue with ECDC as soon as WP agreed
WP9 Task 9.1	Disagreement regarding scope of priorities between MS and JPIAMR	medium	low	Define this early in the process to ensure that JPIAMR's mandate is well understood
WP9 Task 9.1	Lack of description of the differences and communalities between the needs for AMR and HCAI.	medium	high	Firmly engage all stakeholders to participate in this mapping
WP9 Task 9.1	Lack of interest to align public health priorities	medium	medium	Engage countries from the start regarding the importance and cost savings potential of alignment
WP9 Task 9.2	Cost of stimulating greater antibiotic innovation can be significant	high	high	Work with DRIVE-AB and AMR Review to understand the counterfactual cost and different methods of financing

# 10.5. Financial management

The EC financial contribution has been carefully distributed amongst the beneficiaries, based on:

- the effort necessary to perform the JA tasks
- travel and subsistence to JA meetings (GA, WP meetings or workshops)
- logistic costs for the organisation of meetings (catering)
- other costs necessary for perform the WP tasks (printing costs, communication costs)

The Coordinator INSERM has extensive experience in the financial management of research collaborative projects and public health actions (Joint Action Orphanet, Joint Action Alcove...). It will be supported in these tasks by the JA Secretariat.

The JAS will also provide continuous direct support to all beneficiaries. It will check all data reported by beneficiaries before submission to the EC. In particular, the JA Secretariat will verify:

- the quality and accuracy of financial reports submitted (in relation to the work performed)
- the on time uploading of reports to the Participants portal
- the use of funding according to existing guidelines
- that costs actually incurred are consistent with those initially budgeted
- that sufficient justification is provided in case of significant deviation
- that the banking information from the beneficiaries is kept up to date

The JA Secretariat will instruct the beneficiaries on proper time recording practices and prepare comprehensive reporting templates that will be sent to all beneficiaries well before the EC reporting deadline, to allow timely submission of reports. After validation of periodic reports by the EC, distribution of co-funding to beneficiaries will be made by the Coordinator's financial officer without unjustified delay.

Permanent supervision on financial balance of the action will allow the JA Secretariat to alert promptly the ExB as to whether or not resources are being used effectively and efficiently and to give suggestions and recommendations for proper reactions, such as reallocation between partners or WPs.

#### 11. BUDGET

# 11.1. Content description and justification

The EC financial contribution has been carefully distributed amongst the beneficiaries, based on:

- the effort necessary to perform the JA tasks
- travel and subsistence to JA meetings (GA, WP meetings or workshops)
- logistic costs for the organisation of meetings (catering)
- other costs necessary for perform the WP tasks such as printing costs or communication costs

Budget was first discussed individually with WP leaders through conference calls and mail discussions. Templates were then sent to all beneficiaries with:

- The indicative Person-Month per partner per WP and the associated tasks
- Number of meetings/workshops expected to take place during the project (when possible, we have tried
  to combine WP workshops with annual General Assembly meetings to minimize travel costs). Beneficiaries
  took these indications into account to calculate their travel and subsistence costs, according to their
  involvement in each of the WPs.
- Personnel costs represent the highest cost item. Most of the effort (75%), and thus most of the JA costs, concentrates on the following core work packages: WP5: Implementation of One Health national strategies and National Action Plans for AMR; WP6: Policies for prevention of Health-Care-Associated Infections and their implementation; WP7: Appropriate use of antimicrobials in health care.

The costs for the organization of 4 consortium meetings was dispatched between partners FR-1 INSERM, FR2- MOH-FR, IT-17 ISS and SP32- AEMPS.

### 11.2. Summary of staff effort

Participant number	Participant Short name	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	TOTAL PERSON/M ONTH per Participant
01	INSERM	46,0	4,0	3,5	0,0	9,0	12,0	0,0	7,5	31,0	113,0
02	Moh	8,2	1,7	0,6	14,4	4,0	0,0	0,0	1,0	0,0	29,9
03	GOG	0,0	0,1	0,0	0,0	0,0	6,0	5,3	0,0	0,0	11,4

0.4	LEDG LIEGGE	ا م ه ا	0.5	ا م م ا	0.0	4.0	0.0	0.5	ا م م ا	ا م م ا	45.0
04 05	FPS HFCSE	0,0	0,5 0,7	0,0	0,0	4,0 6,7	8,3	2,5	0,0	0,0	15,3
	NCIPD	0,0	,	0,0	0,0	,	0,0	11,0	0,0	0,0	18,4
06	CIPH HZJZ	0,0	0,2	0,0	0,0	0,0	0,0	10,7	0,5	0,0	11,4
07	NIPH	0,0	0,5	0,0	0,0	4,3	24,5	5,3	0,5	0,0	35,0
08	SSI	0,0	0,5	0,0	0,0	0,0	0,0	12,0	0,5	0,0	13,0
09	TA	0,0	2,0	0,0	0,0	0,0	5,0	5,0	5,0	0,0	17,0
10	RKI	0,0	0,1	0,0	0,0	5,4	0,0	5,9	0,1	0,0	11,5
11	HCDCP	0,0	1,0	1,0	0,0	0,0	85,0	12,0	1,0	0,0	100,0
12	ESDY NSPH	0,0	1,0	0,0	0,0	8,2	2,0	38,0	1,0	0,0	50,2
13	SEVEN HC	0,0	0,0	0,0	0,0	0,0	11,5	0,0	0,0	1,5	13,0
14	UNIFG	0,0	0,4	2,5	0,0	6,0	7,0	6,0	1,9	0,0	23,8
15	ISS	0,0	1,0	6,0	0,0	0,0	7,0	12,0	0,0	3,0	29,0
16	PSCUH	0,0	1,0	0,0	0,0	0,0	11,0	0,0	0,0	0,0	12,0
17	LSMULKK	0,0	1,0	0,0	0,0	6,5	12,0	7,0	0,5	0,0	27,0
18	VULSK	0,0	1,0	0,0	0,0	0,0	12,0	0,0	0,0	0,0	13,0
19	HI	0,0	0,5	0,0	0,0	12,0	18,0	9,0	0,5	0,0	40,0
20	NVSC	0,0	0,1	0,0	0,0	0,0	6,0	2,7	2,5	0,0	11,4
21	VWS	0,0	2,0	1,0	0,0	29,0	7,0	2,0	2,0	4,0	47,0
22	HdiR	0,0	0,1	0,0	0,0	0,0	0,0	3,8	0,1	0,0	4,0
23	FHI	0,0	1,5	0,4	0,0	0,0	0,0	33,2	0,0	32,5	67,6
24	NVI	0,0	0,0	0,0	0,0	0,0	0,0	6,0	0,0	1,0	7,0
25	NMI	0,0	0,0	0,0	0,0	7,0	0,0	6,0	0,0	0,0	13,0
26	DGS	0,0	1,0	0,0	0,0	0,0	10,0	5,0	2,5	0,0	18,5
27	UMPIH	0,0	2,5	0,0	0,0	5,5	0,0	4,5	0,0	0,0	12,5
28	NIJZ	0,0	1,5	0,0	0,0	10,0	11,0	0,0	3,5	1,0	27,0
29	AEMPS	0,0	39,0	1,0	2,0	3,0	12,0	18,0	49,0	0,0	124,0
30	GENCAT	0,0	0,0	0,0	0,0	0,0	12,0	12,0	4,0	0,0	28,0
31	IDIBAs	0,0	0,0	0,0	0,0	0,0	2,9	7,3	3,1	2,4	15,8
32	FFIS	0,0	1,0	5,0	0,0	0,0	12,0	4,8	1,0	0,0	23,8
33	FMS	0,0	0,5	0,0	0,0	0,0	0,0	5,0	0,5	0,0	6,0
34	SAS	0,0	1,0	0,0	0,0	0,0	0,0	17,1	0,0	0,0	18,1
35	ISCIII	0,0	0,8	0,0	0,0	0,0	4,0	0,0	0,4	0,0	5,2
36	SERMAS	0,0	0,0	0,0	0,0	0,0	0,0	28,0	3,0	3,3	34,3
37	FOHM	0,0	1,0	1,0	0,0	3,0	41,2	2,0	0,0	0,0	48,2
38	SoS	0,0	0,0	0,0	0,0	0,0	1,0	0,0	0,0	0,0	1,0
39	SBA	0,0	0,0	0,0	0,0	0,8	0,0	0,0	0,0	0,0	0,8
40	NFA	0,0	0,0	0,0	0,0	1,5	0,0	0,0	0,0	0,0	1,5
41	SVA	0,0	0,0	0,0	0,0	0,7	0,0	0,0	0,0	0,0	0,7
42	SRC	0,0	0,4	0,0	0,0	0,0	0,0	0,0	0,0	4,6	5,0
43	UAS	0,0	0,0	0,0	0,0	0,0	1,0	0,0	0,0	0,0	1,0
44	ANSES	0,0	1,0	0,0	0,0	6,0	0,0	35,5	0,0	0,0	42,5
TOTAL		54,2	70,6	22,0	16,4	132,6	341,5	334,6	91,6	84,3	1147,8

Below the breakdown of all direct costs per WP:

Participant number	Participant Short name	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	TOTAL DIRECT COSTS per Participant
01	INSERM	341 954,00	26 366,00	19 077,00	0,00	38 560,00	41 470,00	0,00	50 170,00	207 733,00	725 329,00
02	Moh	58 060,00	10 600,00	4 800,00	88 044,00	26 000,00	0,00	0,00	8 000,00	0,00	195 504,00
03	GOG	14 740,00	593,00	0,00	0,00	0,00	63 957,00	43 926,00	0,00	0,00	123 216,00
04	FPS HFCSE	0,00	2 242,00	0,00	0,00	33 453,00	52 211,00	23 840,00	0,00	0,00	111 745,00
05	NCIPD	7 520,00	620,00	0,00	0,00	18 810,00	0,00	9 550,00	0,00	0,00	36 500,00
06	CIPH HZJZ	7 520,00	700,00	0,00	0,00	0,00	0,00	43 220,00	650,00	0,00	52 090,00
07	NIPH	7 520,00	1 204,00	0,00	0,00	21 388,00	73 189,00	10 153,00	1 204,00	0,00	114 657,00
08	SSI	7 520,00	2 000,00	0,00	0,00	0,00	0,00	70 000,00	2 000,00	0,00	81 520,00
09	TA	7 520,00	3 640,00	0,00	0,00	0,00	14 860,00	9 100,00	12 235,00	0,00	47 355,00
10	RKI	7 520,00	750,00	0,00	0,00	50 660,00	0,00	44 250,00	750,00	0,00	103 930,00
11	HCDCP	0,00	2 200,00	2 200,00	0,00	0,00	276 216,00	27 000,00	2 200,00	0,00	309 816,00
12	ESDY NSPH	7 520,00	2 503,00	0,00	0,00	33 303,00	12 129,00	79 498,00	2 503,00	0,00	137 455,00
13	SEVEN HC	7 520,00	0,00	0,00	0,00	0,00	37 677,00	0,00	0,00	7 741,00	52 938,00
14	UNIFG	7 520,00	1 709,00	11 387,00	0,00	39 190,00	36 183,00	25 220,00	10 984,00	0,00	132 193,00
15	ISS	15 940,00	8 123,00	145 304,00	0,00	0,00	102 698,00	88 435,00	0,00	24 558,00	385 058,00
16	PSCUH	7 520,00	1 938,00	0,00	0,00	0,00	25 372,00	0,00	0,00	0,00	34 830,00
17	LSMULKK	7 520,00	1 800,00	0,00	0,00	11 700,00	19 400,00	5 550,00	900,00	0,00	46 870,00
18	VULSK	7 520,00	2 900,00	0,00	0,00	0,00	43 520,00	0,00	0,00	0,00	53 940,00
19	HI	3 760,00	1 138,00	0,00	0,00	42 458,00	50 156,00	22 592,00	1 255,00	0,00	121 359,00
20	NVSC	7 520,00	279,00	0,00	0,00	0,00	19 495,00	5 158,00	3 230,00	0,00	35 682,00
21	VWS	7 520,00	18 500,00	9 250,00	0,00	303 500,00	96 000,00	55 000,00	17 160,00	31 440,00	538 370,00
22	HdiR	7 520,00	911,00	0,00	0,00	0,00	0,00	39 134,00	1 050,00	0,00	48 615,00
23	FHI	7 520,00	10 843,00	3 543,00	0,00	0,00	0,00	277 561,00	0,00	219 880,00	519 347,00
24	NVI	3 760,00	0,00	0,00	0,00	0,00	0,00	42 000,00	0,00	7 720,00	53 480,00
25	NMI	7 520,00	0,00	0,00	0,00	26 534,00	0,00	9 239,00	0,00	0,00	43 293,00

26	DGS	7 520,00	4 600,00	0,00	0,00	0,00	50 320,00	17 600,00	12 760,00	0,00	92 800,00
27	UMPIH	7 520,00	2 500,00	0,00	0,00	20 020,00	0,00	6 200,00	0,00	0,00	36 240,00
28	NIJZ	7 520,00	3 900,00	0,00	0,00	46 140,00	66 760,00	0,00	11 660,00	6 140,00	142 120,00
29	AEMPS	7 520,00	223 400,00	3 125,00	6 250,00	22 415,00	40 300,00	63 750,00	226 550,00	0,00	593 310,00
30	GENCAT	7 520,00	0,00	0,00	0,00	0,00	29 760,00	24 000,00	11 440,00	0,00	72 720,00
31	IdISBa	7 520,00	0,00	0,00	0,00	0,00	25 179,00	44 563,00	21 099,00	15 702,00	114 063,00
32	FFIS	7 520,00	0,00	18 844,00	0,00	0,00	64 919,00	19 919,00	5 418,00	0,00	116 618,00
33	FMS	7 520,00	2 340,00	0,00	0,00	0,00	0,00	23 364,00	2 333,00	0,00	35 557,00
34	SAS	5 640,00	4 500,00	0,00	0,00	0,00	0,00	87 350,00	0,00	0,00	97 490,00
35	ISCIII	7 520,00	3 200,00	0,00	0,00	0,00	27 280,00	0,00	1 600,00	0,00	39 600,00
36	SERMAS	7 520,00	0,00	0,00	0,00	0,00	0,00	48 000,00	9 000,00	9 923,00	74 443,00
37	FOHM	7 520,00	0,00	0,00	0,00	71 075,00	494 327,00	41 087,00	0,00	0,00	614 009,00
38	SoS	3 760,00	0,00	0,00	0,00	0,00	10 270,00	0,00	0,00	0,00	14 030,00
39	SBA	2 820,00	0,00	0,00	0,00	9 479,00	0,00	0,00	0,00	0,00	12 299,00
40	NFA	3 760,00	0,00	0,00	0,00	12 300,00	0,00	0,00	0,00	0,00	16 060,00
41	SVA	2 850,00	0,00	0,00	0,00	9 587,00	0,00	0,00	0,00	0,00	12 437,00
42	SRC	7 520,00	2 880,00	0,00	0,00	0,00	0,00	0,00	0,00	34 560,00	44 960,00
43	UAS	3 760,00	0,00	0,00	0,00	0,00	15 665,00	0,00	0,00	0,00	19 425,00
44	ANSES	3 760,00	3 724,00	0,00	0,00	32 512,00	0,00	214 773,00	0,00	0,00	254 769,00
TOTAL		682 644,00	352 603,00	217 530,00	94 294,00	869 083,00	1 789 312,00	1 521 032,00	416 149,00	565 397,00	6 508 041,00

# 11.3. Detailed budget

# 1. France – Inserm

Applicant Number	FR-1				
Short Name	INSERM				
(A) Discotorous de coto	Paragradus (italian)	Total Dancar Manuth	T-1-1 C1- (C) -5 (A)		
(A) Direct personnel costs (including Public officials)	Persons (position)	Total Person-Month	Total Costs (€) of (A)		
(including Fubile Officials)	Deputy director ITMO I3M (Evelyne Jouvin-Marche)	4	32 484,00 €		
	Scientific advisor (Antoine Andremont)	6	69 894,18 €		
	Post-doc (WP9) to be hired	18	72 000,00 €		
	Project manager (WP1) to be hired	36	144 000,00 €		
	JA project assistant (WP1) to be hired	13	39 000,00 €		
	Infection control senior expert (WP5) to be appointed*	9	18 000.00 €		
	Senior consultant (WP6) to be appointed*	10	19 830.00 €		
	Assistant (WP6) to be appointed*	2	2 800.00 €		
		Total Costs (€) of (A)	398 008.18 €		
(C) Other direct costs (C.1) Travel	the interface with the governments and institutions of all participating countries. Of French side, three permanent scientists are associated to develop the JA action: Marie Ploy to coordinate the JA, Antoine Andremont to drive the WP9 and Evelyne Jouvin Note to help to identify public health needs and priority in AMR and HCAI research and innote and to communicate on research finding and good practices in France. In addition, Che Hubert, assistant director will contribute to a secretariat work. Contribution to all the of WP5* with special interest in the developing of the tool for the self-assessment national strategies and action plans. Senior consultant (epidemiologist) working at national strategies and action plans. Senior consultant (epidemiologist) working at natively, responsible for executing and/or coordinating all professional tasks listed in Track-1 (WP6a, Tasks 6.1.1., 6.1.2., 6.1.3.). One assistant in WP6* will be responsi organisational and logistical matters as well as accounting tasks related to local padministration of W6 Track-1 (WP6a, Tasks 6.1.1., 6.1.2., 6.1.3.).				
(CIL) Havei	Costs (€)  8 460,00 €	Justification  Travel to 3 GA meetings for	r 3 participants + KoM		
	60 480,00 €		vel to attend 4 Steering eople = 1 laborating partner)		
	9 360,00 €	WP9 travels for task 9.2 = 1 Andremont	.3 visits for Antoine		
	20 560.00 €	Travel of the WP5* infection control senior ex for WP5 country to country assessment (8000) general and one day meetings participation (12560€)			
	11 840.00 €	Travel of the WP6* epidemiologist for WP1 meetings (7520€) and WP6a meetings (2 one-dinterim meetings in conjunction with the G.A.s with 1 national + 2 WP6a pilot hospital representatives) (4320€)			

	17 520,00 €	Additional budget** to cover miscellaneous travel
		expenses:
		- Coordinator travels and attendance at
		European events related to AMR & HCAI to
		disseminate and communicate about the Joint
		Action: expected up to 5 events per year (920 € x
		5 x 3 = 13 800 €)
		- Travels expenses for the project manager
		to attend the KoM and the 3 General Assembly
		(920€ x 4 = 3 720 €). Indeed the project manager
		is located in Limoges near the coordinator and will
		have to attend the KoM in Paris as well as the
		General Assembly meetings.
(C.3) Other goods and	Costs (€)	Justification
services		
	3 000,00 €	Webex platform
	10 300,00 €	Organisation of a General Assembly Meeting in
		Paris (catering, lunch, diner; travels + per diem for
		2 experts) = 69 participants + 2 experts
	7 000.00 €	WP6a accommodation, printings*
Total Costs (€) of (C)	148 520.00 €	
(D) Indirect Costs (Max. 7%	38 256.97 €	
on A, B and C)		
Total estimated eligible	584 785.15 €	
costs		
Total requested EC	350 871.09 €	
contribution (60% max)	000 011 2100 0	

<sup>\*</sup>Due to the situation of both former Hungarian entities (former OCMO & NCE), partners of the JA, and unable to proceed with administrative steps of the Grant Agreement preparation. These partners and INSERM agree to withdraw OCMO and NCE, to transfer and keep their budget at the coordinator's one until their situation will be cleared. Once it will be the case, they will be reintroduced to the consortium in the course of the project. In case both Hungarian partners cannot join the project during its course, INSERM will contact WP leaders of WP5 and WP6 as well as participants of these two Work Packages to assess which entity-ies could carry out the work NCE and OCMO were supposed to perform. Any transfer will be made after detailed justification and validation of the General Assembly.

<sup>\*\*</sup>Due to the withdrawal of the Serbian partner, CCS, this amount (33 280  $\in$ ) will be dedicated to cover additional travel expenses that were at first forgotten (17 520  $\in$ ) and the coordinator (Prof. Marie-Cécile Ploy) involvement in the project that has been refined (+1.03 PM).

