EpiPulse Cases

Diphtheria Reporting Protocol 2024

Surveillance data for 2023 - 2024

Contents

Introduction

This reporting protocol describes the reporting of 2024 measles and rubella cases to **EpiPulse Cases**, which is replacing TESSy.

Please note:

- Since February 2023, the reporting of diphtheria is described in a separate reporting protocol: Diphtheria, Reporting Protocol 2023, Version 1.0.
- The Vaccine Preventable Diseases (VPD) reporting protocol 2024 describes reporting of: pertussis, mumps, poliomyelitis and tetanus.
- The Invasive Bacteria Diseases (IBD) reporting protocol 2024 describes reporting of: invasive H. influenzae disease, invasive meningococcal disease, Neisseria Meningitidis isolates, and invasive pneumococcal disease.

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.

Similarly, the surveillance protocol will contain some of the generic information previously contained in the reporting protocols.

Since the data managers in reporting countries often have multiple roles, subject-specific material is sometimes distributed together with a reporting protocol. To maintain the uniform structure, this type of material is now included in Annex 1 and Annex 2.

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, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- Annex 1 which contains:
  - the metadata set for the subject(s) covered by this reporting protocol.
  - a list of metadata changes for the subject(s) covered by this reporting protocol.
- Annex 2 which contains subject-specific material relevant for distribution with the reporting protocol.

Finding further information

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

- EpiPulse Cases Metadata
- TESSy Metadata sets and change history
- EpiPulse Cases Machine to Machine Technical Documentation
- Tutorials for data transformation using respectively Excel and Access

Copyright

Reporting to EpiPulse Cases

In September 2024 EpiPulse Cases is expected to go live. We have built it as a replacement for TESSy, with the aim of improving the process of reporting, reviewing, and updating surveillance data.

Only Vaccine-Preventable Diseases will be reported to EpiPulse Cases in 2024, all other diseases will continue to be reported to TESSy for now.

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.
- 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 in the Communication section of the 'Documentation and Help' pages.

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.

Specific guidelines for measles and rubella data collection and preparation for EpiPulse Cases are provided in Annex 1 and Annex 2.

Checking 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.

Changes to the metadata for the subject of this reporting protocol are described in Annex 1.

It is especially important to focus on:

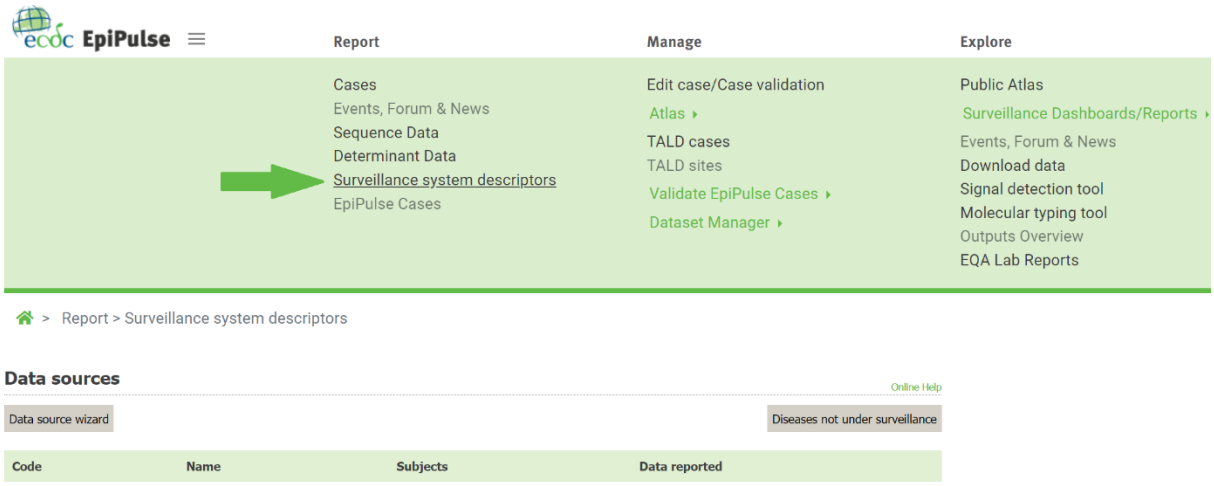
- **Field formats**
  Many fields require the data to be formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.
- **Reference Values (the equivalent of TESSy Coded Values)**
  Some fields only permit the use of specific values (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 Technical Guidelines & Tools section of the 'TESSy Help & Docs' pages.

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.



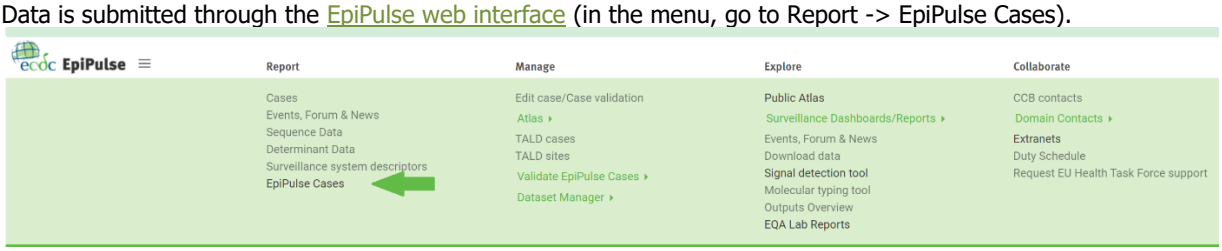
Complete and up-to-date data source information for each subject is important for improving the interpretation of data - each surveillance system has different features that need to be taken into account when comparing data European level.

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 TESSy User Guide, as this functionality is still only available through TESSy.

