TESSy - The European Surveillance System

Coronavirus disease 2019 (COVID-19) Vaccine, Monitoring of vaccine roll out, Reporting Protocol

Version 1.5, 11 March 2021

Contents

How to use this document

This Reporting Protocol provides information for data managers in reporting countries in two main sections:

- *Reporting to TESSy* – contains guidelines on how to prepare data for submission to TESSy, deadlines for reporting, subject-specific information (e.g. new changes to metadata), and links to further information.
- *Annex* – contains:

COVID-19 vaccines reporting protocol   **March 2021**

- o A history of metadata changes for the subject(s) covered by this Reporting Protocol.
- o The metadata set for the subject(s) covered by this Reporting Protocol.

Finding further information

Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned in this Reporting Protocol are included in the *TESSy Technical Guidelines & Tools* (see the menu 'Technical Guidelines and Tools' when logged in TESSy), including:

- Metadata sets and history.
- Tutorials for data transformation using respectively Excel and Access.
- TESSy user documentation.
- *CSV* and *XML* transport protocols.

Copyright

Updates in V1.5

Updated reporting timeline

Updates in V1.4

Updated reporting timeline

Updates in V1.3

Updated reporting timeline

Additional vaccine codes

Clarified that denominators only need to be reported for TargetGroup = "HCW" and "LTCF" and they should be reported every week.

Updates in V1.2

Clarification of the following:

Vaccine doses received by individuals refers to vaccine doses administered to individuals

Unknown dose refers to the dose for which it is unknown if it had been administered as first or second dose. This term has been changed to "unspecified" dose.

TargetGroup "Long-term care facilities" refers to residents in long-term care facilities.

Introduction

This Reporting Protocol describes surveillance of the early phase of the vaccination campaign with COVID-19 vaccine in the EU/EEA. It includes one record-type:

Aggregated reporting of vaccines distributed and number of doses of the vaccine administered to individuals (recordtype: **NCOVVAC**)

The latest available data **should be reported twice a week, i.e. every Tuesday and Thursday EOB**.

- **On Tuesdays, it is expected that the full dataset from the previous week is uploaded**
- **On Thursday, it is expected that a partial dataset of the *current* week is uploaded**
- **It is encouraged to update all data any day of the week (Monday to Friday).**

If you are unable to meet these deadlines, please contact the ECDC VPI team (5.1.2e @ecdc.europa.eu 5.1.2e @ecdc.europa.eu and copy 5.1.2e @ecdc.europa.eu).

Data will be used however please note that:

1. **Daily snapshots of the data will be taken at 08:00 and published at 11:00 to update the ECDC Vaccine Tracker.**
2. **Snapshots of the data will be taken on Wednesdays and Fridays at 11:00**. These snapshots will be used for the production of the ECDC weekly report on the COVID-19 vaccine rollout overview and for the European Commission Integrated Situational Awareness and Analysis report (ISAA report) respectively.
3. All data collected are shared with the World Health Organisation – Regional Office for Europe (WHO/Europe) on a weekly basis to fulfil Member States' reporting requirements to WHO. Duplicate reporting is therefore not required.

Definitions

Healthcare workers (HCW): refer to those who work in healthcare settings who may come into contact with patients, including clinical administration staff, and care home staff.

Doses of vaccines: refers to the total number of vaccine doses, considering that an additional dose may be obtained from each vial (e.g. 6 doses for Pfizer BioNTech® Comirnaty).

Number of doses distributed refers to the doses distributed by the manufacturers to the country.

Number of doses distributed to the country at subnational level refers to the number of doses reallocated to each region among doses received by the country from the manufacturers.

Number of doses administered refers to any individual receiving any dose of the vaccine.

Weekly data refer to:

- Week of vaccine distribution by the manufacturers to the country
- Week of vaccine dose administration to individuals receiving any of the first, second or unspecified dose

Aim

To support the timely and complete reporting of key information on COVID-19 vaccination in the EU/EEA.

Objectives

- To inform about the progress and efficiency of the vaccination campaigns in terms of administration of the vaccine doses to the target populations at national level, in specific target groups and across the countries
- To inform about the capability of the countries to ensure administration of all vaccine doses to individuals
- To identify possible shortcomings in the deployment of the vaccines

Reporting to TESSy

When, what and how to report

Deadline for reporting:

Data should be reported twice a week, every Tuesday and every Thursday EOB. If you are unable to meet these deadlines, please contact the ECDC VPI team (5.1.2e @ecdc.europa.eu 5.1.2e @ecdc.europa.eu and copy 5.1.2e @ecdc.europa.eu).

Data uploaded on Tuesdays should reflect the status of the vaccine rollout as of the previous week and will be published every Thursday in the ECDC weekly report on the COVID-19 vaccine rollout overview.

Data uploaded on Thursdays should reflect the status of the vaccine rollout of the current week and will be shared in the European Commission Integrated Situational Awareness and Analysis report (ISAA report) in which links to both the Tracker and the ECDC weekly report on the COVID-19 vaccine rollout overview are included.

How to report

Please note that data should not be cumulative. This means that each week you should report the actual number of doses received/administered during that week.