Applicant Number	FR-1 Affiliated entity		
Short Name	University of Limoges		
(A) Direct personnel costs	Persons (position)	<b>Total Person-Month</b>	Total Costs (€) of (A)
(including Public officials)	Prof MD & director of laboratory (Marie-Cécile Ploy)	10,03	102 808,16 €
	PharmD (Olivier Barraud)	2,5	6 375,00 €
		Total Costs (€) of (A)	109 183,16 €
	Justification		
	Marie Cécile Ploy to coordinate the JA		
(D) Indirect Costs (Max. 7% on A, B and C)	7 642,82 €		
Total estimated eligible	116 825,98 €		
costs			
Total requested EC contribution (60% max)	70 095,59 €		

Applicant Number	ED 1 Affiliated entity						
Applicant Number	FR-1 Affiliated entity						
Short Name	CHU Limoges						
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)				
(including Public officials)	Prof MD & director of laboratory (Marie-Cécile Ploy)	10,03	51 242,87 €				
	PharmD (Elodie Pfender)	2,5	10 750,00 €				
	PharmD (Olivier Barraud)	2,5	7 625,00 €				
		Total Costs (€) of (A)	69 617,87 €				
	Justification						
	Marie Cécile Ploy to coordinate the JA						
(D) Indirect Costs (Max. 7% on A, B and C)	4 873,25 €						
Total estimated eligible costs	74 491,12 €						
Total requested EC contribution (60% max)	44 694,67 €						

# 2. France – MoH

Applicant Number	FR-2		
<b>Short Name</b>	МоН		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Christian Brun-Buisson - Medical	5,4	43 200,00 €
	doctor trained in Intensive Care		
	Jean-Michel Azanowsky - Medical	2	16 000,00 €
	doctor specialist in Public Health	1.0	45 200 00 6
	Jean-Baptiste Rouffet - Policy Advisor on European Affairs	1,9	15 200,00 €
	Project assistant (to be hired)	20,4	102 800,00 €
	Project assistant (to be fined)	Total Costs (€) of (A)	102 800,00 € 177 200,00 €
	1	Total Costs (€) of (A)	177 200,00 €
	Justification		
	One person will be recruited to ensure		-
	foreseen person will have a policy a	_	· · · · · · · · · · · · · · · · · · ·
	management to enable appropriate up support to the work undertaken and	_	
	throughout the whole Joint Action.		= -
	coordination Team as necessary, and b		
	ongoing development to ensure susta	•	•
	the work done in JAMRAI.		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	6 960,00 €	3 x General meetings fo	or 2 persons (airplanes tickets +
		1 -	at General Assembly + WP4
		annual meeting in the f	ramework of General
(C 2) Other goods and	Costs (5)	Assembly meetings  Justification	
(C.3) Other goods and services	Costs (€)	Justification	
Sel Vides	1 044,00 €	TLC (for instance Go To	Meeting = 29€ per month)
	10 300,00 €	Organisation of a Gener	ral Assembly Meeting (Kick-off
	,		Paris (catering, lunch, diner;
		travels + per diem for 2	experts) = 69 participants + 2
		experts	
Total Costs (€) of (C)	18 304,00 €		
(D) Indirect Costs (Max. 7%	13 685,28 €		
on A, B and C)	200 400 50 5		
Total estimated eligible costs	209 189,28 €		
Total requested EC	125 513,57 €		
contribution (60% max)	123 515,57 €		
CONTRIBUTION (OU/O INIAN)			

# 3. Austria - GÖG

Applicant Number	AT-3		
Short Name	GOG		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Eva Kernstock (Senior Researcher Nursing and Risk-Managment Expert)	2,40	31 003,51 €
	Anton Hlava (Senior Researcher, Epidemiologist and Statistic Expert)	5,40	51 294,39 €
	Vera Buhmann (junior researcher for HCAI and AMR)	3,64	21 578,32 €
		Total Costs (€) of (A)	103 876,22 €
	Justification	·	
(C) Other direct costs	of Health-Care-Associated Infections and E. Kernstock has extensive experience as a supervisor in the work of both W been working on the issue of prevention for many years. V. Buhmann, a junior and has been working in projects defined the healthcare sector. They will all particip	in the field of quality in he Ps. The epidemiologist an In and control of healthcar dvisor, has experience in fice ealing with HCAI and ant	ealthcare. She will be involved and senior advisor A. Hlava has re-associated infections (HCAI) eld of EU project management timicrobial resistances in the
(C.1) Travel	Costs (€)	Justification	
(C.1) Have			var. Ell countries 1 nav 2 day
		_	/ar. EU countries 1 pax 2 day
(c.c.) c.d.	9 200,00 €		2 days
(C.3) Other goods and services	Costs (€)	Justification	
	5 540,00 €		in 2018 incl. 2 speaker nax + 2 speakers according to
Total Costs (€) of (C)	19 340,00 €		
(D) Indirect Costs (Max. 7%	8 625,13 €		
on A, B and C)			
Total estimated eligible	131 841,35 €		
Costs	70.404.04.0		
Total requested EC contribution (60% max)	79 104,81 €		
continuation (60% max)			

GOG will have an affiliated entity: the Austrian Ministry of Health (MoH-AT)

# 4. Belgium - FPS HFCSE

Applicant Number	BE-4		
Short Name	FPS Health, Food Chain Safety and Environment		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Statistician (Dr Versporten - WP6.2)	1,80	12 174,72 €
	Attaché (Mr Van Onacker - WP6.2)	4,50	20 532,00 €
	Attaché (Mr De Raedt - WP5)	4,50	20 174,25 €
	Medical doctor (Dr Legiest - WP6.2 & WP7)	4,50	32 544,44 €
		Total Costs (€) of (A)	85 425,41 €
	Justification		
	Belgian participation to the JA and drive WP5. Gilles Van Onacker will help coordinate the Belgian contribution to the JA in general and WP6.2 in particular. Ann Versporten is statistician and an expert on AMR and HCAI and will contribute to WP6.2 by adapting an implementing existing policies and guidelines and by reviewing if compliance has improved. Barbara Legiest will coordinate Belgian WP7 efforts and will provide medical insight for the specific topic chosen in WP6.2. She will also help with the implementation of the selected guidelines for WP6.2.		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	18 320,00 €	Participation at final co WP7 at proposed rates	onference + WP5 + WP6b +
	8 000,00 €	WP5 country to country	ry assessment
Total Costs (€) of (C)	26 320,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	7 822,18 €		
Total estimated eligible costs	119 567,59 €		
Total requested EC contribution (60% max)	71 740,55 €		

# 5. Bulgaria – NCIPD

Applicant Number	BG-5		
Short Name	NCIPD		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Todor Kantardjiev Microbiologist	4	3 600,00 €
	Ivan Ivanov Microbiologist	4	3 600,00 €
	Martyn Nedyalkov Microbiologist	3,9	3 315,00 €
	Elina Dobreva Microbiologist	4,5	3 825,00 €
	Rumiana Hristova technician	2	1 600,00 €
		Total Costs (€) of (A)	15 940,00 €
	Justification		
	activities will contribute to the recognition of the JA priorities on governmental level. Ivan Ivanov will harmonize the implementation of the objectives from the global AMR plan to national level and participate in the cross-country assessment. Martyn Nedyalkov will design and run pilot projects looking at effective implementation of guidelines.  Elina Dobreva is National Focal point on HAI and will ensure the relations with health care facilities for the implementation of the JA.  Rumiana Hristova will provide technical assistance on each task.		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	7 520,00 €	2 persons partitipation	in 4 GA meetings
	5 040,00 €	1 person partitipation in	n 7 mid-terms for WP5
	8 000,00 €	WP5 country to country	/ assessment
Total Costs (€) of (C)	20 560,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	2 555,00 €		
Total estimated eligible costs	39 055,00 €		
Total requested EC contribution (60% max)	23 433,00 €		

# 6. Croatia - HZJZ/CIPH

Applicant Number	HR-6		
Short Name	CIPH		
(A) Direct personnel	Persons (position)	Total Person-Month	Total Costs (€) of (A)
costs (including Public officials)	Blazenka Hunjak - Microbiologist MD	4	14 000,00 €
	Anamarija Pejnovic - Engineer of laboratory diagnostics	2,75	3 575,00 €
	Vladimir Hunjak Stula - Administrative officer	0,95	1 615,00 €
	Tatjana Unukic – Engineer of laboratory diagnostics	2,75	3 575,00 €
	Martina Jelinic – Financial officer	0,95	1 805,00 €
		Total Costs (€) of (A)	24 570,00 €
	Justification	l.	
(C) Other direct costs	experience. Also we would like t - non Public official person who		rk on the project, Project manager ent and monitor this project.
(C.1) Travel	Costs (€)	Justification	
	7 520,00 €	Kick off meeting + 3 General	Assembly for 2 people 2 days
	10 000,00 €	_	os in 4 different cities in Croatia -
(C.3) Other goods and services	Costs (€)	Justification	
	10 000,00 €	Cost for WP7 materials for w	orkshops (training materials etc)
Total Costs (€) of (C)	27 520,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	3 646,30 €		
Total estimated eligible costs	55 736,30 €		
Total requested EC contribution (60% max)	33 441,78 €		

# 7. Czech Republic – NIPH

Applicant Number	CZ-7		
Short Name	NIPH		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Mackova Barbora - Project manager	2	4 815,00 €
	Zemlickova Helena – Microbiologist	7	13 556,00 €
	Jakubu Vladislav - Data manager	2	3 741,00 €
	Jindrak Vlastimil - Microbiologist	13	28 704,00 €
	Vanis Vaclav - Microbiologist	3	5 407,00 €
	Hedlova Dana - Epidemiologist	4	7 222,00 €
	Adamjak Tomas - Financial expert	4	9 852,00 €
		Total Costs (€) of (A)	73 297,00 €
	Justification		
	and have minimal ten years experience and expert knowledge in topics of proj communicate, in their main topics, with national and international subjects (MECDC, WHO, etc.). They have the experience in the science, research and teach NIPH is a health care establishment for basic disciplines in public health. activities of NIPH comprise science and research, reference and methodologic surveillance of communicable diseases, preparation of legislation in the field protection, including harmonization of Czech legislation with the norms of the Union. NIPH plays an active role in pre- and post graduate training and in a medical education of physicians and other health care workers.		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
(42)		all meetings	
	8 000,00 €		ssessment
(C.3) Other goods and services	Costs (€)	Justification	
	6 000,00 €	organization on the nation	nal workshops
	4 000,00 €	materials for workshops f	•
Total Costs (€) of (C)	41 360,00 €		
(D) Indinest Costs (B4 70)	0.025.00.0		
(D) Indirect Costs (Max. 7% on A, B and C)	8 025,99 €		
Total estimated eligible costs	122 682,99 €		
Total requested EC contribution (60% max)	73 609,79 €		

# 8. Denmark - SSI

<b>Applicant Number</b>	DK-8			
Short Name	SSI			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	B. Kristensen (Head,	3,5	14 000,00 €	
	microbiologist)			
	UW Sönksen (project manager)	4	16 000,00 €	
	S Skovgaard (project manager)	3,5	12 000,00 €	
	Technician	2	4 000,00 €	
		Total Costs (€) of (A)	46 000,00 €	
	Justification			
	B. Kristensen: Coordinating the Danish participation, UW Sönksen: coordinating project. S Skovgaard projectmanaging of the pilot project. Technichian (NN): hadata			
(B) Direct costs of sub-	Costs (€) Tasks subcontracted			
contracting	28 000,00 € In WP7, task 7.4.2 related to animal sector			
Total Costs (€) of (B)	28 000,00 €			
	Justification for resorting to subcontracting			
	Danish National Veterinary Institute skills and expertise to do so.	e (DTU VET) will contribute to	task 7.4.2, having the	
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	7 520,00 €	•		
		(including mid-terms WP7 meetings)		
Total Costs (€) of (C)	7 520,00 €			
(2)				
(D) Indirect Costs (Max. 7% on A, B and C)	5 706,40 €			
Total estimated eligible costs	87 226,40 €			
Total requested EC contribution	52 335,84 €			
(60% max)	51333,54 0			

# 9. Estonia – TA

Applicant Number	EE-9				
Short Name	TA				
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)		
(including Public officials)	Pille Mârtin -	6	10 920,00 €		
	Infectionist, Senior				
	Researcher				
	liris Saluri - Information	5	10 075,00 €		
	specialist				
	Olga Sadikova –	6	10 920,00 €		
	Epidemiologist, Chief specialist				
	Specialist	Total Costs (€) of (A)	31 915,00 €		
	Justification	Total costs (e) of (A)	31 313,00 €		
		tion control doctor omploy	ad by Estapian Health Board 10		
			ed by Estonian Health Board. 10 I level) incl. participation in		
	7		).5 years experience at national		
			nglish. Her experience is needed		
	T		eventing HCAI by implementing		
			iate use of antimicrobials in		
	healthcare).				
	Ma livia Caluvi ia a manag	or of public relations in Est	tonian Health Deard for over 10		
	_	· · · · · · · · · · · · · · · · · · ·	tonian Health Board for over 10 es. Experience in carrying out		
		-	g information sources; excellent		
		· · · · · · · · · · · · · · · · · · ·	to carry out activities in WP8		
	(Awareness raising and co		,		
		_	lealth Board. She has university		
	=		ence in carrying out infection and of English. Dr Sadikova will		
	assist the remaining team		and of English. Di Sadikova will		
	assist the remaining team	THE CHEST			
(C) Other direct costs					
(C.1) Travel	Costs (€)	Justification			
	7 520,00 €	WP1, 2 persons, 4 Genera	l Assembly meetings x 2 days		
	5 760,00 €	WP6 a+b, 1 person, 8 mee	etings x 1 day		
	2 160,00 €	WP8, 3 meetings, 2 persons			
Total Costs (€) of (C)	15 440,00 €				
(D) Indirect Costs (Max. 7% on	3 314,85 €				
A, B and C)  Total estimated eligible costs	50 669,85 €				
Total requested EC contribution (60% max)	30 401,91 €				

# 10. Germany – RKI

Applicant Number	DE-10		
Short Name	RKI		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Epidemiologist (WP7)	6	45 000,00 €
	Epidemiologist (WP5)	5,5	41 250,00 €
		Total Costs (€) of (A)	86 250,00 €
	Justification		
	WP7: we need an experienced epidemiologist who ist able to perform: a review of the literature of measurements to foster the prudent use of antibiotics in the outpatient setting. Especially feedback systems in different health systems will be a focus of the review. E.g. in the German setting one way to do so is the communication channels of the Associations of Health Insurance Doctors. But this is done only in some of the 17 Associations and in different forms. For the country exchanges Germany will provide a structured questionnaire, which will be discussed by the countries in the meeting. WP5: we need an experienced epidemiologist who is experienced in auditing of countries.		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	7 520,00 €	annual GA Meetings (3x) +	KoM
	2 160,00 €	WP5 3 midterms meetings	(outside GA Meetings)
	8 000,00 €	WP5 country to country ass	sessment
Total Costs (€) of (C)	17 680,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	7 275,10 €		
Total estimated eligible costs	111 205,10 €		
Total requested EC contribution (60% max)	66 723,06 €		

# 11. Greece - HCDCP

Applicant Number	GR-11		
Short Name	HCDCP		
(A) Direct personnel costs (including Public officials)	Persons (position)	Total Person- Month	Total Costs (€) of (A)
	(To be hired) Project manager (1)	36	79 200,00 €
	Scientific staff (HCDCP personnel)	39	95 796,21 €
	Technical support (HCDCP personnel)	8	16 000,00 €
	scientific staff for WP6 (HCDCP personnel)	12	28 800,00 €
	scientific staff for WP7 (HCDCP personnel)	5	12 000,00 €
	To	otal Costs (€) of (A)	231 796,21 €
	Justification		
	and infectious diseases with significant in public health. They will participate three tasks of the WP61. Additional implementation of the Universal Infect hospitals and participate in W6.2.1 ar occupied with the collection of surveill project. A project manager- a fulltime monitoring the implementation of the	in all of the activities nally, they are go tion Control Preogrand in W7.4 tasks. The lance data and the and job dedicated property.	s of the leading team of the ing to contribute to the im of the 2nd Task in Greek e technical personel will be dministrative support of the ofessional will be hired for
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
(C.1) Havei	5 760,00 €		
	5 760,00 €	1	
	6 000,00 €	leading team (2 pro	
	0 000,00 €	• , ,	4 main meetings of 6.1
	500,00 €	Interviews of survey	у В
(C.2) Equipment	Costs (€)	Justification	
	·	regarding HAIs prev	
	20 000,00 €	development (WP7	l surveillance data base )
(C.3) Other goods and services	Costs (€)	Justification	
	10 000,00 €	Health economics s	tudy (WP6)
	10 000,00 €	Translation editing	(WP6)
Total Costs (€) of (C)	78 020,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	21 687,13 €		
Total estimated eligible costs	331 503,34 €		
Total requested EC contribution (60% max)	198 902,01 €		

# 12. Greece - ESDY- NSPH

Applicant Number	GR-12					
Short Name	ESDY-NSPH					
(A) Direct personnel costs	Persons (position)	<b>Total Person-Month</b>	Total Costs (€) of (A)			
(including Public officials)	Medical Microbiologist (A. Vatopoulos)	7	22 291,20 €			
	Biologist PhD (P Giakkoupi)	12	30 033,26 €			
	Veterinarian PhD (Em. Papadogianakis)	7	16 604,00 €			
	Veterinarian PhD (M Kontarini)	6	14 706,40 €			
	Sientist (biology. Bioinformatics) 18 27 500,00 €					
		Total Costs (€) of (A)	111 134,86 €			
	Justification					
	AR genes, and molecular typing. He will co (1 PM in WP5, 2WP in 6a, 4 pm in WP 7 studying the molecular mechanisms of AR bacteria in Greece for the last 15 years, wil task "Develop and test near real time s resistant bacteria" on "Select basic indica resistance" and "Reinforce current surve analyzed and available as soon as possible. in WP8.  Em Papadogiannakis and M Kontarini havapproach in Greece will participate in WP7 bringing their expertise will participate at 3 PM.  A. Vatopoulos, P Giakkoupi, Em Papadogai of NSPH. The Biologist / Bioinforamics will data plus strains collection for real time to project.	r). P. Giakkoupi, who pand the dissemination II participate in WP7 (Plurveillance of antimicators for surveillance systems in order He will also dedicated and systems in developed for the veterinarian systems and M Kontarini work in WP7 (we will in the systems).	plays a leading role in of resistant genes and M 10) especially in the robials and multidrug estem of antimicrobial der to have the data 1 PM in WP2 and 1 PM oping the one health each). They will also side of this WP7. Each are already employes include a pilot study of			
(C) Other direct costs						
(C.1) Travel	Costs (€)	Justification				
	5 040,00 €	WP5				
	5 760,00 €					
	7 520,00 €	_	+ 3 General			
	8 000,00 €	Assembly meetings WP5 country to count	try assessment			
Total Costs (€) of (C)	26 320,00 €	VVP3 Country to count	try assessment			
Total Costs (e) of (c)	20 320,00 €					
(D) Indirect Costs (Max. 7% on A, B and C)	9 621,84 €					
Total estimated eligible costs	147 076,70 €					
Total requested EC contribution (60% max)	88 246,02 €					

#### 13. Greece - 7th HR CRETE

<b>Applicant Number</b>	GR-13			
Short Name	7HC			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Aimilia Magkanaraki (Administration	1	2 202,00 €	
	staff, Head of Health Policies Planning			
	and Development Department)			
		Total Costs (€) of (A)	2 202,00 €	
	Justification			
	Mrs Magkanaraki (MSc) will carry out the a	administration and organ	izational procedures	
	neccessary to fullfill the project.			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	7 520,00 €	Travels for KoM + 3 GA meetings		
	5 760,00 €	WP6.1 meetings		
	1 440,00 €	WP9 meetings		
Total Costs (€) of (C)	14 720,00 €			
(D) Indirect Costs (Max. 7% on	1 184,54 €			
A, B and C)				
Total estimated eligible costs	18 106,54 €			
Total requested EC contribution (60% max)	10 863,92 €			

Applicant Number	GR-13 Affiliated entity		
Short Name	University General Hospital of Heraklion- PAGNI		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Gikas Achilles (Prof Int. Medicine - Infectius Diseases at University General Hospital of Heraklion PAGNI)	4	20 800,00 €
	Irini Astrinaki (Infection diseases specialist, University General Hospital of Heraklion PAGNI)	4	7 608,00 €
	Argiri Messaritaki (Infection diseases specialist, University General Hospital of Heraklion PAGNI)	4	7 608,00 €
		Total Costs (€) of (A)	36 016,00 €
	Justification		
	Professor Achilles Gikas is an infectius control and more than 20 years of E participation in projects. Due to his expe Health Region of Crete for all WPs involv qualified infection control specialists with assist in carrying out the tasks assigned in	European experience, a ertise, he will lead the tea red.Mrs Astrinaki and Mr h at least 5 years of hosp	ctive bibliography and am on behalf of the 7th s Messaritaki are highly

(D) Indirect Costs (Max. 7% on	2 521,12 €	
A, B and C)		
Total estimated eligible costs	38 537,12 €	
Total requested EC contribution	23 122,27 €	
(60% max)		

## 14. Italy – UNIFG

Applicant Number	IT-14			
Short Name	UNIFG			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Full professor of Hygiene (Rosa Prato, UNIFG)	7	36 419,25 €	
	Assistant Professor of Hygiene (Domenico Martinelli, UNIFG)	6,8	29 054,65 €	
	Medical doctor (Contractor)	10	38 239,50 €	
		Total Costs (€) of (A)	103 713,41 €	
	Justification			
	The UNIFG Unit is involved in WPs 3, 1 epidemiologist, with approximately 2 disease and chronic disease epidemio An Assistant Professor of Hygiene will Contractor Medical doctor will work f	O years of professional exp logy will coordinate the ta manage the activities and	erience in infectious sks selected in each WPs.	
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	7 520,00 €	4 General Assembly (2-da	y meetings for 2 person)	
	5 040,00 €	€ <b>WP5</b> - 7 mid-terms meetings (one person for 1 d meeting)		
	5 760,00 €	<b>WP6a</b> - 4 mid-terms meet day meeting)	tings (Two persons for 1-	
	8 000,00 €	WP5 country to country a	ssessment	
	2 160,00 €	<b>WP8</b> - 3 (2 Teds & 1 High	Level)	
Total Costs (€) of (C)	28 480,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	9 253,54 €			
Total estimated eligible costs	141 446,94 €			
Total requested EC contribution (60% max)	84 868,17 €			

### 15. Italy - ISS

Applicant Number	IT-15		
Short Name	ISS		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	A. Pantosti - Director of Research	4	43 951,40 €
	A. Carattoli - Director of Research	3	24 369,48 €
	P. Pezzotti - Senior Researcher	5	37 937,35 €
	L. Busani - Senior Researcher	11	75 583,75 €
	F. Prestinaci - Tecnologist	4	29 210,00 €
	A. M. Marella - Technical	2	7 131,90 €
	collaborator		
		Total Costs (€) of (A)	218 183,88 €
	Justification		
	Microbiologist expert in AMR transmission at the molecular level will participate in W PM) and WP9 (2 PM) (task 9.1-9.2). P. Pezzotti, a statistician epidemiologist will particip WP6 (3 PM) and WP7 (2PM) (task 7.3). L. Busani, a veterinarian epidemiologist experience in project evaluation will participate in WP7 (11 PM) and WP9 (1PM). F. Prest a famacist will participate in WP6 (3 PM) and WP7 (1PM). A. M. Marella, a tecl collaborator, will give secretarial assistance to WP3 (2 PM).		
(-)	T- (-)	I	
(B) Direct costs of sub- contracting		Costs (€) Tasks subcontracted	
		WP3 task 3.2-3.5-3.6	
Total Costs (€) of (B)	75 000,00 €		
	Justification for resorting to subco		
	Some of the activities of WP3 will be subcontracted to a party with proven experience in the field of evaluation and experience in the setting and use of appropriate evaluation tool Subcontracting will regard the activities related: 25,000 Euro for task 3.2 (Development evaluation tool): Definition and provision of web-based tools to collect data and run survey. Their testing and revision during the project; 25,000 Euro for task 3.5 (Report of results relevant stakeholders): Preparation of an interim and final reports containing all indicate and data and the evaluation of the impact of the project actions. Presentation of the report to the internal and external stakeholder; 25,000 Euro for the evaluation of the impact Europe. Preparation and analysis of questionnaires to national, regional and local authorities well as to professionals and citizens associations and analysis of official data and other information from EU MS national and subnational web-sites		of appropriate evaluation tools. To for task 3.2 (Development of to collect data and run surveys. For task 3.5 (Report of results to reports containing all indicators ons. Presentation of the reports the evaluation of the impact in al, regional and local authorities
(C) Other direct costs		1	
(C.1) Travel	Costs (€)	Justification	
	5 640,00 €	ISS - 2 person for 2 day p	
	1 440,00 €	•	
	15 040,00 €	persons to visit 4 recruit	or 2 persons + WP6 WP7 2 ed hospitals in Italy ing 2 persons x 1 day (other
		location than Rome)	
(C.2) Equipment	Costs (€)	Justification	
	5 000,00 €	pc, laptops, tablets and	printers

