VigiFlow

Working with the REPORT LIST

Uppsala Monitoring Centre

– Building a global safety culture

Updated October 2019

Disclaimers

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

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

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Content

In this presentation you will find:

- Working with the Report List
- Searching for ICSRs
- Features for workflow support
- Exporting ICSRs

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Working with the Report List

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Functions in the top bar

Import ICSRs in a xml file

Manage user accounts and organisations – available only for administrator users

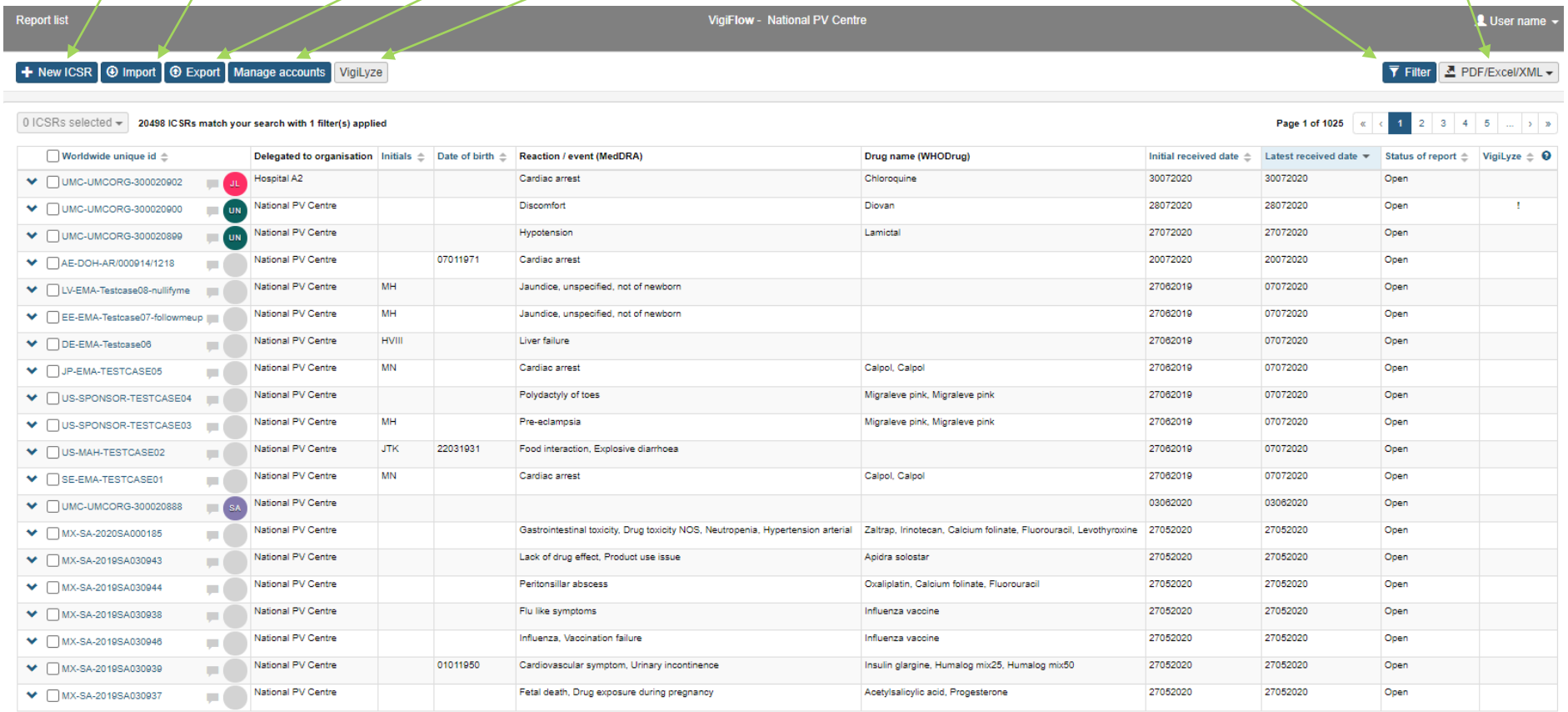
Export ICSRs in PDF, Excel or xml

Go to the Data Entry page to enter a new ICSR

Manage xml files generated by VigiFlow

Open search filters

Direct access to VigiLyze

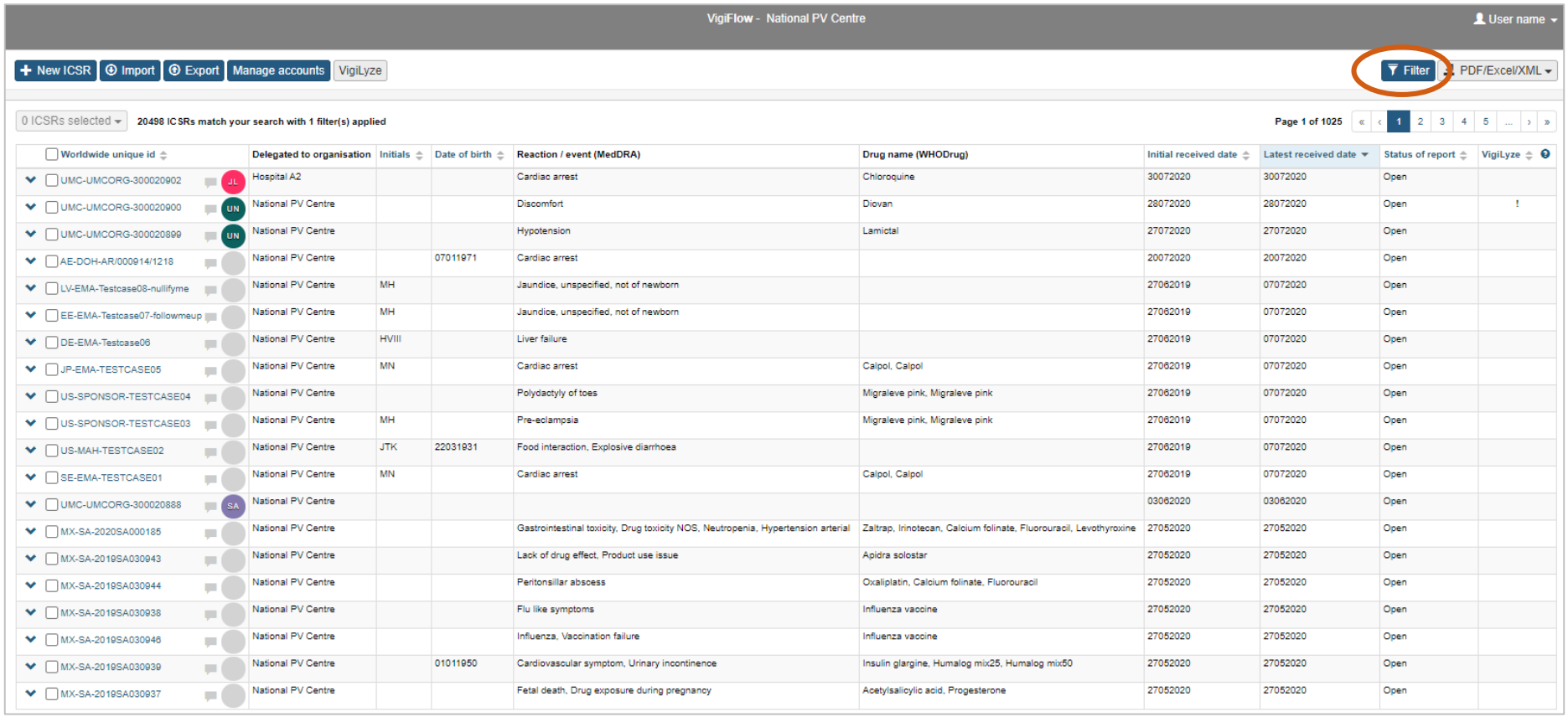


Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
UMC-UMCORG-300020902	Hospital A2			Cardiac arrest	Chloroquine	30072020	30072020	Open	
UMC-UMCORG-300020900	National PV Centre			Discomfort	Diovan	28072020	28072020	Open	!
UMC-UMCORG-300020899	National PV Centre			Hypotension	Lamictal	27072020	27072020	Open	
AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
LV-EMA-Testcase08-nullifyme	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
EE-EMA-Testcase07-followmeup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27062019	07072020	Open	
JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27062019	07072020	Open	
SE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
UMC-UMCORG-300020888	National PV Centre					03062020	03062020	Open	
MX-SA-2020SA000185	National PV Centre			Gastrointestinal toxicity, Drug toxicity NOS, Neutropenia, Hypertension arterial	Zaltrap, Irinotecan, Calcium folinate, Fluorouracil, Levothyroxine	27052020	27052020	Open	
MX-SA-2019SA030943	National PV Centre			Lack of drug effect, Product use issue	Apidra solostar	27052020	27052020	Open	
MX-SA-2019SA030944	National PV Centre			Peritonsillar abscess	Oxaliplatin, Calcium folinate, Fluorouracil	27052020	27052020	Open	
MX-SA-2019SA030938	National PV Centre			Flu like symptoms	Influenza vaccine	27052020	27052020	Open	
MX-SA-2019SA030946	National PV Centre			Influenza, Vaccination failure	Influenza vaccine	27052020	27052020	Open	
MX-SA-2019SA030939	National PV Centre		01011950	Cardiovascular symptom, Urinary incontinence	Insulin glargine, Humalog mix25, Humalog mix50	27052020	27052020	Open	
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.

