VigiFlow

Working with the DATA ENTRY section

Uppsala Monitoring Centre

– Building a global safety culture

Updated October 2019

Disclaimers

This material is based on the latest version of VigiFlow, released in May 2020. Some features are still under development, therefore the system appearance might differ from the slides included in this package.

This PowerPoint presentation has been developed by the UMC for training purposes. This material may be passed on to other users of VigiFlow.

The UMC does not take any liability for the correctness or quality of any altered, translated or partial versions of this material.

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Content

- Features from the Data Entry section
- Important data entry points:
  - *Report information*
  - *Patient*
  - *Case narrative and other information*
  - *Medical and past drug history*
  - *Reaction*
  - *Drug*
  - *Tests and procedures*
  - *Assessment*
  - *Specific fields for Adverse Events Following Immunization (AEFI)*

Important considerations for the data entry

- You should follow your national centre's standard operational procedures for data entry

- Because VigiFlow is compliant with international standards of ICH E2B(R3), it contains a large amount of fields with the aim of allowing a more flexible data entry. **It is not required to fill in all fields to complete the data entry.**

- In some cases there are alternatives to enter the same information either in free text or in structured fields. The UMC recommends to use the structured fields as much as possible because it will facilitate the data analysis later on.

Features from Data Entry section

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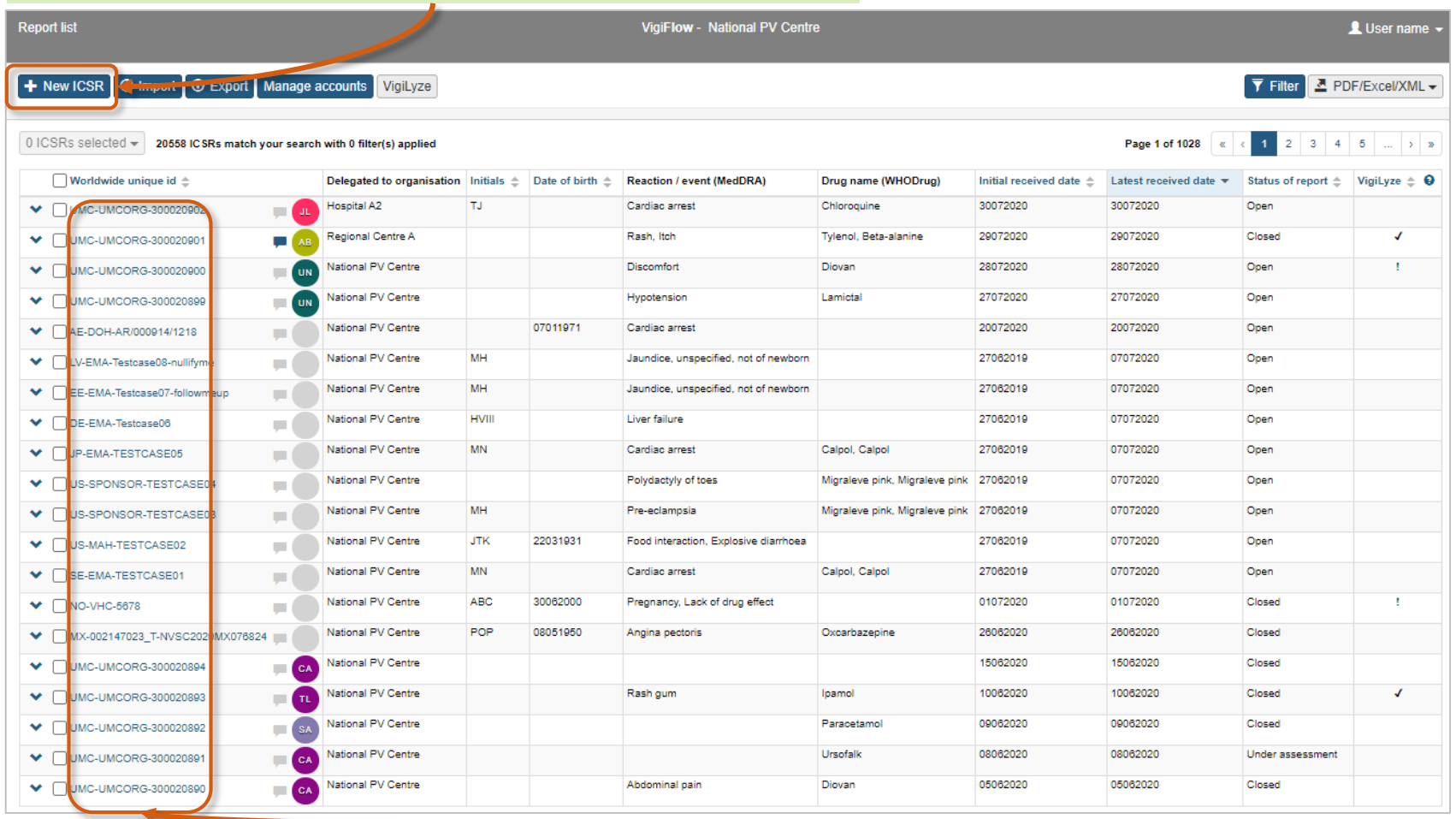
Accessing the Data Entry page

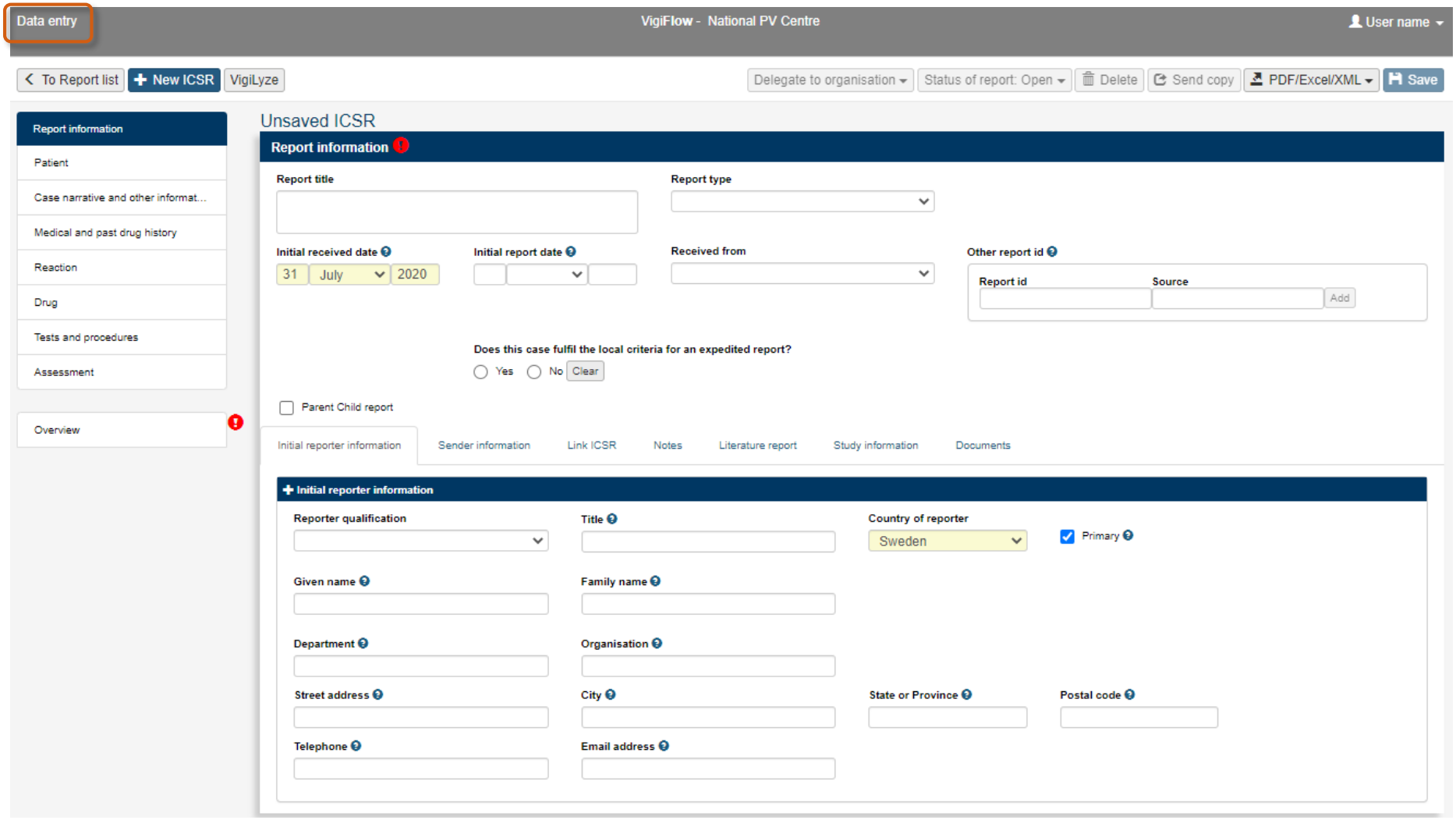
To enter a new report, click **+ New ICSR** in the Report List page



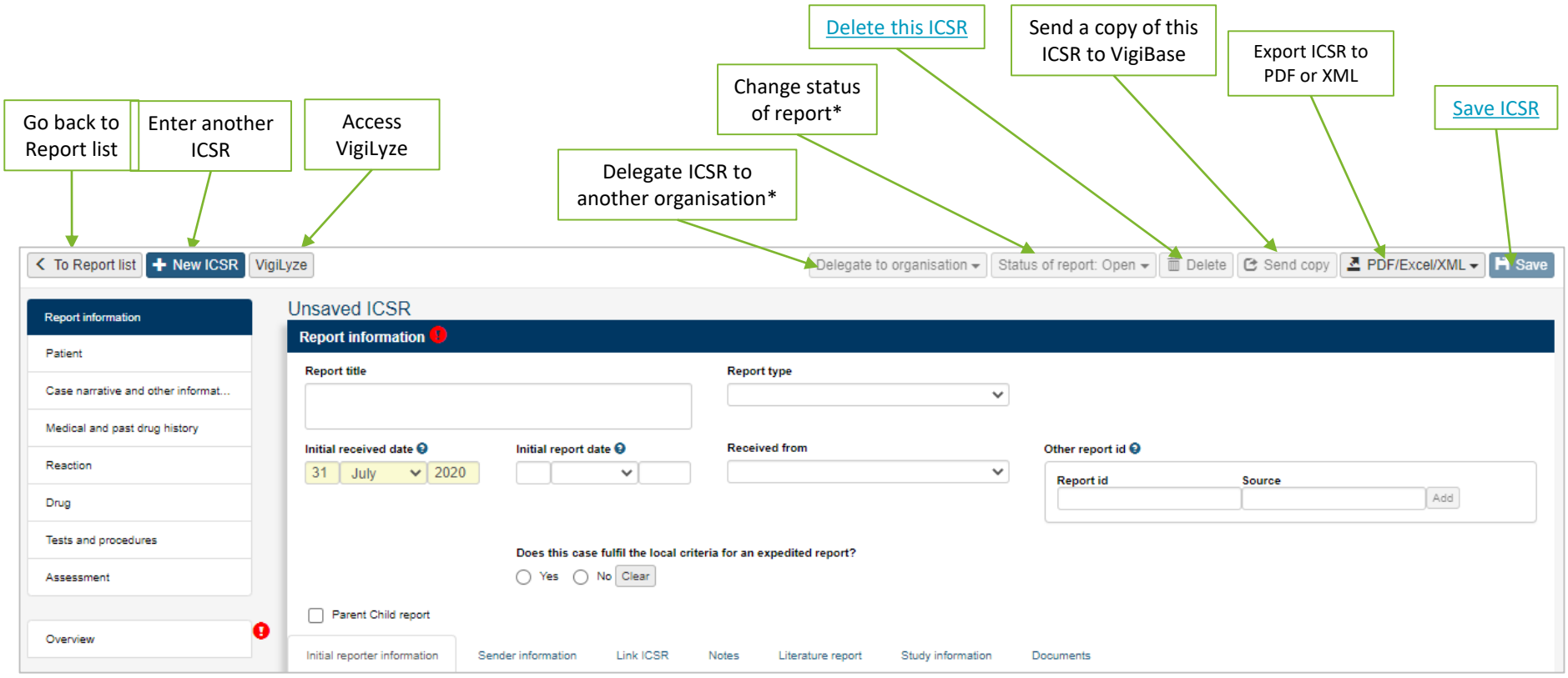
Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
UMC-UMCORG-300020902	Hospital A2	TJ		Cardiac arrest	Chloroquine	30072020	30072020	Open	
UMC-UMCORG-300020901	Regional Centre A			Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Closed	✓
UMC-UMCORG-300020900	National PV Centre			Discomfort	Diovan	28072020	28072020	Open	!
UMC-UMCORG-300020899	National PV Centre			Hypotension	Lamictal	27072020	27072020	Open	
AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
LV-EMA-Testcase08-nullifym	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
EE-EMA-Testcase07-followup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27062019	07072020	Open	
JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
US-SPONSOR-TESTCASE0	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-SPONSOR-TESTCASE0	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27062019	07072020	Open	
SE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
NO-VHC-5678	National PV Centre	ABC	30062000	Pregnancy, Lack of drug effect		01072020	01072020	Closed	!
MX-002147023_T-NVSC202 MX076824	National PV Centre	POP	08051950	Angina pectoris	Oxcarbazepine	26062020	26062020	Closed	
UMC-UMCORG-300020894	National PV Centre					15062020	15062020	Closed	
UMC-UMCORG-300020893	National PV Centre			Rash gum	Ipamol	10062020	10062020	Closed	✓
UMC-UMCORG-300020892	National PV Centre				Paracetamol	09062020	09062020	Closed	
UMC-UMCORG-300020891	National PV Centre				Ursofalk	08062020	08062020	Under assessment	
UMC-UMCORG-300020890	National PV Centre			Abdominal pain	Diovan	05062020	05062020	Closed	

To update an existing report (e.g. enter follow-up information), click on its **worldwide unique id** in the list of reports

Data Entry initial page



Functions in the top bar menu



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*See the slides about decentralisation in VigiFlow available at this link.

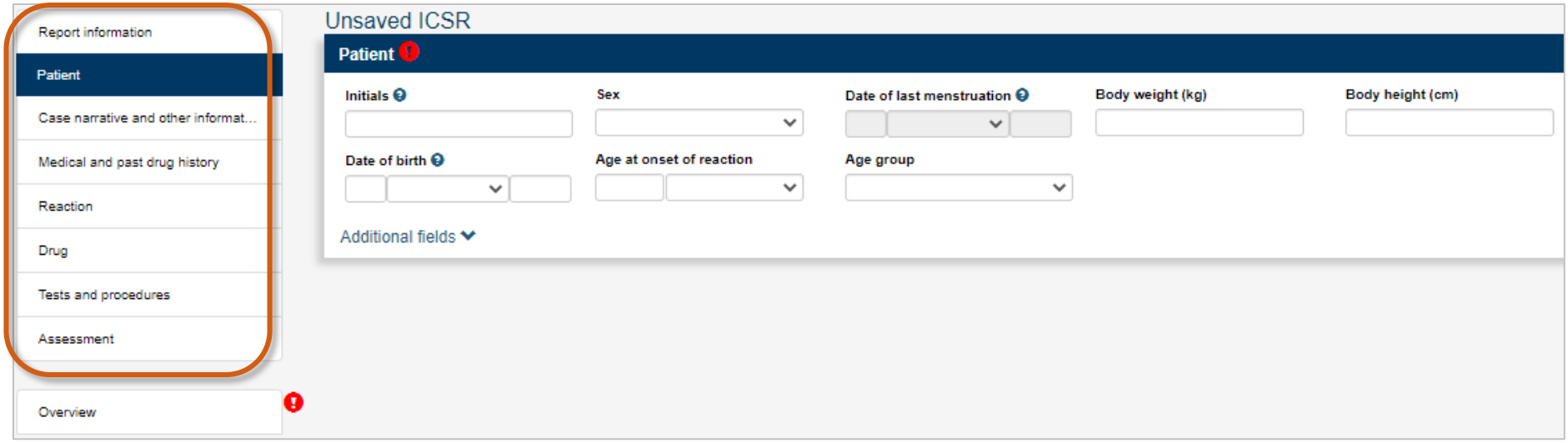
Viewing mode – (1) ICSR Sections

VigiFlow offers 2 viewing modes for data entry:

1) **ICSR sections**: displayed in the left menu

You can move between sections to enter data in the most convenient way for you.

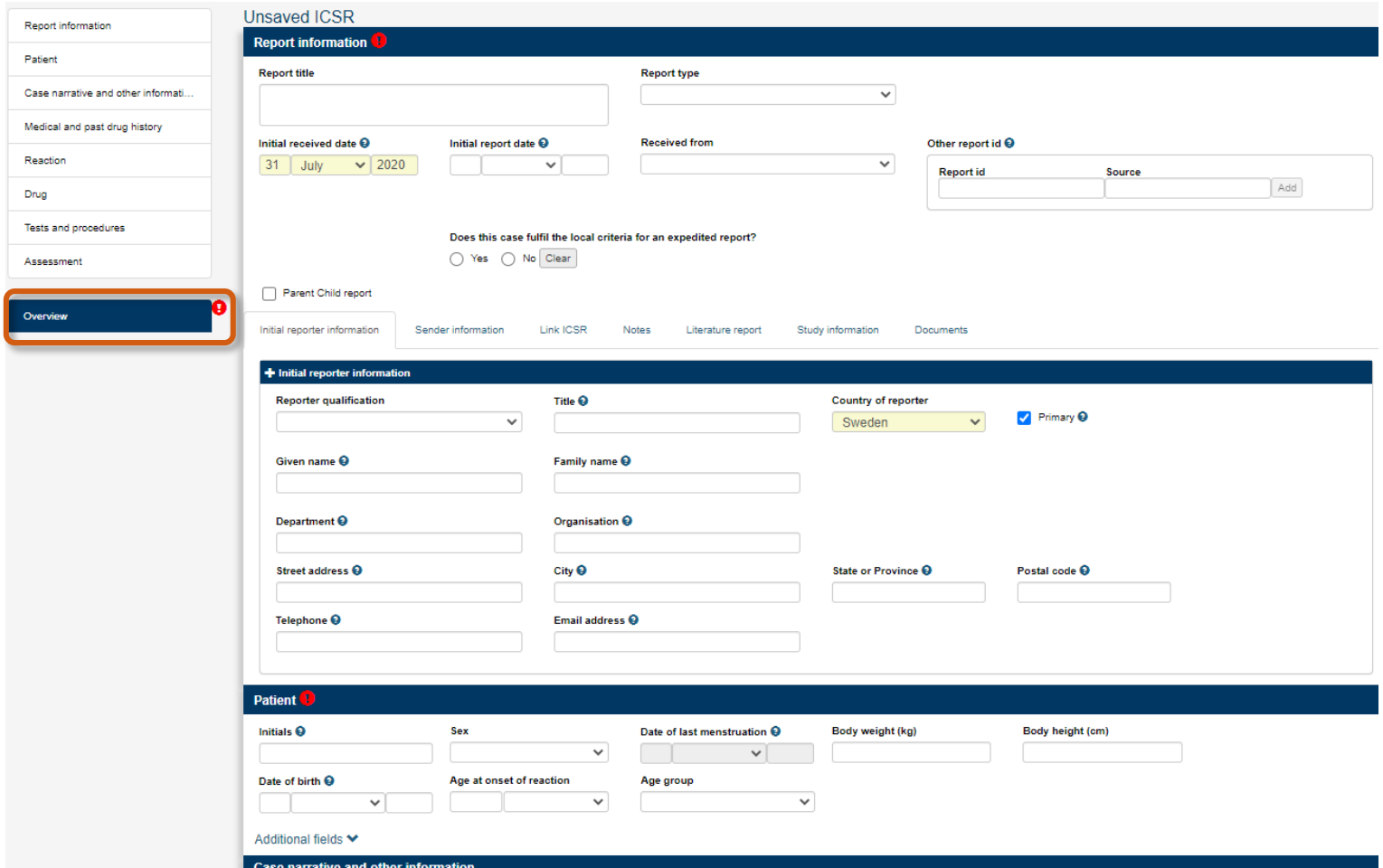
No data will be lost when moving from section to section, but it is recommended to regularly save your work.



Viewing mode – (2) Overview

VigiFlow offers 2 viewing modes for data entry:

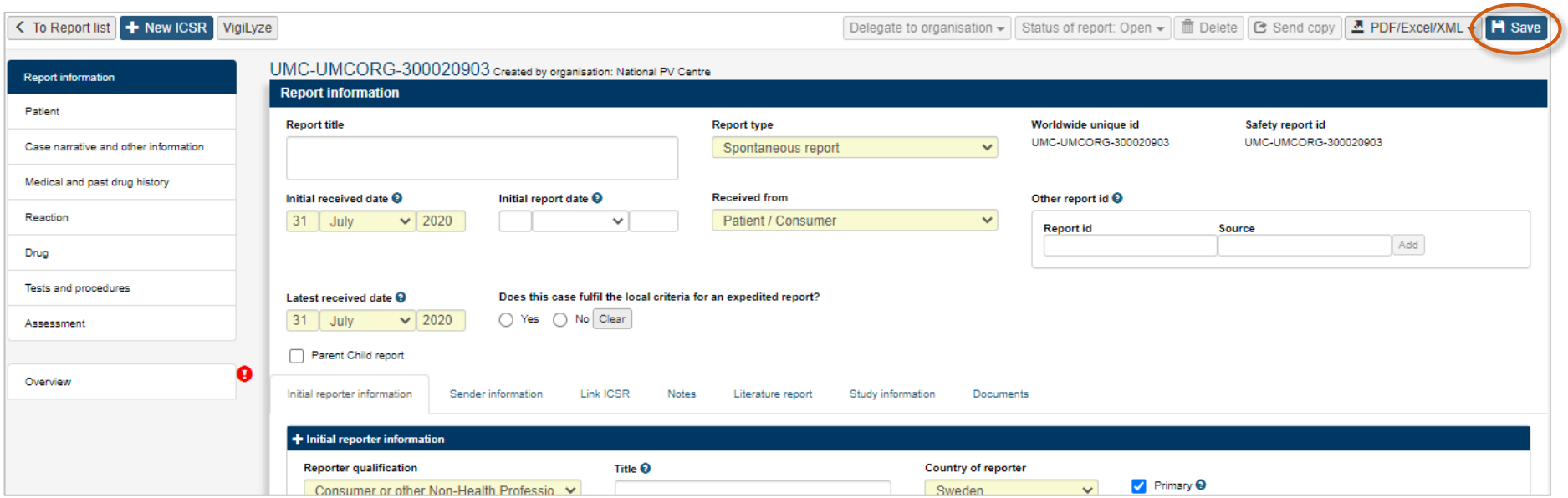
2) **Overview**: all ICSR sections are displayed in the same page



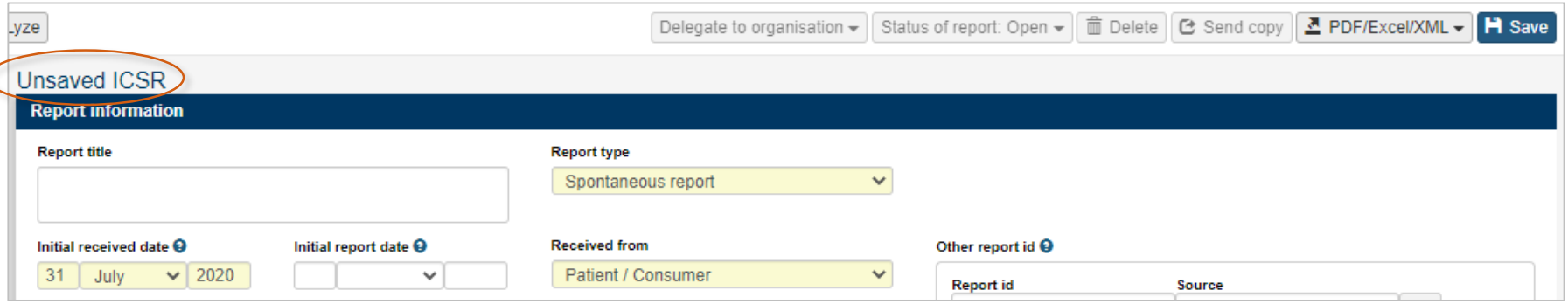
Saving the report

Click **Save** to keep the latest editing done on the ICSR.

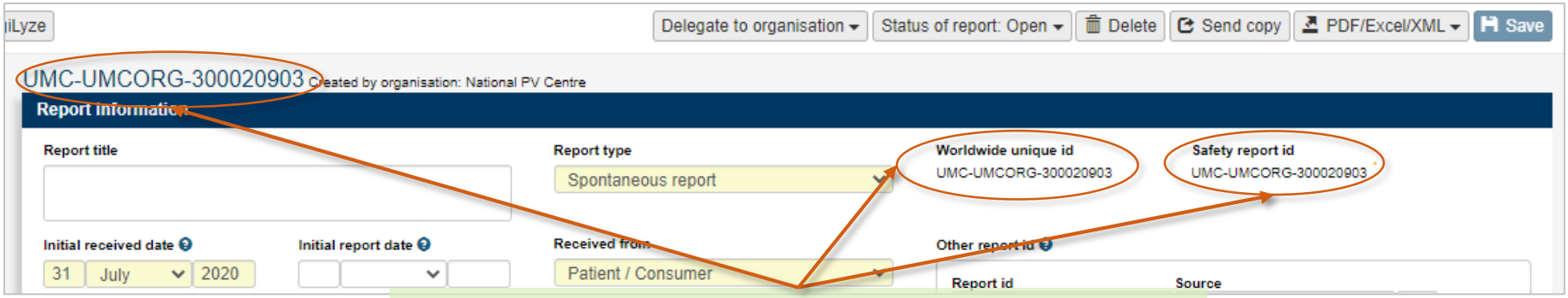
If your PV centre has unstable internet connection, it is recommended to save the report frequently to avoid losing information.



Safety Report ID creation



Once a new ICSR is saved for the first time, the **Safety report ID** will be created, otherwise it will say “Unsaved ICSR”.



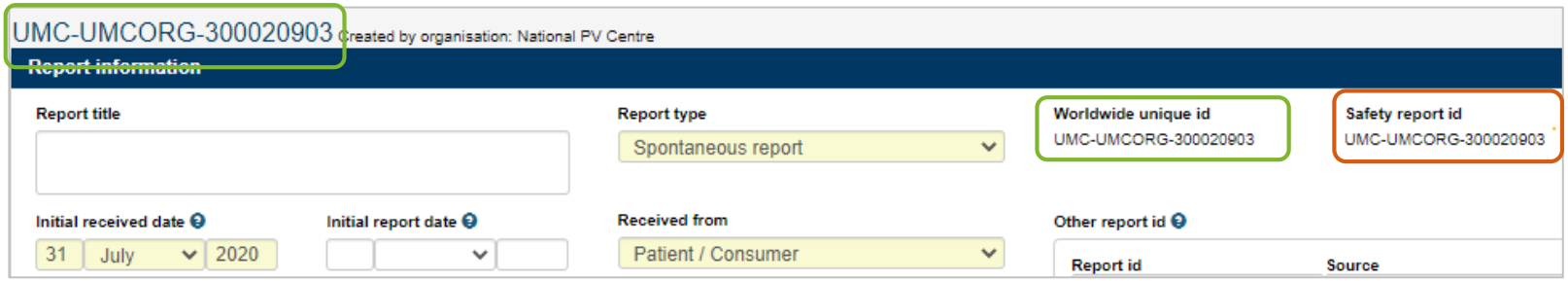
The Safety report id consists of 3 elements:
<country code>-<organization name>-<sequential number>

Worldwide unique id as report header

The **Safety report id** is generated by VigiFlow as an internal identification number for the ICSR.

If the ICSR was entered manually (**example 1**), the **safety report id** and the **worldwide unique id** are identical. However, if the ICSR was imported from an xml-file (**example 2**), it has a **worldwide unique id** that represents the name and country of the organisation that sent the xml-file.

Example 1

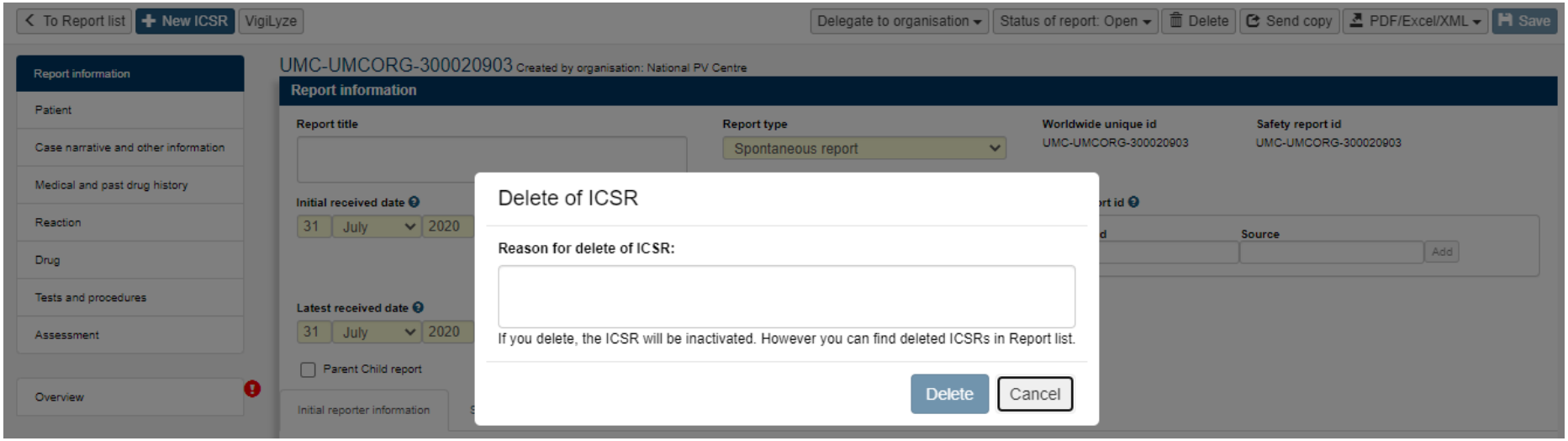


Example 2

Delete ICSR

To delete an ICSR, it is required to specify the reason why the ICSR should be disregarded.

Even when deleted, it is possible to find an ICSR through the search filters in the Report List.



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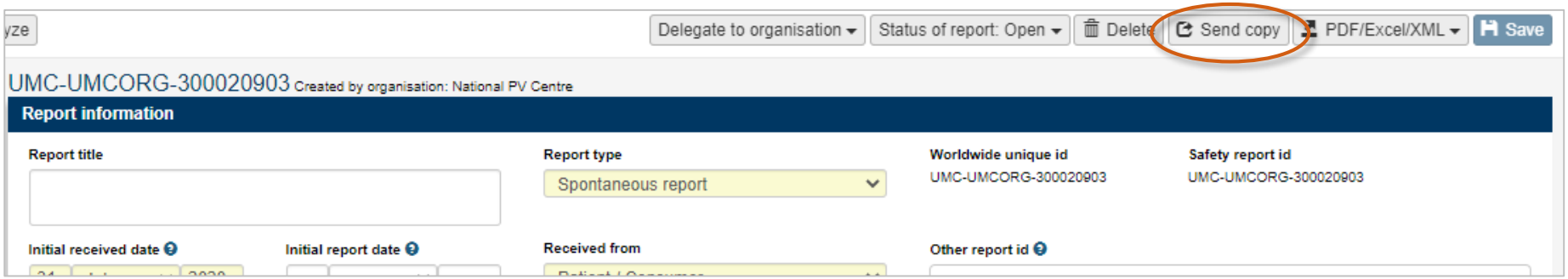
Sending a copy of the ICSR to VigiBase

This functionality is available only for the national pharmacovigilance centre.

By sending a copy of the ICSR to VigiBase, the report will be available for analysis in VigiLyze together with the ICSRs shared by the national pharmacovigilance centres from other member countries of the WHO Programme for International Drug Monitoring.

As VigiLyze is updated once a week, it might take a few days to see the report.

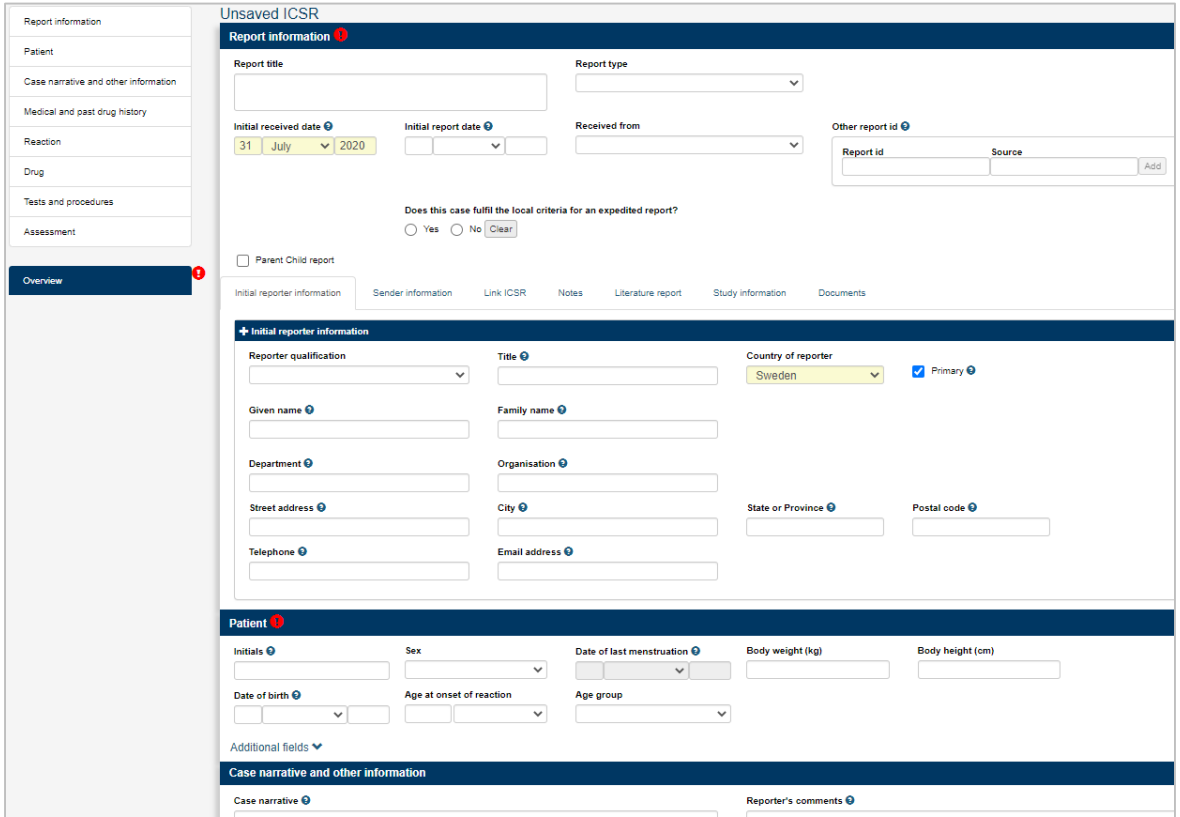
*This functionality is the equivalent to the **commit** functionality in old VigiFlow.*



Minimum information for sending a copy of an ICSR to VigiBase

ICSRs can be sent to VigiBase at any time, i.e., it is not necessary to have them assessed or complete. However, there is a minimum amount of information that an ICSR must contain to be able to send it to VigiBase.

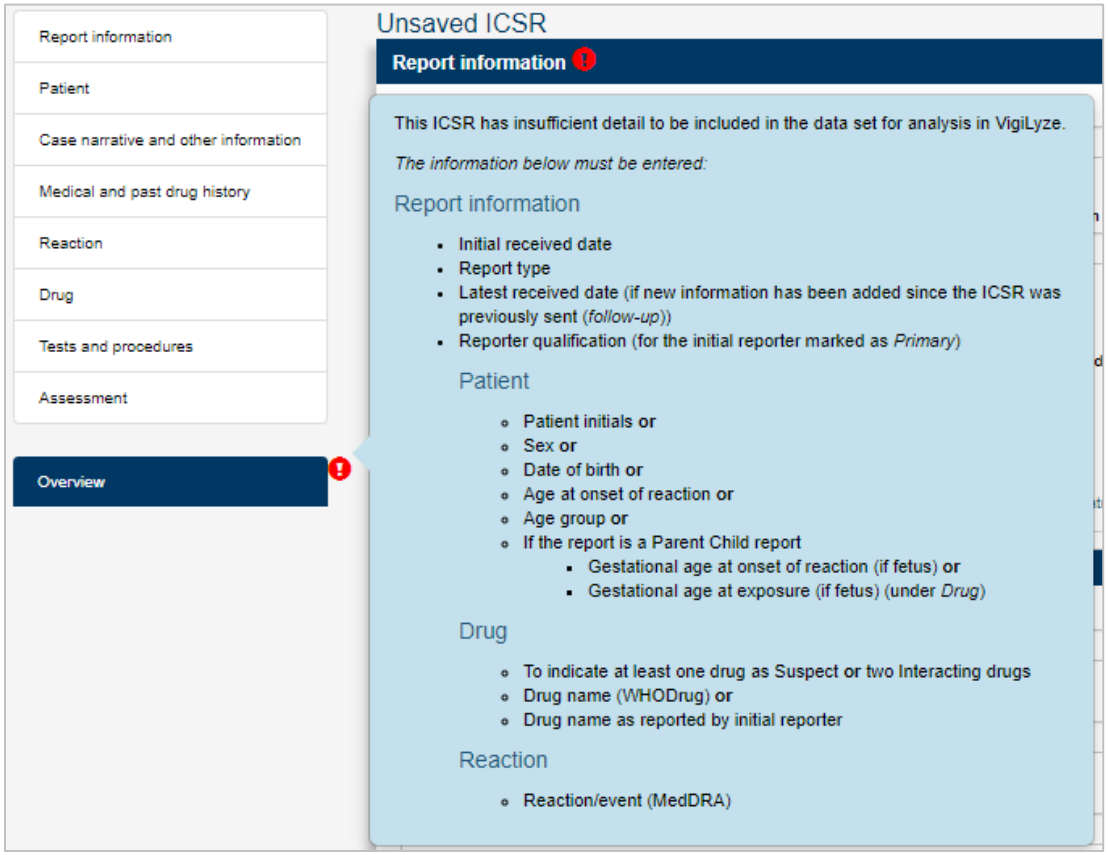
The ❗ symbol indicates that there is information missing in a specific section and the ICSR cannot be sent to VigiBase yet.



