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Pre-release

EU-SRS

# Human Vaccines EU-SRS User Guide

Guidance on the naming and building of human vaccine substance records in EU-SRS

**Disclaimer**

This document is created as part of deliverable D2.8 EU-SRS Data Management Plan of Unicom Work Package 2: Implement IDMP – Substance Management in Europe.

This guide will be a living document, used by the Substances Validation Group (SVG) for creation and maintenance of substances in EU-SRS.

The current version is a pre-release. Your feedback, if any, is welcomed by **8 December 2022.** Comments can be sent to Steven de Wit (e-mail: s.d.wit@cbg-meb.nl ).

Your feedback will be considered when preparing the official release which will be submitted as Unicom deliverable to the European Commission in January 2023.

# Document control

This document is subject to a regular review by the Substance Validation Group (SVG). It is a living document, and changes will be captured in the version history section.

## Document ownership

This document is owned by the SVG.

## Revision history

| Version | Date | Changes made | Author(s) |
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# List of abbreviations

| Abbreviation | Complete Form |
|---|---|
| CV | Controlled Vocabulary |
| EMA | European Medicines Agency |
| EP | European Pharmacopoeia |
| EU | European |
| EU-SRS | European Substance Registration System |
| ICTV | International Committee on Taxonomy of Viruses |
| INN | International Non-proprietary Name |
| ISO IDMP | International Organization of Standardization Identification of Medicinal Products |
| ITIS | Integrated Taxonomic Information System |
| LSPN | List of Prokaryotic names with Standing in Nomenclature |
| MAH | Market Authorization Holder |
| mRNA | messenger Ribonucleic Acid |
| NCBI | National Centre for Biotechnology Information |
| NCI | National Cancer Institute |
| PT | Preferred Term |
| SmPC | Summary of Product Characteristics |
| SMS | Substance Management Services |
| SPOR | Substances, Products, Organizations, Referentials (EMA) |
| SSG1 | Specified Substance Group 1 |
| SVG | Substance Validation Group |

# 1 Introduction

The EU Network is currently implementing the ISO IDMP standards in a phased programme based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (collectively referred to as “SPOR”) master data. ISO IDMP compliant business services for the central management and supervision of data in each of the four SPOR areas will be established through an iterative and incremental delivery approach. Through the Substance Management Services (SMS) of the SPOR programme EMA will provide the EU network centralised substance data management services.
The European Substance Registration System (EU-SRS) will become the scientifically rigorous back-end for the Substance Management Services (SMS) of SPOR. EU-SRS will be accessible by the EU regulatory network, enabling the unambiguous identification of substances used in medicinal products based on their scientific properties in accordance with ISO IDMP standard 11238 and ISO IDMP technical specification standard 19844. EU-SRS allows the unique identification of substances which will support various purposes including the enhancement of traceability of pharmacovigilance, non-clinical, clinical and quality findings with a high degree of precision to substances by their scientific identity.
The Substance Validation Group (SVG) is responsible for the data entry of substance records in EU-SRS. In addition, the SVG defines guidance and best practices for substances management in EU-SRS (per substance type).

## 1.1 Purpose

The purpose of this document is to provide practical guidance regarding naming and building of human vaccine substance records in EU-SRS.

## 1.2 Scope

Naming rules and building guidance for human vaccine substances in EU-SRS are in scope of this document. This document is to be used together with the general EU-SRS Substance Maintenance Process document/ which describes in detail the workflow between EMA and SVG (under development).

## 1.3 Link between EU-SRS and SMS

Vaccine substance harmonisation between SMS and EU-SRS is planned for 2023.

# 2 Defining a Human Vaccine Substance

The scope of this document is the human medicinal products commonly described as vaccines. The definition of a 'Vaccine', according to ISO/TS 19844:2017 Annex I (I3.4), is:

'A vaccine is a biological preparation that provides active acquired immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins.'

Conventional vaccines refer to live, attenuated, or inactivated vaccines. In recent days, non-conventional vaccines have generated an increased interest. Examples of non-conventional vaccines are mRNA-, DNA-, and viral vector vaccines.

## 2.1 EU-SRS hierarchy

EU-SRS provides the opportunity to establish relationships between the records and therefore a hierarchy can be built. This hierarchy consists of three levels:

- **Scientific name/Author level (highest level, mandatory)**
  - **Serovar/Serogroup/Serotype level (middle level, if applicable**)
    - **Strain/Fraction level (lowest level, mandatory)**

The records regarding one substance are interlinked in the hierarchy. One record at the scientific/author level may have many records at the levels below.

