

VigiFlow

Working with the DATA ENTRY section



– Building a global safety culture

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.

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

Accessing the Data Entry page

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

Report list VigiFlow - National PV Centre User name

+ New ICSR Import Export Manage accounts VigiLyze Filter PDF/Excel/XML

0 ICSRs selected 20558 ICSRs match your search with 0 filter(s) applied Page 1 of 1028

<input type="checkbox"/> Worldwide unique id	<input type="checkbox"/> Delegated to organisation	<input type="checkbox"/> Initials	<input type="checkbox"/> Date of birth	<input type="checkbox"/> Reaction / event (MedDRA)	<input type="checkbox"/> Drug name (WHODrug)	<input type="checkbox"/> Initial received date	<input type="checkbox"/> Latest received date	<input type="checkbox"/> Status of report	<input type="checkbox"/> VigiLyze
<input type="checkbox"/> JMC-UMCORG-300020902	JL Hospital A2	TJ		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> JMC-UMCORG-300020901	AB Regional Centre A			Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Closed	✓
<input type="checkbox"/> JMC-UMCORG-300020900	UN National PV Centre			Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> JMC-UMCORG-300020899	UN National PV Centre			Hypotension	Lamictal	27072020	27072020	Open	
<input type="checkbox"/> AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
<input type="checkbox"/> LV-EMA-Testcase08-nullify...	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
<input type="checkbox"/> DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27062019	07072020	Open	
<input type="checkbox"/> JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27062019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27062019	07072020	Open	
<input type="checkbox"/> US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27062019	07072020	Open	
<input type="checkbox"/> SE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
<input type="checkbox"/> NO-VHC-5678	National PV Centre	ABC	30062000	Pregnancy, Lack of drug effect		01072020	01072020	Closed	!
<input type="checkbox"/> MX-002147023_T-NVSC2021MX076824	National PV Centre	POP	08051950	Angina pectoris	Oxcarbazepine	26062020	26062020	Closed	
<input type="checkbox"/> JMC-UMCORG-300020894	CA National PV Centre					15062020	15062020	Closed	
<input type="checkbox"/> JMC-UMCORG-300020893	TL National PV Centre			Rash gum	Ipamol	10062020	10062020	Closed	✓
<input type="checkbox"/> JMC-UMCORG-300020892	SA National PV Centre				Paracetamol	09062020	09062020	Closed	
<input type="checkbox"/> JMC-UMCORG-300020891	CA National PV Centre				Ursolfalk	08062020	08062020	Under assessment	
<input type="checkbox"/> JMC-UMCORG-300020890	CA 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

Data entry

VigiFlow - National PV Centre

User name

< To Report list + New ICSR VigiLyze

Delegate to organisation Status of report: Open Delete Send copy PDF/Excel/XML Save

Report information

- Patient
- Case narrative and other informat...
- Medical and past drug history
- Reaction
- Drug
- Tests and procedures
- Assessment

Overview

Unsaved ICSR

Report information

Report title

Report type

Initial received date

Initial report date

Received from

Other report id

Report id	Source
<input type="text"/>	<input type="text"/>

Add

Does this case fulfil the local criteria for an expedited report?

Yes No

Parent Child report

Initial reporter information

Sender information

Link ICSR

Notes

Literature report

Study information

Documents

+ Initial reporter information

Reporter qualification

Title

Country of reporter

Primary

Given name

Family name

Department

Organisation

Street address

City

State or Province

Postal code

Telephone

Email address

Functions in the top bar menu

The screenshot displays the top bar menu of the Uppsala Monitoring Centre interface. The menu items are: < To Report list, + New ICSR, and VigiLyze. Below the menu, the main content area shows the 'Unsaved ICSR' form with various input fields and buttons. Callouts point to specific functions:

- Go back to Report list (points to < To Report list)
- Enter another ICSR (points to + New ICSR)
- Access VigiLyze (points to VigiLyze)
- Delegate ICSR to another organisation* (points to Delegate to organisation)
- Change status of report* (points to Status of report: Open)
- Delete this ICSR (points to Delete)
- Send a copy of this ICSR to VigiBase (points to Send copy)
- Export ICSR to PDF or XML (points to PDF/Excel/XML)
- Save ICSR (points to Save)

The main content area shows the 'Unsaved ICSR' form with the following fields and buttons:

- Report title (text input)
- Report type (dropdown menu)
- Initial received date (31 July 2020)
- Initial report date (text input)
- Received from (dropdown menu)
- Other report id (text input)
- Report id (text input)
- Source (text input)
- Add (button)
- Does this case fulfil the local criteria for an expedited report? (radio buttons for Yes/No, Clear button)
- Parent Child report (checkbox)
- Initial reporter information (tab)
- Sender information (tab)
- Link ICSR (tab)
- Notes (tab)
- Literature report (tab)
- Study information (tab)
- Documents (tab)

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.

The screenshot displays the VigiFlow interface for viewing an ICSR report. On the left, a vertical menu lists various sections: 'Report information', 'Patient' (which is highlighted with a dark blue background and an orange border), 'Case narrative and other informat...', 'Medical and past drug history', 'Reaction', 'Drug', 'Tests and procedures', and 'Assessment'. Below this menu is an 'Overview' button with a red warning icon. The main content area is titled 'Unsaved ICSR' and features a dark blue header for the 'Patient' section, also with a red warning icon. The form contains several input fields: 'Initials' (text box), 'Sex' (dropdown menu), 'Date of last menstruation' (calendar icon), 'Body weight (kg)' (text box), 'Body height (cm)' (text box), 'Date of birth' (calendar icon), 'Age at onset of reaction' (dropdown menu), and 'Age group' (dropdown menu). At the bottom of the form, there is an 'Additional fields' dropdown menu.

Viewing mode – (2) Overview

VigiFlow offers 2 viewing modes for data entry:

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

The screenshot displays the 'Overview' viewing mode for an 'Unsaved ICSR' report. On the left, a vertical navigation menu lists various report sections: Report information, Patient, Case narrative and other information, Medical and past drug history, Reaction, Drug, Tests and procedures, and Assessment. The 'Overview' option is highlighted with an orange border and a red notification icon.

The main content area is titled 'Unsaved ICSR' and contains several sections:

- Report information:** Includes fields for Report title, Report type, Initial received date (31 July 2020), Initial report date, Received from, and Other report id (with Report id and Source sub-fields).
- Expedited criteria:** A question 'Does this case fulfil the local criteria for an expedited report?' with radio buttons for 'Yes' and 'No', and a 'Clear' button.
- Parent Child report:** A checkbox option.
- Navigation tabs:** Initial reporter information, Sender information, Link ICSR, Notes, Literature report, Study information, and Documents.
- + Initial reporter information:** A detailed form with fields for Reporter qualification, Title, Country of reporter (Sweden), Primary (checked), Given name, Family name, Department, Organisation, Street address, City, State or Province, Postal code, Telephone, and Email address.
- Patient:** Fields for Initials, Sex, Date of last menstruation, Body weight (kg), Body height (cm), Date of birth, Age at onset of reaction, and Age group.
- Additional fields:** A dropdown menu for further data entry.
- Case narrative and other information:** The bottom-most section, partially visible.

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.

The screenshot shows the ICSR report form in the Vigilyze system. The top navigation bar includes a 'Save' button circled in red. The main form area is titled 'UMC-UMCORG-300020903' and contains several sections for report information, including 'Report information', 'Initial reporter information', and 'Initial received date'. The 'Save' button is located in the top right corner of the interface.

Navigation: < To Report list | + New ICSR | Vigilyze

Actions: Delegate to organisation | Status of report: Open | Delete | Send copy | PDF/Excel/XML | **Save**

Report ID: UMC-UMCORG-300020903 | Created by organisation: National PV Centre

Report information

Report title	Report type: Spontaneous report	Worldwide unique id: UMC-UMCORG-300020903	Safety report id: UMC-UMCORG-300020903
Initial received date: 31 July 2020	Initial report date	Received from: Patient / Consumer	Other report id
Latest received date: 31 July 2020	Does this case fulfil the local criteria for an expedited report? <input type="radio"/> Yes <input type="radio"/> No <input type="button" value="Clear"/>		
<input type="checkbox"/> Parent Child report			

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

+ Initial reporter information

Reporter qualification: Consumer or other Non-Health Profession	Title	Country of reporter: Sweden	<input checked="" type="checkbox"/> Primary
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Safety Report ID creation

The screenshot shows the 'Unsaved ICSR' form in the iLyze system. The form is titled 'Report information' and contains several fields: 'Report title' (empty), 'Report type' (Spontaneous report), 'Initial received date' (31 July 2020), 'Initial report date' (empty), 'Received from' (Patient / Consumer), and 'Other report id' (empty). The 'Unsaved ICSR' text is circled in orange.

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

The screenshot shows the 'Saved ICSR' form in the iLyze system. The form is titled 'Report information' and contains several fields: 'Report title' (empty), 'Report type' (Spontaneous report), 'Initial received date' (31 July 2020), 'Initial report date' (empty), 'Received from' (Patient / Consumer), and 'Other report id' (empty). The 'Other report id' field is populated with 'UMC-UMCORG-300020903'. The 'Worldwide unique id' and 'Safety report id' fields are also populated with 'UMC-UMCORG-300020903'. The 'UMC-UMCORG-300020903' text is circled in orange, and arrows point from it to the 'Worldwide unique id' and 'Safety report id' fields.

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

UMC-UMCORG-300020903 Created by organisation: National PV Centre

Report information

Report title	Report type	Worldwide unique id	Safety report id
<input type="text"/>	Spontaneous report	UMC-UMCORG-300020903	UMC-UMCORG-300020903
Initial received date	Initial report date	Received from	Other report id
31 July 2020	<input type="text"/>	Patient / Consumer	Report id Source

Example 2

MX-SA-2020SA000185 Created by organisation: National PV Centre

Report information

Report title	Report type	Worldwide unique id	Safety report id
<input type="text"/>	Spontaneous report	MX-SA-2020SA000185	UMC-UMCORG-300020886
Initial received date	Initial report date	Received from	Other report id
27 May 2020	<input type="text"/>	Pharmaceutical Company	Report id Source

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.

The screenshot displays the UMC-UMCORG-300020903 report page. A modal dialog titled "Delete of ICSR" is centered on the screen. The dialog contains the following text and elements:

- Title:** Delete of ICSR
- Form:** Reason for delete of ICSR: [Text input field]
- Text:** If you delete, the ICSR will be inactivated. However you can find deleted ICSRs in Report list.
- Buttons:** Delete (blue), Cancel (white with black border)

The background interface shows the "Report information" section with the following details:

- Report title:** [Empty field]
- Report type:** Spontaneous report
- Worldwide unique id:** UMC-UMCORG-300020903
- Safety report id:** UMC-UMCORG-300020903
- Initial received date:** 31 July 2020
- Latest received date:** 31 July 2020
- Parent Child report:**

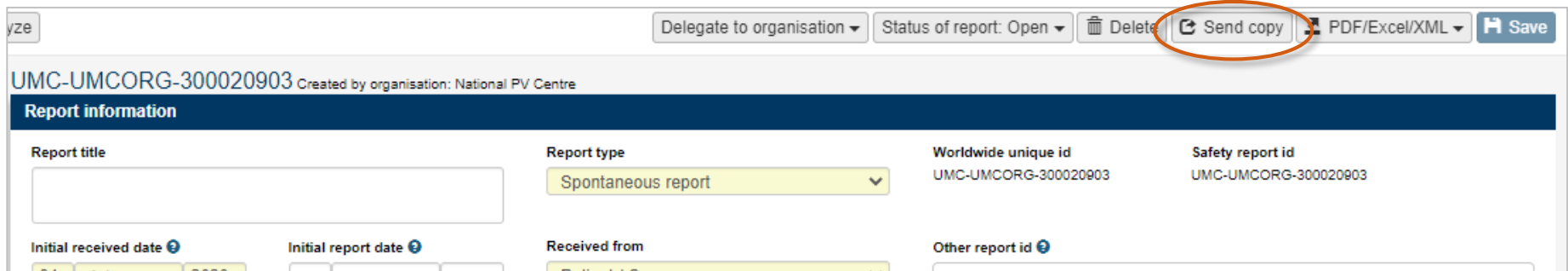
Sending a copy of the ICSR to VigiBase

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.*




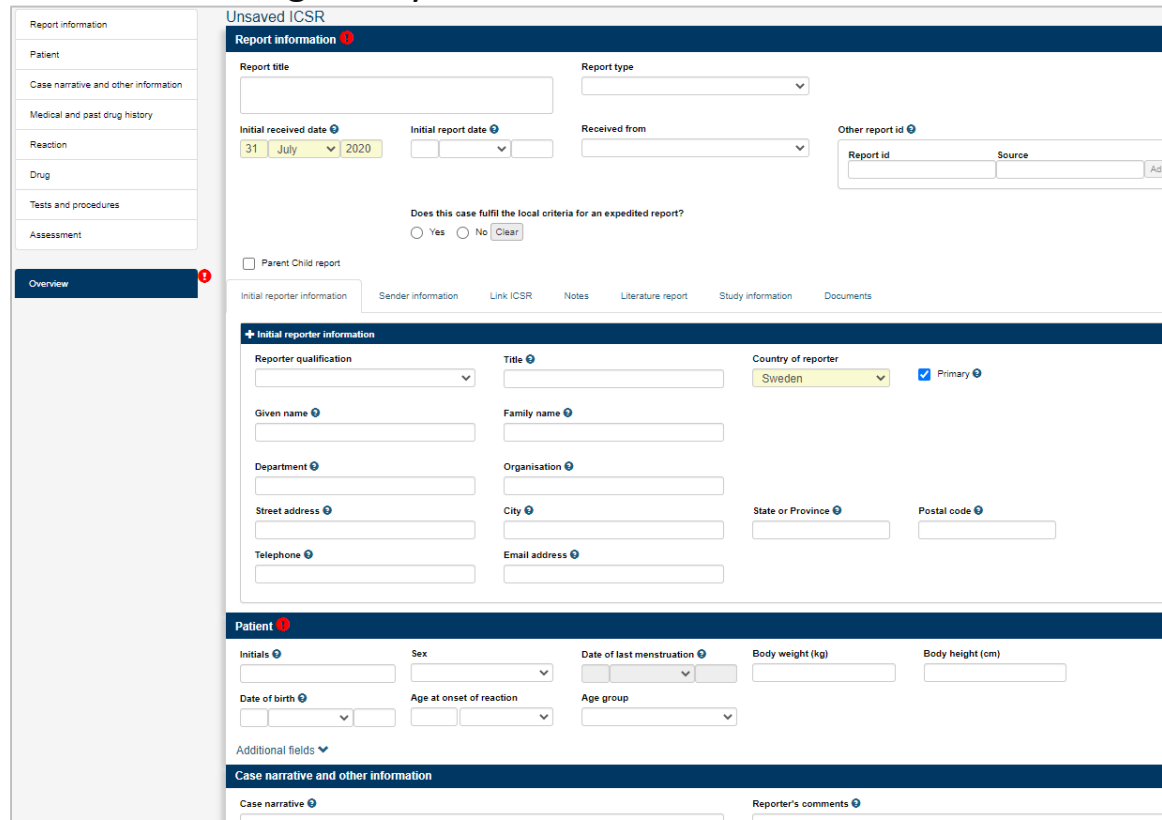
The screenshot shows the VigiLyze interface for a specific ICSR report. At the top right, there is a toolbar with several buttons: 'Delegate to organisation', 'Status of report: Open', 'Delete', 'Send copy', 'PDF/Excel/XML', and 'Save'. The 'Send copy' button is circled in orange. Below the toolbar, the report ID 'UMC-UMCORG-300020903' is displayed, along with the text 'Created by organisation: National PV Centre'. The main section is titled 'Report information' and contains a table with the following data:

Report title	Report type	Worldwide unique id	Safety report id
<input type="text"/>	Spontaneous report	UMC-UMCORG-300020903	UMC-UMCORG-300020903
Initial received date	Initial report date	Received from	Other report id

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.

