



APPENDIX 6

EARS-Vet MANUAL OF METHODS AND STANDARDS



BUILDINGA ONEHEALTH WORLD

to reduce Antimicrobial Resistance (AMR)

WP8.2 | EARS-Vet Manual, version 1.0

Leader acronym | AEMPS, ANSES

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TUTORIAL FOR EARS-VET DATA SUBMISSION¹

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1 INTRODUCTION

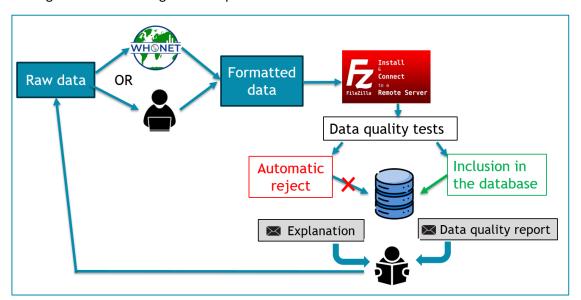
This document is a guide for laboratories in the EARS-Vet network. Its purpose is to detail all the process leading to the integration of national data into the EARS-Vet database.

It explains what data is expected, as well as the processes for sending, validating and integrating this data. In particular, it helps partners with formatting the data, whether this is done with the help of whonet or just an IT specialist.

For more information on the EARS-Vet network and how the data will be analyzed, please refer to the EARS-Vet manual.

2 GENERAL STEPS

The Figure describes the general steps of EARS-Vet data.



3 DATA TO BE SENT

Ideally, we would like to have only bacteria that cause **clinical signs**, as one of the aims of Ears-vet is to provide guidance to practitioners in treating disease. If possible, remove 'background' bacteria isolated during screening analyses.

Antibiotic susceptibility test (AST) results must be **quantitative data** (*=MIC values or disk diameters*) to enable results to be reinterpreted using common standards. The results obtained by ETEST are de facto excluded.

Each line represents the raw AST result of an isolate¹ to an antibiotic. If an AST data does not have raw results (only interpreted values), partners must correct them and delete them if no raw results can be retrieved. This procedure ensures that no data is erroneously deleted by Anses managers.





Each isolate must be identified by a **unique identifier** (see section 4 for duplicate management). An isolate is characterized by the combination of a single animal, the bacterial species, the date of sampling, and the **microbiological test parameters**. This identifier should not disclose any personal information. If partners' original IDs have any personal information, partners need to create new **pseudo-anonymous** EARS-Vet IDs for submission. Pseudo-anonymization means that partners know the correspondence between original IDs and EARS-Vet IDs to facilitate communication. The allocation of new codes must be done before formatting to WHONET, because even if the tool is very well able to generate new identifiers, the correspondence with the original data set will be lost.

¹ An isolate is a single strain of microorganism isolated from a sample. A sample is a collection of material containing multiple microbial types

At least bacteria covered by the **Common scope** should be included in the submission. It is worth noting that the scope is made up of three fields (animal species, infection types, and bacterial species), and that it is not binding for antimicrobials. If partners wish to send unfiltered data or data with missing infection type information, this is totally feasibly. Not filtering data avoids over-filtering errors and gives a better overview of the data available among the partners, making it easier for the EARS-Vet network to adapt the scope of analysis in the future.

The expected data format is fully described in Appendix 4 (<u>Data collection template</u>). In this file, a data dictionary describes the 27 columns of variables and specifies which of them are mandatory. Additional tabs provide lists of expected values for relevant variables. Partners wishing to do their own conversion should use this document as a support, and those wishing to use WHONET should read it to know the definitions of each variable.

Each partner should submit one file per year of testing. The file should be **named** using the format PARTNER_ID_YEAR_OF_TESTING.txt. For example, a file from the French partner ANSES for the year 2017 would be named FR_ANSES_2017.txt.