An example on the hierarchy is provided in **Error! Reference source not found.**.

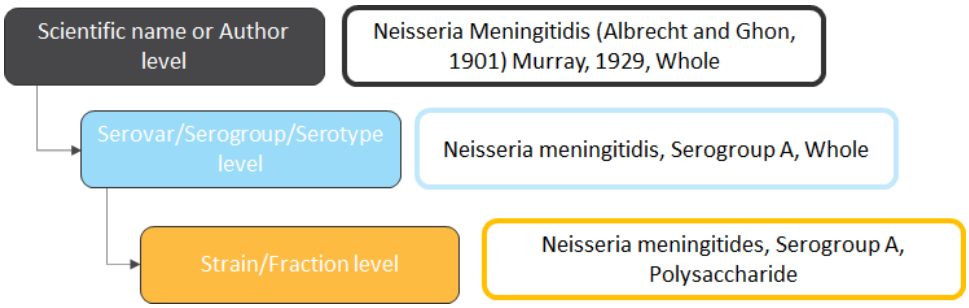


**Figure 1.** Example of a hierarchy in EU-SRS.

# 3 Naming of Human Vaccines

This chapter provides details around the naming of vaccines in EU-SRS. Detailed instructions regarding the building of records in EU-SRS as well as detailed field definitions can be found in section 4 and the appendices (section **Error! Reference source not found.**).

## 3.1 Acceptable sources for naming of human vaccines substances

All names must have at least one public reference. Accepted sources for naming vaccines are listed in Table 1. The reference may be a publicly available database or an authorized naming body, see Table 1. For human vaccines, not all substances can be found in scientific public sources. In that case, the SmPC can be cited as a source. The Official naming bodies (for example INN) are listed in the General EU-SRS User Guide, which will be published at a later stage.

**Table 1.** Accepted sources for naming vaccine substances.

| Name | Hyperlink |
|---|---|
| National Centre for Biotechnology Information (NCBI) | https://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi) |
| International Committee on Taxonomy of Viruses (ICTV) | https://talk.ictvonline.org/taxonomy/ |
| Integrated Taxonomic Information System (ITIS) | https://www.itis.gov |
| European Pharmacopoeia | https://pheur.edqm.eu/home |
| List of Prokaryotic names with Standing in Nomenclature (LPSN) | https://lpsn.dsmz.de/ |
| SmPC (in case all other public sources fail) | NA |

## 3.2 Name types

All records in the EU-SRS system will contain name type information which is chosen from a drop-down list. The Name types used for vaccine substances are.

- **Official Name**: Reflects the organization that assigns or recognizes the name associated with the substance. These names are typically non-proprietary names that are used in the labelling of pharmaceuticals. The domains and jurisdictions in which the official name is used are also captured, tracked, and maintained within the terminology.
- **Common Name**: Any other name or synonym.
- **Code:** Company Code/name for a substance provided in an early stage of development.
- **Scientific name**: is based on the biological taxonomic nomenclature and reflects the current scientific knowledge based on acknowledged scientific/ taxonomic databases, which are however no official naming bodies (no jurisdiction applies) - applicable for naming species of organisms (including e.g. microorganisms, plants and viruses).

### 3.2.1 Jurisdiction

In case of selecting 'Official Name' as Name type, an additional field 'Naming Organizations' is available, where the respective Naming Organization should be included. A full list of acceptable naming organizations and jurisdiction can be found in the General EU-SRS User Guide.

**Table 3.** Acceptable Official Naming Organizations relevant for vaccines and jurisdiction.

| Name | Jurisdiction |
|---|---|
| International Non-proprietary Name (INN) | EU |
| European Pharmacopoeia (EP) | EU |

## 3.3 Naming hierarchy

The use of EU-SRS provides the opportunity to establish relationships between the pathogen and related vaccine substances via a hierarchy consisting of three vaccine syntax levels. The pathogen is represented at the highest hierarchy level – (1) the scientific/author level – and may have several records linked on (2) serovar (if applicable) and (3) strain levels. Information regarding if the vaccine is live, attenuated, inactivated or modified should be included on Strain level. An additional SSG1 level, with for example adjuvant information can also be added in the hierarchy.