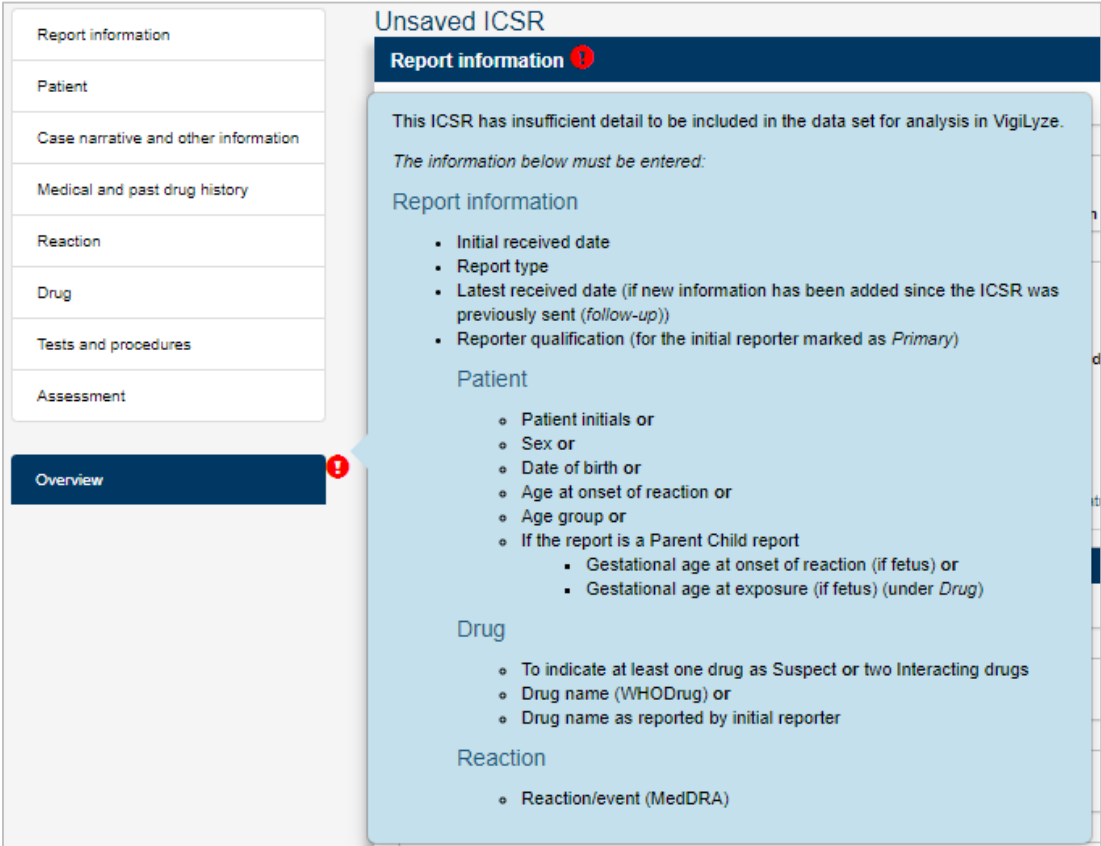


The screenshot displays the 'Unsaved ICSR' form. The left sidebar contains a navigation menu with 'Overview' highlighted and a red exclamation mark icon. The main form area is titled 'Unsaved ICSR' and has a red exclamation mark icon next to the 'Report information' section header. The 'Report information' section includes fields for 'Report title', 'Report type', 'Initial received date' (31 July 2020), 'Initial report date', 'Received from', and 'Other report id'. Below these fields is a question: 'Does this case fulfill the local criteria for an expedited report?' with radio buttons for 'Yes', 'No', and a 'Clear' button. There is also a checkbox for 'Parent Child report'. The 'Initial reporter information' section is expanded and shows fields for 'Reporter qualification', 'Title', 'Country of reporter' (Sweden), 'Primary' (checked), 'Given name', 'Family name', 'Department', 'Organisation', 'Street address', 'City', 'State or Province', 'Postal code', 'Telephone', and 'Email address'. The 'Patient' section is also expanded and shows fields for 'Initials', 'Sex', 'Date of last menstruation', 'Body weight (kg)', 'Body height (cm)', 'Date of birth', 'Age at onset of reaction', and 'Age group'. The 'Case narrative and other information' section is partially visible at the bottom, showing 'Case narrative' and 'Reporter's comments' fields.

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.



The screenshot displays the 'Unsaved ICSR' interface. On the left is a navigation menu with tabs: 'Report information', 'Patient', 'Case narrative and other information', 'Medical and past drug history', 'Reaction', 'Drug', 'Tests and procedures', 'Assessment', and 'Overview'. The 'Overview' tab is selected and has a red exclamation mark icon next to it. The main content area is titled 'Unsaved ICSR' and contains a 'Report information' section with a red exclamation mark icon. Below this, a message states: 'This ICSR has insufficient detail to be included in the data set for analysis in Vigilyze. The information below must be entered:'. The missing information is listed under four categories: 'Report information', 'Patient', 'Drug', and 'Reaction'. Each category has a list of required fields.

Unsaved ICSR

Report information 

This ICSR has insufficient detail to be included in the data set for analysis in Vigilyze.
The information below must be entered:

Report information

- Initial received date
- Report type
- Latest received date (if new information has been added since the ICSR was previously sent (*follow-up*))
- Reporter qualification (for the initial reporter marked as *Primary*)

Patient

- Patient initials or
- Sex or
- Date of birth or
- Age at onset of reaction or
- Age group or
- If the report is a Parent Child report
 - Gestational age at onset of reaction (if fetus) or
 - Gestational age at exposure (if fetus) (under *Drug*)

Drug

- To indicate at least one drug as Suspect or two Interacting drugs
- Drug name (WHODrug) or
- Drug name as reported by initial reporter

Reaction

- Reaction/event (MedDRA)


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

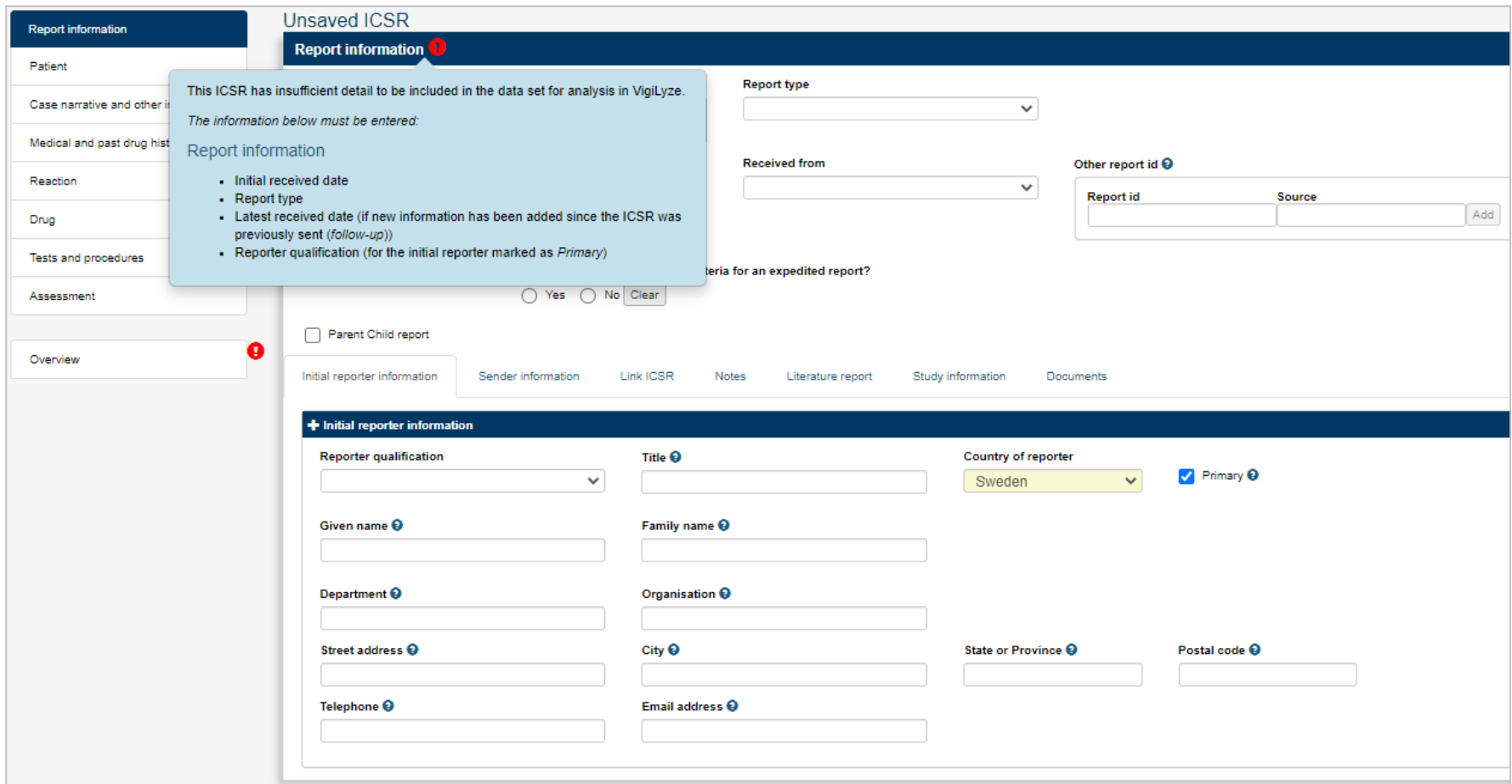
After entering some of the minimum required information, the list of missing information is updated accordingly.

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

The screenshot displays the 'Unsaved ICSR' form interface. On the left, a vertical list of sections is shown, with 'Overview' selected and highlighted in dark blue. A red notification icon is present next to 'Overview'. The main content area is divided into two parts: a top section for 'Report information' and a bottom section for 'Patient'. The 'Report information' section contains fields for 'Report title', 'Report type', 'Initial received date', 'Initial report date', and 'Received from'. The 'Patient' section includes fields for 'Initials', 'Sex' (set to 'Female'), 'Date of last men', 'Date of birth', 'Age at onset of reaction', and 'Age group'. A large blue tooltip box is overlaid on the 'Report information' section, containing the following text: 'This ICSR has insufficient detail to be included in the data set for analysis in Vigilyze. The information below must be entered: Report information: Initial received date, Report type, Latest received date (if new information has been added since the ICSR was previously sent (follow-up)), Reporter qualification (for the initial reporter marked as Primary); Drug: To indicate at least one drug as Suspect or two Interacting drugs, Drug name (WHODrug) or, Drug name as reported by initial reporter; Reaction: Reaction/event (MedDRA)'. Below the tooltip, the 'Department', 'Organisation', 'Street address', 'City', 'Telephone', and 'Email address' fields are visible.

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.



The screenshot displays the 'Unsaved ICSR' form in the VigilLyze system. The 'Report information' section is highlighted with a red exclamation mark icon, indicating missing information. A tooltip provides the following details:


This ICSR has insufficient detail to be included in the data set for analysis in VigilLyze.
The information below must be entered:

- Initial received date
- Report type
- Latest received date (if new information has been added since the ICSR was previously sent (*follow-up*))
- Reporter qualification (for the initial reporter marked as *Primary*)

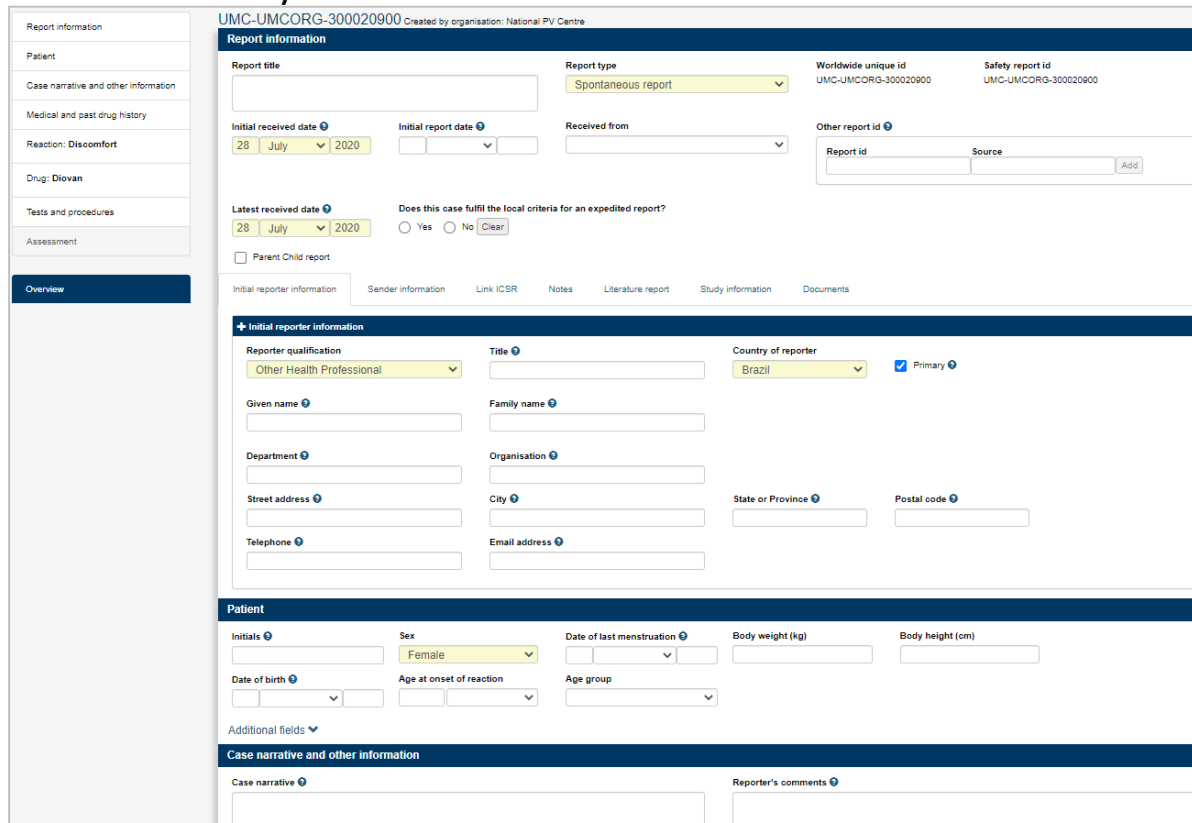
The form includes various input fields and sections:

- Report information:** Report type, Received from, Other report id (Report id, Source, Add), Criteria for an expedited report? (Yes, No, Clear)
- Parent Child report:**
- Initial reporter information:** Reporter qualification, Title, Country of reporter (Sweden), Primary, Given name, Family name, Department, Organisation, Street address, City, State or Province, Postal code, Telephone, Email address.

