

VigiFlow

Working with the REPORT LIST



– 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.

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Content

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- [Working with the Report List](#)
- [Searching for ICSRs](#)
- [Features for workflow support](#)
- [Exporting ICSRs](#)

Working with the Report List

Functions in the top bar

Import ICSRs in a xml file

Manage user accounts and organisations – available only for administrator users

Export ICSRs in PDF, Excel or xml

Go to the Data Entry page to enter a new ICSR

Manage xml files generated by Vigiflow

Direct access to Vigilyze

Open search filters

Report list Vigiflow - National PV Centre User name ▾

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

0 ICSRs selected 20498 ICSRs match your search with 1 filter(s) applied

Page 1 of 1025 « < 1 2 3 4 5 ... > »

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilyze
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> UMC-UMCORG-300020899	National PV Centre	UN		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-nullifyme	National PV Centre		MH	Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followmeup	National PV Centre		MH	Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> DE-EMA-Testcase08	National PV Centre		HVIII	Liver failure		27082019	07072020	Open	
<input type="checkbox"/> JP-EMA-TESTCASE05	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE03	National PV Centre		MH	Pre-eclampsia	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-MAH-TESTCASE02	National PV Centre		JTK	22031931	Food interaction, Explosive diarrhoea	27082019	07072020	Open	
<input type="checkbox"/> SE-EMA-TESTCASE01	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020888	National PV Centre	SA				03082020	03082020	Open	
<input type="checkbox"/> MX-SA-2020SA000185	National PV Centre			Gastrointestinal toxicity, Drug toxicity NOS, Neutropenia, Hypertension arterial	Zaltrap, Irinotecan, Calcium folinate, Fluorouracil, Levothyroxine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030943	National PV Centre			Lack of drug effect, Product use issue	Apidra solostar	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030944	National PV Centre			Peritonsillar abscess	Oxaliplatin, Calcium folinate, Fluorouracil	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030938	National PV Centre			Flu like symptoms	Influenza vaccine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030946	National PV Centre			Influenza, Vaccination failure	Influenza vaccine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030939	National PV Centre		01011950	Cardiovascular symptom, Urinary incontinence	Insulin glargine, Humalog mix25, Humalog mix50	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030937	National PV Centre			Fetal death, Drug exposure during pregnancy	Acetylsalicylic acid, Progesterone	27052020	27052020	Open	

A single Report List

All the reports contained in your database are available at the Report List.

To see a specific set of reports, click on **Filter** to expand the search filter section.

VigiFlow - National PV Centre User name

[+ New ICSR](#) [Import](#) [Export](#) [Manage accounts](#) [VigiLyze](#) Filter PDF/Excel/XML

0 ICSRs selected 20498 ICSRs match your search with 1 filter(s) applied Page 1 of 1025

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> UMC-UMCORG-300020899	National PV Centre	UN		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-nullifyme	National PV Centre		MH	Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followmeup	National PV Centre		MH	Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> DE-EMA-Testcase06	National PV Centre		HVIII	Liver failure		27082019	07072020	Open	
<input type="checkbox"/> JP-EMA-TESTCASE05	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE03	National PV Centre		MH	Pre-eclampsia	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-MAH-TESTCASE02	National PV Centre		JTK	22031931	Food interaction, Explosive diarrhoea	27082019	07072020	Open	
<input type="checkbox"/> SE-EMA-TESTCASE01	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020888	National PV Centre	SA				03082020	03082020	Open	
<input type="checkbox"/> MX-SA-2020SA000185	National PV Centre			Gastrointestinal toxicity, Drug toxicity NOS, Neutropenia, Hypertension arterial	Zatrap, Innotecan, Calcium folinate, Fluorouracil, Levothyroxine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030943	National PV Centre			Lack of drug effect, Product use issue	Apidra solostar	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030944	National PV Centre			Peritonsillar abscess	Oxaliplatin, Calcium folinate, Fluorouracil	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030938	National PV Centre			Flu like symptoms	Influenza vaccine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030946	National PV Centre			Influenza, Vaccination failure	Influenza vaccine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030939	National PV Centre		01011950	Cardiovascular symptom, Urinary incontinence	Insulin glargine, Humalog mix25, Humalog mix50	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030937	National PV Centre			Fetal death, Drug exposure during pregnancy	Acetylsalicylic acid, Progesterone	27052020	27052020	Open	

Report list page

The Report List page is divided in 2 sections:

Search filters

Initial received date (from) [] [] [] [] Initial received date (to) [] [] [] [] Report title [] Status of report [Open] Received from []

Report type [] Initials [] Reaction / event (MedDRA) [] Drug name (WHODrug) []

Means of reporting [] Sex [] Serious [] Active ingredient(s) (WHODrug) []

Reporter qualification [] Date of birth [] Seriousness criteria [] ATC code []

Report identifier [] Outcome of reaction [] Additional drug-related problems []

Study type [] Assigned to [] Batch number / Diluent batch number []

Study name / Study registration number [] Delegated to organisation [] Indication (MedDRA) []

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

[Search] [Clear]

List of reports

0 ICSRs selected 20498 ICSRs match your search with 1 filter(s) applied Page 1 of 1025

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input type="checkbox"/> UMC-UMCORG-300020802	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> UMC-UMCORG-300020899	National PV Centre	UN		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-nullifyme	National PV Centre		MH	Jaundice, unspecified, not of newborn		27062019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followmeup	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"/> DE-EMA-TESTCASE01	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	

Report List - Default view

By default, VigiFlow shows the list of all reports which have the status **Open**.

The **Clear** button will remove any entered data from the search section.

The screenshot displays the VigiFlow Report List interface. At the top, there are search filters for 'Initial received date (from)', 'Initial received date (to)', 'Report title', 'Status of report' (set to 'Open'), 'Received from', 'Drug name (WHODrug)', 'Active ingredient(s) (WHODrug)', 'ATC code', 'Additional drug-related problems', 'Batch number / Diluent batch number', and 'Indication (MedDRA)'. There are also checkboxes for 'Include deleted ICSRs', 'Show only ICSRs that can be copied to VigiLyze', and 'Show only ICSRs with at least one drug or reaction that is not coded'. A 'Search' button and a 'Clear' button are located at the bottom right of the search section.

Below the search filters, the interface shows '0 ICSRs selected' and '20488 ICSRs match your search with 1 filter(s) applied'. The main table displays a list of reports with columns for 'Worldwide unique id', 'Delegated to organisation', 'Initials', 'Date of birth', 'Reaction / event (MedDRA)', 'Drug name (WHODrug)', 'Initial received date', 'Latest received date', 'Status of report', and 'VigiLyze'. The 'Status of report' column is highlighted with a red bracket, showing all reports are 'Open'. The 'VigiLyze' column shows a red exclamation mark for one report.

Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
UMC-UMCORG-300020899	National PV Centre	UN		Hypotension	Lamictal	27072020	27072020	Open	
AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
LV-EMA-Testcase08-nullifyme	National PV Centre	MH		Jaundice, unspecified, not of newborn		27082019	07072020	Open	
EE-EMA-Testcase07-followmeup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27082019	07072020	Open	
DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27082019	07072020	Open	
JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27082019	07072020	Open	
US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27082019	07072020	Open	
US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27082019	07072020	Open	
AE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	

Report list – Sorting of columns


Some columns in the list of reports can be sorted and they are indicated with the symbol (↕)

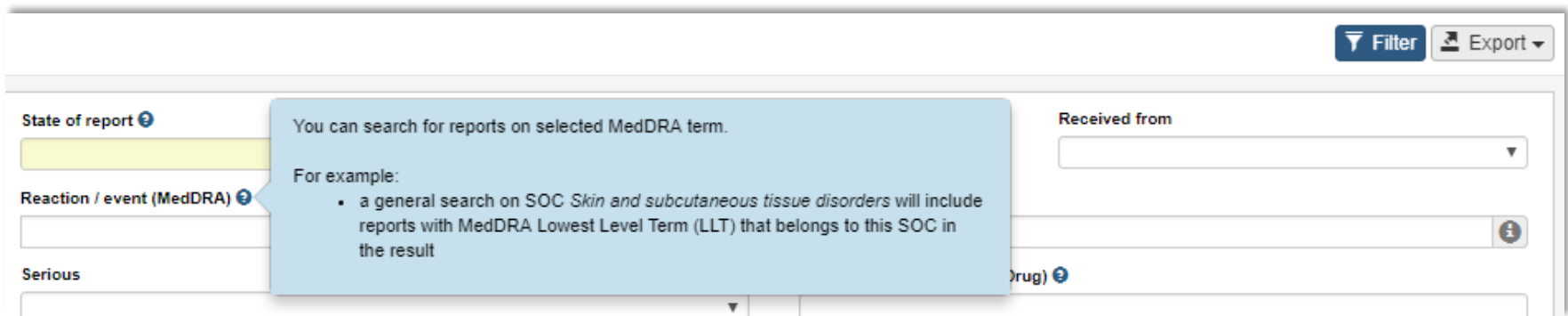
The column in which the sorting is done has a blue background in the heading and the arrow indicates in which way, ascending (▼) or descending (▲)

