

September 2025

Contents

| Introduction | 3 |
|---|---|
| How to use this document | 3 |
| Finding further information | 3 |
| Copyright | |
| Reporting to EpiPulse Cases | 4 |
| Checking the data collection schedule | 4 |
| Preparing data | 4 |
| Using latest metadata | 4 |
| Checking your Surveillance System Descriptors | |
| Uploading your data | 5 |
| Finalising your submission | 6 |
| EpiPulse Cases Helpdesk | 7 |
| Annex 1. PISA | 8 |
| Annex 2. Metadata | 9 |
| General | |
| Qualitative data | |
| | |

Introduction

This reporting protocol describes data collection for reporting of RESPIQUAL to **EpiPulse Cases**. For the 2025/2026 season only PISA indicators are reported to EpiPulse Cases, all other routine respiratory virus reporting will remain in TESSy (please refer to the existing Reporting Protocol for integrated respiratory virus surveillance)

Reporting protocols are data collection guidelines for the data managers of reporting countries, and the protocol design is intended to improve user-friendliness by:

- introducing a uniform structure to make it easier for data managers to find data collection information across different subjects;
- removing information which is not relevant for data managers.

Since the data managers in reporting countries often have multiple roles, subject-specific material is distributed in the multiple Annexes together with the reporting protocol.

How to use this document

This reporting protocol provides information for the data managers of reporting countries in three main sections:

- Reporting to EpiPulse Cases which contains guidelines on how to prepare data for submission to EpiPulse Cases and links to further information.
- Annex 1 which provides an introduction and overview of reporting for the PISA framework
- · Annex 2 which contains the metadata for RESPIQUAL

Finding further information

Updated links to all the schedules, documentation and training materials mentioned in this reporting protocol are included in the EpiPulse Help, including:

- EpiPulse Cases Metadata
- EpiPulse Cases Machine to Machine Technical Documentation

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Reporting to EpiPulse Cases

EpiPulse Cases was built as a replacement for TESSy, with the aim of improving the process of reporting, reviewing, and updating surveillance data. This section provides both an overview of the EpiPulse Cases reporting process and tips on where you can find useful information.

The overall process is as follows:

- Familiarise yourself with the data collection deadlines.
- Prepare (export and transform) your data.
- Check that your data complies with the EpiPulse Cases metadata— see EpiPulse Help.
- Check that your data sources are up to date.
- Submit your file(s) to EpiPulse Cases.
- Finalise and approve your submission.

Checking the data collection schedule

A link to the current data collections schedule can be found the EpiPulse Help section.

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that EpiPulse Cases can accept. EpiPulse Cases accepts only CSV and XML files, optionally ZIP-compressed. The EpiPulse Cases metadata has been developed from the TESSy Metadata, with the aim to make only the minimal number of changes necessary, and to hopefully provide a better experience when reporting your datasets to ECDC.

A file converter tool is also available in EpiPulse Cases to support users in the transition period with the conversion of files in TESSy format to a format that would be compatible to EpiPulse Cases, see section 18 in the EpiPulse Cases Guide – see EpiPulse Help.

Specific guidelines for data collection and preparation for EpiPulse Cases are provided in Annexes.

Using latest metadata

The metadata defines the fields and data formats that are valid as input to EpiPulse Cases for a given subject. The EpiPulse Cases metadata includes a section that compares and highlights the changes between TESSy and EpiPulse Cases, to facilitate the transition.

As the requirements for data to be shared among ECDC Stakeholders can change, the data format changes needed to support the new requirements are identified and agreed upon between the National Surveillance Contact Points, the Network Coordination Groups and ECDC's Disease Experts. These changes are then implemented to the EpiPulse Cases metadata.

The metadata for the subject of this reporting protocol are described in Annex 2.

It is especially important to focus on:

- Field formats
 - Many fields require the data to be formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.
- Reference Values (the equivalent of TESSy Coded Values)

 Some fields only permit the use of specific values (reference values). For example, M, F or OTH are the coded values for 'Gender' and any other value in a 'Gender' field will be rejected. Please note that UNK is no longer a valid code, you may leave the field empty instead.