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.



UMC-UMCORG-300020900 Created by organisation: National PV Centre

Report information

Report title:

Report type: Spontaneous report

Worldwide unique id: UMC-UMCORG-300020900

Safety report id: UMC-UMCORG-300020900

Initial received date: 28 July 2020

Initial report date:

Received from:

Other report id: Source:

Latest received date: 28 July 2020

Does this case fulfill the local criteria for an expedited report?
 Yes No

Parent Child report

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

+ Initial reporter information

Reporter qualification: Other Health Professional

Title:

Country of reporter: Brazil Primary

Given name:

Family name:

Department:

Organisation:

Street address:

City:

State or Province:

Postal code:

Telephone:

Email address:

Patient

Initials:

Sex: Female

Date of last menstruation:

Body weight (kg):

Body height (cm):

Date of birth:

Age at onset of reaction:

Age group:


Additional fields

Case narrative and other information

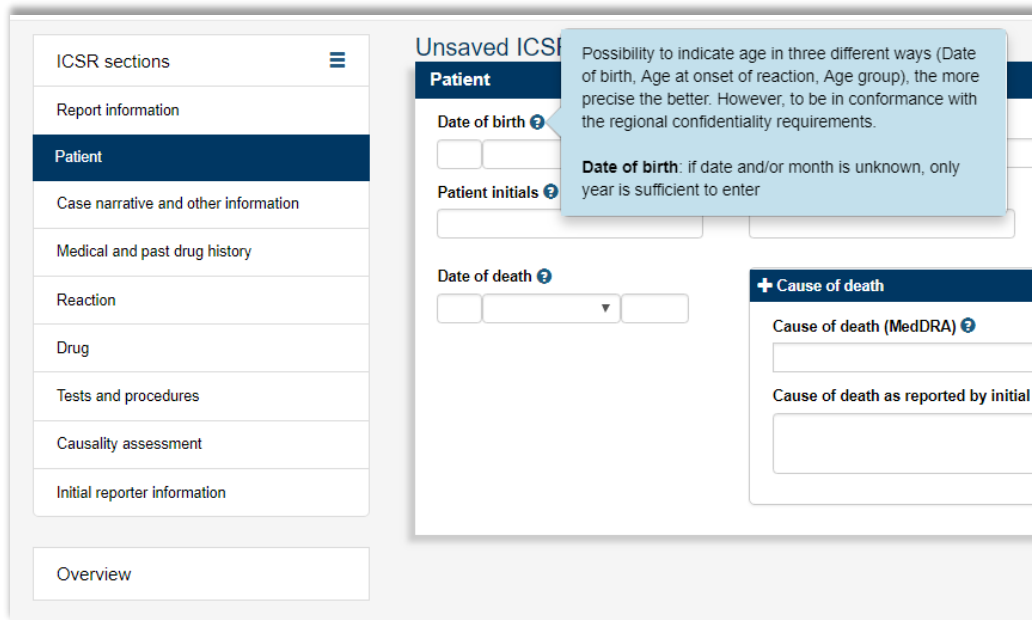
Case narrative:

Reporter's comments:

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)





The screenshot displays the 'Unsaved ICSR' form. On the left is a sidebar with 'ICSR sections' including Report information, Patient (selected), Case narrative and other information, Medical and past drug history, Reaction, Drug, Tests and procedures, Causality assessment, and Initial reporter information. The main form area is titled 'Unsaved ICSR' and contains several fields: 'Date of birth' (with a help icon), 'Patient initials' (with a help icon), and 'Date of death' (with a help icon). A 'Cause of death' section is also visible, containing 'Cause of death (MedDRA)' and 'Cause of death as reported by initial reporter'. A blue help text popup is overlaid on the 'Date of birth' field, providing instructions on how to enter age information.

Unsaved ICSR


Patient


Date of birth 

Patient initials 

Date of death 

+ Cause of death

Cause of death (MedDRA) 

Cause of death as reported by initial reporter 

Possibility to indicate age in three different ways (Date of birth, Age at onset of reaction, Age group), the more precise the better. However, to be in conformance with the regional confidentiality requirements.

Date of birth: if date and/or month is unknown, only year is sufficient to enter

Example of Privacy Data – Patient initials

Report information

Patient

Case narrative and other information

Medical and past drug history

Reaction: **Discomfort**

UMC-UMCORG-300020900 Created by organisation: National PV Centre

Patient

Initials ⓘ If you do not know the initials/name of the patient, fill in 'unknown'.

Note! This data will not be available for other member countries in Vigilyze.

Date of birth ⓘ Age at onset of reaction Age group

Additional fields ▾

Identifying fields containing data

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

UMC-UMCORG-300020900 Created by organisation: National PV Centre

Report information

Report title	Report type Spontaneous report	Worldwide unique id UMC-UMCORG-300020900	Safety report id UMC-UMCORG-300020900
Initial received date 28 July 2020	Initial report date	Received from Health Professional	Other report id
Latest received date 28 July 2020	Does this case fulfil the local criteria for an expedited report? <input type="radio"/> Yes <input type="radio"/> No <input type="button" value="Clear"/>		
<input type="checkbox"/> Parent Child report			

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

+ Initial reporter information

Reporter qualification Other Health Professional	Title	Country of reporter Sweden	<input checked="" type="checkbox"/> Primary
Given name	Family name		
Department Cardiology	Organisation Hospital XYZ		
Street address	City Stockholm	State or Province	Postal code
Telephone	Email address		

Patient

Initials TJ	Sex Female	Date of last menstruation	Body weight (kg)	Body height (cm)
Date of birth	Age at onset of reaction 57 Year	Age group		

Additional fields

Case narrative and other information

Case narrative	Reporter's comments
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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.

The screenshot displays a medical reporting form with several sections. The following sections are highlighted with orange boxes to indicate they are repeatable:

- + Drug**: Located at the top left, containing fields for Drug role, Strength, Marketing Authorisation Holder (WHODrug), Drug name, Active ingredient(s), Drug name as reported by initial reporter, Country where drug is authorised, Country where drug was obtained, and Suspected ingredient.
- + Indication**: Located below the Drug section, containing fields for Indication (MedDRA) and Indication as reported by initial reporter.
- + Additional drug-related problems**: Located below the Indication section, containing a text input field and a plus icon for adding more problems.
- + Dosage information**: Located on the right side, containing fields for Dose, Doses in interval, Dosing interval, Dosage, Pharmaceutical form, Route of administration, Batch number, Start of administration, End of administration, Duration, and a Calculate button.
- + Vaccine information**: Located below the Dosage information section, containing fields for Dose number, Expiry date, Diluent name, Diluent batch number, Site of administration, and Vaccination session.

Other visible sections include:

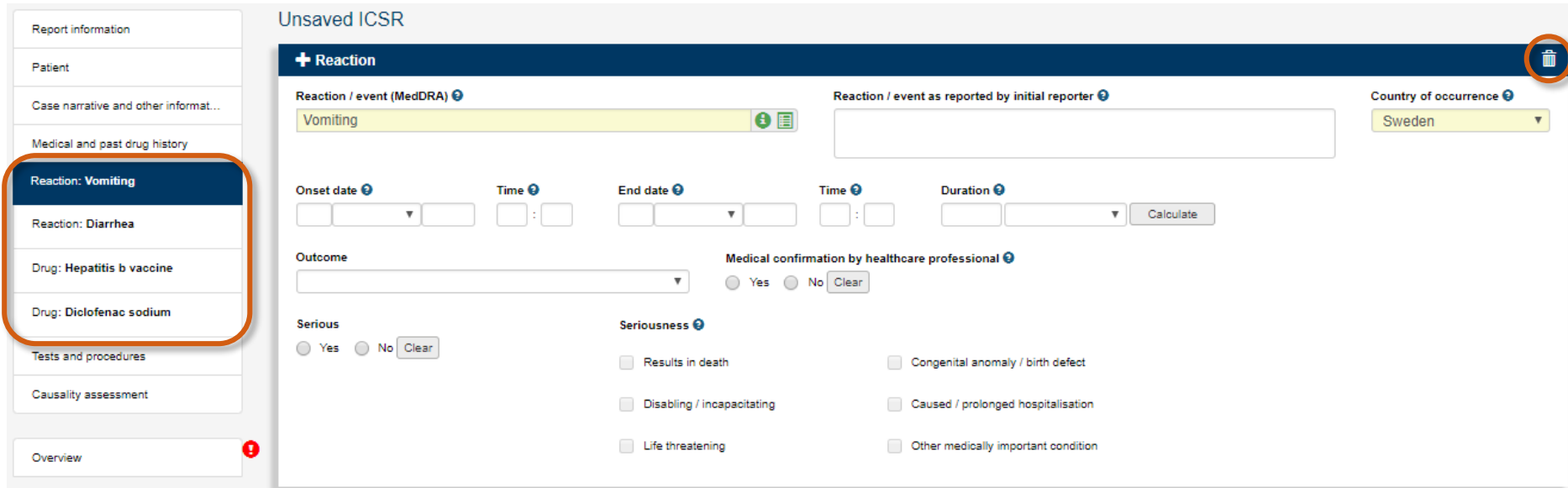
- Action taken**: A dropdown menu.
- Was a rechallenge performed?**: Radio buttons for Yes, No, and Unknown, with a Clear button.
- Additional information on drug**: A text input field.
- Time interval between administration and reaction onset**: A dropdown menu.
- Reaction / event (MedDRA)**: A dropdown menu with a red warning icon and the text "Missing MedDRA term".
- First dose**: A dropdown menu.
- Last dose**: A dropdown menu.
- Cumulative dose to first reaction**: A dropdown menu.

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. 



The screenshot displays the 'Unsaved ICSR' interface. On the left is a sidebar menu with the following items: 'Report information', 'Patient', 'Case narrative and other informat...', 'Medical and past drug history', 'Reaction: Vomiting' (highlighted with an orange border), 'Reaction: Diarrhea', 'Drug: Hepatitis b vaccine', 'Drug: Diclofenac sodium', 'Tests and procedures', 'Causality assessment', and 'Overview' (with a red exclamation mark icon). The main form area is titled '+ Reaction' and contains the following fields and controls:

- Reaction / event (MedDRA):** A text input field containing 'Vomiting' with a green plus icon and a list icon to its right.
- Reaction / event as reported by initial reporter:** An empty text input field.
- Country of occurrence:** A dropdown menu showing 'Sweden'.
- Onset date:** A date and time input field.
- Time:** A time input field.
- End date:** A date and time input field.
- Time:** A time input field.
- Duration:** A duration input field with a 'Calculate' button.
- Outcome:** A dropdown menu.
- Medical confirmation by healthcare professional:** Radio buttons for 'Yes' and 'No', and a 'Clear' button.
- Serious:** Radio buttons for 'Yes' and 'No', and a 'Clear' button.
- Seriousness:** A section with several checkboxes: 'Results in death', 'Disabling / incapacitating', 'Life threatening', 'Congenital anomaly / birth defect', 'Caused / prolonged hospitalisation', and 'Other medically important condition'.

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.

The screenshot displays a web interface for reporting a medical case. On the left is a sidebar with a menu where 'Report information' is highlighted with a vertical red bar. The main content area shows the report details for 'UMC-UMCORG-300020900', created by the 'National PV Centre'. The 'Report information' section is also highlighted with a red bar and contains a red exclamation mark icon. Below this, the 'Initial received date' field is highlighted with a red box and shows an error message: 'Date format is invalid or out of valid range'. The date is currently set to '28' and '2020'. Other fields like 'Report title', 'Initial report date', and 'Drug: Diovan' are also visible.

Report information	UMC-UMCORG-300020900 Created by organisation: National PV Centre
Patient	Report information
Case narrative and other information	Report title
Medical and past drug history	Initial received date 28 2020 <i>Date format is invalid or out of valid range</i>
Reaction: Discomfort	Initial report date
Drug: Diovan	Report title (Sp...)

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.

The screenshot displays the ICSR export interface. At the top right, a dropdown menu is open, showing the following options: Masked PDF (1), Masked XML (1), Unmasked PDF (1), and Unmasked XML (1). The dropdown is highlighted with an orange border. Below the dropdown, the main form contains various fields for report information, including Report title, Report type (Spontaneous report), Worldwide unique id (UMC-UMCORG-300020900), Safety report id, Initial received date (28 July 2020), Initial report date, Received from (Health Professional), Latest received date (28 July 2020), and a checkbox for Parent Child report. The form also includes tabs for Initial reporter information, Sender information, Link ICSR, Notes, Literature report, Study information, and Documents. At the bottom left, a notification box shows a PDF file named 'VigiFlow_UMC-UM....pdf' with an upward arrow, also highlighted with an orange border. The bottom right corner features a 'Show all' button.

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		

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.

```
<?xml version="1.0" encoding="UTF-8"?>
- <MCCI_IN200100UV01 xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3
http://eudravigilance.ema.europa.eu/XSD/multicacheschemas/MCCI_IN200100UV01.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="d2202961-0f8e-4731-a58a-8d1a79c41aa6" root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <creationTime value="20200727131655+0200"/>
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
  <name code="1" codeSystemVersion="2.0" codeSystem="2.16.840.1.113883.3.989.2.1.1.1"/>
- <PORR_IN049016UV>
  <id extension="UMC-UMCORG-300020899" root="2.16.840.1.113883.3.989.2.1.3.1"/>
  <creationTime value="20200727111649+0000"/>
  <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
  <processingCode code="P"/>
  <processingModeCode code="T"/>
  <acceptAckCode code="AL"/>
- <receiver typeCode="RCV">
  - <device determinerCode="INSTANCE" classCode="DEV">
    <id extension="" root="2.16.840.1.113883.3.989.2.1.3.12"/>
  </device>
</receiver>
- <sender typeCode="SND">
  - <device determinerCode="INSTANCE" classCode="DEV">
    <id extension="UMC" root="2.16.840.1.113883.3.989.2.1.3.11"/>
  </device>
</sender>
- <controlActProcess classCode="CACT" moodCode="EVN">
  <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
  <effectiveTime value="20200727111649+0000"/>
  <subject typeCode="SUBJ">
    - <investigationEvent classCode="INVSTG" moodCode="EVN">
      <id extension="UMC-UMCORG-300020899" root="2.16.840.1.113883.3.989.2.1.3.1"/>
      <id extension="UMC-UMCORG-300020899" root="2.16.840.1.113883.3.989.2.1.3.2"/>
      <statusCode code="active"/>
      <effectiveTime>
        <low value="20200727"/>
      </effectiveTime>
      <availabilityTime value="20200727"/>
      <component typeCode="COMP">
        - <observationEvent classCode="OBS" moodCode="EVN">
          <code code="1" codeSystemVersion="2.0" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/>
          <value value="false" xsi:type="BL"/>
        </observationEvent>
      </component>
      <component typeCode="COMP">
        - <observationEvent classCode="OBS" moodCode="EVN">
          <code code="23" codeSystemVersion="2.0" codeSystem="2.16.840.1.113883.3.989.2.1.1.19"/>
          <value xsi:type="BL" nullFlavor="N1"/>
        </observationEvent>
      </component>
      <component typeCode="COMP">
        - <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
          <subject1 typeCode="SBJ">
            - <primaryRole classCode="INVSBJ">
              <player1 determinerCode="INSTANCE" classCode="PSN">
```

Report Information

Fields available in Report Information section

Report information ?