Sorted column is highlighted





Worldwide unique id ↕	Delegated to organisation	Initials ↕	Date of birth ↕	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date ↕	Latest received date ▼	Status of report ↕	VigiLyze ↕ ⓘ
▼ UMC-UMCORG-300000493	AT National Centre	CA			Ery-max	18102019	18102019	Open	
▼ UMC-UMCORG-300000492	JL National Centre					18102019	18102019	Open	
▼ UMC-UMCORG-300000491	c AMC-1	ZZX		Rash	Cephaloxin	18102019	18102019	Open	
▼ UMC-UMCORG-300000490	c AMC-1	ABC		GI pain	Ibuprofen	18102019	18102019	Open	
▼ DE-BoehringerIngelheim-2019-00011	GA National Centre	UNK		Palpitations, Allergic asthma	Pradaxa	17102019	18102019	Open	!
▼ UMC-UMCORG-300000487	HW National Centre		12072016	Polydactyly of toes	Propylthiocol	16102019	16102019	Open	
▼ AE-DOH-AR/000628/0919	National Centre		25011985			14102019	14102019	Open	
▼ AE-DOH-AR/000629/0919	National Centre		20021990			14102019	14102019	Open	
▼ AE-DOH-AR/000630/0919	National Centre		26122017			14102019	14102019	Open	
▼ AE-DOH-AR/000631/0919	National Centre		01011986			14102019	14102019	Open	
▼ AE-DOH-AR/000633/0919	National Centre		21091950			14102019	14102019	Open	

Help texts

Help texts, which can be found at the icon , provide further information on how to use the corresponding field for searching ICSRs.



The screenshot shows a search interface with several fields and a help tooltip. At the top right, there are buttons for 'Filter' and 'Export'. The main search area includes the following fields:

- State of report** : A yellow highlighted dropdown menu.
- Reaction / event (MedDRA)** : An empty text input field.
- Serious** : A dropdown menu.
- Received from**: A dropdown menu.
- (rug)** : A dropdown menu.

A blue tooltip box is overlaid on the 'Reaction / event (MedDRA)' field, containing the following text:

You can search for reports on selected MedDRA term.

For example:

- a general search on SOC *Skin and subcutaneous tissue disorders* will include reports with MedDRA Lowest Level Term (LLT) that belongs to this SOC in the result

Searching for ICSRs

Use the search filters to search for ICSRs

Use the filters to search for ICSRs in your VigiFlow database and the matching results will be shown in the list of reports below.

The filters can be useful for different purposes, for example analysing how many reports you have in your database or detecting duplicates before entering a new ICSR.

Initial received date (from) ⓘ <input type="text"/> <input type="text"/>	Initial received date (to) <input type="text"/> <input type="text"/>	Report title ⓘ <input type="text"/>	Status of report ⓘ <input type="text"/>	Received from <input type="text"/>
Report type <input type="text"/>	Initials ⓘ <input type="text"/>	Reaction / event (MedDRA) ⓘ <input type="text"/>	Reaction / event (MedDRA) ⓘ ⓘ <input type="text"/>	Drug name (WHODrug) ⓘ <input type="text"/>
Means of reporting <input type="text"/>	Sex <input type="text"/>	Serious <input type="text"/>	Seriousness criteria <input type="text"/>	Active ingredient(s) (WHODrug) ⓘ <input type="text"/>
Reporter qualification <input type="text"/>	Date of birth ⓘ <input type="text"/>	Outcome of reaction <input type="text"/>	Outcome of reaction <input type="text"/>	ATC code ⓘ <input type="text"/>
Report identifier ⓘ <input type="text"/>		Assigned to <input type="text"/>	Assigned to <input type="text"/>	Additional drug-related problems <input type="text"/>
Study type <input type="text"/>		Delegated to organisation <input type="text"/>	Delegated to organisation <input type="text"/>	Batch number / Diluent batch number ⓘ <input type="text"/>
Study name / Study registration number ⓘ <input type="text"/>		Created by organisation <input type="text"/>	Created by organisation <input type="text"/>	Indication (MedDRA) ⓘ ⓘ <input type="text"/>
<input type="checkbox"/> Include deleted ICSRs				<input type="button" value="Search"/> <input type="button" value="Clear"/>
<input type="checkbox"/> Show only ICSRs that can be copied to VigiLyze				
<input type="checkbox"/> Show only ICSRs with at least one drug or reaction that is not coded				

Perform a search

Study type:

Study name / Study registration number:

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or device

Assigned to:

Delegated to organisation:

Created by organisation:

Batch number / Diluent batch number:

Indication (MedDRA):

Click the title headers to sort the reports using these parameters

0 ICSRs selected | 20498 ICSRs match your search with 1 filter(s) applied | Page 1 of 1025

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> UMC-UMCORG-300020899	National PV Centre	UN		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-nullifyme	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
<input type="checkbox"/> SE-EMA-Testcase07-followmeup	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	
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<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"/> UMC-UMCORG-300020888	National PV Centre	SA		Gastrointestinal toxicity, Drug toxicity NOS, Neutropenia, Hypertension arterial	Zaltrap, Irinotecan, Calcium folinate, Fluorouracil, Levothyroxine	03062020	03062020	Open	
<input type="checkbox"/> MX-SA-2020SA000185	National PV Centre			Lack of drug effect, Product use issue	Apidra solostar	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030943	National PV Centre			Peritonsillar abscess	Oxaliplatin, Calcium folinate, Fluorouracil	27052020			
<input type="checkbox"/> MX-SA-2019SA030944	National PV Centre			Flu like symptoms	Influenza vaccine	27052020			
<input type="checkbox"/> MX-SA-2019SA030938	National PV Centre			Influenza, Vaccination failure	Influenza vaccine	27052020			
<input type="checkbox"/> MX-SA-2019SA030946	National PV Centre			Cardiovascular symptom, Urinary incontinence	Insulin glargine, Humalog mix25, Humalog mix50	27052020			
<input type="checkbox"/> MX-SA-2019SA030939	National PV Centre		01011950	Fetal death, Drug exposure during pregnancy	Acetylsalicylic acid, Progesterone	27052020			
<input type="checkbox"/> MX-SA-2019SA030937	National PV Centre								

Reports can be opened by clicking on blue link, which is the **Worldwide unique id**.

Search with no ICSRs found

Initial received date (from) [?] <input type="text"/> <input type="text"/> 2000	Initial received date (to) [?] <input type="text"/> <input type="text"/> 2000	Report title [?] <input type="text"/>	Status of report [?] <input type="text"/>	Received from <input type="text"/>
Report type <input type="text"/>	Means of reporting <input type="text"/>	Reporters qualification Consumer or other Non-Health Professional	Report identifier [?] <input type="text"/>	Drug name (WHODrug) [?] <input type="text"/>
Study type <input type="text"/>	Study name / Study registration number [?] <input type="text"/>	Initials [?] <input type="text"/>	Reaction / event (MedDRA) [?] <input type="text"/>	Active ingredient(s) (WHODrug) [?] <input type="text"/>
<input type="checkbox"/> Include deleted ICSRs <input type="checkbox"/> Show only ICSRs that can be copied to VigiLyze <input type="checkbox"/> Show only ICSRs with at least one drug or reaction that is not coded	Sex <input type="text"/>	Date of birth [?] <input type="text"/>	Serious <input type="text"/>	Seriousness criteria <input type="text"/>
			Outcome of reaction <input type="text"/>	Additional drug-related problems <input type="text"/>
			Assigned to <input type="text"/>	Batch number / Diluent batch number [?] <input type="text"/>
			Delegated to organisation <input type="text"/>	Indication (MedDRA) [?] <input type="text"/>
			Created by organisation <input type="text"/>	<input type="button" value="Search"/> <input type="button" value="Clear"/>

No ICSRs found.

This message will be displayed if your search produces no results



- Building a global safety culture

Search by initial receive date

To search for ICSRs that were entered in VigiFlow in a certain time period, search by the initial and final dates of the time interval, even if the date is incomplete.

Initial received date (from) 2012 Initial received date (to) 2012

Report type

Means of reporting

Reporter qualification

Report identifier

Study type

Study name / Study registration number

Include deleted ICSRs
 Show only ICSRs that can be copied to VigiLyze
 Show only ICSRs with at least one drug or reaction that is not coded

Report title

Initials

Sex

Date of birth

Status of report

Reaction / event (MedDRA)

Serious

Seriousness criteria

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Received from

Drug name (WHODrug)

Active ingredient(s) (WHODrug)

ATC code

Additional drug-related problems

Batch number / Diluent batch number

Indication (MedDRA)

Search Clear

0 ICSRs selected 1 ICSRs match your search with 1 filter(s) applied

Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input checked="" type="checkbox"/> UMC-UMCORG-8098	National PV Centre	B_OB		URTI	Tol	01012012	01012018	Open	!

Identify the Mean of Reporting

ICSRs can get into VigiFlow through different means of reporting, such as:

- Manual data entry
- eReporting
- Mobile app (MedSafety app)
- Import of xml files in E2B format

Use the **Means of Reporting** search filter to identify which reports were received through a specific mean.