Full list of minimum information for sending a copy of the report to VigiBase

In general terms, a report must contain at least the 4 minimum criteria to be sent to VigiBase.

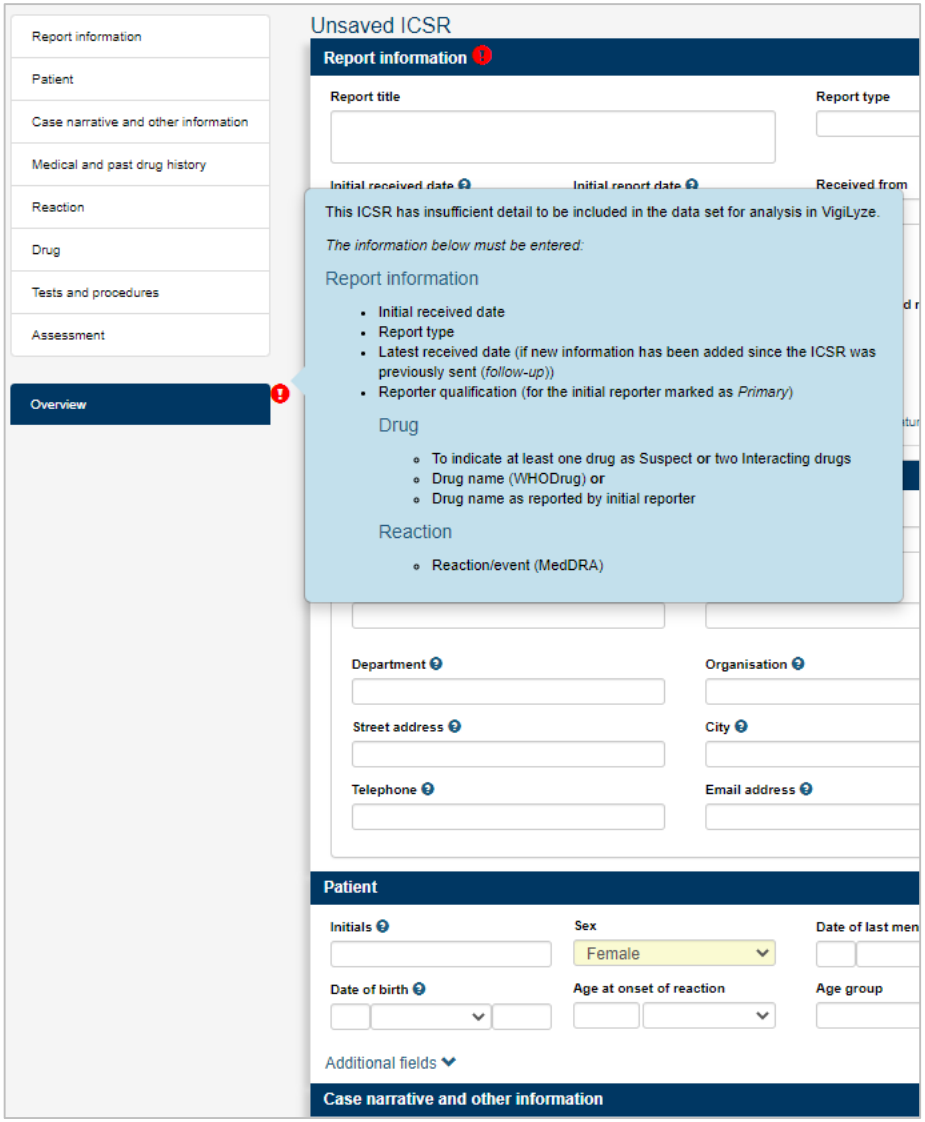
By clicking on the symbol ❗ by the **Overview** tab, it is possible to see the complete list of missing information.



List of minimum information for sending a copy of the report to VigiBase

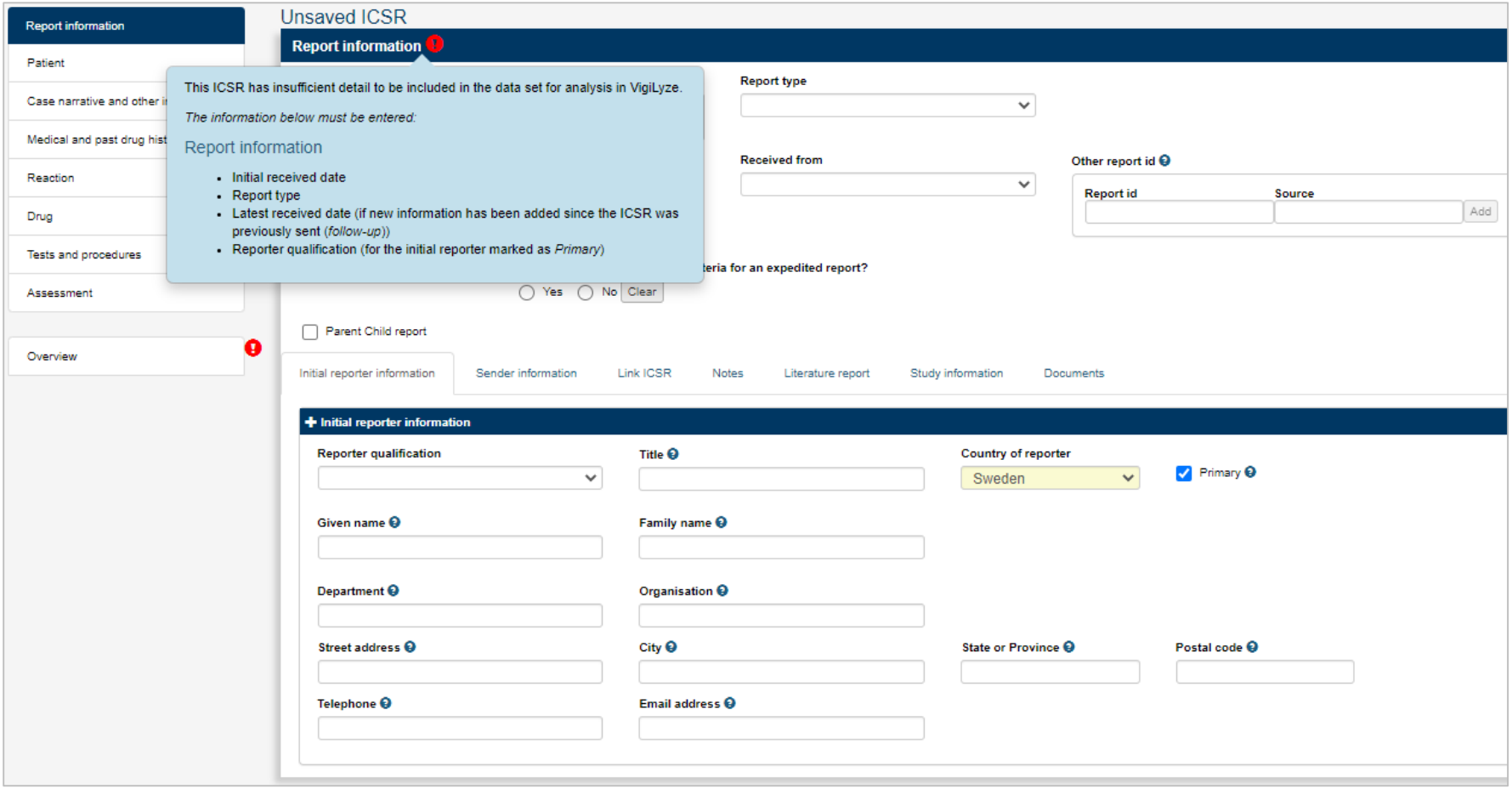
After entering some of the minimum required information, the list of missing information is updated accordingly.

At this example, the minimum information to identify the patient were entered so it does not show on the list anymore.



Missing information in a specific section

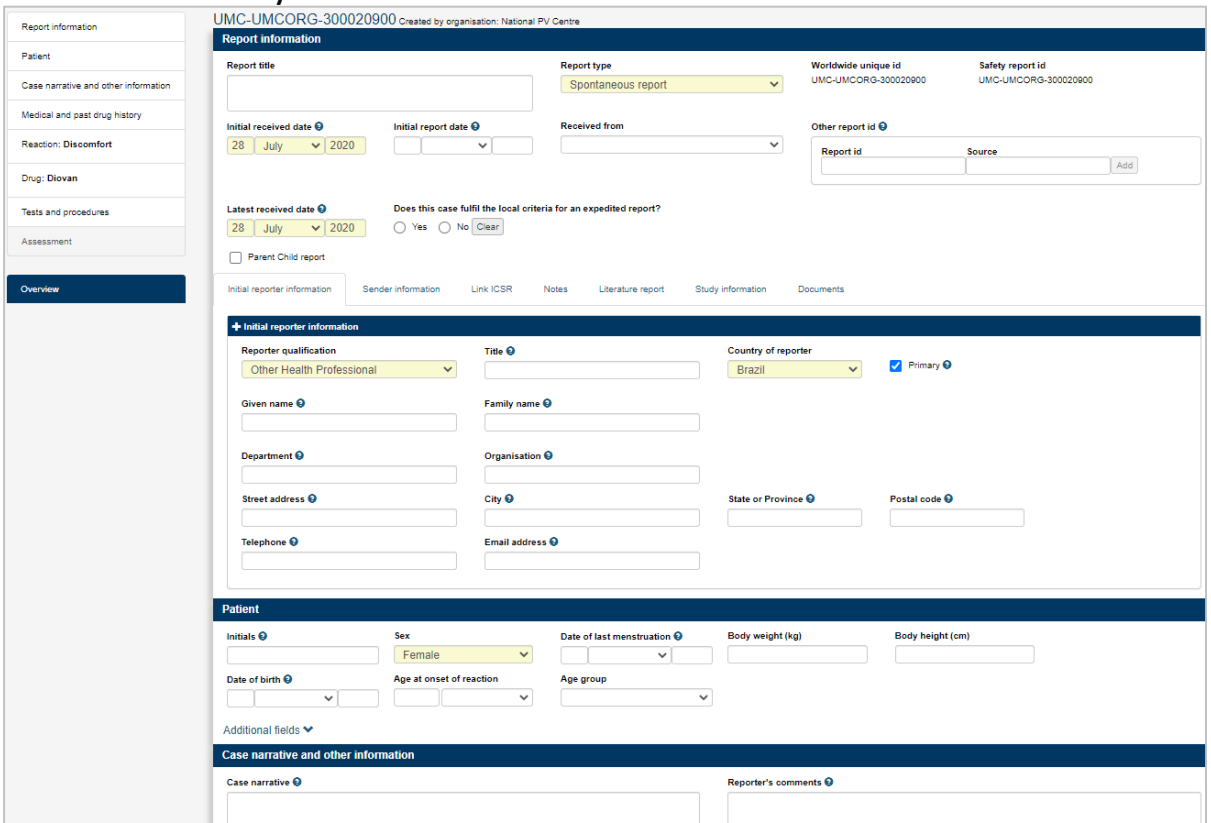
It is also possible to see the list of missing information in a specific section by clicking on the symbol ❗ by its title.



Minimum information does not mean completeness

When the icon disappears, it means that the report contains the **minimum** information required for sharing it with the WHO global ICSR database.

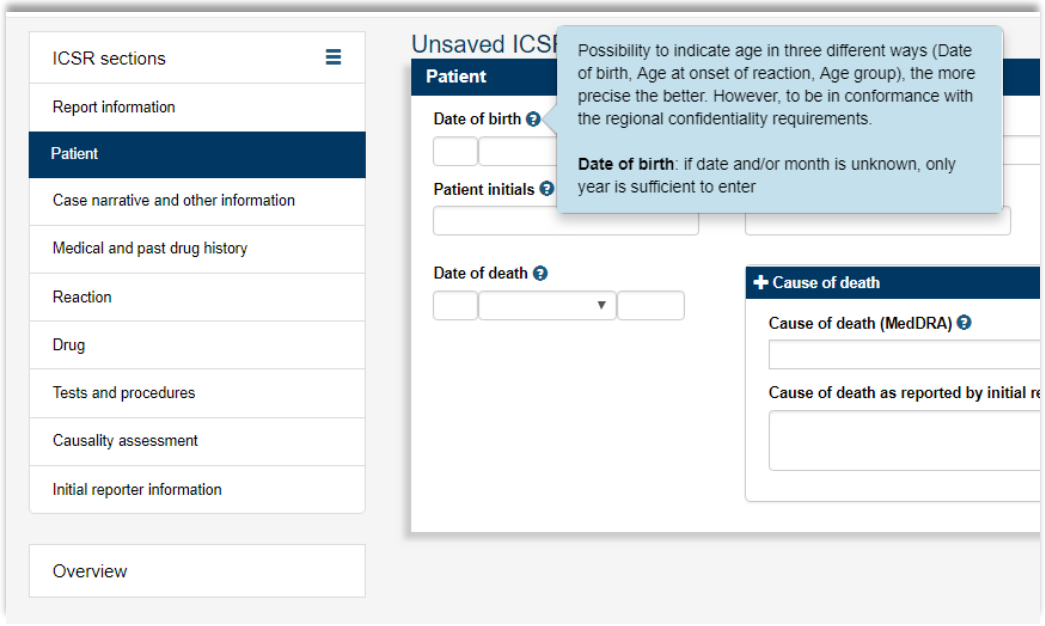
However, it might not mean that the report is complete. The UMC advises to always enter as much data as it is available in the original report. A more complete report will lead to better data analysis.



Help texts

Help texts, which can be found at the icon , support data entry by providing information such as:

- How to enter data in the field
- Which data is private and will not be shared with the WHO global ICSR database (VigiBase)



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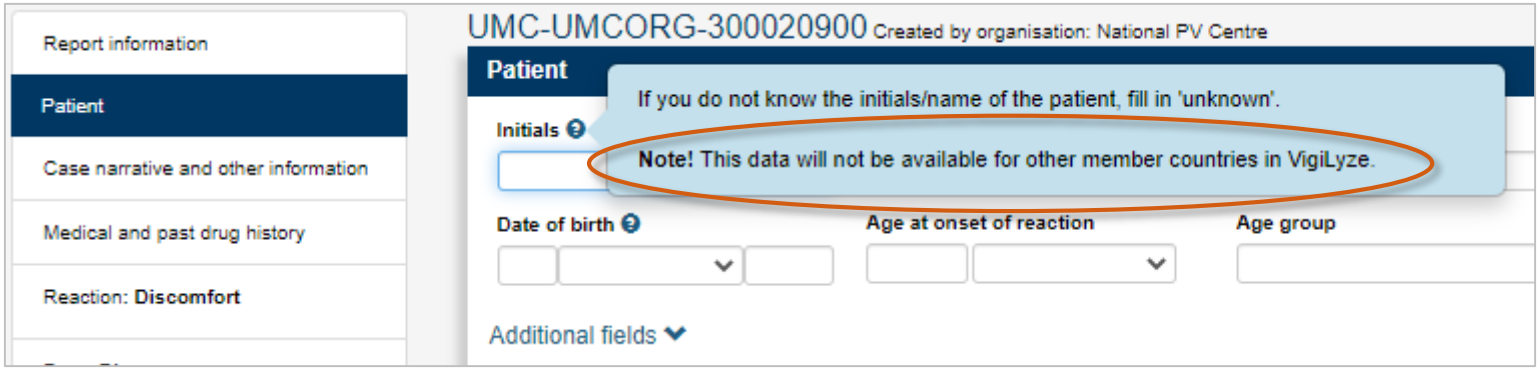
Example of Privacy Data – Patient initials



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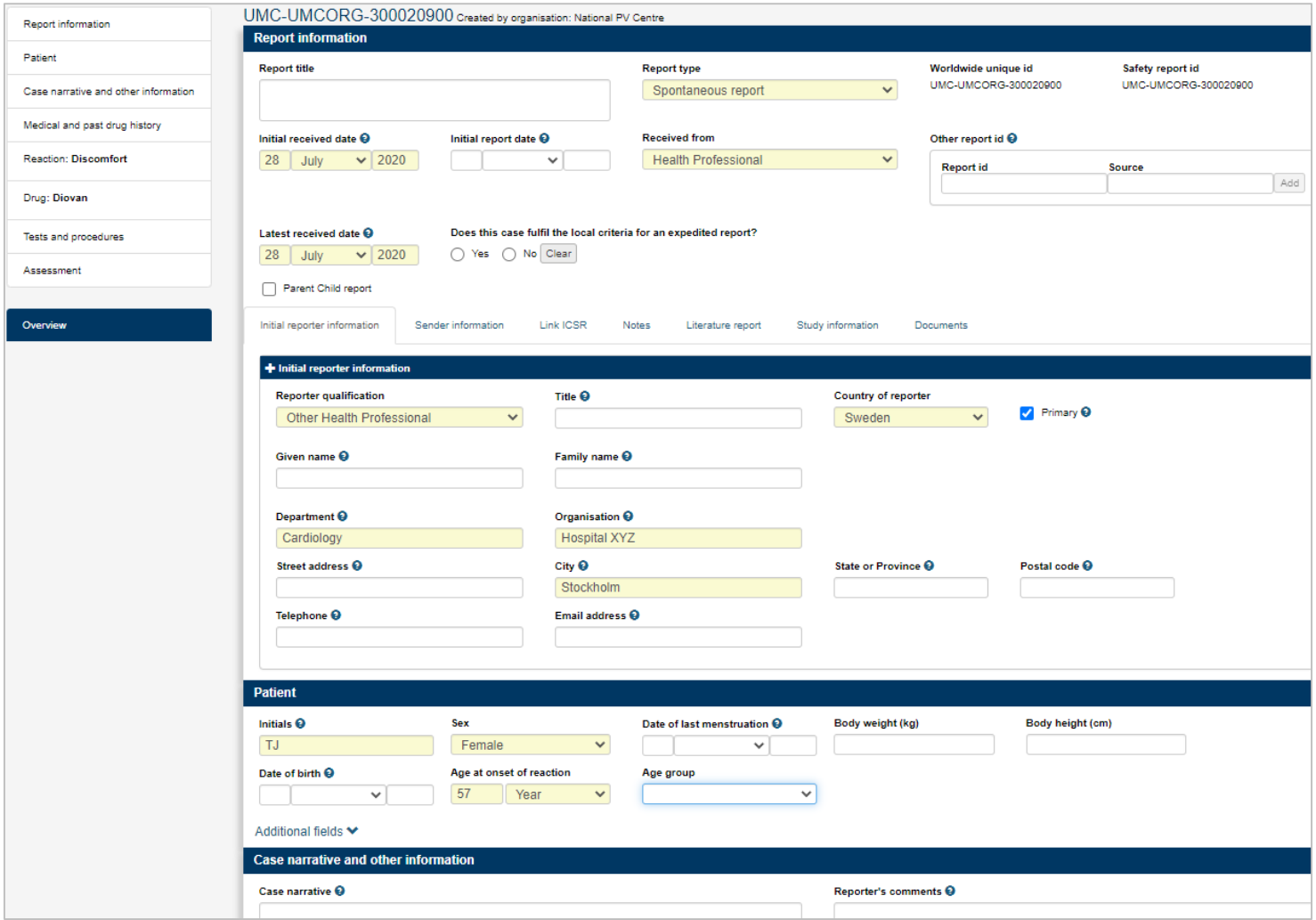
Identifying fields containing data

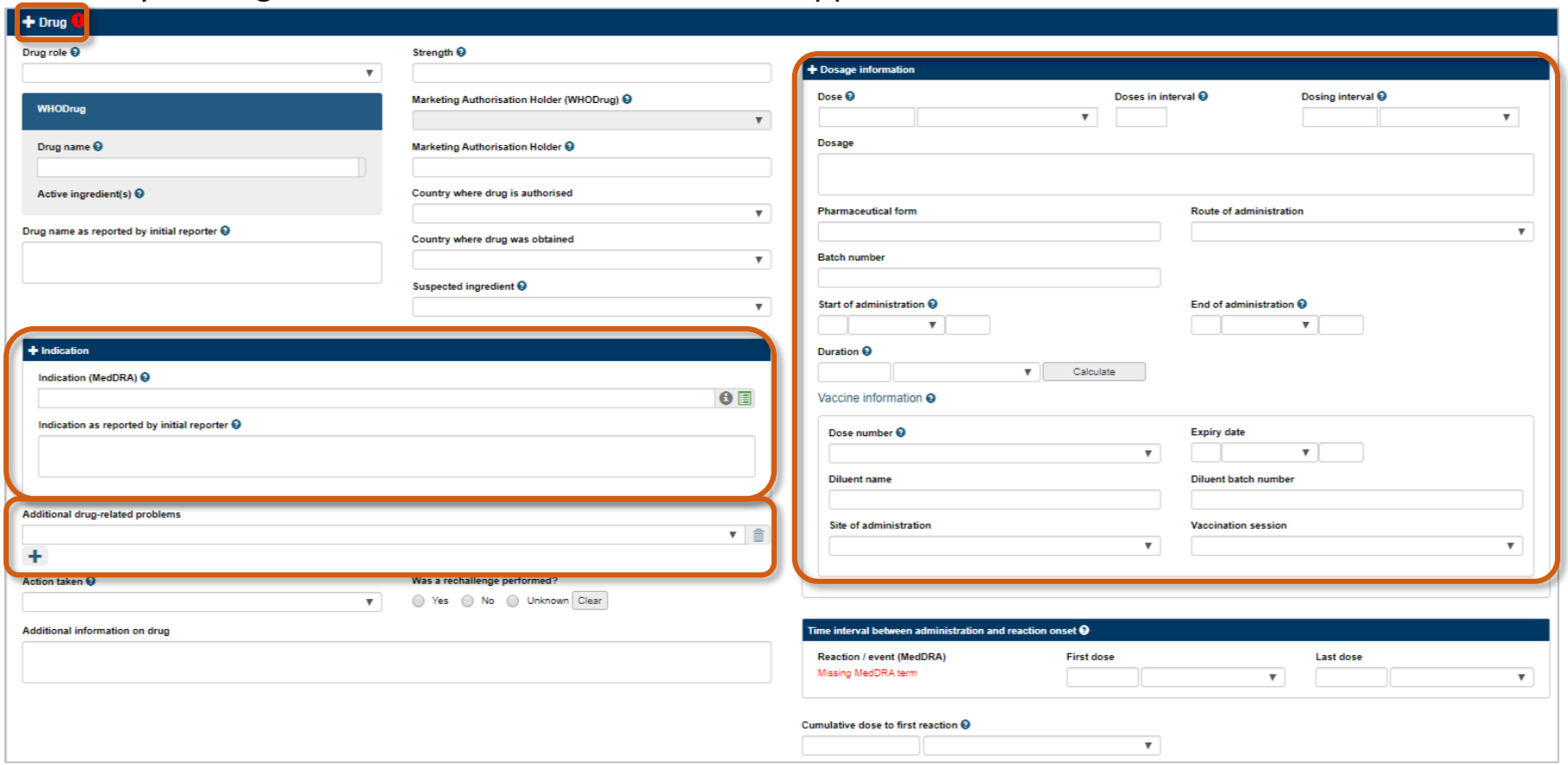
When data is entered into the fields the background turn yellow.



Repeatable sections and fields

The **+** icon indicates that the corresponding section / field can be repeated for adding other drugs, dosages, reactions, etc.

By clicking on the **+**, a new section / field will appear.

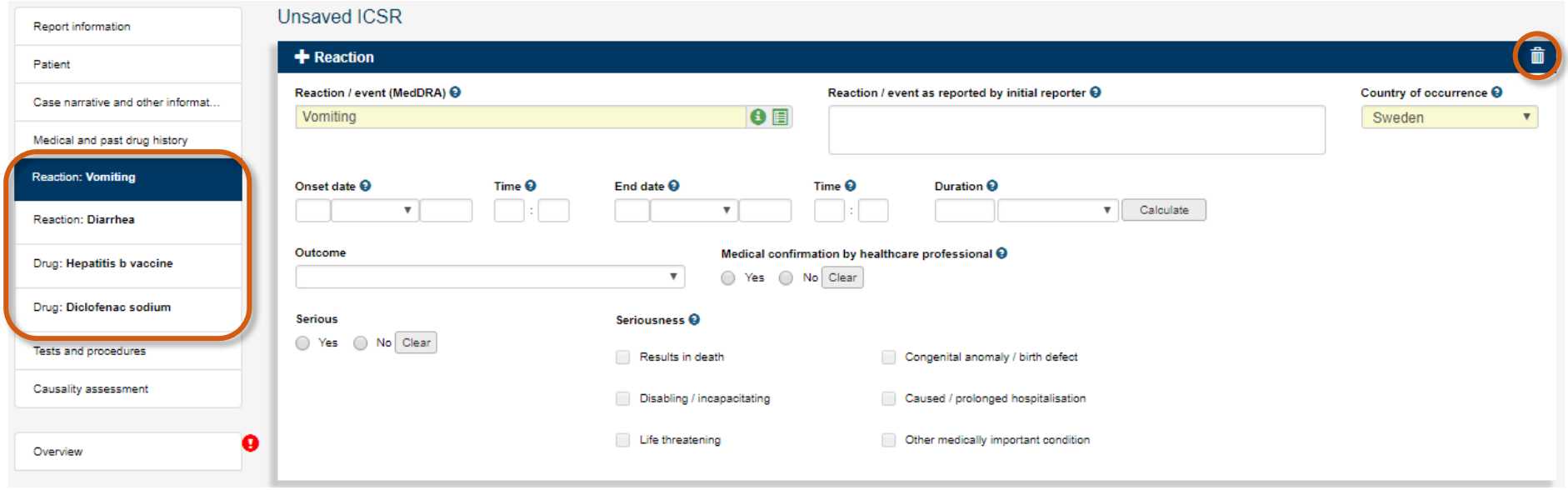


Repeatable sections in the ICSR section menu

To enter more than one reaction or more than one drug, the whole sections can be repeated.

For every repeated section, a specific tab will appear in the ICSR sections menu.

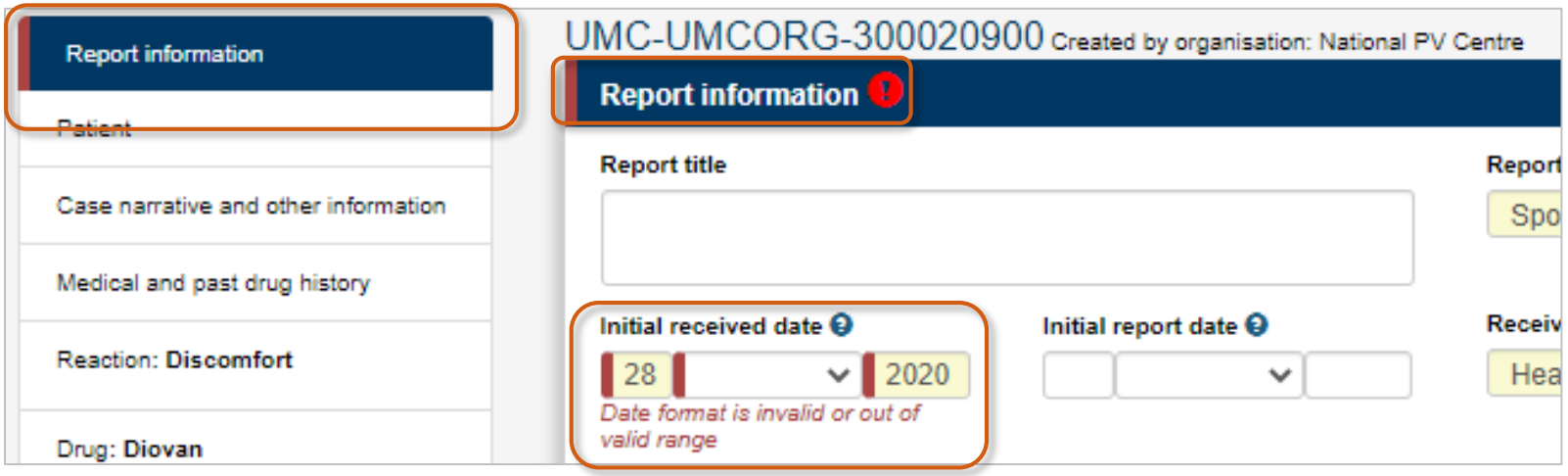
Additional sections and fields can be removed by clicking the trash icon.



Error message

A vertical red bar indicates that information was entered incorrectly in the field / section.

A message in red will provide additional information about the error.



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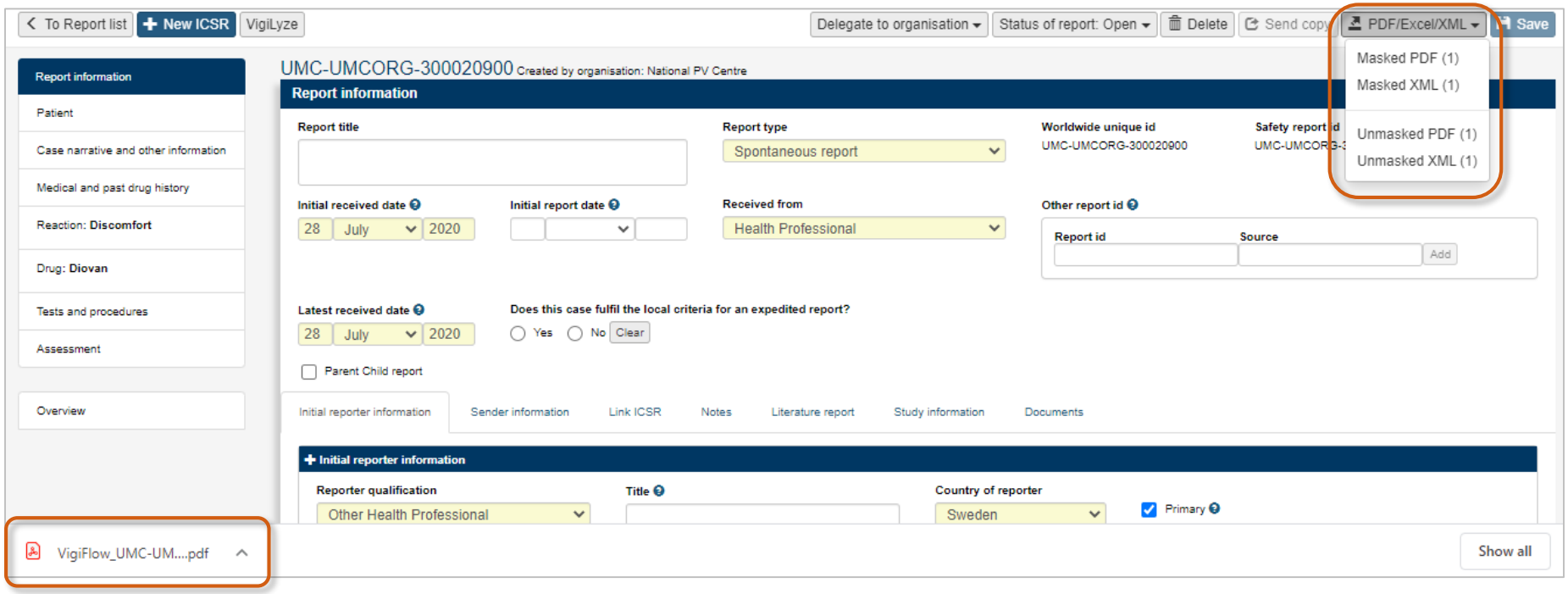
Export the ICSR

The ICSR can be exported in two different file formats (PDF or XML) depending on the purpose of the export.

The file downloaded in the selected format will show in the lower left corner of the screen.



Exporting ICSRs: masked and unmasked data

The PDF and xml files can be exported either masked or unmasked. In the masked file, personal data that can identify the patient and the initial reporter are replaced by the abbreviation MSK. In that way, it is possible to maintain the confidentiality even when the ICSR is shared with other stakeholders.

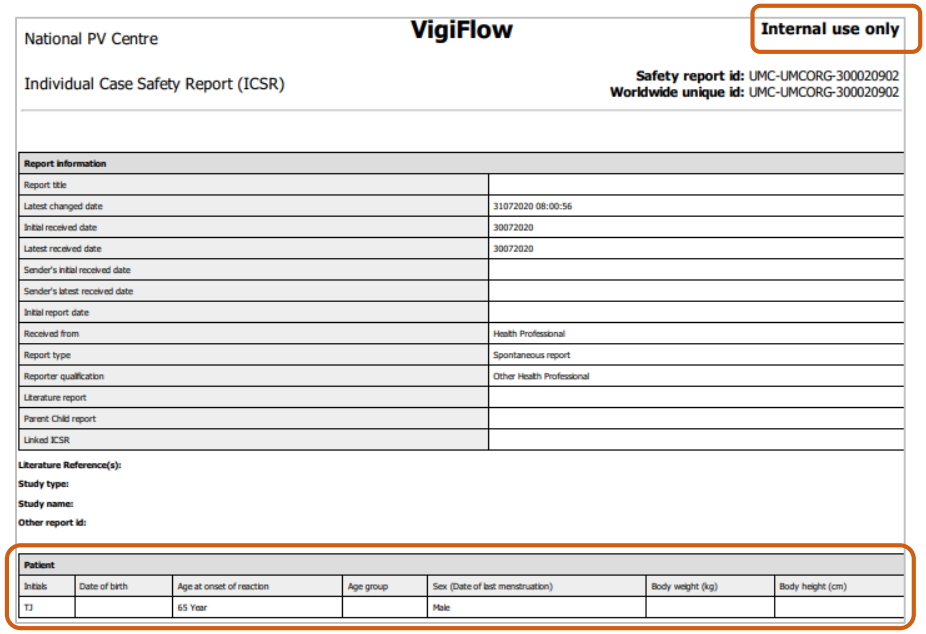
In the unmasked file, personal data is displayed and that is why this format should be used with caution.