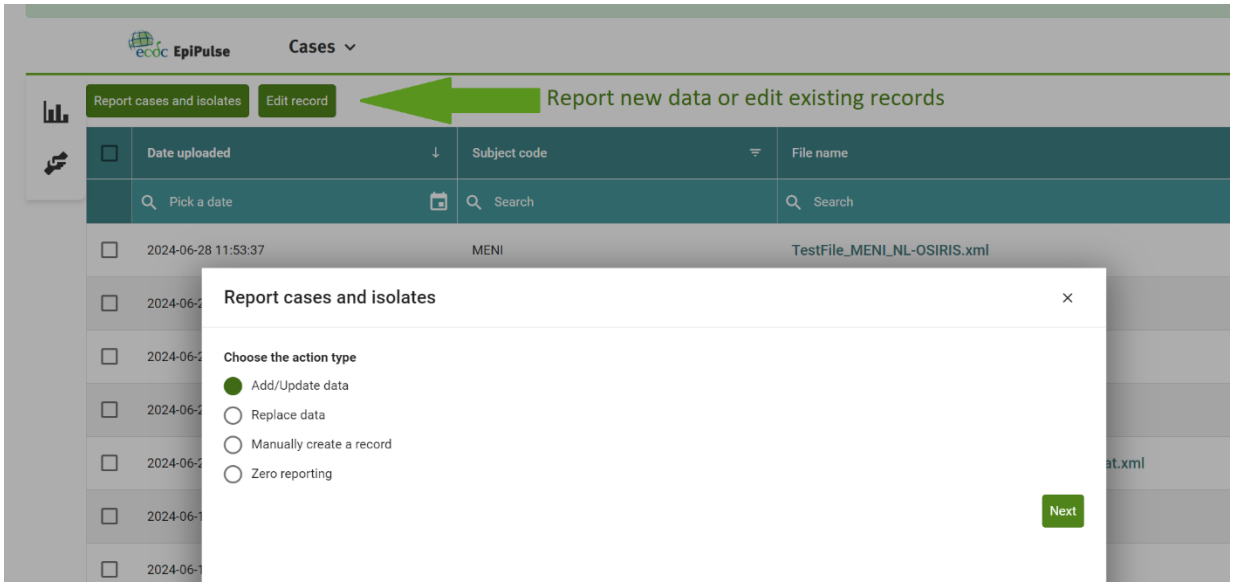
Uploading your data

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

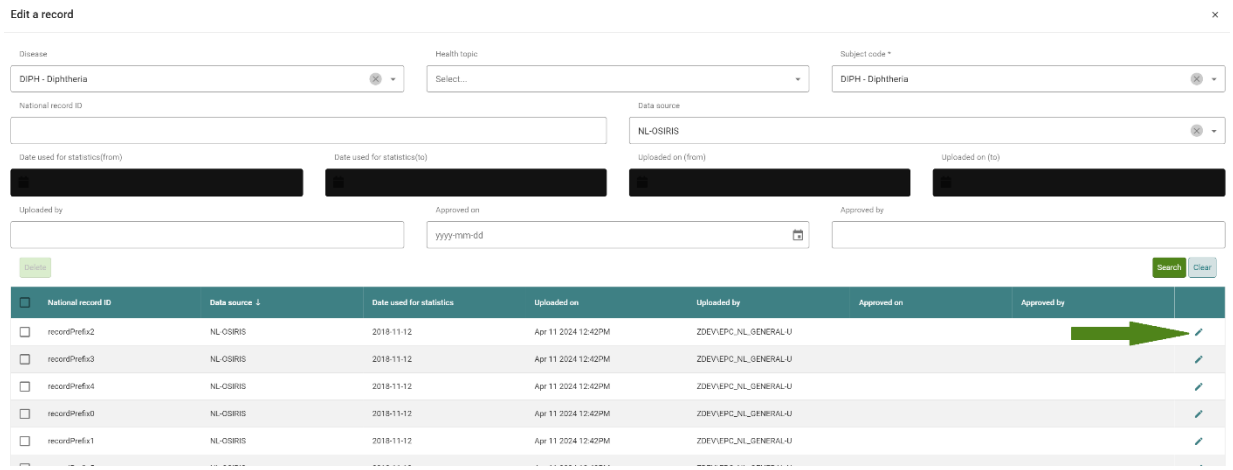


The visual interface for reporting new data and editing existing records has remained very similar to that of TESSy. For those of you that are also responsible for reporting diseases outside of the Vaccine Preventable Diseases group, you will continue to use TESSy (under EpiPulse) in parallel with the new EpiPulse Cases, until all disease groups will have been migrated to the new tool.

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

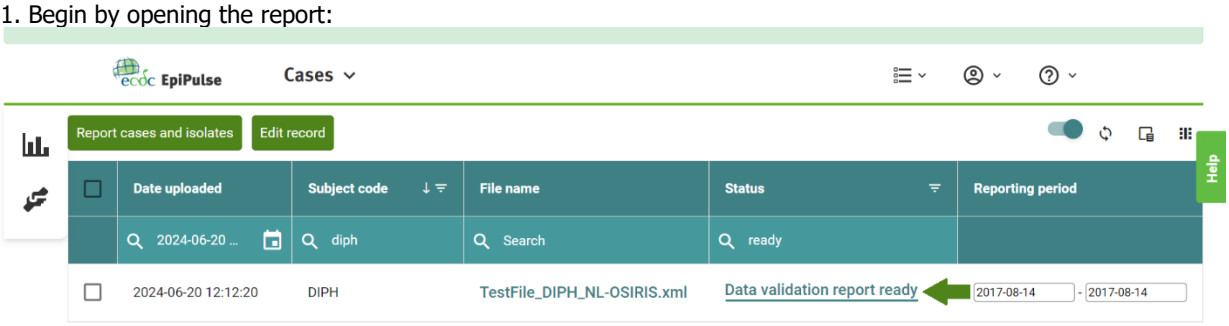
The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process. In EpiPulse Cases this process is called "Technical Validation", and it is the only step where your upload can be rejected, for severe data quality issues, such as the file format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