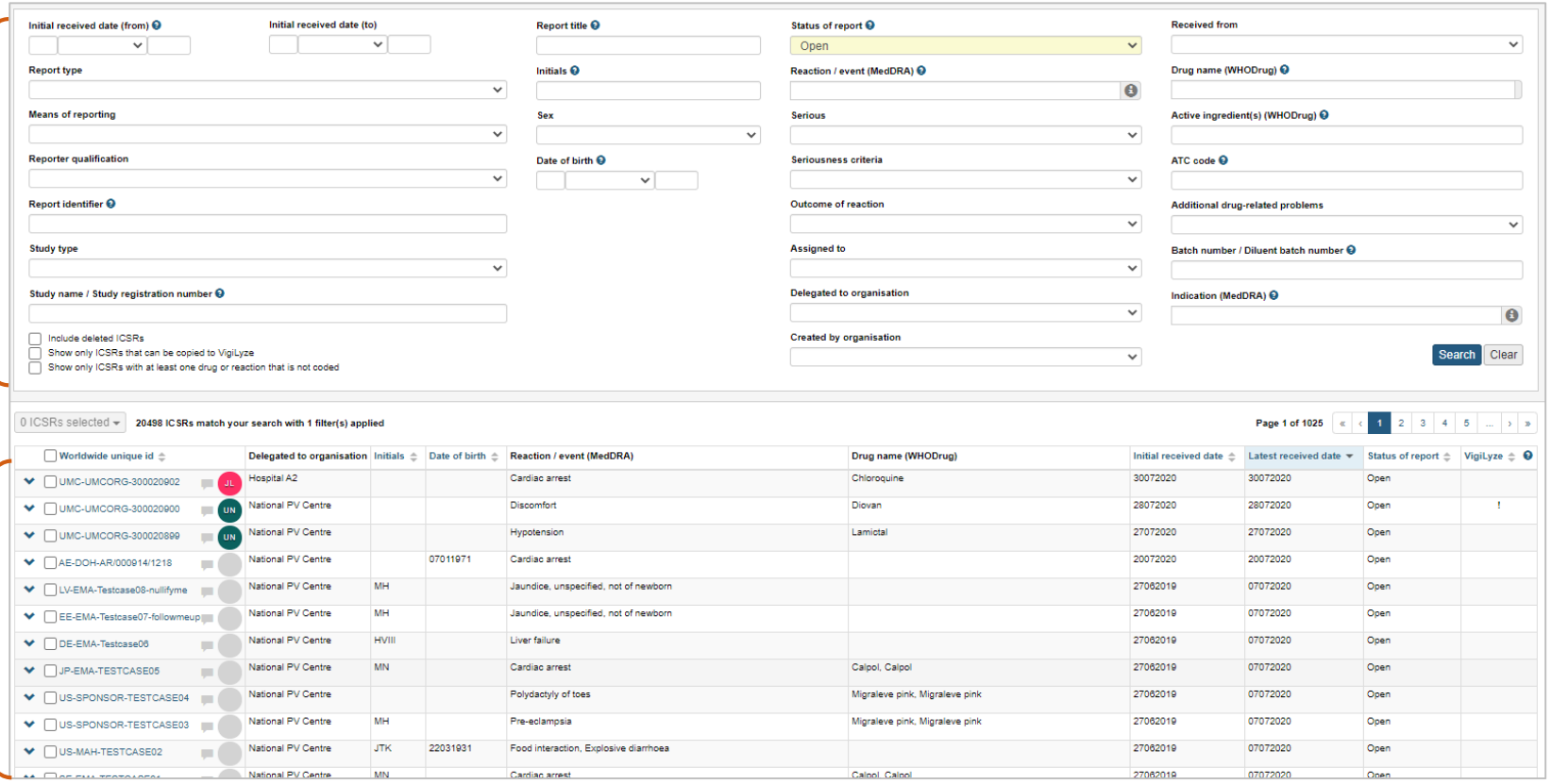


Report list page

The Report List page is divided in 2 sections:

Search filters

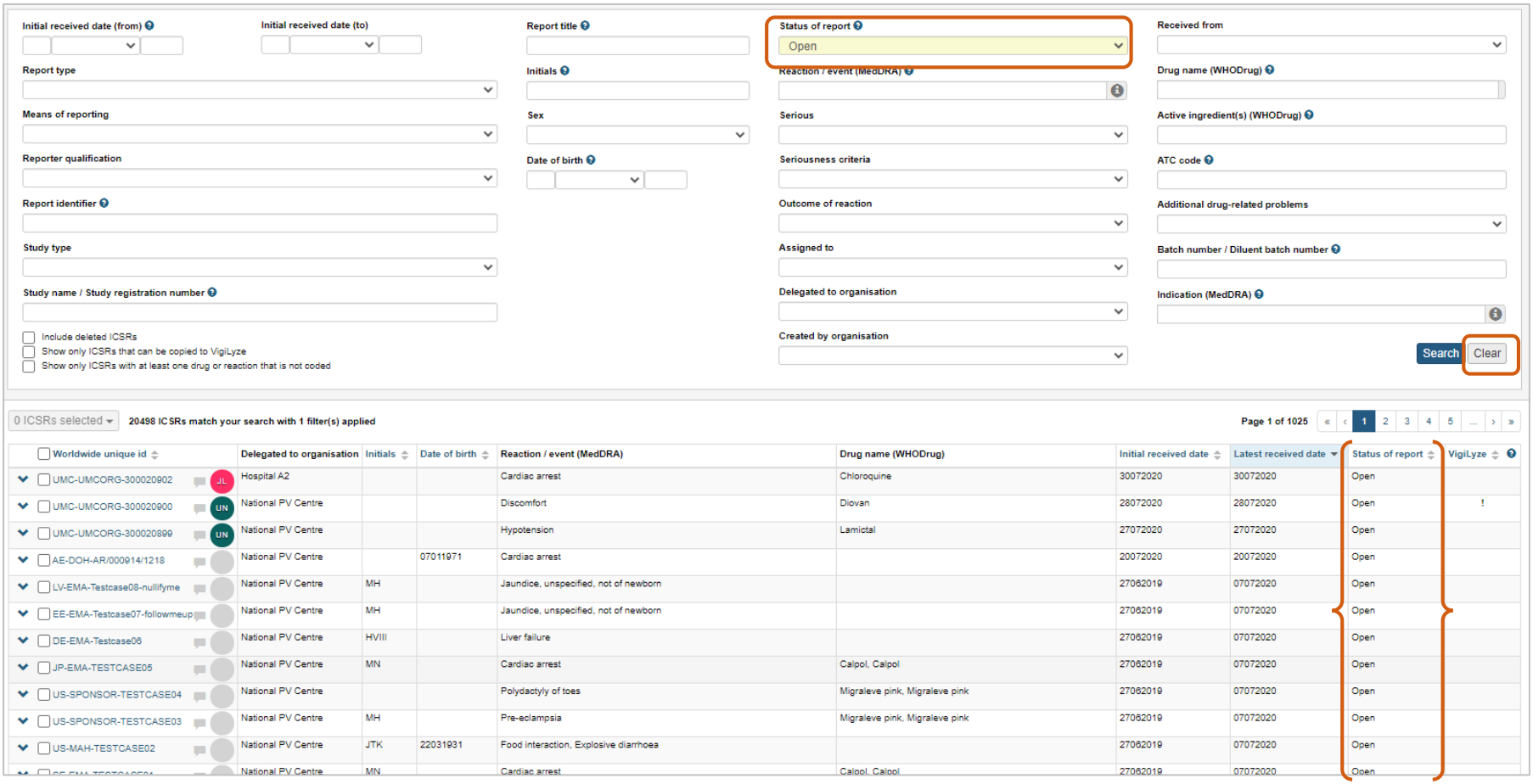
List of reports



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.



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	National Centre	CA			Ery-max	18102019	18102019	Open	
UMC-UMCORG-300000492	National Centre					18102019	18102019	Open	
UMC-UMCORG-300000491	AMC-1	ZZX		Rash	Cephaloxin	18102019	18102019	Open	
UMC-UMCORG-300000490	AMC-1	ABC		GI pain	Ibuprofen	18102019	18102019	Open	
DE-BoehringerIngelheim-2019-00011	National Centre	UNK		Palpitations, Allergic asthma	Pradaxa	17102019	18102019	Open	!
UMC-UMCORG-300000487	National Centre		12072016	Polydactyly of toes	Propylthiocil	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	

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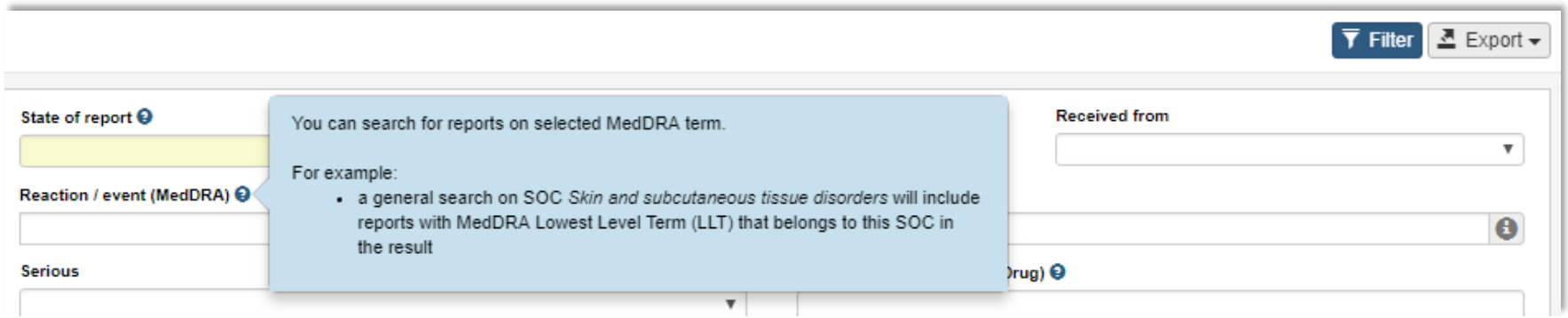
Help texts