The following fields are masked:

Patient	Initials
	Parent initials (in case of a Parent-Child report)
	Specialist record number GP medical record number Hospital record number Investigation number
Initial reporter	All data is masked, except for Reporter Qualification and Country of reporter

Examples of PDF exports

Unmasked PDF



National PV Centre

VigiFlow

Internal use only

Individual Case Safety Report (ICSR)

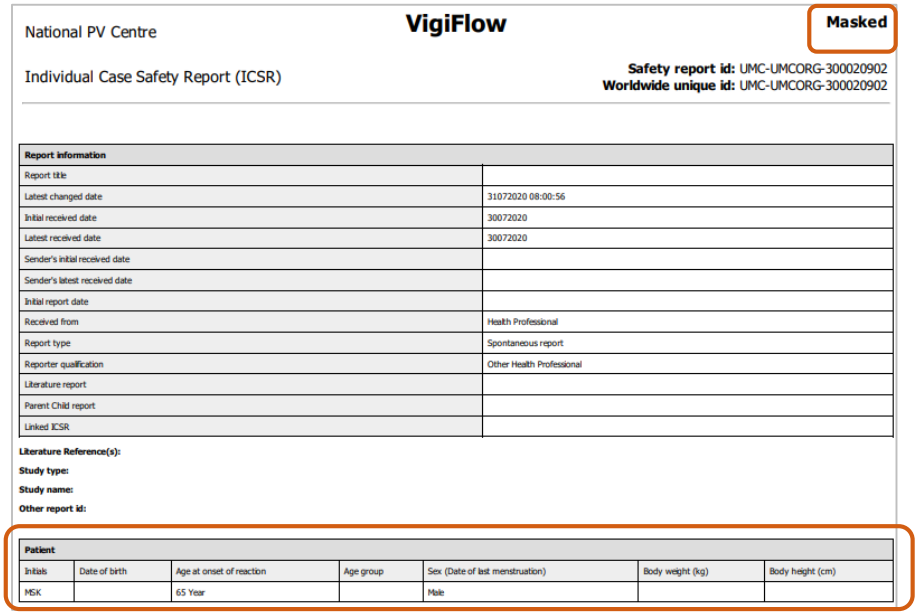
Safety report id: UMC-UMCORG-300020902
Worldwide unique id: UMC-UMCORG-300020902

Report information	
Report title	
Latest changed date	31072020 08:00:56
Initial received date	30072020
Latest received date	30072020
Sender's initial received date	
Sender's latest received date	
Initial report date	
Received from	Health Professional
Report type	Spontaneous report
Reporter qualification	Other Health Professional
Literature report	
Parent Child report	
Linked ICSR	

Literature Reference(s):
Study type:
Study name:
Other report id:

Patient						
Initials	Date of birth	Age at onset of reaction	Age group	Sex (Date of last menstruation)	Body weight (kg)	Body height (cm)
TJ		65 Year		Male		

Masked PDF



National PV Centre

VigiFlow

Masked

Individual Case Safety Report (ICSR)

Safety report id: UMC-UMCORG-300020902
Worldwide unique id: UMC-UMCORG-300020902

Report information	
Report title	
Latest changed date	31072020 08:00:56
Initial received date	30072020
Latest received date	30072020
Sender's initial received date	
Sender's latest received date	
Initial report date	
Received from	Health Professional
Report type	Spontaneous report
Reporter qualification	Other Health Professional
Literature report	
Parent Child report	
Linked ICSR	

Literature Reference(s):
Study type:
Study name:
Other report id:

Patient						
Initials	Date of birth	Age at onset of reaction	Age group	Sex (Date of last menstruation)	Body weight (kg)	Body height (cm)
MSK		65 Year		Male		

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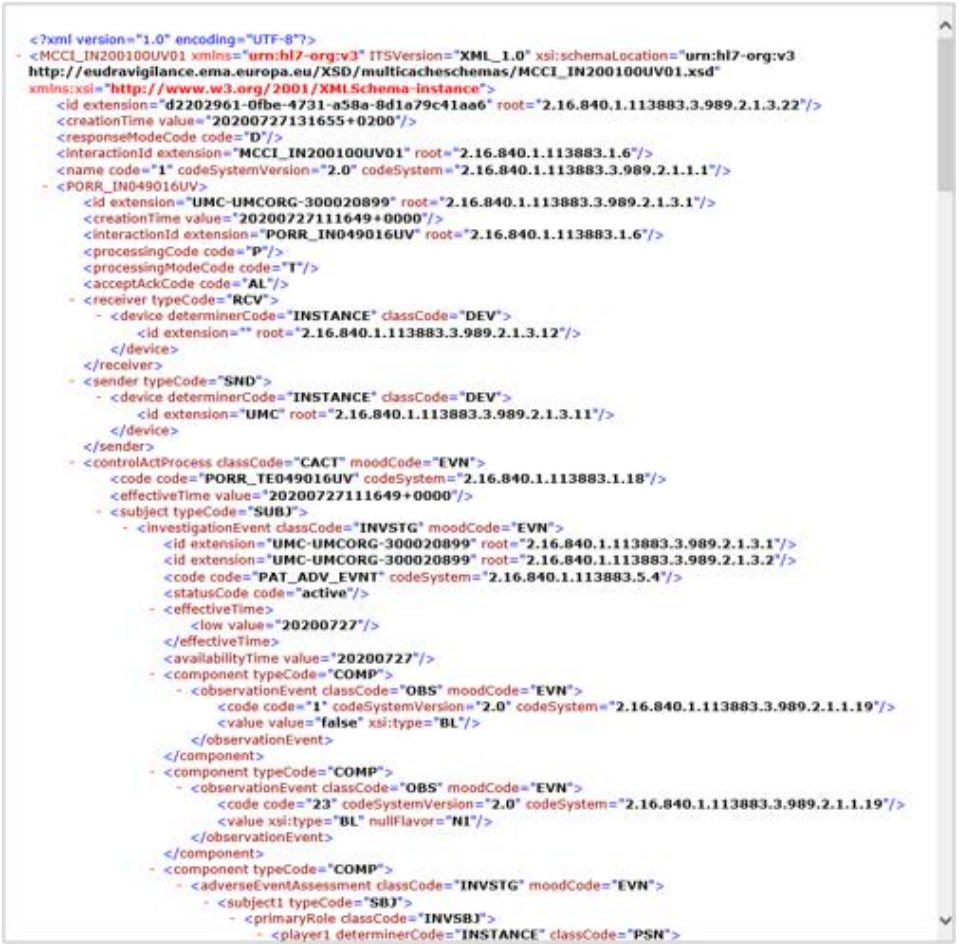
Export to xml

The ICSR in xml format is exported from VigiFlow according to the international standard ICH E2B (R3).

This export format is relevant when it is necessary to share the ICSR with another organisation that has a database compatible with the ICH E2B(R3) standard.



Report Information

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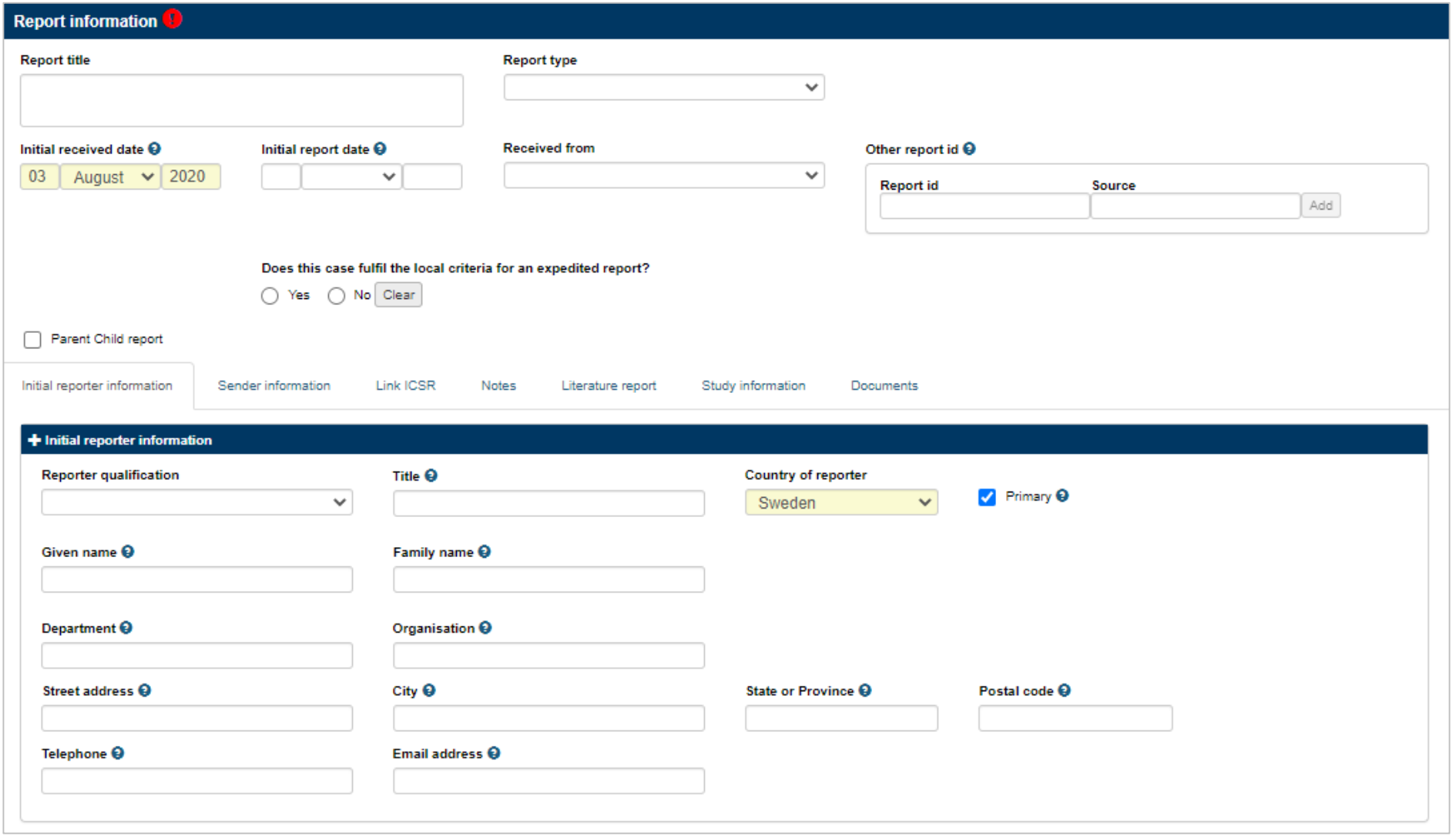
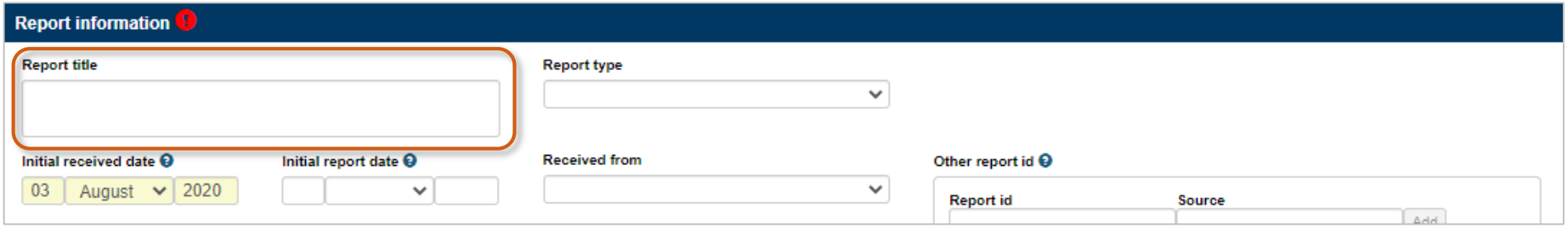
Fields available in Report Information section



Report title

The **Report title** is a free-text field that can be used to label the report according to the standard operating procedures of your organisation



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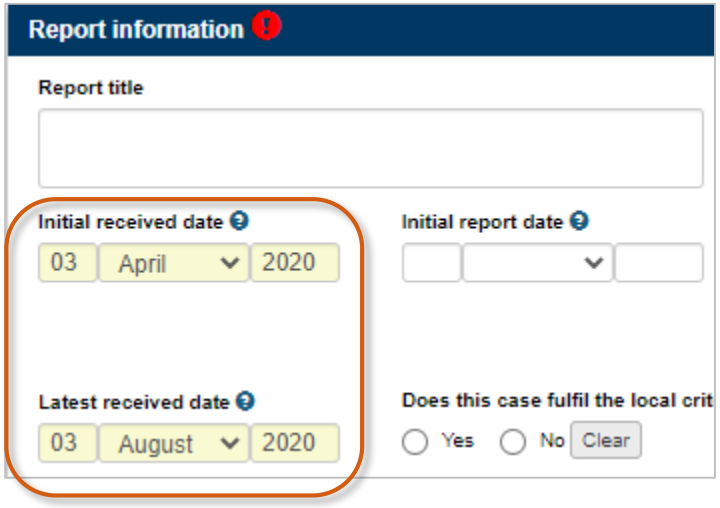
Initial and Latest Received Dates

The initial and latest received dates represent respectively the date when the ICSRs was first received at your organization and the date when your organization received updated information about the ICSR (for example, follow-up information).

For new ICSRs entered manually, the initial received date will be pre-populated with the current date. **Remember to change it if the ICSRs was received at your organization another day.**

The Latest Received Date field will be shown after the ICSR is saved for the first time.



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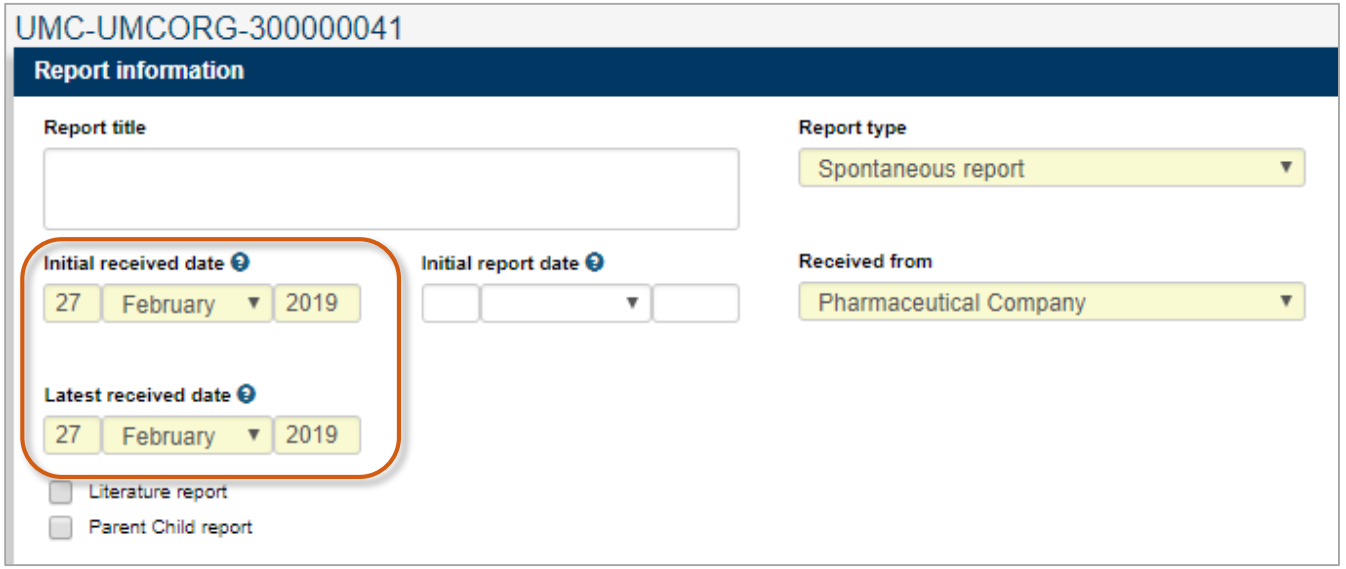
Latest Received Date

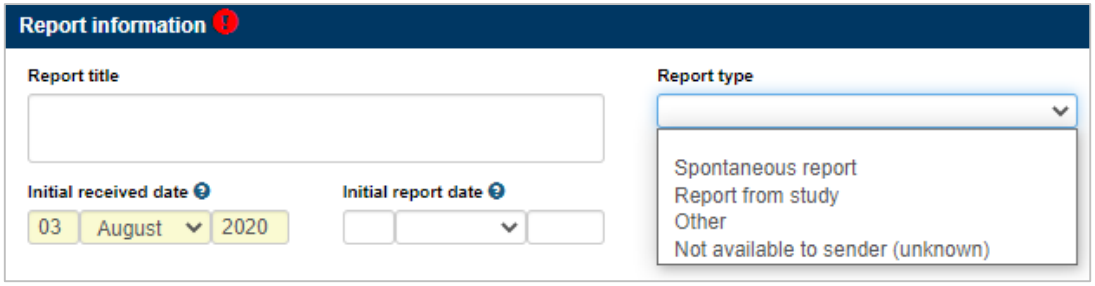
After the ICSR is saved for the first time, the Latest Received Date field is displayed and it will be populated with the same day as in the Initial Received Date.

The Latest Received Date should be changed whenever your organization receives updated information about the report.

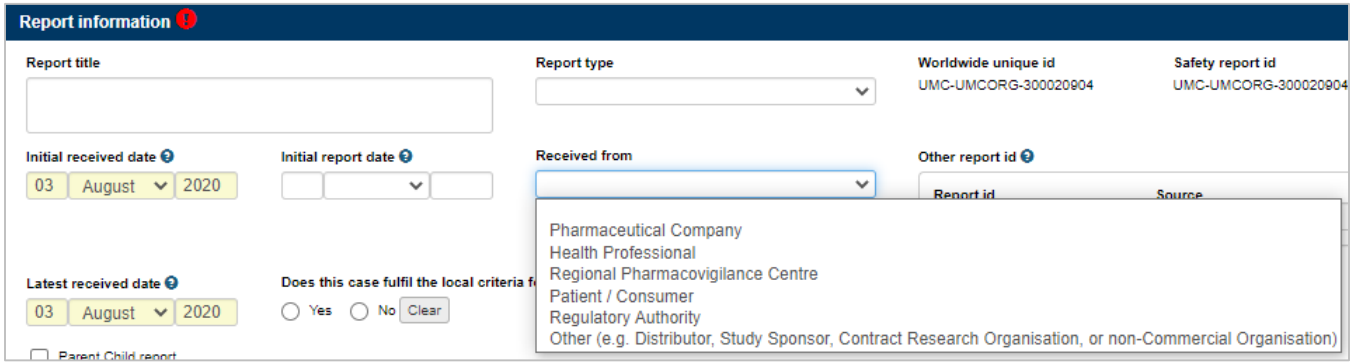


Report type and Received from

The Report type indicates if the ICSR was reported spontaneously (by patients, healthcare professionals, etc), collected in the context of a clinical study or if it was reported in another manner.



The Received from field should be used to indicate the type of sender that sent the report to your organisation. Additional information on the Sender information slide.

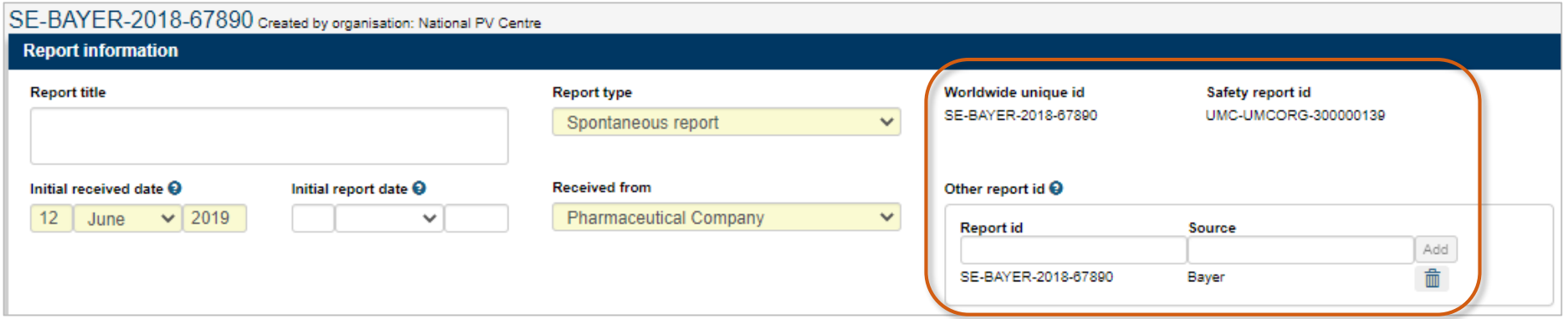


Other report id

As mentioned before, the **safety report id** will be created in VigiFlow after the ICSR is saved for the first time.

If the report has an id number from another **Source** (e.g. from a pharmaceutical company), it can be captured in the **Other report id** field.

All identification numbers are shown in the Report Information section.



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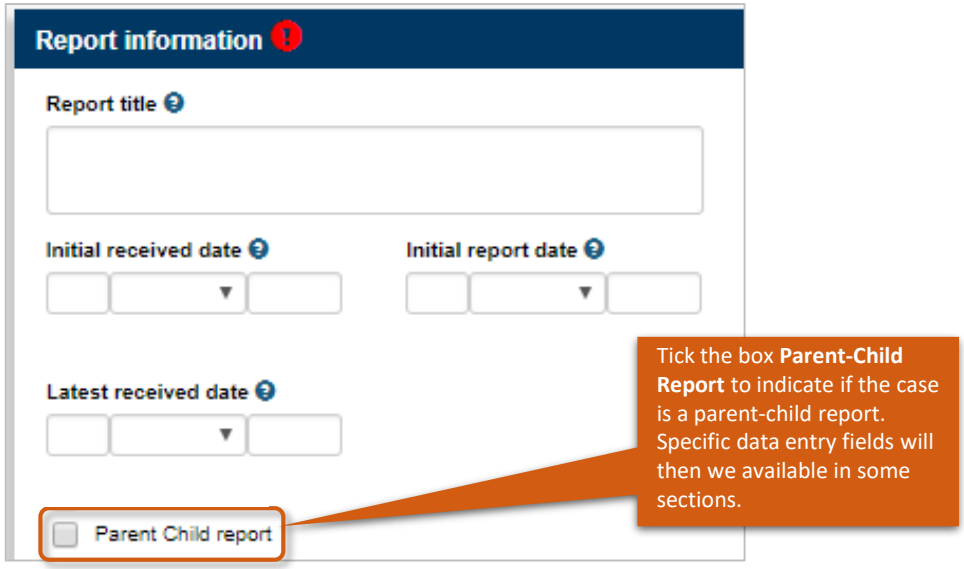
Parent-child report

Definition: Fetus or breast-feeding infant that is exposed to one/several drugs through the parent AND experienced one/several adverse reactions.



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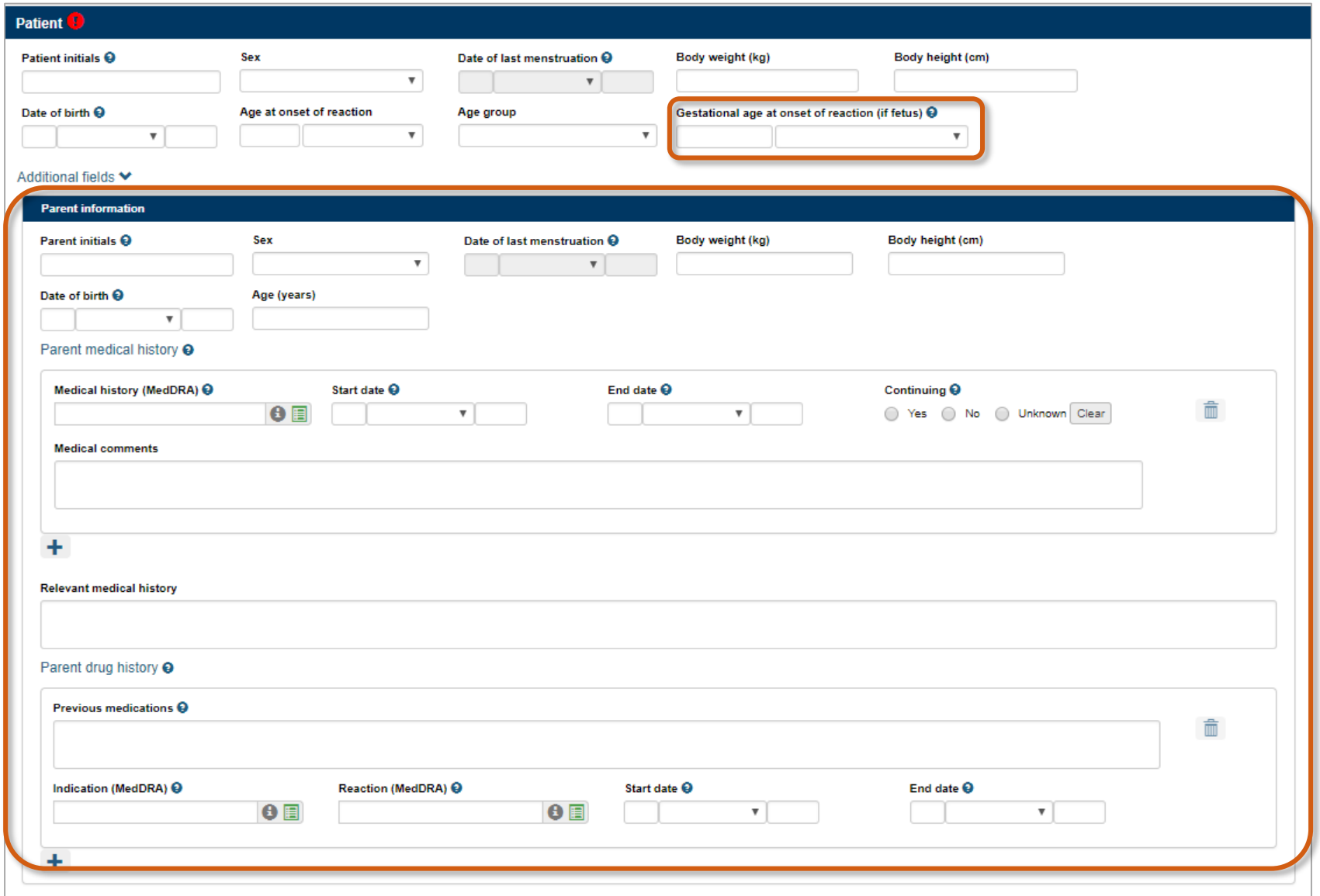
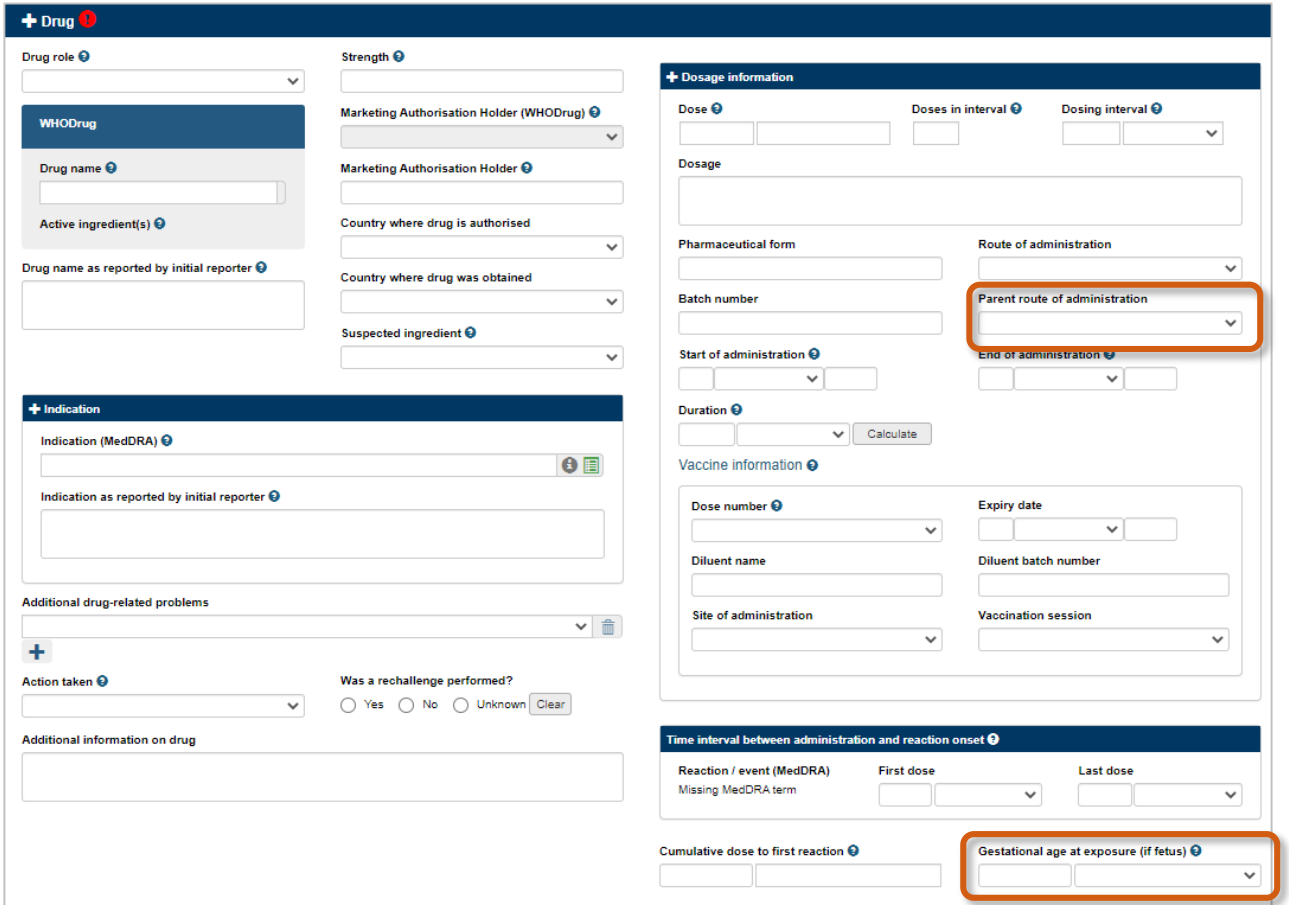
Parent-Child fields in the PATIENT section



Parent-Child fields in the DRUG section

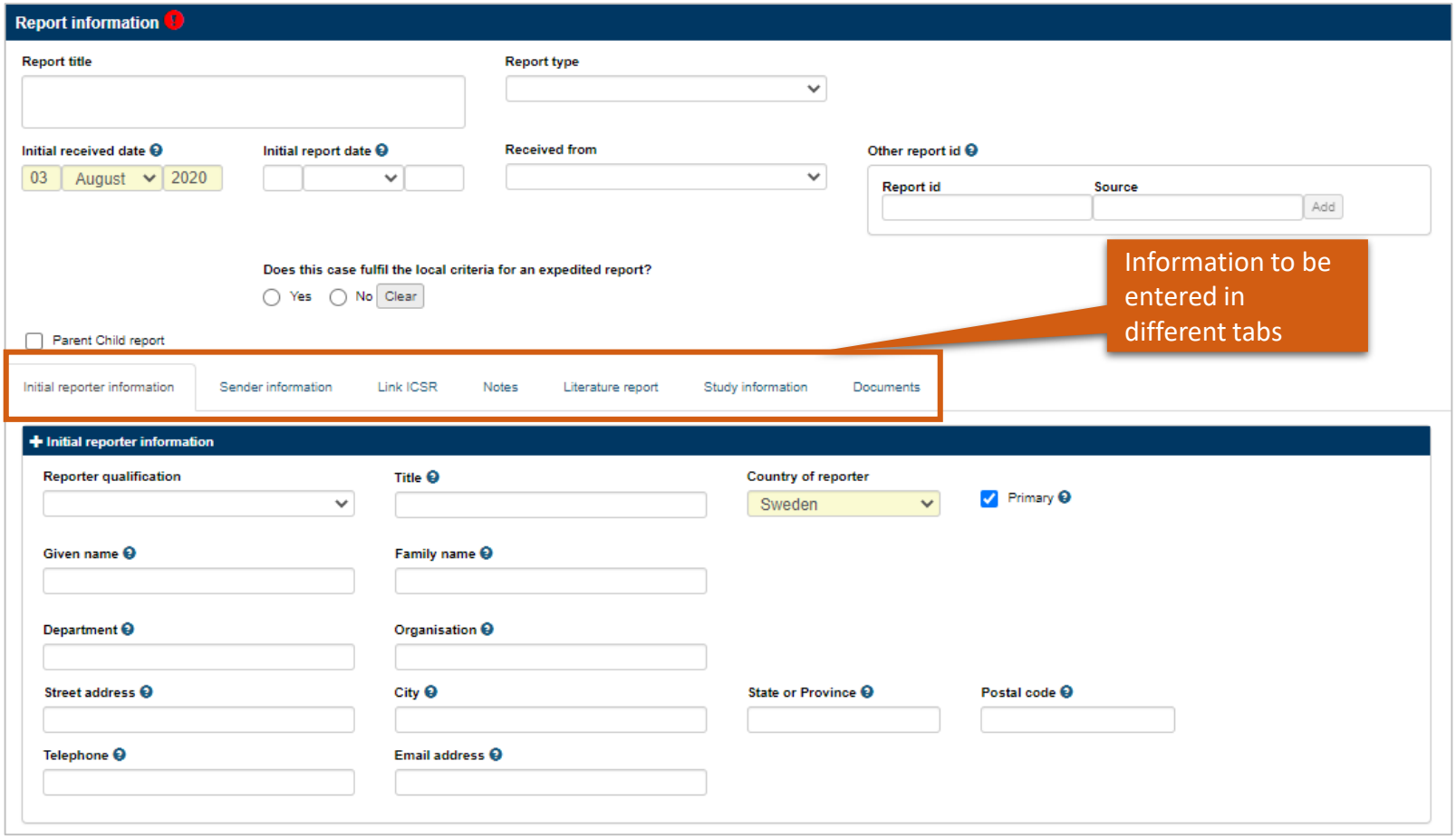
In the **Drug** section, 2 new fields appear when we select Parent-Child report:

- *Gestation age at exposure*
- *Parent route of administration*



Tabs available in Report Information section

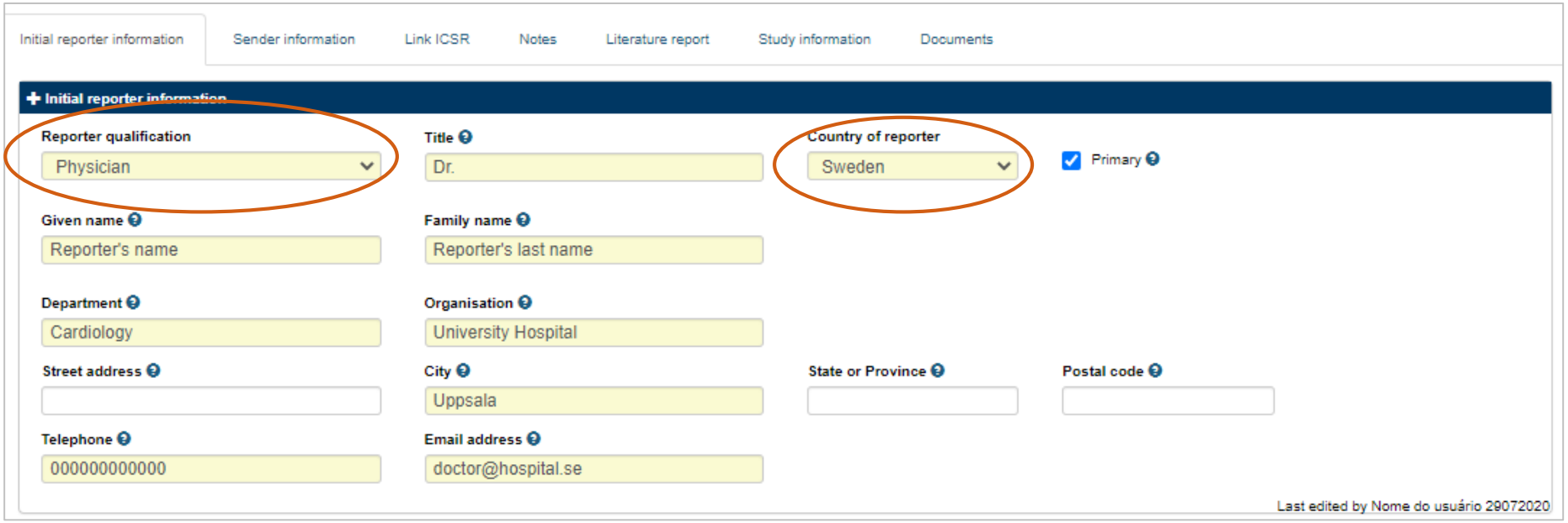
Report information section includes the following tabs:
Initial reporter information, Sender information, Link ICSR, Notes, Literature report, Study information and Documents.



Initial reporter information tab

The reporter is the person who initially reports the facts provided in the case.

Enter the information available about the reporter. For confidentiality reasons, only the **Reporter Qualification** and **Country of reporter** (highlighted below) will be shared with the WHO global ICSR database; the remaining information will be kept in VigiFlow only and they can be useful when you need to contact to reporter to obtain additional information about the case.