The EpiPulse Cases metadata Excel file contains all the definitions and rules necessary to format data correctly. The READ ME sheet of the Excel document explains how to work with the metadata. It can be downloaded from the EpiPulse Help.

Filtering the fields in the file by subject will enable you to see the fields required for your subject and the rules that apply to these fields.

Checking your Surveillance System Descriptors

Before submitting file(s), please review your data source(s) in EpiPulse (in the menu, go to 'Report' -> 'Surveillance systems descriptors') and update the information as necessary.

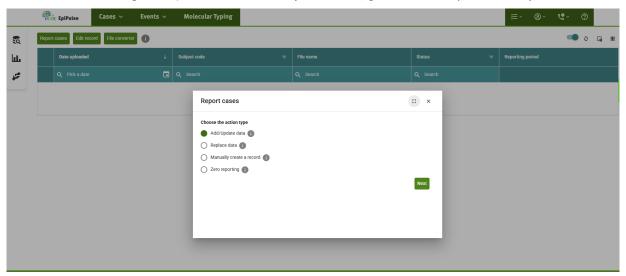
Complete and up-to-date data source information for each subject is important for improving the interpretation of data – each surveillance system has different features that need to be considered when comparing data at European level.

If your data source information is out-of-date and you do not have access rights to update it, please ask your National Focal Point for Surveillance or National Coordinator to do so.

Information on data sources is available in the EpiPulse Cases Guide – see EpiPulse Help.

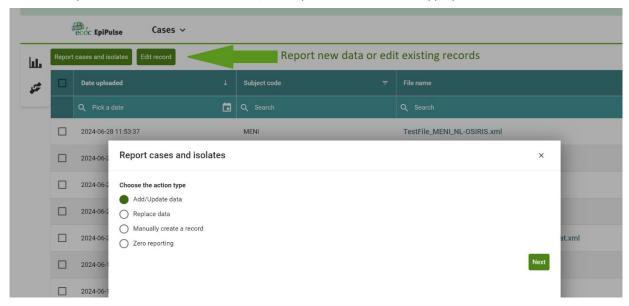
Uploading your data

Data is submitted through the EpiPulse web interface (in the menu, go to Cases -> EpiPulse Cases).



The visual interface for reporting new data and editing existing records has remained very similar to that of TESSy.

Similar to TESSy, you can Add/Update or Replace data with new uploads, using either CSV or XML files. You can also manually create records for some diseases, and report zero cases where appropriate.



The functionality for manually editing existing records is also a familiar experience. Search for the record you wish to edit and modify the existing information as needed.

Finalising your submission

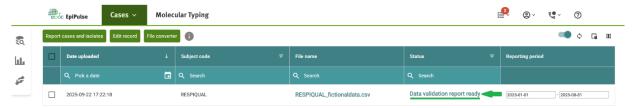
The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process. In EpiPulse Cases this process is called "Technical Validation", and it is the only step where your upload can be rejected by the system, for severe data quality issues, such as the file format not being readable by the system, or (one of the few) technically required variables having missing values.

If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that needs correcting.

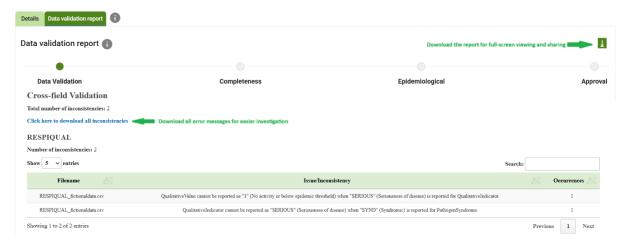
The significant new feature in EpiPulse Cases is the Data Validation Report, which puts your data in the context of the already existing information for the same disease. It provides you a detailed overview of the new data in the file you have just uploaded, as well as an overall epidemiological situation showed with the existing (past) data together with the newly uploaded file(s). This means much more timely feedback on your uploads, including details on data quality, as well as outputs (graphs, charts, and tables) on some of epidemiological indicators. The Data Validation reports will evolve and grow based on your feedback in collaboration with our Disease Experts. These reports will provide a new and better way of understanding and updating the information collected at European level and will hopefully increase the quality and timeliness of the data, while reducing workloads.