The minimum reporting requirements are described below. All countries should report data at national level as a minimum, using the variables "Region" = CountryCode (i.e. data at national level), "VaccineName", "NumberDosesReceived", "TargetGroup", "DoseFirst", "DoseSecond" and "DoseUnk". The following target groups need to be reported as a minimum:

- ALL: for reporting of overall data

- HCW: for reporting of data among healthcare workers

- Age-group: it is preferred to report age-group data using the detailed age categories (18-24, 25-49, 50-59, 60-69, 70-79 and 80+ years), however if data are not available broken down by these age-groups, as a minimum please report using the age-groups <60 and 60+ years. There is no need to report both types of age categorizations.

It is also possible to report data at subnational level, however it is important that data for each "TargetGroup" are first reported at national level. Reporting at subnational level is optional (both overall and by "TargetGroup").

The variable "NumberDosesReceived" needs to be reported only for "TargetGroup" = ALL. It should always be reported at national level, but may also be reported at subnational level.

If there are some national specificities in how the target groups are defined (eg healthcare workers only in long term care facilities), this can be described in the variable "TargetGroupComments".

Further comments on the reported data can be entered in the field "GeneralComment".

When reporting "TargetGroup" = HCW and "TargetGroup" = LTCF, please report the denominator for this population each week. There is no need to report denominators for other target groups as these will be obtained from Eurostat.

Minimum reporting

The above mentioned variables should ensure reporting of the following minimum dataset:

- Weekly number of vaccine doses distributed by the manufacturers and received by the country: total and by vaccine name

- Weekly number of first doses administered to individuals at national level: total and by vaccine name
- Weekly number of second doses administered to individuals at national level: total and by vaccine name
- Weekly number of unspecified doses administered to individuals at national level: total and by vaccine name

- Weekly number of first doses administered to individuals aged < 60 years national level
- Weekly number of second doses administered to individuals aged < 60 years at national level
  Weekly number of unspecified doses administered to individuals aged < 60 years at national level
- Weekly number of first doses administered to individuals aged >= 60 years at national level
- Weekly number of second doses administered to individuals aged >= 60 years at national level
- Weekly number of unspecified doses administered to individuals aged >= 60 years at national level

- Weekly number of first doses administered to healthcare workers at national level
- Weekly number of second doses administered to healthcare workers at national level
- Weekly number of unspecified doses administered to healthcare workers at national level

Preparing data

For all recordtypes, data may be entered directly in TESSy for individual records ('Manually create a record'). For any batch reporting by file upload (CSV or XML format) please note that once the data has been exported from your national database it needs to be in a format that TESSy can accept (see 'checking metadata').

Checking metadata

The TESSy metadata define the fields and valid data formats for input to TESSy for a given subject.

To ensure data can be saved correctly in TESSy, please check the data are correctly formatted according to the most recent metadata set.

Changes to the metadata for the subject of this Reporting Protocol are described in:

- *Changes to current metadata* – changes since the last Reporting Protocol.
- *Annex Metadata change history* – all preceding changes.

It is especially important to focus on:

- **Field formats**

  Many fields require that data are formatted in a specific way. For example, dates must be in the **YYYY-Www** format (e.g 2021-W01); dates in any other format will be rejected.

- **Coded values**

  Some fields only permit the use of specific values (coded values). If any other value is used in the field, the upload will be rejected.

The metadata file contains all the definitions and rules you need to comply with to format your data correctly for every subject (usually a disease). The file can be downloaded as an Excel file from the TESSy documents website.

By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

The *Tessy User Guide* provides an overview of how you work with the metadata file, and the TESSy user documentation provides in-depth details on metadata.

Submitting your data

Data are submitted through the TESSy web interface (go to **Upload**). Previously reported data can be found through the review tab (see below).

| Home | Upload | Review | Query | Reports | Data sources | Network workspace | My profile | Documents |

ⓘ The *Tessy User Guide* provides an overview of how you submit files to TESSy and in-depth descriptions of all the upload methods.

Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the check in the **Validation details** webpage has completed. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to 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 – unapproved uploads can block the approval of other uploads.

- The TESSy user documentation provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

- General training and guidance on reporting is available on the *TESSy website*. A training video on reporting COVID-19 data is available in the *ECDC virtual academy*.

TESSy HelpDesk

Email: 5.1.2e*@ecdc.europa.eu*

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

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

Annex - Coronavirus disease 2019 (COVID-19) vaccine metadata

Revisions of COVID-19 vaccine metadata set

The COVID-19 vaccine metadata have been developed in collaboration with WHO/Europe. The most recent metadata set is available from the TESSy website under technical guidelines and tools tab (as shown below).

| Home | Upload | Review | Query | Reports | Data sources | Network workspace | My profile | Documents |

| General Documents | Communication | Guides And Training | Disease Specific | Technical Guidelines & Tools | Contact Help Desk |

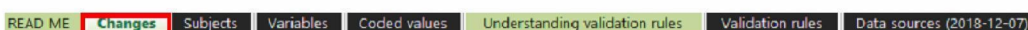## Current record type versions

Table 1 shows the record type versions to be used when reporting COVID-19 vaccine (Record type: NCOVVACC) data to TESSy.