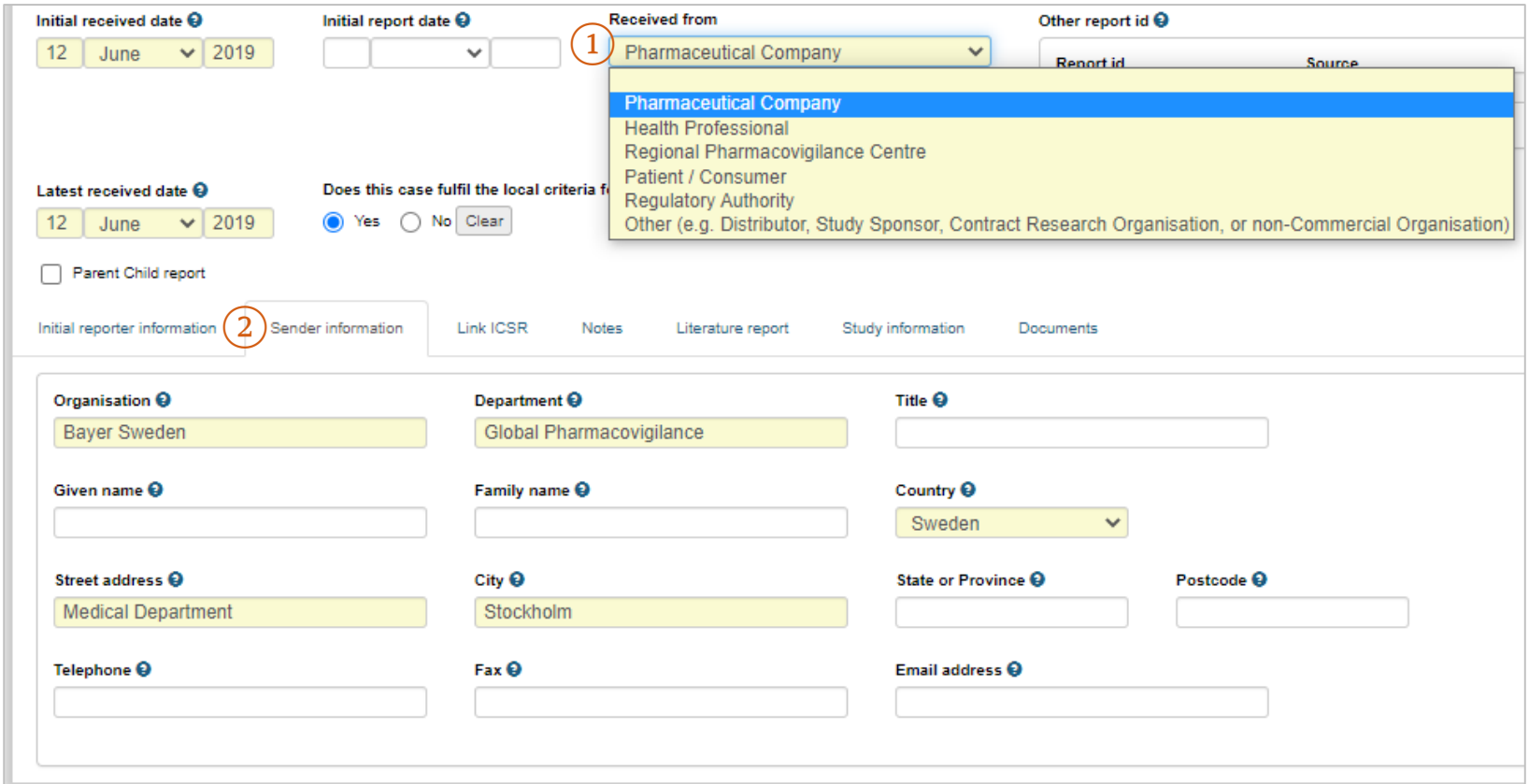
Sender information tab

Sender is the person or entity that sends the report to the pharmacovigilance centre. Very often the reporter and the sender are the same but in some cases it is necessary to distinguish between the two, eg. if a report is received from a MAH (on a CIOMS form etc) initially reported by a physician – then the sender is the MAH and the reporter is the physician.

Information about the sender is entered in;

1. The field **Received from** which will indicate the type of sender.

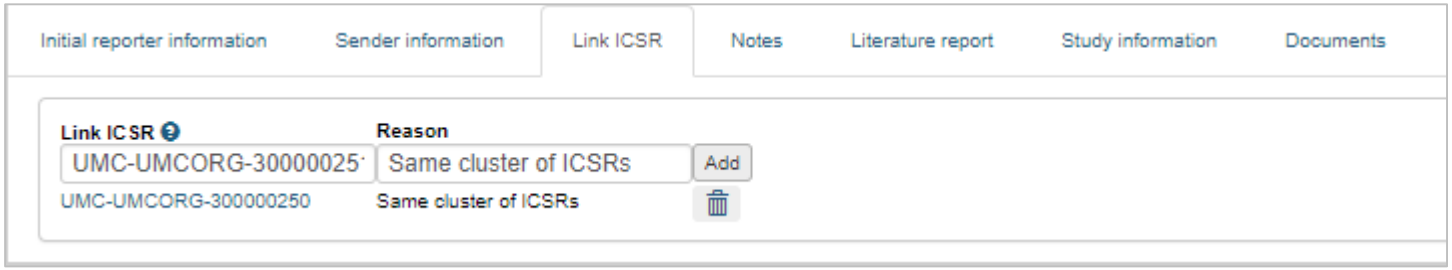
2. The **Sender information tab** where details about the sender can be entered. The sender **Country** of reporter is autopoulated.



Link ICSR tab

This tab can be used to capture the identifier of another report that should be evaluated together with this ICSR as well as the reason why the ICSRs are related. This includes, but is not limited to:

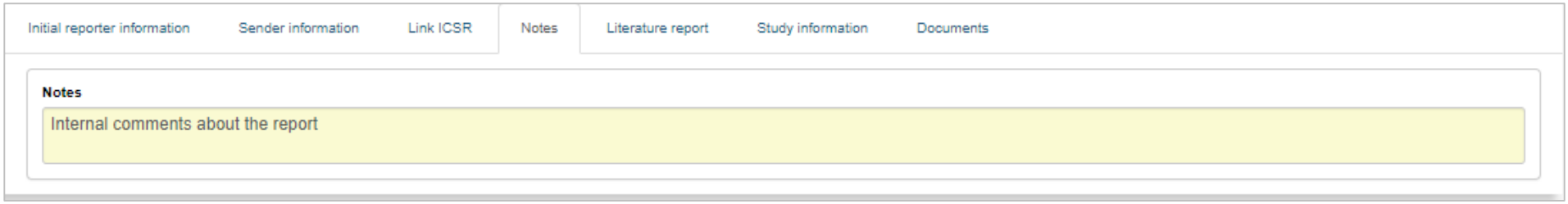
- *a parent-child pair of reports where both had events/reactions*
- *siblings with common exposure*
- *several reports involving the same patient*
- *an ICSR previously sent via paper without a conformant E2B Worldwide Unique Case Identification Number*
- *several similar reports from same reporter (cluster).*



Notes tab

The **Notes** tab is a free-text field to include internal comments about the report.

The information available in the Notes will not be transferred neither to VigiBase nor to the Excel and PDF exports.



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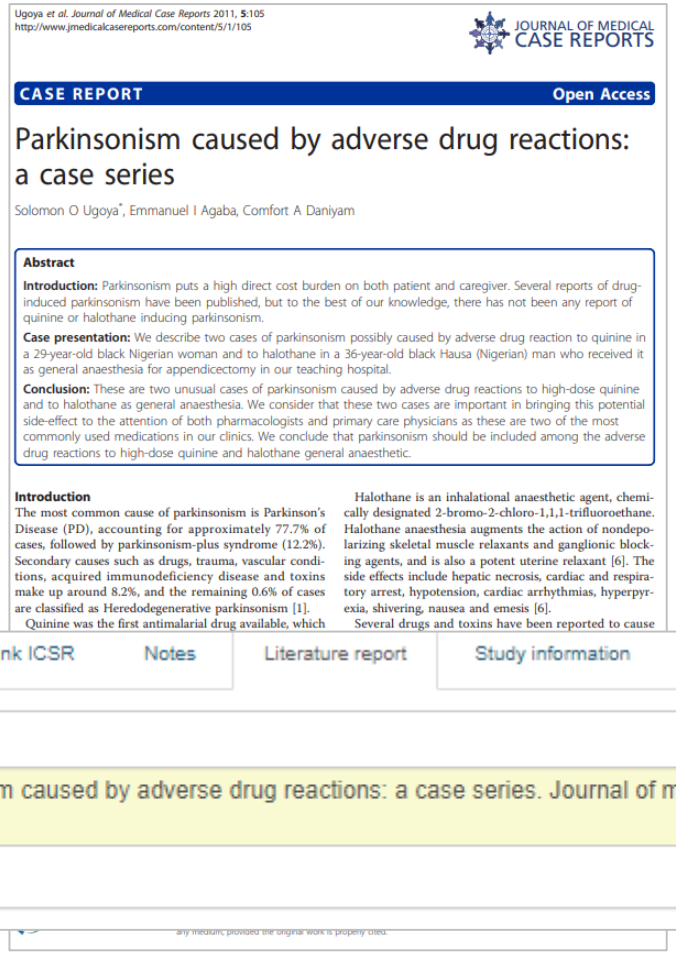
Literature report tab

In the tab **Literature Report** it is possible to enter the literature reference (Vancouver style) when an ICSR is identified in an article.



Ugoya *et al. Journal of Medical Case Reports* 2011, **5**:105
http://www.jmedicalcasereports.com/content/5/1/105

JOURNAL OF MEDICAL CASE REPORTS

CASE REPORT Open Access

Parkinsonism caused by adverse drug reactions: a case series

Solomon O Ugoya*, Emmanuel I Agaba, Comfort A Daniyam

Abstract

Introduction: Parkinsonism puts a high direct cost burden on both patient and caregiver. Several reports of drug-induced parkinsonism have been published, but to the best of our knowledge, there has not been any report of quinine or halothane inducing parkinsonism.

Case presentation: We describe two cases of parkinsonism possibly caused by adverse drug reaction to quinine in a 29-year-old black Nigerian woman and to halothane in a 36-year-old black Hausa (Nigerian) man who received it as general anaesthesia for appendicectomy in our teaching hospital.

Conclusion: These are two unusual cases of parkinsonism caused by adverse drug reactions to high-dose quinine and to halothane as general anaesthesia. We consider that these two cases are important in bringing this potential side-effect to the attention of both pharmacologists and primary care physicians as these are two of the most commonly used medications in our clinics. We conclude that parkinsonism should be included among the adverse drug reactions to high-dose quinine and halothane general anaesthetic.

Introduction

The most common cause of parkinsonism is Parkinson's Disease (PD), accounting for approximately 77.7% of cases, followed by parkinsonism-plus syndrome (12.2%). Secondary causes such as drugs, trauma, vascular conditions, acquired immunodeficiency disease and toxins make up around 8.2%, and the remaining 0.6% of cases are classified as Heredodegenerative parkinsonism [1].

Quinine was the first antimalarial drug available, which

Halothane is an inhalational anaesthetic agent, chemically designated 2-bromo-2-chloro-1,1,1-trifluoroethane. Halothane anaesthesia augments the action of nondepolarizing skeletal muscle relaxants and ganglionic blocking agents, and is also a potent uterine relaxant [6]. The side effects include hepatic necrosis, cardiac and respiratory arrest, hypotension, cardiac arrhythmias, hyperpyrexia, shivering, nausea and emesis [6].

Several drugs and toxins have been reported to cause

Initial reporter information | Sender information | Link ICSR | Notes | Literature report | Study information | Documents

Literature Reference(s)

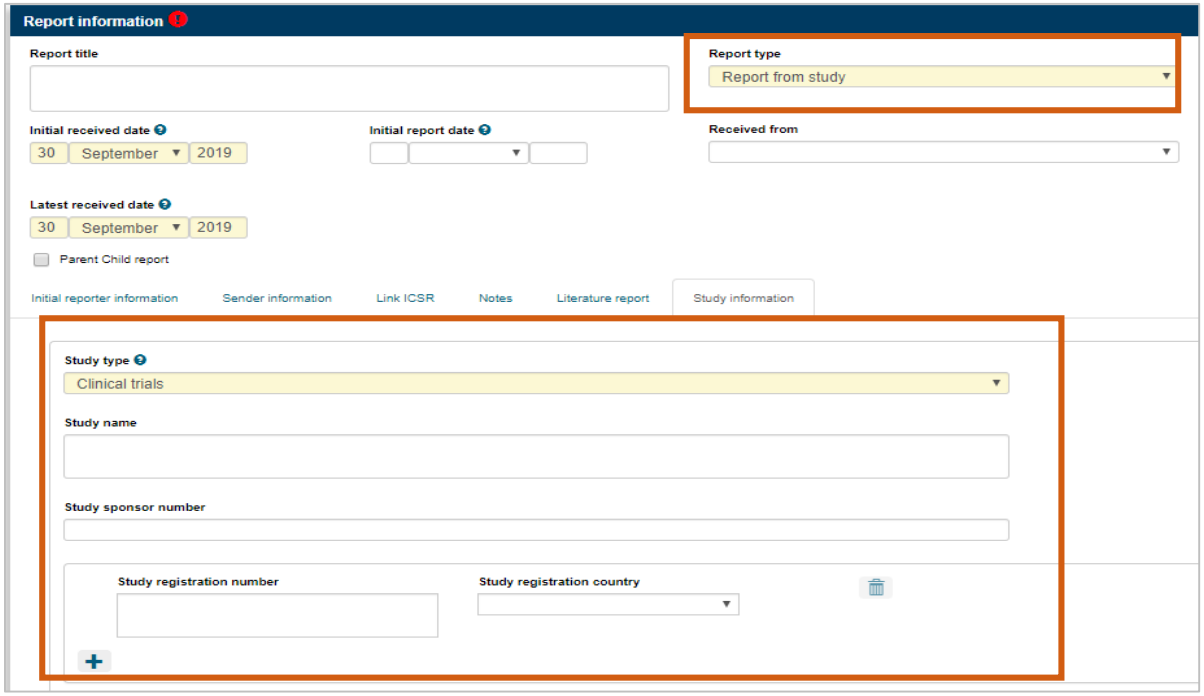
Ugoya SO, Agaba EI, Daniyam CA. Parkinsonism caused by adverse drug reactions: a case series. Journal of medical case reports. 2011 Dec;5(1):1-3.

Study information tab

When selecting Report type = **Report from study**, it becomes mandatory to fill in the Study information fields. The following fields are available in the **Study tab** to capture information about the study:

- *Study type (dropdown list)*
- *Study name*
- *Study sponsor number*
- *Study registration number*
- *Study registration country*

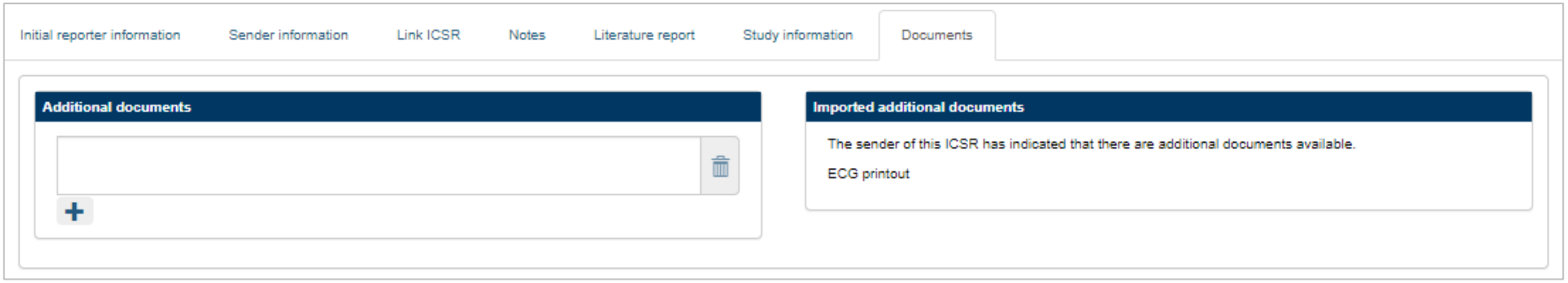
Repeatable section



Documents

If the report contains additional files such as pictures from the adverse event, lab test results, etc, it is possible to indicate which **Additional documents** are available.

If an ICSR imported in VigiFlow through a XML-E2B file contains additional files, the list of documents will be displayed in **Imported additional documents**.



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Patient

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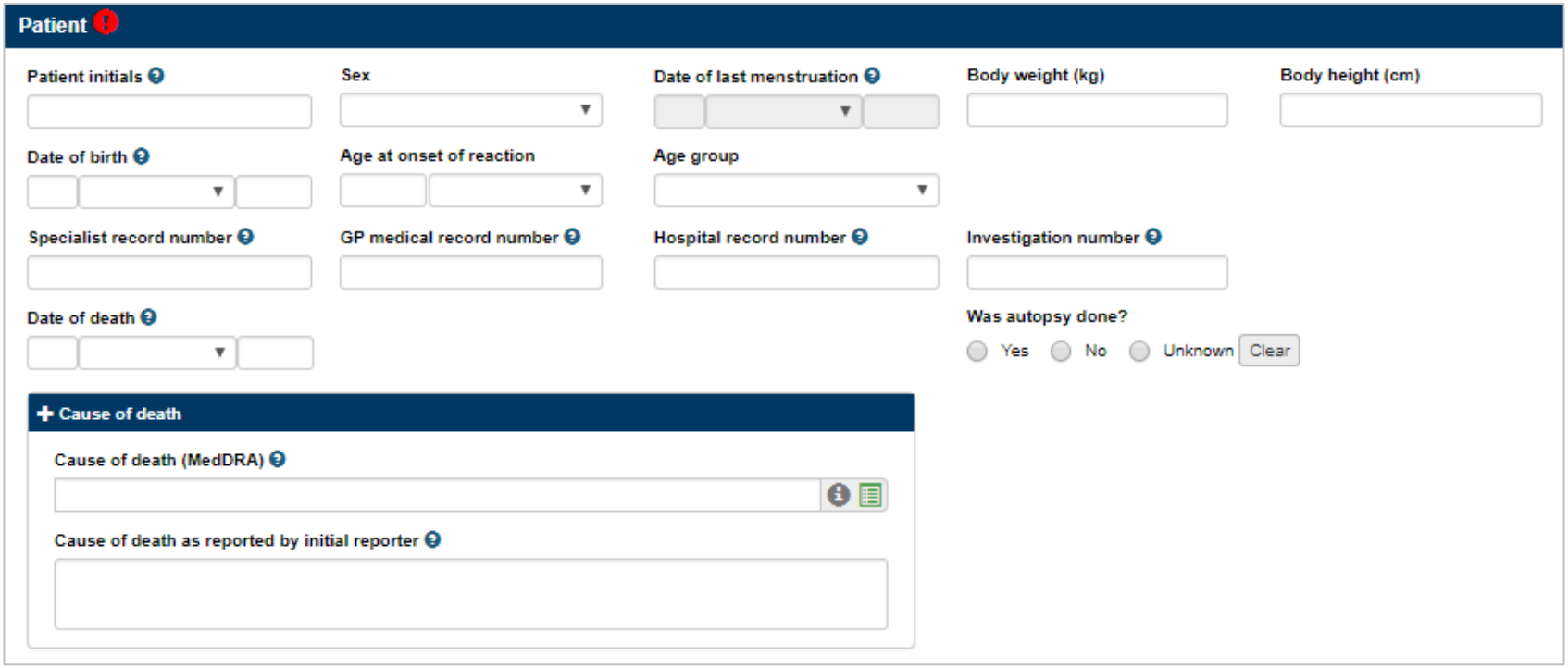
Patient – Additional Information

The most common information to identify the patient are easily visible.

As other patient identifiers (e.g. record numbers) and information about the cause of death are not reported frequently, they are available under the **Additional fields**.

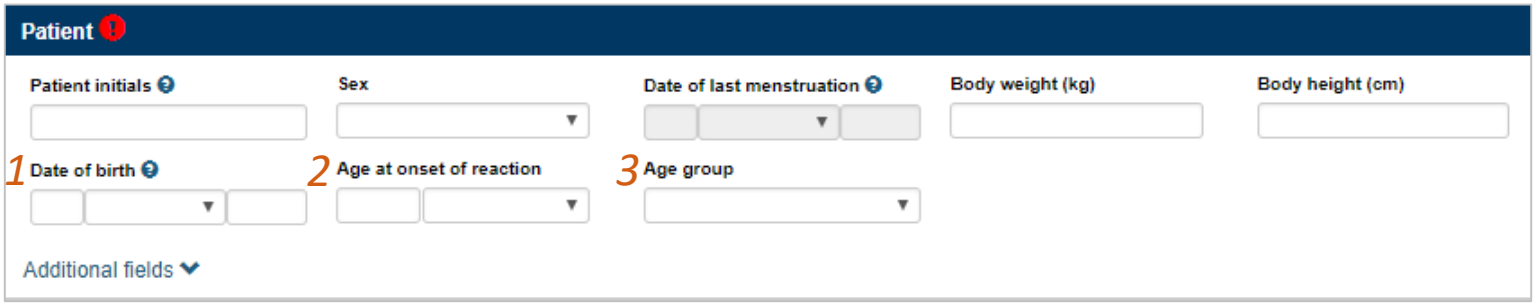
It is not required to fill in all fields for patient identification.



Patient age

There are 3 ways to report patient age.

It is best practice to enter the most specific information available.



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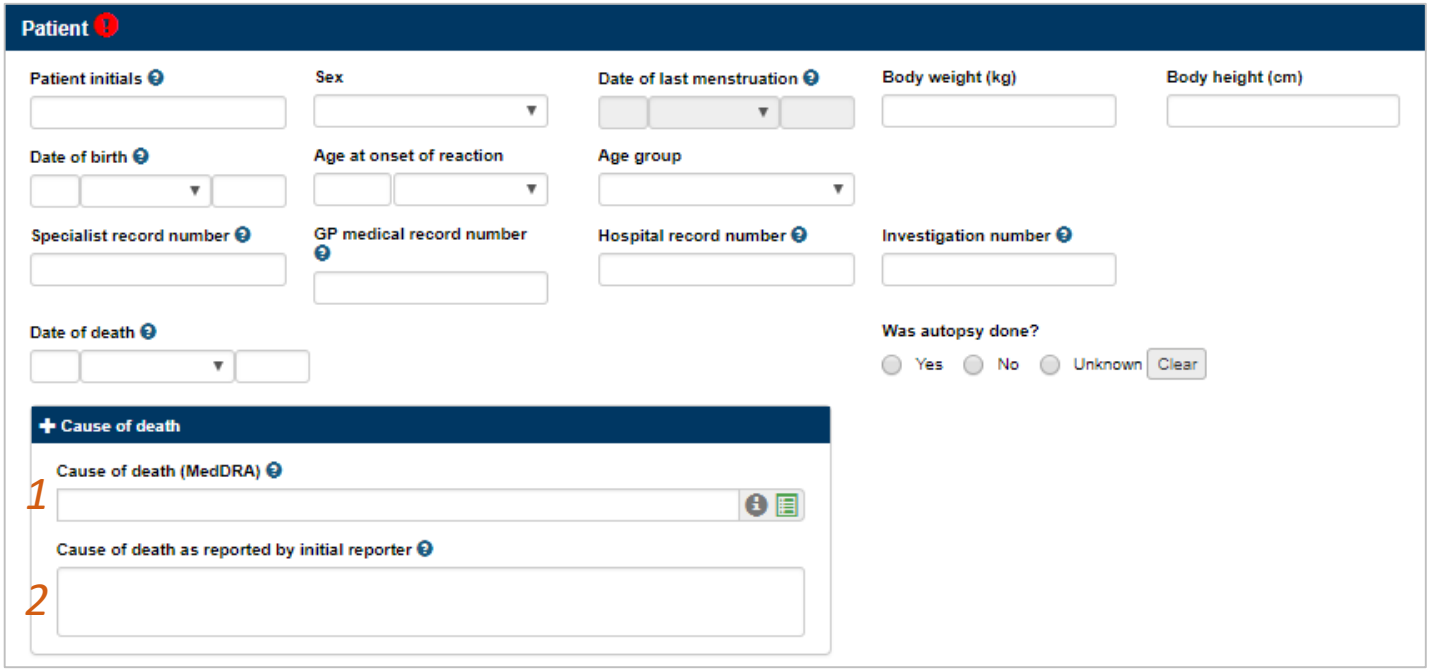
Cause of death

There are 2 options to enter information on cause of death:

1. Either select the corresponding MedDRA term
2. Or type the exact wording from the original ADR form in the **Cause of death as reported by initial reporter** field.

The 2 fields can also be used in combination to reflect both what has been reported originally and its corresponding MedDRA term.

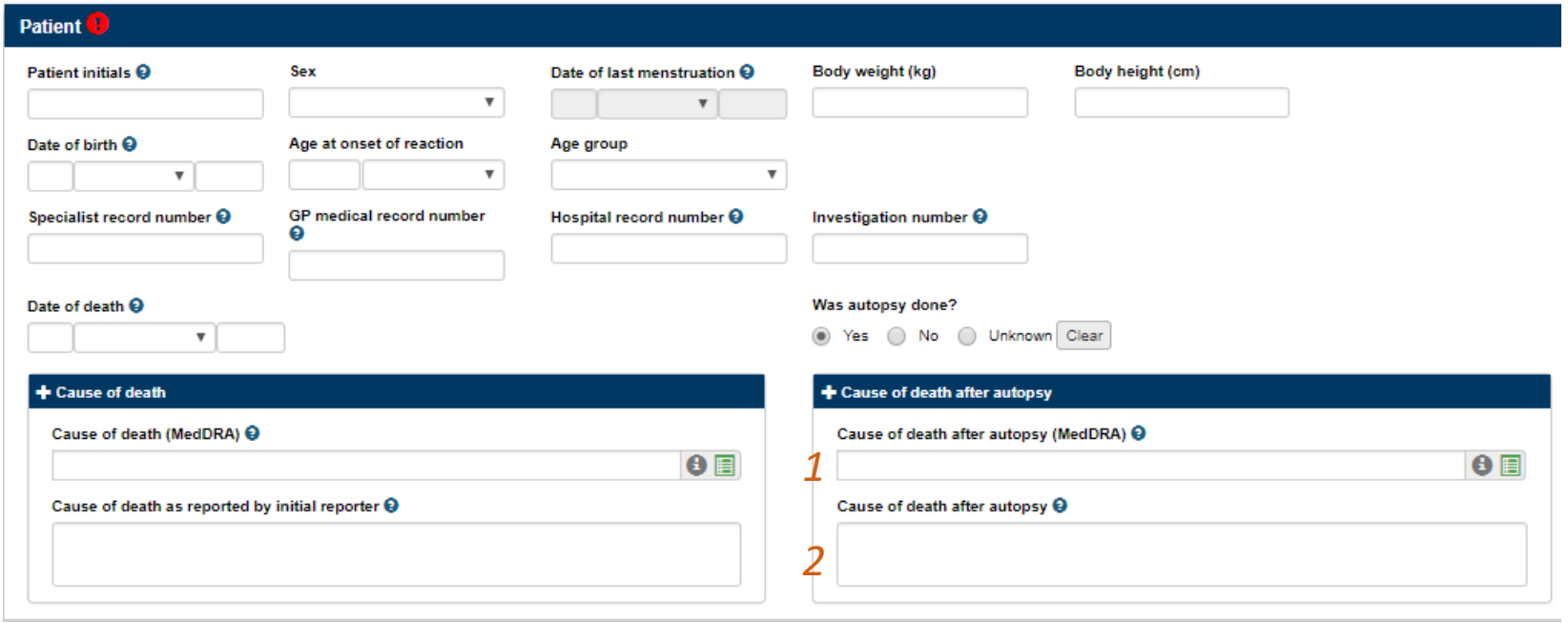


Cause of death after autopsy

If the patient underwent autopsy, it is possible to specify the cause of death after autopsy in 2 different ways:

1. Select the corresponding MedDRA term
2. Type in free text the exact wording from the original ADR form in the **Cause of death after autopsy** field

The 2 fields can also be used in combination to reflect both what has been reported originally and its corresponding MedDRA term.



Case narrative and other information

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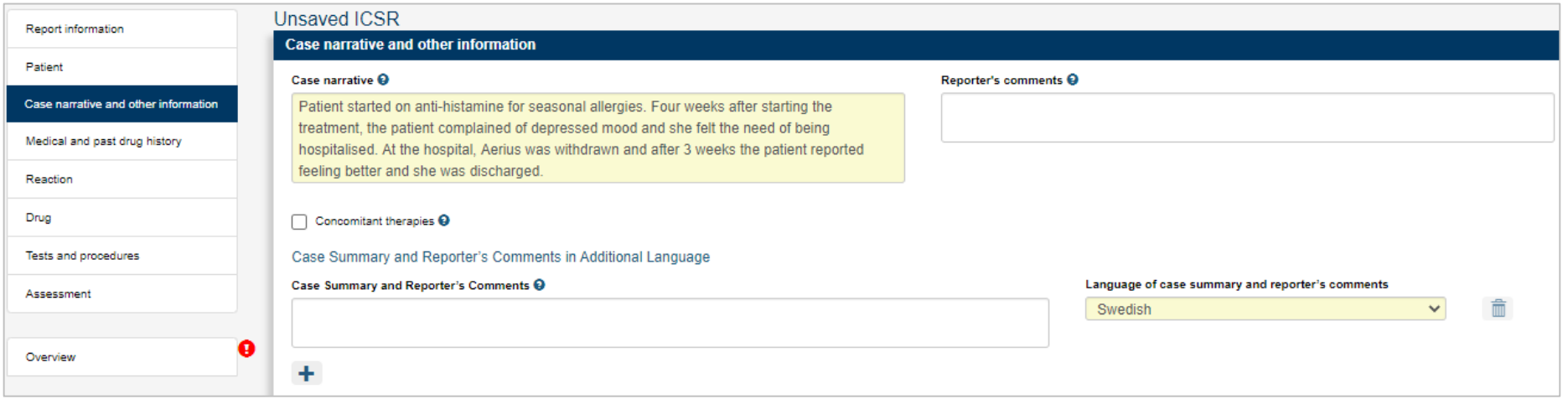
Case narrative and Reporter’s comments

Both case narrative and reporter’s comments fields are free-text fields which can expand to accomodate large texts.

By writing the case narrative with the words and phrases used by the initial reporter, it is possible to keep the original narrative and use it in combination with the structured fields for a better analysis.



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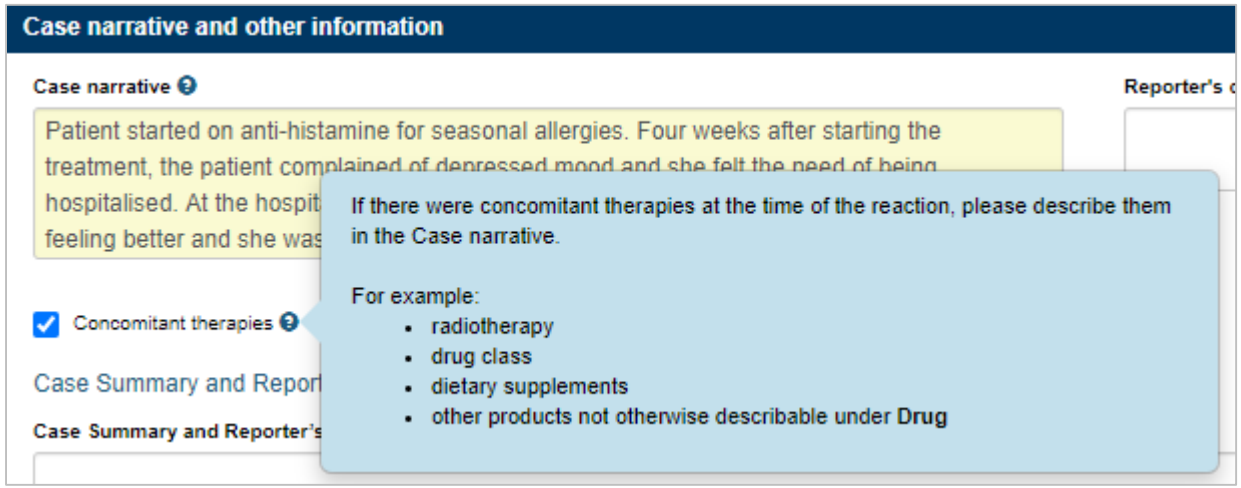
Concomitant therapies

If the patient received other treatments that cannot be captured in the Drug section, select the **Concomitant therapy** checkbox and describe in the case narrative which therapies were received.



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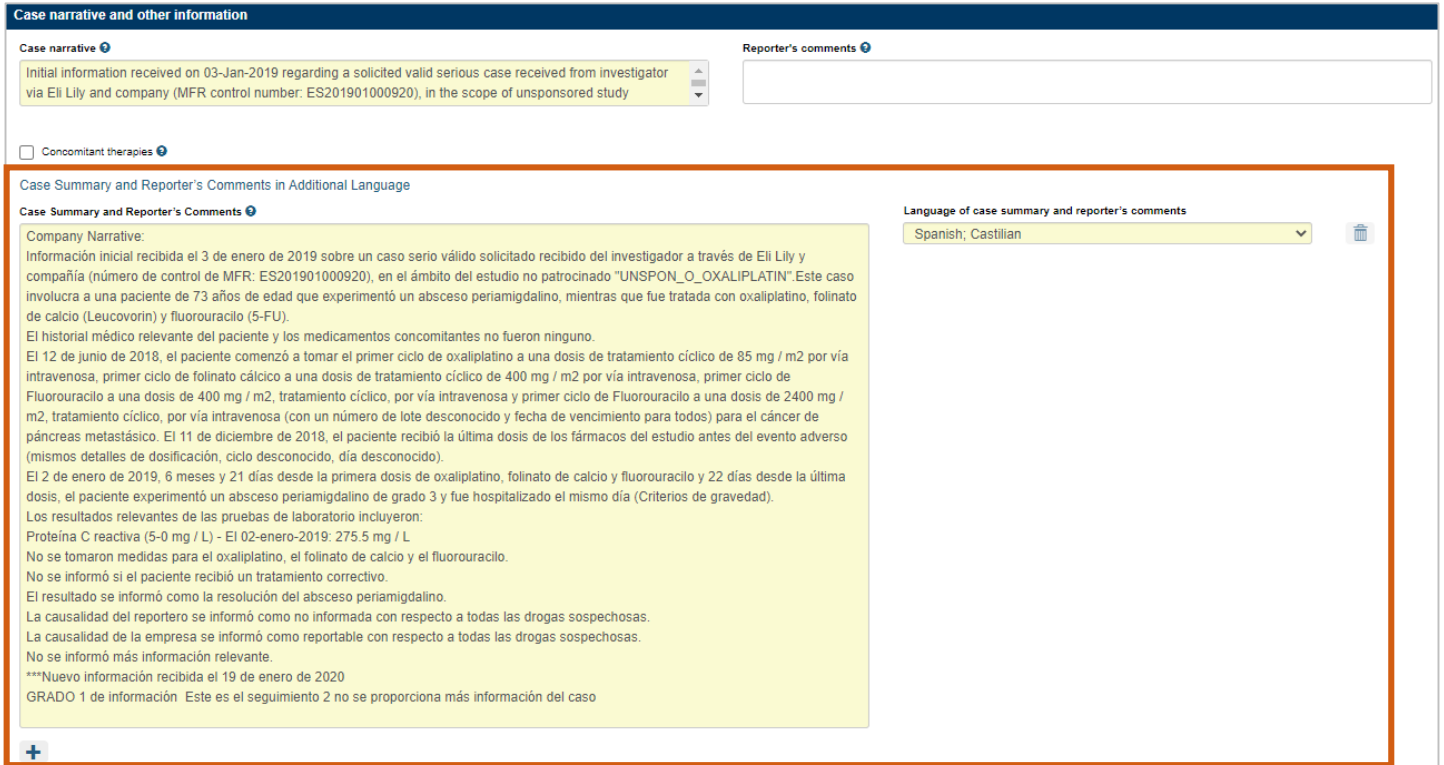
Translations of case narrative and reporter's comment

The field **Case Summary and Reporter's Comments in Additional Language:**

VigiFlow offers a specific field to capture the case narrative and reporter's comment translated to any applicable language. This feature is considerably important for national centres requiring the industry/MAH to share safety information in a specific language. The E2B-files sent by the industry/MAH containing information about narrative/reporters comment translated to any language, will be displayed in these fields when imported to VigiFlow.