(C.3) Other goods and services	Costs (€)	Justification
	11 314,00 €	GA general meeting event preparation + WP3 1st mid-
		term meeting prepartion (13 persons)
	20 000,00 €	teleconferences, web tools, software updating at the
		central and laboratory level (to reinforce surveillance
		system), courier mail, printed materials
	32 000,00 €	·
		WP6 (Universal Infection Control Framework):
		contribution to the expenses of 4 hospitals for
		laboratory investigations and a part-ime infection
		control person in each hospital for 1 year.
Total Costs (€) of (C)	91 874,00 €	
(D) Indirect Costs (Max. 7% on	26 954,05 €	
A, B and C)		
Total estimated eligible costs	412 011,93 €	
Total requested EC contribution (60% max)	247 207,16 €	

Answer to CHAFEA questions about the salary amount: The monthly rate is correct and includes: salary, social security contribution, and direct income taxes

#### 16. Latvia - PSKUS

Applicant Number	LV-16		
Short Name	PSKUS		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Uga Dumpis - Project team leader	2,6	8 794,00 €
	Elina Dimina, Alise Gramatniece - Medical expert	3,4	4 216,00 €
	Jelena Urbena - Infection control nurse	3,4	3 000,00 €
	Liga Grudule - Administrative coordinator	2,6	5 040,00 €
		Total Costs (€) of (A)	21 050,00 €
	Justification		
(C) Other direct costs	level, cooperation with other specialists, data collection and analysis, trainings fo staff. Infection control nurse - applying project guidelines for internal use, implem of infection control measures, reporting on project medical activities and Administrative coordinator - management of financial and administrative communication with lead partner, reporting, organizational work for travels meetings.		
(C.1) Travel	Costs (€)	Justification	
(C.1) Havei	7 520,00 €		gs (2 norsons 2 days)
	· ·	,	
(0.0)	5 760,00 €	J 1	persons, 1 day)
(C.3) Other goods and services	Costs (€)	Justification	
sei vices	500,00 €	Training materials (simulato	ors, disposables, visual aids)
Total Costs (€) of (C)	13 780,00 €	, ,	, , , , , , , , , , , , , , , , , , , ,
(D) Indirect Costs (Max. 7% on A, B and C)	2 438,10 €		
Total estimated eligible costs	37 268,10 €		
Total requested EC contribution (60% max)	22 360,86 €		

#### 17. Lithuania - LSMULKK

Applicant Number	LT-17		
Short Name	LSMULKK		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Astra Dambrauskiene -	9	16 200,00 €
	Information scientist		
	Asta Vitkauskiene –	9	16 200,00 €
	Information scientist		
	Lukas Cemnalianskis –	9	3 510,00 €
	Information scientist		
		Total Costs (€) of (A)	35 910,00 €
	Justification		
(C) Other direct costs	implementation of WP2, WP5, WP6, WP7. Asta Dambrauskiene – MD, phy Laboratory Medicine, the head of Infection Control Service in tertiary health care 10 years of experience in clinical microbiology, the head of hospital infection cont in hospital. She will be staff member in in the implementation of WP5, WP6, WCemnalanskis – MD, the resident of Laboratory Medicine, works in hospital Microbiology, responsible for management of Microbiology Laboratory information. He will be staff member in in the implementation of WP6, WP7.		
(C.1) Travel	Costs (€)	Justification	
(C.1) Havei	2 880,00 €	WP6A meetings	
	4 320,00 €	<u> </u>	
	·		
	3 760,00 €	WP1 Kick-off meeting an	d General Assembly
Total Costs (€) of (C)	10 960,00 €		
			· · · · · · · · · · · · · · · · · · ·
(D) Indirect Costs (Max. 7% on	3 280,90 €		
A, B and C)	50 150,90 €		
Total estimated eligible costs	-		
Total requested EC contribution (60% max)	30 090,54 €		

#### 18. Lithuania - VULSK

Applicant Number	LT-18		
Short Name	VULSK		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Edita Kazenaite – Clinical	3	9 900,00 €
	pharmacologist		
	Silvija Kiveryte – Physician of	3	8 700,00 €
	laboratory medicine		
	Ruta Ambrazaitiene – Physician of	2	5 800,00 €
	laboratory medicine		
	Asta Macioniene – Physician of	2	5 800,00 €
	laboratory medicine		
	Kristina Marcinkeviciene – Physician	2	5 800,00 €
	of laboratory medicine		
	Igne Venceviciute – Physician of	1	2 900,00 €
	laboratory medicine		
		Total Costs (€) of (A)	38 900,00 €
	Justification		
(C) Other direct costs	Clinical pharmacologist - 15 years experience in regulating antimicrobials usage in the hospital, leading HAI surveillance group in hospital, will be a key staff member in the implementation of WP6:2  Physician of laboratory medicine - long experience working with HCAI and AMR, participation in AMR networks, will be a key staff member in the implementation of WP6:2.  Physician of laboratory medicine - long experience working with HCAI and AMR, member of the HAI surveillance group in hospital, will be a key staff member in the implementation of WP6:2.  Physician of laboratory medicine - experience working with AMR, participation in AMR networks, will be a staff member in the implementation of WP6:2.  Physician of laboratory medicine - experience working with AMR, participation in AMR networks, will be a staff member in the implementation of WP6:2.  Project manager - 5 years experience in managing different projects in hospital, will be a key staff member in WP2.		
(C.1) Travel	Costs (€)	Justification	
	5 760,00 €	4 European travel in WP (hospital)	6:2, task 6:2:1, 2 persons
	7 520,00 €	4 General assembly, WP (hospital)	1, meetings, 2 persons
	1 760,00 €		njuction to general rsons. (EUR 220 per diem x
Total Costs (€) of (C)	15 040,00 €	o days) (Hospital)	
(D) Indirect Costs (Max. 7% on A, B and C)	3 775,80 €		
Total estimated eligible costs	57 715,80 €		
Total requested EC	34 629,48 €		
contribution (60% max)			

#### 19. Lithuania - HI

Applicant Number	LT-19		
Short Name	HI		
onore realine			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Akvile Kenstaviciene - WP5 Specialist	3,5	7 965,00 €
	Rolanda Valinteliene - WP5 & 7 Leader	6,5	16 315,00 €
	Agne Plentaite - WP6 Specialist	6	13 654,00 €
	Virginija Kanpeckiene - WP6Leader	6	15 061,00 €
	Greta Gasiunaite - Project coordinator	18	45 184,00 €
		Total Costs (€) of (A)	98 179,00 €
	Justification		
	has experience in organisation and implementation of national AMR and HCAI or programs, initiation and implementation of national legal act, participation in Europrojects and programs, ECDC national focal point for AMR and HCAI. Agne Plentait experience in organisation and implementation of national HCAI surveillance programs initiation and implementation of national legal acts, ECDC national technical focal point HCAI. Virginija Kanpeckiene has experience in planning and organisation of national surveillance and national public health programs. Greta Gasiunaite has experience in pland organisation of national and regional public health projects.		legal act, participation in European AMR and HCAI. Agne Plentaite has ational HCAI surveillance programs, DC national technical focal point for g and organisation of national HCAI Gasiunaite has experience in planning
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	3 760,00 €	*General Assembly: (500+	220+220)x1x4 (WP7)
	5 040,00 €	7 mid-terms: 500+220) x1	x4 (WP5)
	2 880,00 €	4 mid-terms: (500+220) x1	. x4 (WP6b)
	8 000,00 €	WP5 country to country as	ssessment
(C.3) Other goods and services	Costs (€)	Justification	
	3 500,00 €		erence to represent JA project g with stakeholders (conference quipment, travel costs).
Total Costs (€) of (C)	23 180,00 €		·
(D) Indirect Costs (Max. 7% on A, B and C)	8 495,13 €		
Total estimated eligible costs	129 854,13 €		
Total requested EC contribution (60% max)	77 912,48 €		

#### 20. Lithuania - NVSC

Applicant Number	LT-20		
Short Name	NVSC		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Robertas Petraitis (Manager)	1,8	5 016,86 €
	Asta Razmiene (Researcher)	3	6 039,64 €
	Ingrida Skridailiene (Researcher)	2	4 907,73 €
	Giedre Aleksiene (Researcher)	1,7	2 949,73 €
	Brigita Kairiene (Researcher)	1,22	2 029,27 €
	Ginreta Valinciute (Researcher)	1,64	1 458 ?43 €
		Total Costs (€) of (A)	22 401,65 €
	Justification		
(C) Other direct costs (C.1) Travel	Robertas Petraitis a Doctor of Hygiene and Epidemiology with a university degree in medicine and has a half of year of experience in managing Joint Action Programme at national level. The role in JA – managing JA at national level, communication with JA management bodies, communication with national institutions, stakeholders.  Asta Razmiene is a Doctor of Hygiene and Epidemiology with a university degree in medicine and has more than 20 years of professional experience in public health safety control in Vilnius County, including inspections of healthcare institutions, also in communicable and non-communicable diseases epidemiology and environmental health. The role in JA – WP6.2 activities at regional level, focus on study and acting activities. Ingrida Skridailiene is a Public Health Specialist with a university degree; has more than 10 years of professional experience in public health activities at national level, including planning and implementation. The role in JA – WP6.2 activities at national level, focus on planning and implementation measures.  Giedre Aleksiene is an Epidemiologist with a university degree; has more than 20 years of professional experience in public health activities, including control of communicable diseases and hospital acquired infections in Vilnius County and a half of year of experience in public health activities at national level, planning and implementation. The role in JA – WP8 activities at national level, focus on planning and implementation of measures.  Brigita Kairiene – is a Public Health Specialist with a university degree, has more than 13 years of professional experience in Public Health, 4 of them – in communicable diseases epidemiology and 3 years experience in managing antimicrobial resistance (AMR) group activities in Klaipeda County. The role in JA – coordinating WP7 activities in regional level, providing comments and suggestions for implementation of measures at regional level.  Ginreta Valinciute is a Public Health Specialist with a university degree (relate		
(C.I) ITAVEI	Costs (€)	Justification	able (MD4) for 2 many 2
	7 520,00 €		nbly (WP1) for 2 people 2 days
Total Costs (C) - 5 (C)		4 European travels for	WPb
Total Costs (€) of (C)	13 280,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	2 497,72 €		

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Total estimated eligible	38 179,37 €	
costs		
Total requested EC	22 907,62 €	
contribution (60% max)		

#### 21. Netherlands – VWS

Applicant Number	NL-21			
Short Name	VWS			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	(Rosa Peran) WP nr. 5 coordination WVS-IZ	12	111 000,00 €	
	(Jacqueline Pronk) WP nr. 5 coord. Adm. VWS-IZ	3	13 800,00 €	
	(Maria Legrand / Jolanda vd Kamp) WP nr. 5 policy officer WVS-PG	3	22 500,00 €	
	(Merel Langelaar) WP nr. 5 expert VWS-IGZ	7	64 750,00 €	
	(Carline vd Dool) WP nr. 5 expert VWS-RIVM	7	52 500,00 €	
	(Lili Guo) WP nr. 9 policy advisor innovation VWS-GMT	4	30 000,00 €	
	(Arjan Elsenmulder) WP nr. 8 communication spec. VWS-DCO	2	15 000,00 €	
	(Merel Langelaar / Carline vd Dool) WP nr. 6 experts VWS-RIVM/IGZ	2	18 500,00 €	
	(Merel Langelaar / Carline vd Dool) WP nr 6 professional VWS RIVM-IGZ	5	37 500,00 €	
	To be defined WP nr. 7 profesional VWS-RIVM	2	15 000,00 €	
		Total Costs (€) of (A)	380 550,00 €	
	Justification	.,,,,	<u>'</u>	
	activities of the Joint Action. Jacqueline Maria Legrand/Jolanda vd Kamp (or equival specially Task 5.1 and 5.2. Merel Langelaar all task of WP5 and leader Task 5.3. Carli contribution to task 5.1 and 5.2.; WP9: Lil VWS-GMT: contribution to WP9; WP8: Arjs specialist VWS-DCO, contribution to WP8 tasks in this WP. WP6: Merel Langelaar a infection prevention from VWS-RIVM and both WP6 and coordination in the NL of heat this moment: (contribution 3+1,7 perso prevention. WP 7: Carline vd Dool (or experts of VWS-RIVM to the activities of WF + Names not known at this moment (contribution).	lent): Policy offcier VWS-PC (or equivalent): Expert VW ine vd Dool (or equivalent): polican Elsenmulder (or equivalent): an Elsenmulder (or equivalent) and Carline vd Dool (or ectivation Octobrospitals and nursing home in-month) professional of Policy and coordination with hearibution 0,8 person month	G contribution to WP5, /S-IGZ, contribution to t): Expert VWS-RIVM: icy advisor innovation lent): Communication ed for the otehr pther quivalent): experts on 8+0,4) contribution to s. + names not known RIVM/IGZ on infection 1,42 person/month of ospital/nursing homes	
(D) Direct costs of sub	VWS-RIVM (microbiology, phfarmacology a			
(B) Direct costs of sub- contracting	Costs (€)  80 000,00 €	Tasks subcontracted WP 6 & 7: costs of particinursing homes.	pating hospitals and	
Total Costs (€) of (B)	80 000,00 €	nursing nomes.		
,	Justification for resorting to subcontracting	<u>variantinininininininininininininininininin</u>		
	Hospitals and nursing homes don't belong to the Dutch government. They are private instituitions. That's the reason they are considered sub contractors. Based on the available			

information as provided by the WP leaders at the time of stimating this budget, the cost of the subcontracting has been estimated calculating the workload and translating it into person month units. Other cost like travel cost or equipment are not included in this estimation and will be coverd by VWS. WP6: 5,6 person month x 7500 euro = 37500 euro = (incl: professionals on infection prevention and manamgent) WP6B: 5,1 person month x 7500 euro = 37500 euro (incl. professionals on infection prevention). WP7: 3,84 person month x 7500 euro = 28800 euro (incl. micorbiologist/phamacologist/nurse). With the information available at this moment it is not possible to sign start yet a formal dialogue contract with hospitals/nursing homes, and therefore it is not possible to indicate the name of the hospital/nursing homes and provide a more exhaustive estimation of the costs.

	_		
(C) Other direct costs			
(C.1) Travel	Costs (€)		Justification
		5 040,00 €	WP5. One person for a one day pWG meeting
			(720). Seven p WG-meetings. In three years.
			Wp 5 in case of meetings not hold in
			Netherland (but for example in BXL or LUX).
		15 000,00€	WP5, 3 experts invited for one pWG meeting
			(720). 5 pWG meetings in 3 years.
		1 440,00 €	WP 9, two meetings
		2 160,00 €	WP 8 three meetings
		8 000,00 €	WP5: Country to country visits
		7 520,00 €	WP1: AG Assembly meetings (4x2 persons)
		5 760,00 €	report to the One health Workgroup in
			Brussels (4)
(C.3) Other goods and services	Costs (€)		Justification
		30 800,00 €	Organisation seven physical meetings.
			Average 50 participants. 88 euro per person.
		2 100,00 €	Webex/Audio conference 14 times 150€
Total Costs (€) of (C)		77 820,00 €	
(D) Indirect Costs (Max. 7%		37 685,90 €	
on A, B and C)			
Total estimated eligible		576 055,90 €	
costs			
Total requested EC		345 633,54 €	
contribution (60% max)			

## 22. Norway – Hdir

Applicant Number	NO-22			
Short Name	HdiR			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Senior advisor 1, antiobiotic use in GP	2,00	18 217,00 €	
	Senior advisor 2, AMR action plans	2,00	20 998,00 €	
		Total Costs (€) of (A)	39 215,00 €	
	Justification			
	following employees: Senior adviser 1 is working at the department of Community Healt Services and is responsible for infectious diseases and for the Norwegian guidelines for antibiotic use in General Practice. Senior adviser 2 is working at the Department of Medicinal Devices and Medicinal products and especially with implementing policies an interventions in health care services, including clinical guidelines and action plans against antimicrobial resistance. Tasks 7.1, 7.3 and workshop 7.2. Participation in 7.4 is currently not clarified yet.			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	7520 €	KoM + 3 GA meetings for	2 people 2 days	
	1 880,00 €	Additional WP 7 meeting,	2 days, 2 people	
Total Costs (€) of (C)	9 400,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	3 403,05 €			
Total estimated eligible costs	52 018,05 €			
Total requested EC contribution (60% max)	31 210,83 €			

### 23. Norway – FHI

Applicant Number	NO-23			
Short Name	FHI			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Senior Advisor - Christine Årdal (WP9)	16,37	120 006,60 €	
	Advisor - Live Storehagen (WP9)	16,33	91 980,05 €	
	Senior physician - Oliver Kacelnik (WP7)	14,52	150 786,92 €	
	Physcian PhD candidate - Cecilia Kållberg (WP7)	18,00	101 706,52 €	
	Senior Researcher - Hege Salvesen Blix (WP7)	2,41	25 027,18 €	
		Total Costs (€) of (A)	489 507,27 €	
	Justification			
(C) Other direct costs	work packages - WP7 and WP9. contributions as well as support staff.			
	Costs (6)	Justification		
(C.1) Travel	Costs (€)		ropean travels for one person of WP9	
	9 360,00 €	(9.1=3; 9.2=6)	eis for one person of WP9	
	12 960,00 €		nt in WP7 to cover face to nplementation of the pilot	
	7 520,00 €	General Assembly - 2 permeetings	ersons for 2 days for 4	
Total Costs (€) of (C)	29 840,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	36 354,31 €			
Total estimated eligible costs	555 701,58 €			
Total requested EC contribution (60% max)	333 420,95 €			

## 24. Norway – NVI

Applicant Number	NO-24			
Short Name	NVI			
(A) Direct personnel costs (including Public officials)	Persons (position)	Total Person- Month	Total Costs (€) of (A)	
	WP9, NVI staff members with	7,00	49 000,00 €	
	complementary expertise as			
	described in partner description			
	form (senior scientists)			
	٦	Total Costs (€) of (A)	49 000,00 €	
	Justification			
	Research staff at the Norwegian Veterinary Institute (NVI) that will be involved in the acceptable to have complementary backgrounds as described in partner description form. These members have been active in development and implementation of the Norwegian strain and action plan against AMR in the veterinary sector and are involved in several acceptable and development projects. The total costs may seem high, but simply reflects high costs in Norway.			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	720,00 €	Mandatory meeting	WP9, one person	
	3 760,00 €	Three mandatory GA	A meeting, 1 persons + KOM	
Total Costs (€) of (C)	4 480,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	3 743,60 €			
Total estimated eligible costs	57 223,60 €			
Total requested EC contribution (60% max)	34 334,16 €			

### 25. Poland - NMI

Applicant Number	PL-25			
Short Name	NMI			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Waleria Hryniewicz - Prof. in medicine expert in AMR and HAI	4	9 638,55 €	
	Dorota Zabicka - PhD specialist in clinical microbiology and AMR	5	7 831,33 €	
	Anna Olczak-Pienkowska – Public health professional, specialist in antibiotic consumption	4	5 263,16 €	
	,	Total Costs (€) of (A)	22 733,04 €	
	Justification			
		the experience in the particip	ne National Program for Antibiotic nation in the program in Poland; antibiotic consumption.	
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	7 520,00 €	4 General Assembly meetings for 2 persons (1 national/regional)		
	5 040,00 €	WP5 7 meetings one day for 3	1 person	
	8 000,00 €	WP5 country to country asses	ssment	
Total Costs (€) of (C)	20 560,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	3 030,51 €			
Total estimated eligible costs	46 323,55 €			
Total requested EC contribution (60% max)	27 794,13 €			

### 26. Portugal – DGS

Applicant Number	PT-26			
Short Name	DGS			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Paulo André Fernandes - Physician,	2	9 200,00 €	
	Intensivist, IPC&AMR practicioner			
	Carlos André Palos - Physician,	2	9 200,00 €	
	Intensivist, IPC&AMR practicioner			
	Pedro Pacheco - Physician, General	2	9 200,00 €	
	Practicioner		0.400.00.0	
	Ana Paula Cruz - Reg. Nurse	3	8 400,00 €	
	Specialist, IPC practicioner	4.5	12.600.00.6	
	Margarida Valente - Reg. Nurse Specialist, IPC practicioner	4,5	12 600,00 €	
	Isabel Neves - Physician,	5	23 000,00 €	
	Infecciologist,IPC&AMR practicioner	3	23 000,00 €	
	intecciologist, in each with practicioner	Total Costs (€) of (A)	71 600,00 €	
	Justification			
	work in ES, IPC & AMR Pedro Pacheco—Physician, General Practicioner, member of IPC&AM national program coordination, field work in ES, IPC, AMR. Ana Paula Cruz — RN Specialis MasterD in HAI, member of IPC&AMR national program coordination, field work in ES IPC&AMR. Margarida Valente - RN Pediatric Specialist, Postgraduate in HAI, member of IPC&AMR national program coordination, field work in ES, IPC&AMR. Isabel Neves - Physician Infecciologist, member of IPC&AMR national program coordination, field work in ES IPC, AMR.			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	11 520,00 €	WP6 A & B meetings (5720 meetings in Europe for 2 p	=	
	2 160,00 €	WP8 three meetings		
	7 520,00 €	WP1 : Kick-off meeting + 3	General Assembly	
		meetings for 2 people 2 da	=	
Total Costs (€) of (C)	21 200,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	6 496,00 €			
Total estimated eligible costs	99 296,00 €			
Total requested EC	59 577,60 €			
contribution (60% max)				