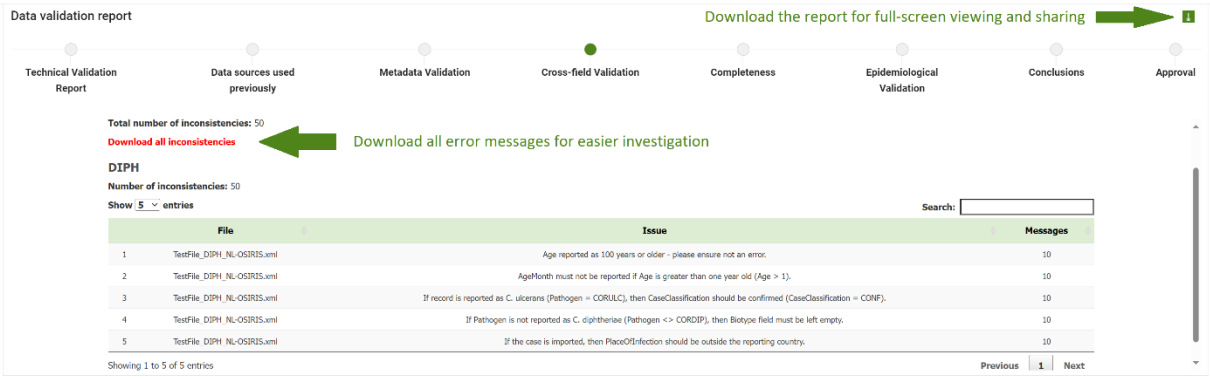
The significant new feature in EpiPulse Cases is the Data Validation Report, which puts your data in the context of the already existing information for the same disease, and provides you with a detailed overview of the new data in the file you have just uploaded, as well as the resulting overall epidemiological situation painted by 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.

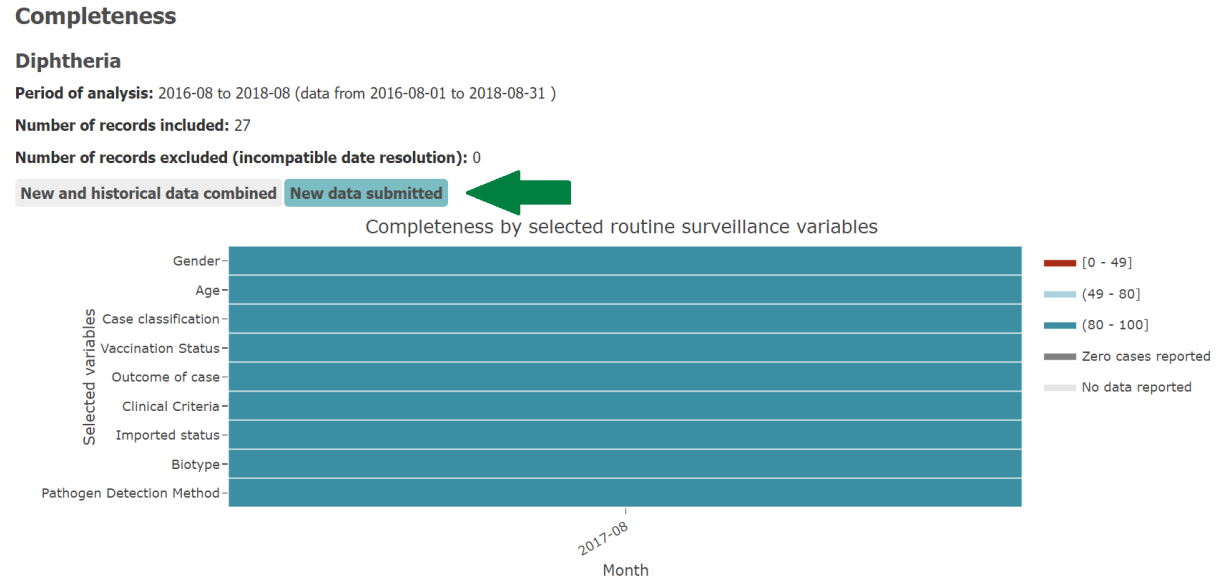
1. Begin by opening the report:

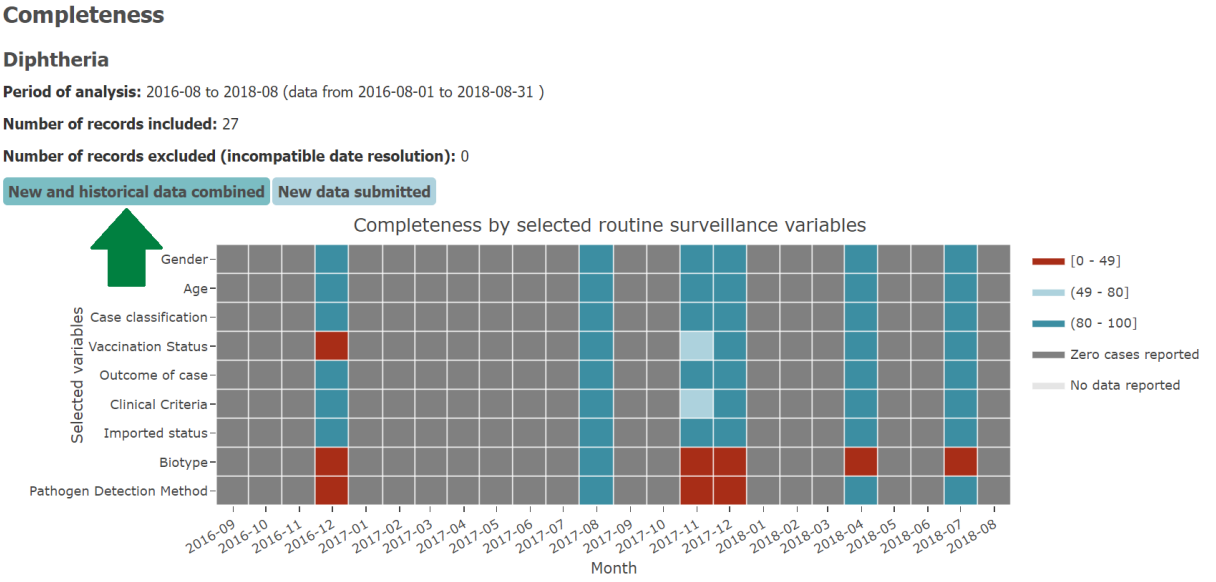


2. View the report in a window, download the list of eventual validation messages, or download the report

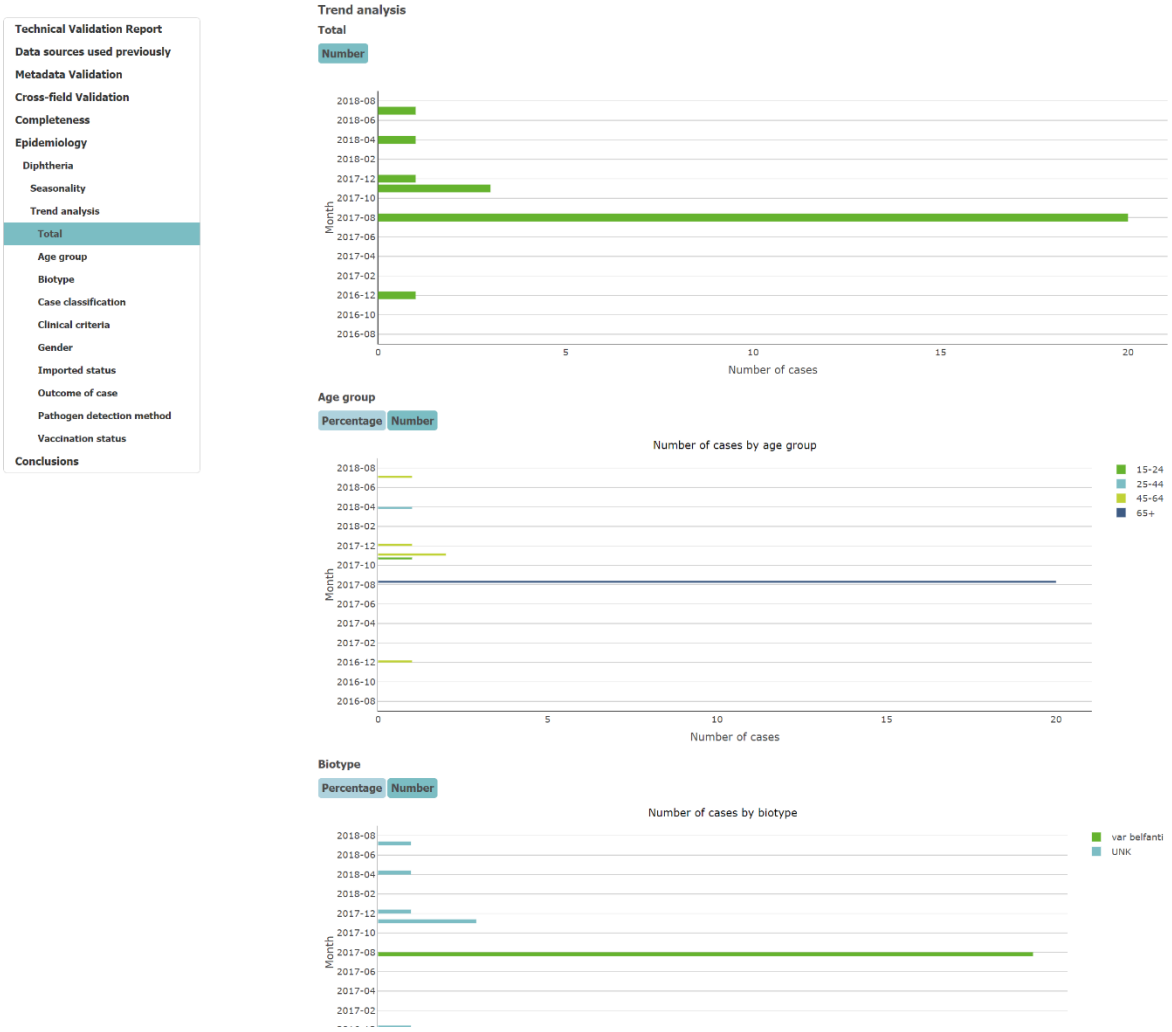


3. Check data completeness; both for the new upload, and in the context of historical data

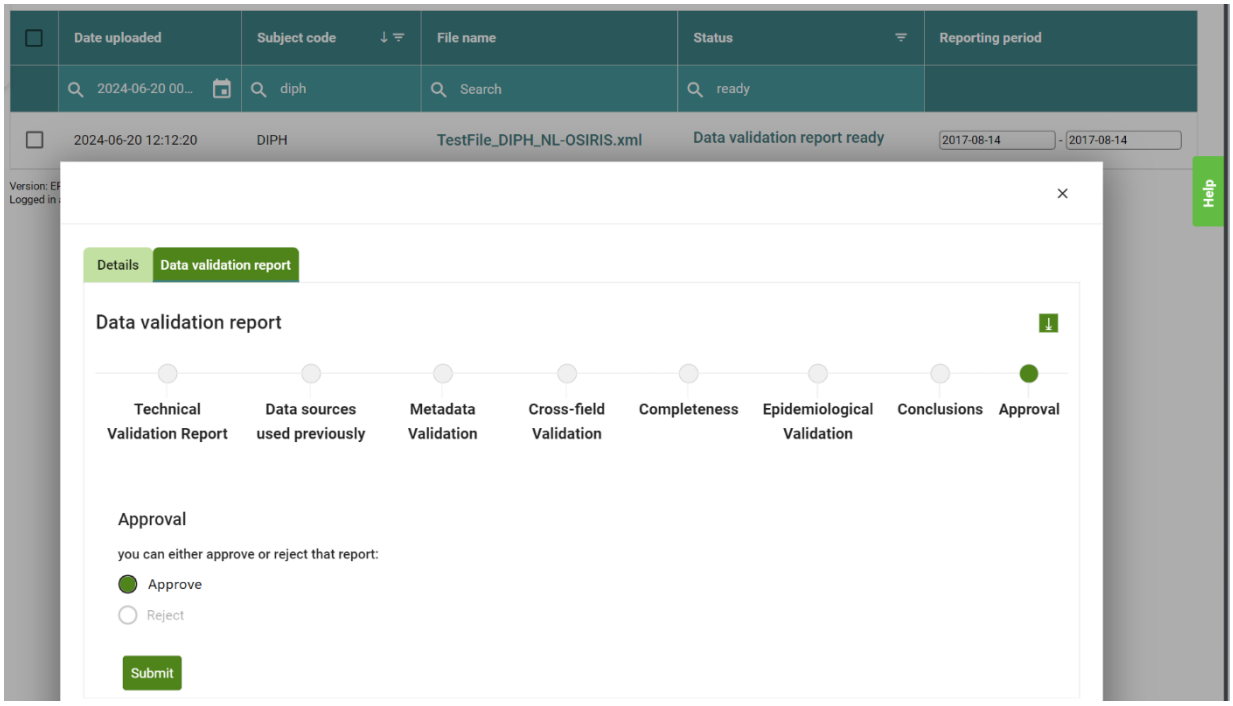




4. The downloaded report can be opened full screen for easier viewing and navigation. This is a preview of the currently developed epidemiological indicators/stratifications.



5. After reviewing the information in the Data Validation Report you can choose to approve or reject it.



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 Epi 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. Unapproved uploads can block the approval of other related uploads.

EpiPulse Cases Helpdesk

Email: EpiPulseCases@ecdc.europa.eu

Telephone number: +46-(0)8-5860 1601

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

Diphtheria-specific reporting

Monthly and annual reporting

Monthly data collection – deadline last day of each month

Diphtheria data should be uploaded monthly by the last day of the month. Possible, probable and confirmed cases should be reported.

Annual data collection – deadline 15 October of each year

An annual data call will still be carried out in order to finalise datasets for the previous year for use in the annual epidemiological report. In the annual data call it will also be necessary to report "zero cases" if no cases have occurred.

Once the data are validated by the disease experts at ECDC, they are made publicly available on a monthly basis on the Surveillance Atlas of Infectious Diseases with a choice of weekly, monthly and annual temporal resolution, and through annual surveillance reports on the ECDC website.

Narrative information

Changes over time in the number of cases reported in a surveillance system do not always reflect true changes in the incidence of disease. New reporting practices, improved laboratory capacities and changes in legislation are some of the factors that can influence the number of cases reported. It is important to be aware of such "surveillance artefacts" when analysing surveillance data and countries are encouraged to describe changes in the surveillance environment that may impact on the number of cases reported. It is equally important to report if the surveillance environment has remained the same from one year to the next. We encourage reporting countries to provide this information at the same time as data submission to TESSy and to *VPD.VPD@ecdc.europa.eu*.

Case definition

Cases of diphtheria should be reported to TESSy if they meet any of the following criteria:

Clinical Criteria