The screenshot shows a search interface for ICSRs. The 'Means of Reporting' dropdown menu is open, showing the following options: Manual data entry, eReporting, eReporting - Industry, Mobile app, Import - validated, Import - non-validated, and Unknown. The dropdown is highlighted with an orange border. Other search filters include: Initial received date (from/to), Report title, Status of report, Received from, Report type, Initials, Reaction / event (MedDRA), Drug name (WHODrug), Sex, Serious, Active ingredient(s) (WHODrug), Date of birth, Seriousness criteria, ATC code, Outcome of reaction, Additional drug-related problems, Assigned to, Batch number / Diluent batch number, Delegated to organisation, Indication (MedDRA), Created by organisation, and Study name / Study registration number. There are also checkboxes for 'Include deleted ICSRs', 'Show only ICSRs that can be copied to VigiLyze', and 'Show only ICSRs with at least one drug or reaction that is not coded'. A 'Search' button and a 'Clear' button are located at the bottom right.

Search by report identifier

If you want to search for a report by its identification number, you can use the **Report identifier** search filter to find it by either the whole identification number or parts of it.

The search will be done in any of the report identifiers, such as:

- Worldwide unique id
- Safety report id (visible only in the data entry page)
- Other report id (visible only in the data entry page)

Report identifier

BR-galderma

Study type

Study name / Study registration number

Include deleted ICSRs

Show only ICSRs that can be copied to VigilYZe

Show only ICSRs with at least one drug or reaction that is not coded

0 ICSRs selected ▾ 63 ICSRs match your search with 1 filter(s) applied

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reac
<input type="checkbox"/> BR-GALDERMA-BR17002884	National PV Centre	MKBS	13121983	Drug
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002868	National PV Centre	ALMS	08012003	Stor
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002732	National PV Centre	SNN	12011986	Oily
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002402	National PV Centre	NLPM	18111995	Acne
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002314	National PV Centre	CFA	11051986	Drug
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002077	National PV Centre	JFC	04081987	Skin
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002050	National PV Centre	IMD	27121977	Drug
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002028	National PV Centre	PAB	04041980	Pimp
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002023	National PV Centre	LD	02041987	Skin
<input checked="" type="checkbox"/> BR-GALDERMA-BR17002001	National PV Centre	JCM	03091999	Abdo
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000198	National PV Centre	VRSS	15041982	Sore
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000071	National PV Centre	GSS	28031987	Skin
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000982	National PV Centre	MR	18091940	Diso
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000879	National PV Centre	RBS		Conc
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000800	National PV Centre	AML	03111981	Drug
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000750	National PV Centre	RABB	20042006	Drug
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000703	National PV Centre	RJX	04072003	Red
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000677	National PV Centre	MAAN	20051943	Appl
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000661	National PV Centre	TN		Inter
<input checked="" type="checkbox"/> BR-GALDERMA-BR17000660	National PV Centre	TOS	19081986	Conc

Search for study reports

When using the filters **Study type** and **Study name / Study registration number**, it is possible to search for ICSRs that occurred in the context of e.g. a clinical trial.

Initial received date (from) Initial received date (to)

Report type

Means of reporting

Reporter qualification

Report identifier

Study type

Study name / Study registration number

Include deleted ICSRs

Show only ICSRs that can be copied to Vigilize

Show only ICSRs with at least one drug or reaction that is not coded

Report title

Initials

Sex

Date of birth

Status of report

Reaction / event (MedDRA)

Serious

Seriousness criteria

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Include sub organisations

Received from

Drug name (WHODrug)

Active ingredient(s) (WHODrug)

ATC code

Additional drug-related problems

Batch number / Diluent batch number

Indication (MedDRA)

0 ICSRs selected ▾ 2 ICSRs match your search with 2 filter(s) applied Page 1 of 1 << < 1 > >>

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input checked="" type="checkbox"/> MX-ELI_LILLY_AND_COMPANY-MX202002000067	National PV Centre			Myocardial infarction	Abemaciclib	17022020	17022020	Open	
<input checked="" type="checkbox"/> MX-ELI_LILLY_AND_COMPANY-MX202001000053	National PV Centre			Myocardial infarction	Abemaciclib	30012020	30012020	Open	

Search by patient details

Using the patient information (initials, date of birth or sex) to find ICSRs can be particularly useful to investigate if the database contains previous ICSRs from the same patient and avoid entering the same ICSR twice.

Initial received date (from) [] [] Initial received date (to) [] [] Report title [] Status of report [] Received from []

Report type [] Reaction / event (MedDRA) [] Drug name (WHODrug) []

Means of reporting [] Serious [] Active ingredient(s) (WHODrug) []

Reporter qualification [] Seriousness criteria [] ATC code []

Report identifier [] Outcome of reaction [] Additional drug-related problems []

Study type [] Assigned to [] Batch number / Diluent batch number []

Study name / Study registration number [] Delegated to organisation [] Indication (MedDRA) []

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Include sub organisations

Search Clear

0 ICSRs selected 3 ICSRs match your search with 2 filter(s) applied Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> SE-UMCPRS-dfade7f6-12cf-43d5-9167-9ccf31cad79b	National PV Centre	JD	28081974	11-beta-hydroxylase deficiency		30072019	30072019	Open	
<input type="checkbox"/> UMC-UMCORG-300000052	National PV Centre	JD			Betaferon	01032019	01032019	Open	
<input type="checkbox"/> UMC-UMCORG-300000025	National PV Centre	JD		Flu-like symptoms	Betaferon	10012019	10012019	Open	

Search by Reactions / events (MedDRA)

The **Reaction/event (MedDRA)** field allows to search terms on any MedDRA hierarchy level

Initial received date (from) Initial received date (to)

Report title

Status of report

Received from

Report type

Initials

Reaction / event (MedDRA)

Drug name (WHODrug)

Means of reporting

Sex

Serious

Active ingredient(s) (WHODrug)

Reporter qualification

Date of birth

Seriousness criteria

ATC code

Report identifier

Outcome of reaction

Additional drug-related problems

Study type

Assigned to

Batch number / Diluent batch number

Study name / Study registration number

Delegated to organisation

Indication (MedDRA)

Created by organisation

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

0 ICSRs selected | 14 ICSRs match your search with 1 filter(s) applied | Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-I-en	08082020	12082020	Under assessment	
<input type="checkbox"/> MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-I-en	08082020	08082020	Open	
<input type="checkbox"/> SE-UMCDEMO-2020-00002	Regional Centre			Bruising	Pradaxa	14052020	14052020	Open	
<input type="checkbox"/> SE-UMCDEMO-2020-00002	National Centre	CA		Bruising	Pradaxa	14052020	14052020	Open	
<input type="checkbox"/> SE-UMCDEMO-2020-00002	Regional Centre			Bruising	Pradaxa	13052020	13052020	Open	
<input type="checkbox"/> 123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-I-en	11022020	11022020	Open	
<input type="checkbox"/> ES-ABBVIE-18P-144-1455794-00	National Centre			Syncope, Fall, Compression of fractured vertebra, Pain	Cisplatin, Pemetrexed, Folidoec, Optovite b12, Fortecortin	25112019	25112019	Open	
<input type="checkbox"/> AU-ABBVIE-18P-008-1455908-00	National Centre	ED	02021990	Drug exposure during pregnancy		25112019	25112019	Open	
<input type="checkbox"/> UMC-UMCORG-127	National Centre			Wrong dosage form	Predso	03092019	03092019	Open	
<input type="checkbox"/> UMC-UMCORG-126	National Centre	JUI		Bug bite	DeBug	03092019	03092019	Open	
<input type="checkbox"/> UMC-UMCORG-101	National Centre			Drug not taken in context of intercepted medication error	Alvedon, Ipren	28032019	28032019	Open	
<input type="checkbox"/> SE-ENC-2018-11126	National Centre		12121926	Drug name confusion, Palpitations, Dizziness		31102018	27112018	Open	
<input type="checkbox"/> UMC-UMCORG-88	National Centre	JG	04041976	Bus accident	Bambus	27022019		Open	
<input type="checkbox"/> UMC-UMCORG-8	National Centre	unknown		Angina attack, Heart injury	Irbesartan, Crestor, Serenoa repens			Open	

Search by seriousness criteria

You can search for reports according to the seriousness criteria attributed to one of the reactions.

The screenshot shows a search form with various filters. The 'Seriousness criteria' dropdown menu is highlighted with a red box, showing the following options: Results in death (selected), Caused / prolonged hospitalisation, Congenital anomaly / birth defect, Disabling / incapacitating, Life threatening, and Other medically important condition.