#### 27. Romania – UMPIH

Applicant Number	RO-27		
Short Name	UMPIH		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Mihu Dan - Professor	3,5	7 000,00 €
	Ciortea Razvan - Lecturer	4	4 400,00 €
	Malutan Andrei - Assistant professor	2,5	2 500,00 €
	Iuhas Cristian - Assistant professor	2,5	2 500,00 €
		Total Costs (€) of (A)	16 400,00 €
	Justification		
	clinical research; can have an study, having access in clinic international health networ	h results. Lecturer - extensive essential contribution in initial cal settings. Assistant professor ks. Assistant professor - has chical support for project impleduded in WP2, WP5, WP7.	ting and managing a pilot r - focuses on developing s experience in financial
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	11 840,00 €	4 General Assembly (2 days meetings)- WP1 and WP5 meetings	
	8 000,00 €	WP5 country to country assess	ment
Total Costs (€) of (C)	19 840,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	2 536,80 €		
Total estimated eligible costs	38 776,80 €		
Total requested EC contribution (60% max)	23 266,08 €		

#### 28. Slovenia – NIJZ

Applicant Number	SI-28		
Short Name	NIJZ		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Jana Kolman (senior researcher)	13	61 100,00 €
	Maja Subelj (junior epidemiologist)	6	18 000,00 €
	Mojca Serdt (junior epidemiologist)	3	6 300,00 €
	Mitja Vrdelja (communication	2	5 600,00€
	researcher)  Katja Turk (communication researcher)	2	4 800,00 €
	Petra Džinić (administration and financial officer)	1	2 000,00 €
		Total Costs (€) of (A)	97 800,00 €
	Justification		
	Jana Kolman, Mojca Serdt and Maja Subelj are experts in the field of AMR and HCAI involved in WP5 to contribute to the tasks (Task 5.1, Task 5.3); in WP6 to contribute and Task 6.2.2 and with 1 PM in WP9. Mitja Vrdelja and Katja Turk, experts in cor and Maja Subelj, will be involved in WP8 to contribute to the Tasks 8.4. Maja Sub Turk will be actively involved in the activities of dissemination of the JA results (WP		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
(0.2)	7 520,00 €	€ 4 GA meetings (2 persons)	
	5 040,00 €		
	2 160,00 €		
	8 640,00 €		
	0 040,00 €	national/regional and 2 hosp	·
	2 640,00 €		n to general assembly, one diem x 8 days) (1
	2 880,00 €		
		WP5 country to country asse	*
	1 440,00 €	· ·	
(C.3) Other goods and services	Costs (€)	Justification	
Scrvices	6 000,00 €	national meetings (room hiri capacities in all hospitals (no involved in the pilot)	
Total Costs (€) of (C)	44 320,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	9 948,40 €		
Total estimated eligible costs	152 068,40 €		
Total requested EC contribution (60% max)	91 241,04 €		

### 29. Spain – AEMPS

Applicant Number	SP-29			
Short Name	AEMPS			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	WP4,5,6,7, AEMPS Manager	36	112 500,00 \$	
	WP2 Communication Officer	30	93 750,00	
	WP8 Communication Officer	18	56 250,00	
	Communication Strategy	22	68 750,00	
	AEMPS Coordinator WP7	6	24 000,00	
	WP2&WP8 AEMPS Coordinator	12	42 000,00	
		Total Costs (€) of (A)	397 250,00	
	Justification	,		
	types of activities and promotions. It is need a Strategy Manager (partial time) and a Communication Officer (almost full time). AEMPS also participates as leader in WP7 and as associate partners in other WPs and our activity hast to be managed for a staff similar to Project manager. This would be coordinated for a AEMPS staff (6 months) and almost sure we will need to manage much information beetween partners and it would be very useful a manager assistance.			
(B) Direct costs of sub-	Costs (€)	Tasks subcontracted		
contracting	32 000,00 €	32 000,00 € Website Design and Implementation		
	22 000,00 €	, ,		
	25 000,00 €	SOCIAL CAMPAIGN 1 UNI	Т	
Total Costs (€) of (B)	79 000,00 €			
	Justification for resorting to subcontracting			
	Develop a website as central hub for internal communication as well as main platform to communicate outputs and disseminate the information to the targeted audiences: Design a document sharing or repository platform as for internal communication, and design and implementation of a web platform as for external dissemination. The benefit of developing this website in a way that best suits the needs of the project will ensure the key role of WP2 as the coordinating body of the dissemination activities for the project and make sure that results and relevant information produced over the lifetime of the project will not be lost and can continue to be a crucial part of JA products and services well into the future			
	In the WP8 we propose to carry out or School students or university students at the general public, journalists and horganizations. This event will cover the groups in a clear, accurate way so to conference could be divided in several and to be selected from, for example,	as speakers. It will focus of ealthcare/veterinary profe e most recent data on AMF that, eventually, we raise presentations by different	on scientific spreading targete ssionals or their representativ R in order to inform all of thes awareness on the topic. Th experts participating in JAMRA	

In the WP8, a Social campaign will be designed in order to address general public and healthcare professionals in both human and animal health, according to the One Health approach. The social campaign will be mainly structured online, on the basis of a video that will be promoted through

social media profiles. The video will be made as a creative and visually attractive piece of work that grabs general attention on the AMR problem. The project budget will consider organizing different online complementary materials/activities to the video (e.g. gifs, collaboration with influencers) in order to improve chances of it going viral and for the better spreading of our messages. All of the actions involved in this social campaign should be planned in detail and finally agreed upon between all the members of the JAMRI WP8 team in collaboration with the rest of participant or collaborating entities, (JA coordinator, ECDC, WHO-Europe) for this proposal to work as a starting point.

(C) Other direct costs		
(C.1) Travel	Costs (€)	Justification
	15 360,00 €	WP1, 5,6a,6b, 8 AEMPS travel costs
	3 000,00 €	Awards report and video 4 flights and DSA
	13 000,00 €	High level and Dissemination Conference 20 flights and DSA
	8 000,00 €	WP5 country to country assessment
(C.3) Other goods and services	Costs (€)	Justification
	12 000,00 €	Visual identity: logo, layman report, leaflets
	25 300,00 €	Catering high level and dissemination Conference 300 px + Organisation of a General Assembly meeting
	3 300,00 €	catering WP8 6 F2F
		15px
	6 000,00 €	·
		4 prizes
	2 500,00 €	·
		campaign as
		competition or game
	7 000,00 €	High level and Dissemination Conference streaming and short interviews
	21 600,00 €	3 promotional online campaigns to atract traffic to the website
Total Costs (€) of (C)	117 060,00 €	
(D) Indirect Costs (Max. 7% on A, B and C)	41 531,70 €	
Total estimated eligible costs	634 841,70 €	
Total requested EC contribution (60% max)	380 905,02 €	

# 30. Spain – GENCAT

Applicant Number	SP-30			
Short Name	GENCAT			
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
(including Public officials)	Gloria Oliva - Public health specialist	8	20 000,00 €	
	Marta Massanes - Pharmacy technician	8	20 000,00 €	
	Laura Navarro - Infectious disease physician	12	18 000,00 €	
		Total Costs (€) of (A)	58 000,00 €	
	Justification			
	Down below we detail the breakdown between the Work Package for Public Health specialist (PHS), the Pharmacy technician (PT) and the two Infectious disease physicians (IDP):			
	PHS: 3 months WP6 + 3 months WP7 + 2 months WP8: 8 months * 2.500 € = 20.000 €			
	PT: 3 months WP6 + 3 months WP7 + 2 months WP8: 8 months * 2.500 € = 20.000 €			
	IDP: 6 months WP6 + 6 months WP7: 12 months * 1.500 € = 18.000 €			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	5 760,00 €	Two persons for 1-day meet	ing corresponding to WP6a	
	1 440,00 €	Corresponding to WP8		
	7 520,00 €	General Assembly meetings	+ KoM	
Total Costs (€) of (C)	14 720,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	5 090,40 €			
Total estimated eligible costs	77 810,40 €			
Total requested EC contribution (60% max)	46 686,24 €			

## 31. Spain – IdISBa

Applicant Number	SP-31				
Short Name	IdISBa				
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)		
(including Public officials)	Benito Prosper - General	1,44	7 971,21 €		
	Manager of Planning, Evaluation				
	and Pharmacy	2.00	45.400.55.0		
	Eusebi Castano - Head Service of Health Planning	2,88	16 180,56 €		
	Antonio Oliver - Clinical	4,68	28 803,45		
	Microbiologist	4,00	20 003,43		
	Leonor Perianez - Clinical	4,32	32 693,50 €		
	Pharmacist				
	Elena Ferragut - Project Manager	2,52	8 654,29 €		
		Total Costs (€) of (A)	94 303,01 €		
	Justification				
	A General Manager from the Re	gional Ministry of Health to	critical review the documents		
	_	A General Manager from the Regional Ministry of Health to critical review the documents generated in WP6, 7, 8 and 9. A Head Service of Health Planning from the Regional Ministry of			
	Health to critical review th				
	A Clinical Microbiologist from the	_			
	Espases) to actively contribute to				
	generated in WP6, 8 and 9. A Clinical Pharmacist from the Health Service of the Balearics (Hospital Universitario Son Espases) to actively contribute to Task 1, 3 and 4 of WP7 and critical				
	review of documents generated in				
	budgetary, legal and administrativ	e aspects of the JA.			
(C) Other direct costs		T			
(C.1) Travel	Costs (€)	Justification			
	7 520,00 €		neetings, 2 persons, 2 days (1		
	0.510.00.0	regional and 2 hospital)			
	8 640,00 €	•	3 persons, 1 day (1 regional		
	2 160 00 €	and 2 hospital) WP8: 3 Mid-term meetings,	1 nercons 1 days		
		WP9: 2 Mid-term meetings,	<u> </u>		
Total Costs (€) of (C)	19 760,00 €	WF 3. 2 Wild-term meetings,	T persons, I day		
Total costs (e) of (c)	19 700,00 €				
(D) Indirect Costs (Max. 7%	7 984,41 €				
on A, B and C)					
Total estimated eligible	122 047,42 €				
costs					
Total requested EC contribution (60% max)	73 228,45 €				

## 32. Spain - FFIS

Applicant Number	SP-32 Fundacion para la For de Murcia	macion e Investigacio	n Sanitarias de la region
Short Name	FFIS		
- Short Hume	1113		
(A) Direct representations	Parana (nasitian)	Total Dance Manual	Total Casts (C) of (A)
(A) Direct personnel costs (including Public officials)	Persons (position)  Maria del Pilar Lopez Acuna -	Total Person-Month	Total Costs (€) of (A)
(including Fublic Officials)	Project Manager Coordinator		
	(FFIS)	7,50	23 857,50 €
	Gema Martin Ayala -	7,00	20 007,000
	Pharmacist/Project research		
	technician(2)(FFIS)	2,20	5 555,00 €
	Hana Hukelova - Project		
	management Technician (FFIS)	3,00	6 627,00 €
		Total Costs (€) of (A)	36 039 ,50 €
	Justification		
	responsible use of antibiotics in	infectious diseases, and	development of community
(C) Other direct costs	interventions to promote the Technician (FFIS) Participation in skills.	responsible use of antibe	piotics. Project management
(C) Other direct costs (C.1) Travel	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)	responsible use of antibe evaluation, administrative	piotics. Project management support and communication
	interventions to promote the Technician (FFIS) Participation in skills.	Justification 4 General assambly 2-da (WP1)	piotics. Project management support and communication ys meetings (2 persons)
	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)	Justification 4 General assambly 2-da (WP1)	piotics. Project management e support and communication  ys meetings (2 persons)  ings (2 persons) (WP6a) + 4
	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €	Justification  4 General assambly 2-da (WP1)  4 mid-terms 1-day meeting mid-terms 1-day meeting	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a
	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €	Justification 4 General assambly 2-da (WP1) 4 mid-terms 1-day meeting 1 meeting 1-day (1 perso pre-final meeting for 13	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)
	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €  1 734,00 €	Justification  4 General assambly 2-da (WP1)  4 mid-terms 1-day meeting indication 1 meeting 1-day (1 personal personal meeting for 13 1 Ted and 1 high level 1-d (WP8)	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)
(C.1) Travel  Total Costs (€) of (C)	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €  1 734,00 €  1 440,00 €	Justification 4 General assambly 2-da (WP1) 4 mid-terms 1-day meeting 1 meeting 1-day (1 perso pre-final meeting for 13 1 Ted and 1 high level 1-(WP8)	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)
(C.1) Travel  Total Costs (€) of (C)  (D) Indirect Costs (Max. 7%	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €  1 734,00 €  1 440,00 €	Justification 4 General assambly 2-da (WP1) 4 mid-terms 1-day meeting 1 meeting 1-day (1 perso pre-final meeting for 13 1 Ted and 1 high level 1-(WP8)	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)
(C.1) Travel  Total Costs (€) of (C)  (D) Indirect Costs (Max. 7% on A, B and C)	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €  1 734,00 €  1 440,00 €  4 077,75 €	Justification  4 General assambly 2-da (WP1)  4 mid-terms 1-day meeting indicating indic	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)
(C.1) Travel  Total Costs (€) of (C)  (D) Indirect Costs (Max. 7% on A, B and C)  Total estimated eligible	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €  1 734,00 €  1 440,00 €	Justification  4 General assambly 2-da (WP1)  4 mid-terms 1-day meeting indicating indic	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)
(C.1) Travel  Total Costs (€) of (C)  (D) Indirect Costs (Max. 7% on A, B and C)	interventions to promote the Technician (FFIS) Participation in skills.  Costs (€)  7 520,00 €  11 520,00 €  1 734,00 €  1 440,00 €  4 077,75 €	Justification 4 General assambly 2-da (WP1) 4 mid-terms 1-day meeting 1 meeting 1-day (1 perso pre-final meeting for 13 1 Ted and 1 high level 1-(WP8)	ys meetings (2 persons) ings (2 persons) (WP6a) + 4 gs (2 persons) (WP6b) on) and cost for preparing a persons (WP3)

Applicant Number	SP-32 FFIS – Affiliated entity	/	
Short Name	DGPIFAC		
(A) Direct personnel costs	Davague (magistiam)	Tatal Danson Manth	T . 10 . (c) ((A)
(A) Direct personner costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Casimiro Jimenez Guillen -	Total Person-Wonth	Total Costs (€) of (A)
		Total Person-Wonth	Total Costs (€) of (A)
	Casimiro Jimenez Guillen -	0,50	2 720,00 €

	Justification	
	Pharmacist/Project Research Manager (DGPIFAC) Support the design of strategies for action related to AMR HCAIs in the region in Primary Care and Hospitals.	
(D) Indirect Costs (Max. 7% on A, B and C)	190,40 €	
Total estimated eligible costs	2 910 ?40 €	
Total requested EC contribution (60% max)	1 746,24 €	

Applicant Number	SP-32 FFIS - Affiliated entity		
Short Name	SMS		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Ricardo Garcia de Leon Gonzalez		
	- Pediatrician/Project		
	Research(1) (SMS)	1,70	12 211,10
	Santiago Alfayate Miguelez -		
	Medical Clinician Expert(1) (SMS)	2,50	13 750,00
	Olga Monteagudo - Public Health		
	/ Project Research (SMS)	1,50	5 859,00
	Manuel Alcaraz Quinonero -		
	Medical Clinician Expert (SMS)	2,20	12 927,20
	Jose Arnau Sanchez - Nurse/		
	Project Research Technician		
	(SMS)	2,70	10 897,20
		Total Costs (€) of (A)	55 644,50 €
	Justification		
	Pediatrician/Project Research(1) (SMS )Support relief actions for the appropriate use of		
	antimicrobials, implementation and prioritization of evidence for the use in specific		
	contexts, analysis of implementation and change of attitude in the responsible use of		
	antibiotics, selection of AMR indicators and support communication actions and		
	awareness on the issue. Medical Clinic Expert(1) (SMS) Participation in evaluation and		
	support in the top-down and the bottom-up approach for HCAI for institutional behavior		
	change and clinical change. He works in our Region in the AMR and control infections al		
	Hospital Level. Medical Clinician Expert (2) (SMS) Support actions for the appropriate use		
	· ·		
	of antimicrobials, implementation		vidence for the use in specific
	of antimicrobials, implementation contexts, analysis of implementation	tion and change of attit	vidence for the use in specific ude in the responsible use of
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in	tion and change of attit ndicators and support	vidence for the use in specific ude in the responsible use of communication actions and
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary	tion and change of attit ndicators and support y Care and has a wide cli	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care.
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR is awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. walth / Project Research (SMS)
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR is awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for present the selection.	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. valth / Project Research (SMS)
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Falth / Project Research (SMS) implementation, activities to g communication strategy's at
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project F	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SM:	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Halth / Project Research (SMS) implementation, activities to g communication strategy's at S) Actions to implement clinical
	of antimicrobials, implementation contexts, analysis of implementation antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project R guidelines and the analysis of	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and
	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project F	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and
(D) Indirect Costs (Max. 7%	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project Figuidelines and the analysis of qualitative research to explore the	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and
(D) Indirect Costs (Max. 7% on A. B and C)	of antimicrobials, implementation contexts, analysis of implementation antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project R guidelines and the analysis of	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and
on A, B and C)	of antimicrobials, implementation contexts, analysis of implementation antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project R guidelines and the analysis of qualitative research to explore the	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and
on A, B and C) Total estimated eligible	of antimicrobials, implementation contexts, analysis of implemental antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project Figuidelines and the analysis of qualitative research to explore the	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and
on A, B and C)	of antimicrobials, implementation contexts, analysis of implementation antibiotics, selection of AMR in awareness on the issue in Primary and good promoter of the chang Principal's promoters of the AMR Evaluation process, policies for primplement appropriate use of AM professional level. Nurse/ Project R guidelines and the analysis of qualitative research to explore the	tion and change of attit ndicators and support y Care and has a wide cli e both, in hospital envir in the region. Public He revention HCAI and their in Health care developin Research Technician (SMS social-health context, t	vidence for the use in specific ude in the responsible use of communication actions and nical and manager experience conment and in Primary Care. Palth / Project Research (SMS) implementation, activities to g communication strategy's at SActions to implement clinical raining of professionals and

## 33. Spain – FMS

Applicant Number	SP-33		
Short Name	FMS		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Carmen Ezpeleta - Principal investigator-Clinician	3	14 037,00 \$
	Albetro Gil - Specialist Microbiology	3	14 000,00 =
		Total Costs (€) of (A)	28 037,00
	Justification		
	20 years in clinical microbiolo bacteremia, infection control, a		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	7 520,00 €	1 KoM & 3 General assembly	y for 2 days 1 people
Total Costs (€) of (C)	7 520,00 €		
(D) Indirect Costs (Max. 7% on A B and C)	, 2 488,99 €		
Total estimated eligible costs	38 045,99 €		
Total requested EC contribution (60% max)	22 827,59 €		

## 34. Spain - SAS

<b>Applicant Number</b>	SP-34		
Short Name	SAS		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Jose Miguel Cisneros (PI Task coord medical staff)4	4	15 750,00 €
	Jose Antonio Lepe - Microbiologist	3	11 250,00 €
	Maria Victoria Gil Navarro - Farmaceutic	3	13 500,00 €
	Raquel Valencia - Infectious Disease Clinician	3,1	13 950,00 €
		Total Costs (€) of (A)	54 450,00 €
	Justification		
	Jose Miguel Cisneros - PI task coor Expertise: Infectious Diseases Role: Coordination of activities an José Antonio Lepe (Expertise: mici Pharmacy) + Raquel Valencia (Prev Role: They will take the lead of the system (Resistance and consumpt	d risks assessment. robiology) + María Victoria G ventive Medicine) e definition and updating of i	indicators for surveillance
(D) Indirect Costs (Max. 7% on A, B and C)	3 811,50 €		
Total estimated eligible costs	58 261,50 €		
Total requested EC contribution (60% max)	34 956,90 €		

Applicant Number	SP-34 Affiliated entity			
Short Name	FISEVI			
(A) Direct personnel costs	Persons (position)	Persons (position) Total Person-Month		
(including Public officials)	Research assistant: to be	6	17 400,00 €	
	selected by Public offer - actual			
	staff involved: German Penalva			
		Total Costs (€) of (A)	17 400,00 €	
	Justification	<u>.</u>		
	Research assistant: to be selected by Public offer - actual staff involved: Germán Peñalva.			
	Expertise: Data management	•		
	Role: Database design and implementation; data management follow-up; quality of data			
	issues.	_		
(B) Direct costs of sub-	Costs (€)	Tasks subcontracted		
contracting	10 000,00 €	Database		
	10 000,00 €	Training database manage	ment	
Total Costs (€) of (B)	20 000,00 €			
	Justification for resorting to subc	ontracting		

(C) Other direct costs		
(C.1) Travel	Costs (€)	Justification
	5 640,00 €	KoM + General Assembly
Total Costs (€) of (C)	5 640,00 €	
(D) Indirect Costs (Max. 7% on A, B and C)	3 012,80 €	
Total estimated eligible costs	46 052,80 €	
Total requested EC contribution (60% max)	27 631,68 €	