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



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Searching for ICSRs

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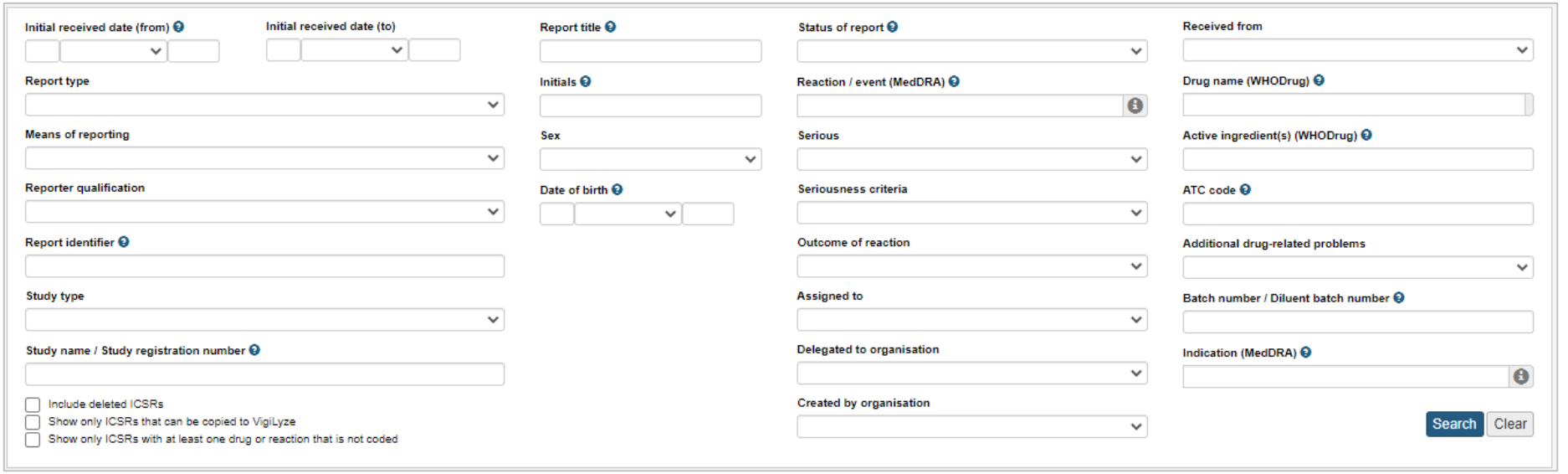
Use the search filters to search for ICSRs

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.



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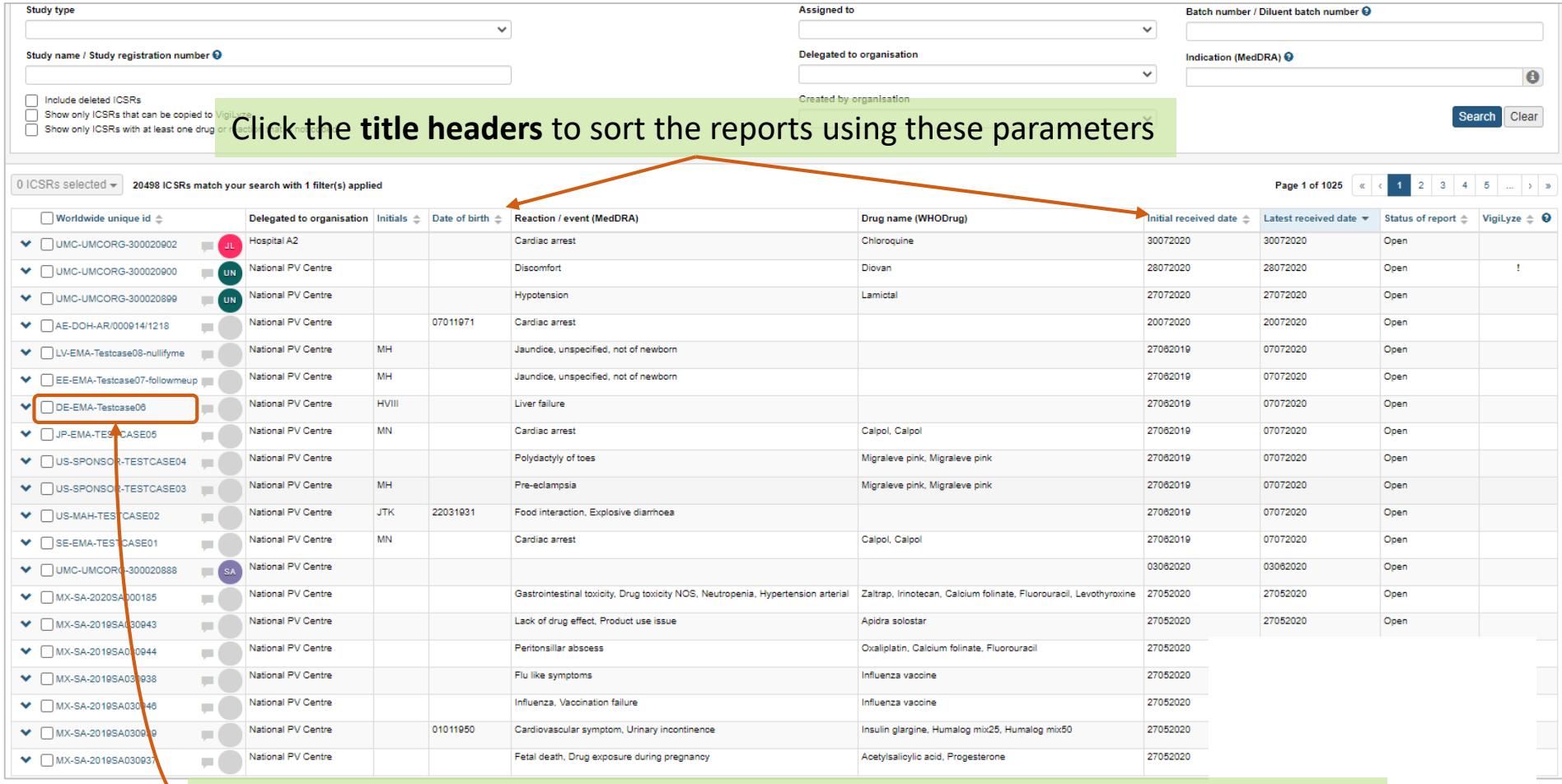
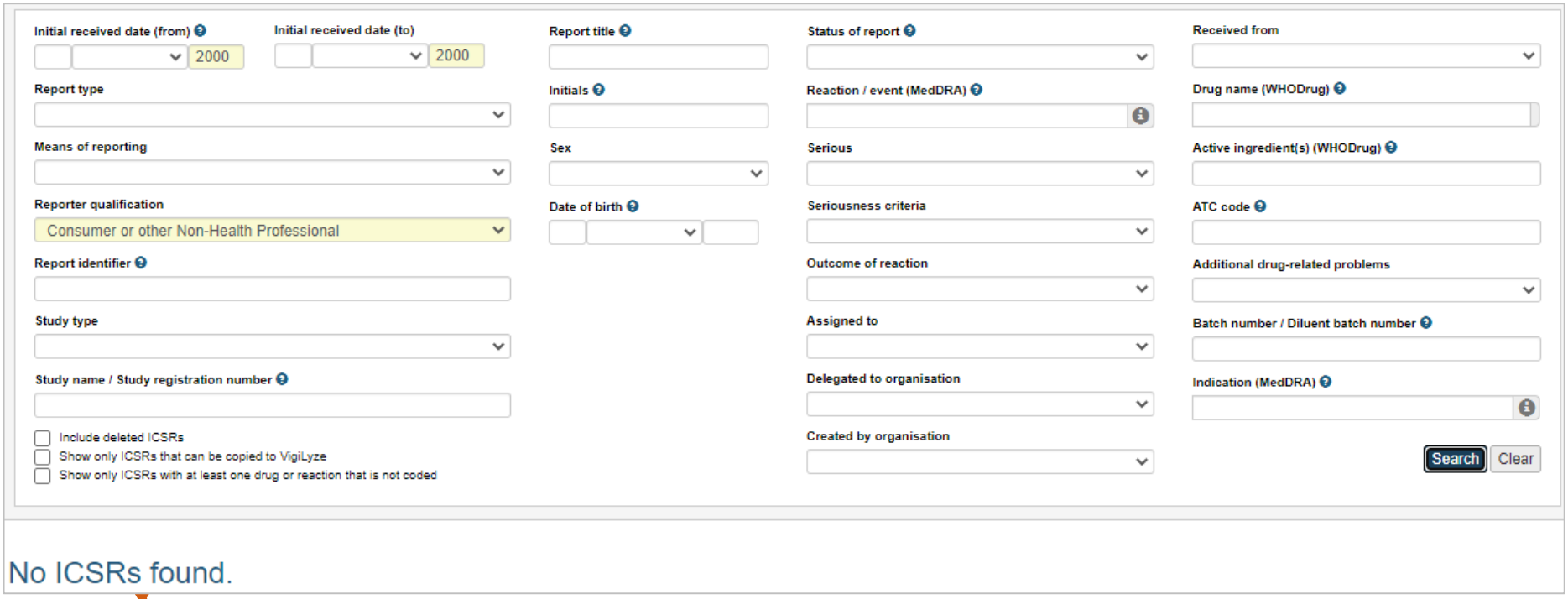
Perform a search