0 ICSRs selected ▾ 23 ICSRs match your search with 1 filter(s) applied Page 1 of 2 « 1 2 »

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> ZZZ-ZZZORG-347238947	National Centre	ZZ	01012010	Accessory breast, Chronic prostatitis, Cranial sutures widening, Bone giant cell tumor malignant, Gallbladder edema, Fascioliasis, Chlamydia trachomatis infection		03082020	03082020	Open	
<input type="checkbox"/> ZZ-MINION-00009944	National Centre	MINION	01012010	Accessory breast, Chronic prostatitis, Cranial sutures widening		18052020	18052020	Open	
<input type="checkbox"/> ZZZ-ZZZORG-100000184	National Centre	ZZ	01012010	Angitis neurotizing, Chronic prostatitis, Cranial sutures widening, Bone giant cell tumor malignant, Gallbladder edema, Fascioliasis, Chlamydia trachomatis infection		01052020	01052020	Open	
<input type="checkbox"/> UMC-UMCORG-190	National Centre			Headache	Nifed	03042020	03042020	Open	
<input type="checkbox"/> UMC-UMCORG-190	National Centre			Headache	Nifed	03042020	03042020	Open	
<input type="checkbox"/> SE-MPA-49078	National Centre	JK		Rash	Atenolol, Nicardipina	06122019	06122019	Open	
<input type="checkbox"/> IE-ABBVIE-17P-229-1454774-00	National Centre	AT		Coughing, Nausea, Vomiting, Myocardial infarction	Robitussin	25112019	25112019	Open	
<input type="checkbox"/> RS-KRKA-RS2019K07918SPO	National Centre			Weight loss, Therapeutic response unexpected	Nolpaza	05112019	05112019	Closed	✓
<input type="checkbox"/> SE-ZZZ-TESTSENDREC	National Centre	ZZ		Cardiac arrest	Calpol	16082019	16082019	Open	
<input type="checkbox"/> SE-ZZZ-TESTFLOOW	National Centre			Cardiac arrest	Calpol, Calpol	15082019	15082019	Open	
<input type="checkbox"/> COMPANYNUMBSerious	National Centre			17 ketosteroids urine normal		27022019	21052019	Under assessment	

Search by Drug name (WHODrug)

Searches by drug name (trade name or generic name) will be based in the WHODrug dictionary.

Initial received date (from) Initial received date (to)

Report type

Means of reporting

Reporter qualification

Report identifier

Study type

Study name / Study registration number

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Report title

Initials

Sex

Date of birth

Status of report

Reaction / event (MedDRA)

Serious

Seriousness criteria

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Include sub organisations

Received from

Drug name (WHODrug)

Active ingredient(s) (WHODrug)

ATC code

Additional drug-related problems

Batch number / Diluent batch number

Indication (MedDRA)

0 ICSRs selected 2 ICSRs match your search with 1 filter(s) applied

Page 1 of 1 << < 1 > >>

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input checked="" type="checkbox"/> UMC-UMCORG-1003	National PV Centre		1970	Hypersomnia	Cymbalta	25032020	03042020	Open	
<input checked="" type="checkbox"/> UMC-UMCORG-1003	National PV Centre	HW	1970	Hypersomnia	Cymbalta	23022016	02032017	Open	

Search by Active ingredients

Searches using the Active Ingredient(s) will display ICSRs with products containing the selected active ingredient(s).

Initial received date (from) [] [] [] [] Initial received date (to) [] [] [] []

Report type []

Means of reporting []

Reporter qualification []

Report identifier []

Study type []

Study name / Study registration number []

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Report title []

Initials []

Sex []

Date of birth [] [] []

Status of report []

Reaction / event (MedDRA) []

Serious []

Seriousness criteria []

Outcome of reaction []

Assigned to []

Delegated to organisation []

Created by organisation []

Include sub organisations

Received from []

Drug name (WHODrug) []

Active ingredient(s) (WHODrug) []
Paracetamol [x]

ATC code []

Additional drug-related problems []

Batch number / Diluent batch number []

Indication (MedDRA) []

[Search] [Clear]

0 ICSRs selected 28 ICSRs match your search with 1 filter(s) applied Page 1 of 2 << 1 2 >>

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input type="checkbox"/> MA-NCMA-123456	National Centre		02011988		Paracetamol	25082020	26082020	Under assessment	
<input type="checkbox"/> UMC-UMCORG-1008	University Hospital	TE	18071904	Patchy rash	Acetylsalicylic acid,Caffeine,Paracetamol	15052020	15052020	Open	
<input type="checkbox"/> SE-OPB-2020-00024	National Centre			Urticaria	Pamol	14052020	14052020	Open	
<input type="checkbox"/> UMC-UMCORG-209	National Centre	YY	01011988	Rash NOS	Febicret	07052020	07052020	Open	
<input type="checkbox"/> UMC-UMCORG-208	National Centre			Palpitations, Dizziness	Metafex	07052020	07052020	Open	
<input type="checkbox"/> EE-EMA-R3Testcase07-followmeup	National Centre	MH		Jaundice, unspecified, not of newborn	Paracetamol	14122018	30032020	Open	
<input type="checkbox"/> UMC-UMCORG-300010748	National Centre		26091982	Depression, Gambling disorder	Sifrol, Paracetamol	18032020	18032020	Open	
<input type="checkbox"/> UMC-UMCORG-172	National Centre				Pamol, Amoxiolav	04122019	04122019	Open	
<input type="checkbox"/> TR-ABBVIE-19P-161-1457038-00	National Centre			Atrial fibrillation	Carboplatin, Paclitaxel, Vesicare, Duphalac, Kordexa, Kordexa, Gaviscon, Panadol, Atrovent, Ronkotol, Ondansetron, Ondansetron, Benison, Benison	25112019	25112019	Open	
<input type="checkbox"/> SE-ZZZ-TESTSENDREC	National Centre	ZZ		Cardiac arrest	Calpol	16082019	16082019	Open	

Search by ATC code

Type in a full or partial ATC code (*Anatomical Therapeutic Chemical*) to perform the search.

The search will bring all the reports which contain at least one drug that matches the ATC code

The screenshot shows a search interface with multiple filter categories. The 'ATC code' field is highlighted with an orange box and contains the value 'N02'. Other filters include 'Initial received date (from/to)', 'Report type', 'Means of reporting', 'Reporter qualification', 'Report identifier', 'Study type', 'Study name / Study registration number', 'Report title', 'Initials', 'Sex', 'Date of birth', 'Status of report', 'Reaction / event (MedDRA)', 'Serious', 'Seriousness criteria', 'Outcome of reaction', 'Assigned to', 'Delegated to organisation', 'Created by organisation', 'Received from', 'Drug name (WHODrug)', 'Active ingredient(s) (WHODrug)', 'Batch number / Diluent batch number', and 'Indication (MedDRA)'. There are also checkboxes for 'Include deleted ICSRs', 'Show only ICSRs that can be copied to Vigilize', 'Show only ICSRs with at least one drug or reaction that is not coded', and 'Include sub organisations'. A 'Search' button and a 'Clear' button are located at the bottom right of the filter section.

0 ICSRs selected | 5243 ICSRs match your search with 1 filter(s) applied

Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Status	Vigilize	
UMC-UMCOORG-300020801	Regional Centre /	AB			Tylenol, Beta-alanine	29072020		✓	
JP-EMA-TESTCASE05	National PV Cent			ast	Calpol, Calpol	27082019			
US-SPONSOR-TESTCASE04	National PV Cent			of toes	Migraleve pink, Migraleve pink	27082019	07072020	Open	
US-SPONSOR-TESTCASE03	National PV Cent			asia	Migraleve pink, Migraleve pink	27082019	07072020	Open	
SE-EMA-TESTCASE01	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
MX-002147023_T-NVSC2020MX076824	National PV Centre		POP	08051950	Angina pectoris	Oxcarbazepine	28082020	28082020	Closed
UMC-UMCOORG-300020893	National PV Centre	TL			Rash gum	Ipamol	10062020	10062020	Closed
UMC-UMCOORG-300020892	National PV Centre	SA				Paracetamol	09062020	09062020	Closed
MX-SA-2019SA030937	National PV Centre				Fetal death, Drug exposure during pregnancy	Acetylsalicylic acid, Progesterone	27052020	27052020	Open

Annotations: A green box highlights 'Tylenol paracetamol N02BE' with an arrow pointing to the 'Tylenol, Beta-alanine' row. Another green box highlights 'Oxcarbazepine N02BG, N03AF' with an arrow pointing to the 'Oxcarbazepine' row.

Search by batch numbers

You can search for reports by typing in the first characters of a batch number or the complete batch number.

The search will be made on both batch number for *Drug* and *vaccine diluent*.

Initial received date (from) Initial received date (to)

Report type

Means of reporting

Reporter qualification

Report identifier

Study type

Study name / Study registration number

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Report title

Initials

Sex

Date of birth

Status of report

Reaction / event (MedDRA)

Serious

Seriousness criteria

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Include sub organisations

Received from

Drug name (WHODrug)

Active ingredient(s) (WHODrug)

ATC code

Additional drug-related problems

Batch number / Diluent batch number

Indication (MedDRA)

0 ICSRs selected 1 ICSRs match your search with 1 filter(s) applied

Page 1 of 1 << < 1 > >>

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input checked="" type="checkbox"/> UMC-UMCORG-300000031	National PV Centre	MOG		Burning skin	Folitropina alfa	27072020		Open	

Search by drug indication

The search filter **Indication (MedDRA)** allows to search by terms in any level of the MedDRA hierarchy.