## 35. Spain – ISCIII

Applicant Number	SP-35		
Short Name	ISCIII		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	Carlos Segovia – Public official	0,8	3 200,00 €
	Maria Jose Gonzalez – Public official	0,8	3 200,00 €
	Pilar Gallego – Public official	1,8	7 200,00 €
	José Campos – Public official	1,8	7 200,00 €
		Total Costs (€) of (A)	20 800,00 €
	Justification		
(C) Other direct costs	_		National Centre for Epidemiology ational Centre for Microbiolody -
(C.1) Travel	Costs (€)	Justification	
(C.L) Have	8 640,00 €		6:2, task 6:2:1, 3 persons (1 ital)
	7 520,00 €		P1, meetings, 2 persons (1
	2 640,00 €		on to general assembly, one day, m x 8 days) (1 national/regional
Total Costs (€) of (C)	18 800,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	2 772,00 €		
Total estimated eligible costs	42 372,00 €		
Total requested EC contribution (60% max)	25 423,20 €		

### 36. Spain – SERMAS

SERMAS budget will be totally managed by its affiliated entity, see below

Applicant Number	SP-36 – Affiliated Entity		
Short Name	FBRIPC		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	José Manuel Izquierdo Palomares, Ainhoa Aranguren Oyarzabal and Tomas Gomez Gascon - Internal coordination WP7,8,9	10,31	30 922,50 €
	To be hired – Computer programmer	12	18 000,00 €
	To be hired – pharmacists	12	18 000,00 €
		Total Costs (€) of (A)	66 922,50 €
	Justification		
	and infectious diseases clinical physician hospital settings will also participate main awareness and communication plan of timplementation of evidence-informed prombatting AMR and HCAI of task WP 9.3. There will be necessary to hire a comput Subtask 7.4.1 Antimicrobial surveillance in Select basic indicators for surveillance systindicators for surveillance systindicators for surveillance system of antimit the different sites - Coordinate the actions the different data bases, design and imple and the analysis of the results. The com will be developed specifically to carry information, and the website that collect the	ly in the pilots under the trasks WP 8.2 and 8.3 and ublic health policies and the programmer and pharmacisem of antimicrobials constitution of the website, puter programmer will create the pilot, combining	asks of WP 7.3, 7.4.1, d contribution of the practices related to macist to work in the t will contribute to: - umption Select basic out the information of etings, information of validate the software eate the software that
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
	7 520,00 €	4 General Assembly for 2	people
Total Costs (€) of (C)	7 520,00 €		
(D) Indirect Costs (Max. 7% on A, B and C)	5 210,98 €		
Total estimated eligible costs	79 653,48 €		
Total requested EC contribution (60% max)	47 792,09 €		

## 37. Sweden – FOHM

Applicant Number	SE-37		
Short Name	FOHM		
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)
(including Public officials)	PHAS AMR Expert, MD, WP 6 – Olof Aspevall	7,2	103 579,00 €
	PHAS Analyst, AMR competence, project leader for WP6, to hire	36	310 737,00 €
	PHAS Pharmacist WP5&7 – Malin Grape	5	88 333,33 €
		Total Costs (€) of (A)	502 649,33 €
	Justification	<u>'</u>	
	WP6:2: A project leader with a experience in infection control. E ongoing as of January 2017. Olov 15 years of professional experiinternational multicentre improvicontrol. WP5 and WP7: Malin Gresistance and 5 years professionantibiotic stewardship.	xperience in international processions of Aspevall, a senior MD special ence with focus on AMR. ement projects within the frape, a pharmacist with a F	roject management. Recruitment lised in clinical microbiology with 5 years' experience of leading field of infection prevention and PhD in the area of antimicrobial
(B) Direct costs of sub-	Costs (€)	Tasks subcontracted	
contracting	20 000,00 €	Conference facilites, 4 Europ	pean meetings, approx 50
Total Costs (€) of (B)	20 000,00 €	participants at 150 EUR.	
1000100000 (0) 01 (0)	Justification for resorting to subc	ontracting	
	Venues with proper equipment ar	=	potings
	verides with proper equipment ar	e essential for productive me	etiligs.
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
(CI2) Have	• •	4 European travel in WP6:2, (national/regional)	task 6:2:1 & 2, 2 persons
	7 520,00 €	4 General assembly, WP1, n (national/regional)	neetings, 2 persons
	4 320,00 €		, national/regional
	8 000,00 €		
	5 760,00 €	4 mid-terms WP6a, 2 persor	ns national/regional
(C.3) Other goods and services	Costs (€)	Justification	
	60 000,00 €	1 1 1	tion on different subjects becific HCAI), etc. with different ated costs are; communicator,
Total Costs (€) of (C)	91 360,00 €	(	
(D) Indirect Costs (Max. 7% on A, B and C)	42 980,65 €		
Total estimated eligible costs	656 989,992 €		
Total requested EC contribution (60% max)	394 193,99 €		

#### 38. Sweden - SoS

Applicant Number	SE-38			
Short Name	SoS			
(A) Direct personnel costs (including Public officials)	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
	Axana Haggar (participant in WP6)	1	6 509,59 €	
	Total Costs (€) of (A) 6 509,99 €			
	Justification			
	I am representing the National Board of Health and Welfare, Sweden. My participation will be in WP6 and WP1 and I will contribute with my experience on AMR, infectious diseases and hospital acquired infections with a major focus on patient safety.			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	2 880,00 €	4 European travel in WP6:2, task 6:2:1, 1 persons (1 national/regional)		
	3 760,00 €	4 General assembly, WP1, meetings, 3 persons (1 national/regional)		
	880,00 €	4 WP6:2 meetings in conjuction to general assembly, one day, 1 persons. (EUR 220 per diem x 12 days) (1 national/regional)		
Total Costs (€) of (C)	7 520,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	982,07 €			
Total estimated eligible costs	15 011,67 €			
Total requested EC contribution (60% max)	9 007,00 €			

#### 39. Sweden – SBA

Applicant Number	SE-39			
Short Name	SBA			
(A) Direct personnel costs (including Public officials)	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
	Senior Veterinary Advisor	0,8	6 658,60 €	
		Total Costs (€) of (A)	6 658,60 €	
	Justification			
	Participation WP 5			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	2 820,00 €	D € Annual General Assembly, 1 person 3 occasions		
	2 820,00 €	3 Workshops 2 days (?) Task 1 and 2, 1 person		
Total Costs (€) of (C)	5 640,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	860,90 €			
Total estimated eligible costs	13 159,50 €			
Total requested EC contribution (60% max)	7 895,70 €			

# 40. Sweden – NFA

Applicant Number	SE-40				
Short Name	NFA				
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)		
(including Public officials)	Jakob Ottoson - Associate 1,5 professor		12 300,00 €		
	Total Costs (€) of (A) 12 300,0		12 300,00 €		
	Justification				
	Microbiologist and risk assessor that will take active part in the development and evaluation of a self-assessment tool to monitor country progress and identify gaps in the implementation of national strategies and action plans (WP5, tasks 1 and 2).				
(C) Other direct costs					
(C.1) Travel	Costs (€)	Justification			
	3760,00€	KoM + 3 General assembly meeting			
Total Costs (€) of (C)	3 760,00 €				
(D) Indirect Costs (Max. 7% on A, B and C)	1 124,20 €				
Total estimated eligible costs	17 184,20 €				
Total requested EC contribution (60% max)	10 310,52 €				

#### 41. Sweden – SVA

Applicant Number	SE-41			
Short Name	SVA			
(A) Direct personnel costs (including Public officials)	Persons (position)	Total Person-Month	Total Costs (€) of (A)	
	Bjorn Bengtsson - Associate professor	0,7	7 466,67 €	
		Total Costs (€) of (A)	7 466,67 €	
	Justification			
	A person with insight and knowledge in issues related to antimicrobial resistance (AMR) in the veterinary field and in national strategies and action plans to mitigate emergence and spread of AMR in animals and food.			
(C) Other direct costs				
(C.1) Travel	Costs (€)	Justification		
	2 850,00 €	Participation in 3 yearly GA-meetings		
	2 120,00 €	Participation in 3 yearly workshops		
Total Costs (€) of (C)	4 970,00 €			
(D) Indirect Costs (Max. 7% on A, B and C)	870,57 €			
Total estimated eligible costs	13 307,23 €			
Total requested EC contribution (60% max)	7 984,34 €			

# 42. Sweden – SRC

Applicant Number	SP-42					
Short Name	SRC					
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)			
(including Public officials)	Scientific officer (Maria Starborg)	2,5	18 000,00 €			
	Scientific officer (Patriq Fagerstedt)	2,5	18 000,00 €			
		Total Costs (€) of (A)	36 000,00 €			
	Justification					
	The Swedish Research Council will mainly take part in task 1 and 3 in WP9. Maria Starborg is experienced scientific officer that work in the secretariat of JPIAMR focusing on JPIAMR or research infrastructure as well as databases. Maria is also the Swedish expert at the He committee in SC1. Patriq Fagersdtedt is an experienced scientific officer at the JPIAMR secretary well as the SRC representative at JPND. Patriq's main task is to coordinate scientific activities call topics, scientific workshops, bibliometrics etc.					
(C) Other direct costs						
(C.1) Travel	Costs (€)	Justification				
	7 520,00 €	7 520,00 € General assembly meetings 2 persons				
	1 440,00 €	WP9 2 meetings, 1 person				
Total Costs (€) of (C)	8 960,00 €					
(D) Indirect Costs (Max. 7% on A, B and C)	3 147,20 €					
Total estimated eligible costs	48 107,20 €					
Total requested EC contribution (60% max)	28 864,32 €					

# 43. Sweden – UAS

Applicant Number	SE-43								
Short Name	UAS								
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)						
(including Public officials)	Birgitta Lytsy - MD Infection Control specialist	1	11 904,76 €						
		Total Costs (€) of (A)	11 904,76 €						
	Justification								
	epidemiology and infection prevention and control having also a high command of the Englis language. 5 years' experience of leading international multicenter improvement projects with the field of infection prevention and control.								
(C) Other direct costs									
(C.1) Travel	Costs (€)	Justification							
	3 760,00 =	£4 European travel in WP6:	2, task 6:2:1, 2 persons						
	3 760,00 =	meetings, 2 persons							
Total Costs (€) of (C)	7 520,00	E							
(D) Indirect Costs (Max. 7% on A, B and C)	1 359,73	E							
Total estimated eligible costs	20 784,49	E							
Total requested EC contribution (60% max)	12 470,70 :	E							

# 44. France – ANSES

<b>Applicant Number</b>	FR - 44					
Short Name	ANSES					
(A) Direct personnel costs	Persons (position)	Total Person-Month	Total Costs (€) of (A)			
(including Public officials)	Deputy Director Anses - Lyon Lab - Head of AMR unit	7	59 488,00 €			
	Deputy Head Microbiology Unit	1	5 360,00 €			
	Deputy Head Epidemiology Unit	1	7 081,00 €			
	microbiology Technical support (3)	3	11 173,00 €			
	Epidemiologist	1	4 619,00 €			
	Post Doctorate - scientific staff	30	138 015,00 €			
		Total Costs (€) of (A)	225 736,00 €			
	Justification					
	professional experience in AMR and antibiotic use in animals, in relation with AMR and antibiotic use in humans. Two also are veterinary doctors. One of them, who will be the coordinator of the tasks, has over 10 years of experience in supervising, coordinating and managing activities on AMR, and particularly as National Supervisor on AMR issues at Anses within the One Health National Strategic Plan on AMR, including daily contacts with relevant stakeholders, professional bodies and national/EU authorities. The latter also has over 5 years of experience in coordinating workpackages in several EU or international scientific projects on AMR. The four technical staff have daily experience with managing the surveillance network of AMR and collecting antibiotic use in animals in France.					
(C) Other direct costs						
(C.1) Travel	Costs (€)	Justification				
(C.1) ITavei			ng 2 nows 2 days			
		General Project meeti	<u> </u>			
		Mid term meeting for				
		Mid term meeting for WP7  Travels for visiting up to 25 countries				
	23 393.07 €	About 40 institutions take part in the project, in 25 In order to assess and understand what is alread existant) in these countries as for AMR surveillance decided to go for short visits (average of 2 days) the countries involved. The junior scientist (Post does recruited) will either go on his own, or be accordinated that the task coordinator (senior scientist).  We consider each visit to cost 500+ 2*220 = 9 estimated cost has therefore been calculated at 9 500, automatic calculations on the project expression reconsidering it to 23 393,07 €.  This amount will allow Anses to either go to all 2 (1 person, 2 days) or most of them (2 people, 1 or				
Total Costs (€) of (C)	29 033,07 €	, , , , , , , , , , , , , , , , , , , ,	, , , , , , , , , , , , , , , , , , , ,			

D) Indirect Costs (Max. 7% on A, B and C)	17 833.83 €
Total estimated eligible costs	272 602.90 €
Total requested EC contribution (60% max)	163 561.74 €

# Below table of subcontracting per partners

Partner number	Short name	Amount subcontracting	WP & task related	Justification
8	SSI	28 000,00 €	WP7 tasks 7.4.2	Danish National Veterinary Institute (DTU VET) will contribute to task 7.4.2, having the skills and expertise to do so.
15	ISS	75 000,00 €	WP3 tasks 3.2, 3.5, 3.6	Some of the activities of WP3 will be subcontracted to a party with proven experience in the field of evaluation and experience in the setting and use of appropriate evaluation tools (University of Udine). Subcontracting will regard the activities related: 25,000 Euro for task 3.2 (Development of evaluation tool): Definition and provision of web-based tools to collect data and run surveys. Their testing and revision during the project; 25,000 Euro for task 3.5 (Report of results to relevant stakeholders): Preparation of an interim and final reports containing all indicators and data and the evaluation of the impact of the project actions. Presentation of the reports to the internal and external stakeholder; 25,000 Euro for the evaluation of the impact in Europe. Preparation and analysis of questionnaires to national, regional and local authorities as well as to professionals and citizens associations and analysis of official data and other information from EU MS national and subnational web-sites
21	VWS	80 000,00 €	WP6 WP7	Hospitals and nursing homes don't belong to the Dutch government. They are private instituitions. That's the reason they are considered sub-contractors. Based on the available information as provided by the WP leaders at the time of stimating this budget, the cost of the subcontracting has been estimated calculating the workload and translating it into person month units. Other cost like travel cost or equipment are not included in this estimation and will be coverd by VWS. WP6: 5,6 person month x 7500 euro = 37500 euro = (incl: profesionals on infection prevention and manamgent) WP6B: 5,1 person month x 7500 euro = 37500 euro (incl. professionals on infection prevention). WP7: 3,84 person month x 7500 euro = 28800 euro (incl. micorbiologist/phamacologist/nurse). With the information available at this moment it is not possible to sign start yet a formal dialogue contract with hospitals/nursing homes, and therefore it is not possible to indicate the name of the hospital/nursing homes and provide a more exhaustive estimation of the costs.
30	AEMPS	32 000,00 €	WP2	Develop a website as central hub for internal communication as well as main platform to communicate outputs and disseminate the information to the targeted audiences: Design a document sharing or repository platform as for internal communication, and design and implementation of a web platform as for external dissemination. The benefit of developing this website in a way that best suits the needs of the project will ensure the key role of WP2 as the coordinating body of the dissemination activities for the project and make sure that results and relevant information produced over the lifetime of the project will not be lost and can continue to be a crucial part of JA products and services well into the future.
		22 000,00 €	WP8	In the WP8 we propose to carry out one conference, with scientific communicators or with High School students or university students as speakers. It will focus on scientific spreading targeted at the general public, journalists and healthcare/veterinary professionals or their representative organizations. This event will cover the most recent data on AMR in order to inform all of these groups in a clear, accurate way so

				that, eventually, we raise awareness on the topic. The conference could be divided in several presentations by different experts participating in JAMRAI and to be selected from, for example, ECDC, WHO experts). The event will be held in a location to be confirmed. All the details related to this conference's contents and organization will be studied and decided by the JAMRI WP8 team.
		25 000,00 €	WP8	In the WP8, a Social campaign will be designed in order to address general public and healthcare professionals in both human and animal health, according to the One Health approach. The social campaign will be mainly structured online, on the basis of a video that will be promoted through social media profiles. The video will be made as a creative and visually attractive piece of work that grabs general attention on the AMR problem. The project budget will consider organizing different online complementary materials/activities to the video (e.g. gifs, collaboration with influencers) in order to improve chances of it going viral and for the better spreading of our messages. All of the actions involved in this social campaign should be planned in detail and finally agreed upon between all the members of the JAMRI WP8 team in collaboration with the rest of participant or collaborating entities, (JA coordinator, ECDC, WHO-Europe) for this proposal to work as a starting point.
35	SAS	20 000,00 €	WP7	Database and training database management
37	FOHM	20 000,00 €	WP6	Conference facilites, 4 European meetings, approximately 50 participants' at 150 EUR. Venues with proper equipment are essential for productive meetings.

# 12. Previous and current grants relevant to the programme (limited to the last 3 years)

#### EU project EFFORT :

EFFORT against antimicrobial resistance (Ecology from Farm to Fork Of microbial drug Resistance and Transmission)

http://www.effort-against-amr.eu/

• <u>EU network GRACE</u>: the European Network of Excellence to combat resistance to antibiotics in the community.

http://www.grace-Irti.org/portal/en-GB/homepage

- <u>EU project COMBACTE</u>: Combatting Bacterial Resistance in Europe improving clinical trials for antibiotics http://www.combacte.com/
- <u>Joint Programming Initiative on Anti Microbial Resistance (JPI AMR)</u>:

European strategic research agenda on Antimicrobial Resistance

http://www.jpiamr.eu/wp-

content/uploads/2014/05/SRA1 JPIAMR.pdf?bcsi scan 628cd39dca2568d2=0&bcsi scan filename=SRA 1 JPIAMR.pdf

#### IMI project Drive AB

Driving reinvestment in research and development and responsible antibiotic use:

Collaborative public-private research project focused on developing detailed economic policies to stimulate antibiotic innovation that meets global health needs.

http://drive-ab.eu/

IMI project ENABLE (European Gram Negative AntiBacterial Engine)

Public private partnership to advance the development of potential antibiotics against Gram-negative bacteria, such as *Escherichia coli*.

http://nd4bb-enable.eu/

• IMI project ND4BB (New Drugs for Bad Bugs)

Public private partnership to bring new antimicrobials closer to patients, to share information and to boost research on improving the uptake and decreasing the efflux of antibiotics into Gram-negative bacteria http://www.nd4bb.eu/

IMI Initiative

Call for proposals on Antimicrobial resistance

http://www.imi.europa.eu/

#### 13. CURRENT APPLICATIONS RELEVANT TO THE PROGRAMME

No current applications relevant to the programme.

## 14. EXCEPTIONAL UTILITY

Non-application for the Joint Action AMR- HCAI

#### 15. COLLABORATING STAKEHOLDERS

Below the list of up to 20 most important collaborating stakeholders and/or external experts participating in your project. This list excluding the "de facto" collaborating stakeholders that will join the Stakeholders Forum such as ECDC, WHO, FAO, OECD etc.

Institution	Contact person	City & Country

	(First name and last name)	
University Hospital for Infectious Diseases	Arjana Tambic Andrasevic	Zagreb, Croatia
Ministry of Health	Dr Niki Pafitou ( <u>elpnik@gmail.com</u> )	Cyprus
National Institute for Health and Welfare	Jari Jalava ( <u>jari.jalava@thl.fi</u> )	Helsinki, Finland
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail	Salma Elreedy (salma.elreedy@anses.fr)	Paris, France
Santé Publique France	Bruno Coignard (bruno.coignard@santepubliquefrance.fr)  Anne Berger-Carbonne (anne.berger-carbonne@santepubliquefrance.fr)	Paris, France
Ministry of Health	Irini Kyriaki (ekyriaki@moh.gov.gr)	Athenes, Greece
Semmelweis University	Balázs Hankó MD. (hanko.balazs@pharma.semmelweis-univ.hu)	Hungary
University of Debrecen	István Várkonyi MD. (varkonyi.istvan@med.unideb.hu)	Hungary
Department of Health (Patient Safety Unit)	Rosarie Lynch  (rosarie_lynch@health.gov.ie)  Eithne Barron	Dublin, Ireland
NATIONAL PUBLIC HEALTH SURVEILLANCE LABORATORY	(eithne_barron@health.gov.ie)  Greta Vizuje (greta.vizuje@nvspl.lt)	Lithuania
Pathology Department – Mater Dei Hospital	Dr. Christopher Barbara (Christopher.barbara@gov.mt)	Malta
Public Institution Coordination, Implementation and Monitoring Unit of the Health System Projects.	Nicolae Furtuna (nfurtuna@cnsp.md)	Moldova
Norwegian Medicines Agency	Seline Gustavsen (seline.gustavsen@legemiddelverket.no)	Norway
Ministry of Health of Republic of Serbia	Ljiljana Jovanovic, MD ( <u>ljiljana.jovanovic@zdravlje.gov.rs</u> )	Serbia
Clinical Center of Serbia, Clinic for Infectious and Tropical Diseases	Goran STEVANOVIC - goran_drste@yahoo.com	Serbia
Ministry of Health of the Slovak republic	Zuzana Matloňová (zuzana.matlonova@helath.gov.sk)	Slovakia
National Reference Centre for HIV/AIDS prevention, Slovak Medical University	Danica Staneková (danica.stanekova@szu.sk)	Bratislava, Slovakia
Public Health Authority of the Slovak republic	Dagmar Némethová (dagmar.nemethova@uvzsr.sk)	Slovakia

Fundación para el Fomento de la Investigación Biomédica y Sanitaria de la Comunidad Valenciana Consellería Sanitat Universal i Salut Pública	Hector Perpinan (perpinan hec@gva.es)	Valencia, Spain
The Swedish Association of Local Authorities and Regions (SALAR)	Eva Estling, ( <u>eva.estling@skl.se</u> )  Agneta Andersson ( <u>agneta.andersson@skl.se</u> )	Stockholm, Sweden
University Carlos III of Madrid, Department of Journalism and Communication	Carlos Elias Peres ( <u>celias@hum.uc3m.es</u> )  Daniel Catalan Matamoros ( <u>dacatala@hum.uc3m.es</u> )	Madrid, Spain
Public Health England	George Leahy (George.Leahy@phe.gov.uk)	London, United Kingdom

#### 16. APPENDIX 1 - DETAILED MANAGEMENT STRUCTURE

#### 16.1.1. Governing bodies of the project consortium and their functions

a. The **General Assembly** is the decision-making body of the JA. It is chaired by the Coordinator and is composed of one representative from each partner. The GA monitors the work progress of the Joint Action and provides awareness on related projects, actions or changes within the EU Health Program. The Coordinator chairs the GA and ensures liaison with the ExB.