## 3.4 Naming syntax

The vaccine syntax is described and will consider bacteria, viruses and parasites. If the active substance is a recombinant or purified protein (a 'Fraction'), the syntax used conforms to the respective parent organism. Capitalization of pathogen names will follow formal taxonomic rules and other syntax groups will begin with an upper case.

### 3.4.1 Preferred term and Aliases

One substance can have several names but the preferred term (PT) in EU-SRS is usually based on the scientific name in accordance with the ISO 11238/TS19844. The PT is independent of level and is also the Display name. Syntax details for the three levels are provided below. Other relevant names can be included as aliases in EU-SRS. In case there is a need to differentiate between MAH between similar products, which can't be separated on a name level due to confidentiality, the MAH name will be added to the PT at the end of the syntax.

### 3.4.2 Syntax for the Preferred term for conventional vaccines

The syntax for the three levels will reflect the source material. On the scientific/author level, information related to source material is captured. When the complete organism is the source the substance name also includes the 'Part' or 'Whole'. The PT is based on the author level name in combination with the serovar/serogroup/serotype for bacteria and viruses or species in the case of parasites. The Strain/fraction level refers to a genetic variant, modification or subtype describing the antigen and may include additional information such as MAH.

The list of antigen types currently in use are listed below.

Bacterium, Whole, Inactivated
Bacterium, Whole, Live, Attenuated
mRNA
Polymer (polysaccharide)
Polymer (polysaccharide) conjugated to carrier protein
Polymer (polysaccharide) conjugated to toxoid
Polymer (polysaccharide) conjugated to toxoid adsorbed to Aluminium
Polymer conjugated to carrier protein adsorbed to Aluminium
Protein
Protein adsorbed on Aluminium
Protein adsorbed on Aluminiumhydroxide
Toxoid
Toxoid adsorbed on Aluminium
Virus, Live Whole. Chimeric, Recombinant
Virus, Whole, Live, Attenuated
Virus, Whole, Live, Recombinant
Virus, Whole, Inactivated
Virus, Whole, Inactivated adsorbed on Aluminium

Syntax Author level:

Bacteria: <Microorganism name>, <(Primary) secondary author>, <Year>, <Part>
Virus: <Microorganism name>, <Part>
Parasites: Microorganism name>, <(Primary) secondary author>, <Year>, <Part>

Syntax Serovar level:

Bacteria: <Microorganism name>, <Serovar/ Serogroup/ Serotype>, <Part>

Virus <Microorganism name>, <Serovar/ Serogroup/ Serotype>, <Part>

Parasite: <Microorganism name>, <Species>, <Part>

Syntax Strain level:

| |
|---|
| Bacteria: <Microorganism name>, <Serogroup/Serovar/Serotype>, <Strain>, <Antigen>, <Part>, <Status><br>Virus <Microorganism name>, <Serogroup/Serovar/Serotype>, <Strain>, <Antigen*>, <Part>, <Status><br>Parasite: <Microorganism name>, <Species>, <Strain>, <Antigen>, <Part>, <Status> |

## 3.5 Non-conventional vaccines – information on strain level

Non-conventional vaccines often follow the approach for the conventional vaccines up to strain level. Information on strain level differs between the non-conventional vaccines and is visible in the syntax, where any genetic modifications should be described between <strain> and <status>. See details for the specific vaccines below.

Syntax (Preferred term):

| |
|---|
| <Microorganism name>, <Serogroup/Serovar/Serotype>, <Strain>, <Antigen>, <Part>, <Status> |

### 3.5.1 Vaccines using deletion mutants

For vaccines using deletion mutants the strain may include modification information and Status will include modification e.g. Inactivation.

Syntax (Preferred term):

| |
|---|
| <Microorganism name>, <Serogroup/Serovar/Serotype>, <Serovar>, <Strain>, <Modification>, <Part>, <Status> |

### 3.5.2 Viral vector vaccines

Syntax (Preferred term):

| |
|---|
| <Vector>, <Strain>, <Inserted microorganism>, <Antigen>, <Part>, <Status> |

### 3.5.3 DNA vaccines

If no DNA sequence is available, then a ‘Structurally Diverse’ record should be created and may be later a ‘Nucleic acid ‘Alternative definition’ record can be attached.