Initial received date (from) Initial received date (to)

Report type

Means of reporting

Reporter qualification

Report identifier

Study type

Study name / Study registration number

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Report title

Initials

Sex

Date of birth

Status of report

Reaction / event (MedDRA)

Serious

Seriousness criteria

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Include sub organisations

Received from

Drug name (WHODrug)

Active ingredient(s) (WHODrug)

ATC code

Additional drug-related problems

Batch number / Diluent batch number

Indication (MedDRA)

0 ICSRs selected 6 ICSRs match your search with 1 filter(s) applied

Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre			Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> MX-SA-2019SA030943	National PV Centre			Lack of drug effect, Product use issue	Apidra solostar	27052020	27052020	Open	
<input type="checkbox"/> BR-GALDERMA-BR17001502	National PV Centre	NAC		Hair loss, Expired drug used	Aviois, Glifage	29042020	29042020	Open	
<input type="checkbox"/> MX-ELI_LILLY_AND_COMPANY-MX202001000070	National PV Centre			Hair loss, Rash		30012020	30012020	Open	
<input type="checkbox"/> MX-ABBVIE-19P-107-2670948-00	National PV Centre			Diabetes mellitus aggravated	Risankizumab, Bezafibrate, Bezafibrate, Metformin, Pravastatin, Pravastatin, Paracetamol, Paracetamol, Paracetamol, Sulindac, Sulindac, Omeprazole, Nph insulin, Microdacyn, Recoveron	12122019	12122019	Open	
<input type="checkbox"/> MX-002147023-PHHY2018MX061211	National PV Centre	AC	11101980	Kidney infection	Co-diovan, Panclasa, Buscapina, Amikin, Ciloprin, Vytorin, Micardisplus	17092019	17092019	Open	

Search including deleted ICSRs

To include deleted ICSRs in your search, mark the tick box **Include deleted ICSRs**.

Deleted ICSRs cannot be opened by clicking on **Worldwide unique id**. They are only viewable from the list.

Initial received date (from) [] [] [] Initial received date (to) [] [] [] Report title [] Status of report [] Received from []

Report type [] Initial [] Reaction / event (MedDRA) [] Serious [] Seriousness criteria [] Outcome of reaction [] Assigned to [] Delegated to organisation [] Created by organisation []

Means of reporting [] Sex [] Date of birth []

Reporter qualification []

Report identifier []

Study type []

Study name / Study registration number []

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Include sub organisations

Search Clear

0 ICSRs selected 241 ICSRs match your search with 1 filter(s) applied

Page 1 of 13 << 1 2 3 4 5 ... >>

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input type="checkbox"/> UMC-UMCORG-248	National Centre					27072020	27072020	Open	
<input type="checkbox"/> UMC-UMCORG-245	National Centre			Pain	Metformin	27072020	27072020	Open	
<input type="checkbox"/> UMC-UMCORG-244	National Centre			Congenital hepatitis B infection		14072020	14072020	Open	
<input type="checkbox"/> UMC-UMCORG-211	University Hospital		1044	Pain in limb, Leg oedema	Actapax	14072020	14072020	Open	
<input type="checkbox"/> HR-PFIZER-INC-2020232065	University Hospital			Leukopenia, Back pain	Ibrance, Fulvestrant	06072020	06072020	Closed	
<input type="checkbox"/> NO-VHC-5678	National Centre					26062020	26062020	Open	!
<input checked="" type="checkbox"/> SE-BAYER-2018-42346	University Hospital			Palpitations, Allergie-asthma		20062020	20062020	Open	
<input type="checkbox"/> NO-VHC-5678	National Centre	ABC	30062000			26062020	26062020	Open	

ICSRs available in Vigilyze

The Vigilyze column indicates if the ICSR has been shared with VigiBase and therefore visible in Vigilyze for analysis:

- <blank>: the ICSR has not been shared
- ✓: the latest version of the report has been shared
- !: the latest version of the ICSR has not been shared

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilyze
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020901	Regional Centre A	AB		Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Closed	✓
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> UMC-UMCORG-300020899	National PV Centre	UN		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-nullifyme	National PV Centre		MH	Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followmeup	National PV Centre		MH	Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> DE-EMA-Testcase06	National PV Centre		HVIII	Liver failure		27082019	07072020	Open	
<input type="checkbox"/> JP-EMA-TESTCASE05	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE03	National PV Centre		MH	Pre-eclampsia	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-MAH-TESTCASE02	National PV Centre		JTK	22031931	Food interaction, Explosive diarrhoea	27082019	07072020	Open	
<input type="checkbox"/> SE-EMA-TESTCASE01	National PV Centre		MN	Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> NO-VHC-5678	National PV Centre		ABC	30082000	Pregnancy, Lack of drug effect	01072020	01072020	Closed	!
<input type="checkbox"/> MX-002147023_T-NVSC2020MX076824	National PV Centre		POP	08051950	Angina pectoris	26082020	26082020	Closed	
<input type="checkbox"/> UMC-UMCORG-300020894	National PV Centre	CA				15082020	15082020	Closed	
<input type="checkbox"/> UMC-UMCORG-300020893	National PV Centre	TL		Rash gum	Ipamol	10082020	10082020	Closed	✓
<input type="checkbox"/> UMC-UMCORG-300020892	National PV Centre	SA			Paracetamol	09082020	09082020	Closed	
<input type="checkbox"/> UMC-UMCORG-300020891	National PV Centre	CA			Ursolfalk	08082020	08082020	Under assessment	
<input type="checkbox"/> UMC-UMCORG-300020890	National PV Centre	CA		Abdominal pain	Diovan	05082020	05082020	Closed	

Knowing which ICSRs can be shared with the WHO Programme

Use the search filter **Show only ICSRs that can be copied to Vigilyze**, to know which reports contain at least the minimum information to be shared with the WHO Programme of International Drug Monitoring.

Initial received date (from) Initial received date (to)

Report type

Means of reporting

Reporter qualification

Report identifier

Study type

Study name / Study registration number

Include deleted ICSRs

Show only ICSRs that can be copied to Vigilyze

Show only ICSRs with at least one drug or reaction that is not coded

Report title

Initials

Sex

Date of birth

Status of report

Reaction / event (MedDRA)

Serious

Seriousness criteria

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Include sub organisations

Received from

Drug name (WHODrug)

Active ingredient(s) (WHODrug)

ATC code

Additional drug-related problems

Batch number / Diluent batch number

Indication (MedDRA)

0 ICSRs selected 8068 ICSRs match your search with 1 filter(s) applied Page 1 of 404

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilyze
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020901	Regional Centre A	AB		Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Closed	✓
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	UN		Discomfort	Diovan	28072020	28072020	Open	!
<input type="checkbox"/> AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020903	National PV Centre MN			Cardiac arrest	Calool, Calool	27082019	07072020	Open	

Find reports with uncoded drugs or reactions

Having all drugs coded in WHODrug and all reactions coded in MedDRA will guarantee that your searches are more accurate.

Use the filter **Show only ICSRs with at least one drug or reaction that is not coded** to identify which cases have at least one uncoded drug or reaction so you can prioritize the coding.

Study name / Study registration number ?

Delegated to organisation

Indication (MedDRA) ?

Include deleted ICSRs

Show only ICSRs that can be copied to Vigilize

Show only ICSRs with at least one drug or reaction that is not coded

Created by organisation

Include sub organisations

0 ICSRs selected 3282 ICSRs match your search with 1 filter(s) applied

Page 1 of 165 « < 1 2 3 4 5 ... > »

<input type="checkbox"/> Worldwide unique id ↕	Delegated to organisation	Initials ↕	Date of birth ↕	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date ↕	Latest received date ↕	Status of report ↕	VigiLyze ?
<input type="checkbox"/> UMC-UMCORG-300020899	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-nullifyme	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followmeup	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	Migravele pink, Migravele pink	27062019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migravele pink, Migravele 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"/> UMC-UMCORG-300020894	National PV Centre					15062020	15062020	Closed	

Audit trail and previous versions of a report

To see the audit trail and the previous versions of a specific report, click on the arrow next to its worldwide unique id.

By clicking on a specific worldwide unique id under the audit trail, a PDF is generated with the information contained on that version, which allows the comparison with the current version of the report.

Page 1 of 1 « < 1 > » 20 ICSRs match your search with 1 filter(s) applied

<input type="checkbox"/> Worldwide unique id	Organisation	Patient initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> SE-XX-12345	Uppsala Monitoring Centre	JJ FUP 3		17 ketosteroids urine normal		19022019	Open	
Audit trail								
Worldwide unique id	Initial received date	Latest received date	Status of report	Description	Changed date	Last edited by		
SE-XX-12345	19022019	19022019	Closed	Edited	19022019 14:46:54	Helöisa Conesa		
SE-XX-12345	19022019	19022019	Open	Imported				
SE-XX-12345	19022019	19022019	Open	Imported				
<input checked="" type="checkbox"/> UMC-UMCORG-1008	Uppsala Monitoring Centre	TE	16071964	Patchy rash	Acetylsalicylic acid;Caffeine;Paracetamol	04102018	Open	
<input checked="" type="checkbox"/> UMC-UMCORG-2109	Uppsala Monitoring Centre	UMC	17051978	Fever, Sneezing	Nezeril	13112017	Open	
<input checked="" type="checkbox"/> UMC-UMCORG-5761	Uppsala Monitoring Centre	GD		Rhabdomyolysis	Thiamazol	02032017	Open	
<input checked="" type="checkbox"/> UMC-UMCORG-5698	Uppsala Monitoring Centre	UAS	1936	Abnormal dreams, Ethmoid sinus surgery	Dill, Drill	02032017	Closed	✓

Features for workflow support

Add a comment to an ICSR

To communicate with the other VigiFlow users in your country about a certain ICSR, use the speech bubble icon to add comments.