Medical and past drug history

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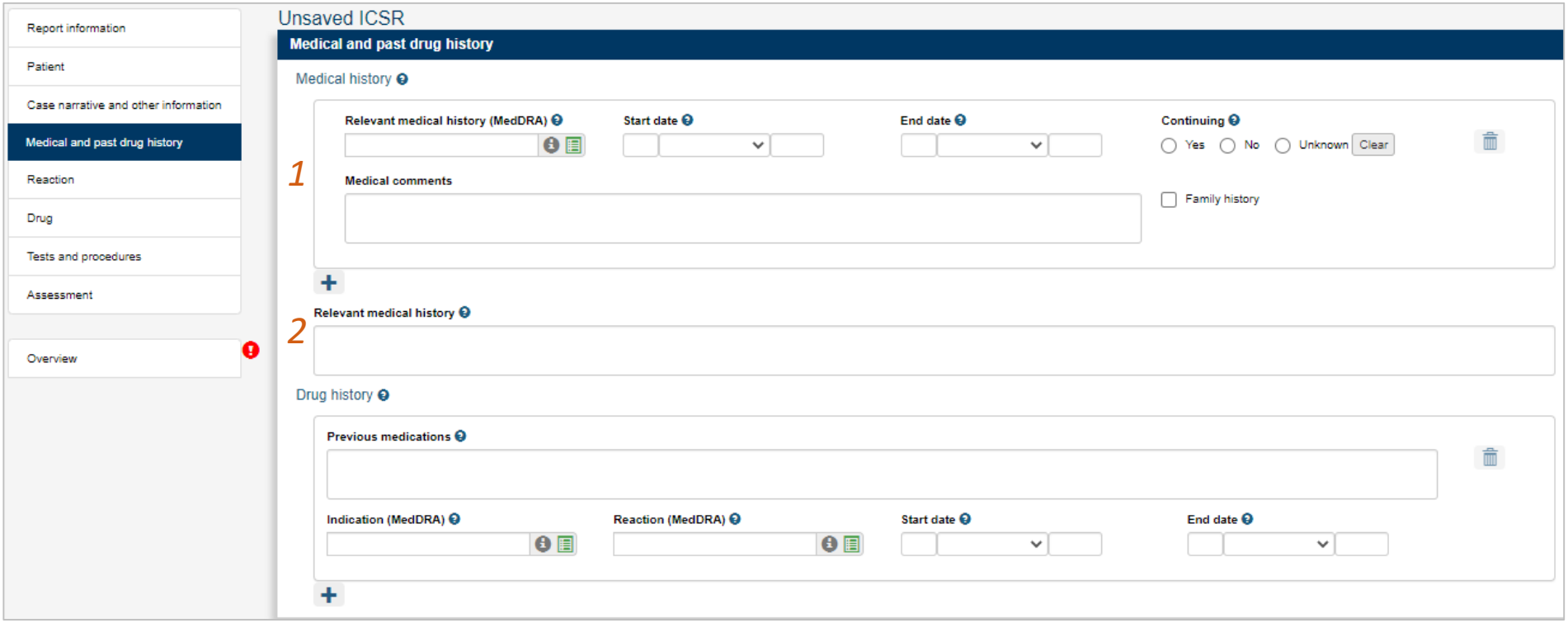
Medical history

There are 2 options to enter information about medical history:

1. either using the structured fields

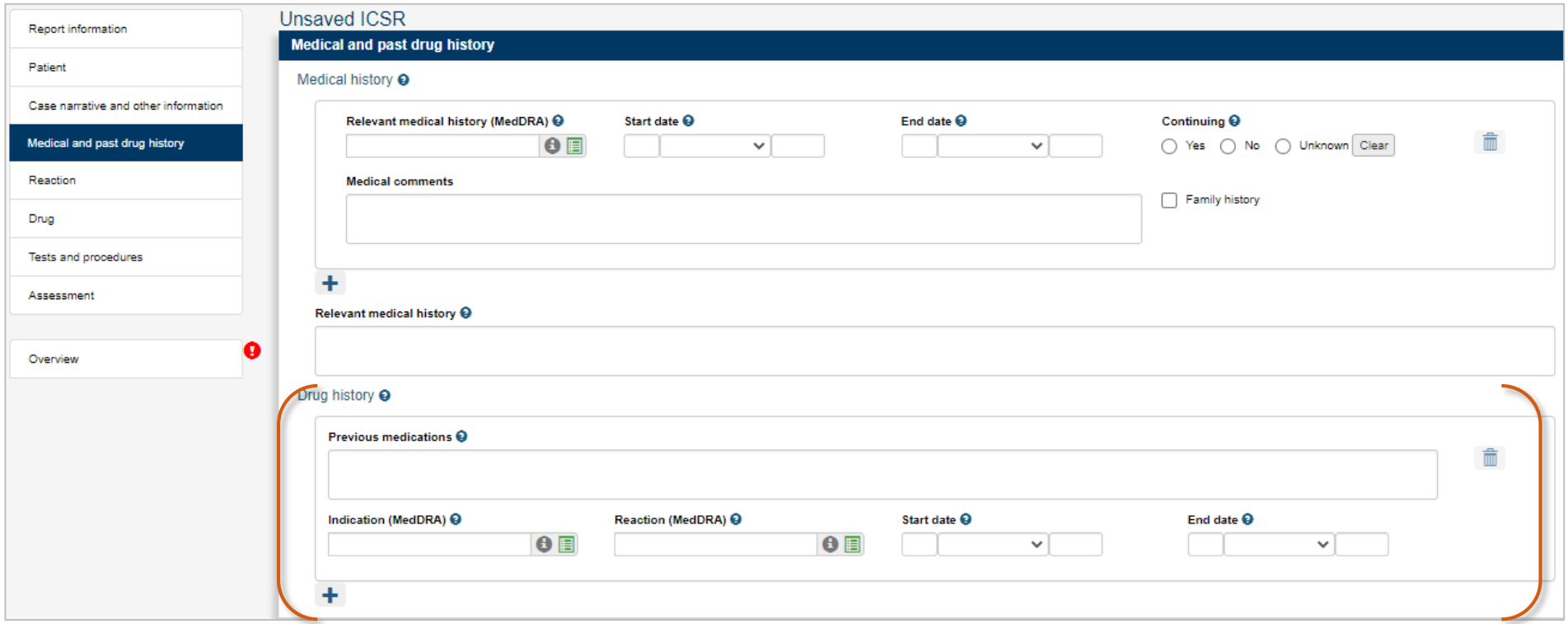
   Relevant medical history (MedDRA); Start date; End date; Continuing Yes/No; Medical comments

2. or using the free-text field below it



Past drug history

This section concerns relevant drugs administered which have been **discontinued before the reaction onset date**.



Reaction

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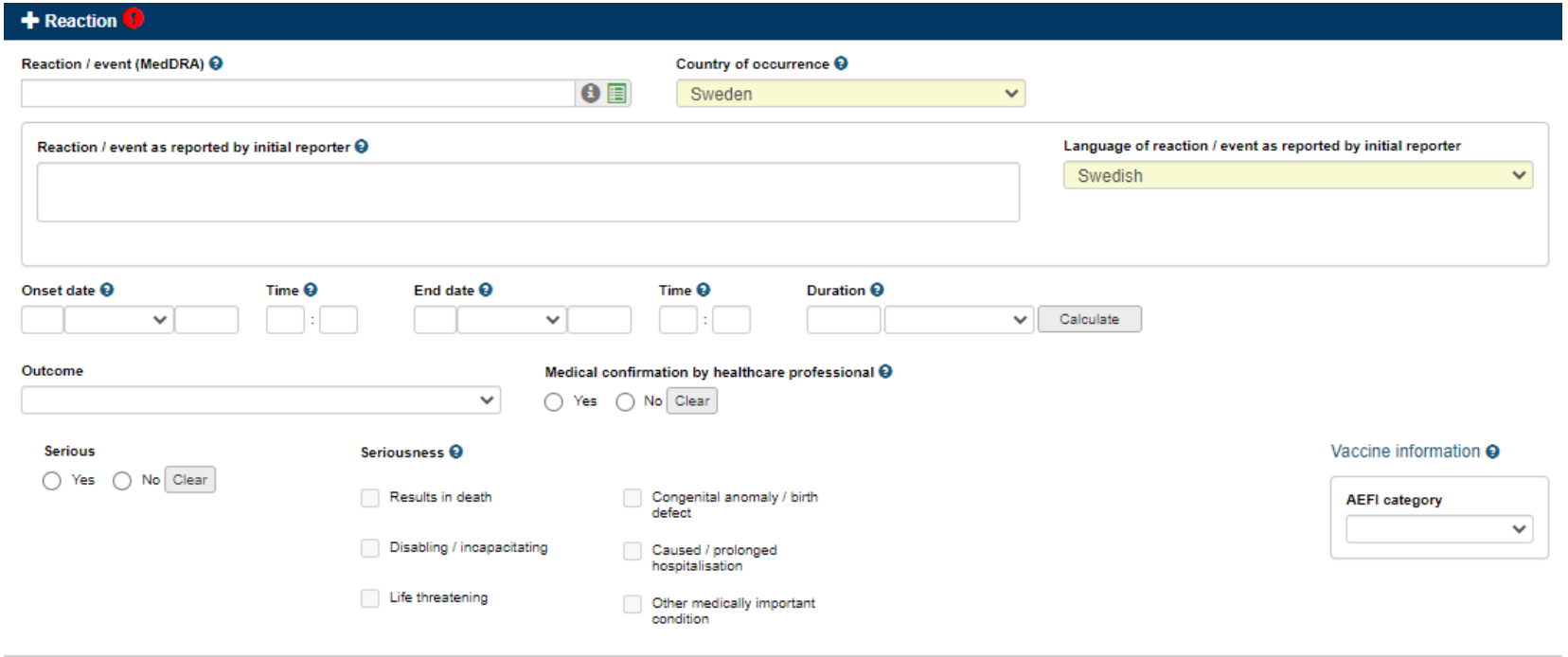
Fields available in the REACTION section



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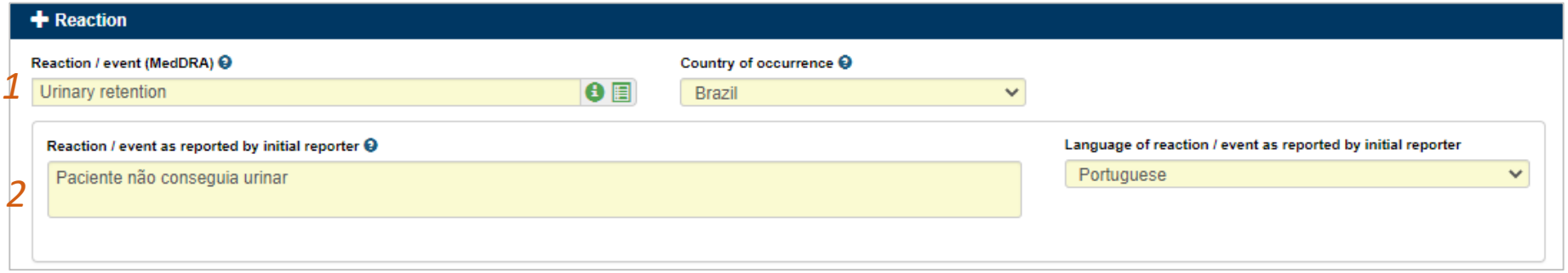
Entering a Reaction / Event

There are 2 options to enter a reaction:

1. Select the corresponding MedDRA term* for the reaction
2. Write the **Reaction / event as reported by the initial reporter** in free-text and pick the **language** in which the reporter described the adverse reaction. These fields can be used when the reaction described by the reporter is different than the MedDRA term or when you don't find an adequate MedDRA term. ***Be aware that reactions entered in free-text will not be searchable in VigiLyze for analysis.***

The 2 fields can also be used in combination to reflect both what has been reported originally and its corresponding MedDRA term.



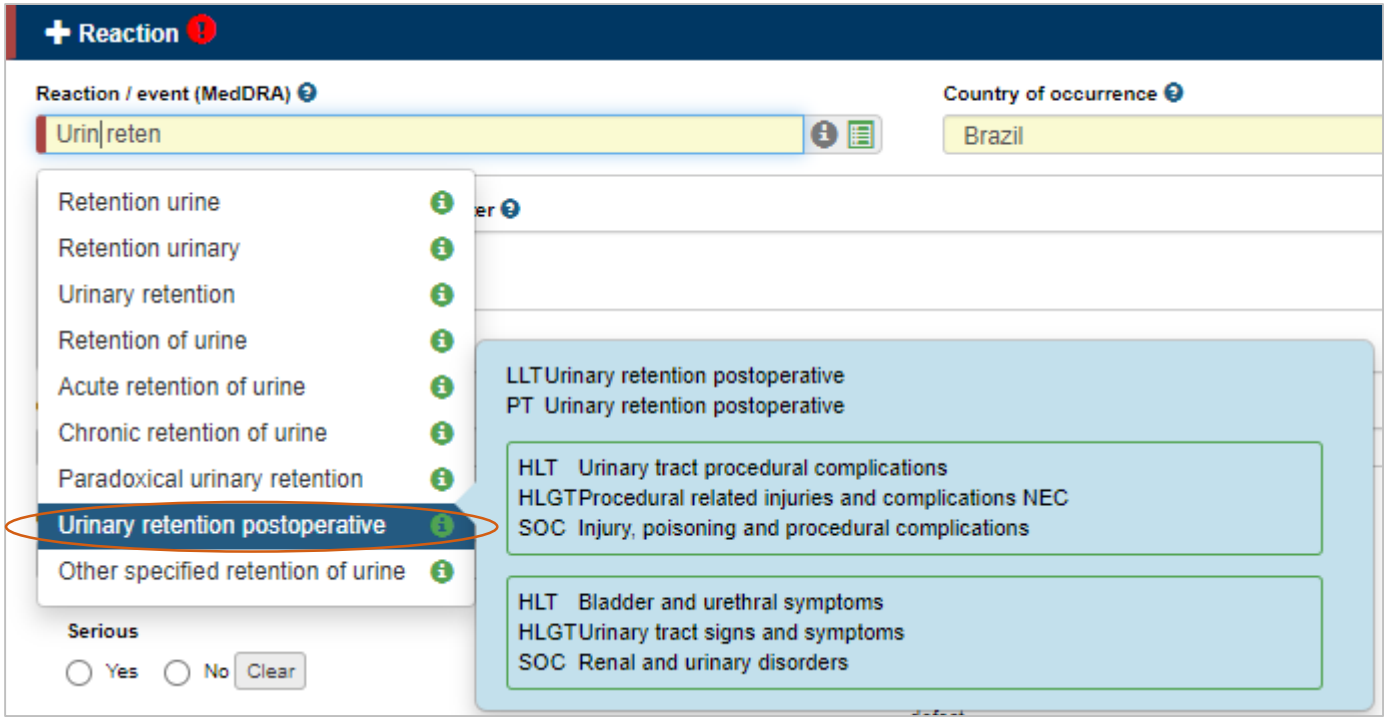
**The procedure of how to select a MedDRA term must be handled by the NC. Contact MedDRA MSSO if you have questions.*

Finding the right MedDRA term

When searching for a MedDRA term, a drop-down list appears with suggestions of Lowest Level Terms (LLT).

If you are not certain about how to find the most accurate term, type parts of words and the list will bring the matching results.

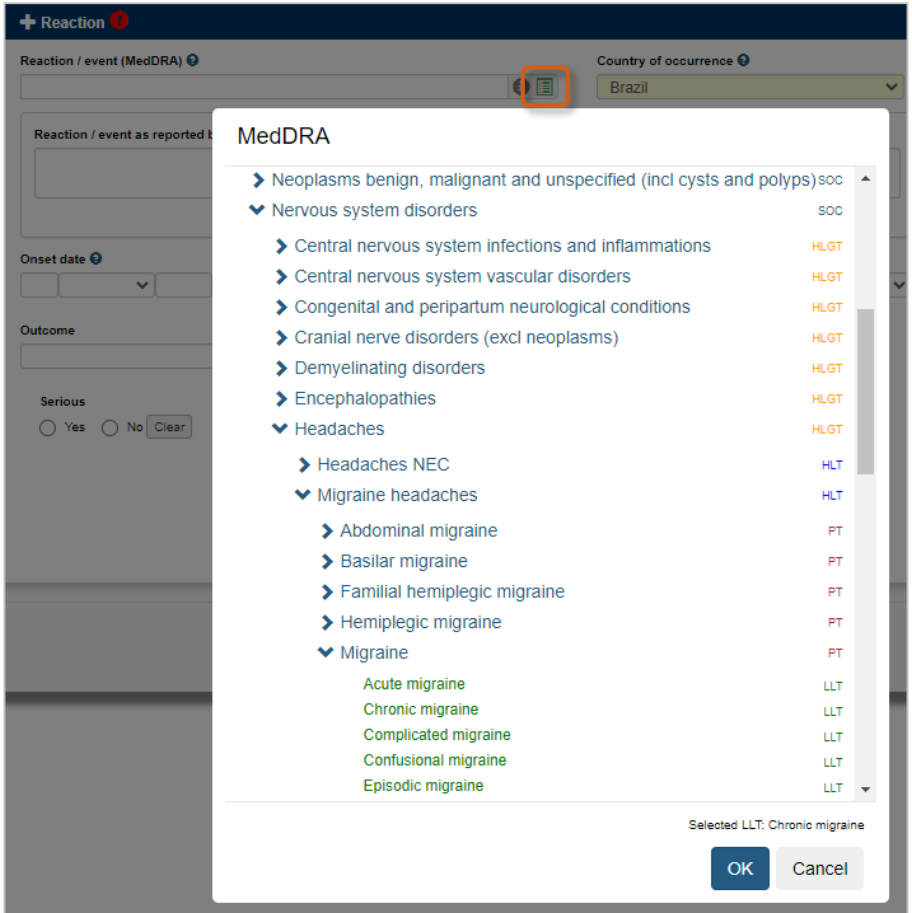
By clicking on the icon ⓘ, it is possible to check the MedDRA hierarchy with all SOCs. Select the term that best matches the reaction originally reported.



Search the MedDRA term directly on the hierarchy

It is possible to browse the full MedDRA hierarchy to search for the best term by clicking on the icon .

When a term is selected, the Reaction/event (MedDRA) field is automatically filled in.



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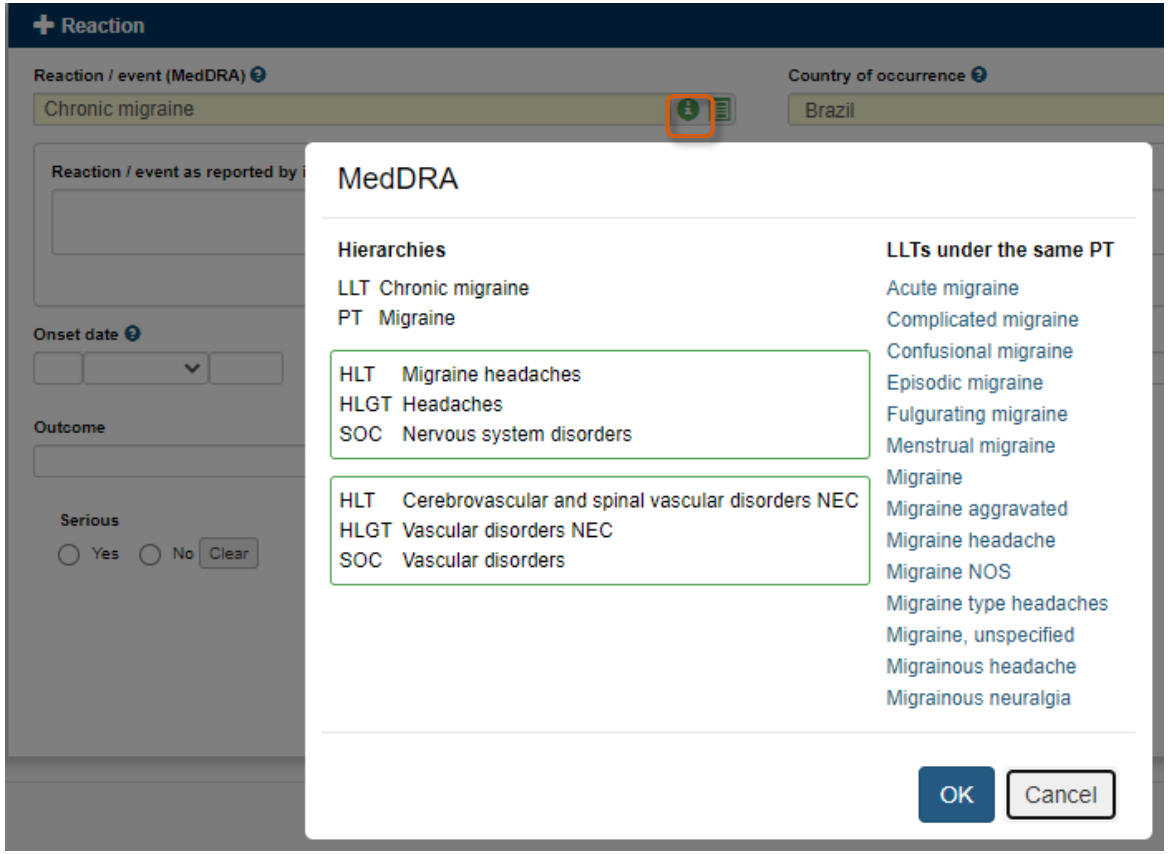
Suggestions of other LLTs

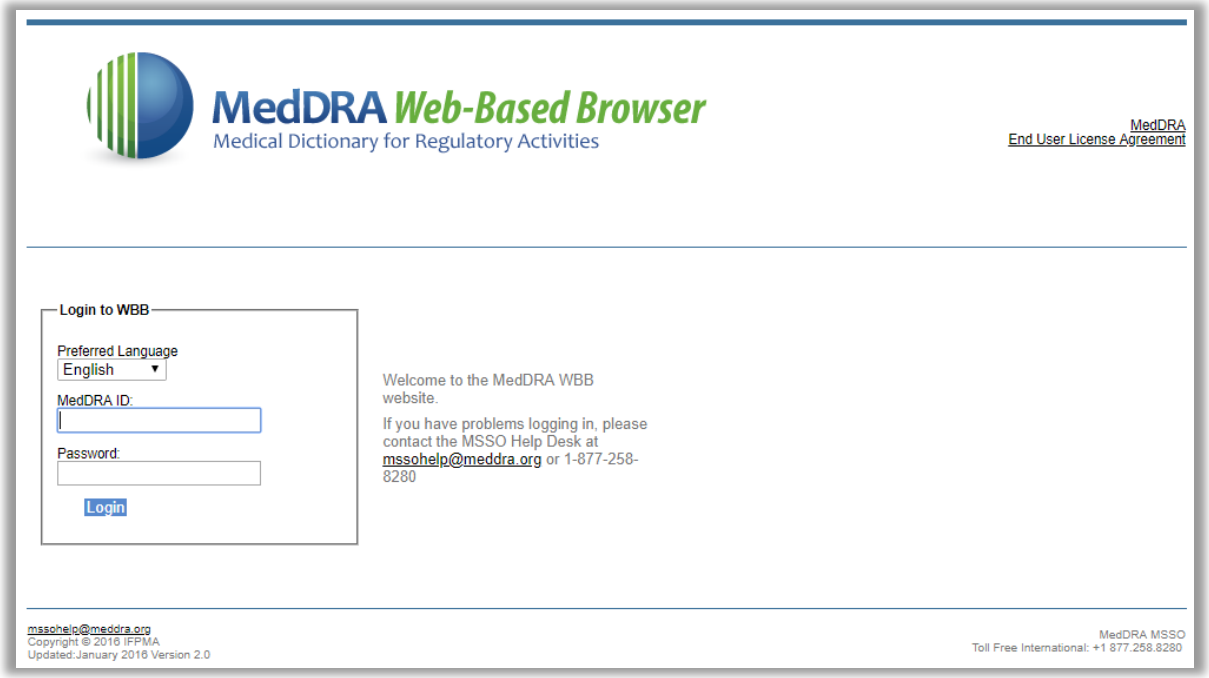
When selecting a LLT, by clicking on the icon, it is possible to see the other LLTs which are related to the same preferred term (PT). In that way, you can easily check if there is another term which is more similar to the one reported and that is related to the same medical concept of the PT.



Help to find the best matching term in MedDRA

If your organization has a MedDRA license, you have the rights to access the MedDRA browser. The MedDRA browser can be used as a reference for assigning MedDRA terms.

If you can't find a MedDRA term, contact MedDRA MSSO to suggest its inclusion in the terminology.



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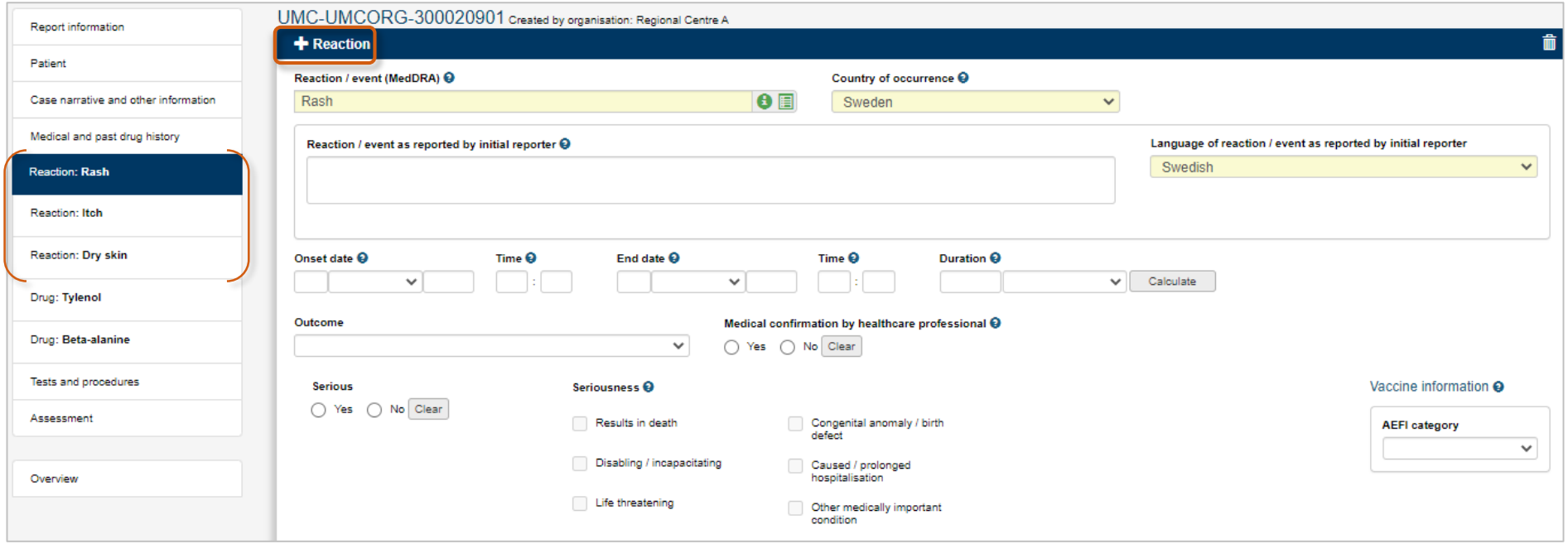
Adding more reactions

If more than 1 reaction has been reported, click the **+ Reaction** to add as many Reaction sections as needed.

Each reaction has its own section.



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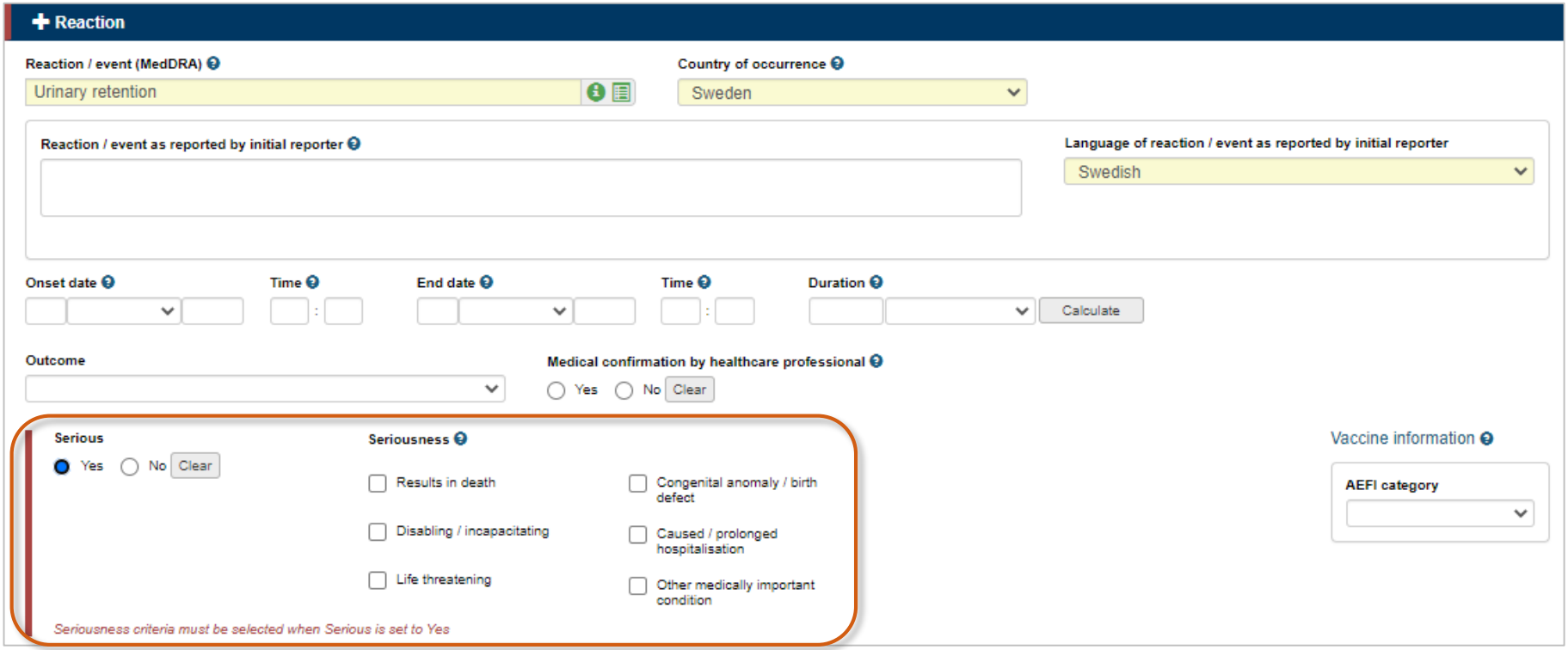
Serious and Seriousness – Data entry

When a reaction is identified as **Serious**, it is mandatory to select at least one **Seriousness** criterion for that reaction.

NOTE: The serious / seriousness is associated with the specified reaction.

Seriousness criteria serves as a guide for defining regulatory reporting obligations (i.e. expedited reporting).

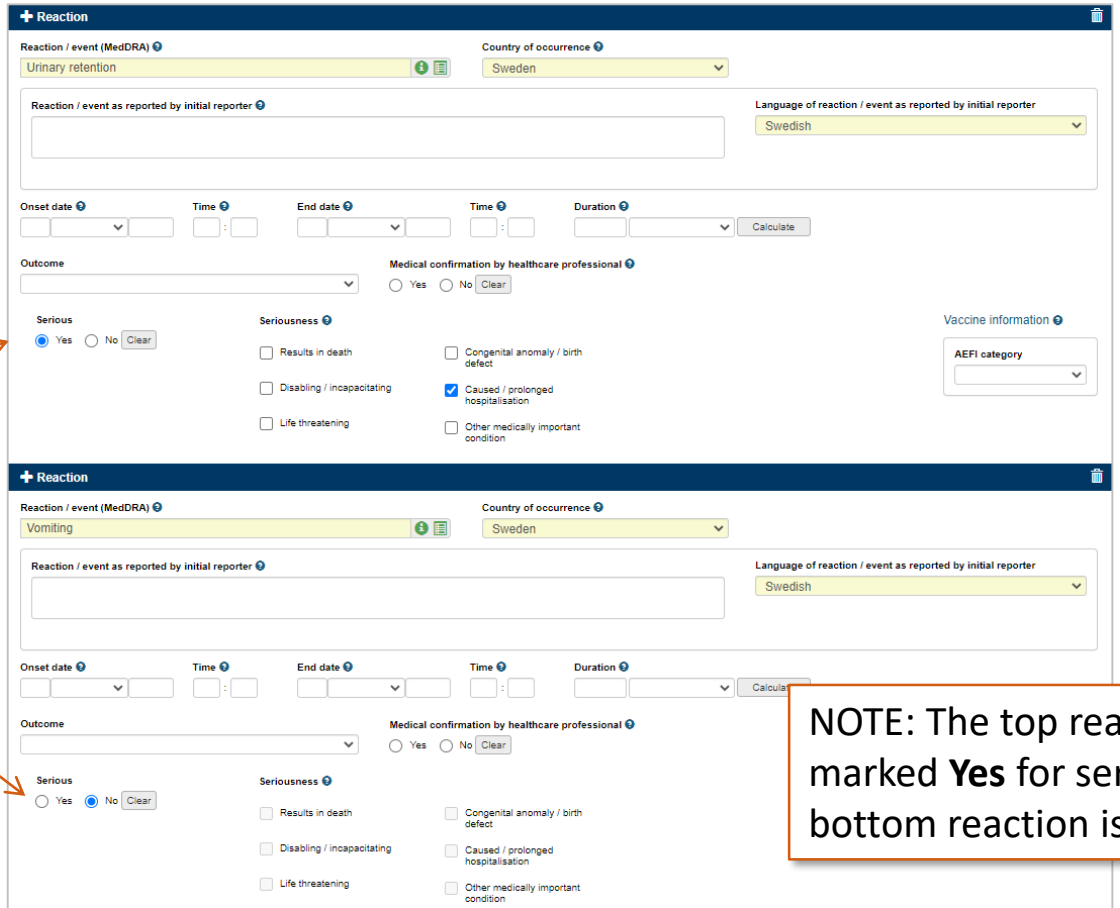


Seriousness - New concept in ICH E2B(R3)

The latest international standard of ICH E2B(R3) established that seriousness should be considered on the ***reaction level***.

Thus, each entered reaction has it's own corresponding serious / seriousness field.

Seriousness on ***reaction level***

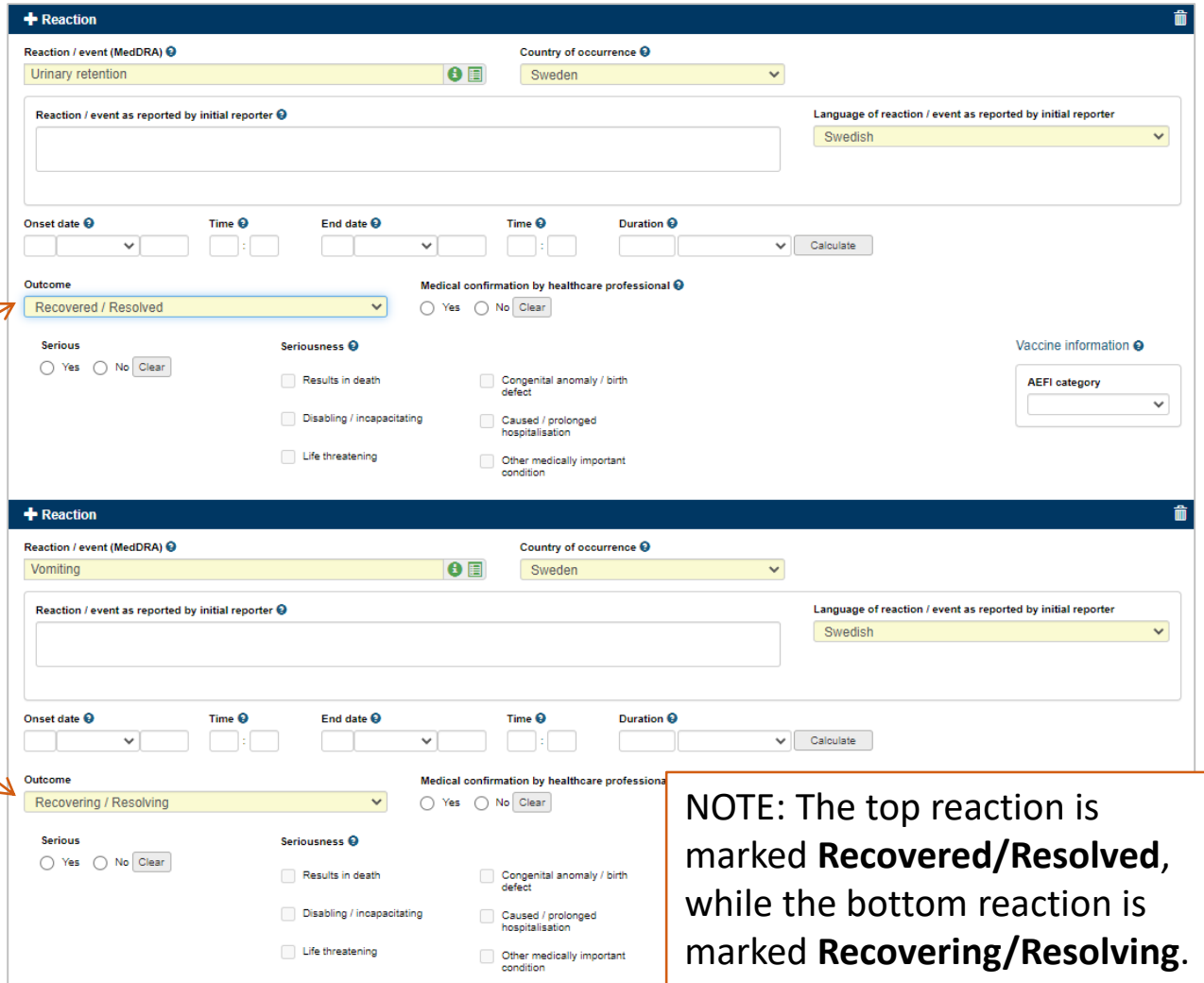


NOTE: The top reaction is marked **Yes** for serious, while the bottom reaction is marked **No**.

Outcome

Similar to the seriousness criteria, the outcome is defined for each reaction.

Outcome on ***reaction level***



NOTE: The top reaction is marked **Recovered/Resolved**, while the bottom reaction is marked **Recovering/Resolving**.