Below you can find a few screenshots of the Data Validation Report.

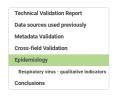
1. Begin by opening the report:

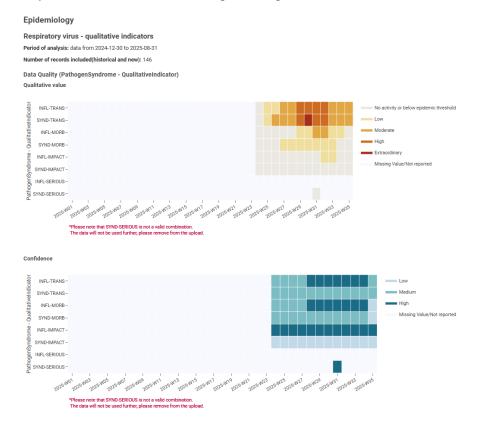


2. View the report in a window, download the list of eventual validation messages, or download the report



3. The downloaded report can be opened full screen for easier viewing and navigation.





4. After reviewing the information in the Data Validation Report you can choose to approve or reject it. You can download the Data Validation Report file and email it to whomever needs to check it before approval.



If you choose to reject it, no data will be saved in the EpiPulse Cases system, but your file will remain visible should you wish to re-download it or resubmit it for a new Data Validation at a later date or after further checks. Please check the Data Validation Report carefully, there might be warnings and remarks relating to possible data quality issues or potential overwriting of existing records that you should consider.

When your file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval or rejection. <u>Unapproved uploads will block</u> the approval of <u>other related uploads for the same disease</u>.

EpiPulse Cases Helpdesk

Email: <u>EpiPulseCases@ecdc.europa.eu</u>
Telephone number: +46-(0)8-5860 1601

Availability: 9:00 – 16:00 Stockholm time, Monday to Friday (except ECDC holidays)

Annex 1. PISA

The World Health Organization pandemic influenza severity assessment (PISA) framework (set out in full in a guide available here) provides a systematic approach for interpreting data collected through existing surveillance systems and improving their usefulness for risk communication and decision-making. The approach enables the severity of current influenza and syndromic respiratory illness activity to be assessed relative to previous years by using historical data to set thresholds that then allow for the qualitative categorization of such activity. PISA is designed to be implemented continuously based on stable/routine reporting systems, enabling activity during epidemic and pandemic periods to be compared.

The seven PISA indicators as per the 2024 update to the PISA framework are set out in the Table below. Reporters can choose which PISA indicators to report based on the surveillance systems in place (options for setting threshold and possible data sources to use are described in the protocol). There are also non-mandatory comment and confidence variables for each indicator. PISA data submitted to EpiPulse Cases will be transferred on a weekly basis to a global WHO platform (available via the <u>PISA landing page</u>) where they will be visualized and publicly available (including confidence and comment data).

| PISA indicator | Description | Frequency of submission |
|---|--|---------------------------------------|
| Transmissibility - influenza | Measure of how many people get sick with influenza and therefore reflects the ease of movement of influenza between individuals and communities (example parameter: percentage positivity for influenza amongst ILI cases) | Weekly |
| Transmissibility - syndromic | Measure of how many people get sick with acute respiratory diseases (example parameter: ILI consultation rate) | |
| Morbidity & mortality - influenza | Measures of the level of serious disease and death in the population due to influenza (example parameter: percentage positivity for influenza amongst SARI patients) | |
| Morbidity & mortality - syndromic | Measure of the level of serious disease and death in the population due to acute respiratory disease (example parameter: counts or rates of SARI cases) | |
| Impact on healthcare capacity - influenza | Describes how the influenza epidemic or pandemic is affecting health care system capacity (example parameter: the proportion of ICU or hospital beds occupied by patients with influenza) | |
| Impact on healthcare capacity - syndromic | This indicator describes how acute respiratory diseases are affecting health care system capacity (example parameter: the proportion of ICU or hospital beds occupied due to respiratory diseases) | |
| Seriousness of disease of influenza | The seriousness of disease indicator describes the extent to which individuals become ill when infected with an influenza virus (e.g. the ratio of influenza hospitalizations: deaths) | Twice per season (peak and end) |