The comments are internal only, which means that they will not be visible if the report is exported either in PDF or in the Excel.

When a report has comments the icon is blue

Click on the comment icon to add a new comment

Comments for UMC-UMCORG-300000086

Add comment

Close

The screenshot shows a table of 74 ICSRs. The table has columns for 'Unique id', 'Organisation', 'Patient initials', 'Date of', and 'Reaction / event (MedDRA)'. The first row is highlighted. A blue callout points to a speech bubble icon in the first row, and an orange callout points to the same icon in the second row. A dialog box is open over the second row, showing a text input field and an 'Add comment' button. A 'Close' button is at the bottom right of the dialog box.

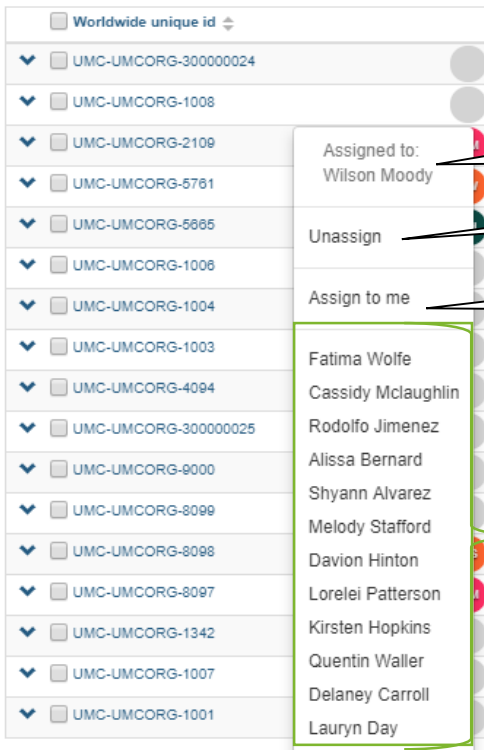
Unique id	Organisation	Patient initials	Date of	Reaction / event (MedDRA)
SE-EMA-R3-TESTCASE01	National PV Centre ABC	MN		
AE-ZZZ-MM/000913/1217	Regional Centre A			
US-SPONSOR-TESTCASE04	Regional Centre A			
UMC-UMCORG-300000082	Hospital	Jl	0101199	
UMC-UMCORG-300000081	Hospital	DDA	0101200	
UMC-UMCORG-300000080	Hospital			
UMC-UMCORG-300000079	Hospital	QQQ		
UMC-UMCORG-300000078	Hospital			
UMC-UMCORG-300000077	Hospital	ABC	280220	
UMC-UMCORG-300000075	Hospital			
UMC-UMCORG-300000074	Hospital	Demo patient		

Assign reports to users

Assign a report to you or another user at your organization so you can divide the workload within your team.

Click on the grey circle near the worldwide unique id to open the menu below.

It is important that your PV centre has clear procedures about reassigning reports.



If the report already is assigned to a user it is specified here

Here you can unassign the report

Here you can assign the report to yourself

Users within your organisation are listed and you can assign the report to any one of them

Find the reports assigned to an user

Use the search filter **Assigned To** to easily see the list of reports that have been assigned to you or someone else at your organisation and know who is working with a specific set of reports.

Study type

Study name / Study registration number

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Assigned to

Delegated to organisation

Created by organisation

Include sub organisations

Batch number / Diluent batch number

Indication (MedDRA)

0 ICSRs selected 9 ICSRs match your search with 1 filter(s) applied Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input type="checkbox"/> UMC-UMCORG-244	National Centre			Congenital hepatitis B infection		14072020	14072020	Open	
<input type="checkbox"/> UMC-UMCORG-235	National Centre					18082020	18082020	Under assessment	
<input type="checkbox"/> UMC-UMCORG-223	National Centre			Paracetamol, Genu varum	Ad, Gmc, Plavix	15052020	15052020	Open	
<input type="checkbox"/> UMC-UMCORG-197	National Centre			Hepatic enzyme increased, Hepatic enzyme increased	Lopinavir/Ritonavir	22042020	22042020	Open	
<input type="checkbox"/> UMC-UMCORG-195	National Centre					16042020	16042020	Open	
<input type="checkbox"/> UMC-UMCORG-300010748	National Centre		26091982	Depression, Gambling disorder	Sifrol, Paracetamol	18032020	18032020	Open	
<input type="checkbox"/> US-ABBVIE-19P-183-1457123-00	National Centre			Fever	Creon	25112019	25112019	Open	
<input type="checkbox"/> US-ABBVIE-19P-183-1457040-00	National Centre	JM	15011964	Shock, Peritonitis	Humira	25112019	25112019	Open	
<input type="checkbox"/> US-ABBVIE-18K-183-1456105-00	National Centre	VJ	08111949	Hospitalization	Humira	25112019	25112019	Open	

Search for reports delegated to a specific PV centre

Use the **Delegated to organisation** search filter to know to which PV centre a certain report is currently delegated to.

Your PV centre will always be able to view all the reports that have been either created by or delegated to your PV centre.

The screenshot shows a search interface for ICSRs. The search criteria include:

- Initial received date (from) and (to)
- Report type
- Means of reporting
- Reporter qualification
- Report identifier
- Study type
- Study name / Study registration number
- Initials
- Sex
- Date of birth
- Report title
- Status of report
- Reaction / event (MedDRA)
- Serious
- Seriousness criteria
- Outcome of reaction
- Assigned to
- Received from
- Drug name (WHODrug)
- Active ingredient(s) (WHODrug)
- ATC code
- Additional drug-related problems
- Batch number / Diluent batch number
- Indication (MedDRA)

Additional options include:

- Include deleted ICSRs
- Show only ICSRs that can be copied to Vigilize
- Show only ICSRs with at least one drug or reaction that is not coded

The search results show 1 ICSR matching the search with 1 filter(s) applied. The filter 'Delegated to organisation' is highlighted in orange. The dropdown menu for 'Delegated to organisation' is also highlighted in orange and shows the following options:

- Hospital A2
- National PV Centre
- CE 1
- CE 2
- CE3
- GIC
- Hospital A2
- Hospital A3
- Hospital A4
- Hospital A5
- Hospital B1
- HOSPITALE LA SAMARITANA
- Regional Centre A
- Regional Centre B

The search results table shows:

Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)
UMC-UMCORG-300020902	Hospital A2	JL		Cardiac arrest

Page 1 of 1

Search for reports created by a specific PV centre

All ICSRs are created by a specific organisation within VigiFlow and this property will never change.

Use the **Created by organisation** search filter to track which PV centre created certain reports, even though they might be delegated to other organisations.

Study name / Study registration number

Delegated to organisation

Indication (MedDRA)

Include deleted ICSRs
 Show only ICSRs that can be copied to VigiLyze
 Show only ICSRs with at least one drug or reaction that is not coded

Created by organisation
Regional Centre A
 Include sub organisations

Search Clear

0 ICSRs selected 5 ICSRs match your search with 1 filter(s) applied Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> UMC-UMCORG-300020901	Regional Centre A	AB			meta-alanine	29072020	29072020	Closed	✓
<input type="checkbox"/> authoritynumb	National PV Centre	Patient (name or initials)	28081974			19032019	08012020	Open	
<input type="checkbox"/> UMC-UMCORG-300000552	National PV Centre					19112019	19112019	Under assessment	
<input type="checkbox"/> UMC-UMCORG-300000074	National PV Centre	Demo patient			max	19032019	19032019	Under assessment	
<input type="checkbox"/> UMC-WHOUMC-2016-44385	National PV Centre	JL Gandalf	14023016		nderer	19032019	19032019	Open	

These ICSRs were created by Regional Centre A but they are delegated to the National PV Centre

Search report by status

Use the filter **Status of report** to identify which ICSRs are open, under assessment or closed.

Initial received date (from) [] [] Initial received date (to) [] [] Report title [] Status of report [Under assessment] Received from []

Report type [] Initials [] Open Under assessment Closed

Means of reporting [] Sex [] Seriousness criteria [] Drug name (WHODrug) []

Reporter qualification [] Date of birth [] Outcome of reaction [] Active ingredient(s) (WHODrug) []

Report identifier [] Assigned to [] ATC code [] Additional drug-related problems []

Study type [] Delegated to organisation [] Batch number / Diluent batch number []

Study name / Study registration number [] Created by organisation [] Indication (MedDRA) []

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Include sub organisations

Search Clear

0 ICSRs selected 7 ICSRs match your search with 1 filter(s) applied Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input checked="" type="checkbox"/> MA-NCMA-123456	National Centre		02011988		Paracetamol	25082020	26082020	Under assessment	
<input checked="" type="checkbox"/> UMC-UMCORG-235	National Centre	CA				18082020	18082020	Under assessment	
<input checked="" type="checkbox"/> MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-i-en	08082020	12082020	Under assessment	
<input checked="" type="checkbox"/> UMC-UMCORG-117	National Centre					14082019	14082019	Under assessment	
<input checked="" type="checkbox"/> SE-BAYER-2018-12345	National Centre			Palpitation		10082019	10082019	Under assessment	
<input checked="" type="checkbox"/> COMPANYUMBSerious	National Centre	JW		17 ketosteroids urine normal		27022019	21052019	Under assessment	
<input checked="" type="checkbox"/> ZZZ-ZZZSWE-10998888888	National Centre	TL	ZZ	01012010	Accessory breast, Chronic prostatitis, Cranial sutures widening, Bone giant cell tumor malignant, Gallbladder edema, Fascioliasis, Chlamydia trachomatis infection	09042019	09042019	Under assessment	

Exporting ICSRs

Formats to export ICSRs

VigiFlow facilitates the retrieval / export of ICSRs in different formats, depending on the needs:

- **PDF:** generates individual PDFs for each of the reports selected in the list of reports
- **Excel:** generates a list with all the reports based on the specific filters that are applied to the report list
- **Admin statistics:** generates an Excel file that provides a quantitative overview of the data. This functionality can be useful for compilation of annual reports or similar
- **XML:** generates xml files according to the ICH E2B (R3) standards that can be shared with stakeholders that have a database compatible with this standard.