The tasks of the GA are as follows:

- Take decisions as to the implementation of the JA and its deliverables, as proposed by the ExB;
- Decide on the overall development of the project based on input from the Coordinator and the ExB;
- Monitor and review the progress of the project;
- Validate re-allocation of budget whenever changes need to be done;
- Take the necessary actions and corrective measures in case of default of a partner.

The GA will meet once a year from the start of the project execution. Intermediate meetings will be held by web-conference if needed (allowing sharing and modification of documents online while talking over the phone). The GA meetings will be convened and prepared by the Coordinator with the support of the Joint Action Secretariat. The JAS will prepare in writing the agenda of the meetings and send it to each GA member at least 2 weeks before meetings, with all relevant background information and supporting documents to any decision proposed to be taken. Quorum and majority requirements will be laid down in the Consortium Agreement. In the event of a tie, the decision by the Coordinator will prevail. These decisions may be taken via email, tele- or videoconferences or face to face meetings. Minutes of GA will be sent by the Joint Action Secretariat to all members.

Delegates of the EC DG SANTE and CHAFEA may participate in GA meetings but will have no voting right.

b. The **Steering Committee (SC)** will be made up of representatives of competent authorities (Ministry of Health) of each Member State willing to be part of the Joint Action. The SC will thus gather 31 representatives representing the 28 Member States of the European Union, and 3associated countries to this project: Norway Moldova and Serbia . The chair will be elected during the Kick-off Meeting at the very beginning of the project. SC members will provide strategic directions to the GA on behalf of their respective government and contribute to the successful implementation of the Joint Action results. SC meetings will be held 4 times within the project duration – at the official Kick-off Meeting and once per year, in parallel to GA meetings. If necessary, additional meetings could be held. The Coordinator and JA Secretariat will be invited to attend all SC meetings.

The SC will provide support, guidance and oversight of the JA progress. In particular, the tasks of the SC include:

Provide input to the development of the JA, including the evaluation strategy;

- Review documents prepared by the JA and provide prompt feedback to the GA
- Identify the priorities in the JA where the most energy should be directed;
- Identify potential risks and propose recommended courses of action;
- Monitor the quality of the JA as it develops;
- Provide advice about changes to the JA work plan as it develops;
- Define and help to achieve the JA outcomes at the national level;
- Promptly inform the GA of any potential obstacles regarding national commitment
- Contribute to the sustainability of the JA activities at the national, local or regional level
- c. The **Executive Board (ExB)** is the main executive body of the Joint Action. It is made up of the Work Package leaders, the JA secretariat and is chaired by the Coordinator. The ExB will put forward and then ensure the proper implementation and execution of the strategic orientations of the JA and of any decision committing the participating organisations. The ExB will prepare all the management decisions needed to keep the JA focused on its objectives. These decisions will then be put to the vote of the GA. The ExB will meet at least every 4 months. Every second meeting will be held via conference call. The ExB specific tasks will thus be to:
  - Monitor and review the project's progress;
  - Prioritize the projects objectives and outcomes;
  - Prepare draft decisions to be considered by the GA;
  - Formulate risk management strategies and ensure that risks are regularly reassessed;
  - Propose re-allocation of budget whenever changes need to be done;
  - Help the Coordinator resolve potential conflicts and disputes.

#### 16.1.2. <u>Day-to-day management of the Joint Action</u>

#### **JA Coordinator**

The Coordinator will act as the direct link and intermediary between the Agency and the consortium. It will request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency. In these tasks, the Coordinator will be assisted by JA Secretariat and the ExB.

Responsibilities of the Coordinator:

To the European Commission:

- Responsible for the management and the achievement of the objectives of the project;
- Intermediary in all communications (interim/final progress reports);
- Receives and distributes all payments (from the EC to Partners);
- Ensures timely delivery of the project deliverables.

#### To the Partners:

- Informs of the requirements from the EC;
- Informs of any events that may delay WP implementation;
- Facilitates communication between WPs (using restricted access area on the project website);
- Gives budgetary and financial information necessary for WP implementation;
- Provides overview of project status;
- Act as a mediator in case of conflicts or disagreement between partners

#### **Work Package leaders**

All JA activities will be coordinated at the Work Package (WP) level, under the responsibility of one or two WP leader(s). WP leaders will coordinate the work within the individual WPs, ensuring that the work plan is executed as anticipated, in close collaboration with the participating WP partners. Additionally, the WP leaders will be responsible for the timely implementation of the GA decisions within their WP. They will also report WP progress to the Coordinator and to the ExB. WP leaders' specific tasks include:

- Coordinate and supervise their respective WP;
- Follow-up the WP deliverables and milestones and ensure their timely achievement;
- Ensure that each participant fulfils its commitment to the WP;

- Present progress reports on the state of advancement of the WP;
- Make proposals on the allocation of WP tasks, financial need and allocation among the contractors;
- Draft and validate WP deliverables to be submitted to the EC;
- Identify potential risk(s) within the WP and propose contingency plans;
- Organise WP meetings with the WP teams whenever necessary;
- Inform the coordinator and the GA of any work plan modification, adjustment or other difficulty arising in connection with the WP.

#### The JA secretariat

A JA secretariat will be constituted to assist the ExB and the GA in the administrative and financial management of the JA. It will be composed of a project manager at Inserm and an administrative assistant at MoH-FR.

The JA secretariat will be responsible for the following activities:

- Preparation and signature of the Consortium Agreement and any other legal document pertaining to the JA;
- Preparation of GA and ExB meetings' agenda and minutes;
- Compilation and review of periodic and final reports to the commission;
- Day to day administrative and financial management;
- Management of a secured extranet platform for the exchange of information between the partners;
- Organization of webconferences and physical meetings;
- Ensure transparency in communication between all JA partners;
- Coordinate activities of the Stakeholder Forum.

#### 16.1.3. Advisory body: the Stakeholders Forum

In order to have a permanent structure for involvement of stakeholders during the JA, a Stakeholders Forum will be constituted as part of the management structure. The Stakeholders Forum will be composed of representatives of the major stakeholders having a legitimate interest in the Joint Action, such as:

- International organisations in charge of policies and guidelines (WHO, OECD, ECDC, FAO, OIE, EFSA, ...)
- Industries
- Healthcare professionals (may be representatives of scientific societies as European Society for Clinical Microbiology and Infectious Diseases)
- Representatives of European programs such as JPI AMR and IMI programs (COMBACTE, DRIVE-AB, ...)
- Patient associations
- Other possible interested partners (EPHA,...)

The primary role of the Stakeholders Forum will be one of strategic advice to the ExB as well as maintaining the flow of information with relevant organisations or societies. The Forum will reflect on and contribute to overall conceptual development during the Joint Action based on their respective expertise, with a particular emphasis on sustainability beyond the project period.

Members of the Stakeholders Forum will be invited to all GA physical meetings, and consulted by the Coordinator and WP leaders when needed for the JA implementation. The ultimate goal in equipping the project with this independent body is to guarantee that the consortium decisions will be strategically connected to the global challenges and developments in the field and that the JA outputs are commensurate with ground realities.

The existence of a Stakeholders Forum does not preclude the consultation of other stakeholders whose insight will be needed during the course of the JA.

The below table presents all the organizations willing to collaborate and/or contribute to the EU-JAMRAI project:

Organisation name	Short name	Type of stakeholders	Contact name	Contribution to WP #		
European Centre for Disease Prevention and Control	ECDC	International organisations	Dominique Monnet	WP6, WF	7	
World Health Organization	WHO	International organisations	Danilo Lo Fo Wong	WP5		
Organisation for Economic Co-operation and Development	OECD	International organisations	Michele Cecchini	To defined	be	
World Organization for Animal Health	OIE	International organisations	In contact	WP5		
Food and Agriculture Organization of the United Nations	FAO	International organisations	In contact	WP5		
European Food Safety Agency	EFSA	International organisations	In contact	WP5		
European Public Health Alliance	ЕРНА	Healthcare professionals	Sascha Marschang	To defined	be	
Pharmaceutical Group in the European Union	PGEU	Healthcare professionals	Jamie Wilkinson	To defined	be	
Health First Europe	HFE	Healthcare professionals	Melina Raso	To defined	be	
Pfizer	Pfizer	Pharmaceutical company	Eva Grut-Aandahl & Bruce Altevogt	WP9		
International Federation of Medical Students Associations	IMFSA	Healthcare professionals	In contact	To defined	be	
European Wound Management Association	EWMA	Healthcare professionals	Niels Fibaek Bertel	To defined	be	
European Federation of Pharmaceutical Industries and Associations	EFPIA	Industries	In contact	To defined	be	
International Federation of Pharmaceutical Manufacturers	IFPMA	Industries	In contact	To defined	be	
Standing Committee of European Doctors	СРМЕ	Healthcare professionals	Carole Rouaud	To defined	be	
Council of European Dentists	CED	Healthcare professionals	Lea Pfefferle	To defined	be	

# **Responsibilities of the JA Partners**

JA partners are responsible for the implementation of their respective WP tasks, as described in the Grant Agreement. They shall take all necessary steps to perform and fulfil promptly, actively and on time all of their agreed upon obligations. They shall endeavor to be represented at all GA meetings and will be responsible for:

- Ensuring the participation of appropriate members in the SC;
- Being familiar with national procedures regarding agreement on the key aspects of the project implementation;
- Promptly informing the consortium of any potential obstacles regarding national commitment through regular contact with SC members.

Responsibilities of the JA partners:

#### To the WP leaders:

• Timely provision of information necessary for WP implementation and adherence to the work plan.

#### To the Coordinator:

- Timely provision of all data for reports, financial statements and other documents;
- Immediately inform of any event delaying the implementation of the project;
- Provide updated contact information for all representatives involved in the project.

#### **Administrative and Legal Provisions**

#### **JA Meetings**

Meetings of the different project groups (e.g. ExB, GA, SC and WP teams) will take place as planned in the Consortium agreement. The exact schedule will be posted and updated as necessary in the members-only section of the JA AMR HCAI website.

#### **GA Quorum and voting rules**

Quorum and voting rules will be provided for in the Consortium Agreement. Decisions shall only be executed once the relevant part of the minutes is accepted.

#### **Decision without meeting**

Any GA decision may also be taken without a meeting by circulating to all partners a written document then signed electronically by the defined majority of partners or by answering by emails.

#### **Minutes**

Minutes of the ExB, GA, SC and WP meetings shall be made available to all partners. Corrections shall be returned by email within a period specified by the WP leader (for WP meetings) or the JA Secretariat (for GA, SC and ExB meetings), and shall become official upon publication on the extranet (project members only area) of JA AMR HCAI website.

#### **Internal communication strategy**

Internal communication within the JA will be key to keep the project on track, keep the partners motivated and involved and bring the JA to a successful conclusion. The Joint Action Secretariat will set up an effective communication strategy to ensure that all partners:

- Have the same level of information (what is done, why and when, responsibilities, deadlines, etc.);
- Identify with the main aims of the JA and feel like they are part of the JA;
- Know their responsibilities and tasks and those of other JA partners.

Tools provided by the Joint Action Secretariat to improve workflows include:

- Support to the organisation of face-to-face or online meetings
- Animation of a secured online collaborative platform for file sharing and online storage of files (WP2 deliverable), with restricted access
- Uploading written minutes with "action items" for all JA meetings on the secured platform
- Uploading of JA reports on the secured platform
- Maintenance of a complete and up-to-date JA address book
- Video-conferencing system available on request
- Information/events posted on the JA public website

Information contained on the JA secured platform will be continually updated by the Joint Action Secretariat, to ensure that the action runs at critical mass and that there is no information missing which could have an impact on the programme.

# ESTIMATED BUDGET FOR THE ACTION (page 1 of 5 Associated with document Ref. Ares(2017)4194538 - 28/08/2017

1	Estimated eligible costs (per budget category)					ELI contribution Action's actimated received					
							EU contribution		Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate %	Maximum EU contribution <sup>3</sup>	Maximum grant amount <sup>4</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>5</sup>	Actual	Actual	Actual	Flat-rate 7% <sup>6</sup>							
	a	b	С	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	g= e×f	h	k	1	m=k+l
1. INSERM	398008.18	0.00	148520.00	38256.97	584785.15			350871.09	0.00	0.00	0.00
- CHU Limoges	69617.87	0.00	0.00	4873.25	74491.12			44694.67	0.00	0.00	0.00
- UL	109183.16	0.00	0.00	7642.82	116825.98			70095.59	0.00	0.00	0.00
Total beneficiary	576809.21	0.00	148520.00	50773.04	776102.25			465661.35	0.00	0.00	0.00
2. MoH-FR	177200.00	0.00	18304.00	13685.28	209189.28			125513.57	0.00	0.00	0.00
3. GÖG	103876.22	0.00	19340.00	8625.14	131841.36			79104.82	0.00	0.00	0.00
4. FPS HFCSE	85425.41	0.00	26320.00	7822.18	119567.59			71740.55	0.00	0.00	0.00
5. NCIPD	15940.00	0.00	20560.00	2555.00	39055.00			23433.00	0.00	0.00	0.00
6. CIPH	24570.00	0.00	27520.00	3646.30	55736.30			33441.78	0.00	0.00	0.00
7. NIPH	73297.00	0.00	41360.00	8025.99	122682.99			73609.79	0.00	0.00	0.00
8. SSI	46000.00	28000.00	7520.00	5706.40	87226.40			52335.84	0.00	0.00	0.00
9. TA	31915.00	0.00	15440.00	3314.85	50669.85			30401.91	0.00	0.00	0.00
10. RKI	86250.00	0.00	17680.00	7275.10	111205.10			66723.06	0.00	0.00	0.00
11. HCDCP	231796.21	0.00	78020.00	21687.13	331503.34			198902.00	0.00	0.00	0.00
12. ESDY-NSPH	111134.86	0.00	26320.00	9621.84	147076.70			88246.02	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 2 of 5 Associated with document Ref. Ares(2017)4194538 - 28/08/2017

	Estimated eligible costs (per budget category)					EU contribution			Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate %	Maximum EU contribution <sup>3</sup>	Maximum grant amount <sup>4</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>5</sup>	Actual	Actual	Actual	Flat-rate 7% <sup>6</sup>							
	a	b	С	$d = 0.07 \times (a + b + c)$	e = a+b+c+d	f	g= e×f	h	k	1	m=k+l
13. 7HC	2202.00	0.00	14720.00	1184.54	18106.54			10863.92	0.00	0.00	0.00
- GH Heraklion	36016.00	0.00	0.00	2521.12	38537.12			23122.27	0.00	0.00	0.00
Total beneficiary	38218.00	0.00	14720.00	3705.66	56643.66			33986.19	0.00	0.00	0.00
14. UNIFG	103713.41	0.00	28480.00	9253.54	141446.95			84868.17	0.00	0.00	0.00
15. ISS	218183.88	75000.00	91874.00	26954.05	412011.93			247207.16	0.00	0.00	0.00
16. PSKUS	21050.00	0.00	13780.00	2438.10	37268.10			22360.86	0.00	0.00	0.00
17. LSMULKK	35910.00	0.00	10960.00	3280.90	50150.90			30090.54	0.00	0.00	0.00
18. VULSK	38900.00	0.00	15040.00	3775.80	57715.80			34629.48	0.00	0.00	0.00
19. HI	98179.00	0.00	23180.00	8495.13	129854.13			77912.48	0.00	0.00	0.00
20. NVSC	22401.65	0.00	13280.00	2497.72	38179.37			22907.62	0.00	0.00	0.00
21. VWS	380550.00	80000.00	77820.00	37685.90	576055.90			345633.54	0.00	0.00	0.00
22. HdiR	39215.00	0.00	9400.00	3403.05	52018.05			31210.83	0.00	0.00	0.00
23. FHI	489507.27	0.00	29840.00	36354.31	555701.58			333420.95	0.00	0.00	0.00
24. NVI	49000.00	0.00	4480.00	3743.60	57223.60			34334.16	0.00	0.00	0.00
25. NMI	22733.04	0.00	20560.00	3030.51	46323.55			27794.13	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 3 of 5 Associated with document Ref. Ares(2017)4194538 - 28/08/2017

		Estimated elig	ible <sup>1</sup> costs (per bu				EU contribution	· •	Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate %	Maximum EU contribution <sup>3</sup>	Maximum grant amount <sup>4</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>5</sup>	Actual	Actual	Actual	Flat-rate 7% <sup>6</sup>							
	a	b	С	$d = 0.07 \times (a + b + c)$	e = a+b+c+d	f	g= e×f	h	k	1	m=k+l
26. DGS	71600.00	0.00	21200.00	6496.00	99296.00			59577.60	0.00	0.00	0.00
27. UMPIH	16400.00	0.00	19840.00	2536.80	38776.80			23266.08	0.00	0.00	0.00
28. NIJZ	97800.00	0.00	44320.00	9948.40	152068.40			91241.04	0.00	0.00	0.00
29. AEMPS	397250.00	79000.00	117060.00	41531.70	634841.70			380905.02	0.00	0.00	0.00
30. GENCAT	58000.00	0.00	14720.00	5090.40	77810.40			46686.24	0.00	0.00	0.00
31. IdISBa	94303.01	0.00	19760.00	7984.41	122047.42			73228.45	0.00	0.00	0.00
32. FFIS	36039.50	0.00	22214.00	4077.75	62331.25			37398.75	0.00	0.00	0.00
- DGPIFAC	2720.00	0.00	0.00	190.40	2910.40			1746.24	0.00	0.00	0.00
- SMS	55644.50	0.00	0.00	3895.12	59539.62			35723.77	0.00	0.00	0.00
Total beneficiary	94404.00	0.00	22214.00	8163.27	124781.27			74868.76	0.00	0.00	0.00
33. FMS	28037.00	0.00	7520.00	2488.99	38045.99			22827.59	0.00	0.00	0.00
34. SAS	54450.00	0.00	0.00	3811.50	58261.50			34956.90	0.00	0.00	0.00
- FISEVI	17400.00	20000.00	5640.00	3012.80	46052.80			27631.68	0.00	0.00	0.00
Total beneficiary	71850.00	20000.00	5640.00	6824.30	104314.30			62588.58	0.00	0.00	0.00
35. ISCIII	20800.00	0.00	18800.00	2772.00	42372.00			25423.20	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 4 of 5 Associated with document Ref. Ares(2017)4194538 - 28/08/2017

	Estimated eligible costs (per budget category)							7.0000	Action's actimated respires		
			•			EU contribution			Action's estimated receipts		
	A. Direct personnel costs	B. Direct costs of subcontracting	C. Other direct costs	D. Indirect costs <sup>2</sup>	Total costs	Reimbursement rate %	Maximum EU contribution <sup>3</sup>	Maximum grant amount <sup>4</sup>	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services								
Cost form <sup>5</sup>	Actual	Actual	Actual	Flat-rate 7% <sup>6</sup>							
	a	b	С	$d = 0.07 \times (a +b+c)$	e = a+b+c+d	f	g= e×f	h	k	1	m=k+l
36. SERMAS	0.00	0.00	0.00	0.00	0.00			0.00	0.00	0.00	0.00
- FBRIPC	66922.50	0.00	7520.00	5210.98	79653.48			47792.09	0.00	0.00	0.00
Total beneficiary	66922.50	0.00	7520.00	5210.98	79653.48			47792.09	0.00	0.00	0.00
37. FoHM	502649.33	0.00	111360.00	42980.65	656989.98			394193.99	0.00	0.00	0.00
38. SoS	6509.59	0.00	7520.00	982.07	15011.66			9007.00	0.00	0.00	0.00
39. SBA	6658.60	0.00	5640.00	860.90	13159.50			7895.70	0.00	0.00	0.00
40. NFA	12300.00	0.00	3760.00	1124.20	17184.20			10310.52	0.00	0.00	0.00
41. SVA	7466.67	0.00	4970.00	870.57	13307.24			7984.34	0.00	0.00	0.00
42. SRC	36000.00	0.00	8960.00	3147.20	48107.20			28864.32	0.00	0.00	0.00
43. UAS	11904.76	0.00	7520.00	1359.73	20784.49			12470.69	0.00	0.00	0.00
44. ANSES	225736.00	0.00	29033.07	17833.83	272602.90			163561.74	0.00	0.00	0.00
Total consortium	4948366.62	282000.00	1277675.07	455562.92	6963604.61	607	4178162.75	4178162.75	0.00	0.00	0.00

# ESTIMATED BUDGET FOR THE ACTION (page 5 of 5 Associated with document Ref. Ares(2017)4194538 - 28/08/2017

- (1) See Article 6 for the eligibility conditions
- (2) The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme). A beneficiary that receives an operating grant during the action's duration cannot claim any indirect costs for the year(s)/reporting period(s) covered by the operating grant
- (3) This is the theoretical amount of the EU contribution that the system calculates automatically (by multiplying all the budgeted costs by the reimbursement rate). This theoretical amount is capped by the 'maximum grant amount' (that the Agency decided to grant for the action) (see Article 5.1)
- (4) The 'maximum grant amount' is the maximum grant amount decided by the Agency. It normally corresponds to the requested grant, but may be lower
- (5) See Article 5 for the cost forms
- (6) flat rate: 7% of eligible direct costs
- (7) The reimbursement rate is applied at consortium level only (i.e. to the total costs). The reimbursement rate is normally 60% (or 80% in cases of exceptional utility)

MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE (MoH-FR), N/A, established in AVENUE DUQUESNE 14, PARIS CEDEX 75350, France, N/A ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('2')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

**GESUNDHEIT ÖSTERREICH GMBH (GÖG)** GMBH, FN281909Y, established in STUBENRING 6, WIEN 1010, Austria, ATU62777178 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('3')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