Search with no ICSRs found



This message will be displayed if your search produces no results

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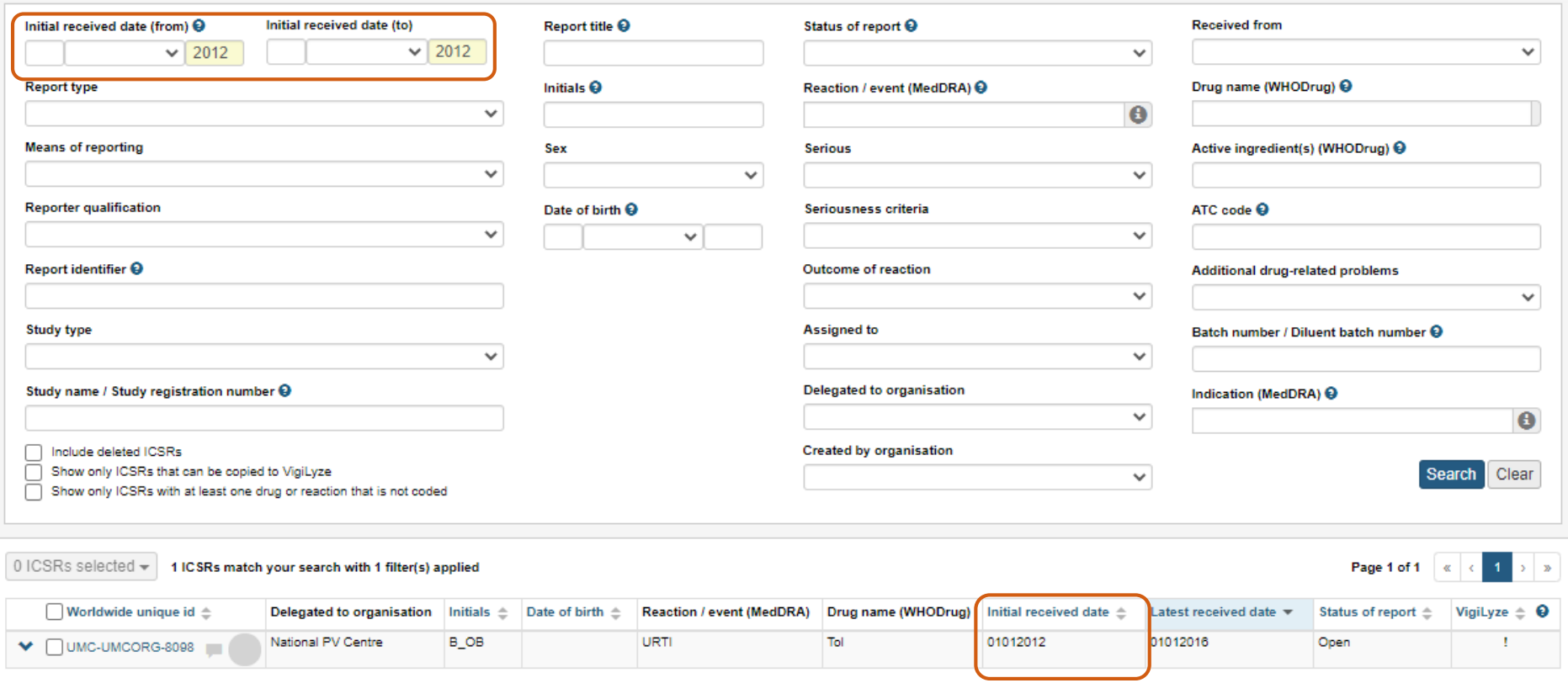
Search by initial receive date

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.

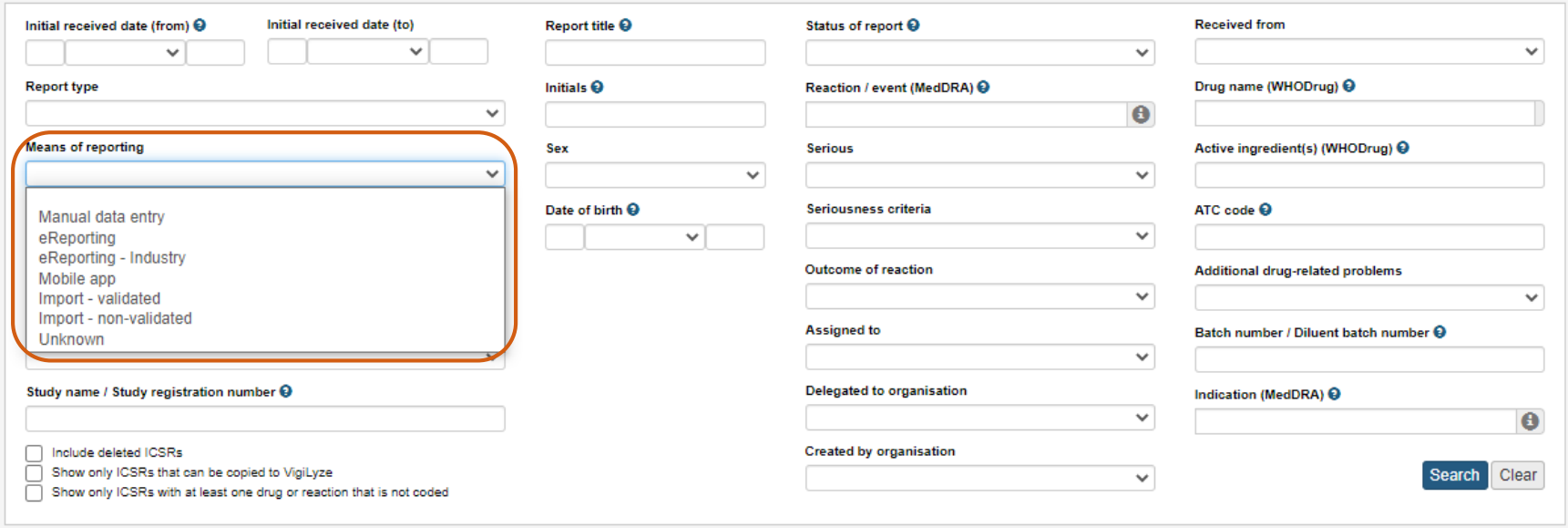


Identify the Mean of Reporting

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.

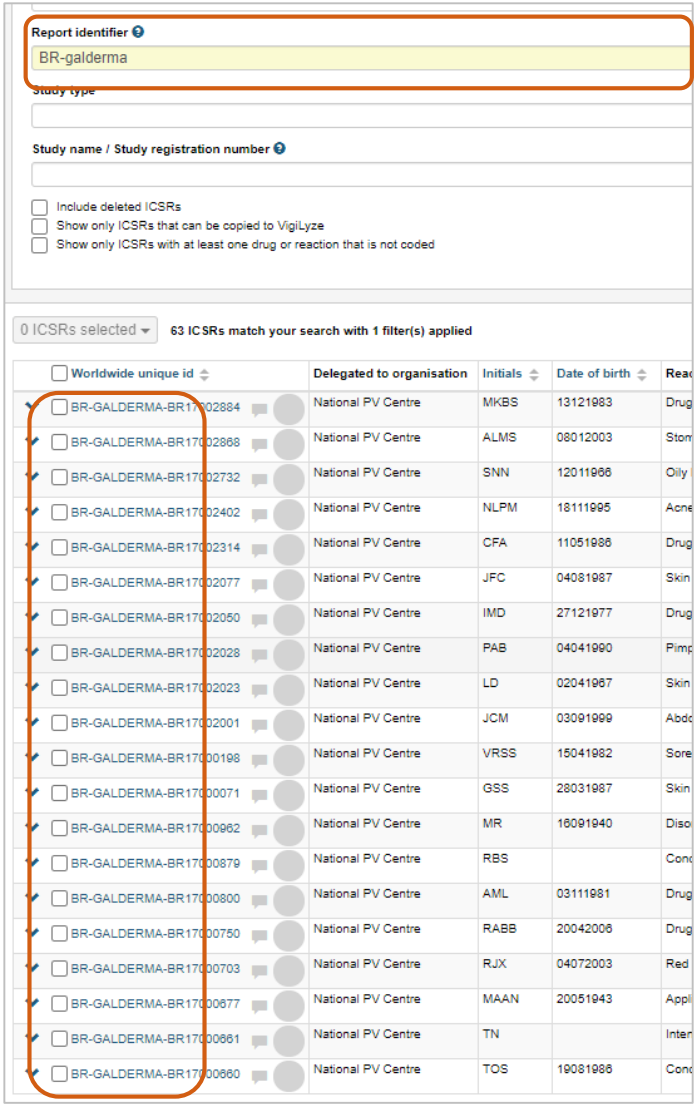


Search by report identifier

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.