Syntax (Preferred term):

| |
|---|
| <Parent strain name>, <DNA used as active substance>, <Part>, <Status> |

### 3.5.4 Other types (placeholder)

Syntax (Preferred term):

| |
|---|
| <Parent strain name>, <placeholder>, <Part>, <Status> |

# 4 Building Human Vaccine Records

## 4.1 New entry

**Table 2.** High level steps to register a human vaccine substance at author level.

| Step | Activity | Step action |
|---|---|---|
| Step 1 | Collect information | Open the dossier of the vaccine that you want to build in EU-SRS.<br><br>Information is needed on:<br>- Name of the marketed product<br>- Which pathogen is the vaccine used for?<br>- Active substance: is it a virus, bacterium, parasite, polymer, protein, mRNA etc.?<br>- What are the specifics of the virus (e.g. strain), bacterium (e.g. serovar), etc?<br>- If the virus/bacterium/… is inactivated, look for information on how this is done (formaldehyde, β-Propiolactone, heat, etc); you will need details on concentration of the inactivating agent, time of inactivation, temperature, etc.<br><br>You will need REFERENCES to substantiate your records, so look for definitions in NCBI taxonomy, NCI thesaurus, scientific papers, etc. to find information on the virus/bacterium/parasite.<br><br>➔ Save the scientific papers since they can be linked to the record<br>- Write down the NCBI taxonomy/NCI thesaurus numbers to use in CODES<br><br>➔ The information you gather can be easily displayed in a WORD document where you can add relevant parts from dossier sections, NCBI numbers, information from scientific articles, etc.<br><br>If needed (e.g. to add additional information), you can always EDIT THE RECORD (use the pencil icon) after it has been saved to add more information or change the information already present. |
| Step 2 | Search Substance | Is the Author Level already present in EU-SRS?<br><br>➔ Search via SEARCH SUBSTANCES (top right), start typing and a list with suggestions will be displayed at the bottom of the SEARCH field<br><br>➔ Be careful to select the EU entries and not the USA entries. USA entries can be recognised by their NAME in CAPITALS |

| Step | Activity | Step action |
|---|---|---|
| | | and the presence of a **red number** in the top right-hand corner.<br><br>***Yes***: finalize the record according to the steps below<br>***No***: create the record from the start, see below under CREATE NEW RECORD |
| **FINALIZE THE RECORD** | | |
| Step 3 | Adjust Substance Type | Some records are present as CONCEPTS. In that case, the SUBSTANCE TYPE needs to be changed to STRUCTURALLY DIVERSE:<br><br>➔ You will need ADMIN RIGHTS for this<br><br>- Open the CONCEPT, click on the pencil icon to EDIT, select ADVANCED FEATURES (top middle), select CHANGE SUBSTANCE CLASS, select NEW CLASS, STRUCTURALLY DIVERSE<br><br>Fill out the required fields, such as NAMES, CODES, REFERENCES, etc and VALIDATE AND SUBMIT (top right)<br><br>➔ Sometimes you will find that a DROP-DOWN list with values (named CV in EU-SRS) opens when you start typing in a field.<br><br>➔ The warning messages will tell you what is happening with your record<br>○ RED WARNING: you cannot save the record and need to fix the problem that is stated<br>○ ORANGE warning: you can DISMISS this warning and save the record<br>○ GREEN warning: this record can be saved immediately |
| **CREATE A NEW RECORD** | | |
| Step 3 | Register structurally diverse | If the record, you need for your vaccine is not already present build a new record in EU-SRS.<br><br>- Select REGISTER, STRUCTURALLY DIVERSE (top left)<br>- Fill out the OVERVIEW and add a DEFINITIONAL REFERENCE by using the CREATE NEW (+) button<br><br>➔ If a record is no longer valid, tick the DEPRECATED box; you will not need this when building a vaccine, but it may be useful if your vaccine is BLOCKED by the system. You can then DEPRECATE the blocking record and continue building your record. |