Drug

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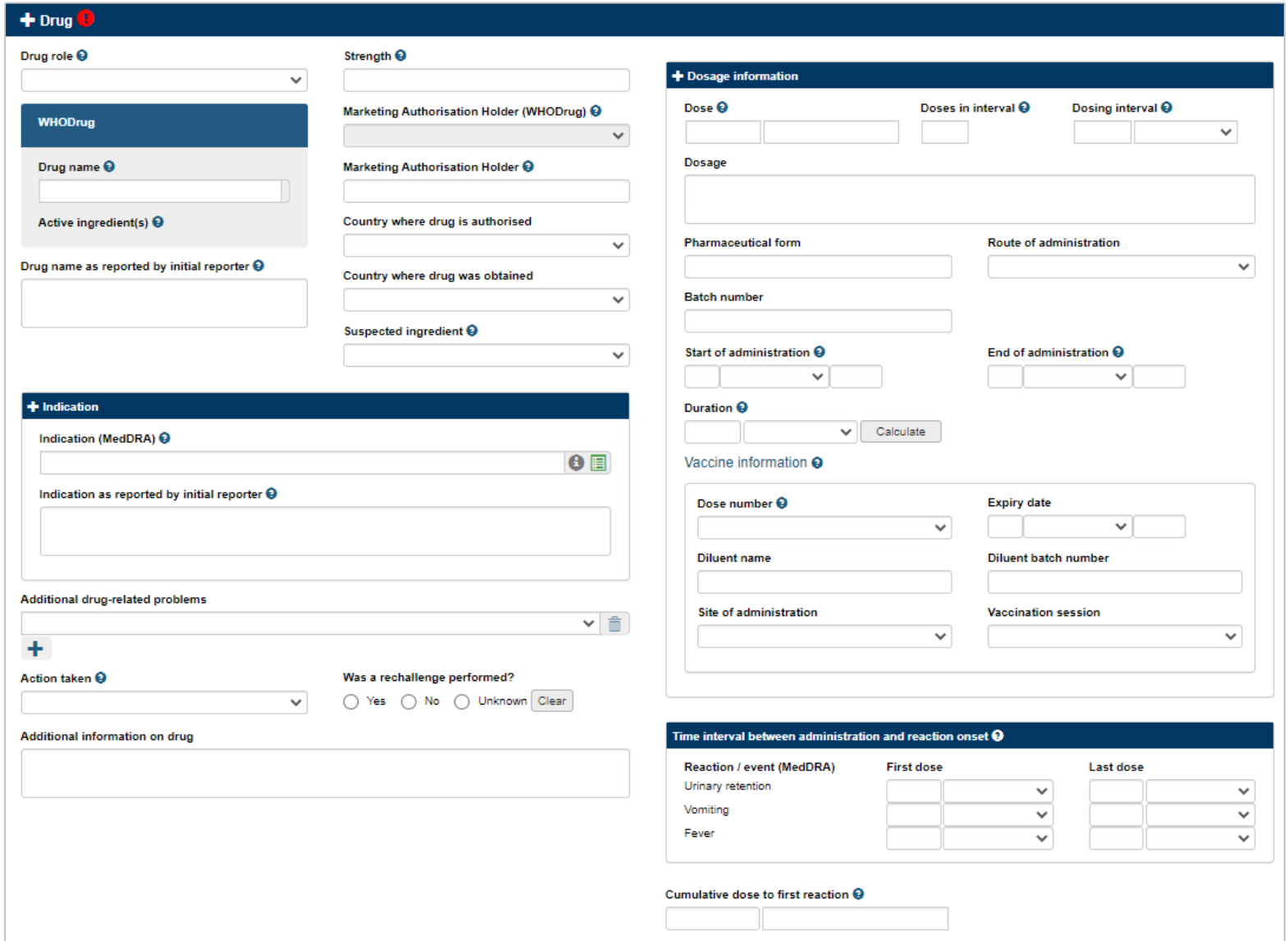
Fields available in the Drug section

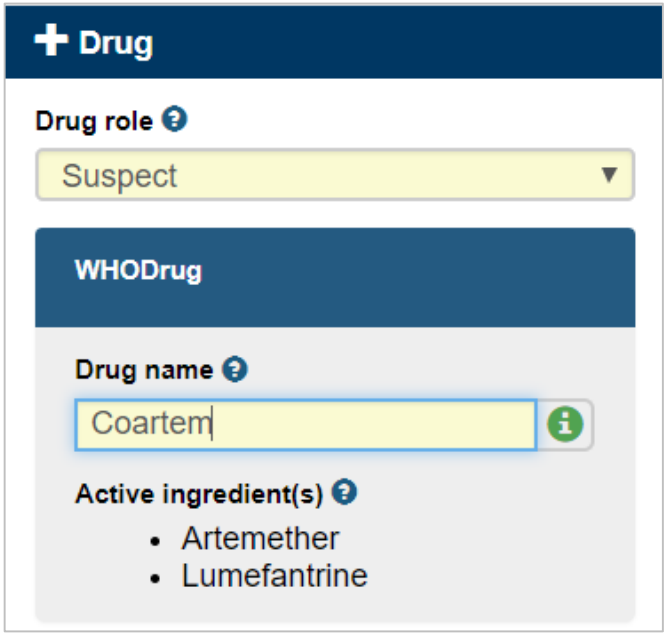


Drug role

Use it to indicate if the drug is **Suspect**, **Concomitant**, **Interacting** or **Drug not administered**.

The causality assessment will be available only for drugs characterized as either **Suspect** or **Interacting**.

The drug role is one of the minimum information required for sending a copy of the report to VigiBase.



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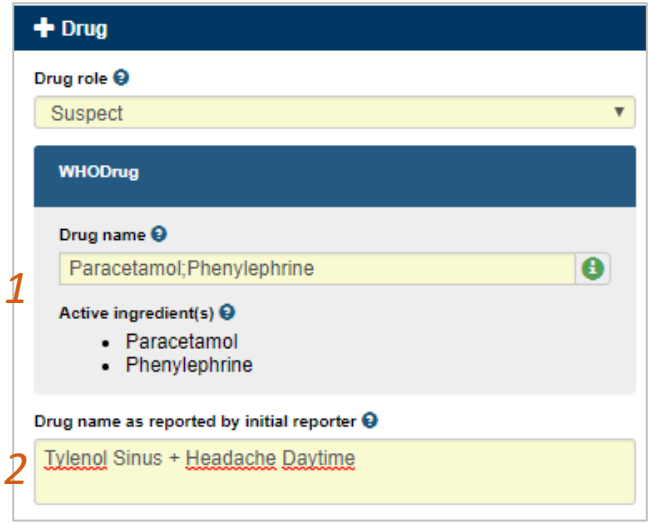
Entering the drug name

There are 2 options for entering a drug:

1. Find the drug in WHODrug (Recommended)
2. Use the **drug name as reported by the initial reporter** the write the drug name in free-text. It can be used when the drug name provided by the reporter is different than the drug name in WHODrug or when you don't find the correct drug in WHODrug. ***Be aware that drugs entered in free-text will not be searchable in VigiLyze for analysis.***

The 2 fields can also be used in combination to reflect both what has been reported originally and the corresponding match in WHODrug.



Using WHODrug

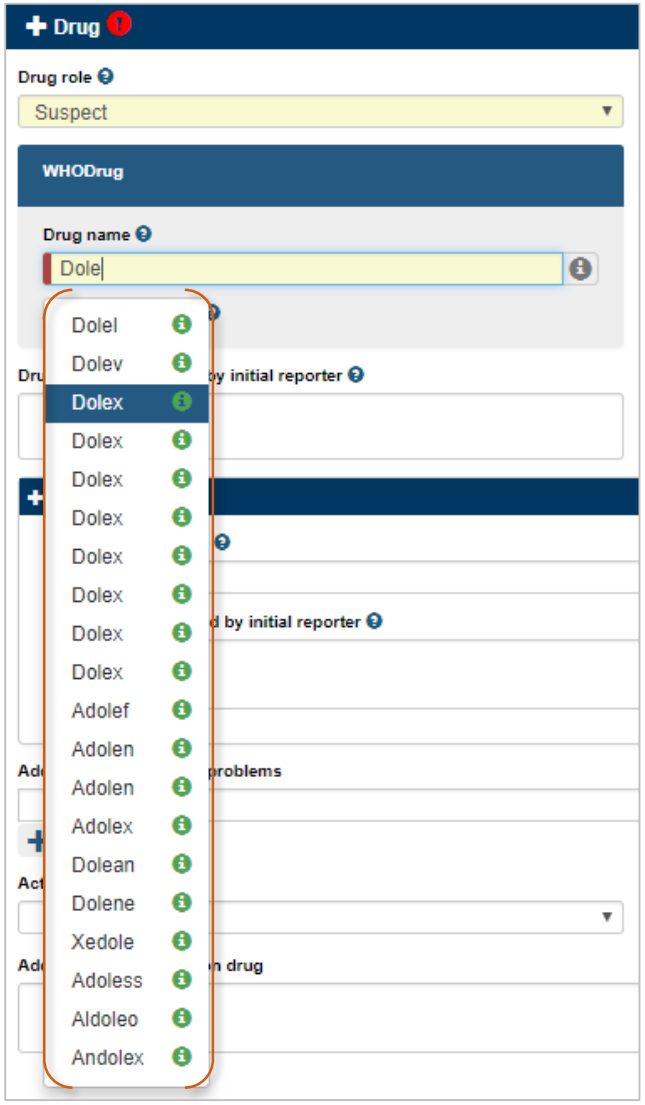
When searching for a drug in WHODrug, you can either:

- *Enter the complete drug name*
- *Enter the first letters of the drug name*

You can search for brand names or active substances.

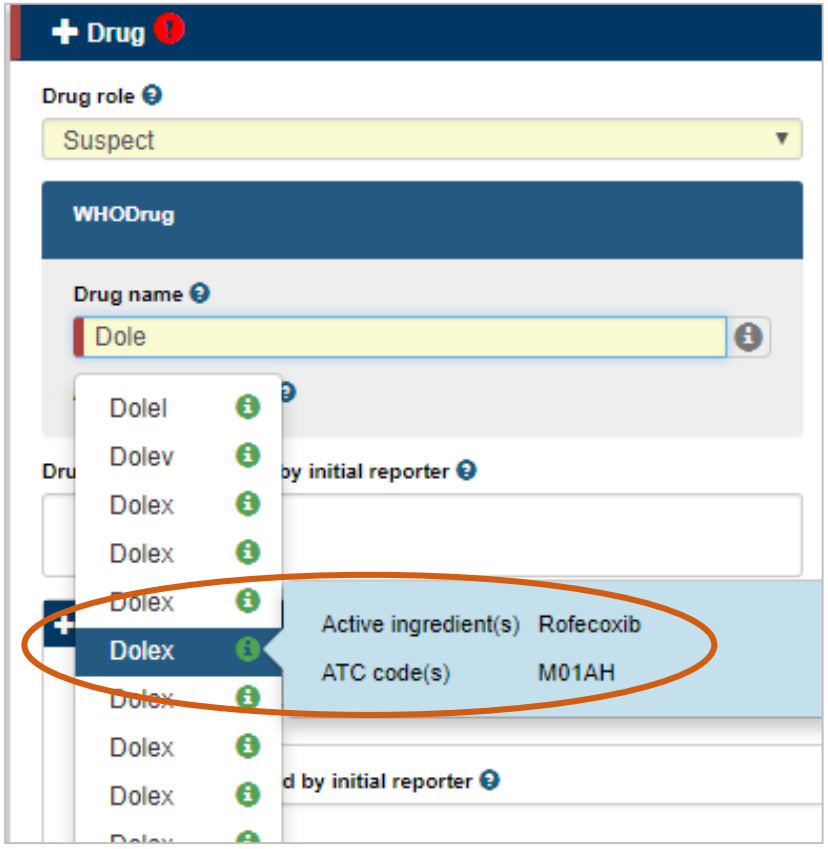
A drop-down list appears with the results matching your search.

If you can't find a good match in WHODrug, contact the UMC to suggest its inclusion in the dictionary.



Checking the Active Ingredients

To ensure that you select the most accurate suggestion, click on the icon ⓘ to verify the active ingredients and ATC codes.



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Visible active ingredients

After the drug has been selected, the active substances will be displayed in read-only mode.

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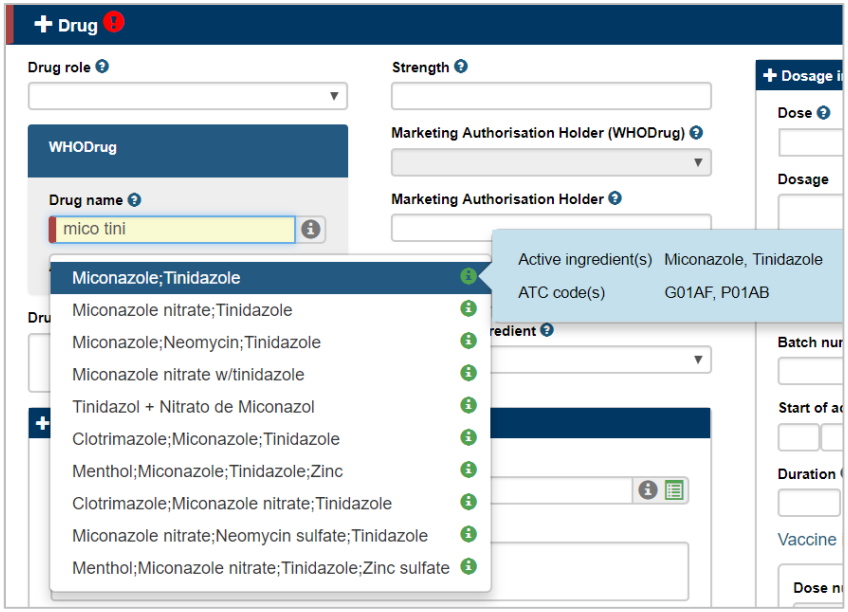
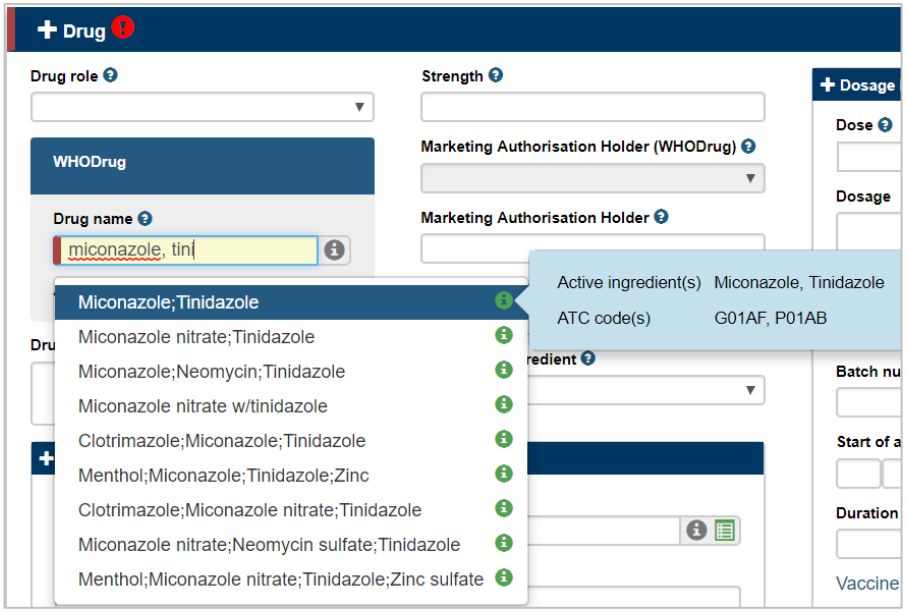
Searching for combination drugs in WHODrug – active substances

To search for combination drugs use “space” or “semicolon”.

For example, the combination drug miconazole and tinidazole can be found by typing:

- “mico tini”
- “miconazole;tini”





Searching for combination drugs in WHODrug – Brand names

Omeclamox-Pak®

omeprazole
clarithromycin
amoxicillin

TRIPLE THERAPY SIMPLIFIED

+ Drug

Drug role

Suspect

WHODrug

Drug name

Omeclamox Pak

Active ingredient(s)

- Amoxicillin trihydrate
- Clarithromycin
- Omeprazole

Drug name as reported by initial reporter

Strength

Marketing Authorisation Holder (WHODrug)

Marketing Authorisation Holder

Authorisation country

Suspected ingredient

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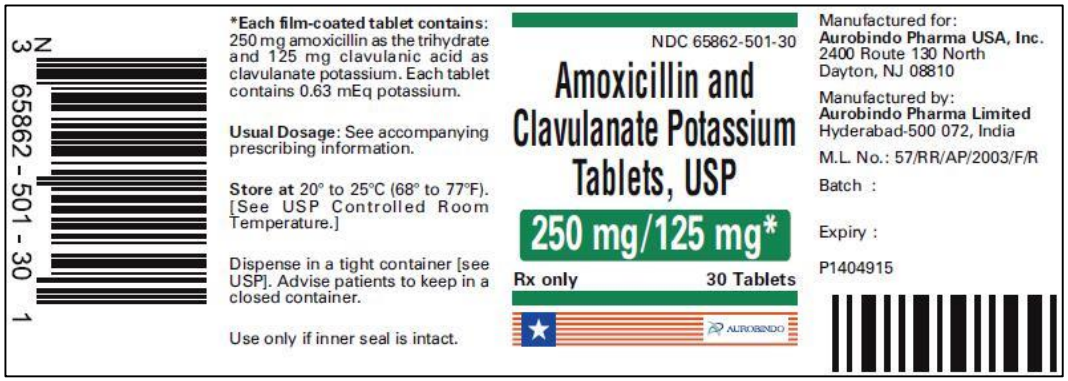
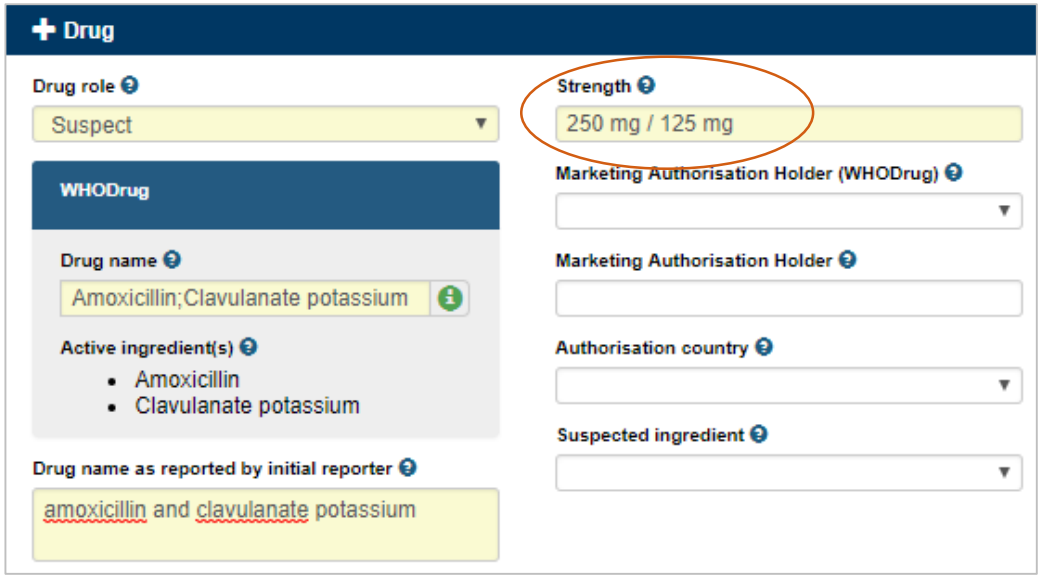
Strength of the active ingredient(s)

For example, if the drug has multiple active ingredients





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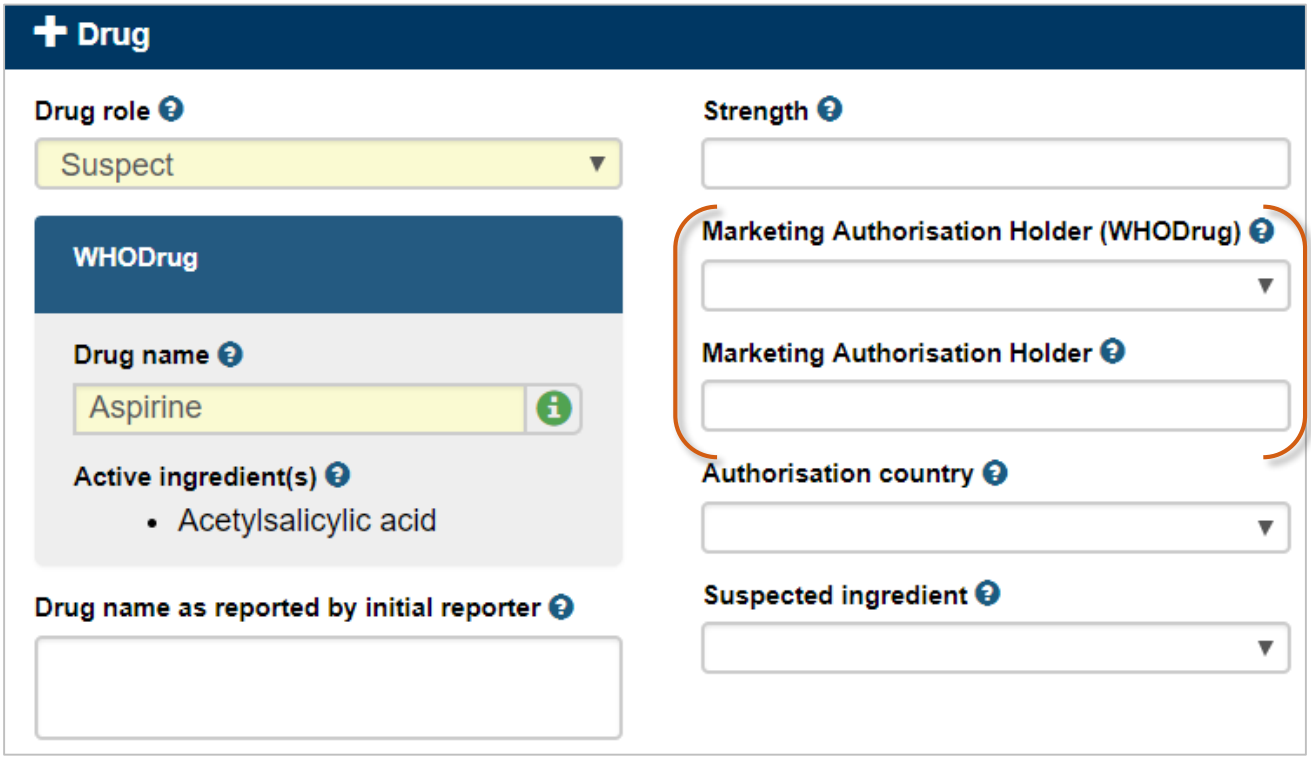
Identifying the Marketing Authorisation Holder

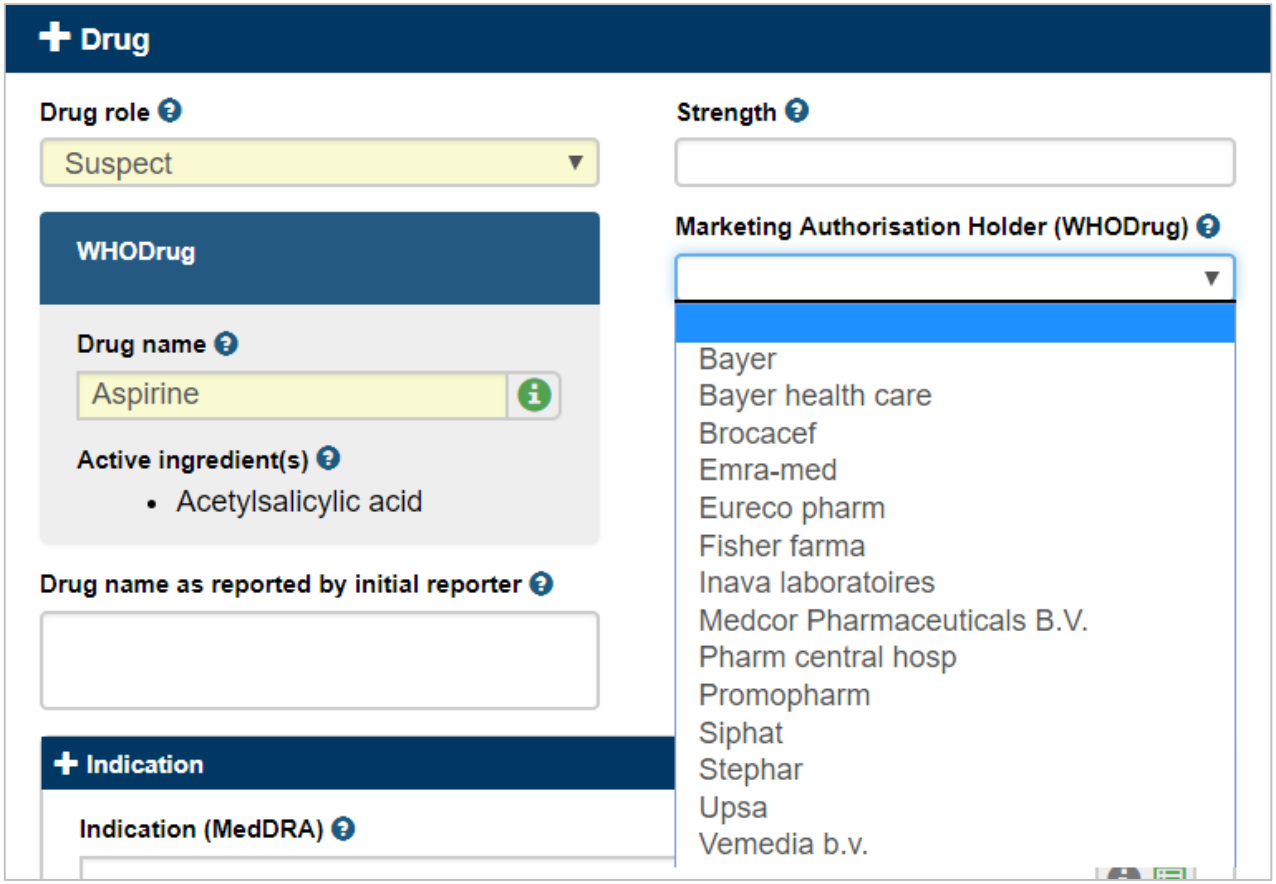
There are 2 options to identify the Marketing Authorization Holder (MAH):

- Find the corresponding MAH connected to the selected drug name in WHODrug.
- Enter the MAH name in the corresponding free-text field if the right MAH is not found in WHODrug



Finding the corresponding MAH in WHODrug

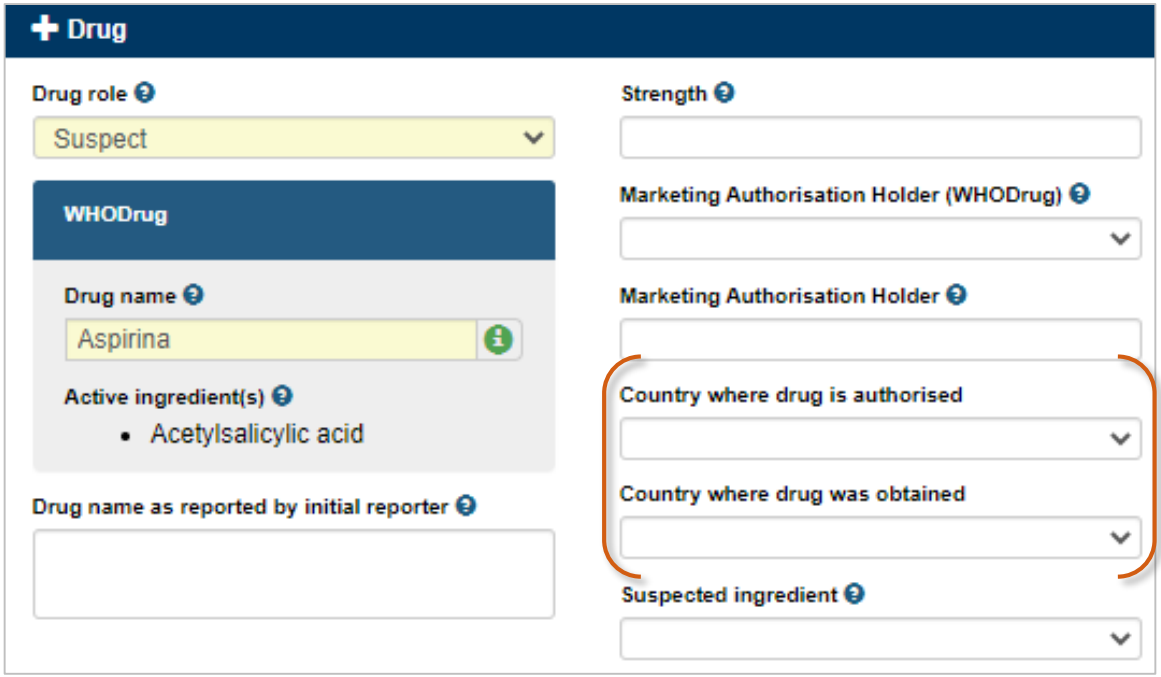
By selecting a drug in WHODrug, VigiFlow will automatically bring the list of corresponding MAHs that are registered in WHODrug for this specific drug.



Country where drug is authorised and Country where drug was obtained

In most cases, the drugs mentioned in the ICSR are registered and bought in the same country where the adverse event occurred.

However, is the drug is registered in another country, select the corresponding coutnry in **Country where drug is authorised**. Similarly, if the drug was bought in another country, select it in **Country where drug was obtained**.



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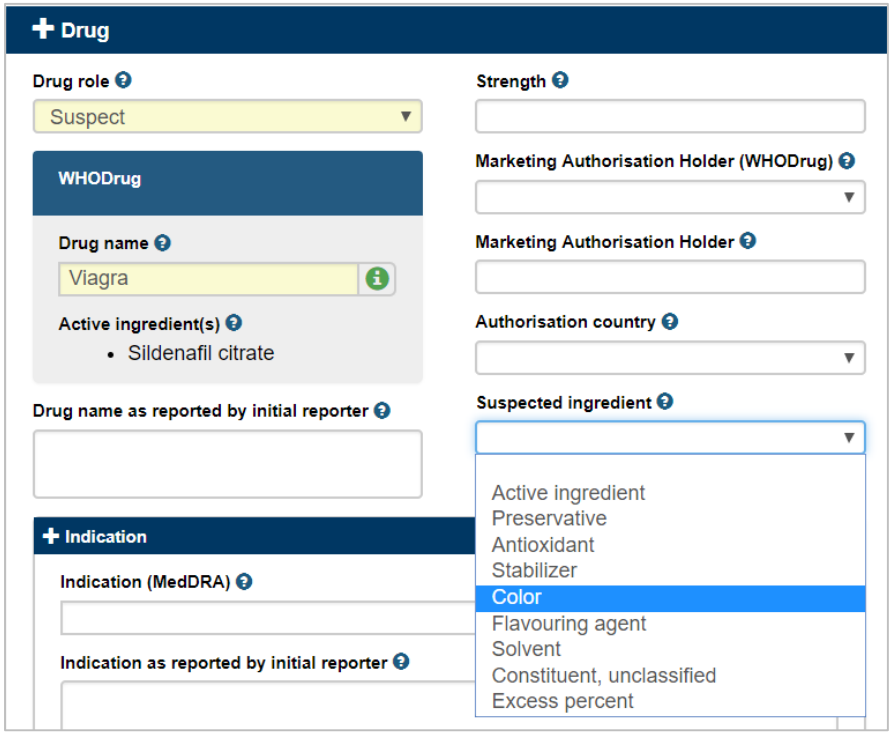
Suspected ingredient

It is possible to indicate which component of the medicinal product is the suspect of causing the events according to the following list:

- Active ingredient
- Preservative
- Antioxidant
- Stabilizer
- Color
- Flavouring agent
- Solvent
- Constituent
- Excess percent

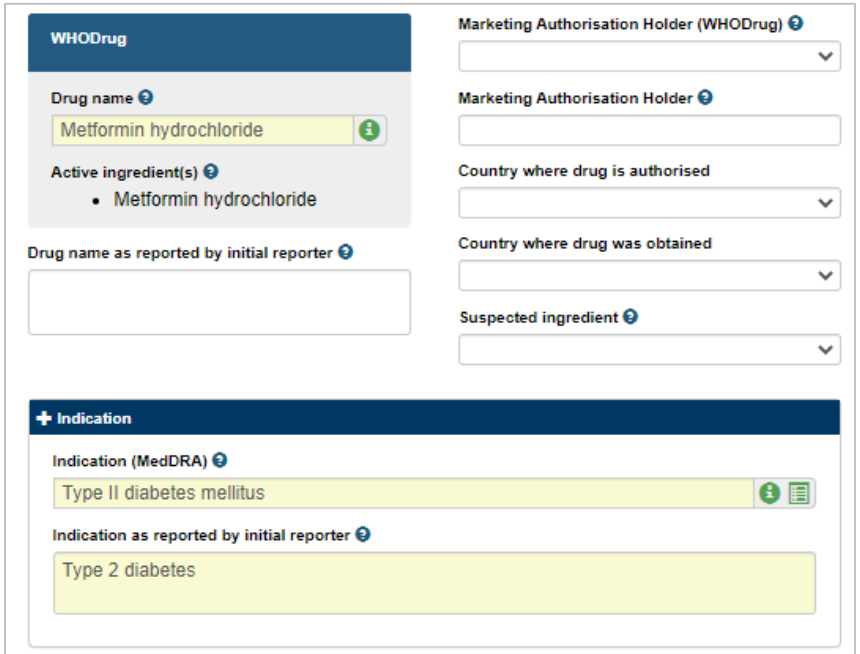


Indication

The indication to which the drug was prescribed can be registered in 2 ways:

1. Select the corresponding MedDRA term for the indication
2. Write the **Indication as reported by the initial reporter** in free-text. This field can be used when the indication described by the reporter is different than the MedDRA term or when you don't find an adequate MedDRA term.

The 2 fields can also be used in combination to reflect both what has been reported originally and its corresponding MedDRA term.



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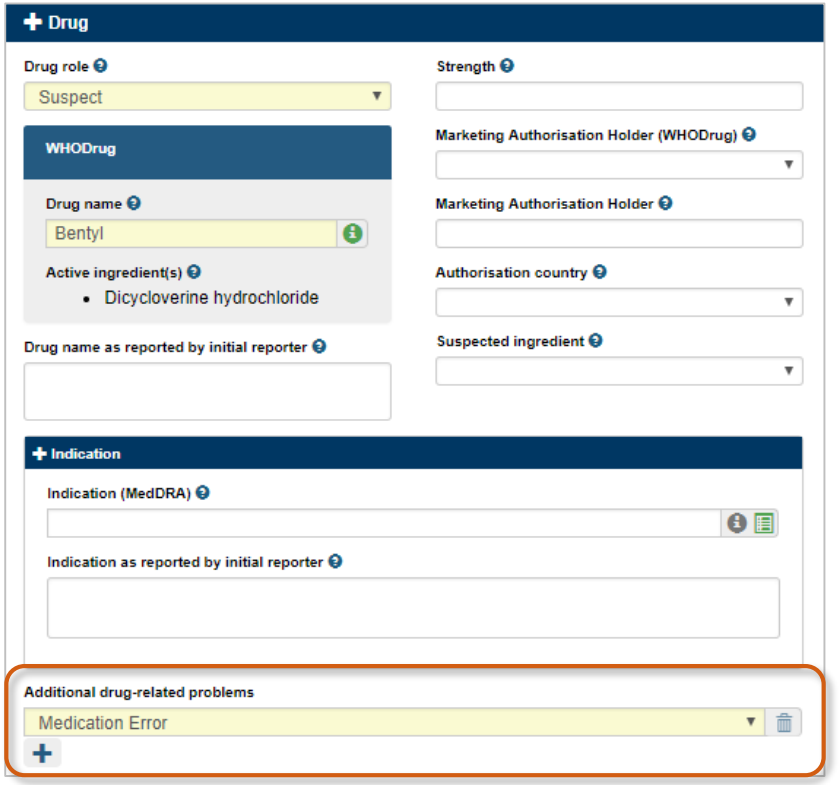
Additional drug-related problems

Use this field to indicate if the case is also related to:

- Counterfeit
- Overdose
- Drug taken by the father
- Drug taken beyond expiry date
- Batch and lot tested and found within specifications
- Batch and lot tested and found not within specifications
- Medication error
- Misuse
- Abuse
- Occupational exposure
- Off-Label use



By using this field, it will be easier to search for reports related to the same problem.

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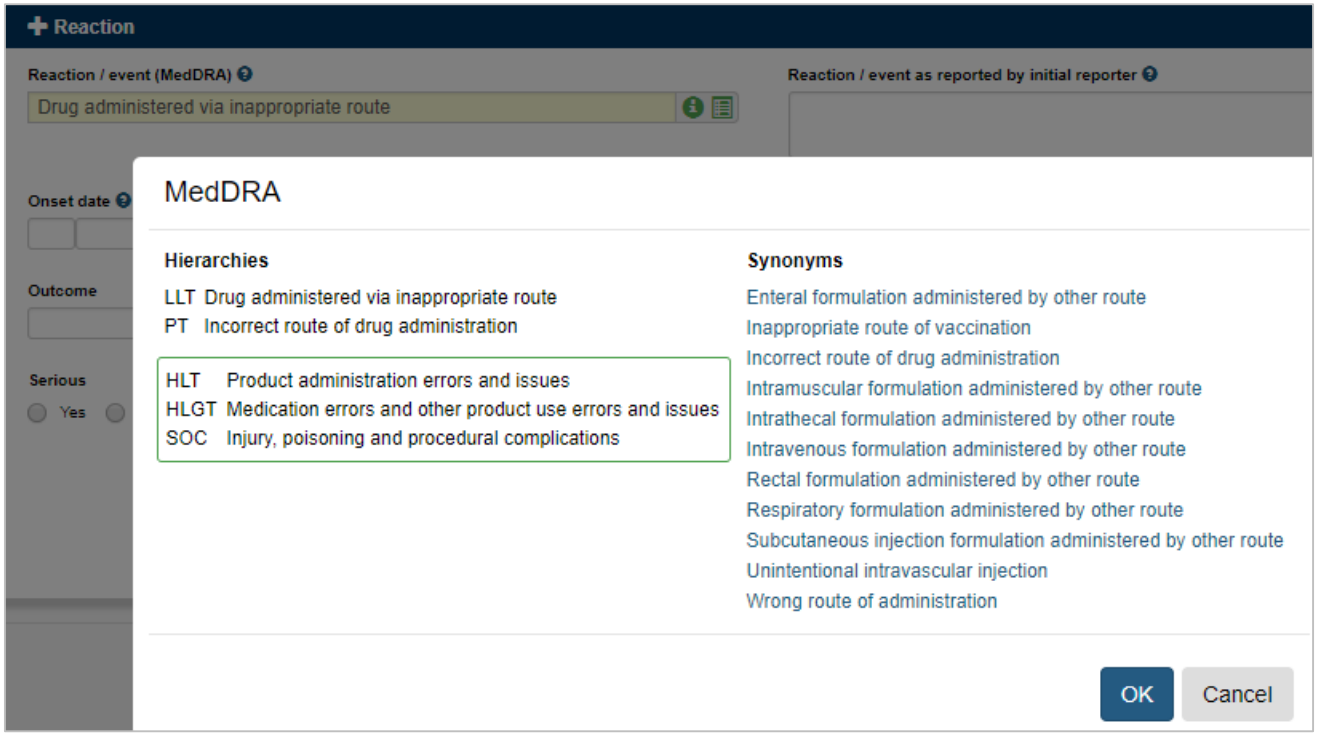
Additional drug-related problems as a reaction

The specific drug-related problem should also be included as a reaction by finding the corresponding MedDRA term.