Report title

Report type

Initial received date ?

Initial report date ?

Received from

Other report id ?

Report id

Source

Add

Does this case fulfil the local criteria for an expedited report?

Yes No

Parent Child report

Initial reporter information

Sender information

Link ICSR

Notes

Literature report

Study information

Documents

+ Initial reporter information

Reporter qualification

Title ?

Country of reporter

Primary ?

Given name ?

Family name ?

Department ?

Organisation ?

Street address ?

City ?

State or Province ?

Postal code ?

Telephone ?

Email address ?

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

Report information ⓘ

Report title

Report type

Initial received date ⓘ Initial report date ⓘ

03 August 2020

Received from

Other report id ⓘ

Report id	Source

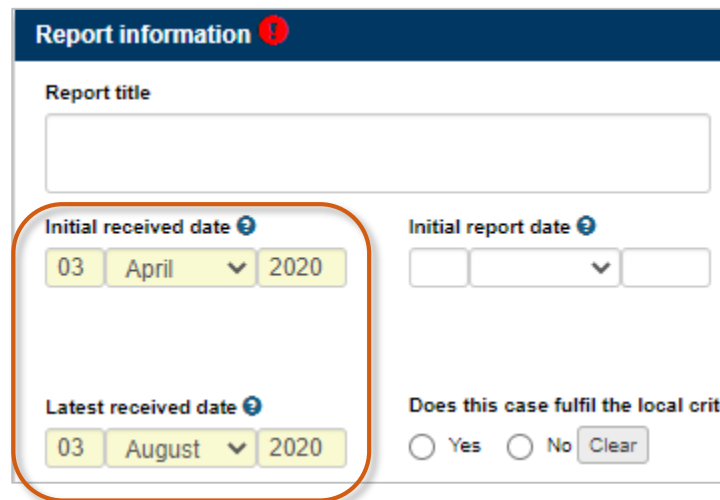
Add

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.



The screenshot shows a web form titled "Report information" with a red warning icon. The form includes a "Report title" text box. Below it, there are two date selection fields: "Initial received date" and "Initial report date". The "Initial received date" field is highlighted with an orange rounded rectangle and shows "03 April 2020". The "Initial report date" field is empty. Below these, there is a "Latest received date" field showing "03 August 2020". To the right of the date fields, there is a section titled "Does this case fulfil the local crit" with radio buttons for "Yes" and "No", and a "Clear" button.

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.

UMC-UMCORG-300000041

Report information

Report title

Report type Spontaneous report ▼

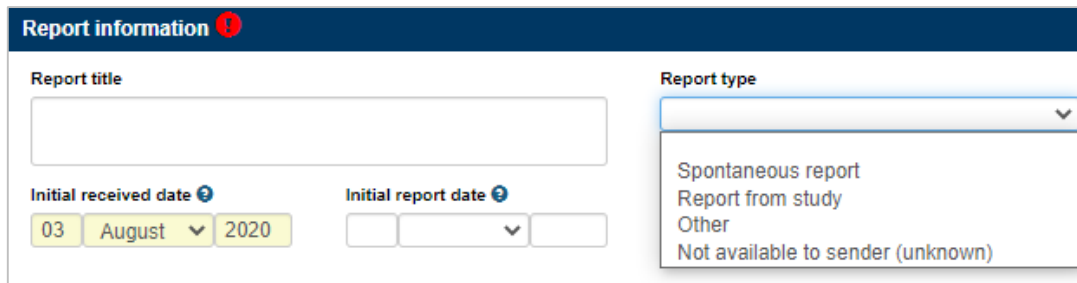
Initial received date 27 February 2019 Initial report date ▼ Received from Pharmaceutical Company ▼

Latest received date 27 February 2019

Literature report
 Parent Child report

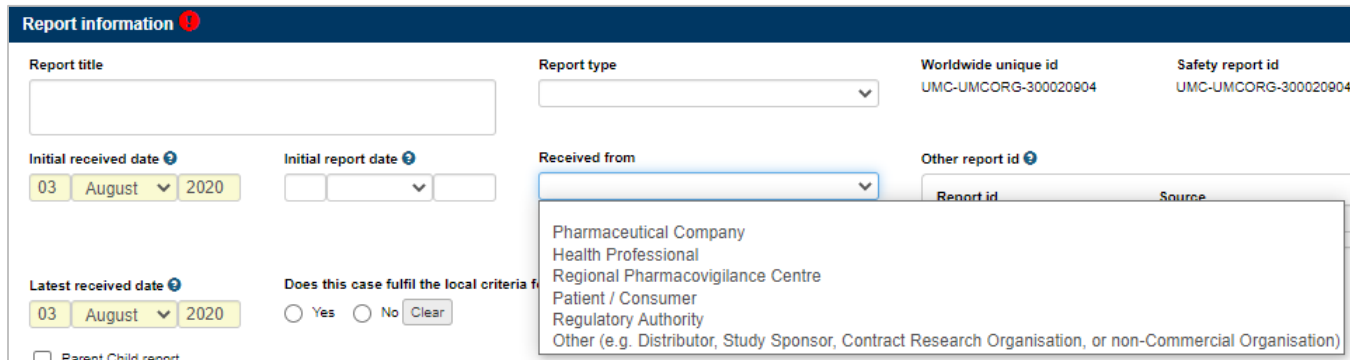
Report type and Received from

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 screenshot shows a form titled "Report information" with a red warning icon. The "Report type" dropdown menu is open, showing the following options: "Spontaneous report", "Report from study", "Other", and "Not available to sender (unknown)". Other fields visible include "Report title", "Initial received date" (03 August 2020), and "Initial report date".

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.



The screenshot shows a more complete view of the "Report information" form. The "Received from" dropdown menu is open, showing the following options: "Pharmaceutical Company", "Health Professional", "Regional Pharmacovigilance Centre", "Patient / Consumer", "Regulatory Authority", and "Other (e.g. Distributor, Study Sponsor, Contract Research Organisation, or non-Commercial Organisation)". Other fields visible include "Report title", "Report type", "Worldwide unique id" (UMC-UMCORG-300020904), "Safety report id" (UMC-UMCORG-300020904), "Initial received date" (03 August 2020), "Initial report date", "Latest received date" (03 August 2020), and "Does this case fulfil the local criteria for reporting?" (Yes/No radio buttons).

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.

SE-BAYER-2018-67890 Created by organisation: National PV Centre

Report information

Report title <input type="text"/>	Report type Spontaneous report	Worldwide unique id SE-BAYER-2018-67890	Safety report id UMC-UMCORG-300000139
Initial received date 12 June 2019	Initial report date <input type="text"/>	Received from Pharmaceutical Company	Other report id
		Report id SE-BAYER-2018-67890	Source Bayer

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.



The screenshot shows a web form titled "Report information" with a red warning icon. The form contains the following fields:

- Report title (text input)
- Initial received date (date picker)
- Initial report date (date picker)
- Latest received date (date picker)
- Parent Child report (checkbox, highlighted with an orange box)

Tick the box **Parent-Child Report** to indicate if the case is a parent-child report. Specific data entry fields will then be available in some sections.

Parent-Child fields in the PATIENT section

Patient ⓘ

Patient initials ⓘ

Sex

Date of last menstruation ⓘ

Body weight (kg)

Body height (cm)

Date of birth ⓘ

Age at onset of reaction

Age group

Gestational age at onset of reaction (if fetus) ⓘ

Additional fields ▾

Parent information

Parent initials ⓘ

Sex

Date of last menstruation ⓘ

Body weight (kg)

Body height (cm)

Date of birth ⓘ

Age (years)

Parent medical history ⓘ

Medical history (MedDRA) ⓘ ⓘ

Start date ⓘ

End date ⓘ

Continuing ⓘ Yes No Unknown

Medical comments

+

Relevant medical history

Parent drug history ⓘ

Previous medications ⓘ

Indication (MedDRA) ⓘ ⓘ

Reaction (MedDRA) ⓘ ⓘ

Start date ⓘ

End date ⓘ

+

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*

The screenshot displays the 'Drug' section of a form, divided into several panels. The 'Drug' panel includes fields for Drug role, Strength, WHODrug, Drug name, Active ingredient(s), Drug name as reported by initial reporter, Marketing Authorisation Holder (WHODrug), Marketing Authorisation Holder, Country where drug is authorised, Country where drug was obtained, and Suspected ingredient. The 'Indication' panel includes Indication (MedDRA) and Indication as reported by initial reporter. The 'Additional drug-related problems' panel includes a dropdown menu and a plus sign. The 'Action taken' panel includes a dropdown menu and radio buttons for 'Was a rechallenge performed?' (Yes, No, Unknown) with a 'Clear' button. The 'Additional information on drug' panel includes a text input field. The 'Dosage information' panel includes Dose, Doses in interval, Dosing interval, Dosage, Pharmaceutical form, Route of administration, Batch number, Start of administration, End of administration, Duration, and a 'Calculate' button. The 'Vaccine information' panel includes Dose number, Expiry date, Diluent name, Diluent batch number, Site of administration, and Vaccination session. The 'Time interval between administration and reaction onset' panel includes Reaction / event (MedDRA), First dose, and Last dose. The 'Cumulative dose to first reaction' panel includes a text input field. Two fields are highlighted with orange boxes: 'Parent route of administration' in the 'Route of administration' dropdown and 'Gestational age at exposure (if fetus)' in the 'Gestational age at exposure (if fetus)' dropdown.

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.

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

+ Initial reporter information

Reporter qualification Physician	Title Dr.	Country of reporter Sweden	<input checked="" type="checkbox"/> Primary
Given name Reporter's name	Family name Reporter's last name		
Department Cardiology	Organisation University Hospital		
Street address	City Uppsala	State or Province	Postal code
Telephone 000000000000	Email address doctor@hospital.se		

Last edited by Nome do usuário 29072020

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 autopopulated.

The screenshot shows a web form for entering sender information. At the top, there are date pickers for 'Initial received date' (12 June 2019) and 'Initial report date'. A dropdown menu for 'Received from' is open, showing a list of sender types: Pharmaceutical Company, Health Professional, Regional Pharmacovigilance Centre, Patient / Consumer, Regulatory Authority, and Other (e.g. Distributor, Study Sponsor, Contract Research Organisation, or non-Commercial Organisation). Below this, there are fields for 'Latest received date' (12 June 2019) and a radio button for 'Does this case fulfil the local criteria for...' (Yes/No). A 'Parent Child report' checkbox is also present. The form has several tabs: 'Initial reporter information', 'Sender information' (which is active and circled with a red '2'), 'Link ICSR', 'Notes', 'Literature report', 'Study information', and 'Documents'. The 'Sender information' section contains the following fields: Organisation (Bayer Sweden), Department (Global Pharmacovigilance), Title, Given name, Family name, Country (Sweden), Street address (Medical Department), City (Stockholm), State or Province, Postcode, Telephone, Fax, and Email address.

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).*

Initial reporter information	Sender information	Link ICSR	Notes	Literature report	Study information	Documents									
<table border="1"><thead><tr><th>Link ICSR</th><th>Reason</th><th></th></tr></thead><tbody><tr><td>UMC-UMCORG-30000025</td><td>Same cluster of ICSRs</td><td>Add</td></tr><tr><td>UMC-UMCORG-300000250</td><td>Same cluster of ICSRs</td><td></td></tr></tbody></table>							Link ICSR	Reason		UMC-UMCORG-30000025	Same cluster of ICSRs	Add	UMC-UMCORG-300000250	Same cluster of ICSRs	
Link ICSR	Reason														
UMC-UMCORG-30000025	Same cluster of ICSRs	Add													
UMC-UMCORG-300000250	Same cluster of ICSRs														

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.

Initial reporter information

Sender information

Link ICSR

Notes

Literature report

Study information

Documents

Notes

Internal comments about the report

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 appendectomy 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
- } Repeatabe section

The screenshot displays the 'Report information' form. The 'Report type' dropdown is set to 'Report from study'. The 'Study information' tab is active, showing the following fields:

- Report title
- Initial received date: 30 September 2019
- Initial report date
- Latest received date: 30 September 2019
- Parent Child report:
- Received from
- Study type: Clinical trials
- Study name
- Study sponsor number
- Study registration number
- Study registration country

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**.

The screenshot displays a web interface with a navigation bar at the top containing the following tabs: Initial reporter information, Sender information, Link ICSR, Notes, Literature report, Study information, and Documents. The 'Documents' tab is currently selected. Below the navigation bar, there are two main sections:

- Additional documents:** This section features a large empty text input field with a trash icon on the right side. A plus sign (+) is located at the bottom left of the input field, indicating the option to add new documents.
- Imported additional documents:** This section contains a text box with the message: "The sender of this ICSR has indicated that there are additional documents available." Below this message, the text "ECG printout" is listed as an example of an imported document.

Patient









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

Patient initials 	Sex	Date of last menstruation 	Body weight (kg)	Body height (cm)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of birth 	Age at onset of reaction	Age group		
<input type="text"/>	<input type="text"/>	<input type="text"/>		
Specialist record number 	GP medical record number 	Hospital record number 	Investigation number 	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of death 			Was autopsy done?	
<input type="text"/>			<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="button" value="Clear"/>	

+ Cause of death

Cause of death (MedDRA) 

Cause of death as reported by initial reporter 

Patient age

There are 3 ways to report patient age.

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

The screenshot shows a form titled "Patient" with a red exclamation mark icon. The form contains several input fields:

- Patient initials**: A text input field.
- Sex**: A dropdown menu.
- Date of last menstruation**: A date input field.
- Body weight (kg)**: A text input field.
- Body height (cm)**: A text input field.
- 1 Date of birth**: A date input field, highlighted with a red "1".
- 2 Age at onset of reaction**: A dropdown menu, highlighted with a red "2".
- 3 Age group**: A dropdown menu, highlighted with a red "3".

At the bottom left of the form, there is a link labeled "Additional fields" with a downward arrow.

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.

The screenshot shows a patient data entry form with a dark blue header labeled 'Patient'. The form contains several input fields and dropdown menus for patient information. At the bottom, a section titled '+ Cause of death' is expanded, showing two fields: 'Cause of death (MedDRA)' and 'Cause of death as reported by initial reporter'. A red '1' is placed to the left of the first field, and a red '2' is placed to the left of the second field, corresponding to the numbered list in the text above. The 'Cause of death as reported by initial reporter' field is a large text area.