| Step | Activity | Step action |
|---|---|---|
| | | ➔ You can open multiple instances of EU-SRS on different screens so you can DEPRECATE an old record in one instance while continue your building process in the second instance.<br><br>- Add a NAME by selecting ADD NAMES (+)<br>  o Always register an OFFICIAL NAME and tick the DN circle on the left<br>  o Select the drop-down arrow next to MORE (top right in NAMES) and fill out DOMAINS (biologic and Hum. Vac) and JURISDICTION (European union)<br>  o Add a REFERENCE<br>- Multiple names could be added in this way, for example a COMMON NAME; then tick the AL square on the left; only 1 record can be OFFICIAL AND DN<br>- Fill out SOURCE MATERIAL (SOURCE MATERIAL CLASS = ORGANISM, SOURCE MATERIAL TYPE = BACTERIUM/VIRUS/PARASITE/…, for the AUTHOR LEVEL, we always choose WHOLE)<br>- Add ORGANISM DETAILS (FAMILY, GENUS, SPECIES, AUTHOR (if applicable), DEVELOPMENTAL STAGE (if applicable))<br>- Add CODES (these are the NCBI TAXONOMY NUMBER, NCI THESAURUS NUMBER, VACCINE NAME, etc) |

The steps in Table 4 can be repeated to build other records, such as a VIRUS STRAIN (structurally diverse) and a MODIFIED VIRUS STRAIN (SSG1), e.g. an inactivated strain. Please note that the SSG1 (or G1SS) level will contain confidential information. It is also possible to create PROTEINS as (part of) a vaccine substance (please refer to the PROTEIN GUIDE).

These records can then be LINKED to the author level. This will result in a hierarchy where all the strains belonging to a parent organism can be seen in an overview. An example of a vaccine record is provided in **Error! Reference source not found.**.

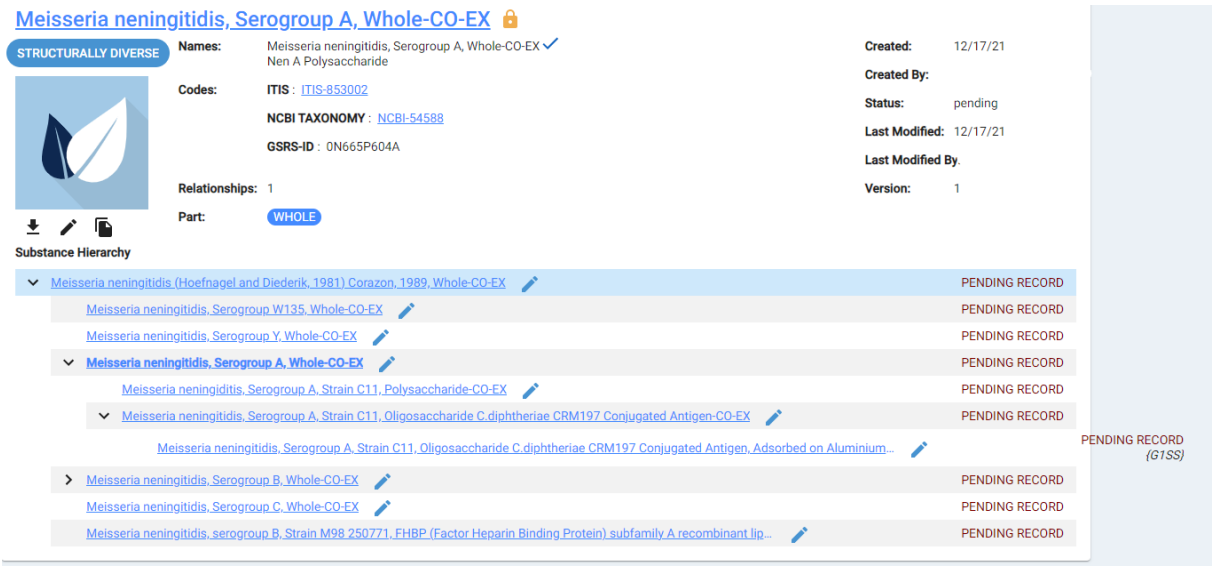


**Figure 2.** Example of a hierarchy in EU-SRS.

## 4.2 References

When building a vaccine in EU-SRS the “PUBLIC_DOMAIN_RELEASE” tag must be populated to make the record public. In general, the SmPC should contain this information. Once a reference is added to a record the references can be reused by selecting the tick box. Independently of the “PUBLIC_DOMAIN_RELEASE” tag, names can be marked as public using the tick box “Public Domain”. This is specific for this name and has no influence on the accessibility of the whole record.

# 5 Appendices

## 5.1 EU-SRS Field Guide

This section lists all EU-SRS fields and provides an explanation what rules apply to each field and when a certain field is used.