The preferred **file format** is a text file (.txt) with tab-separated values. The first line of the file should contain the variable names. Each subsequent line should represent a single record, with column values separated by tabs. csv and xlsx files are also acceptable if necessary. However, maintaining consistency with the .txt format is encouraged for ease of data processing and integration. Format requirements will be directly managed by baclink/whonet for partners wishing to use this tool.

Regardless of how the data is formatted, partners are advised to keep their raw data formats as stable as possible to facilitate formatting in EARS-Vet format each year.

4 MANAGEMENT OF REPEATS

Partners must remove duplicates for only two cases: when a data entry error has led to the same isolate being recorded twice, or in the rare cases where two isolates from the same sample have exactly the same SIR profile (duplicates due to the way the tests were carried out in the laboratory). Isolates of the same bacterial species collected repeatedly from the same companion animal or farm



within the same year (including multiple samplings over time) or on the same day should not be discarded.

5 POINTS THAT MAY RAISE QUESTIONS

The data dictionary can normally be used on its own. Details are provided to clarify certain points that may raise questions.

- It is normal that **no information on the interpreted results** is requested as each AST will be reinterpreted thanks to "AST technique", "Disk diameter or MIC value" and "AST standard" as well as "Disk content" for disk diffusion.
- The 'mandatory' column indicates the information required for each line. Fields in nonmandatory columns may be empty
- Sometimes the partners are not able to know the standard used for broth microdilution
 tests or agar dilution tests. This is not critical because the methodology used with these
 techniques does not have too much influence on the raw results obtained. In this case,
 partners can very well enter 'other' and put a short, free explanation in the 'AST standard'
 column. For results obtained by disc diffusion, the standard used must be provided because
 the methodology conditions the results and is essential for re-interpretation.
- Partners need to follow the data dictionary:
 - Columns must have exactly the same name (a change with lower cases and "_" won't be validated).
 - For variables with a dictionary listing all possible values, each cell must contain only one option and must not be mixed of various options separated with a '/'.
- The year requested is the **year of testing**. It would have been more relevant epidemiologically to ask for the sampling year, but this information is not available for all partners. The test year makes it possible to have homogenous information among partners.
- For the first call for data, 9 different files, one for each year between 2016 and 2024, should be submitted if possible.
- Some data dictionary lists may appear long, but this is deliberate in the hope of achieving
 exhaustiveness and anticipating all the values that may be present in the various partners.
 For information, these dictionaries are often derived from whonet.
- The field that will be used during the analysis will be the 'infection type' field. The 'specimen type' field is only used to provide a link to the infection and may in fact be incomplete, as it is difficult to be exhaustive. As dictionaries need to be synchronised with those of whonet and the EARS-Vet database, changes to add rare specimens will not be made. If partners have a a specimen type that can't be found in the list, they need to leave Specimen type empty and to classify manually the Infection type if possible, or leave blank if not.
- As specified in the data collection template, the bacterial species are required without specifying the serovar (e.g., Escherichia coli O157:H7 should be changed to Escherichia coli).





Verification of unique species names in the dictionary list was conducted solely for bacterial species within the defined scope because this is not binding for bacteria that we do not yet wish to analyse.

• The antimicrobial agent "rifampin" is also known as rifampicin". Please name it "rifampin".

6 SPECIFIC SECTION FOR WHONET USERS

In practice, partners convert their data in two stages: first, they create an SQLite intermediate file using Baclink, and then they transform it into the required format using WHONET. To use baclink/whonet, partners can refer to the tutorials published on the whonet training-center.

Partners only have to do a few checks before integrating their data into Baclink:

- Removal of AST data with missing raw results must be done
- Isolate IDs should not display any personal information
- Manage isolates from the same animal, or provide whonet with the 'animal identifier' columns and the precise date of sampling so that the tool can do this (section 4)
- Check that all the information they have from their dataset that could be useful to EARS-Vet is written down in the columns of their dataset.