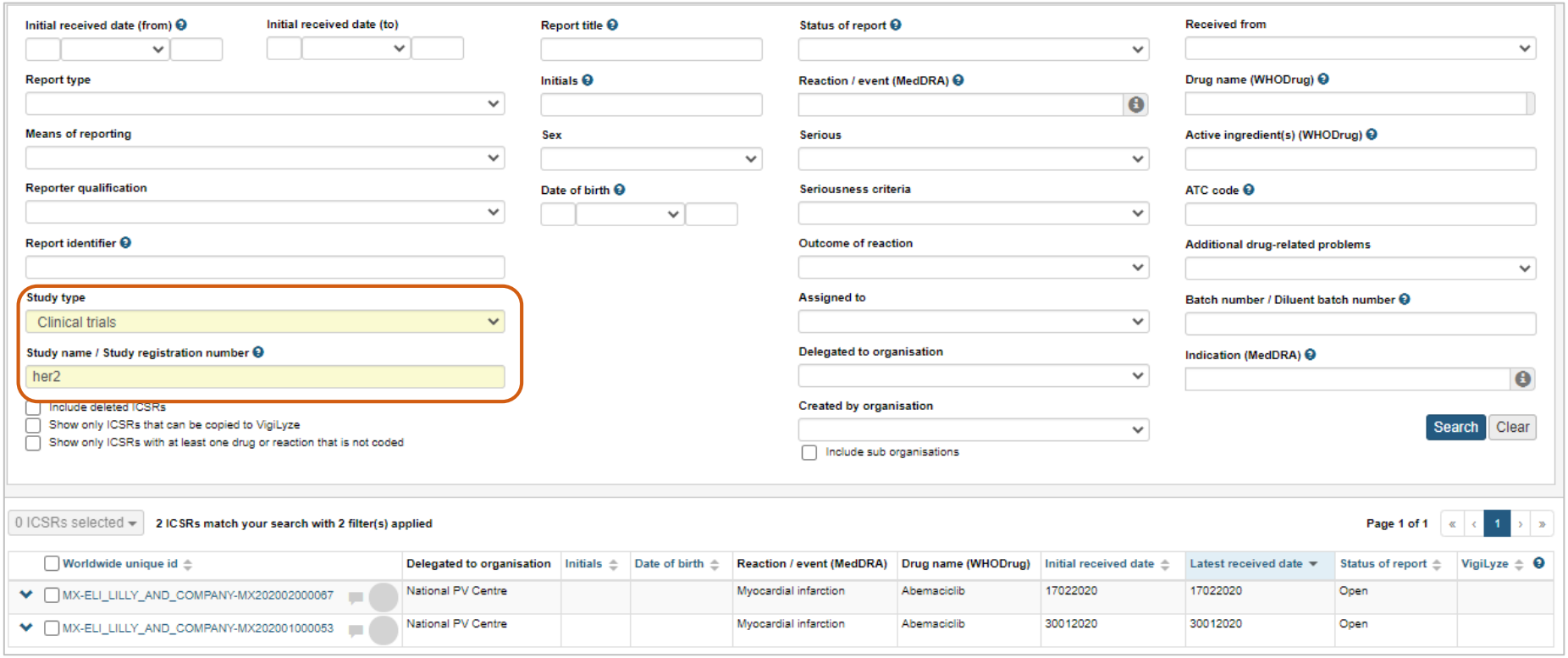
The search will be done in any of the report identifiers, such as:

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



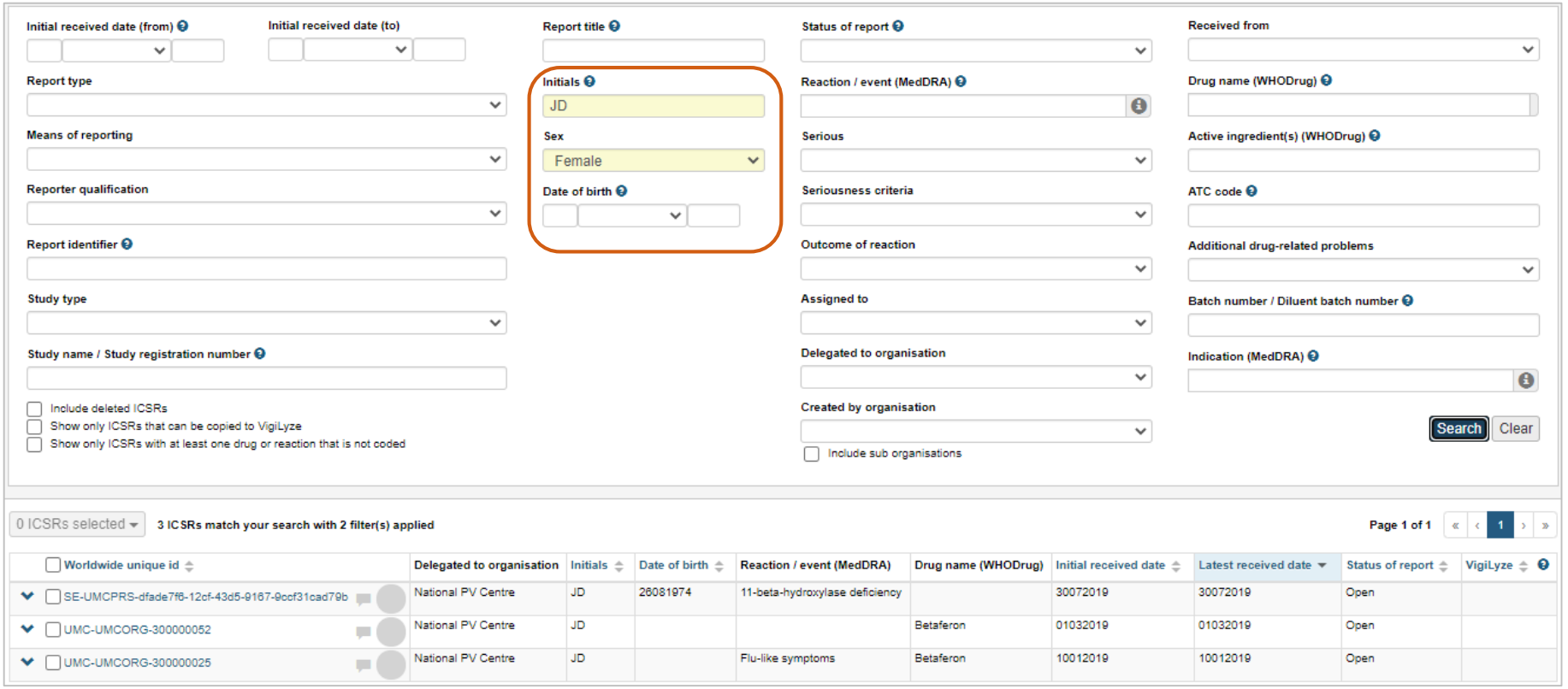
Search for study reports

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.



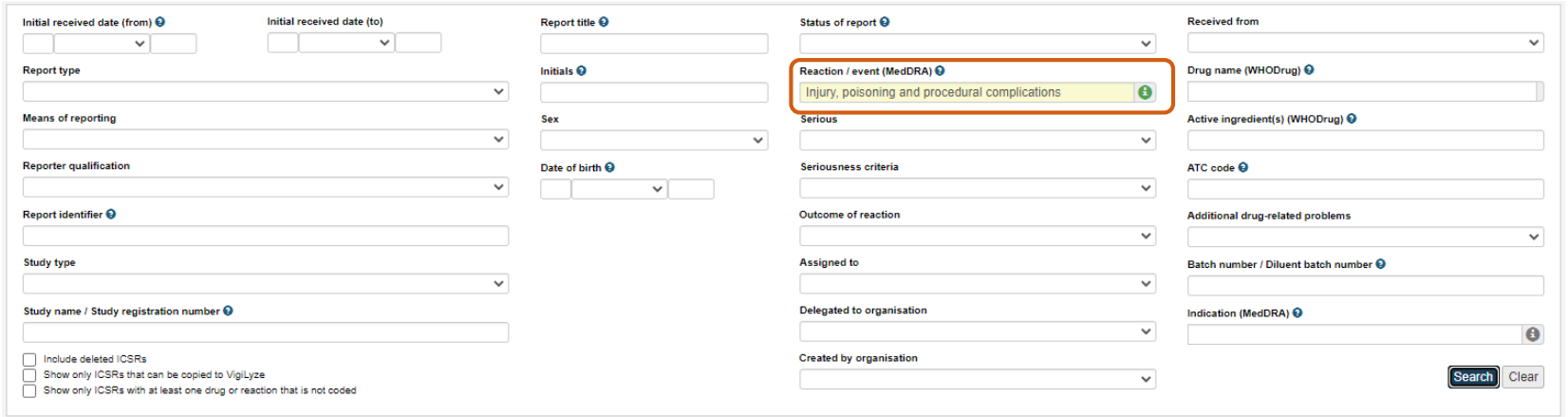
Search by patient details

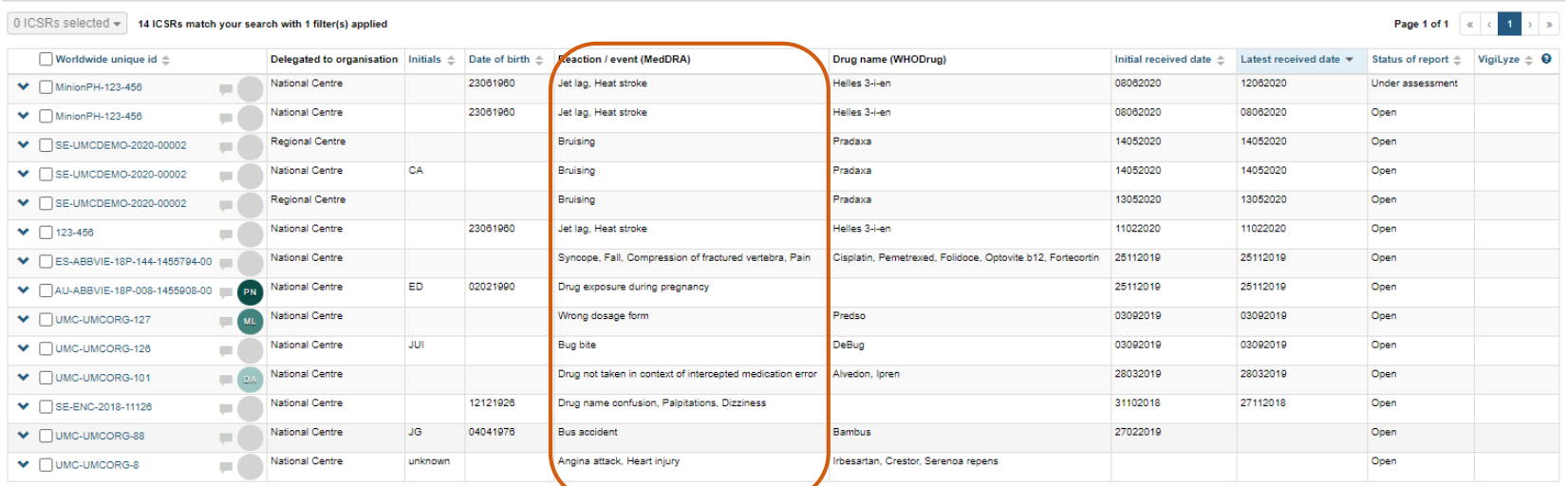
Using the patient information (initials, date of birth or sex) to find ICSRs can be particularly useful to investigate if the database contains previous ICSRs from the same patient and avoid entering the same ICSR twice.