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Dechallenge and Rechallenge according to ICH

Dechallenge:

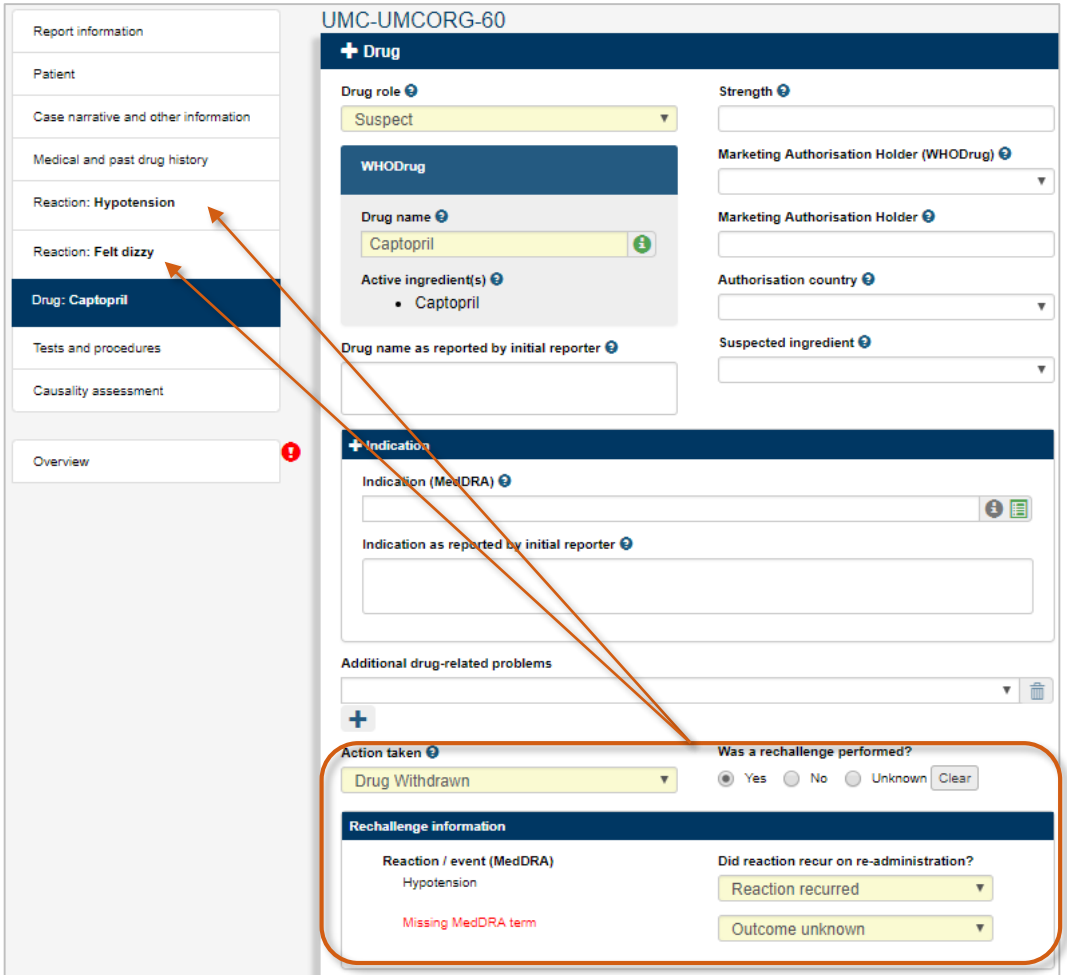
Action taken with suspect drug (i.e. drug withdrawn) due to the reaction together with the outcome of the reaction (if the patient recovered or not).

Rechallenge:

Re-administration of the suspected drug and the outcome of the rechallenge (i.e. If reaction recurred or not).

Capturing Dechallenge and Rechallenge

If answered **Yes** to the question ”**Was a rechallenge performed?**”, then a new section appears to indicate the result of each reaction.



Dosage information

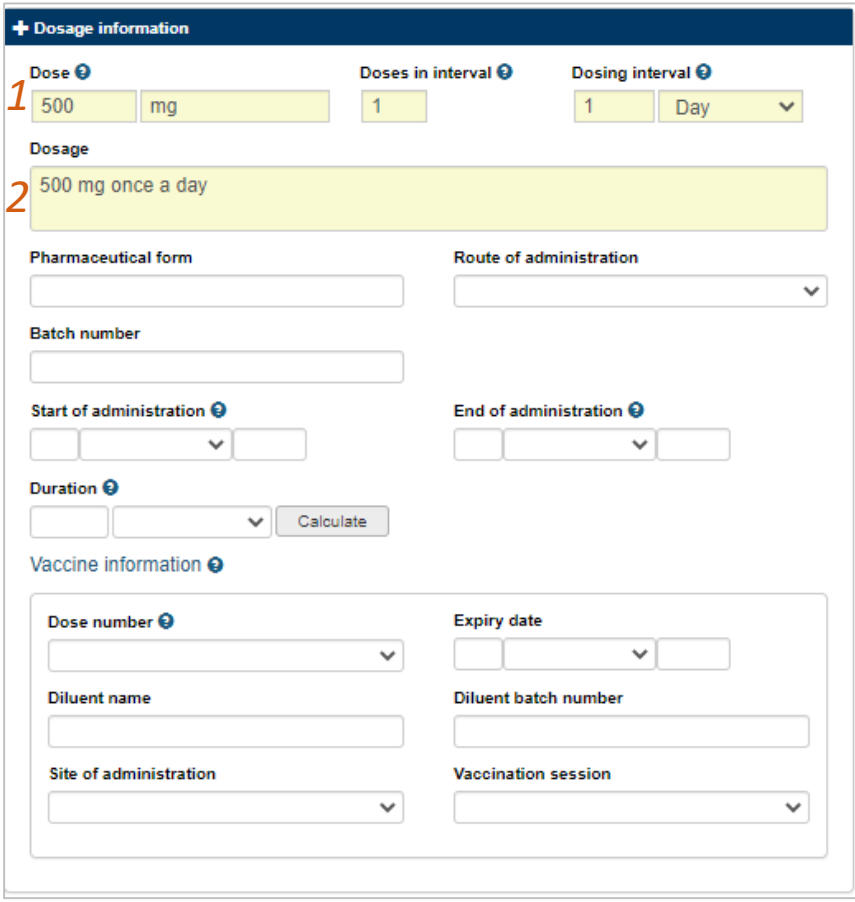
There are 2 options to enter Dosage information:

1. Use the structured fields

- **Dose**: quantity of a drug taken or recommended to be taken at a particular time
- **Doses in interval / dosing interval**: amount of doses and time interval between doses.

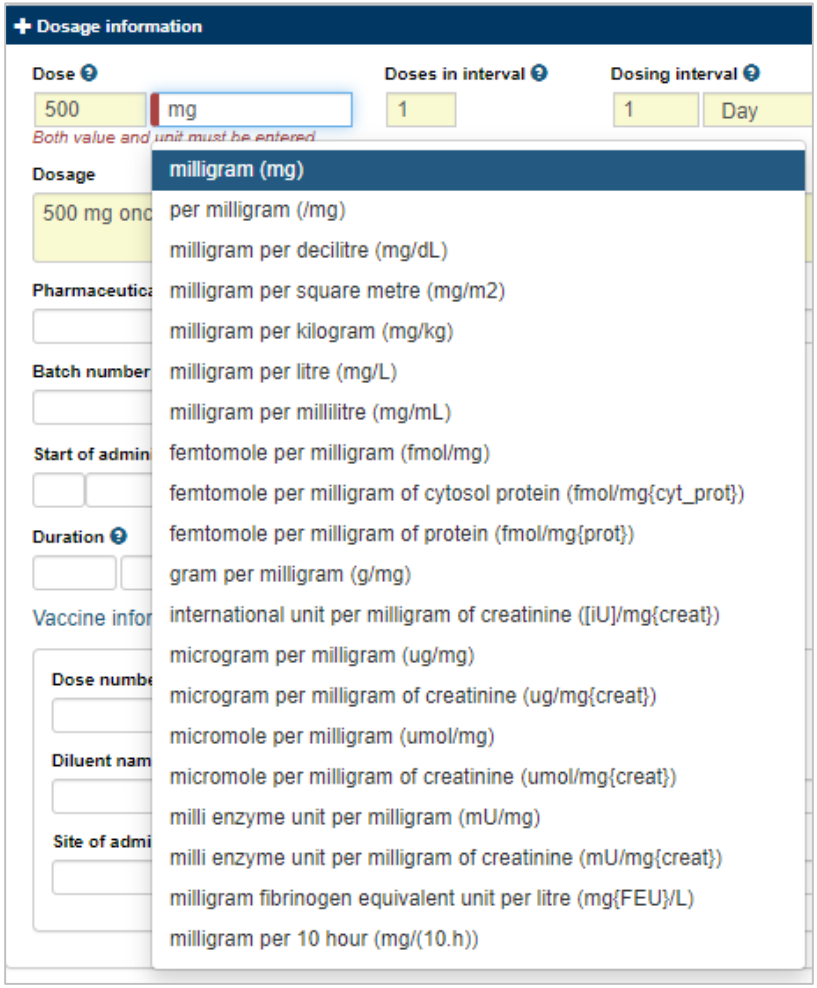
2. Entering the **Dosage** in the free-text field

The 2 options can also be used in combination to reflect both what has been reported originally and the structured representation of dosage.



Entering the dose unit

Type either the abbreviation or the description of the dose unit to see all the corresponding options available on the list.



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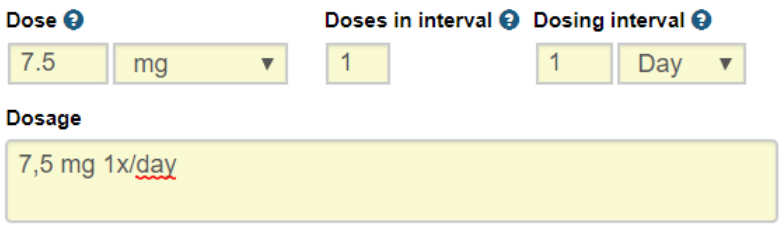
Examples: Dose / Dosing interval / Dosage

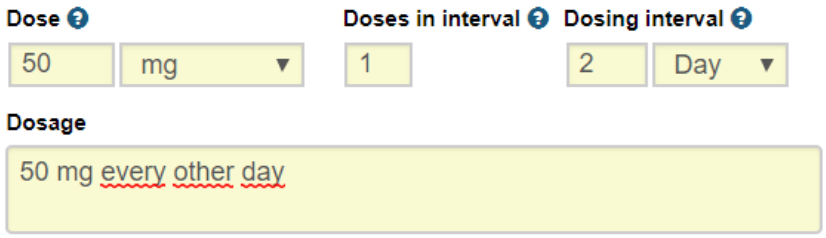
7.5 mg once daily

- Dose= 7.5 mg
- Doses in interval = 1
- Dosing interval= 1 Day



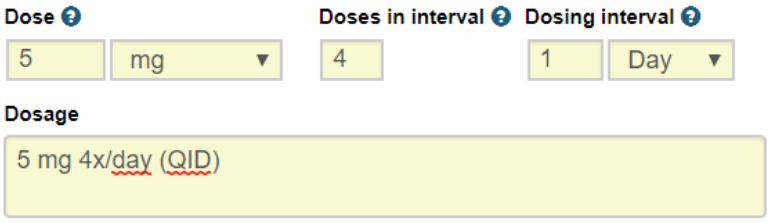
50 mg every other day

- Dose = 50 mg
- Doses in interval = 1
- Dosing interval = 2 Day



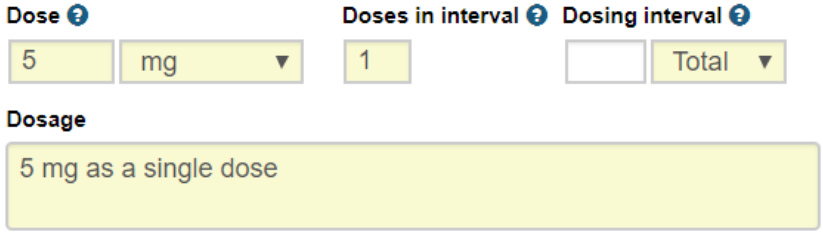
5 mg four times in one day (QID)

- *Dose=5 mg*
- *Doses in interval = 4*
- *Dosing interval = 1 Day*



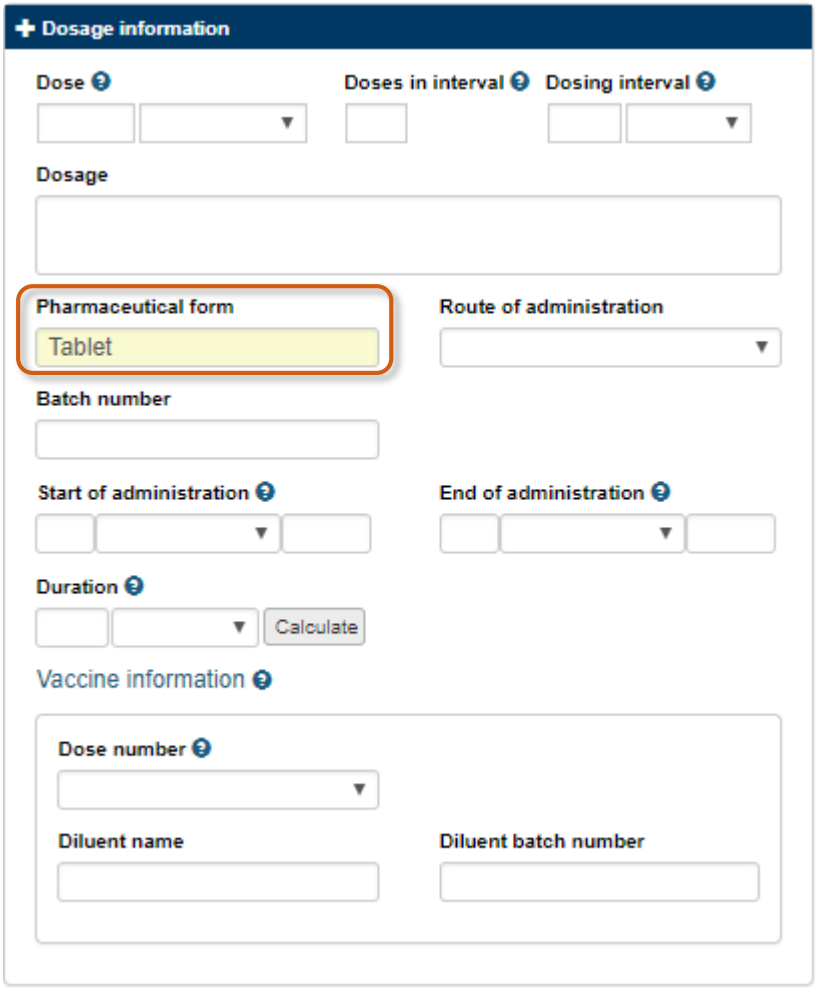
5 g as a single dose (e.g. in case of an overdose)

- Dose = 5 g
- Doses in interval = 1
- Dosing interval = Total



Pharmaceutical form

Currently, **Pharmaceutical form** is available only as free-text.



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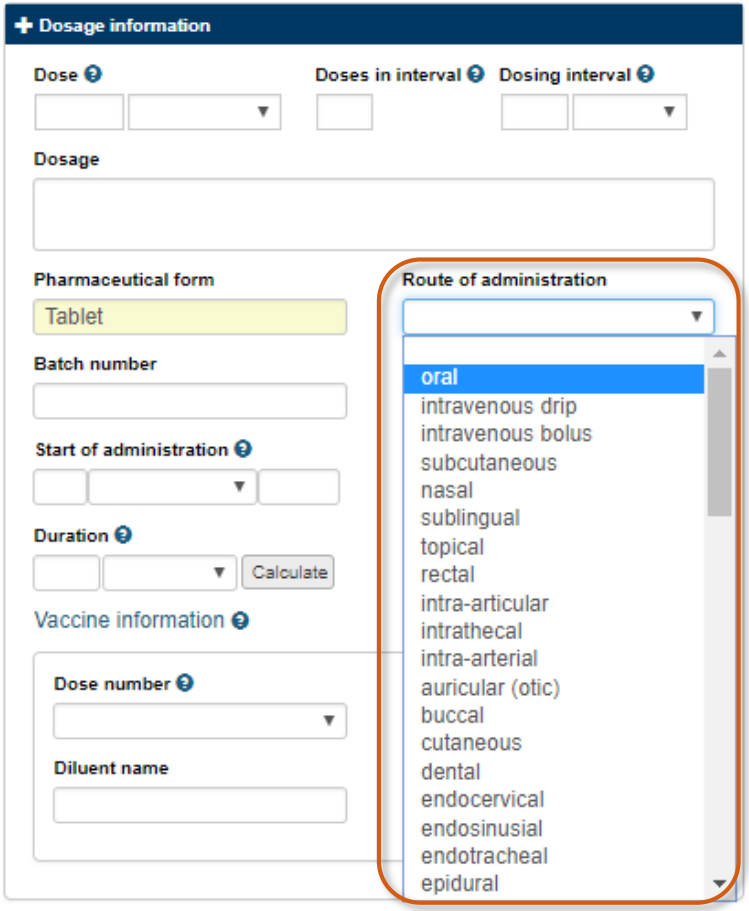
Route of administration

Route of administration can be selected from a drop-down list. If there is not an appropriate option, type the route of administration in the Dosage field.



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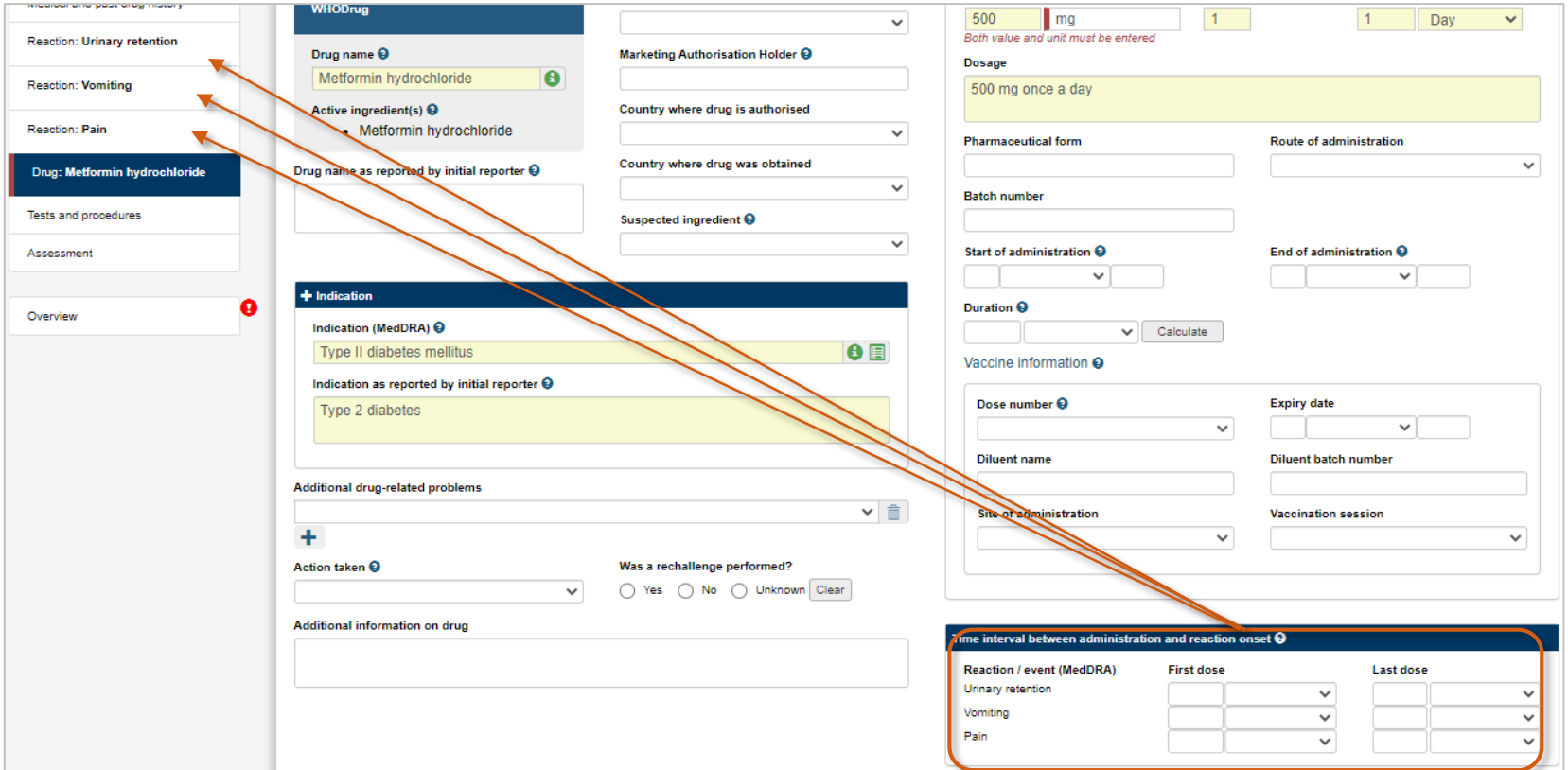
Time interval between drug administration and reaction onset

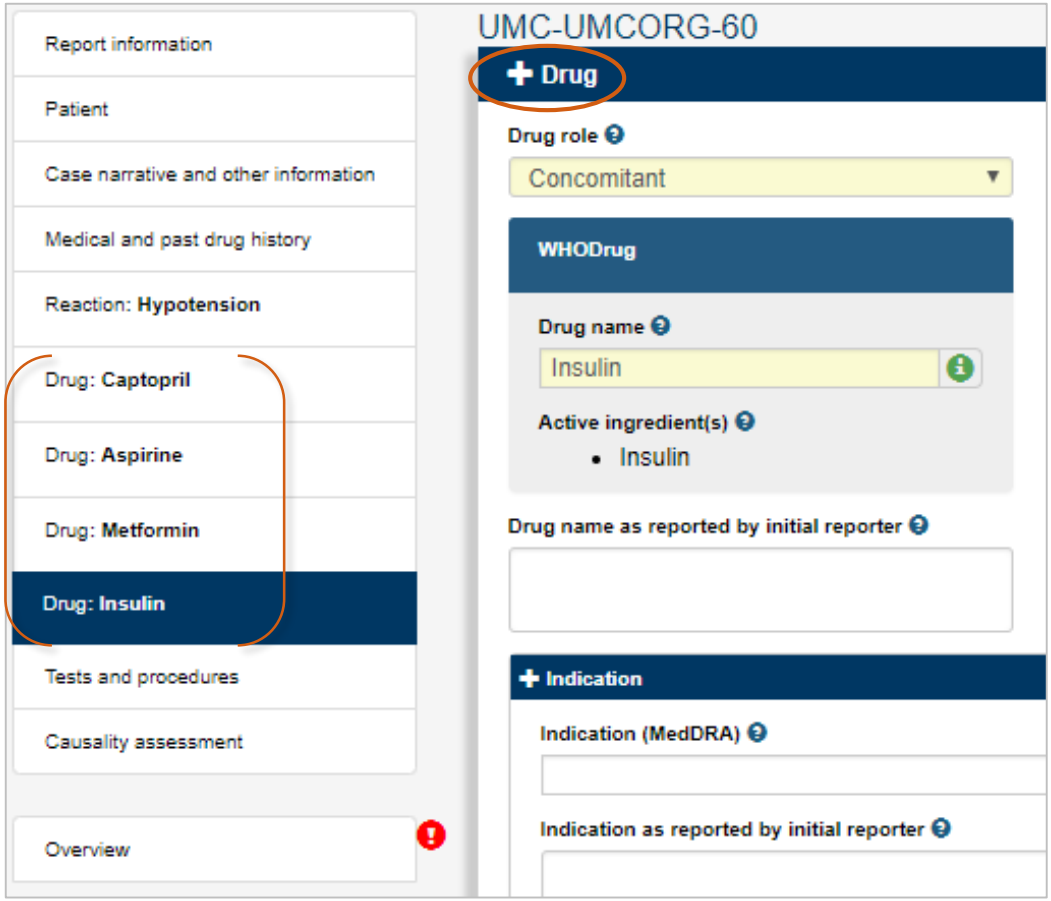
This field can be used particularly on cases when the interval between the therapy dates and the reaction onset date is too short (e.g. anaphylactic reaction).

All the listed reactions will appear automatically, no matter if they are coded in MedDRA or not.



Adding more drugs

If the ICSR refers to more than 1 drug, click the **+ Drug** to add as many sections as needed. All added drugs appear on the ICSR sections menu.



Tests and procedures

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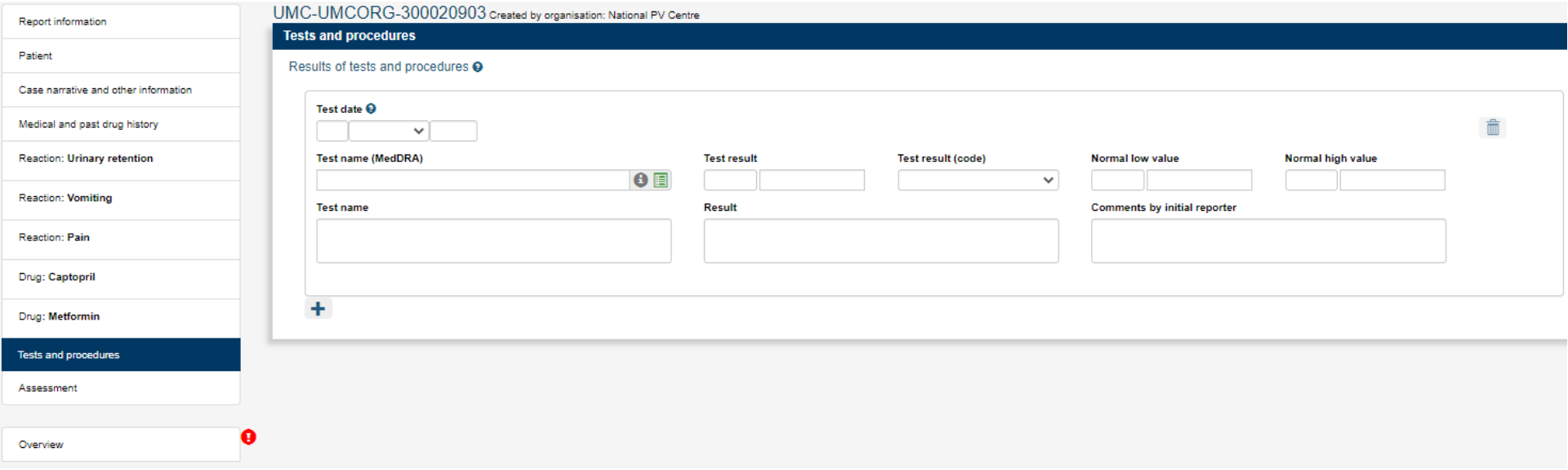
Test and procedures section

In this section, enter lab tests results that are relevant for the case assessment.



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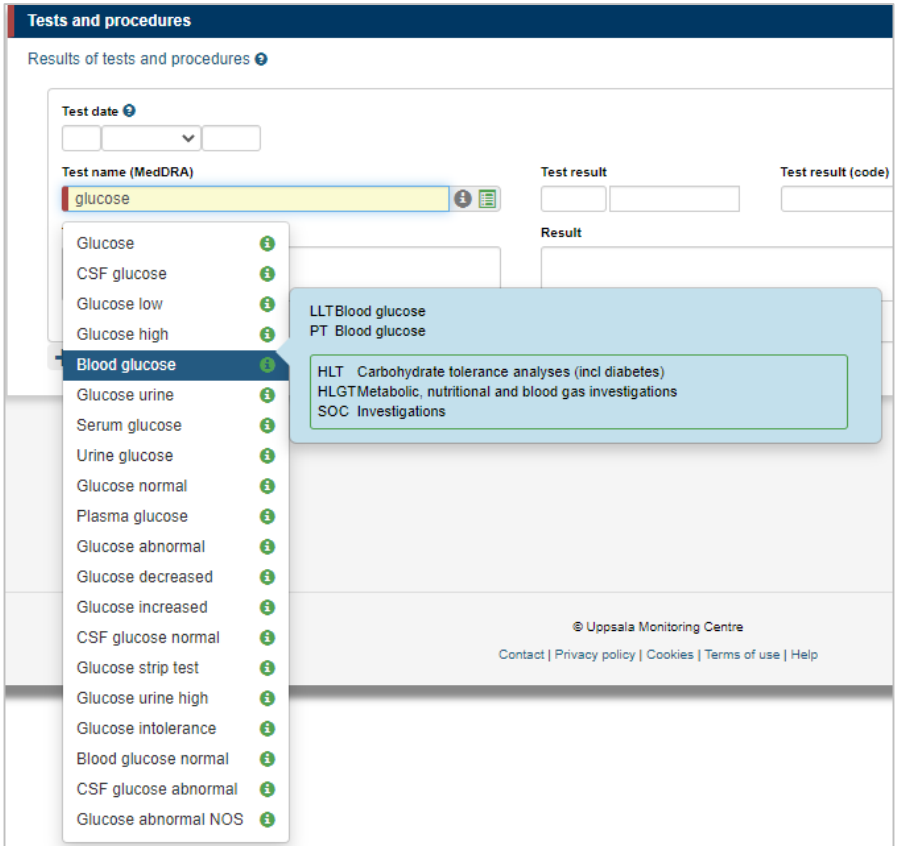
Test name

There are two options to enter the test name:

- **Test name (MedDRA)**: choose the corresponding MedDRA term under the **SOC Investigations**
- **Test name**: enter the test name in free text



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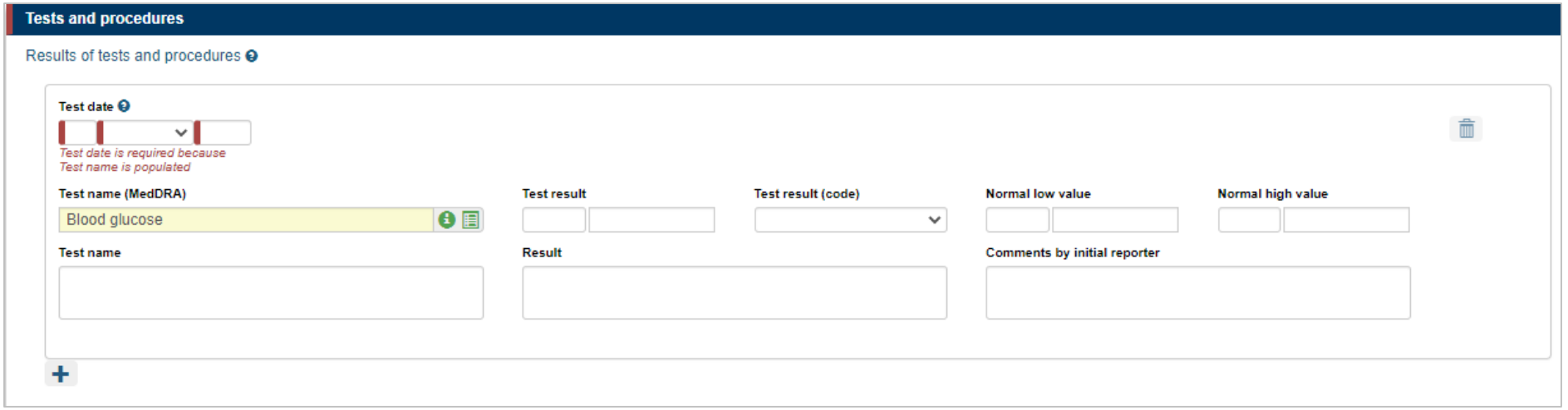
Test date

When entering a test, it becomes mandatory to enter the date when the test was performed.



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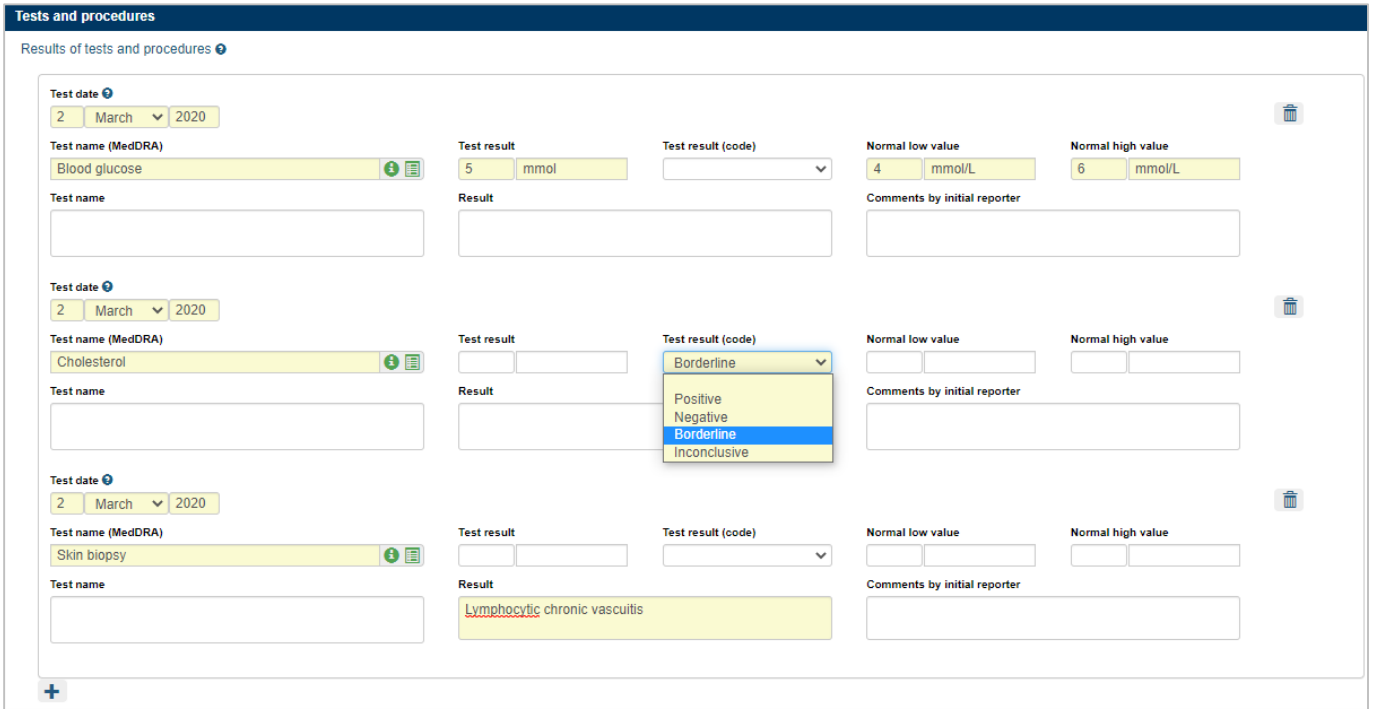
Test results

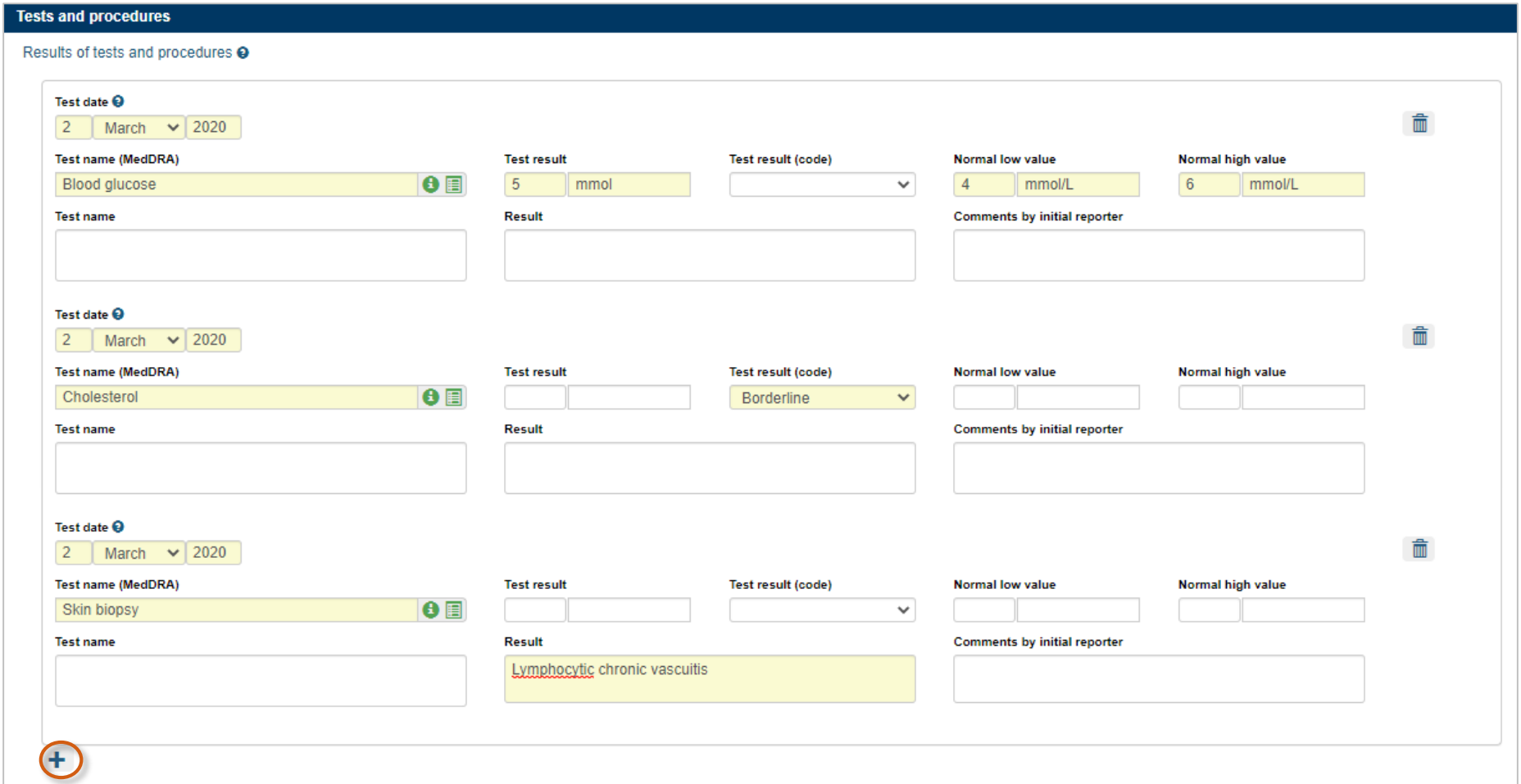
There are three options to enter the test results:

- **Test result / Normal low value / Normal high value**: for tests with measurable results
- **Test result (code)**: for tests whose results are indicated as positive, negative, borderline or inconclusive
- **Result**: for tests with free-text results that cannot be properly entered in the structured fields



Adding more test results

By clicking on the **+** button, it is possible to add more test results for either repeated tests in different dates or multiple tests.