### 5.1.1 EU-SRS field guidance

| EU-SRS field name | Field details |
|---|---|
| **Overview** | |
| Display Name | *Automatically filled in from name section, OFFICIAL NAME, DN.* |
| Record Level Access | Public or Restricted (standard = Public). |
| Deprecated | *Relevant for a Deprecated Record. If a record is no longer valid this box should be ticked* |
| Definition Type | Always Primary. |
| Definition Level | Always Complete. |
| Definitional References | Field linked to References |
| **Names** | |
| Name<br>*(Display Name/Preferred Term in EU-SRS)* | Each record needs an 'Official Name' (TYPE which should be a scientifically correct name It is the Scientific/ taxonomic name, which is in 'English-Latin' and includes the Part (WHOLE, FRACTION). The Status is included with the value 'Inactivated' if applicable since 'Whole' is implicit the live organism.<br>Mandatory details:<br>Language = 'English',<br>-tick DN circle,<br>-choose Domains 'biologic' and 'Hum. Vac.',<br>-choose a naming organisation ('Naming Organizations'), add a PUBLIC REFERENCE.<br>-Jurisdiction = European Union<br>Further detailed information on the single fields can be found below. |
| Name<br>*(Additional name)* | Additional names (e.g., name type 'Common Name') can be included in the record. At least one reference is needed per name.<br>Mandatory details:<br>-language = English<br>-tick 'AL square |
| Type | .<br>An OFFICIAL NAME is mandatory (from e.g. ITIS, NCBI, ICTV, Ph. Eur., INN.) |

| EU-SRS field name | Field details |
|---|---|
| Access | If the information in the record is confidential, *Access* can be set to 'PROTECTED'. |
| Languages | If the name is in Latin, *Language* = *English*. |
| DN circle | Tick box to indicate what name should be the Display Name in EU-SRS . |
| AL square | Field is mandatory for the SMS-PT (not to be ticked for other aliases) and only needed if the EU-SRS PT differs from SMS-PT. |
| Naming Organization (Name orgs) | see TYPE for naming organisations. |
| Name Jurisdiction | EUROPEAN UNION |
| Domain | Field is mandatory (and only included in the official name) - choose Domain 'biologic' and 'Hum. Vac.'. |
| References | At least one public reference is needed per name. |
| **Concept upgrade** | |
| Concept Upgrade | Choose the respective Substance Type (mostly 'Structurally Diverse'). The site will then be reloaded, and new fields appear (please see table 'EU-SRS field guidance for editing a Structurally Diverse'). See table 4 for details on how to change a concept to structurally diverse. |
| **Source Material** | |
| Source Material Class | Organism' |
| Source Material Type | Field is conditional. Choose one (in most cases Bacterium, Virus or Parasite). |
| Source Material State | Live/Attenuated/Killed |
| **Source Material Record Type** | |
| Whole / Part / Fraction | Default is 'Whole'. 'Part/Fraction' not applicable on author level but may be on other levels. |
| **Organism Details** | |
| Organism Family | Field is mandatory. |
| Organism Genus | Field is optional. |
| Organism Species | This should come from ITIS or NCBI. |
| Organism Author | Mandatory on Author level (except for a virus). Copy taxonomic database for name. |
| Developmental Stage | Field is optional. (Might be relevant for some vaccines.) |
| Infraspecific Type | *Not applicable.* |

| EU-SRS field name | Field details |
|---|---|
| Infraspecific Name | *Not applicable.* |
| **Agent Modifications** | |
| Agent substance | Might be something like formaldehyde (for inactivation); might be aluminium hydroxide for adsorption |
| Modification process | Formaldehyde is an inactivation agent; aluminium hydroxide is for adsorption |
| Modification type | Formaldehyde is an inactivation agent (not a typo, same as modification process); aluminium hydroxide is for adsorption |
| Modification role | Formaldehyde is a crosslinker; aluminium hydroxide is an adsorbent agent |
| Amount | Fill in the amount of formaldehyde, the time formaldehyde may work on the vaccine bulk and the temperature at which the bulk is kept during inactivation. The amount may be in mg/ml, % w/w, etc.; same for aluminium hydroxide |
| **Codes** | |
| Code system | Fill in the NCBI taxonomy reference number, the NCI thesaurus number reference, the vaccine name; use the appropriate code system, e.g. NCBI, NCI, CBG dossier, EMA list, EMA EPAR, etc. |
| Code System Type | *This is a default value (automatically filled in and managed by Admin).* |
| Type | In nearly all cases default 'Primary'. When the code is tied to the group use ‘General’. |
| Code | Your text |
| URL | This field is conditional: Mandatory for NCBI Taxonomy and ITIS (copy the URL), |
| References | Fill in the references, e.g. NCBI, NCI, CBG dossier, EMA list, etc. |
| Code Text | This field is optional and useful to describe a definition used in the source (e.g., Ph. Eur.) or other relevant information. |
| Access | Set to Public |
| **Relationships** | |
| Related Substance | *This section could be used for creating a different type of relationship to the active moiety.* |
| References | *Fill out the reference; references may be REUSED* |
| Type<br>*(purpose hierarchy)* | *PARENT-> INFRASPECIFIC* |
| Access | *Public or restricted* |
| Qualification | *Not applicable.* |
| Interaction Type | *Not applicable.* |