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

Export to Excel

By clicking **Export**, all the ICSRs shown in the Report List will be included in the Excel spreadsheet.

The number in brackets shows the amount of reports which will be included in the list. The Excel export allows a maximum of 3000 ICSRs per file.

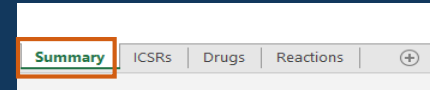
+ New ICSR Import Export VigilLyze Filter PDF/Excel/XML

0 ICSRs selected 221 ICSRs match your search with 0 filter(s) applied Page 1 of 12

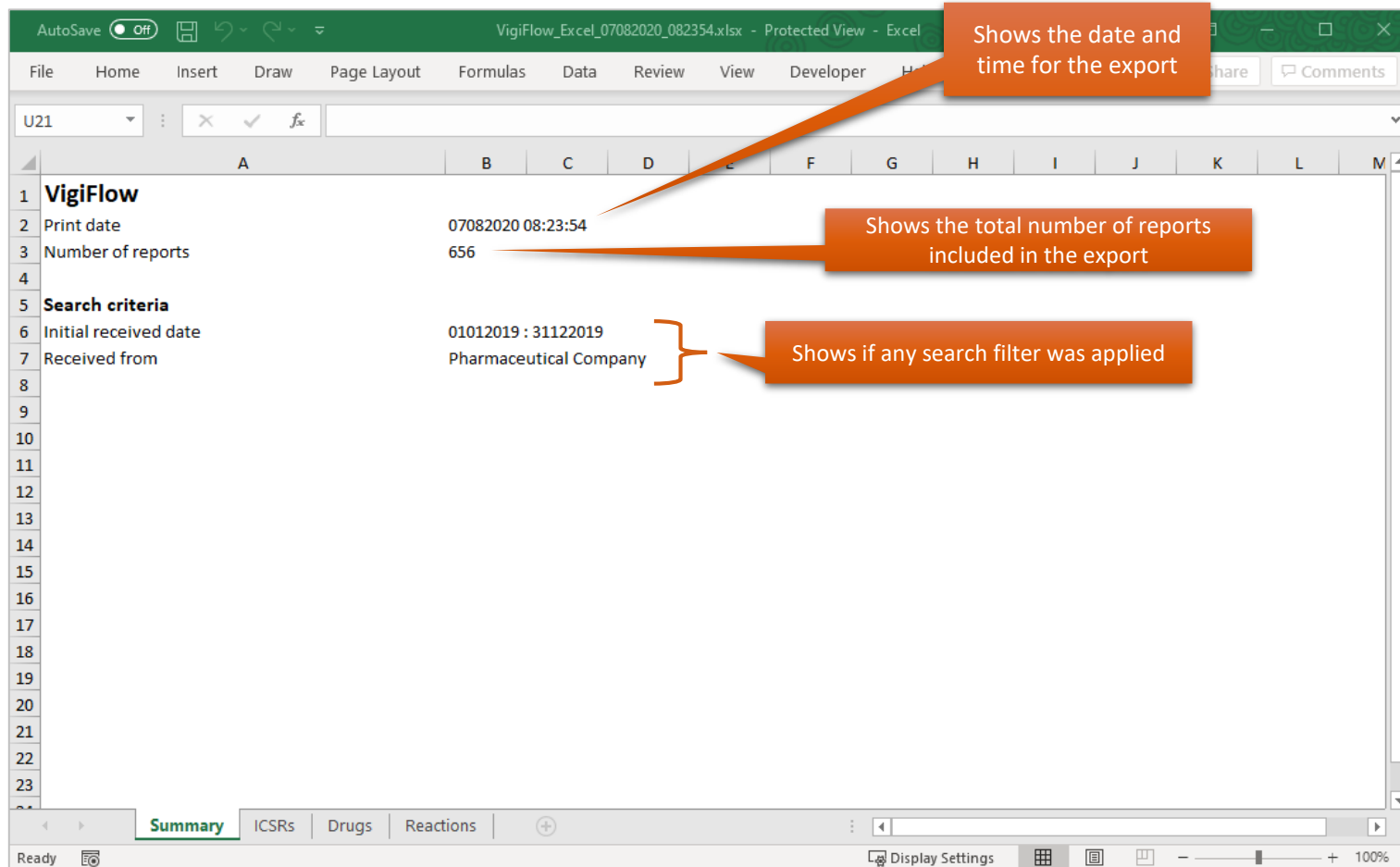
<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date		
<input type="checkbox"/> UMC-UMCORG-248	National Centre					27072020	27072020		
<input type="checkbox"/> UMC-UMCORG-245	National Centre			Pain	Metformin	27072020	27072020	Excel (221)	
<input type="checkbox"/> UMC-UMCORG-244	National Centre			Congenital hepatitis B infection		14072020	14072020	Open	
<input type="checkbox"/> UMC-UMCORG-211	University Hospital		1944	Pain in limb, Leg oedema	Actapax	14072020	14072020	Open	
<input type="checkbox"/> HR-PFIZER INC-2020232665	University Hospital			Leukopenia, Back pain	Ibrance, Fulvestrant	06072020	06072020	Closed	
<input type="checkbox"/> NO-VHC-5678	National Centre					29062020	29062020	Open	!
<input type="checkbox"/> NO-VHC-5678	National Centre	ABC	30062000			26062020	26062020	Open	
<input type="checkbox"/> MA-NCMA-123456	National Centre		02011986		Paracetamol	25062020	26062020	Under assessment	
<input type="checkbox"/> UMC-UMCORG-235	National Centre					18062020	18062020	Under assessment	
<input type="checkbox"/> MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-i-en	08062020	12062020	Under assessment	
<input type="checkbox"/> MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-i-en	08062020	08062020	Open	

Masked PDF (0)
Masked XML (0)
Unmasked PDF (0)
Unmasked XML (0)
Admin statistics (221)

Summary sheet in the Excel



The **Summary** sheet provides brief information about the data included in the Excel-export.



The screenshot shows the Excel Summary sheet with the following data and callouts:

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	VigiFlow												
2	Print date			07082020 08:23:54									
3	Number of reports			656									
4													
5	Search criteria												
6	Initial received date			01012019 : 31122019									
7	Received from			Pharmaceutical Company									
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													

Callouts:

- Shows the date and time for the export (points to cell B4)
- Shows the total number of reports included in the export (points to cell B3)
- Shows if any search filter was applied (points to cells B6 and B7)

ICSRs sheet in the Excel



The **ICSRs sheet** presents the ICSR information row-by-row, i.e. one row for each ICSR. If an ICSR contains several Drugs and/or Reactions they will be included in the same cell.

Worldwide unique id	Safety report id	Reaction / event (MedDRA)	Serious	Seriousness	Outcome	Onset date/ Time	End date/Time	Duration	Drug role	Drug name (WHODrug)
UMC-UMCORG-1000	UMC-UMCORG-1000	Jaundice Acute hepatic failure Coma			Fatal				Suspect Concomitant Concomitant	Cimetidine Digoxin Ranitidine
UMC-UMCORG-1002	UMC-UMCORG-1002	Fever Diarrhoea Neutropenia	Yes	Caused / prolonged hospitalisation	Recovered / Resolved Recovered / Resolved Recovered / Resolved	20030511 20030511 20030526	20030515 20030520 20030602	4 Day 9 Day	Suspect Concomitant	
UMC-UMCORG-1005	UMC-UMCORG-1005	Anaphylaxis Shortness of breath Hypotension	Yes	Life threatening, Caused / prolonged hospitalisation	Recovered / Resolved Recovered / Resolved Recovered / Resolved	20160714 08:21	20160716 14:23		Interacting Interacting Concomitant Concomitant	Captopril Aspirin Metformin Insulin

Drugs sheet in the Excel

The **Drugs sheet** shows the information for each drug in separate rows. This means that if an ICSR contains several Drugs the same ICSR appears in multiple rows.