**SERVICE PUBLIC FEDERAL SANTE PUBLIQUE, SECURITE DE LA CHAINE ALIMENTAIRE ET ENVIRONNEMENT (FPS HFCSE)**, N/A, established in SQUARE VICTOR HORTA 40 BUR 1D 1G, BRUSSELS 1060, Belgium, N/A ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('4')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Els EEMAN with ECAS id neemanel signed in the Participant Portal on 31/08/2017 at 10:44:03 (transaction id Sigld-34412-Y8ysTPhRxs0KPvBMAfRYpQYusLJb57NzoDsnZYjL3Vvk 6ctNalHxl1n6oWKRGJIMCozKnmgHaUrAPtwdi5bzRRW-Jj71zxYb8yrN6HT4pVHCoC-

NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES (NCIPD), 000662721, established in blvd. Yanko Sakazov 26, SOFIA 1504, Bulgaria ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('5')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH), 080407487, established in ROCKEFELLEROVA 7, ZAGREB 10000, Croatia, HR75297532041 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('6')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

#### ACCESSION FORM FOR BENEFICIARIES

**STATNI ZDRAVOTNI USTAV (NIPH)**, 75010330, established in Srobarova 48, PRAHA 10 10042, Czech Republic ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

## hereby agrees

to become beneficiary ('7')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

For the beneficiary

Jitka SOSNOVCOVA with ECAS id nsosnoji signed in the Participant Portal on 29/08/2017 at 10:34:03 (transaction id Sigld-13543-4T7V32SIzUpZqYcPO5ZgtlLNZARpmGKBOHi39HAxFNy 4R5k8zT5fLQFXNgs9tgnVEYTwXbwQj6xAeagSiUX38j-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**STATENS SERUM INSTITUT (SSI)**, 46837428, established in ARTILLERIVEJ 5, KOBENHAVN S 2300, Denmark, DK46837428 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

## hereby agrees

to become beneficiary ('8')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Kare MOLBAK with ECAS id nmolbaka signed in the Participant Portal on 29/08/2017 at 14:48:45 (transaction id Sigld-17588-Awkh0fRtyeCyKwNajPdQ2HbUaj4LfXgozizJUc2C7zyaA7 WCKe46rk0LX6gQP0QXPESqzTGHQzQUuDF8uYrn761-Jj71zxYb8yrN6HT4pVHCoC-

**TERVISEAMET (TA)**, 70008799, established in PALDISKI MNT 81, TALLINN 10617, Estonia, EE101339803 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('9')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

#### ACCESSION FORM FOR BENEFICIARIES

**ROBERT KOCH-INSTITUT (RKI)**, n/a, established in Nordufer 20, Berlin 13353, Germany ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

#### hereby agrees

to become beneficiary ('10')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Katharina SCHMITT with ECAS id nschmawg signed in the Participant Portal on 31/08/2017 at 09:16:16 (transaction id Sigld-32608-gLLT5gzvOe4R1Q4tGqZRiM8imGprBvxpieNAxRY4XNW CJI6KMfdV90aUUEzcDS6sLxQzjxAMnpykp4IXgFMN9O0-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**KENTRO ELENCHOU & PROLIPSIS NOSIMATON (HCDCP)** GR8, 2071, established in AGRAFON STREET 3-5, MAROUSI 15123, Greece, EL090193594 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('11')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

**ETHNIKI SCHOLI DIMOSIAS YGEIAS (ESDY-NSPH)**, 2194, established in 196 ALEXANDRAS AVENUE, ATHINA 11521, Greece, EL099017070 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('12')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

**DIOIKHSH YGEIONOMIKHS PERIFEREIAS KRHTHS (7HC)**, ., established in 3RD KM NATIONAL ROAD HERAKLION MOIRES, HERAKLION 71500, Greece, EL999161778 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

## hereby agrees

to become beneficiary ('13')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Eleni MAVROMMATI with ECAS id nmvroele signed in the Participant Portal on 28/08/2017 at 20:56:14 (transaction id Sigld-10371-Mzrl779OblrMAxcsRVkH8teHhcRyX2zhyfbFMcOPpX7Da OaY2Ky8ULOBVmLEO8wxziHKSZzu5v06VKGZxzjszfzq-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**UNIVERSITA DEGLI STUDI DI FOGGIA (UNIFG)**, CF94045260711, established in VIA GRAMSCI 89/91, FOGGIA 71122, Italy, IT03016180717 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('14')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

For the beneficiary

Maurizio RICCI with ECAS id nrimauri signed in the Participant Portal on 29/08/2017 at 07:55:00 (transaction id Sigld-11208-RP6e1smP9UT5vSZOO3dcZOZ9D44FK9bfqSl2jze3maZ viXCeDFosZLT8fPrCAUhCYa9PcXxZ5RdDF7yELGehgG-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**ISTITUTO SUPERIORE DI SANITA (ISS)**, 80211730587, established in Viale Regina Elena 299, ROMA 00161, Italy ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

## hereby agrees

to become beneficiary ('15')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

For the beneficiary

Gualtiero RICCIARDI with ECAS id ngaracen signed in the Participant Portal on 31/08/2017 at 11:17:17 (transaction id Sigld-35204skjbB9zwBPtBHK1jGCzXm8HDjFNpw0CwXaWVBQ1Oyk UzH0b00OG9pH7COjFQ76J8jdtlVGx54Fugspy5jMiE7Vm -Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA (PSKUS)** SIA, 40003457109, established in PILSONU IELA 13, RIGA 1002, Latvia, LV40003457109 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('16')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

**LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS (LSMULKK)** LT3, 135163499, established in EIVENIU 2, KAUNAS 50009, Lithuania, LT351634917 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('17')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

**VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS (VULSK)** LT3, 124364561, established in SANTARISKIU G 2, VILNIUS 08661, Lithuania, LT243645610 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('18')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Elena JUREVIČIENĖ with ECAS id njurevel signed in the Participant Portal on 29/08/2017 at 08:43:25 (transaction id Sigld-11679-IFF8pW4JJSh2EKOqYZtCHzHYuR096quzdvDzHAnJzxELG0uZjzg6bJWAQnIXAP2szeRf3abDdzdXxc4sMUxJI0PG-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**HIGIENOS INSTITUTAS (HI)**, 111958286, established in DIDZIOJI STREET 22, VILNIUS LT-01128, Lithuania ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

## hereby agrees

to become beneficiary ('19')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

## **SIGNATURE**

For the beneficiary

Ausra GRIGOSAITIENE with ECAS id ngrigaus signed in the Participant Portal on 29/08/2017 at 09:42:25 (transaction id Sigld-12582-OLIZGgAZc9A6m3aL6gf5mMDQXsYAOc27BFXaFHkiyKFPjlK60Z6tbagkEzNua3lcbDB1ULpOAyQKDeZAU907Ce-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS (NVSC), 291349070, established in KALVARIJU 153, VILNIUS LT-08221, Lithuania ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('20')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

INGRIDA SKRIDAILIENE with ECAS id nskridin signed in the Participant Portal on 30/08/2017 at 09:53:56 (transaction id Sigld-23107-jvVN1odVSBYEnG2MAYUEEh0gb4FNbWlsKQKYIG6apy BryeFzTugzh5w6q3mhHEBJye5i1tiuPsuNlbbRwyxkfN-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

MINISTERIE VAN VOLKSGEZONDHEID, WELZIJN EN SPORT (VWS), N/A, established in PARNASSUSPLEIN 5, DEN HAAG 2500 EJ, Netherlands ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('21')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

**HELSEDIREKTORATE** (HdiR), 983544622, established in UNIVERSITETSGATA 2, OSLO 0164, Norway ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('22')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

For the beneficiary

Marit ENDRESEN with ECAS id nenmarit signed in the Participant Portal on 01/09/2017 at 09:08:50 (transaction id Sigld-42262-QPKdfthYuWCYPtBd08fou1Qv9hkQ2rYeUyJPsf1VoIOA9 oEPxVCVzNomaK66by5FtycHPmuMYPURaKXrHCAeL0-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**FOLKEHELSEINSTITUTTET (FHI)**, 983744516, established in LOVISENBERGGATA 8, OSLO 0456, Norway, NO983744516MVA ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('23')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

For the beneficiary

Geir BUKHOLM with ECAS id nbukhoge signed in the Participant Portal on 29/08/2017 at 11:55:45 (transaction id Sigld-14819-gvuizV7Oo5cIJ9C2MssSwFuD3dfpasd1IN8H19yzIKEUHI M0XHJxNFo6pzWhovvXQwE86kdEN2fZP2kwHNH29aG-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**VETERINAERINSTITUTTET - NORWEGIAN VETERINARY INSTITUTE (NVI)**, 970955623, established in ULLEVALSVEIEN 68, OSLO 0454, Norway ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('24')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

For the beneficiary

Gaute LENVIK with ECAS id nlenvgau signed in the Participant Portal on 01/09/2017 at 10:14:48 (transaction id Sigld-43125-RL6vm7qKuIVXNezoG4XW6uKmzzTIJBKFhY4Uj0RIBaPzhjNHMsYbIOTQZ9Tm2SZQcxXXvCsbJZxbKCBysuKrgNu-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**NARODOWY INSTYTUT LEKOW (NMI)**, 015244176, established in ULICA CHELMSKA 30/34, WARSZAWA 00 725, Poland, PL5213212384 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('25')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

## ACCESSION FORM FOR BENEFICIARIES

**MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA (DGS)**, Decreto-Lei n.º 212/2006, de 27 de Outubro , established in Av. João Crisóstomo, 9, LISBOA 1049-062 , Portugal ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('26')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

UNIVERSITATEA DE MEDICINA SI FARMACIE IULIU HATIEGANU CLUJ-NAPOCA (UMPIH), 263327, established in Emil Isac Street 13, Cluj-Napoca 400023, Romania, RO4288047 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('27')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

ALEXANDRU IRIMIE with ECAS id nirialex signed in the Participant Portal on 29/08/2017 at 08:20:05 (transaction id Sigld-11433-7HZ4wzsJh0NCDqzXmyEu9Y84RAopfBsTZfZCNGmfQvlbpPoLuAkP2Vp17LQheY8r6iSviO5QbY06fTFAJzcXfs0-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ) SI2, 6462642000, established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia, SI44724535 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('28')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Ivan ERŽEN with ECAS id nerzivan signed in the Participant Portal on 29/08/2017 at 06:12:40 (transaction id Sigld-10823-MVZv4zkRE1GzrpjrbjkMuEvMg7NgO4bJg8vGyLVvAzLx G3ZwzTrzMHw6ZwDcmsQ3pNK8oaedSFySR3kp0nm5TI v-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**AGENCIA ESPANOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)**, established in c/ Campezo Edificio 8 1, MADRID 28022, Spain, ESQ2827023I ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('29')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

**DEPARTAMENT DE SALUT - GENERALITAT DE CATALUNYA (GENCAT)**, established in Trav. de les Corts (Pavelló Ave Maria) 131-159, BARCELONA 08028, Spain ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('30')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

**CONSELLERIA DE SALUD (IdISBa)** ES8, established in PLAZA DE ESPANA 9, PALMA DE MALLORCA 07002, Spain, ESS0711001H ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('31')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

For the beneficiary

Patricia GOMEZ with ECAS id ngomeaaz signed in the Participant Portal on 29/08/2017 at 08:03:15 (transaction id Sigld-11275-M2180SzduqdlklQ2lixzvxcGhSthelk0k5PlKu27lnNfx7zza mjBiXTAWWoQJR66znlN1edeVhSpzRbqzdkEfaAS-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**FUNDACION PARA LA FORMACION E INVESTIGACION SANITARIAS DE LA REGION DE MURCIA (FFIS)** ES3, 92, established in CALLE LUIS FONTES PAGAN 9 EDIF EMI HOSPITAL REINA SOFIA, MURCIA 30003, Spain, ESG73338857 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('32')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Jesus Angel SANCHEZ with ECAS id nsajeusa signed in the Participant Portal on 29/08/2017 at 14:20:03 (transaction id Sigld-16926-kftB0W0wQ5vDzQTQ0R558HisxnDNCWhq18zty52R5qZv9eDNkMFzqYaqx3zVD8AT72STHjVkugztckce3QFipdC-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**FUNDACION PUBLICA MIGUEL SERVET (FMS)** ES3, 406, established in CALLE IRUNLARREA 3 CENTRO INVESTIGACION BIOMEDICA RECINTO COMPLEJO HOSPITALARIO DE NAVARRA, PAMPLONA 31008, Spain, ESG31187420 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('33')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Iñigo LASA UZCUDUN with ECAS id nlasauin signed in the Participant Portal on 29/08/2017 at 07:43:27 (transaction id Siglid-11139-bJ9Xh4cgxoSzabngJHRS6wRzmlWNgZbcTuEBvUU3xf1 1IKuUrM1L9ufC3ccloSHHqu1RVpO1xGmfJvfVlG2w1l-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**SERVICIO ANDALUZ DE SALUD (SAS)**, not applicable, established in AVENIDA DE LA CONSTITUCION 18, SEVILLA 41071, Spain, ESQ9150013B ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('34')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

## ACCESSION FORM FOR BENEFICIARIES

**INSTITUTO DE SALUD CARLOS III (ISCIII)**, established in MONFORTE DE LEMOS 5, MADRID 28029, Spain, ESQ2827015E ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('35')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

#### ACCESSION FORM FOR BENEFICIARIES

**SERVICIO MADRILENO DE SALUD (SERMAS)**, 142005, established in PLAZA CARLOS TRIAS BERTRAN 7, MADRID 28020, Spain, ESQ2801221I ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('36')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

#### ACCESSION FORM FOR BENEFICIARIES

**FOLKHALSOMYNDIGHETEN (FoHM)**, 2021006545, established in NOBELS VAG 18, SOLNA 171 82, Sweden, SE202100654501 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('37')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

# and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Anders TEGNELL with ECAS id ntegande signed in the Participant Portal on 29/08/2017 at 15:21:45 (transaction id Sigld-18261-8sa5zZKyUYLCrlUdAUTzK3a2kPhojFt6P2SOE3aduxff4fgI7n0qCSAk7VD0qGdouvYLUWpJocSjU2L2ZCMhyO-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**SOCIALSTYRELSEN (SoS)**, 2021000555, established in RALAMBSVAGEN 3, STOCKHOLM 106 30, Sweden, SE202100055501 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('38')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

the coordinator to submit and sign in its name and on its behalf any amendments to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

For the beneficiary

Axana HAGGAR with ECAS id nhaggaax signed in the Participant Portal on 29/08/2017 at 09:40:14 (transaction id Sigld-12538-0AeJ2CziGNNDDviM9TKiwknlbN0M7PRirAwIP6QqBQtH 840VI4oEIETAtFHLIiXJui5XS1Fo8RYnoS8iLMuk70-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**STATENS JORDBRUKSVERK (SBA)**, 2021004151, established in JONKOPING, JONKOPING 551 82, Sweden, SE202100415101 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('39')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

#### ACCESSION FORM FOR BENEFICIARIES

**LIVSMEDELS VERKET (NFA)**, 202100-1850, established in Hamnesplanaden 5, UPPSALA 751 26, Sweden ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('40')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

#### ACCESSION FORM FOR BENEFICIARIES

**STATENS VETERINAERMEDICINSKA ANSTALT (SVA)**, 2021001868, established in Ulls Vaeg 2B, UPPSALA 75189, Sweden ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('41')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

For the beneficiary

Jens MATTSSON with ECAS id nmattsje signed in the Participant Portal on 29/08/2017 at 06:39:24 (transaction id Sigld-10881-zyEommeFxUjNFHcTco9YoWfae1zdairwa3azQRad7ojFgZaq5Tjx52TmCRdTq0hDAyXvp5hu5GMHgH1d1zzYSqn-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

**VETENSKAPSRADET - SWEDISH RESEARCH COUNCIL (SRC)**, 2021005208, established in VASTRA JARNVAGSGATAN 3, STOCKHOLM 111 64, Sweden ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('42')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

## ACCESSION FORM FOR BENEFICIARIES

**UPPSALA LANS LANDSTING (UAS)**, 2321000024, established in PO BOX 602, UPPSALA 751 25, Sweden, SE232100002401 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('43')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

## and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

# **SIGNATURE**

For the beneficiary

Staffan ISLING with ECAS id nislinst signed in the Participant Portal on 01/09/2017 at 08:41:36 (transaction id Sigld-41950-9zvfwHYn0IDC3LCUzLcjfnzk9Y5RMFvL78KwWB0fqWTN ANJXRzhkPVovcnrDuVzZhszj2YXRXtoNI1vrZ6mzM6ti-Jj71zxYb8yrN6HT4pVHCoC-

#### ACCESSION FORM FOR BENEFICIARIES

AGENCE NATIONALE DE LA SECURITE SANITAIRE DE L ALIMENTATION DE L ENVIRONNEMENT ET DU TRAVAIL (ANSES), 130012024, established in 14 RUE PIERRE ET MARIE CURIE, MAISONS ALFORT 94700, France, FR54130012024 ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

# hereby agrees

to become beneficiary ('44')

in Grant Agreement No 761296 ('the Agreement')

**between** INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE **and** the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission'),

**for the action entitled** 'European Joint Action on antimicrobial resistance and associated infections (EU-JAMRAI)'.

#### and mandates

**the coordinator** to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the grant in accordance with the Agreement, with all the obligations and conditions it sets out.

**SIGNATURE** 

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# MODEL ANNEX 4 CHAFEA MGA — MULTI

# FINANCIAL STATEMENT FOR [BENEFICIARY [name]/AFFILIATED ENTITY [name]] FOR REPORTING PERIOD [reporting period]

	Eligible <sup>1</sup> costs (per budget category)						EU contribution		
	A. Direct personnel costs	B. Direct costs of subcontracting	3		Total costs	Income generated by the action	Financial contributions given by third parties to the beneficiaries	Total receipts	Requested EU contribution <sup>3</sup>
	A.1 Employees A.2 Natural persons under direct contract and seconded persons		C.1 Travel C.2 Equipment C.3 Other goods and services						
Cost form 4	Actual	Actual	Actual	Flat-rate 7%					
	a	b	С	d = 0,07 * (a + b + c)	e = a + b + c + d	f	g	h = f + g	i
[short name beneficiary/affiliated entity]									

# The beneficiary/affiliated entity hereby confirms that:

The information provided is complete, reliable and true.

The costs declared are eligible (see Article 6).

The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 12, 13 and 17).

For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

① Please declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace other costs that are found to be ineligible.

 $<sup>^{\</sup>mathrm{1}}$  See Article 6 for the eligibility conditions

The indirect costs claimed must be free of any amounts covered by an operating grant (received under any EU or Euratom funding programme); see Article 6.2.D. If you have received an operating grant during this reporting period, you cannot claim any indirect costs

You may request up to 100% of the total cost declared. The reimbursement rate mentioned in Article 5.2 applies only at consortium level (and will only be checked by the Agency at the payment of the balance)

See Article 5 for the cost forms

<sup>&</sup>lt;sup>5</sup> Flat rate : 7% of eligible direct costs

# ANNEX 4 CHAFEA MGA — MULTI: Details

Direct personnel costs							
1 Employees	Name/Function		No of hours worked for the project	Hourly rate	Total costs		
			(a)	, (b)	(c) = (a) * (b)		
<u> </u>					(5) (5)		
				Total for A.1 Employees			
					1		
2 Natural persons under direct contract							
	Name/Function		No of hours worked for the project (a)	Hourly rate (b)	Total costs (c) = (a) * (b)		
			(α)	(5)	(6) (4) (5)		
			Total for A.2 Natural persons				
			Total fo	seconded persons r A. Direct personnel costs			
Direct costs of subcontracting							
Invoice Number	Subcontractor and Description of task				Price		
_			Total for B. Dire	ect costs of subcontracting			
Other direct costs							
1 Travel							
Description (Name of per	son travelling, meeting as referenced in the technical report, place of the meeting)	Travel cost	No of days	Daily rate	Total costs		
		(a)	(b)	(c)	(d) = (a) + ((b) * (c))		
				Total for C.1 Trave			
2 Equipment						1	
Invoice Number	Description of the equipment	Purchase price	Date of purchase	Depreciation method (36 or 60 month)	Number of month of depreciation allocated to the project	% of use for the purpose of the project	Total cost
		(a)	(b)	(c)	(d)	(e)	(f) = ((d)/(c) * (e)
		+					
1		1	1			Total for C.2 Equipment	
3 Other goods and services							
Invoice Number	Description of service or good				Purchase price		
				Other goods and services			
			Tot	Total for C. Other direct costs			

ANNEX 5

# MODEL OF THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- > For options [in italics in square brackets]: choose the applicable option. Options not chosen should be deleted.
- For fields in [grey in square brackets]: enter the appropriate data

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- 1. TERMS OF REFERENCE FOR INDEPENDENT CERTIFICATE ON FINANCIAL STATEMENTS AND REPORT ON FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HEALTH AND CONSUMER PROGRAMMES 2014-2020
- **2.**MODEL OF CERTIFICATE ON FINANCIAL STATEMENTS TO BE PROVIDED BY INDEPENDENT AUDITOR
- 3. TEMPLATE OF THE REPORT ON FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER HEALTH AND CONSUMER PROGRAMMES 2014-2020

Terms of Reference for an Independent Certificate on Financial Statements and Report on Findings on costs declared under a Grant Agreement financed under the Health and Consumer Programmes 2014-2020

This document sets out the 'Terms of Reference (ToR)' under which

[insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[insert legal name of the auditor] ('the Auditor')

to issue an Independent Certificate on the Financial Statements' ('CFS') referred to in Articles 15.3 and 15.4 of the Agreement based on the compulsory reporting template stipulated by the Agency, and

to produce an independent Report of findings ('the Report') concerning the Financial Statement(s)<sup>1</sup> drawn up by the [Beneficiary] [Affiliated Entity] for the [Health] / [Consumer] Programme 2014-2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'),

The Agreement has been concluded under the [Health] / [Consumer] Programme 2014-2020 between the Beneficiary and Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) ('the Agency'), under the powers delegated by the European Commission ('the Commission').

The *Agency* is mentioned as a signatory of the Agreement with the Beneficiary only. The Agency is not a party to this engagement.