Search by Reactions / events (MedDRA)

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

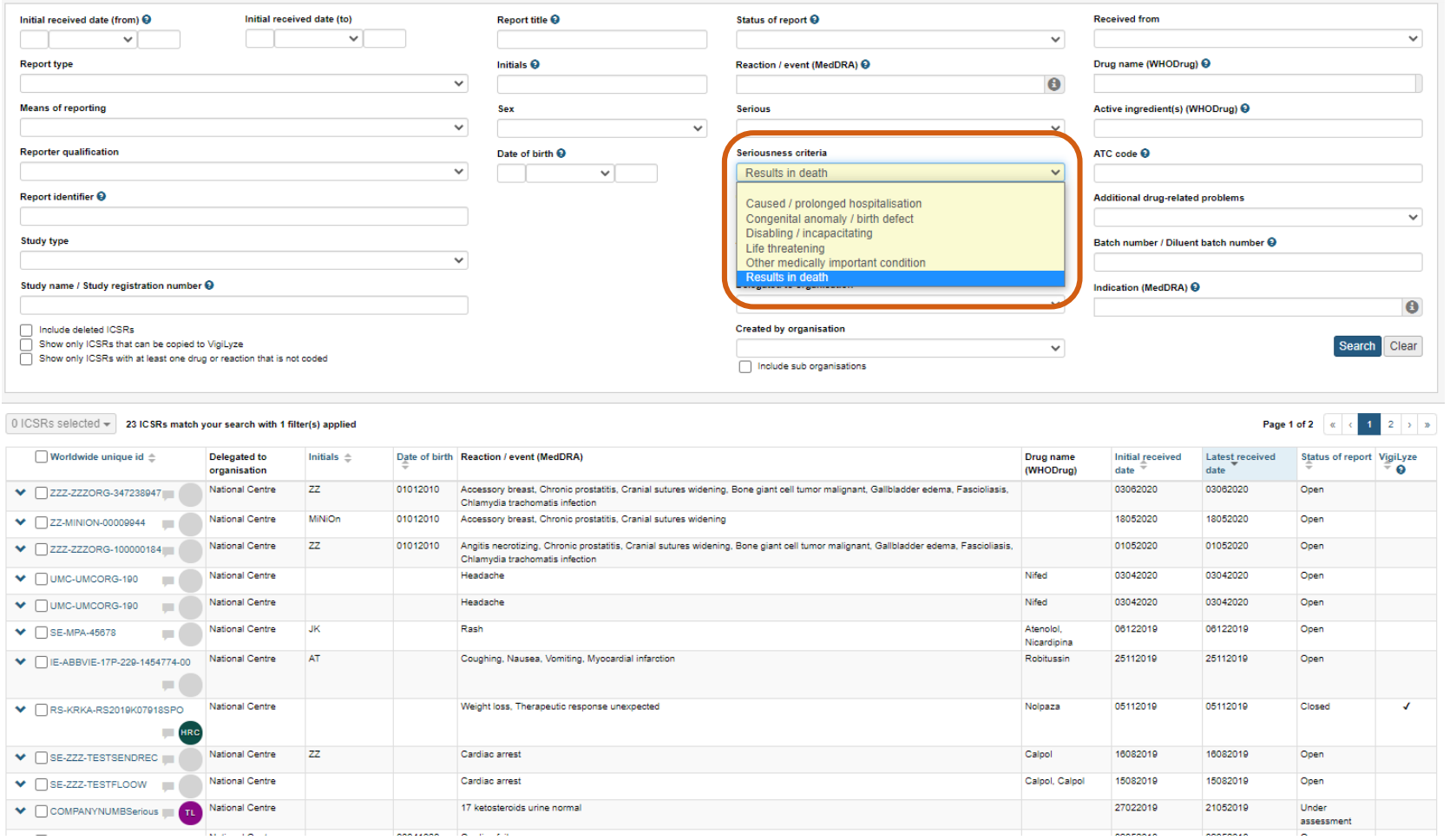




Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-i-en	08062020	12062020	Under assessment	
MinionPH-123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-i-en	08062020	08062020	Open	
SE-UMCDEMO-2020-00002	Regional Centre			Bruising	Pradaxa	14052020	14052020	Open	
SE-UMCDEMO-2020-00002	National Centre	CA		Bruising	Pradaxa	14052020	14052020	Open	
SE-UMCDEMO-2020-00002	Regional Centre			Bruising	Pradaxa	13052020	13052020	Open	
123-456	National Centre		23061960	Jet lag, Heat stroke	Helles 3-i-en	11022020	11022020	Open	
ES-ABBVIE-18P-144-1455794-00	National Centre			Syncope, Fall, Compression of fractured vertebra, Pain	Cisplatin, Pemetrexed, Folidoce, Optovite b12, Fortecortin	25112019	25112019	Open	
AU-ABBVIE-18P-008-1455908-00	National Centre	ED	02021990	Drug exposure during pregnancy		25112019	25112019	Open	
UMC-UMCORG-127	National Centre			Wrong dosage form	Predso	03092019	03092019	Open	
UMC-UMCORG-126	National Centre	JUI		Bug bite	DeBug	03092019	03092019	Open	
UMC-UMCORG-101	National Centre			Drug not taken in context of intercepted medication error	Alvedon, Ipren	28032019	28032019	Open	
SE-ENC-2018-11126	National Centre		12121926	Drug name confusion, Palpitations, Dizziness		31102018	27112018	Open	
UMC-UMCORG-88	National Centre	JG	04041976	Bus accident	Bambus	27022019		Open	
UMC-UMCORG-8	National Centre	unknown		Angina attack, Heart injury	Irbesartan, Crestor, Serenoa repens			Open	