Worldwide unique id	Safety report id	Drug role	Drug name as reported by initial reporter	Drug name (WHODrug)	Active ingredient(s) (WHODrug)
UMC-UMCORG-1000	UMC-UMCORG-1000	Suspect	Cimetidine	Cimetidine	Cimetidine
UMC-UMCORG-1000	UMC-UMCORG-1000	Concomitant	Digoxin	Digoxin	Digoxin
UMC-UMCORG-1000	UMC-UMCORG-1000	Concomitant	Ranitidine	Ranitidine	Ranitidine
UMC-UMCORG-1002	UMC-UMCORG-1002	Suspect	Danthium		
UMC-UMCORG-1002	UMC-UMCORG-1002	Concomitant	Domperidone		
UMC-UMCORG-1005	UMC-UMCORG-1005	Interacting	Captopril	Captopril	Captopril

Reactions sheet in the Excel

The **Reactions** sheet shows the information for each reaction in separate rows, including the MedDRA hierarchy. This means that if an ICSR contains several Reactions the same ICSR appears in multiple rows.

Worldwide unique id	Safety report id	Reaction / event as reported by initial reporter	Reaction / event (MedDRA) LLT	PT	HLT	HLGT	SOC
UMC-UMCORG-1000	UMC-UMCORG-1000		Jaundice	Jaundice	Cholestasis and jaundice	Hepatic and hepatobiliary disorders	Hepatobiliary disorders
UMC-UMCORG-1000	UMC-UMCORG-1000		Acute hepatic failure	Acute hepatic failure	Hepatic failure and associated disorders	Hepatic and hepatobiliary disorders	Hepatobiliary disorders
UMC-UMCORG-1000	UMC-UMCORG-1000		Coma	Coma	Coma states	Neurological disorders NEC	Nervous system disorders
UMC-UMCORG-1002	UMC-UMCORG-1002	Fever 38° C	Fever	Pyrexia	Febrile disorders	Body temperature conditions	General disorders and administration site conditions
UMC-UMCORG-1002	UMC-UMCORG-1002		Diarrhoea	Diarrhoea	Diarrhoea (excl infective)	Gastrointestinal motility and defaecation conditions	Gastrointestinal disorders
UMC-UMCORG-1002	UMC-UMCORG-1002		Neutropenia	Neutropenia	Neutropenias	White blood cell disorders	Blood and lymphatic system disorders
UMC-UMCORG-1005	UMC-UMCORG-1005	Anaphylaxis presented initially as shortness of breath and severe hypotension.	Anaphylaxis	Anaphylactic reaction	Anaphylactic and anaphylactoid responses	Allergic conditions	Immune system disorders

Admin statistics

Admin statistics, based on the displayed report list can be exported to Excel.

The screenshot shows a web application interface for managing ICSRs. At the top, there are buttons for '+ New ICSR', 'Import', 'Export', and 'VigiLyze'. A 'Filter' button and a 'PDF/Excel/XML' dropdown menu are also visible. Below the buttons, it indicates '0 ICSRs selected' and '221 ICSRs match your search with 0 filter(s) applied'. The main area is a table with columns: 'Worldwide unique id', 'Delegated to organisation', 'Initials', 'Date of birth', 'Reaction / event (MedDRA)', 'Drug name (WHODrug)', 'Initial received date', 'Latest received date', and 'Open'. The table contains several rows of data, including reports from 'National Centre' and 'University Hospital'. An orange callout box points to the 'Admin statistics (221)' option in the 'PDF/Excel/XML' dropdown menu.

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Open	
<input type="checkbox"/> UMC-UMCORG-248	National Centre					27072020	27072020		
<input type="checkbox"/> UMC-UMCORG-245	National Centre			Pain	Metformin	27072020	27072020		
<input type="checkbox"/> UMC-UMCORG-244	National Centre			Congenital hepatitis B infection		14072020			
<input type="checkbox"/> UMC-UMCORG-211	University Hospital		1944	Pain					
<input type="checkbox"/> HR-PFIZER INC-2020232665	University Hospital			Leuk					
<input type="checkbox"/> NO-VHC-5678	National Centre					29062020	29062020	Open	!
<input type="checkbox"/> NO-VHC-5678	National Centre	ABC	30062000			28062020	28062020	Open	
<input type="checkbox"/> MA-NCMA-123456	National Centre		02011986		Paracetamol	25062020	28062020	Under assessment	
<input type="checkbox"/> UMC-UMCORG-235	National Centre					18062020	18062020	Under assessment	
<input type="checkbox"/> MinionPH-123-456	National Centre		23061980	Jet lag, Heat stroke	Helles 3-i-en	08062020	12062020	Under assessment	
<input type="checkbox"/> UMC-UMCORG-235	National Centre		23061980	Jet lag, Heat stroke	Helles 3-i-en	08062020	08062020	Open	

All the ICSRs shown in the Report List will be included in the Admin statistics. In the brackets, it is shown the number of reports which will be considered in the statistics

Admin statistics in Excel

The admin statistics Excel consists of several sheets with statistics from VigiFlow.

First is a Summary with Print date, number of reports and the search filters applied.

Then there are the following sheets:

- *Sex*
- *Age group*
- *Serious*
- *Reporter qualification*
- *Country of reporter*
- *Report type*
- *Received from*
- *Created by organisation*

Summary	Sex	Age group	Serious	Reporter qualification	Country of reporter	Report type	Received from	Created by organisation
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Admin statistics in Excel

The statistics are presented by Year, Month and values in respective sheet, for example:

from sheet **Serious**:

	A	B	C	D
1	Year	Month	No	Yes
2	2002	February	0	1
3	2014	June	0	1
4	2016	February	0	1
5	2016	April	1	0
6	2016	May	0	1
7	2017	April	0	1
8	2017	Novembe	1	0
9	2018	October	0	1
10	2019	June	2	6

Export to PDF

A batch of ICSRs can be exported to individual PDFs from the **Report List**. It is also possible to export individual ICSRs to PDF from the **Data Entry** page.

Report list

VigiFlow - National PV Centre

User name

+ New ICSR Import Export Manage accounts VigiLyze

Filter PDF/Excel/XML

3 ICSRs selected 5 ICSRs match your search with 1 filter(s) applied

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report
<input checked="" type="checkbox"/> UMC-UMCORG-300020901	Regional Centre A	AB		Rash, Itch	Tylenol, Beta-alanine	29072020		Closed
<input checked="" type="checkbox"/> authoritynumb	National PV Centre	Patient (name or initials)	29081974					Open
<input checked="" type="checkbox"/> UMC-UMCORG-300000552	National PV Centre							Under assessment
<input type="checkbox"/> UMC-UMCORG-300000074	National PV Centre	Demo patient						Under assessment
<input type="checkbox"/> UMC-WHOUMC-2016-44385	National PV Centre	JL	14023019	Dermatophytosis of scalp and beard	Happy wanderer	19032019	19032019	Open

Masked PDF (3)
Masked XML (3)
Unmasked PDF (3)
Unmasked XML (3)
Excel (5)
Admin statistics (5)

Several ICSRs can be exported to PDF at once from the report list view.

Data entry

VigiFlow - National PV Centre

User name

< To Report list + New ICSR VigiLyze

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

Report information

UMC-UMCORG-300000552 Created by organisation: Regional Centre A

Report information

Report title

Report type Spontaneous report

Worldwide unique id UMC-UMCORG-300000552

Safety report id UMC-UMCORG-300000552

Masked PDF (1)
Masked XML (1)
Unmasked PDF (1)
Unmasked XML (1)

The ICSR can be exported to PDF within the data entry view.

PDF-export from the report list

For exporting ICSRs from the report list to PDF, they must be selected first. It is possible to multiselect ICSRs to export to PDF using the tick-boxes.

The number in parenthesis indicates how many ICSRs have been selected and, therefore, how many PDFs will be generated.

The screenshot shows the VigiFlow National PV Centre report list interface. At the top, there are navigation buttons: '+ New ICSR', 'Import', 'Export', 'Manage accounts', and 'VigiLyze'. A 'Filter' button and a 'PDF/Excel/XML' dropdown menu are also visible. The main area displays a table of ICSRs with columns for 'Worldwide unique id', 'Delegated to organisation', 'Initials', 'Date of birth', 'Reaction / event (MedDRA)', 'Drug name (WHODrug)', 'Initial received date', 'Latest received date', and 'Status of report'. Three ICSRs are selected, indicated by blue checkmarks in the first column. A dropdown menu on the left shows '3 ICSRs selected'. A dropdown menu on the right shows export options: 'Masked PDF (3)', 'Masked XML (3)', 'Unmasked PDF (3)', 'Unmasked XML (3)', 'Excel (5)', and 'Admin statistics (5)'. The table data is as follows:

Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report
<input checked="" type="checkbox"/> UMC-UMCORG-300020901	Regional Centre A			Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Closed
<input checked="" type="checkbox"/> authoritynumb	National PV Centre	Patient (name or initials)	26081974	Visual field checking procedures	Alvedon	19032019	08012020	Open
<input checked="" type="checkbox"/> UMC-UMCORG-300000552	National PV Centre			Chills	Dil	19112019	19112019	Under assessment
<input type="checkbox"/> UMC-UMCORG-300000074	National PV Centre	Demo patient		Caffeine consumption	Caffeine max	19032019	19032019	Under assessment
<input type="checkbox"/> UMC-WHOUMC-2016-44385	National PV Centre	Gandalf	14023019	Dermatophytosis of scalp and beard	Happy wanderer	19032019	19032019	Open

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">
```

Questions:
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– Building a global safety culture

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