Information about AST techniques, AST standards, AST instrument, or year of testing is often known by the partner but absent from the data file. The partner might manually add these columns to the raw dataset because WHONET cannot guess this information and would leave the associated columns empty. If the information on AST techniques, AST standards, or year of testing is not homogeneous within a column, partners need to add the information, if not WHONET will be able to retrieve the information. For the AST instrument, the columns should always be added.

There are some column names that have different names between Baclink and the EARS-Vet data dictionary (see Table bellow). This information is provided for information purposes only to help partners allocate the correct data to the correct columns. The columns in the WHONET output file will automatically have the ears-vet names requested.

EARS-Vet name	Baclink name
Isolate ID	Isolate number
Year of sampling	Data year
Bacterial species	Organism
AMPc phenotype	AMPc production
ESBL profile	ESBL
AST technique*	Antibiotic test method
AST standard	Guideline



*An important note: partners who have only one AST method used in their dataset (specified in the 'file structure' description) will not see the 'AST technique' column in baclink. in all cases, the column will be present in the WHONET export.

7 SENDING DATA

At the moment, to carry out the sending tests, partners can send the formatted files to servane.bareille@anses.fr. She will be responsible for carrying out the data quality tests to determine whether the file can be integrated into the common EARS-Vet database hosted at ANSES (section 8).

To facilitate the automatic integration of files into the database, a server meeting SFTP (secure file transfer protocol) standards is currently being created by the ANSES national IT department. Once the server is up and running, the data files will no longer be sent by e-mail but will be uploaded on an SFTP site using a software named Filezilla. Every day at midnight, the database connects with the remote server and retrieves the files retrieved during the day. Quality tests are automatically then carried out on the file to determine whether it can be integrated into the common EARS-Vet database hosted at ANSES (section 8).

Each partner will have a single login to facilitate collaboration. This login corresponds to the partner identifiers used in the data dictionary used for formatting data. The configuration implemented on this SFTP server restricts laboratories' access to their own submission folder. They can only submit to this folder and cannot access the submission folders of other laboratories.

A specific tutorial for uploading data to Filezilla will be created.

8 QUALITY TESTS RUN BY THE DATA BASE BEFORE INTEGRATION

Before being integrated into the database, the file undergoes a series of quality tests to check compliance with the data dictionary.

If the EARS-Vet format is not respected, the file is not integrated and an automatic e-mail outlining all the errors is automatically sent to the person(s) responsible for sending the data. For this purpose, the identifier of each partner is linked to the e-mail address(es) of the people active in the data submission. The list is available and can be modified on the sharepoint.

If the EARS-Vet format is respected, the file is integrated in the database and a user report is created (section 9).

9 USER REPORTS

Once a file has been successfully integrated into the database, a user report describing the data is automatically generated and e-mailed to the person(s) responsible for sending the data.



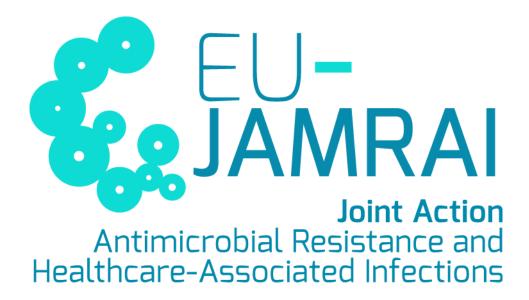


This user report is intended to give you a brief overview of the data received.

In particular, information will be displayed to show you:

- Data integrated to the database and which belongs into the scope
- Data integrated to the database and which doesn't belong into the scope
- Information that was not recognized in our EARS-Vet dictionary:

Partners are kindly requested to carefully review this section. Checking that the number of strains included is realistic is crucial. Additionally, a closer review may uncover a default in the data conversion. For instance, a species listed as "kitty" (in the partner's language) and not attributed to "cat" should be corrected. If partners identify any errors, they should re-send the corrected file. This new file will again be tested for integration and the partner will then receive a new user report if successful.



EU-JAMRAI Partners involved in the elaboration of this document:

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