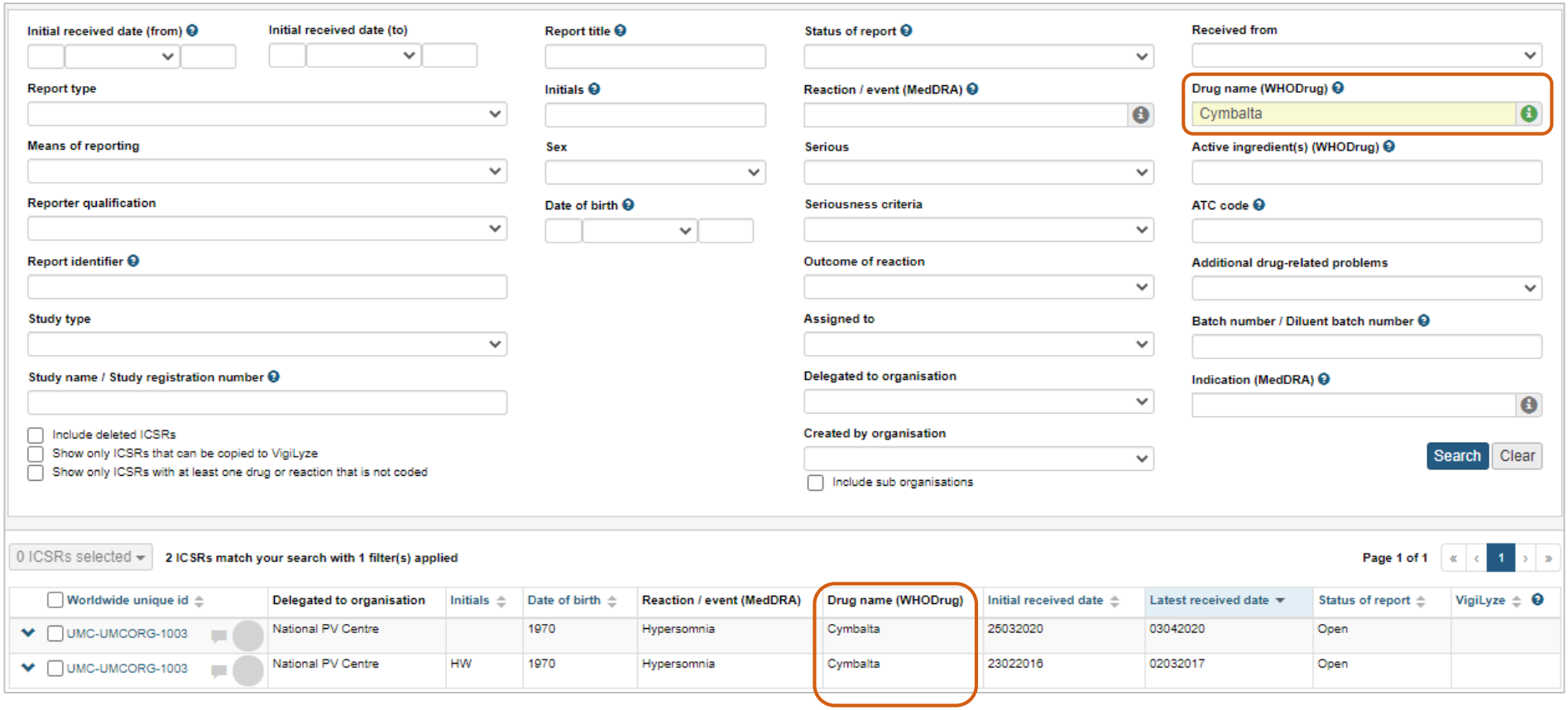
Search by seriousness criteria

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



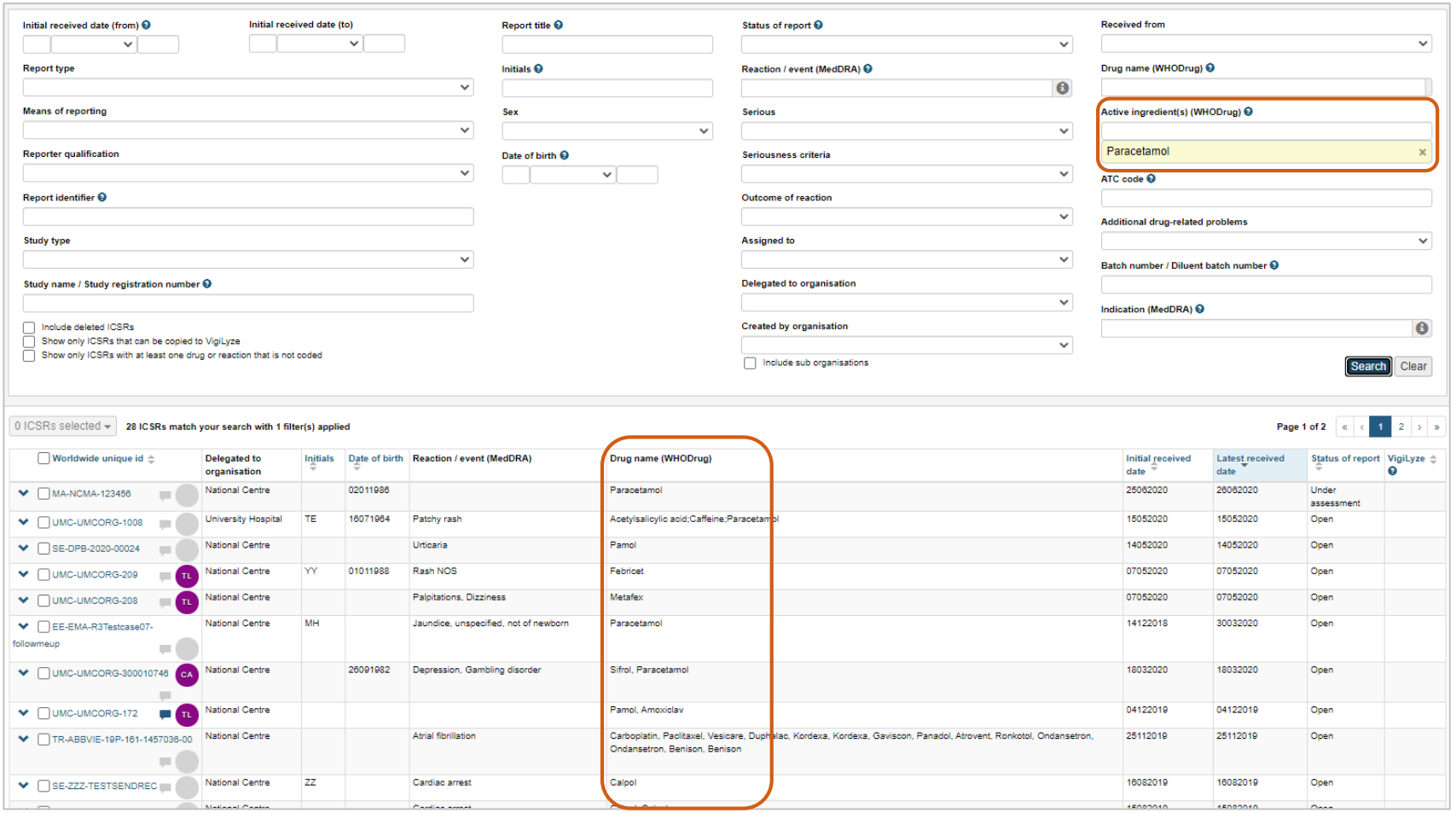
Search by Drug name (WHODrug)

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



Search by Active ingredients

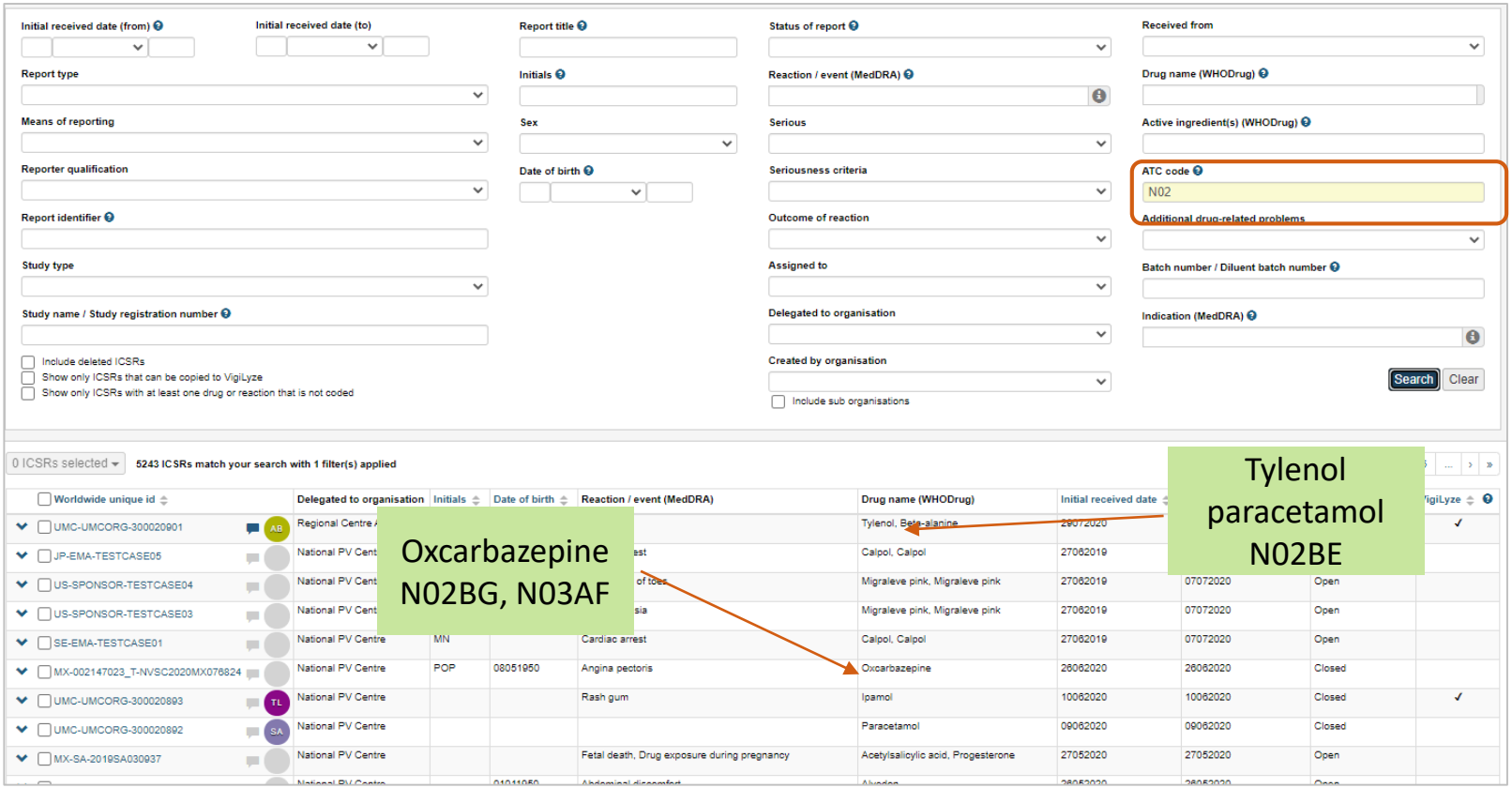
Searches using the Active Ingredient(s) will display ICSRs with products containing the selected active ingredient(s).