Any person with at least one of the following clinical forms:

Classic Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis
AND
an adherent membrane/pseudomembrane

Mild Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis
WITHOUT
an adherent membrane/pseudomembrane.

Cutaneous Diphtheria:

Skin lesion

Diphtheria of other sites:

Lesion of conjunctiva or mucous membranes

Laboratory Criteria

Isolation of toxin-producing *Corynebacterium diphtheriae, Corynebacterium ulcerans* or *Corynebacterium pseudotuberculosis* from a clinical specimen.

Epidemiological Criteria

At least one of the following epidemiological links:

— Human to human transmission

— Animal to human transmission

Case Classification

A. *Possible case*

Any person meeting the clinical criteria for classical respiratory diphtheria

B. *Probable case*

Any person meeting the clinical criteria for diphtheria (Classic Respiratory Diphtheria, Mild Respiratory Diphtheria, Cutaneous Diphtheria, Diphtheria of other sites) with an epidemiological link to a human confirmed case or with an epidemiological link to animal to human transmission

C. *Confirmed case*

Any person meeting the laboratory criteria AND at least one of the clinical forms.

Annex 1. Diphtheria metadata

This section describes:

- *The diphtheria metadata set*
- *Changes to the diphtheria metadata*

Diphtheria metadata set

Current record type versions

Table 1 shows the subject codes to be used when reporting diphtheria surveillance data to TESSy. Cases should be reported according to the EU Case Definition[1].

We strongly encourage **case-based reporting**. If case-based data are not available, aggregated data may be reported.

Table 1. Diphtheria subject code

Disease	Case-based subject code	Aggregated subject code
Diphtheria	DIPH	DIPHAGGR

Case-based reporting

The metadata set has variables that are common across the VPD and disease specific variables. All variables relevant to the reporting of diphtheria are summarised in alphabetical order in Table 2.

Table 2. Case-based metadata for the reporting of diphtheria (DIPH)

Variable	Description	Coded value list
Age	Age of patient in years as reported in the national system at the time of disease onset.	
AgeMonth	Age of patient in months as reported in the national system for cases < 2 years of age at the time of disease onset.	
AntimicrobialAgent	Antibiotic tested for susceptibility.	CIP = Ciprofloxacin CLI = Clindamycin ERY = Erythromycin LNZ = Linezolid MEM = Meropenem PEN = Penicillin RIF = Rifampin SXT = Sulfamethoxazole + trimethoprim TCY = Tetracyclines
Biotype	Biotype of DIP - C. diphtheriae only	NST = Not subtypeable OTH = Other

[1] EU case definitions (europa.eu)