Patient initials	Sex	Date of last menstruation	Body weight (kg)	Body height (cm)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of birth	Age at onset of reaction	Age group		
<input type="text"/>	<input type="text"/>	<input type="text"/>		
Specialist record number	GP medical record number	Hospital record number	Investigation number	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of death	Was autopsy done?			
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="button" value="Clear"/>			

+ Cause of death

1 Cause of death (MedDRA)

2 Cause of death as reported by initial reporter

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.

Patient ⓘ

Patient initials ⓘ	Sex	Date of last menstruation ⓘ	Body weight (kg)	Body height (cm)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of birth ⓘ	Age at onset of reaction	Age group		
<input type="text"/>	<input type="text"/>	<input type="text"/>		
Specialist record number ⓘ	GP medical record number ⓘ	Hospital record number ⓘ	Investigation number ⓘ	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of death ⓘ			Was autopsy done?	
<input type="text"/>			<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="button" value="Clear"/>	

+ Cause of death

Cause of death (MedDRA) ⓘ

Cause of death as reported by initial reporter ⓘ

+ Cause of death after autopsy

Cause of death after autopsy (MedDRA) ⓘ

Cause of death after autopsy ⓘ

1

2

Case narrative and other information

Case narrative and Reporter's comments

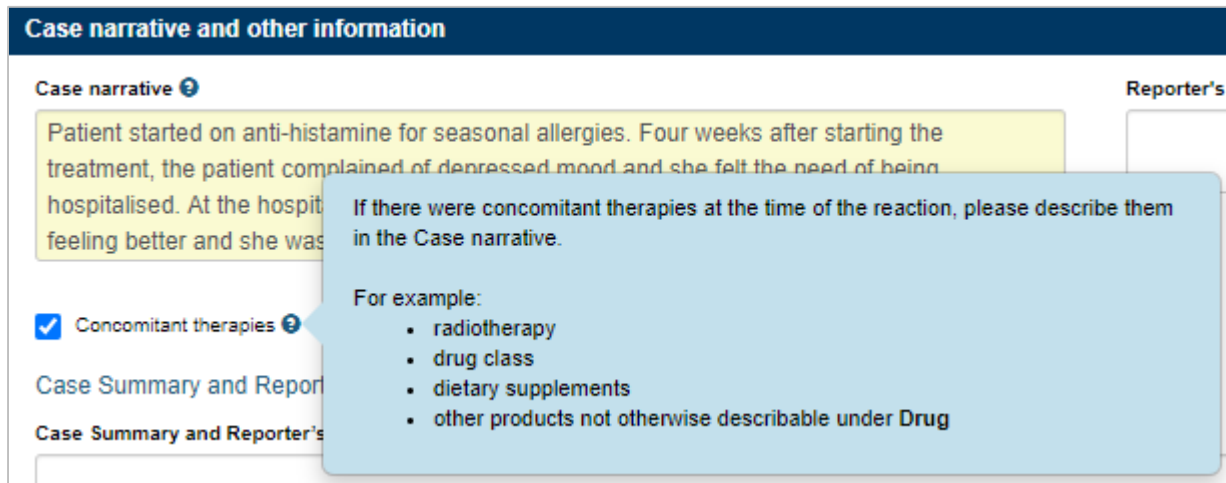
Both case narrative and reporter's comments fields are free-text fields which can expand to accommodate large texts.

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.

The screenshot displays the 'Unsaved ICSR' form. On the left is a navigation menu with the following items: Report information, Patient, Case narrative and other information (highlighted), Medical and past drug history, Reaction, Drug, Tests and procedures, Assessment, and Overview. The main content area is titled 'Unsaved ICSR' and 'Case narrative and other information'. It contains a 'Case narrative' field with a text area containing: 'Patient started on anti-histamine for seasonal allergies. Four weeks after starting the treatment, the patient complained of depressed mood and she felt the need of being hospitalised. At the hospital, Aeriuss was withdrawn and after 3 weeks the patient reported feeling better and she was discharged.' Below this is a checkbox for 'Concomitant therapies'. There is also a section for 'Case Summary and Reporter's Comments in Additional Language' with a text area and a dropdown menu for 'Language of case summary and reporter's comments' set to 'Swedish'. A trash icon is visible next to the language dropdown. A red exclamation mark icon is present in the bottom right of the navigation menu.

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.



The screenshot shows a form titled "Case narrative and other information". It includes a "Case narrative" text area with a yellow highlight and a "Concomitant therapies" checkbox that is checked. A light blue tooltip points to the checkbox, providing instructions and examples.

Case narrative and other information

Case narrative ⓘ

Patient started on anti-histamine for seasonal allergies. Four weeks after starting the treatment, the patient complained of depressed mood and she felt the need of being hospitalised. At the hospital she was treated with antidepressants and she was feeling better and she was discharged.

Reporter's contact information

Concomitant therapies ⓘ

Case Summary and Report

Case Summary and Reporter's

If there were concomitant therapies at the time of the reaction, please describe them in the Case narrative.

For example:

- radiotherapy
- drug class
- dietary supplements
- other products not otherwise describable under Drug

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.

Case narrative and other information

Case narrative

Initial information received on 03-Jan-2019 regarding a solicited valid serious case received from investigator via Eli Lilly and company (MFR control number: ES201901000920), in the scope of unsponsored study

Concomitant therapies

Case Summary and Reporter's Comments in Additional Language

Case Summary and Reporter's Comments

Language of case summary and reporter's comments

Spanish; Castilian

Company Narrative:
Información inicial recibida el 3 de enero de 2019 sobre un caso serio válido solicitado recibido del investigador a través de Eli Lilly y compañía (número de control de MFR: ES201901000920), en el ámbito del estudio no patrocinado "UNSPON_O_OXALIPLATIN". Este caso involucra a un paciente de 73 años de edad que experimentó un absceso periamigdalino, mientras que fue tratada con oxaliplatino, folinato de calcio (Leucovorin) y fluorouracilo (5-FU).
El historial médico relevante del paciente y los medicamentos concomitantes no fueron ninguno.
El 12 de junio de 2018, el paciente comenzó a tomar el primer ciclo de oxaliplatino a una dosis de tratamiento cíclico de 85 mg / m² por vía intravenosa, primer ciclo de folinato cálcico a una dosis de tratamiento cíclico de 400 mg / m² por vía intravenosa, primer ciclo de Fluorouracilo a una dosis de 400 mg / m², tratamiento cíclico, por vía intravenosa y primer ciclo de Fluorouracilo a una dosis de 2400 mg / m², tratamiento cíclico, por vía intravenosa (con un número de lote desconocido y fecha de vencimiento para todos) para el cáncer de páncreas metastásico. El 11 de diciembre de 2018, el paciente recibió la última dosis de los fármacos del estudio antes del evento adverso (mismos detalles de dosificación, ciclo desconocido, día desconocido).
El 2 de enero de 2019, 6 meses y 21 días desde la primera dosis de oxaliplatino, folinato de calcio y fluorouracilo y 22 días desde la última dosis, el paciente experimentó un absceso periamigdalino de grado 3 y fue hospitalizado el mismo día (Criterios de gravedad).
Los resultados relevantes de las pruebas de laboratorio incluyeron:
Proteína C reactiva (5-0 mg / L) - El 02-enero-2019: 275.5 mg / L
No se tomaron medidas para el oxaliplatino, el folinato de calcio y el fluorouracilo.
No se informó si el paciente recibió un tratamiento correctivo.
El resultado se informó como la resolución del absceso periamigdalino.
La causalidad del reportero se informó como no informada con respecto a todas las drogas sospechosas.
La causalidad de la empresa se informó como reportable con respecto a todas las drogas sospechosas.
No se informó más información relevante.
***Nueva información recibida el 19 de enero de 2020
GRADO 1 de información Este es el seguimiento 2 no se proporciona más información del caso

Medical and past drug history

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

Unsaved ICSR

Medical and past drug history

Medical history ⓘ

1

Relevant medical history (MedDRA) ⓘ Start date ⓘ End date ⓘ Continuing ⓘ

ⓘ Yes No Unknown ⓘ

Medical comments

Family history

+

2

Relevant medical history ⓘ

Drug history ⓘ

Previous medications ⓘ

ⓘ

Indication (MedDRA) ⓘ Reaction (MedDRA) ⓘ Start date ⓘ End date ⓘ

ⓘ ⓘ

+

Past drug history

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

Unsaved ICSR

Medical and past drug history

Medical history ⓘ

Relevant medical history (MedDRA) ⓘ Start date ⓘ End date ⓘ Continuing ⓘ

ⓘ Yes No Unknown

Medical comments

Family history

+

Relevant medical history ⓘ

Drug history ⓘ

Previous medications ⓘ

ⓘ

Indication (MedDRA) ⓘ Reaction (MedDRA) ⓘ Start date ⓘ End date ⓘ

ⓘ ⓘ

+

Report information

Patient

Case narrative and other information

Medical and past drug history

Reaction

Drug

Tests and procedures

Assessment

Overview ⓘ

Reaction

Fields available in the REACTION section

+ Reaction

Reaction / event (MedDRA)

Country of occurrence

Reaction / event as reported by initial reporter

Language of reaction / event as reported by initial reporter

Onset date Time :

End date Time :

Duration

Outcome

Medical confirmation by healthcare professional Yes No

Serious Yes No

Seriousness

- Results in death
- Disabling / incapacitating
- Life threatening
- Congenital anomaly / birth defect
- Caused / prolonged hospitalisation
- Other medically important condition

Vaccine information

AEFI category

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.

+ Reaction

Reaction / event (MedDRA) ? + ☰ Country of occurrence ? ▼


Reaction / event as reported by initial reporter ? Language of reaction / event as reported by initial reporter ▼

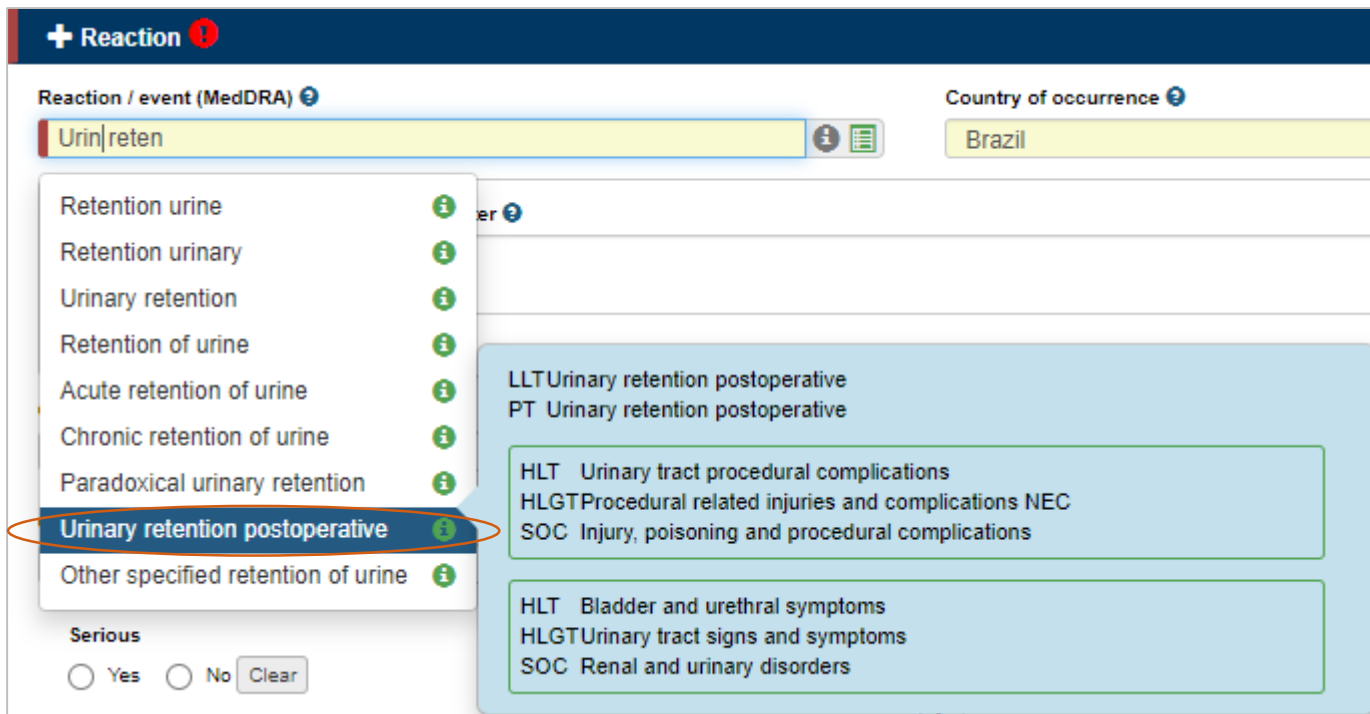
*The procedure of how to select a MedDRA term must be handled by the NC. Contact [MedDRA MSSO](#) if you have questions.

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.

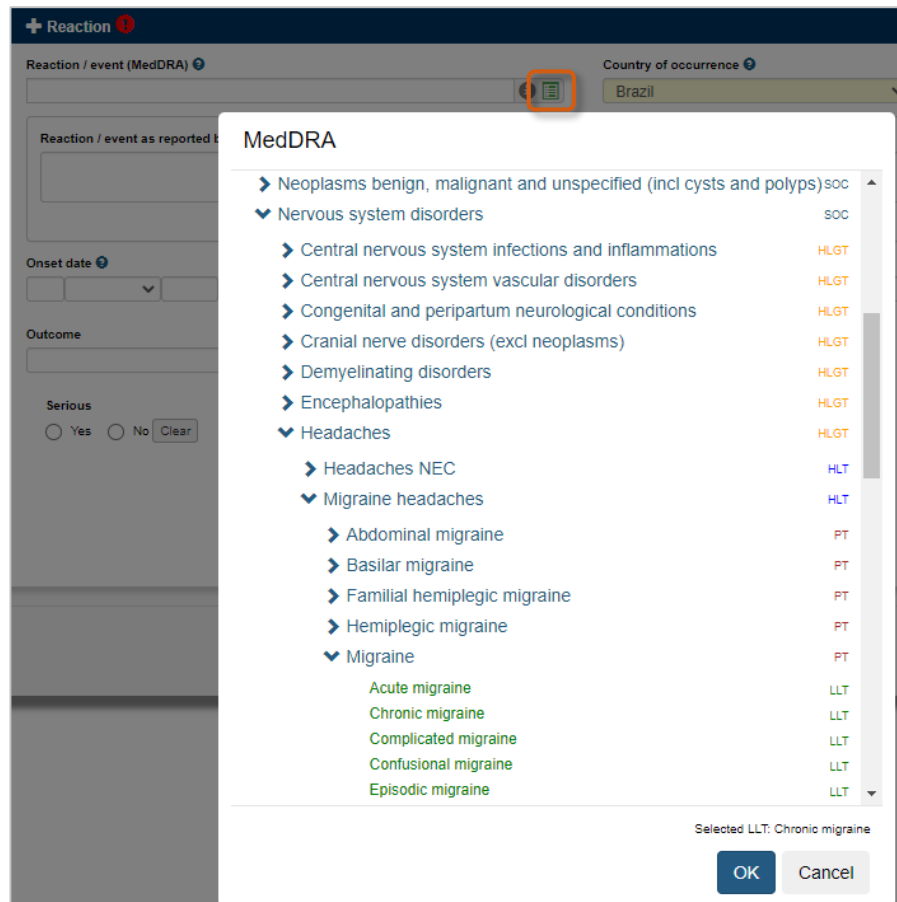


The screenshot shows a web interface for searching MedDRA terms. At the top, there is a header with a plus sign and the word "Reaction" followed by a red exclamation mark icon. Below this, there are two search fields: "Reaction / event (MedDRA)" and "Country of occurrence". The first field contains the text "Urin|reten" and has an information icon (i) and a list icon. The second field contains "Brazil". A dropdown menu is open below the first field, listing several terms, each with an information icon (i). The term "Urinary retention postoperative" is highlighted in blue and circled in orange. To the right of the dropdown, there are two panels showing the hierarchy for the selected term. The first panel shows "LLT Urinary retention postoperative" and "PT Urinary retention postoperative". The second panel shows "HLT Urinary tract procedural complications", "HLGT Procedural related injuries and complications NEC", and "SOC Injury, poisoning and procedural complications". The third panel shows "HLT Bladder and urethral symptoms", "HLGT Urinary tract signs and symptoms", and "SOC Renal and urinary disorders". At the bottom left, there are radio buttons for "Serious" with options "Yes" and "No", and a "Clear" button.