| EU-SRS field name | Field details |
|---|---|
| Amount | *Fill out the Type (mol ratio, weight ratio or other, for example a %), Average (100% in case where the vaccine consists of this parent strain), references may be REUSED* |
| Mediator Substance | *Not applicable.* |
| Comments | *May be used* |
| **Notes** | |
| Note | Field is optional and automatically populated by the system. System messages may be deleted (you will see many validation messages appearing here). |
| References | Field is optional. |
| Access | *Not applicable* |
| **References** | |
| Source Type | Drop-down list (CV-List); Mandatory field; Other (new value) may be used if the source type is not in the list |
| Source text | Mandatory field and should represent the related value of the type, e.g., the headline mentioned in the ITIS record. |
| Public Domain | Default is Public (Tick box), but it may be set 'Non-Public' in combination with a public reference. NOTE: a public reference is mandatory for a record, you cannot create a record with only NON_PUBLIC references |
| Access | Default is Open. Protected = confidential |
| URL | Fill in the URL for the reference, may be left blank |
| Source Id | Should have the Code of the Source Type |
| Upload a Document | This field is optional, scientific papers may be added here |
| Tags | This field should be populated by at least one value (‘Public domain release’) and if applicable other values. |

| Parent Organism Details– only displayed if ‘Part/Fraction’ is chosen | |
|---|---|
| Source Material Parent | Field is conditional. It is necessary to delete the Organism details populated in the ‘Whole’ mode of the record because reference is made to this information in the selected ‘Parent organism’. |
| **Parts And Fractions – only displayed if ‘Part/Fraction’ was chosen** | |
| Part | This field is optional for a certain type of vaccine, in most cases capsule or cell wall. |
| Part Location | *Not applicable.* |

| | |
|---|---|
| Fraction Name | This field is conditional for a certain type of vaccine (e.g., toxin). |
| Fraction Material Type | This field is conditional for a certain type of vaccine (e.g., protein). |
| **Structural Modifications** | |
| Modification Type | Optional at strain level for certain types of vaccines, in most cases proteins or polysaccharides. |
| Fragment | Optional at strain level for certain types of vaccines. The structure must be present in EU-SRS or should be pre-registered. |
| Location Type | Optional at strain level for certain types of vaccines, in most cases partial or complete. |
| Extent | Optional at strain level for certain types of vaccines. |
| Group | Not applicable. |
| Access | Optional at strain level for certain types of vaccines (Yes or Not Protected information). |
| **Physical Modifications** | |
| Modification Role | Optional at strain level for certain types of vaccines. To be used in e.g. heat inactivated material. |
| Parameters: Parameter Name | Optional at strain level for certain types of vaccines. |
| Parameters: Amount | Optional at strain level for certain types of vaccines. |
| **Properties** | |
| Name | Optional for certain types of vaccines, e.g., to be used in stability registration or Inactivation conditions other than Physical modifications. |
| Property Type | Optional for certain types of vaccines. |
| Amount | Optional for certain types of vaccines. |
| Parameter: Name | Optional for certain types of vaccines. |
| Parameter: Type | Optional for certain types of vaccines. |
| Parameter: Amount (see above) | Optional for certain types of vaccines. |
| Referenced Substance | Optional for certain types of vaccines. |
| Defining | Optional for certain types of vaccines, conditional for certain properties. |
| References | Optional for certain types of vaccines. |
| Access | Optional for certain types of vaccines. |
| | |

## 5.2 Human vaccine data field overview EU-SRS Examples (placeholder)