		VARBELF = var belfanti VARGRAV = var gravis VARINTMED = var intermedius VARMITIS = var mitis
CaseClassification	Case classification according to EU case definition.	CONF = Confirmed DISCARDED = Discarded POSS = Possible PROB = Probable
ClinicalCriteria	Clinical presentation (criteria) of the case.	CONJ = Conjunctival presentation CUTA = Cutaneous GEN = Genital presentation NASAL = Uni- or bilateral nasal discharge intially clear becoming bloody OTH = Other RESPCUTA = Respiratory and cutaneous presentation RESPMEMBR = Classic Respiratory with membrane RESPNOMEMBR = Respiratory with no membrane
ClusterID	Unique identifier of the cluster as provided by the country epidemiologist.	
ClusterRelated	Is the case part of an outbreak/cluster?	
ClusterSetting	Setting of the cluster (for epidemiologically-linked cases).	CHILDCARE = Kindergarten or child care DET = Migrant detention centre FAM = Family MIL = Military NOS = Nosocomial (hospital) OTH = Other SCH = School SPORT = Sports team UNI = University
ComplicationDiagnosis	Any secondary disease that occurs as a consequence of Diphtheria.	CARDIACDIS = Cardiac disorder NEURO = Neurological complications

		NEUROCARD = Neurological & Cardiac disorder OTH = Other
CountryOfBirth	Country of birth of the case.	*Consult the reference values in mdLocation dataset*
DataSource	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.	*Consult the reference values in mdDataSource dataset*
DateOfDiagnosis	First date of clinical or lab diagnosis. In case the DateOfOnset is missing this date is used for analysis.	
DateOfEntry	Date of entry into country where sampling and diagnosis occurred.	
DateOfFirstSample	The date of the first diagnostic sample that was positive for diphtheria.	
DateOfLastVaccination	Date of administration of the last vaccination dose - indicates the date when the last dose of vaccine was given before disease onset (if exact date is not known, then provide month or year).	
DateOfNotification	Date when the case report is first notified to public health authorities.	
DateOfOnset	Date of onset of disease. Leave empty for asymptomatic cases.	
DateUsedForStatistics	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date.	
Disease	The code of the disease that is being reported.	DIPH = Diphtheria
EpiLinkCaseId	Provide record identifiers (NationalRecordId) of epilinked cases.	
Gender	Gender of the reported case.	F = Female M = Male OTH = Other
ImportedStatus	Imported: Having been outside the country of notification during the incubation period of the reported disease, and no links to local transmisison has been identified. Import related case: case epidemiologically linked to an imported case, i.e. cases that acquired the infection locally through a direct link to an imported case in the first chain (only) of transmission as supported by	END = Endemic case IMP = Imported case IMPREL = Import related case

	epidemiological and/or virological evidence. Indigenous case: is a case infected within the country of residence (based on epidemiological and virological evidence) and that is not import-related, or any case with unknown source of infection (no epidemiological or virological evidence).	
MainPathogenDetectionMethod	Pathogen detection method used on MainSpecimen for confirmation of the case (Isolation of toxin-producing C. diphtheriae/C. ulcerans/C pseudotuberculosis from a clinical specimen). More than one method can be reported.	CULT = Culture ELEK = Elek plate test OTH = Other PCR = PCR confirmation RTPCR = Real time PCR
Main Specimen	Main type of specimen with positive result to be reported (can include material and/or sampling method and/or site).	MEMBR = Membrane NASALSWAB = Nasal swab OTH = Other SKINSWAB = Skin swab THROATSWAB = Throat swab
NationalRecordId	Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.	
Outcome	Information on whether the case is alive or deceased. The death should be due to the reported disease.	A = Alive D = Died
Pathogen	Species and genus of the pathogen which is the cause of the reported disease.	CORDIP = Corynebacterium diphtheriae CORPSE = Corynebacterium pseudotuberculosis CORSPP = Corynebacterium species, not specified CORULC = Corynebacterum ulcerans
PlaceOfInfection	If ImportedStatus = 'IMP': The probable place of infection should be provided at the country level. One entry for each country visited before or during the diagnosis of the disease. Note this is a repeatable field.	*Consult the reference values in mdLocation dataset*
PlaceOfNotification	Place of the first notification of the case to a regional authority. Select the most detailed NUTS level possible.	*Consult the reference values in mdLocation dataset*

PlaceOfResidence	Place of residence of patient at the time of disease onset. Select the most detailed NUTS level possible.	*Consult the reference values in mdLocation dataset*
ReportingCountry	The country reporting the record.	*Consult the reference values in mdLocation dataset*
SecondPathogenDetectionMethod	Pathogen detection method used on SecondSpecimen for confirmation of the case (Isolation of toxin-producing C. diphtheriae/C. ulcerans/C pseudotuberculosis from a clinical specimen). More than one method can be reported.	CULT = Culture ELEK = Elek plate test OTH = Other PCR = PCR confirmation RTPCR = Real time PCR
SecondSpecimen	Second type of specimen with positive result to be reported as optional (can include material and/or sampling method and/or site).	MEMBR = Membrane NASALSWAB = Nasal swab OTH = Other SKINSWAB = Skin swab THROATSWAB = Throat swab
SequenceType	Diphtheria sequence type. Obtained by multi locus sequence typing (MLST) or core genome multi locus sequence typing (cgMLST).	
SIR_CIP	Susceptibility to Ciprofloxacin as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_CLI	Susceptibility to Clindamycin as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_ERY	Susceptibility to Erythromycin as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_LNZ	Susceptibility to Linezolid as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_MEM	Susceptibility to Meropenem as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_PEN	Susceptibility to Benzylpenicillin (penicillin G) as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_RIF	Susceptibility to Rifampicin as the final interpretation based on one or more test	I = Intermediate R = Resistant

	results according to clinical breakpoints from EUCAST.	S = Susceptible
SIR_SXT	Susceptibility to Trimethoprim-sulfamethoxazole as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
SIR_TCY	Susceptibility to Tetracycline as the final interpretation based on one or more test results according to clinical breakpoints from EUCAST.	I = Intermediate R = Resistant S = Susceptible
Status	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.	DELETE = Delete a previously reported record NEW/UPDATE = Update a previously reported record (default)
SubjectCode	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	DIPH = Diphtheria
SuspectedVehicle	Suspected vehicle or source of infection - contact within the last 1-7 days (C. ulcerans only).	FARMANIMAL = Farm animal such as cattle or sheep OTH = Other OTHERANIM = Other animal PET = Pet animal such as dog or cat RAWMILK = Raw milk/raw milk products
TravelPlaces	Only applicabel if case is imported (ImportedStatus = 'IMP'). The list can be left empty even if the case is known to be imported. Note that this is a repeatable field: List each country visited recently before/during diagnosis.	*Consult the reference values in mdLocation dataset*
VaccinationStatus	Indicates if the case is vaccinated and number of vaccine doses received.	10DOSE = 10 doses 1DOSE = 1 dose 2DOSE = 2 doses 3DOSE = 3 doses 4DOSE = 4 doses 5DOSE = 5 doses 6DOSE = 6 doses 7DOSE = 7 doses 8DOSE = 8 doses