# 1.1 Subject of the engagement

The coordinator must submit to the Agency the final report within 60 days following the end of the each reporting period which should include, amongst other documents, a CFS for each beneficiary (and linked affiliated entity), for which the total contribution in the form of reimbursement of actual costs as referred to in Article 5.2 of the Agreement is at least EUR 750.000, and which requests a reimbursement in that form of EUR 325 000 or more, as reimbursement of actual costs calculated on the basis of its usual cost accounting practices. The CFS must cover the reporting period of the beneficiary (or linked Affiliated Entity) concerned by the payment.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked Affiliated Entity, if the CFS must be included in the interim and final reports according to Articles 15.3 and 15.4 of the Agreement.

The CFS is composed of the following documents:

By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Terms of Reference ('the ToR') to be signed by the [Beneficiary] [Affiliated Entity] and the Auditor;
- the Auditor's Certificate on Financial Statements and Independent Report of Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon checks (laid down in the Annex I to the Report) to be performed by the Auditor, and the standard findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the interim and final report according to Articles 15.3 and 15.4 of the Agreement, the request for interim payment or payment of the balance to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the Agency, the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 17 of the Agreement.

# 1.2 Responsibilities

The [Beneficiary] [Linked Affiliated Entity]:

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the [Beneficiary's] [Linked Affiliated Entity's] accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the checks.;
- accepts that the Auditor cannot carry out the checks unless he/she is given full access to the [Beneficiary's] [Linked Affiliated Entity's] staff and accounting as well as any other relevant records and documentation.

# The Auditor:

- [Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations].
- [Option 2 if the Beneficiary or Linked Affiliated Officer has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary].

# The Auditor:

- must be independent from the Beneficiary [and the Linked Affiliated Entity], in particular, it must not have been involved in preparing the [Beneficiary's] [Linked Affiliated Entity's] Financial Statement(s);
- must plan work so that the checks may be carried out and the Findings may be assessed:
- must adhere to the checks laid down in Annex I to the Report and the compulsory report format;
- must carry out the engagement in accordance with this ToR;

- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the [Beneficiary] [Linked Affiliated Entity].

The Agency sets out the list of checks to be carried out by the Auditor which is defined in detail in the Annex I to the Report. The Auditor has to examine the Financial Statements and verify the supporting documentation in order to provide a reasonable assurance on their correctness.

# 1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with<sup>2</sup>:

- the International Standard on Related Services ('ISRS') 4400 Engagements to perform Agreed-upon Procedures regarding Financial Information as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants (IESBA). Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon checks, the Agency requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary [and the Linked Affiliated Entity], and must specify if the service is invoiced - the total fee paid to the Auditor for providing the Report.

# 1.4 Reporting

The Report must be written in the language of the Agreement.

Under Article 17 of the Agreement, the Agency, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from *the European Union* budget. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the Agency, the European Anti-Fraud Office or the European Court of Auditors requests them.

# 1.5 Timing

The CFS must be provided together with the request for the interim and balance payment, if required according to Articles 15.3 and 15.4 of the Agreement.

# 1.6 Other terms

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Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

Grant Agreement number: [insert number] [insert acronym] [insert call\_identifier] Associated with document Ref. Ares(2017)4194538 - 28/08/2017

# CHAFEA Model Grant Agreements: CHAFEA MGA — Multi: 09.01.2015

[The [Beneficiary] [Linked Affiliated Entity] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor [legal name of the [Beneficiary]][Linked Affiliated Entity]]
[name & function of authorised representative]
[name & function of authorised representative]
[dd Month yyyy]
[dd Month yyyy]
Signature of the Auditor
Signature of the [Beneficiary]][Linked Affiliated

Entity]

# Independent certificate on the financial statements declared under grant agreements signed under the Health and Consumer Programmes 2014-2020

(To be submitted by each beneficiary if the maximum grant amount in the form of reimbursement of 'actual costs' is at least EUR 750 000 and if it requests a reimbursement of actual costs of at least EUR 325 000 (see Articles 15.3 and 15.4)

To be drawn up and signed by an approved auditor or, in case of public bodies, by a competent and independent public officer (and printed on their letterhead).)

Ί	0
	name of contact person(s)], [Position]
[	[Beneficiary's] [Linked Affiliated Entity's] name]
[	Address]
	dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with [OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked Affiliated Entity ('the Linked Affiliated Entity), Affiliated Entity linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')],

we [name of the auditor] ('the Auditor'), established at [full address/city/state/province/country], represented by [name and function of an authorised representative],

have carried out an audit relating to the provisions of the Terms of Reference, the costs declared in the Financial Statement(s)<sup>3</sup> of the [Beneficiary] [Linked Affiliated Entity], the documents provided in their support, to which this Certificate is attached, and which is to be presented to Agency together with the request for payment under the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'), for the following period (s) covered by Agreement [insert period(s) covered by the Financial Statements].

The audit and subsequent checks were carried out solely to assist Agency in evaluating whether the [Beneficiary] [Linked Affiliated Entity's] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The Agency will draw its own conclusions from the Report and any additional information it may require.

The above mentioned Financial Statement(s) of the [Beneficiary] [Linked Affiliated Entity], their supporting documentation and accounting records were examined in accordance with

By which the Beneficiary declares costs under the Agreement (see template 'Financial Statement' in Annex 4 to the Agreement).

the upon-agreed checks, as detailed in Annex I to the Report, in order to provide Agency with the following reasonable assurance:

- the amount of the total eligible costs ([insert amount in number] ([insert amount in words<sup>4</sup>])) declared in the attached Financial Statement(s) of the [Beneficiary] [Linked Affiliated Entity] is complying with the following cumulative conditions, as defined in the Article 6.1 of the Agreement:
  - ✓ they are actual and recorded in the [Beneficiary's] [Linked Affiliated Entity's] accounts at the date of the establishment of this audit certificate;
  - ✓ they have been incurred during the periods covered by the Financial Statement(s) concerned by this audit certificate;
    - [they also include the eligible costs incurred in drawing up the final reports referred to in Article 15 of the Agreement, which may be incurred up to two calendar months after the end of the action;]
  - ✓ they are determined in accordance with the beneficiary's accounting standards applicable in the country where the [Beneficiary] [Linked Affiliated Entity] is established, and with the beneficiary's usual cost accounting practices;
  - ✓ they comply with the national law on taxes, labour and social security applicable in the country where the [Beneficiary] [Linked Affiliated Entity] is established;
  - ✓ they are exclusive of any non-eligible costs identified below which are established in Article 6.4 of the above mentioned agreement with the Agency:
    - return on capital;
    - debt and debt service charges;
    - provisions for future losses or debts;
    - interest owed:
    - doubtful debts;
    - currency exchange losses;
    - bank costs charged by the beneficiary's bank for transfers from the Agency;
    - deductible VAT;
    - costs incurred during suspension of the implementation of the action;
    - excessive or reckless expenditure;
    - contributions in kind provided by third-parties;
    - costs declared under another EU or Euratom grant, in particular, indirect costs if beneficiary is already receiving an operating grant financed by EU or Euratom in the same period.
  - ✓ [they are claimed according to the EUR conversion rate as defined in the Article 15.5 of the Agreement;
- as declared in the Financial Statement(s) of the [Beneficiary] [Linked Affiliated Entity] and only for the request of payment of the balance, the total amount of receipts for the total period covered by this(those) Financial Statement(s) is equal to ([insert amount in number] ([insert amount in words<sup>5</sup>]);

<sup>5</sup> In EUR.

<sup>&</sup>lt;sup>4</sup> In EUR.

- accounting procedures used in the recording of eligible costs and receipts respect the accounting rules of the State in which the beneficiary is established and permit the direct reconciliation between the costs and receipts incurred for the implementation of the project covered by the Agreement and the overall statement of accounts relating to the beneficiary's overall business activity<sup>6</sup>;
- based on our audit, we can conclude that the financial management of the grant was carried out in an acceptable manner and in compliance with the requirements of [grant agreement reference: title, acronym, number]
- our company [organisation for competent public officers] is qualified to deliver this audit certificate in full compliance with the Articles 15.3 and 15.4 of the agreement;
  - [Relevant information establishing this qualification is included with this audit certificate;]<sup>7</sup>

The list of Findings, Exceptions and Further remarks, if any, is presented in the Report annexed to this Certificate.

The Certificate on Financial Statement(s) and Report was prepared solely for the confidential use of the [Beneficiary] [Linked Affiliated Entity] and the Agency, and only to be submitted to the Agency in connection with the requirements set out in Articles 15.3 and 15.4 of the Agreement. The Certificate and Report may not be used by the [Beneficiary] [Linked Affiliated Entity] or by the Agency for any other purpose, nor may it be distributed to any other parties. The Agency may only disclose these documents to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

Both Certificate and Report relate only to the Financial Statement(s) submitted to the Agency by the [Beneficiary] [Linked Affiliated Entity] for the Agreement. Therefore, they do not extend to any other of the [Beneficiary's] [Linked Affiliated Entity's] Financial Statement(s).

There was	no conflict	of interest <sup>8</sup>	between	the Aud	itor and	the Bene	eficiary [	and Linked
Affiliated E	<i>Intity]</i> in esta	ablishing the	se docum	ents. As	declared	l in the Fi	nancial S	Statement(s)
the total fe	ee paid to the	he Auditor	for provi	ding the	Report	was EUR		(including
EUR	of deductib	ole VAT).						

[legal name of the Auditor]
[name and function of an authorised representative]

<sup>7</sup> If the auditor is not known internationally or for a competent public officer whose competence to provide an audit certificate has not been attested to by its national authorities.

<sup>&</sup>lt;sup>6</sup> Article 6.1.

A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:

<sup>-</sup> was involved in the preparation of the Financial Statements;

<sup>-</sup> stands to benefit directly should the certificate be accepted;

<sup>-</sup> has a close relationship with any person representing the beneficiary;

<sup>-</sup> is a director, trustee or partner of the beneficiary; or

<sup>-</sup> is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

[dd Month yyyy] Signature of the Auditor

# Report of Findings on costs declared under grant agreement signed under Health and Consumer Programmes 2014-2020

# **Not applicable Findings**

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

## Explanation (to be removed from the Report):

If a Finding was not applicable, it must be marked as 'N.A.' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related check(s) did not have to be carried out.

The reasons of the non-application of a certain Finding must be obvious i.e.

- i) if no cost was declared under a certain category then the related Finding(s) and check(s) are not applicable;
- ii) if the condition set to apply certain check(s) are not met the related Finding(s) and those check(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the check and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and check(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

••••

#### **Exceptions**

The [Beneficiary] [Linked Affiliated Entity] provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested checks and evaluate the Findings.

Explanation (to be removed from the Report):

- If the Auditor was not able to successfully complete a procedure requested,. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the audit must be indicated below.
- If the Auditor cannot corroborate a standard finding after having carried out the corresponding audit, it must state, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

• • • •

Example (to be removed from the Report):

- 1. The Beneficiary was unable to substantiate the Finding number 1 on ... because ....
- 2. Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate daily costs was different from the one accepted by the Agency. The differences were as follows: ...
- 3. After carrying out the agreed checks to confirm the Finding number 31, the Auditor found a difference of \_\_\_\_\_\_EUR. The difference can be explained by ...

# **Further Remarks**

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

### Example (to be removed from the Report):

- 1. Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because ...
- 2. In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ....

#### ANNEX I to the Report on Findings: Agreed-upon checks to be performed and standard findings to be confirmed by the Auditor

The Agency reserves the right to i) provide the auditor with additional guidance regarding the checks to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the checks, by notifying the Beneficiary in writing. The list of checks to be carried out by the auditor in order to confirm the standard findings is laid down in the table below.

If this certificate relates to a Linked Affiliated Entity, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Affiliated Entity'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- > 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard finding' and, therefore, there is no exception to be reported.
- ➤ 'E' stands for 'exception' and means that the Auditor carried out the checks but cannot confirm the 'standard finding', or that the Auditor was not able to carry out a specific check (e.g. because it was impossible to reconcile key information or data were unavailable),
- N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related check(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and check(s) are not applicable; ii) if the condition set to apply certain checks(s) are not met then the related Finding(s) and checks(s) are not applicable. For instance, if no additional remuneration is paid, the related Finding(s) and check(s) for additional remuneration are not applicable.

Ref	Checks	Standard finding	Result (C / E /N.A)
A	ACTUAL PERSONNEL COSTS CALCULATED BY THE BENEFICIARY IN ACCOUNTING PRACTICE	ACCORDANCE WITH ITS US	UAL COST
	The Auditor draws the full list of persons (including <i>employees and natural persons working under a direct contract</i> ) whose costs were declared in the Financial Statement(s) in order to carry out the checks indicated in the consecutive points of this section A.  (The Auditor sampled people out of the total of people.		

Ref	Checks	Standard finding	Result (C / E /N.A)
A.1	PERSONNEL COSTS  For the persons declared by the beneficiary or Linked Affiliated Entity in the Financial Statement, and working under an employment contract or equivalent act (general procedures for individual actual personnel costs)  To confirm standard findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary:  o a list of the persons declared by Beneficiary or Linked Affiliated Entity indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract;  the paysling of the employees:	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
	the accounting system (project accounting and general ledger) and payroll system; information concerning the employment status and employment conditions of the declared personnel, in particular their employment contracts or equivalent; the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); applicable national law on taxes, labour and social security and any other document that supports the personnel costs declared.	Personnel costs were recorded in the Beneficiary's accounts/payroll system.  3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		<ul> <li>4) Personnel costs did not contain any ineligible elements.</li> <li>5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.</li> </ul>	

Ref	Checks	Standard finding	Result (C / E /N.A)
	Further procedures if 'additional remuneration' is paid  To confirm standard factual findings 6-8 listed in the next column, the Auditor:  oreviewed relevant documents provided by the Beneficiary (legal form, legal/statutory obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation);  recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.).  If any part of the remuneration paid to the employee is not mandatory according to the national law or the employment contract ("additional remuneration") and is eligible under the provisions of article 6.2.A., this can be charged as eligible cost to the action.	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.  7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required.  8) The criteria used to calculate the additional remuneration	
	For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).  To confirm standard factual findings 9-13 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary:	were objective and generally applied by the Beneficiary regardless of the source of funding used.  9) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions).  10) They worked on the Beneficiary's premises (unless otherwise agreed with the	

			Result
Ref	Checks	Standard finding	(C / E /N.A)
	<ul> <li>the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary;</li> </ul>	Beneficiary).	
	<ul> <li>the employment conditions of staff in the same category to compare costs and;</li> </ul>		
	<ul> <li>any other document that supports the costs declared and its registration (e.g. invoices, accounting records, etc.).</li> </ul>	11) The results of work carried out belong to the Beneficiary.	
		12) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		13) The costs were supported by audit evidence and registered in the accounts.	
A.2	PRODUCTIVE HOURS  To confirm standard factual findings 14-19 listed in the next column, the Auditor	14) The Beneficiary applied method [choose one option and delete the others]	
	reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that:	[ <b>A</b> : 1720 hours]	
	<ul> <li>the annual productive hours applied were calculated in accordance with one of the methods described below,</li> </ul>	[ <b>B</b> : the 'total number of hours worked']	
	<ul> <li>the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated.</li> </ul>	[C: 'annual productive hours' used correspond to usual accounting practices]	
	If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual	15) Productive hours were calculated annually.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	workable hours.  If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the	16) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
	standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts.	<ul><li>If the Beneficiary applied method B.</li><li>17) The calculation of the</li></ul>	
	Beneficiary's Productive Hours' for Persons working full time shall be one of the following methods:  A. 1720 annual productive hours (pro-rata for Persons not Working full-time)	number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the	
	B. THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT	Beneficiary.  If the Beneficiary applied method C.	
	CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE).  C. THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR	18) The calculation of the number of 'standard annual workable hours' was verifiable	
	ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT	based on the documents provided by the Beneficiary.	

			Result
Ref	Checks	Standard finding	(C / E /N.A)
	COLUMN). This number must be at least 90% of the standard annual workable hours.  'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.	19) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	TIME RECORDING SYSTEM  To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records:	20) All persons recorded their time dedicated to the action on a daily/ weekly/ monthly basis using a paper/computer-based system. (delete the answers that are not applicable)	
	<ul> <li>description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system);</li> <li>its actual implementation;</li> <li>time records were signed at least monthly by the employees (on paper or</li> </ul>	21) Their time-records were authorised at least monthly by the project manager or other superior.	
	electronically) and authorised by the project manager or another manager;  the hours declared were worked within the project period;  there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below);	22) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	o the hours charged to the action matched those in the time recording system.  ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).	23) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	If the persons are working exclusively for the action and without time records  For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	24) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	
В	COSTS OF SUBCONTRACTING		
B.1	The Auditor obtained the detail/breakdown of subcontracting costs and sampled cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest).  To confirm standard factual findings 25-29 listed in the next column, the Auditor reviewed the following for the items included in the sample:  o the use of subcontractors was foreseen in Annex 1 of grant agreement;  subcontracting costs were declared in the subcontracting category of the Financial Statement;	25) The use of claimed subcontracting costs was foreseen in Annex 1 to the Agreement and costs were declared in the Financial Statements under the subcontracting category.  26) There were documents of requests to different providers, different offers and assessment	

Ref	Checks	Standard finding	Result (C/E
	<ul> <li>supporting documents on the selection and award procedure were followed;</li> <li>the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment).</li> <li>In particular,         <ol> <li>if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement.</li> <li>ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement</li> </ol> </li> <li>For the items included in the sample the Auditor also verified that:         <ol> <li>the subcontracts were not awarded to other Beneficiaries in the consortium;</li> <li>there were signed agreements between the Beneficiary and the subcontractor;</li> <li>there was evidence that the services were provided by subcontractor;</li> </ol> </li> </ul>	the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money.  (When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Agency will analyse this information to evaluate whether these costs might be accepted as eligible)  27) The subcontracts were not awarded to other Beneficiaries of the consortium.  28) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	/N.A)

			Result
Ref	Checks	Standard finding	(C / E /N.A)
		subcontractors.	
C	OTHER ACTUAL DIRECT COSTS		
<b>C.1</b>	COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES	30) Costs were incurred,	
	The Auditor sampled cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).	approved and reimbursed in line with the Beneficiary's usual policy for travels.	
	The Auditor inspected the sample and verified that:	31) There was a link between the	
	<ul> <li>travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy;</li> </ul>	trip and the action.  32) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled	
	o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct	with time records and accounting.	
	project account, their consistency with time records or with the dates/duration of the workshop/conference;	33) No ineligible costs or excessive or reckless expenditure was declared.	
	o no ineligible costs or excessive or reckless expenditure was declared.	expenditure was decrared.	
C.2	DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS	34) Procurement rules, principles and guides were	
	The Auditor sampled cost items selected randomly (full coverage is required	followed.	

			Result
Ref	Checks	Standard finding	(C / E /N.A)
	if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest).	35) There was a link between the grant agreement and the asset charged to the action.	
	For "equipment, infrastructure or other assets" selected in the sample the Auditor verified that:	36) The asset charged to the action was traceable to the	
	<ul> <li>the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures;</li> <li>they were correctly allocated to the action (with supporting documents such as</li> </ul>	accounting records and the underlying documents.	
	delivery note invoice or any other proof demonstrating the link to the action)	37) The depreciation method used to charge the asset to the	
	<ul> <li>they were entered in the accounting system;</li> <li>the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table);</li> </ul>	action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy.	
	The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value).	38) The amount charged corresponded to the actual usage	
	The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.4 GA).	for the action.  39) No ineligible costs or excessive or reckless expenditure were declared.	
С.3	COSTS OF OTHER GOODS AND SERVICES  The Auditor sampled cost items selected randomly (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item,	43) Contracts for works or services did not cover tasks described in Annex 1to the Grant Agreement.	

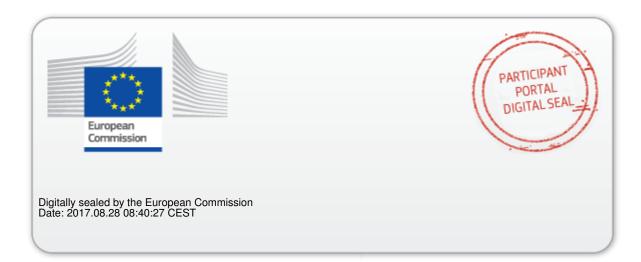
Ref	Checks	Standard finding	Result (C / E /N.A)
	<ul> <li>or 10% of the total, whichever number is highest).</li> <li>For the purchase of goods, works or services included in the sample the Auditor verified that:         <ul> <li>the contracts did not cover tasks described in Annex 1;</li> <li>they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting);</li> </ul> </li> </ul>	<ul> <li>44) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment.</li> <li>45) The costs were charged in line with the Beneficiary's accounting policy and were</li> </ul>	
	<ul> <li>the goods were not placed in the inventory of durable equipment;</li> <li>the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices;</li> <li>no ineligible costs or excessive or reckless expenditure were declared (see Article 6.4 GA).</li> </ul>	adequately supported.  46) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
	In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular:  o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement.  o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement.  For the items included in the sample the Auditor also verified that:  o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best	47) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment);  Such Goods and Services include, for instance, consumables and supplies, dissemination (including open access), protection of results, specific evaluation of the action if it is required by the Agreement, certificates on the Financial Statements if they are required by the Agreement and certificates on the Methodology, translations, reproduction.	(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Agency will analyse this information to evaluate whether these costs might be accepted as eligible)	
D	USE OF EXCHANGE RATES		
D.1	a) For Beneficiaries with accounts established in a currency other than euros  The Auditor sampled cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):  Costs incurred in another currency shall be converted into euro at the average of the daily exchange rates published in the C series of Official Journal of the European Union (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html ), determined over the corresponding reporting period.  If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in Question, conversion shall be made at the Average of the monthly accounting rates established by the Commission and	48) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final figures.	

Ref	Checks	Standard finding	Result (C / E /N.A)
	PUBLISHED ON ITS WEBSITE ( <a href="http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm">http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm</a> ), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.		
	b) For Beneficiaries with accounts established in euros  The Auditor sampled cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement (full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest):  Costs incurred in another currency shall be converted into euro by applying the Beneficiary's usual accounting practices.	49) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]

[dd Month yyyy] <Signature of the Auditor



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