Table 1: COVID-19 vaccine record type versions

Record type	Type of data	Record type version
NCOVVACC	Case-based[1]	1

NCOVVACC metadata change history

When you open a metadata set, the Excel file has a tab 'Changes', recording historical changes.

| READ ME | Changes | Subjects | Variables | Coded values | Understanding validation rules | Validation rules | Data sources (2018-12-07) |

NCOVVACC metadata recordtype version 1

Common TESSy variables

Record Identifier (mandatory)

Field: RecordId

Coding: Text (max 80 characters)

The record identifier is provided by the Member State. It must be:

- unique within the national COVID-19 disease surveillance system
- anonymous.

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[1] Note NCOVVACC is a "case-based" recordtype as it allows multiple rows for the same week, due to the region, vaccine name and target group variables. However the number of tests is aggregated over these variables.

Record type (mandatory)

Field: RecordType

Coding: NCOVVACC

The record type defines the structure and the format of the data reported. The record types are defined by ECDC and are related to the subject. Only valid combinations of subject, record type and data source are accepted.

Record type version

Field: RecordTypeVersion

Coding: 1

The version of the record type defines the current structure of the data reported. The current version of the NCOVVACC record type is 1.

This variable is not mandatory as TESSy concludes the record type version from the metadataset indicated by default. However, the variable RecordTypeVersion can override this default.

Subject (mandatory)

Field: Subject

Coding: NCOVVACC

The subject describes the data to be reported.

Data source (mandatory)

Field: DataSource

Coding: Pre-assigned as CountryCode-NCOVVACC to each country; can be modified by National Coordinator

The data source specifies the surveillance system from which the data originates and is generated and revised/updated by the national contact point for surveillance in each Member State. The descriptions of the surveillance systems submitted to TESSy should be kept up to date and will be used to assist with data interpretation.

Reporting country (mandatory)

Field: ReportingCountry

Coding: International organization for standardization (ISO) 3166-1-alpha-2, (two-letter code)

This variable identifies the country reporting the case.

Date used for statistics (mandatory)

Field: DateUsedForStatistics

Coding: yyyy-Www

Date when the vaccine was received/administered. Only weeks are allowed (e.g. "2021-W01").

Status (mandatory)

Field: Status

Coding: NEW/UPDATE

                DELETE

The field 'Status' is used for updating data; the default is 'New/Update'. By choosing 'Delete' the selected record (or batch of data) will remain in TESSy but be marked as inactive; this data can be used to reconstruct data for a given date in the past.

Epidemiological variables

Region (mandatory)
Field: Region
Coding: Country/NUTS1 or 2/GAUL1/Country specific

Region where vaccine doses received/administered. As a minimum data should be reported at national level (Region = country code).

Vaccine name (mandatory)
Field: VaccineName
Coding: COM = Comirnaty – Pfizer/BioNTech
                MOD = mRNA-1273 – Moderna
                CN = BBIBV-CorV – CNBG
                SIN = Coronavac – Sinovac
                SPU = Sputnik V - Gamaleya Research Institute
                AZ = AZD1222 – AstraZeneca
                UNK = UNKNOWN

Name of vaccine. Additional vaccines will be added on approval or as requested.

Number of doses received (mandatory)
Field: NumberDosesReceived
Coding: Numeric

Number of vaccine doses distributed by the manufacturer to the country during the reporting week.

Target group (mandatory)
Field: TargetGroup
Coding: ALL = Overall
                HCW = Healthcare workers
                LTCF = Residents in long term care facilities
                Age18_24 = 18-24 year-olds
                Age25_49 = 25-49 year-olds
                Age50_59 = 50-59 year-olds
                Age60_69 = 60-69 year-olds
                Age70_79 = 70-79 year-olds
                Age80+ = 80 years and over
                AgeUnk = Unknown age
                1_Age<60 = below 60 years of age
                1_Age60+ = 60 years and over

Target group for vaccination. As a minimum the following should be reported: "ALL" for the overall figures, "HCW" for healthcare workers and age-groups (preferably using the detailed age-groups)

Dose first (mandatory)
Field: DoseFirst
Coding: Numeric

Number of first dose vaccine administered to individuals during the reporting week.

Dose second (mandatory)
Field: DoseSecond
Coding: Numeric

Number of second dose vaccine administered to individuals during the reporting week.

Dose unknown (mandatory)
Field: DoseUnk
Coding: Numeric

Number of doses administered during the reporting week where the type of dose was not specified (i.e. it is not known whether it was a first or second dose).

Dose first refused
Field: DoseFirstRefused
Coding: Numeric

Number of individuals refusing the first vaccine dose.

Denominator
Field: Denominator
Coding: Numeric

Population denominators for target groups (total population and age-specific population denominators do not need to be reported and will be obtained from Eurostat/UN). Denominators only need to be reported for TargetGroup = "HCW" and TargetGroup = "LTCF". They should be reported every week for these target groups.

Target group comment
Field: TargetGroupComment
Coding: Text

Details on target group.

General comment
Field: GeneralComment
Coding: Text

Additional comment on the reported data.