		9DOSE = 9 doses NOTVACC = Not vaccinated UNKDOSE = Vaccinated, dose unknown
Wgs	Information on whether whole genome sequencing has been performed on isolates from the case.	
WgsAccession	Accession number if sequencing data have already been uploaded to any public repository.	
WgsSequenceId	Sequence Read Archive (SRA) run identifier, based on which the sequence read data can be retrieved.	

Aggregated reporting

Please refer to Table 3 to see the format for aggregated reporting for diphtheria.

If only a few variables can be reported, it is recommended to give the following priority for reporting: AgeGroup, CaseClassification, VaccinationStatus, Gender.

Table 3: Aggregate metadata for diphtheria (DIPHAGGR)

Variable	Description	Coded value list
AgeGroup	Age group of the reported record.	*See Table 4 below.*
CaseClassification	Case classification according to EU case definition.	CONF = Confirmed POSS = Possible PROB = Probable
DataSource	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.	*Consult the reference values in mdDataSource dataset*
DateUsedForStatistics	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date.	
Disease	The code of the disease that is being reported.	DIPH = Diphtheria
Gender	Gender of the reported case.	F = Female M = Male OTH = Other
NumberOfCases	Total number of cases during the reported period for the specified disease.	
ReportingCountry	The country reporting the record.	*Consult the reference values in mdLocation dataset*

SubjectCode	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	DIPH = Diphtheria
VaccinationStatus	Indicates if the case is vaccinated and number of vaccine doses received.	10DOSE = 10 doses 1DOSE = 1 dose 2DOSE = 2 doses 3DOSE = 3 doses 4DOSE = 4 doses 5DOSE = 5 doses 6DOSE = 6 doses 7DOSE = 7 doses 8DOSE = 8 doses 9DOSE = 9 doses NOTVACC = Not vaccinated UNKDOSE = Vaccinated, dose unknown

When reporting age, the age groups listed in Table 4 should be used.

Table 4. Age categories compatible with aggregate diphtheria reporting

Variable	Narrative description	Coded value of the variable AgeGroup
AgeGroup	<1 year	0
	1-4 years	01-04
	5-9 years	05-09
	10-14 years	10-14
	15-19 years	15-19
	20-24 years	20-24
	25-29 years	25-29
	30-34 years	30-34
	35-39 years	35-39
	40-44 years	40-44
	45-49 years	45-49
	50-54 years	50-54
	55-59 years	55-59
	60-64 years	60-64
	65 and over	65+

Changes to the diphtheria metadata

Metadata changes prior to 2014 can be found on the TESSy documents website. Changes from 2014 onwards have been summarised in Table 5 below.

Table 5. Summary of implemented changes in case-based and aggregated record types for diphtheria from 2014 to current

Year of change	Subject	Variables	Description
2024	**DIPH**	**ALL**	**Reporting moved from TESSy to the Epipulse Cases platform. This transition has led to changes in some variable names and categorical values (see below).**
	DIPH	AccNumber Antibiotic Classification ClinicalPresentation ClusterIdentification Complications DateLastVaccDose EpiLinkCaseID Imported ProbablyCountryOfInfection RecordId RecordType ResultBiotype ResultSeqType Specimen1 Specimen2 Subject TestMethod1 TestMethod2 VaccStatus WGS	**Variable names changed from (TESSy) → to (Epipulse Cases):** AccNumber → WgsAccession Antibiotic → AntimicrobialAgent Classification → CaseClassification ClinicalPresentation → ClinicalCriteria ClusterIdentification → ClusterId Complications → ComplicationDiagnosis DateLastVaccDose → DateOfLastVaccination EpiLinkCaseID → EpiLinkCaseId Imported → ImportedStatus ProbablyCountryOfInfection → PlaceOfInfection RecordId → NationalRecordId RecordType → SubjectCode ResultBiotype → Biotype ResultSeqType → SequenceType Specimen1 → MainSpecimen Specimen2 → SecondSpecimen Subject → Disease TestMethod1 → MainPathogenDetectionMethod TestMethod 2→ SecondPathogenDetectionMethod VaccStatus → VaccinationStatus WGS → Wgs
		ResultRibotype RecordTypeVersion	Variable removed
		AntimicrobialAgent SIR_CIP SIR_CLI SIR_ERY SIR_LNZ SIR_MEM SIR_PEN SIR_RIF SIR_SXT SIR_TCY	Discontinued values: "NA", "UNK"
		ClinicalCriteria Gender MainSpecimen SecondSpecimen MainPathogenDetectionMethod SeondPathogenDetectioMethod	Discontinued values: UNK; Remapping of: "O" to "OTH"
		Biotype	Discontinued values: "NA", "NUS", "UNK"; Remapping of: "O" to "OTH"
		CaseClassification	Discontinued values: UNK
		ClusterRelated Wgs	Discontinued values: UNK; Variable changed from coded value to Boolean (0 = No ; 1 = Yes)
		ClusterSetting	Discontinued values: "NA", "UNK"; Remapping of: "HOSP" to "NOS", "MIGR" to "DET"
		ComplicationDiagnosis	Discontinued values: UNK; Remapping of: "NEURODIS" to "NEURO", "O" to "OTH"
		ImportedStatus	Discontinued values: UNK; Remapping of: "N" to "END", "Y" to "IMP"
		Outcome	Discontinued values: NUS, UNK