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.



The screenshot shows a web form for reporting a reaction. The 'Reaction / event (MedDRA)' field is highlighted with a red box, and a red icon (a list of horizontal lines) is visible next to it. A dropdown menu is open, displaying the MedDRA hierarchy. The hierarchy is organized into categories, with 'Nervous system disorders' expanded. Under this category, 'Migraine headaches' is expanded, and 'Chronic migraine' is selected. The background form shows fields for 'Country of occurrence' (Brazil), 'Onset date', 'Outcome', and 'Serious' (Yes/No/Clear).

Reaction / event (MedDRA)  Country of occurrence
 Brazil

Reaction / event as reported to

Onset date

Outcome

Serious
 Yes No


MedDRA

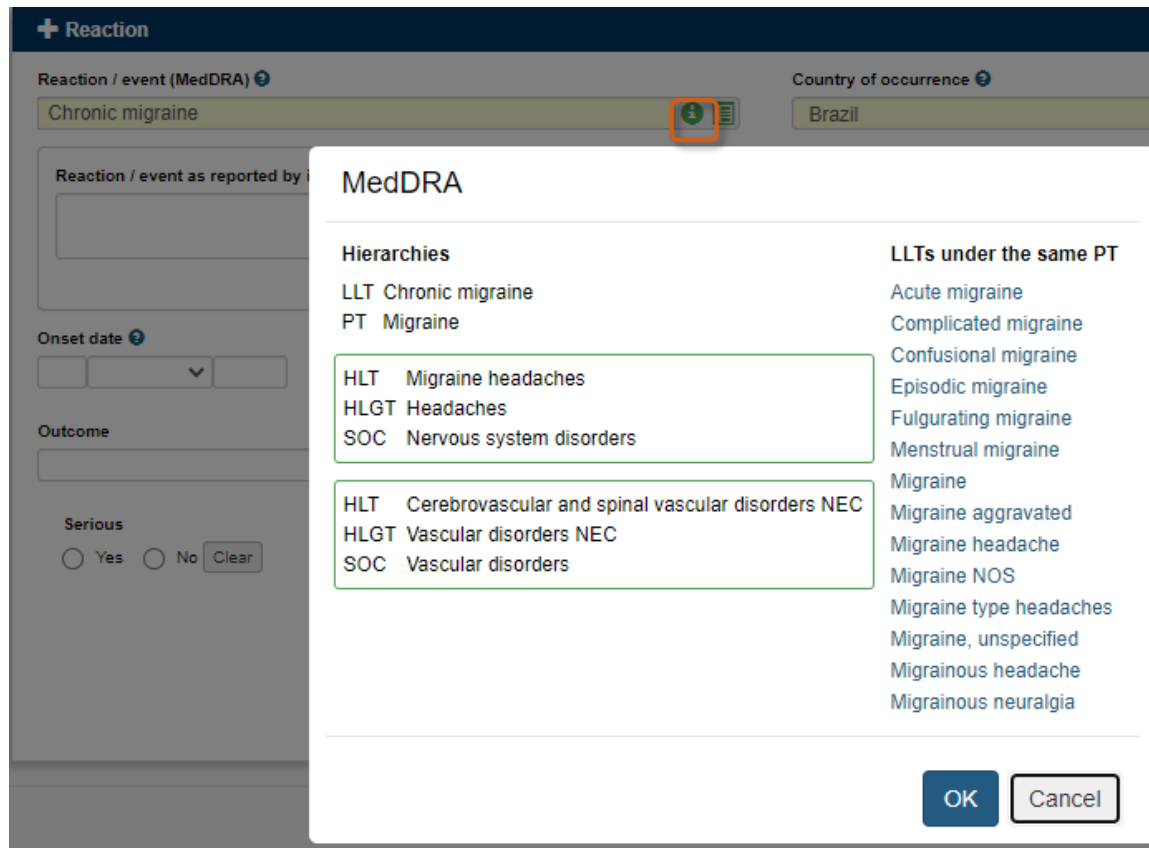
- Neoplasms benign, malignant and unspecified (incl cysts and polyps) soc
- Nervous system disorders soc
 - Central nervous system infections and inflammations HLT
 - Central nervous system vascular disorders HLT
 - Congenital and peripartum neurological conditions HLT
 - Cranial nerve disorders (excl neoplasms) HLT
 - Demyelinating disorders HLT
 - Encephalopathies HLT
 - Headaches HLT
 - Headaches NEC HLT
 - Migraine headaches HLT
 - Abdominal migraine PT
 - Basilar migraine PT
 - Familial hemiplegic migraine PT
 - Hemiplegic migraine PT
 - Migraine PT
 - Acute migraine LLT
 - Chronic migraine LLT
 - Complicated migraine LLT
 - Confusional migraine LLT
 - Episodic migraine LLT

Selected LLT: Chronic migraine

OK Cancel

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.



The screenshot shows a web application interface for entering a reaction. The main form has a header '+ Reaction' and a search bar containing 'Chronic migraine'. An information icon (i) next to the search bar is highlighted with an orange box. A modal window titled 'MedDRA' is open, displaying related terms. The modal is divided into two columns: 'Hierarchies' and 'LLTs under the same PT'. The 'Hierarchies' column lists 'LLT Chronic migraine' and 'PT Migraine'. Below this, two boxes highlight related terms: one for 'Migraine headaches' (HLT) and one for 'Cerebrovascular and spinal vascular disorders NEC' (HLT). The 'LLTs under the same PT' column lists various migraine-related terms such as 'Acute migraine', 'Complicated migraine', 'Confusional migraine', 'Episodic migraine', 'Fulgurating migraine', 'Menstrual migraine', 'Migraine', 'Migraine aggravated', 'Migraine headache', 'Migraine NOS', 'Migraine type headaches', 'Migraine, unspecified', 'Migrainous headache', and 'Migrainous neuralgia'. At the bottom of the modal are 'OK' and 'Cancel' buttons.

MedDRA	
Hierarchies	
LLT	Chronic migraine
PT	Migraine
LLTs under the same PT	
HLT	Migraine headaches
HLGT	Headaches
SOC	Nervous system disorders
HLT	Cerebrovascular and spinal vascular disorders NEC
HLGT	Vascular disorders NEC
SOC	Vascular disorders
	Acute migraine
	Complicated migraine
	Confusional migraine
	Episodic migraine
	Fulgurating migraine
	Menstrual migraine
	Migraine
	Migraine aggravated
	Migraine headache
	Migraine NOS
	Migraine type headaches
	Migraine, unspecified
	Migrainous headache
	Migrainous neuralgia

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.



The screenshot shows the MedDRA Web-Based Browser (WBB) login page. At the top left is the MedDRA logo, a blue sphere with green vertical bars. To its right is the text "MedDRA Web-Based Browser" in green and "Medical Dictionary for Regulatory Activities" in blue. In the top right corner, there is a link for "MedDRA End User License Agreement".

The main content area is divided into two sections. On the left is a "Login to WBB" form with the following fields:

- Preferred Language: A dropdown menu currently set to "English".
- MedDRA ID: A text input field.
- Password: A text input field.
- A blue "Login" button.

On the right side of the login form, there is a welcome message: "Welcome to the MedDRA WBB website." Below this, it says: "If you have problems logging in, please contact the MSSO Help Desk at mssohelp@meddra.org or 1-877-258-8280".

At the bottom left of the page, there is contact information: "mssohelp@meddra.org", "Copyright © 2016 IFFMA", and "Updated: January 2016 Version 2.0". At the bottom right, there is the text "MedDRA MSSO" and "Toll Free International: +1 877.258.8280".

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.

Report information

Patient

Case narrative and other information

Medical and past drug history

Reaction: Rash

Reaction: Itch

Reaction: Dry skin

Drug: Tylenol

Drug: Beta-alanine

Tests and procedures

Assessment

Overview

UMC-UMCORG-300020901 Created by organisation: Regional Centre A

+ Reaction

Reaction / event (MedDRA) [?] Rash

Country of occurrence [?] Sweden

Reaction / event as reported by initial reporter [?]

Language of reaction / event as reported by initial reporter Swedish

Onset date [?] Time [?] End date [?] Time [?] Duration [?] Calculate

Outcome

Medical confirmation by healthcare professional [?] Yes No Clear

Serious Yes No Clear

Seriousness [?]

Results in death Congenital anomaly / birth defect

Disabling / incapacitating Caused / prolonged hospitalisation

Life threatening Other medically important condition

Vaccine information [?]

AEFI category

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).

+ Reaction

Reaction / event (MedDRA)

Country of occurrence

Reaction / event as reported by initial reporter

Language of reaction / event as reported by initial reporter

Onset date Time : End date Time : Duration

Outcome

Medical confirmation by healthcare professional Yes No

Serious

Yes No

Seriousness

Results in death

Disabling / incapacitating

Life threatening

Congenital anomaly / birth defect

Caused / prolonged hospitalisation

Other medically important condition

Vaccine information

AEFI category

Seriousness criteria must be selected when Serious is set to Yes

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.

The image displays two screenshots of the ICH E2B(R3) reaction form. The top screenshot shows a reaction for 'Urinary retention' with 'Serious' set to 'Yes'. The bottom screenshot shows a reaction for 'Vomiting' with 'Serious' set to 'No'. Both screenshots show the 'Seriousness' section with various checkboxes for severity.

Reaction / event (MedDRA)	Country of occurrence	Language of reaction / event as reported by initial reporter	Onset date	Time	End date	Time	Duration	Outcome	Medical confirmation by healthcare professional	Serious	Seriousness	Vaccine information	AEFI category
Urinary retention	Sweden	Swedish							<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Results in death <input type="checkbox"/> Disabling / incapacitating <input type="checkbox"/> Life threatening <input type="checkbox"/> Congenital anomaly / birth defect <input checked="" type="checkbox"/> Caused / prolonged hospitalisation <input type="checkbox"/> Other medically important condition		
Vomiting	Sweden	Swedish							<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Results in death <input type="checkbox"/> Disabling / incapacitating <input type="checkbox"/> Life threatening <input type="checkbox"/> Congenital anomaly / birth defect <input type="checkbox"/> Caused / prolonged hospitalisation <input type="checkbox"/> Other medically important condition		

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

The image shows two instances of a 'Reaction' form. The top form is for 'Urinary retention' and has its 'Outcome' dropdown set to 'Recovered / Resolved'. The bottom form is for 'Vomiting' and has its 'Outcome' dropdown set to 'Recovering / Resolving'. Both forms include fields for 'Country of occurrence' (Sweden), 'Language of reaction / event as reported by initial reporter' (Swedish), and various checkboxes for 'Seriousness' and 'Medical confirmation by healthcare professional'. The 'Outcome' dropdown is highlighted with an orange arrow pointing to it from the text 'Outcome on reaction level'.

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

Drug

Fields available in the Drug section

+ Drug

Drug role ?

WHODrug

Drug name ?

Active ingredient(s) ?

Drug name as reported by initial reporter ?

Strength ?

Marketing Authorisation Holder (WHODrug) ?

Marketing Authorisation Holder ?

Country where drug is authorised

Country where drug was obtained

Suspected ingredient ?

+ Indication

Indication (MedDRA) ?

Indication as reported by initial reporter ?

Additional drug-related problems

+ Action taken ?

Was a rechallenge performed?

Yes No Unknown

Additional information on drug

+ Dosage information

Dose ? **Doses in interval** ? **Dosing interval** ?

Dosage

Pharmaceutical form **Route of administration**

Batch number

Start of administration ? **End of administration** ?

Duration ?

Vaccine information ?

Dose number ? **Expiry date**

Diluent name **Diluent batch number**

Site of administration **Vaccination session**

Time interval between administration and reaction onset

Reaction / event (MedDRA)	First dose	Last dose
Urinary retention	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
Vomiting	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
Fever	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>


Cumulative dose to first reaction ?

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.



The screenshot shows a form titled '+ Drug' with the following fields:

- Drug role** (with a help icon): A dropdown menu currently showing 'Suspect'.
- WHODrug** (header): A dark blue header for the next section.
- Drug name** (with a help icon): A text input field containing 'Coartem' and an information icon.
- Active ingredient(s)** (with a help icon): A list of ingredients:
 - Artemether
 - Lumefantrine

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** to 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.

The screenshot shows a form titled '+ Drug' with the following fields:

- Drug role:** A dropdown menu with 'Suspect' selected.
- WHODrug section:**
 - Drug name:** A dropdown menu with 'Paracetamol;Phenylephrine' selected. A red '1' is next to this field.
 - Active ingredient(s):** A list containing 'Paracetamol' and 'Phenylephrine'.
- Drug name as reported by initial reporter:** A text input field containing 'Tylenol Sinus + Headache Daytime'. A red '2' is next to this field.