Using surveillance system data, threshold approaches are used to define five reporting levels for six of the seven PISA indicators (seriousness of disease has no baseline category): No activity or below epidemic threshold, Low, Moderate, High and Extraordinary.

Not all combinations of Indicator & Value and, separately, Indicator & Pathogen/Syndrome are valid. Namely, 'No activity or below epidemic threshold' is not a valid entry for 'Seriousness of disease' and 'Seriousness of disease' and 'SYND = Syndromic' is not a valid combination. While all combinations can be submitted to TESSy, these invalid combinations will be flagged as inconsistencies in Data Validation Report. Data submitted for invalid combination will not be subsequently used in analysis or visualizations.

Annex 2. Metadata

General

Subject code (required)

Field: SubjectCode

Coding: RESPIQUAL=Respiratory virus - qualitative indicators

Description: SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and

format of a record (case based or aggregate reporting).

Status

Field: Status

Coding: DELETE=Delete a previously reported record.

NEW/UPDATE=Update a previously reported record (default).

Description: The Status value is used to provide the functionality for a record within EpiPulse Cases database. Default value: NEW/UPDATE. If set to DELETE, the record with the specified NationalRecordId is deleted (invalidated) from EpiPulse Cases database, if it exists. If set to NEW/UPDATE, the record is inserted into the database: If the same NationalRecordId already exists for the same data source and subject code, then the current

submitted record updates (replace) the existing one.

Health topic

Field: HealthTopic

Coding: RESPI=Respiratory viruses

Description: The code of the health topic that is being reported.

Reporting country (required)

Field: ReportingCountry
Coding: [Countries]

Description: The country reporting the record.

National record identifier (required)

Field: NationalRecordId

Coding: Text

Description: Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.

Data source (required)

Field: DataSource

Coding: [Data sources]

Description: The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.

Date used for statistics (required)

Field: DateUsedForStatistics

Coding: yyyy-Www

Description: The reference week (yyyy-Www) for the reported qualitative indicator.

Qualitative data

Pathogen or syndrome (required)

Field: PathogenSyndrome
Coding: INFL=Influenza
SYND=Syndromic

Description: Pathogen or syndrome that applies.

Surveillance type (required)

Field: SurveillanceType Coding: PISA=PISA

Description: Type of surveillance system.

Qualitative indicator (required)

Field: QualitativeIndicator

Coding: IMPACT=Impact on healthcare capacity

MORB=Morbidity and mortality SERIOUS=Seriousness of disease

TRANS=Transmissibility

Description: Please select the qualitative indicator that you would like to report. The reporting protocol includes considerations for each qualitative indicator.

Qualitative value (required)

Field: QualitativeValue

Coding: 1=No activity or below epidemic threshold

2=Low

3=Moderate

4=High

5=Extraordinary

Description: Please select the value corresponding to the selected combination of pathogen/sydrome, surveillance type and qualitative indicator.

Confidence

Field: Confidence
Coding: H=High
L=Low
M=Medium

Description: Level of confidence for the qualitative value reported for the selected combination of pathogen/sydrome, surveillance type and qualitative indicator.

Comment

Field: Comment Coding: Text

Description: Information should be included on any factors which may have influenced the assessment (for example, changes in health care seeking behaviour, testing practices and capacities and so on), and any differences in activity in certain age groups, at-risk groups or regions highlighted.

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