Assessment

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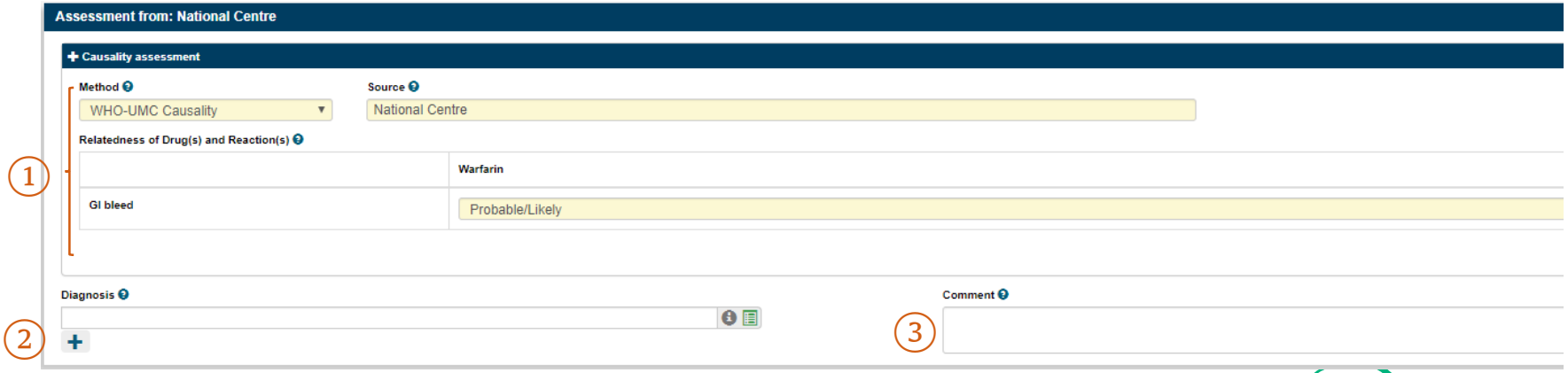
Fields available in the Assessment section

1. The causality assessment matrix
2. The field **Diagnosis** provides the opportunity to flag the case with a MedDRA-term that was not explicitly reported by the initial reporter(s); e.g. combine reported signs and symptoms into a diagnosis or if you disagree with the diagnoses given by the initial reporter(s),
3. The **Comment** field is a free text filed to capture and document any additional comments and assessments about the case (*review comment*, *pharmacovigilance comment etc.*).



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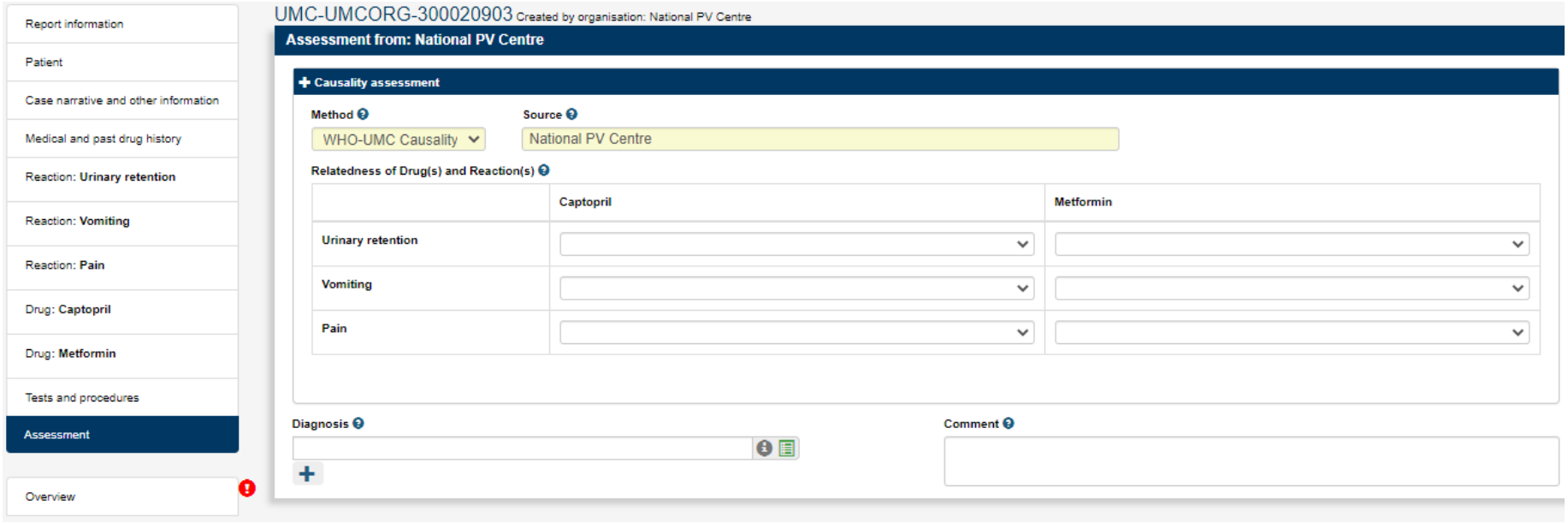
Matrix of Relatedness of Drug(s) and Reaction(s)

The matrix consists of:

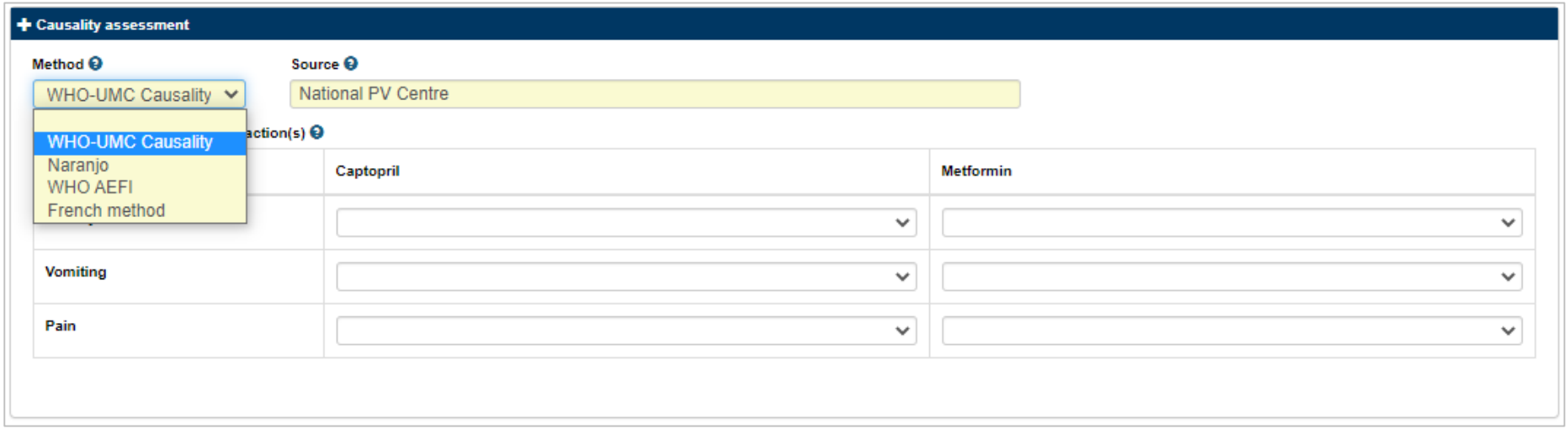
- Drugs that have been classified as either **Suspect** or **Interacting**, no matter if they were categorized in WHODrug or described in free text
- Reactions, no matter if they were categorized in MedDRA or described in free text



Causality assessment methods

VigiFlow allows to capture the causality assessment **results** of four different methods:

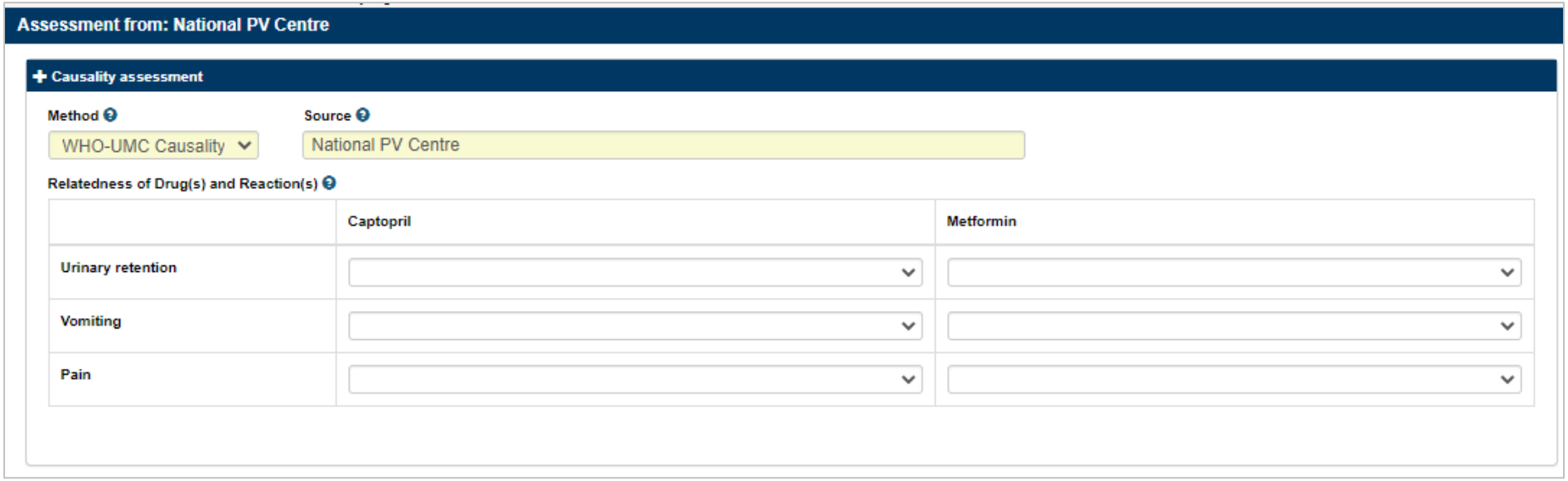
- WHO-UMC Causality (default method)
- Naranjo
- WHO AEFI
- The French method



Causality assessment - Source

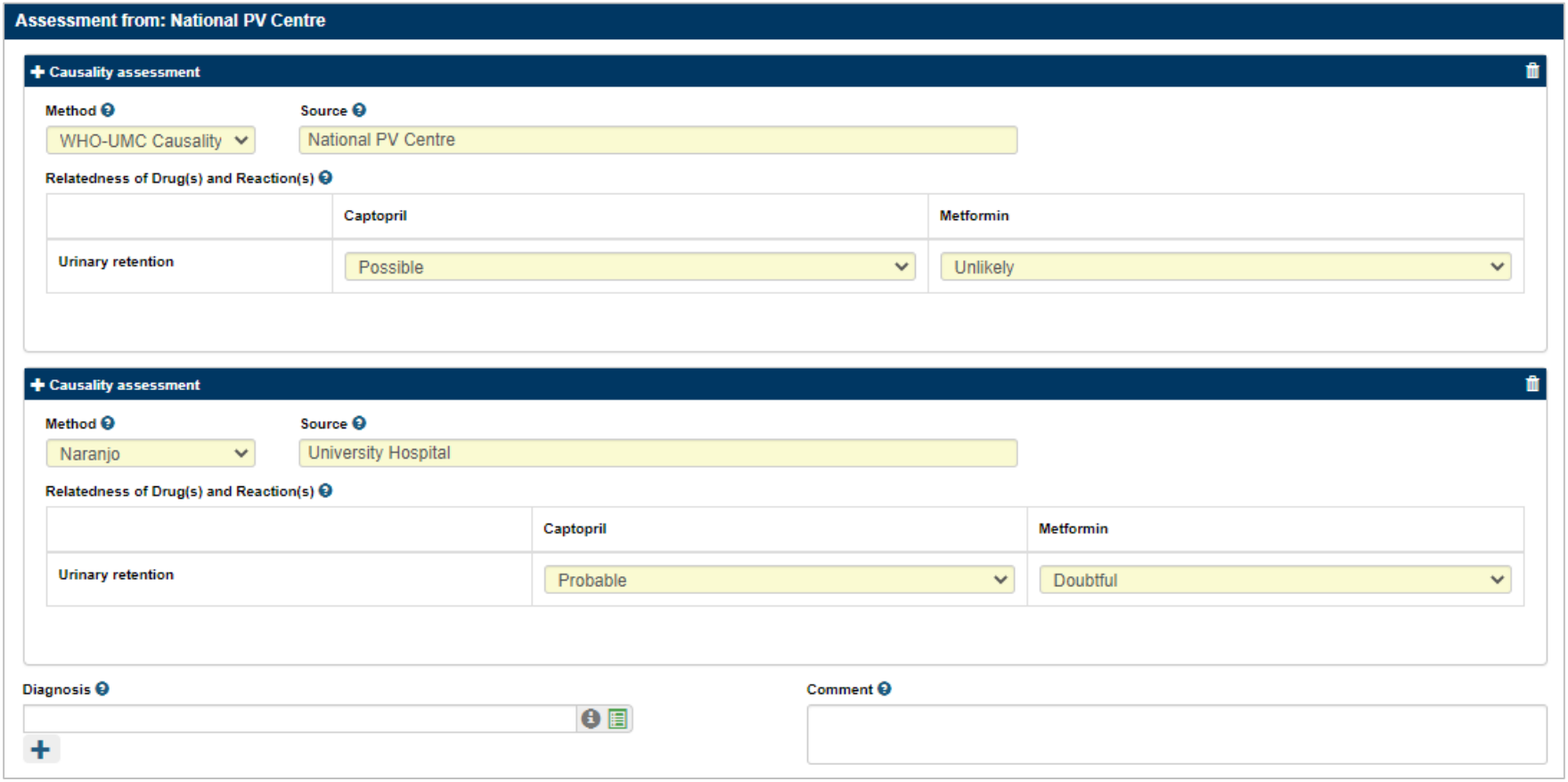
Source is the name of the organisation that performed the assessment. It can be the initial reporter, the national PV centre or any other organization.

By default, VigiFlow shows the name of the organisation to which the user belongs to.



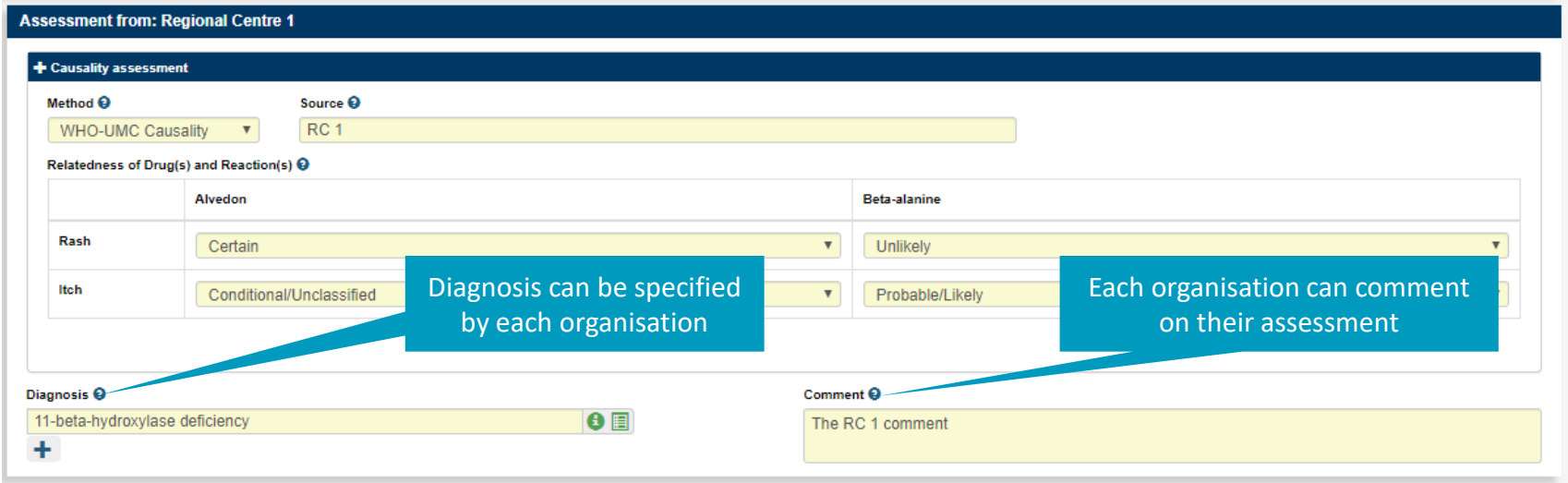
Causality assessment results

If the national PV centre disagrees with the causality assessment made by the initial reporter or uses a different method, VigiFlow allows to capture the different assessments in separate matrices indicating the different sources.



Assessment section – for a decentralized organisational VigiFlow structure

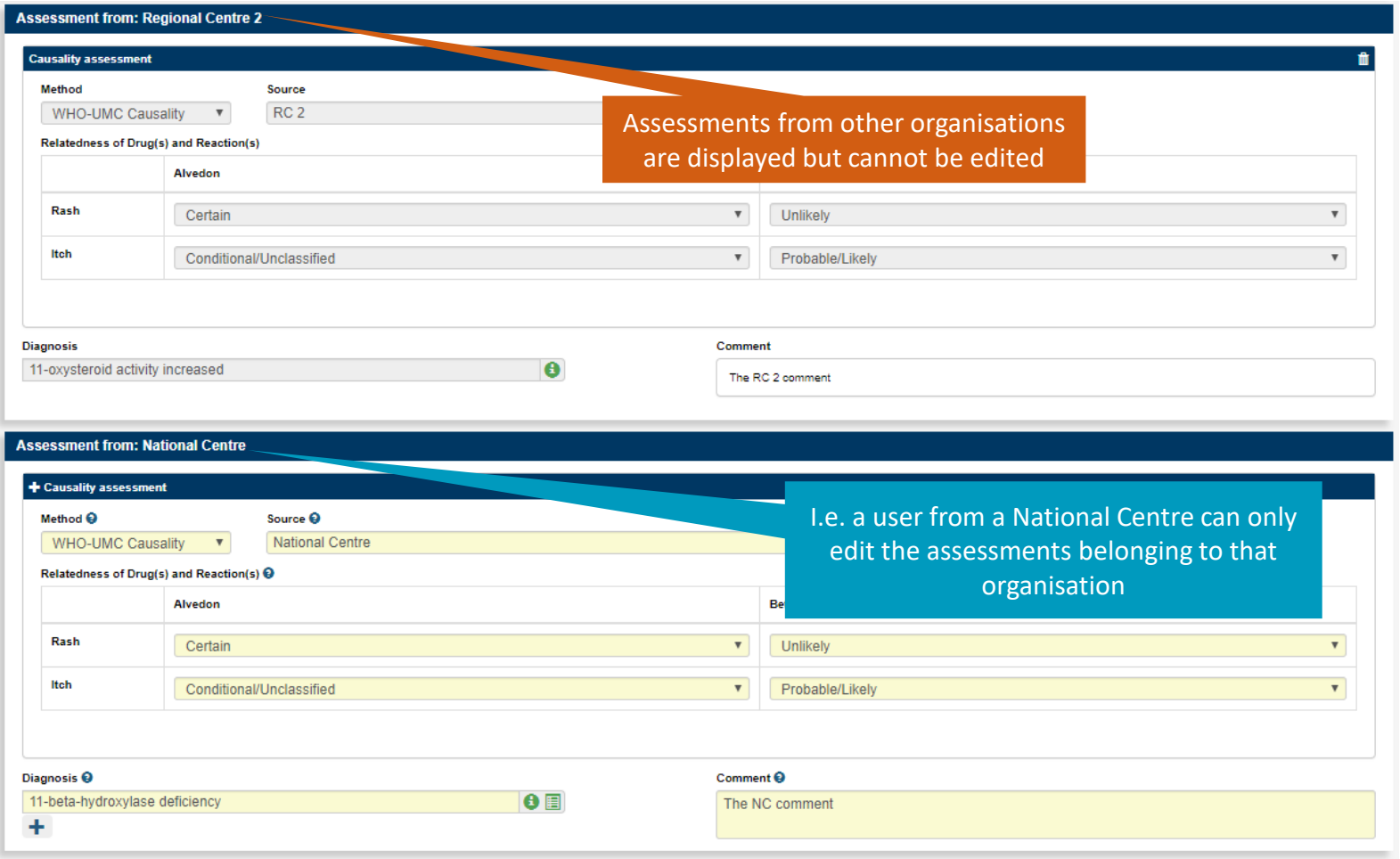
To allow for flexibility in the case management process, all organisations in the structure can enter *causality, diagnosis and comment* in the assessment section, not only National Centres.



It is only National Centres that can delete assessments, ie Regional Centres can add and edit assessments but not delete.

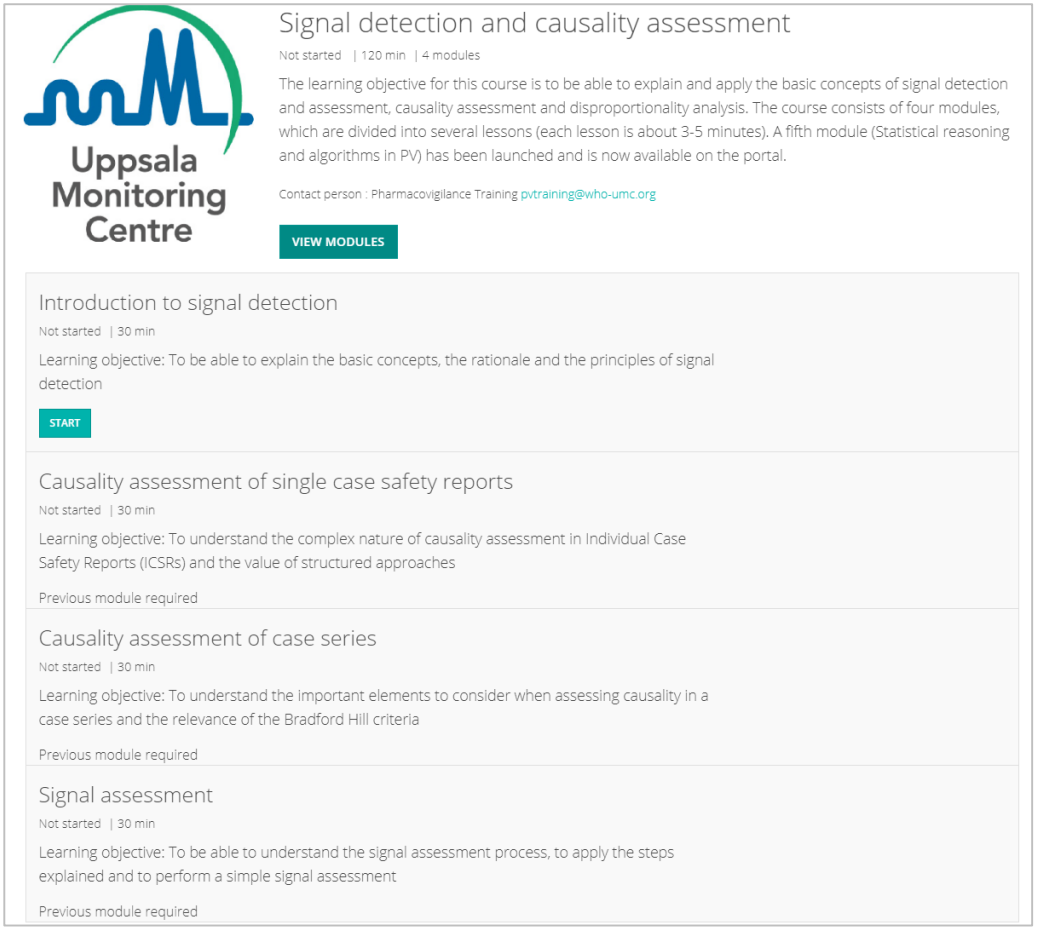
Assessment section – for a decentralized organisational VigiFlow structure

Each organisation can view all assessments in a report but can only edit their own.



UMC's online course on signal detection and causality assessment

If you would like to learn more about Assessment and signal detection, sign up for the free online course developed by the UMC at https://www.who-umc.org/education-training/online-courses/



Specific fields for Adverse Events Following Immunization (AEFIs)

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Enter AEFIs in VigiFlow

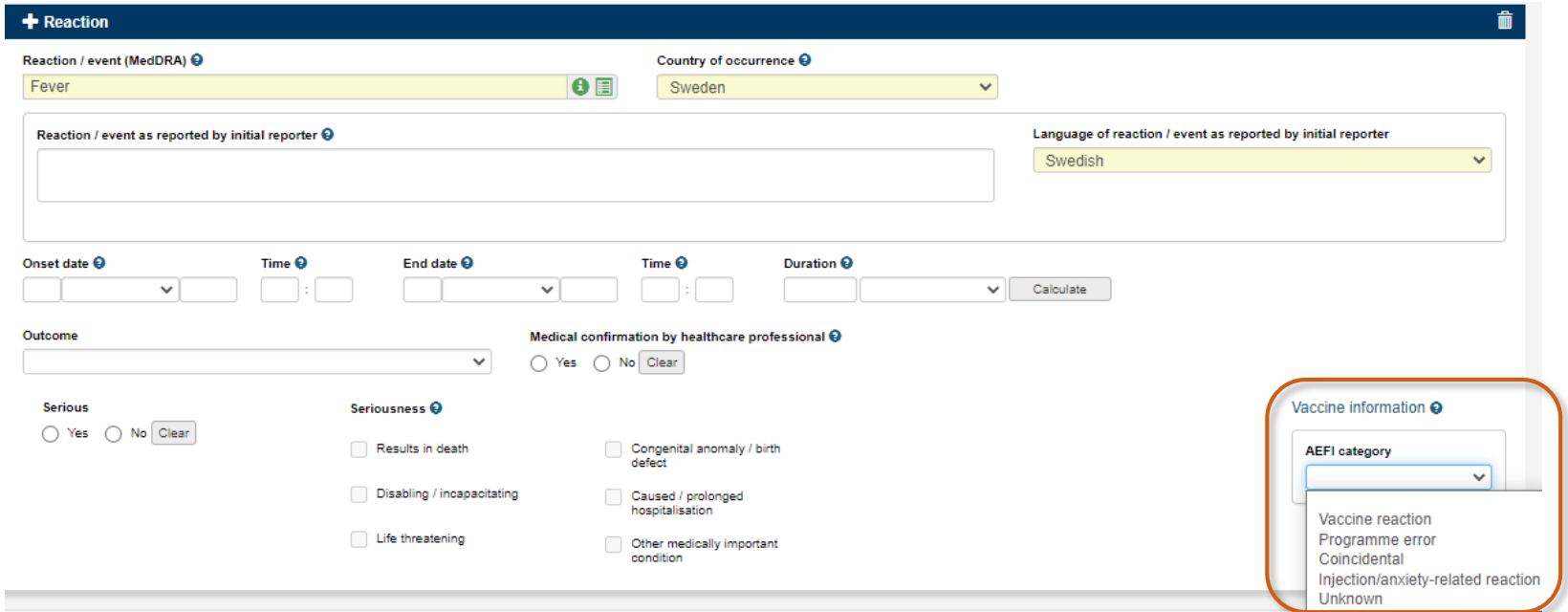
In the same way as suspected adverse drug reactions are registered in VigiFlow, it is possible to use the same data entry fields to register adverse events following immunization (AEFIs).

Due to the particularities of AEFIs, there are fields to capture specific data from the vaccines suspected of having caused adverse events and they will be explained in the upcoming slides.

Reaction – AEFI category

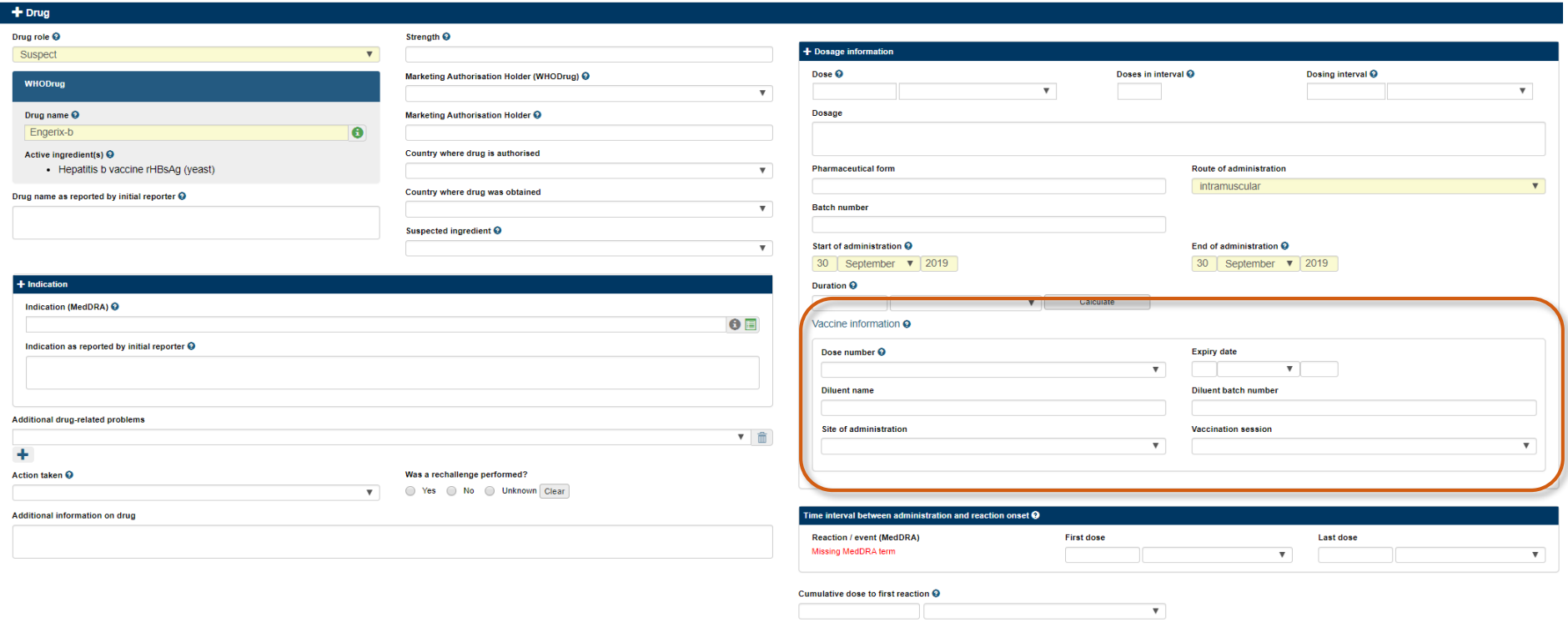
The AEFI category field can be used to indicate if each adverse event is related to:

- Vaccine reaction
- Programme error
- Coincidental
- Injection / anxiety-related reaction
- Unknown



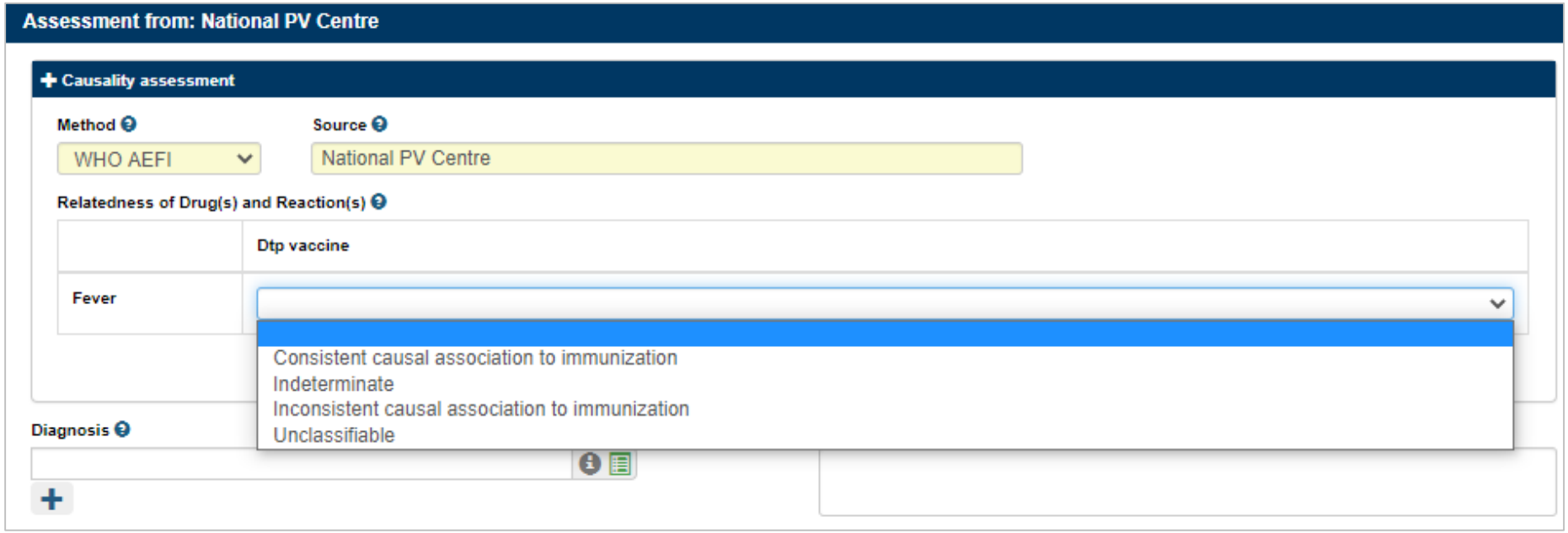
Drug - Vaccine information

If the ICSR is related to a vaccine, the suspect vaccine information shall be entered as any other drug. In addition, there are specific fields to capture information about vaccines; ***Dose number, Expiry date, Diluent name, Diluent batch number, Site of administration and Vaccination session***



Assessment

It is possible to register the results of causality assessment performed with the method developed by WHO to evaluate adverse events following immunization by selecting the **WHO AEFI** option.



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Questions:
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