		Pathogen	Discontinued values: NUS Remapping of: "DIP" to "CORDIP", "PSEU" to "CORPSE", "ULC" to "CORULC", "O" to "CORSPP", "UNK" to "CORSPP"
		SuspectedVehicle	Discontinued values: "NA", "NUS", "UNK"; Remapping of: "FARMAN" to "FARMANIMAL", "O" to "OTH"
		VaccinationStatus	Discontinued values: UNK; Remapping of: "DOSEUNK" to "UNKDOSE"
		Disease Status	Changed "Required" from "Yes" to "No"
	DIPHAGGR	AgeClass Classification RecordType Subject	**Variable names changed from (TESSy) → to (Epipulse Cases):** AgeClass → AgeGroup Classification → CaseClassification RecordType → SubjectCode Subject → Disease
		AgeGroup CaseClassification	Discontinued values: "UNK"
		Disease	Changed "Required" from "Yes" to "No"
		Gender	Discontinued values: "UNK" Remapping of: "O" to "OTH"
		RecordTypeVersion	Variable removed
		SubjectCode	Remapping of: "AGGR" to "DIPHAGGR"
		VaccinationStatus	New variable
2023	DIPH		• The following variables were added: DateOfEntry o CountryOfBirth TravelPlaces o ClusterIdentification o ClusterRelated o ClusterSetting o EpiLinkCaseId o WGS o WgsSequenceId o AccNumber o DateOfFirstSample o ResultSeqType o Antibiotic o SIR_PEN o SIR_ERY o SIR_CIP o SIR_CLI o SIR_LNZ o SIR_MEM o SIR_RIF o SIR_TCY o SIR_SXT
2017	All VPD	DateLastVaccDose	• The description of the variable 'DateLastVaccDose' was updated to specify that the date given should be the date of last dose before disease onset.
	DIPH	Classification Pathogen ClinicalPresentation TestMethod	• The validation rules regarding the variables 'Classification' and 'Pathogen' were changed to 'error' so that cases with Classification==CONF could not be reported with unknown or missing data on Pathogen. • A validation rule (warning) was added for cases reported as Classification==CONF but ClinicalPresentation==”UNK”. • A validation rule (warning) for cases of Pathogen==ULC with ClinicalPresentation!=CUTA was removed. • For the variable 'ClinicalPresentation', the coded value 'NUS' (not under surveillance) was dropped. • For the variable 'ClinicalPresentation', the coded values 'CONJ' (conjunctival) and "GEN" (genital) were added. • The variable 'ClinicalPresentation' was made a mandatory variable. • The variable 'TestMethod' was made a mandatory variable.

			• A validation rule (warning) was added where, for cases reported as Classification==CONF, at least one of TestMethod1 or TestMethod2 must be reported as 'PCR', 'RTPCR' , 'ELEK' or 'O'.
2016	DIPH	TestMeth1 TestMeth2 AgeMonth ClinicalPresentation'	• The variables 'TestMeth1' and TestMeth2' were renamed 'TestMethod1' and 'TestMethod2', in line with other VPDs. • The variable 'AgeMonth' was added. • The description of the variable 'ClinicalPresentation' was edited to match other VPDs.
2015	All VPD	EpiLink ClinicalCriteria Labresult	• The variables 'EpiLink', 'ClinicalCriteria' and 'Labresult' were removed.
	DIPH	Classification DateLastVaccDose Pathogen	• The description of the variable 'Classification' was edited to ensure consistency with the EU case definition. • The RecordType 'HAGGR' was removed. • The variable 'DateLastVaccDose' was added. • Two new coded values were added to the variable 'Pathogen'. The coded value were PSEU=Corynebacterium pseudotuberculosis and NUS = Not under surveillance. This change reflects the update of the case definition in 2012.
2014	All VPD	VaccStatus	• The description of the coding for DOSEUNK (VaccStatus variable) was changed in the 2014 metadata for Measles, Mumps, Rubella, Pertussis, and Diphtheria. The name of the DOSEUNK coding was changed from "Unknown number of doses" to "Vaccinated with unknown number of doses". This modification did not imply any operational change during data upload.
	All		• Update NUTS codes according to the NUTS Codes 2010 classification from EUROSTAT.

Annex 2. Changes in case definition

Countries are encouraged to use the 2018 EU case definition for the data collection. In the 2018 definition, no changes are implemented for diphtheria. For the 2018 EU Case Definition, see:

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945&from=EN

or https://ecdc.europa.eu/en/surveillance-and-disease-data/eu-case-definitions

The changes in the 2012 EU case definition as compared to 2008 are indicated in red:
(*Corynebacterium diphtheriae, Corynebacterium ulcerans* and *Corynebacterium pseudotuberculosis*)

Clinical Criteria

Any person with at least one of the following clinical forms:

Classic Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis
AND
an adherent membrane/pseudomembrane

Mild Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis
WITHOUT
an adherent membrane/pseudomembrane.

Cutaneous Diphtheria:

Skin lesion

Diphtheria of other sites:

Lesion of conjunctiva or mucous membranes

Laboratory Criteria

Isolation of toxin-producing *Corynebacterium diphtheriae, Corynebacterium ulcerans* or *Corynebacterium pseudotuberculosis* from a clinical specimen.

Epidemiological Criteria

At least one of the following epidemiological links:

— Human to human transmission

— Animal to human transmission

Case Classification

A. *Possible case*

Any person meeting the clinical criteria for classical respiratory diphtheria

B. *Probable case*

Any person meeting the clinical criteria for diphtheria (Classic Respiratory Diphtheria, Mild Respiratory Diphtheria, Cutaneous Diphtheria, Diphtheria of other sites) with an epidemiological link to a human confirmed case or with an epidemiological link to animal to human transmission

C. *Confirmed case*

Any person meeting the laboratory criteria AND at least one of the clinical forms