Using WHODrug

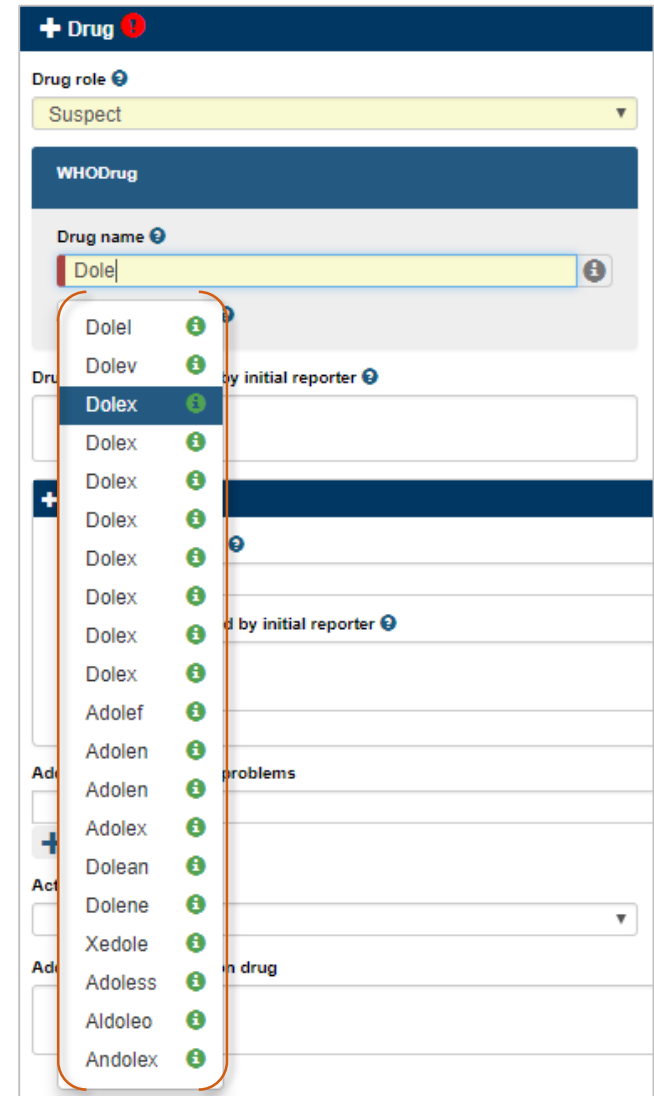
When searching for a drug in WHODrug, you can either:

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


You can search for brand names or active substances.

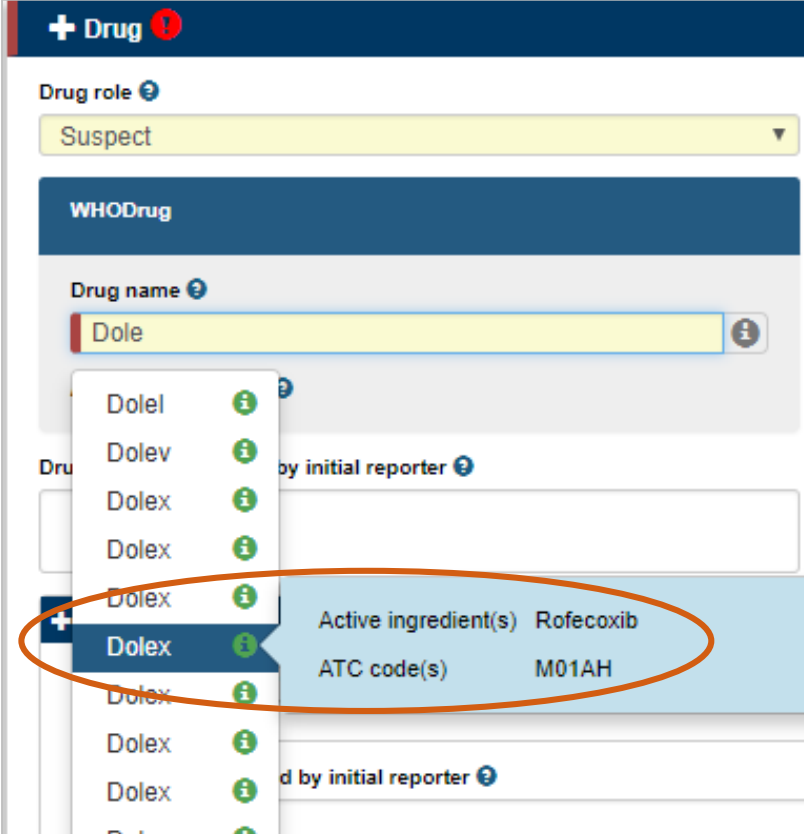
A drop-down list appears with the results matching your search.

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.



The screenshot shows a web interface for drug entry. At the top, there is a header with a plus sign and the word 'Drug' followed by a red warning icon. Below this is a 'Drug role' dropdown menu set to 'Suspect'. A 'WHODrug' section is visible. The 'Drug name' field contains 'Dole' and has an information icon to its right. A dropdown menu is open, listing several suggestions: 'Dolel', 'Dolev', 'Dolex', 'Dolex', 'Dolex', 'Dolex', 'Dolex', 'Dolex', 'Dolex', 'Dolex', and 'Dolex'. The 'Dolex' entry is highlighted in blue and contains the following details:

Active ingredient(s)	Rofecoxib
ATC code(s)	M01AH

Visible active ingredients

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

+ Drug

Drug role ⓘ
Suspect ▼

WHODrug

Drug name ⓘ
Dolex ⓘ

Active ingredient(s) ⓘ
• Rofecoxib

Drug name as reported by initial reporter ⓘ

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”

The screenshot shows the WHODrug search interface. The 'Drug name' field contains the text 'mico tini'. A dropdown menu is open, displaying a list of search results. The top result is 'Miconazole;Tinidazole', which is highlighted. A tooltip is visible over this result, showing the active ingredients 'Miconazole, Tinidazole' and the ATC code(s) 'G01AF, P01AB'. Other results in the list include 'Miconazole nitrate;Tinidazole', 'Miconazole;Neomycin;Tinidazole', 'Miconazole nitrate w/tinidazole', 'Tinidazol + Nitrato de Miconazol', 'Clotrimazole;Miconazole;Tinidazole', 'Menthol;Miconazole;Tinidazole;Zinc', 'Clotrimazole;Miconazole nitrate;Tinidazole', 'Miconazole nitrate;Neomycin sulfate;Tinidazole', and 'Menthol;Miconazole nitrate;Tinidazole;Zinc sulfate'.

The screenshot shows the WHODrug search interface. The 'Drug name' field contains the text 'miconazole;tini'. A dropdown menu is open, displaying a list of search results. The top result is 'Miconazole;Tinidazole', which is highlighted. A tooltip is visible over this result, showing the active ingredients 'Miconazole, Tinidazole' and the ATC code(s) 'G01AF, P01AB'. Other results in the list include 'Miconazole nitrate;Tinidazole', 'Miconazole;Neomycin;Tinidazole', 'Miconazole nitrate w/tinidazole', 'Clotrimazole;Miconazole;Tinidazole', 'Menthol;Miconazole;Tinidazole;Zinc', 'Clotrimazole;Miconazole nitrate;Tinidazole', 'Miconazole nitrate;Neomycin sulfate;Tinidazole', and 'Menthol;Miconazole nitrate;Tinidazole;Zinc sulfate'.

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 ⓘ

Strength of the active ingredient(s)

For example, if the drug has multiple active ingredients

*Each film-coated tablet contains: 250 mg amoxicillin as the trihydrate and 125 mg clavulanic acid as clavulanate potassium. Each tablet contains 0.63 mEq potassium.

Usual Dosage: See accompanying prescribing information.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Dispense in a tight container [see USP]. Advise patients to keep in a closed container.

Use only if inner seal is intact.

NDC 65862-501-30

Amoxicillin and Clavulanate Potassium Tablets, USP

250 mg/125 mg*

Rx only 30 Tablets

Manufactured for: Aurobindo Pharma USA, Inc. 2400 Route 130 North Dayton, NJ 08810

Manufactured by: Aurobindo Pharma Limited Hyderabad-500 072, India

M.L. No.: 57/RR/AP/2003/F/R

Batch :

Expiry : P1404915

+ Drug

Drug role ⓘ
Suspect

WHODrug

Drug name ⓘ
Amoxicillin;Clavulanate potassium ⓘ

Active ingredient(s) ⓘ
• Amoxicillin
• Clavulanate potassium

Drug name as reported by initial reporter ⓘ
amoxicillin and clavulanate potassium

Strength ⓘ
250 mg / 125 mg

Marketing Authorisation Holder (WHODrug) ⓘ

Marketing Authorisation Holder ⓘ

Authorisation country ⓘ

Suspected ingredient ⓘ

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

The screenshot shows a form titled '+ Drug' with the following fields:

- Drug role**: A dropdown menu with 'Suspect' selected.
- WHODrug**: A section containing:
 - Drug name**: A text field with 'Aspirine' and an information icon.
 - Active ingredient(s)**: A list containing 'Acetylsalicylic acid'.
- Drug name as reported by initial reporter**: A text input field.
- Strength**: A text input field.
- Marketing Authorisation Holder (WHODrug)**: A dropdown menu, highlighted with a red circle.
- Marketing Authorisation Holder**: A text input field, also highlighted with a red circle.
- Authorisation country**: A dropdown menu.
- Suspected ingredient**: A dropdown menu.

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.

The screenshot displays the WHODrug interface for a drug entry. The main header is '+ Drug'. The 'Drug role' is set to 'Suspect'. The 'Drug name' is 'Aspirine', with an active ingredient of 'Acetylsalicylic acid'. The 'Marketing Authorisation Holder (WHODrug)' dropdown menu is open, showing a list of MAHs: Bayer, Bayer health care, Brocacef, Emra-med, Eureco pharm, Fisher farma, Inava laboratoires, Medcor Pharmaceuticals B.V., Pharm central hosp, Promopharm, Siphat, Stephar, Upsa, and Vemedica b.v.

+ Drug

Drug role ⓘ
Suspect ▼

WHODrug

Drug name ⓘ
Aspirine ⓘ

Active ingredient(s) ⓘ
• Acetylsalicylic acid

Drug name as reported by initial reporter ⓘ

Strength ⓘ

Marketing Authorisation Holder (WHODrug) ⓘ

- Bayer
- Bayer health care
- Brocacef
- Emra-med
- Eureco pharm
- Fisher farma
- Inava laboratoires
- Medcor Pharmaceuticals B.V.
- Pharm central hosp
- Promopharm
- Siphat
- Stephar
- Upsa
- Vemedica b.v.

+ Indication

Indication (MedDRA) ⓘ

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

The screenshot shows a web form for reporting a drug-related adverse event. The form is titled '+ Drug' and contains several fields:

- Drug role**: A dropdown menu with 'Suspect' selected.
- WHODrug**: A section containing:
 - Drug name**: A text input field with 'Aspirina' entered.
 - Active ingredient(s)**: A list containing 'Acetylsalicylic acid'.
- Drug name as reported by initial reporter**: A text input field.
- Strength**: A text input field.
- Marketing Authorisation Holder (WHODrug)**: A dropdown menu.
- Marketing Authorisation Holder**: A text input field.
- Country where drug is authorised**: A dropdown menu, highlighted with a red box.
- Country where drug was obtained**: A dropdown menu, highlighted with a red box.
- Suspected ingredient**: A dropdown menu.

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

The screenshot displays a web form for reporting a drug. The form is titled '+ Drug' and contains several sections. The 'Drug role' dropdown is set to 'Suspect'. The 'WHODrug' section shows the drug name 'Viagra' and the active ingredient 'Sildenafil citrate'. The 'Suspected ingredient' dropdown is open, showing a list of options: Active ingredient, Preservative, Antioxidant, Stabilizer, Color (highlighted in blue), Flavouring agent, Solvent, Constituent, unclassified, and Excess percent. Other fields include Strength, Marketing Authorisation Holder (WHODrug), Marketing Authorisation Holder, Authorisation country, Drug name as reported by initial reporter, and Indication (MedDRA) and Indication as reported by initial reporter.

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.

The screenshot displays a form with two main sections: 'WHODrug' and '+ Indication'.
WHODrug section:
- **Drug name:** Metformin hydrochloride
- **Active ingredient(s):** Metformin hydrochloride
- **Marketing Authorisation Holder (WHODrug):** (Dropdown menu)
- **Marketing Authorisation Holder:** (Text field)
- **Country where drug is authorised:** (Dropdown menu)
- **Country where drug was obtained:** (Dropdown menu)
- **Suspected ingredient:** (Dropdown menu)
- **Drug name as reported by initial reporter:** (Text field)
+ Indication section:
- **Indication (MedDRA):** Type II diabetes mellitus
- **Indication as reported by initial reporter:** Type 2 diabetes

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

The screenshot shows a form for reporting drug-related problems. It is divided into several sections:

- + Drug**:
 - Drug role: Suspect
 - WHODrug: [Empty]
 - Drug name: Bentyl
 - Active ingredient(s): Dicycloverine hydrochloride
 - Drug name as reported by initial reporter: [Empty]
 - Strength: [Empty]
 - Marketing Authorisation Holder (WHODrug): [Empty]
 - Marketing Authorisation Holder: [Empty]
 - Authorisation country: [Empty]
 - Suspected ingredient: [Empty]
- + Indication**:
 - Indication (MedDRA): [Empty]
 - Indication as reported by initial reporter: [Empty]
- Additional drug-related problems**: Medication Error (highlighted with an orange box)

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

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.

The screenshot shows a web interface for adding a reaction. The main form has a text input field containing "Drug administered via inappropriate route". A modal dialog box titled "MedDRA" is open, displaying a list of terms. The "HLT" term "Product administration errors and issues" is highlighted with a green border. The dialog also shows hierarchies (LLT, PT, SOC) and a list of synonyms.

MedDRA	
Hierarchies	Synonyms
LLT Drug administered via inappropriate route	Enteral formulation administered by other route
PT Incorrect route of drug administration	Inappropriate route of vaccination
HLT Product administration errors and issues	Incorrect route of drug administration
HLGT Medication errors and other product use errors and issues	Intramuscular formulation administered by other route
SOC Injury, poisoning and procedural complications	Intrathecal formulation administered by other route
	Intravenous formulation administered by other route
	Rectal formulation administered by other route
	Respiratory formulation administered by other route
	Subcutaneous injection formulation administered by other route
	Unintentional intravascular injection
	Wrong route of administration

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.

The screenshot displays a web-based form for reporting a drug reaction. The main header is "UMC-UMCORG-60". On the left is a navigation menu with items: "Report information", "Patient", "Case narrative and other information", "Medical and past drug history", "Reaction: Hypotension", "Reaction: Felt dizzy", "Drug: Captopril" (highlighted), "Tests and procedures", "Causality assessment", and "Overview".

The main content area is divided into sections:

- + Drug**
 - Drug role: Suspect
 - Strength: (empty)
 - Marketing Authorisation Holder (WHODrug): (empty)
 - Marketing Authorisation Holder: (empty)
 - Authorisation country: (empty)
 - Suspected ingredient: (empty)
- WHODrug**
 - Drug name: Captopril
 - Active ingredient(s): Captopril
 - Drug name as reported by initial reporter: (empty)
- + Indication**
 - Indication (MedDRA): (empty)
 - Indication as reported by initial reporter: (empty)
- Additional drug-related problems**: (empty)
- Action taken**: Drug Withdrawn
- Was a rechallenge performed?**: Yes (selected), No, Unknown, Clear
- Rechallenge information**
 - Reaction / event (MedDRA): Hypotension
 - Did reaction recur on re-administration?
 - Reaction recurred: Reaction recurred
 - Outcome unknown: Outcome unknown

Two orange arrows point from the "Reaction: Hypotension" and "Reaction: Felt dizzy" items in the left menu to the "Rechallenge information" section. A red exclamation mark icon is visible next to the "Overview" menu item.

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.

The screenshot shows a form titled '+ Dosage information'. It contains several input fields and dropdown menus. A red '1' is placed next to the 'Dose' field, which contains '500' and 'mg'. A red '2' is placed next to the 'Dosage' free-text field, which contains '500 mg once a day'. Other fields include 'Doses in interval' (1), 'Dosing interval' (1 Day), 'Pharmaceutical form', 'Route of administration', 'Batch number', 'Start of administration', 'End of administration', 'Duration', 'Calculate' button, 'Vaccine information' section with 'Dose number', 'Expiry date', 'Diluent name', 'Diluent batch number', 'Site of administration', and 'Vaccination session'.

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.

+ Dosage information

Dose Doses in interval Dosing interval

Both value and unit must be entered

Dosage

Pharmaceutic

Batch number

Start of admin

Duration

Vaccine info

Examples: Dose / Dosing interval / Dosage

7.5 mg once daily

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

Dose ⓘ Doses in interval ⓘ Dosing interval ⓘ

7.5 mg 1 1 Day

Dosage

7,5 mg 1x/day

50 mg every other day

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

Dose ⓘ Doses in interval ⓘ Dosing interval ⓘ

50 mg 1 2 Day

Dosage

50 mg every other day

5 mg four times in one day (QID)

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

Dose ⓘ Doses in interval ⓘ Dosing interval ⓘ

5 mg 4 1 Day

Dosage

5 mg 4x/day (QID)

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

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

Dose ⓘ Doses in interval ⓘ Dosing interval ⓘ

5 mg 1 Total

Dosage

5 mg as a single dose

Pharmaceutical form

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

+ Dosage information

Dose ⓘ Doses in interval ⓘ Dosing interval ⓘ

▼ ▼

Dosage

Pharmaceutical form

Tablet

Route of administration

▼

Batch number

Start of administration ⓘ End of administration ⓘ

▼ ▼

Duration ⓘ

▼ Calculate

Vaccine information ⓘ

Dose number ⓘ

▼

Diluent name Diluent batch number

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.

The image shows a screenshot of a web-based form titled '+ Dosage information'. The form contains several input fields and dropdown menus. The 'Route of administration' dropdown menu is open, showing a list of options: oral, intravenous drip, intravenous bolus, subcutaneous, nasal, sublingual, topical, rectal, intra-articular, intrathecal, intra-arterial, auricular (otic), buccal, cutaneous, dental, endocervical, endosinusial, endotracheal, and epidural. The 'oral' option is highlighted in blue. Other fields include 'Dose', 'Doses in interval', 'Dosing interval', 'Dosage', 'Pharmaceutical form' (set to 'Tablet'), 'Batch number', 'Start of administration', 'Duration', 'Vaccine information', 'Dose number', and 'Diluent name'.

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.

The screenshot shows a web-based form for reporting a drug reaction. The left sidebar contains a navigation menu with items like 'Reaction: Urinary retention', 'Reaction: Vomiting', 'Reaction: Pain', 'Drug: Metformin hydrochloride', 'Tests and procedures', 'Assessment', and 'Overview'. The main form area is divided into several sections:

- WHODrug:** Includes fields for Drug name (Metformin hydrochloride), Active ingredient(s) (Metformin hydrochloride), and Drug name as reported by initial reporter.
- Marketing Information:** Fields for Marketing Authorisation Holder, Country where drug is authorised, Country where drug was obtained, and Suspected ingredient.
- Indication:** Fields for Indication (MedDRA) (Type II diabetes mellitus) and Indication as reported by initial reporter (Type 2 diabetes).
- Additional drug-related problems:** A section with a plus sign and a trash icon.
- Action taken:** A dropdown menu and radio buttons for 'Was a rechallenge performed?' (Yes, No, Unknown).
- Additional information on drug:** A text input field.
- Administration Details:** Fields for Dose (500 mg), Frequency (1), Unit (Day), Dosage (500 mg once a day), Pharmaceutical form, Route of administration, Batch number, Start and End of administration, and Duration.
- Vaccine information:** Fields for Dose number, Expiry date, Diluent name, Diluent batch number, Site of administration, and Vaccination session.
- Time interval between administration and reaction onset:** A table with the following structure:

Reaction / event (MedDRA)	First dose	Last dose
Urinary retention	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
Vomiting	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
Pain	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

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.

The image shows a software interface for reporting adverse events. On the left is a sidebar menu with the following items: Report information, Patient, Case narrative and other information, Medical and past drug history, Reaction: Hypotension, Drug: Captopril, Drug: Aspirine, Drug: Metformin, Drug: Insulin (highlighted with a blue background and an orange circle), Tests and procedures, Causality assessment, and Overview (with a red exclamation mark icon). The main area is titled 'UMC-UMCORG-60' and features a '+ Drug' button circled in orange. Below this button is a 'Drug role' dropdown menu set to 'Concomitant'. A 'WHODrug' section contains a 'Drug name' dropdown set to 'Insulin' and an 'Active ingredient(s)' list with 'Insulin'. Below that is a text input field for 'Drug name as reported by initial reporter'. A '+ Indication' section follows, with an 'Indication (MedDRA)' dropdown and a text input field for 'Indication as reported by initial reporter'.

Tests and procedures

Test and procedures section

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

Report information

Patient

Case narrative and other information

Medical and past drug history

Reaction: Urinary retention

Reaction: Vomiting

Reaction: Pain

Drug: Captopril

Drug: Metformin

Tests and procedures

Assessment

Overview !

UMC-UMCORG-300020903 Created by organisation: National PV Centre

Tests and procedures

Results of tests and procedures ⊕

Test date ⓘ

Test name (MedDRA) ⊕ 📄

Test name

Test result

Test result (code)

Normal low value

Normal high value

Comments by initial reporter

+

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

The screenshot shows a web form titled "Tests and procedures" with a sub-header "Results of tests and procedures". It includes a "Test date" field, a "Test name (MedDRA)" dropdown menu, and fields for "Test result" and "Test result (code)". The dropdown menu is open, showing a list of glucose-related terms. "Blood glucose" is highlighted. A tooltip box is visible over the dropdown, listing the following MedDRA terms: "LLTBlood glucose", "PT Blood glucose", "HLT Carbohydrate tolerance analyses (incl diabetes)", "HLG Metabolic, nutritional and blood gas investigations", and "SOC Investigations".

Test name (MedDRA)	Test result	Test result (code)
glucose		

Result

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Test date

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

Tests and procedures

Results of tests and procedures

Test date ⓘ

*Test date is required because
Test name is populated*

Test name (MedDRA)

ⓘ

Test name

Test result

Test result (code)

Normal low value

Normal high value

Result

Comments by initial reporter

+

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

The screenshot displays a web interface titled "Tests and procedures" with a sub-header "Results of tests and procedures". It contains three identical form templates for entering test results. Each form includes a date selector (set to 2 March 2020), a test name field (e.g., "Blood glucose", "Cholesterol", "Skin biopsy"), and several input fields for results and values. The "Test result (code)" dropdown menu is open for the "Cholesterol" test, showing the following options: Positive, Negative, Borderline, and Inconclusive. The "Result" field for the "Skin biopsy" test contains the text "Lymphocytic chronic vasculitis".

Test name (MedDRA)	Test result	Test result (code)	Normal low value	Normal high value
Blood glucose	5 mmol		4 mmol/L	6 mmol/L
Cholesterol		Borderline		
Skin biopsy				

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.

Tests and procedures

Results of tests and procedures

Test date 2 March 2020	Test name (MedDRA) Blood glucose	Test result 5 mmol	Test result (code) [dropdown]	Normal low value 4 mmol/L	Normal high value 6 mmol/L	[trash icon]
Test name		Result		Comments by initial reporter		
Test date 2 March 2020	Test name (MedDRA) Cholesterol	Test result	Test result (code) Borderline	Normal low value	Normal high value	[trash icon]
Test name		Result		Comments by initial reporter		
Test date 2 March 2020	Test name (MedDRA) Skin biopsy	Test result	Test result (code)	Normal low value	Normal high value	[trash icon]
Test name		Result Lymphocytic chronic vasculitis		Comments by initial reporter		

+



Assessment


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 field to capture and document any additional comments and assessments about the case (*review comment, pharmacovigilance comment etc.*).





Assessment from: National Centre


+ Causality assessment

Method  WHO-UMC Causality Source  National Centre

Relatedness of Drug(s) and Reaction(s) 

	Warfarin
GI bleed	Probable/Likely

Diagnosis    

Comment 

1

2

3

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

Report information

Patient

Case narrative and other information

Medical and past drug history

Reaction: Urinary retention

Reaction: Vomiting

Reaction: Pain

Drug: Captopril

Drug: Metformin

Tests and procedures



Assessment


Overview


UMC-UMCORG-300020903 Created by organisation: National PV Centre







Assessment from: National PV Centre


+ Causality assessment




Method  Source 


WHO-UMC Causality  National PV Centre


Relatedness of Drug(s) and Reaction(s) 

	Captopril	Metformin
Urinary retention		
Vomiting		
Pain		

Diagnosis 

Comment 



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

Method [?] Source [?]

WHO-UMC Causality National PV Centre

action(s) [?]

	Captopril	Metformin
	<input type="text"/>	<input type="text"/>
Vomiting	<input type="text"/>	<input type="text"/>
Pain	<input type="text"/>	<input type="text"/>

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.

Assessment from: National PV Centre

+ Causality assessment

Method ⓘ Source ⓘ

WHO-UMC Causality ▼ National PV Centre

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



	Captopril	Metformin
Urinary retention	<input type="text"/>	<input type="text"/>
Vomiting	<input type="text"/>	<input type="text"/>
Pain	<input type="text"/>	<input type="text"/>


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 from: National PV Centre

+ Causality assessment



Method  Source 


WHO-UMC Causality  National PV Centre


Relatedness of Drug(s) and Reaction(s) 



	Captopril	Metformin
Urinary retention	Possible 	Unlikely 


+ Causality assessment




Method  Source 


Naranjo  University Hospital

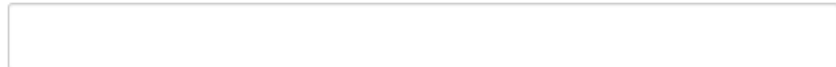
Relatedness of Drug(s) and Reaction(s) 

	Captopril	Metformin
Urinary retention	Probable 	Doubtful 

Diagnosis 

Comment 



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.

Assessment from: Regional Centre 1

+ Causality assessment

Method [?] WHO-UMC Causality Source [?] RC 1

Relatedness of Drug(s) and Reaction(s) [?]

	Alvedon	Beta-alanine
Rash	Certain	Unlikely
Itch	Conditional/Unclassified	Probable/Likely

Diagnosis [?] 11-beta-hydroxylase deficiency

Comment [?] The RC 1 comment

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

Assessment from: Regional Centre 1

Causality assessment

Method WHO-UMC Causality Source RC 1

The delete button is only shown when a user from a National Centre is logged in

Assessment section – for a decentralized organisational VigiFlow structure

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

Assessment from: Regional Centre 2

Causality assessment

Method: WHO-UMC Causality | Source: RC 2

Relatedness of Drug(s) and Reaction(s)

	Alvedon	
Rash	Certain	Unlikely
Itch	Conditional/Unclassified	Probable/Likely

Diagnosis: 11-oxyteroid activity increased

Comment: The RC 2 comment

Assessment from: National Centre

+ Causality assessment

Method: WHO-UMC Causality | Source: National Centre

Relatedness of Drug(s) and Reaction(s)

	Alvedon	Be
Rash	Certain	Unlikely
Itch	Conditional/Unclassified	Probable/Likely

Diagnosis: 11-beta-hydroxylase deficiency


Comment: The NC comment

Assessments from other organisations are displayed but cannot be edited

i.e. a user from a National Centre can only edit the assessments belonging to that organisation

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/>



Signal detection and causality assessment

Not started | 120 min | 4 modules

The learning objective for this course is to be able to explain and apply the basic concepts of signal detection and assessment, causality assessment and disproportionality analysis. The course consists of four modules, which are divided into several lessons (each lesson is about 3-5 minutes). A fifth module (Statistical reasoning and algorithms in PV) has been launched and is now available on the portal.

Contact person : Pharmacovigilance Training pvtraining@who-umc.org

[VIEW MODULES](#)

Introduction to signal detection

Not started | 30 min

Learning objective: To be able to explain the basic concepts, the rationale and the principles of signal detection

[START](#)

Causality assessment of single case safety reports

Not started | 30 min

Learning objective: To understand the complex nature of causality assessment in Individual Case Safety Reports (ICSRs) and the value of structured approaches

Previous module required

Causality assessment of case series

Not started | 30 min

Learning objective: To understand the important elements to consider when assessing causality in a case series and the relevance of the Bradford Hill criteria

Previous module required

Signal assessment

Not started | 30 min

Learning objective: To be able to understand the signal assessment process, to apply the steps explained and to perform a simple signal assessment

Previous module required

Specific fields for Adverse Events Following Immunization (AEFIs)

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

The screenshot shows a web-based form for reporting a reaction. The form includes the following fields and options:

- Reaction / event (MedDRA):** Fever
- Country of occurrence:** Sweden
- Reaction / event as reported by initial reporter:** (Empty text box)
- Language of reaction / event as reported by initial reporter:** Swedish
- Onset date:** (Date and time input fields)
- End date:** (Date and time input fields)
- Duration:** (Duration input field)
- Calculate:** (Button)
- Outcome:** (Dropdown menu)
- Medical confirmation by healthcare professional:** Radio buttons for Yes, No, and a Clear button.
- Serious:** Radio buttons for Yes, No, and a Clear button.
- Seriousness:** Checkboxes for:
 - Results in death
 - Disabling / incapacitating
 - Life threatening
 - Congenital anomaly / birth defect
 - Caused / prolonged hospitalisation
 - Other medically important condition
- Vaccine information:** A callout box highlighting the **AEFI category** dropdown menu, which lists:
 - 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***

+ Drug

Drug role Suspect

WHODrug

Drug name Engerix-b

Active ingredient(s)

- Hepatitis b vaccine rHBsAg (yeast)

Drug name as reported by initial reporter

Strength

Marketing Authorisation Holder (WHODrug)

Marketing Authorisation Holder

Country where drug is authorised

Country where drug was obtained

Suspected ingredient

+ Indication

Indication (MedDRA)

Indication as reported by initial reporter

Additional drug-related problems

+ Action taken

Action taken

Was a rechallenge performed?

Yes No Unknown

Additional information on drug

+ Dosage information

Dose

Doses in interval

Dosing interval

Dosage

Pharmaceutical form

Route of administration intramuscular

Batch number

Start of administration

30 September 2019

End of administration

30 September 2019

Duration

Calculate

Vaccine information

Dose number

Expiry date

Diluent name

Diluent batch number

Site of administration

Vaccination session

Time interval between administration and reaction onset

Reaction / event (MedDRA)

Missing MedDRA term

First dose

Last dose

Cumulative dose to first reaction

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.

Assessment from: National PV Centre

+ Causality assessment

Method ⓘ Source ⓘ

WHO AEFI National PV Centre

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

	Dtp vaccine
Fever	

Consistent causal association to immunization
Indeterminate
Inconsistent causal association to immunization
Unclassifiable

Diagnosis ⓘ

+ ⓘ

Questions:
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– Building a global safety culture

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