Search by ATC code

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

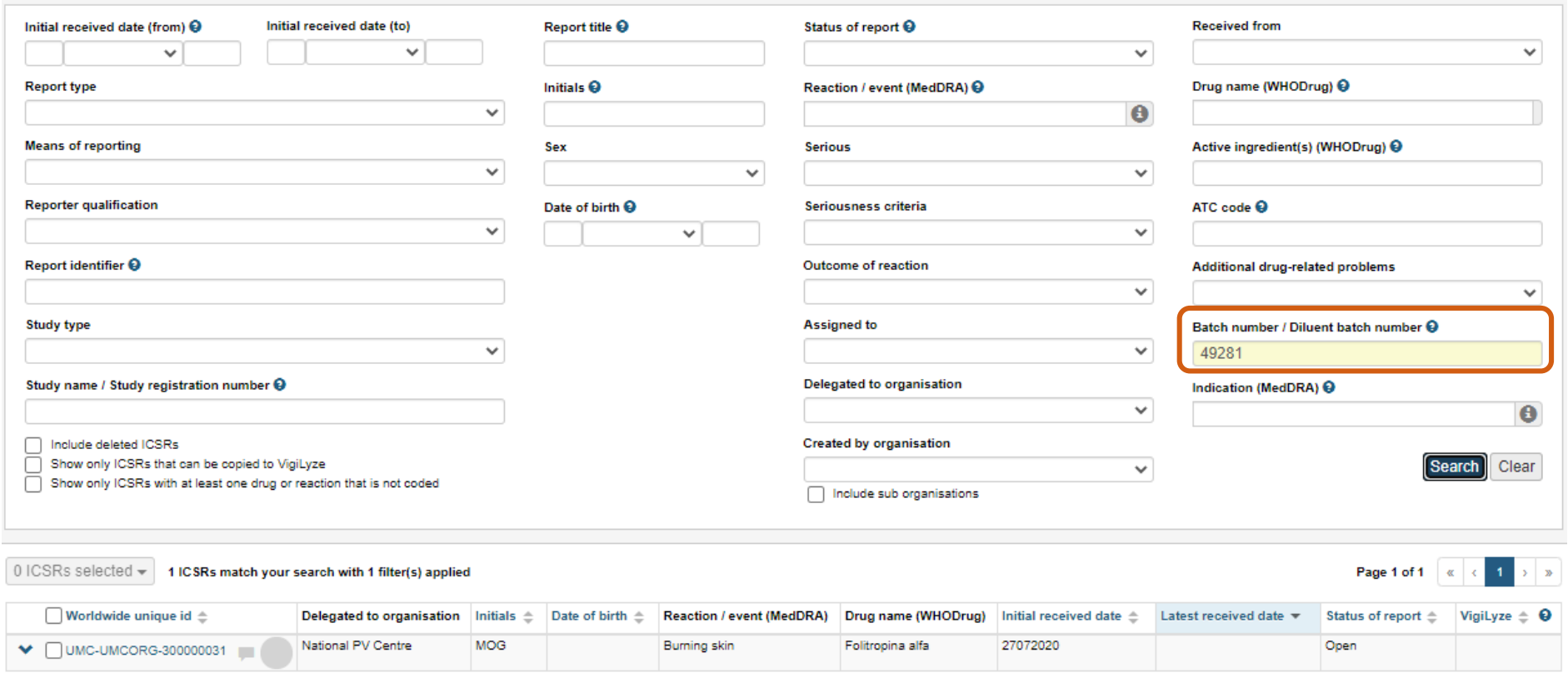
The search will bring all the reports which contain at least one drug that matches the ATC code



Search by batch numbers

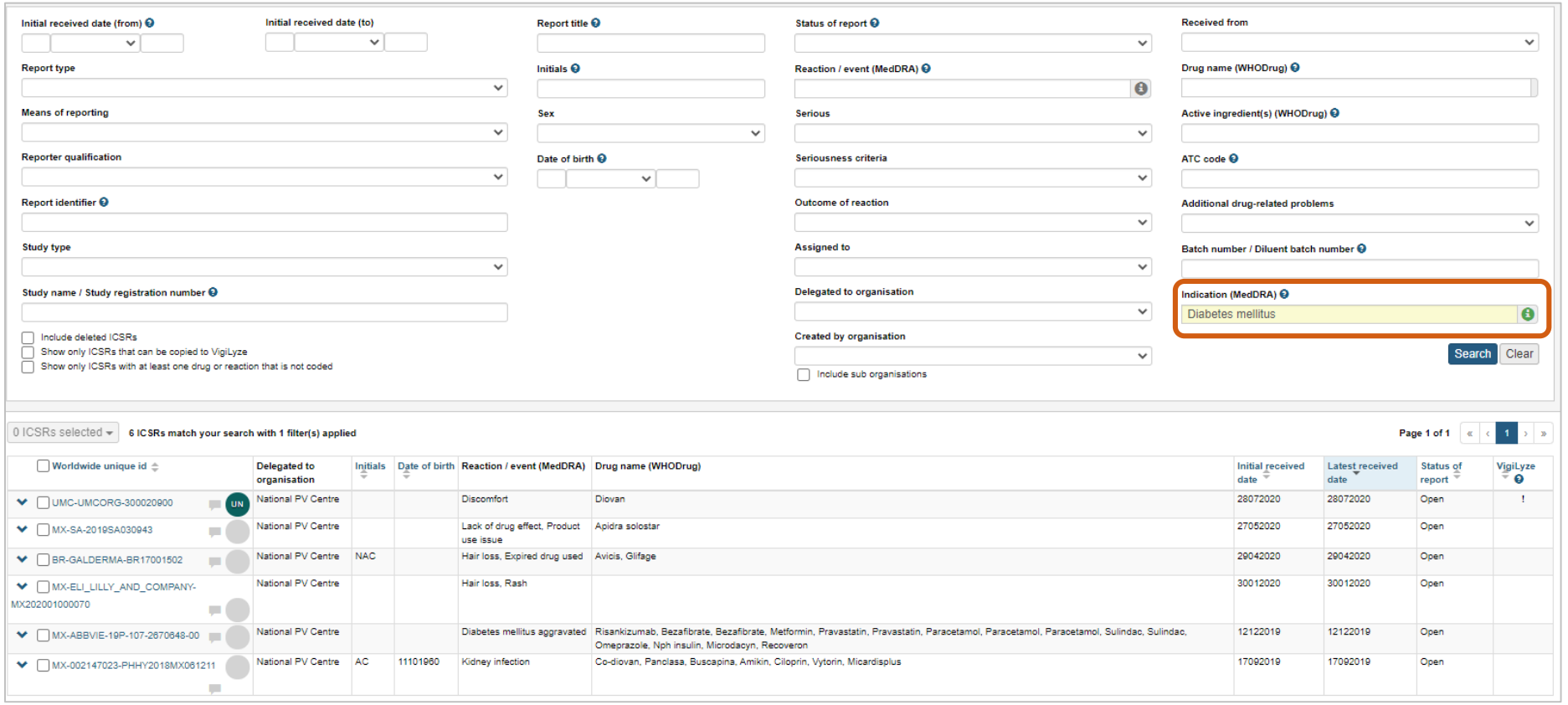
You can search for reports by typing in the first characters of a batch number or the complete batch number.

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



Search by drug indication

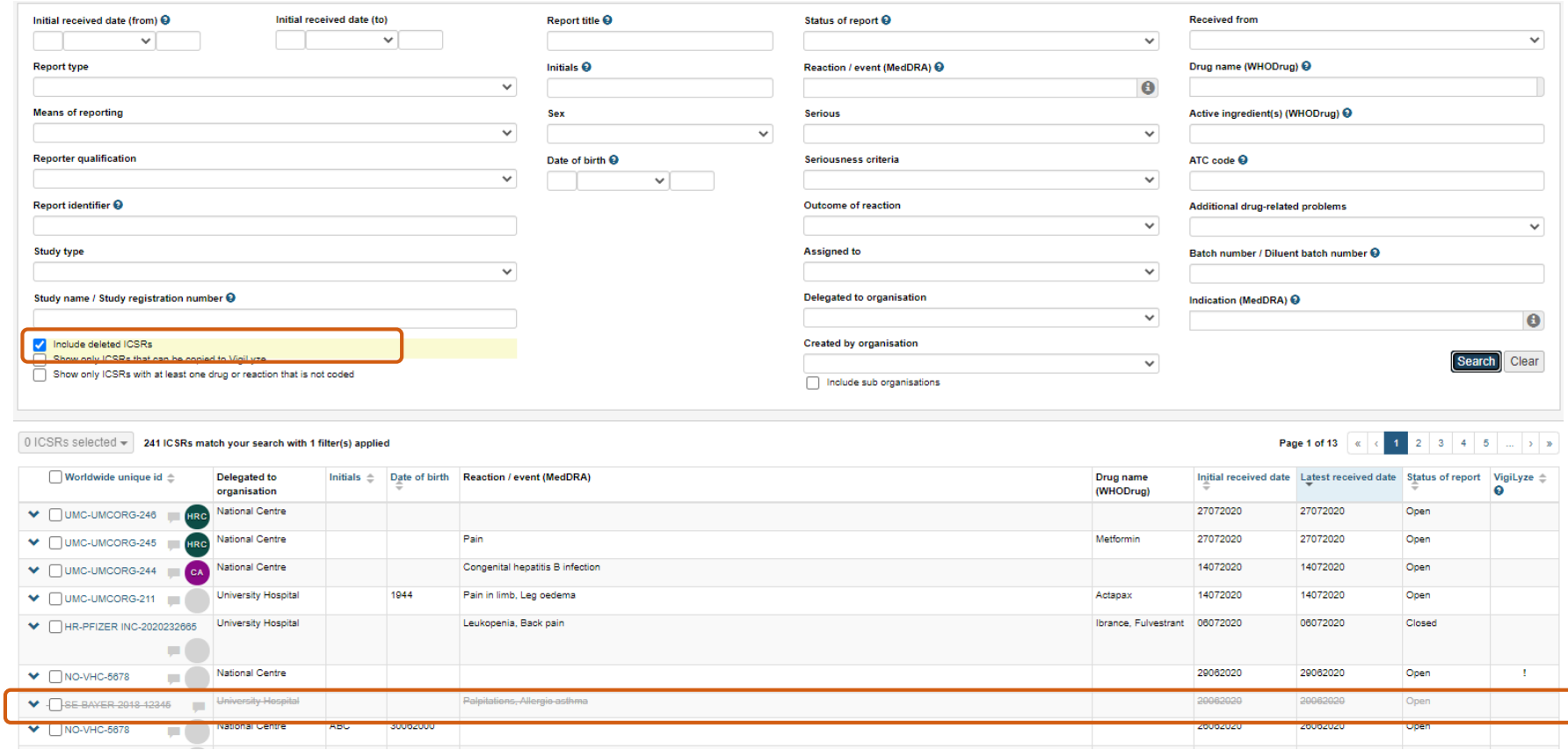
The search filter **Indication (MedDRA)** allows to search by terms in any level of the MedDRA hierarchy.



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.



ICSRs available in VigiLyze

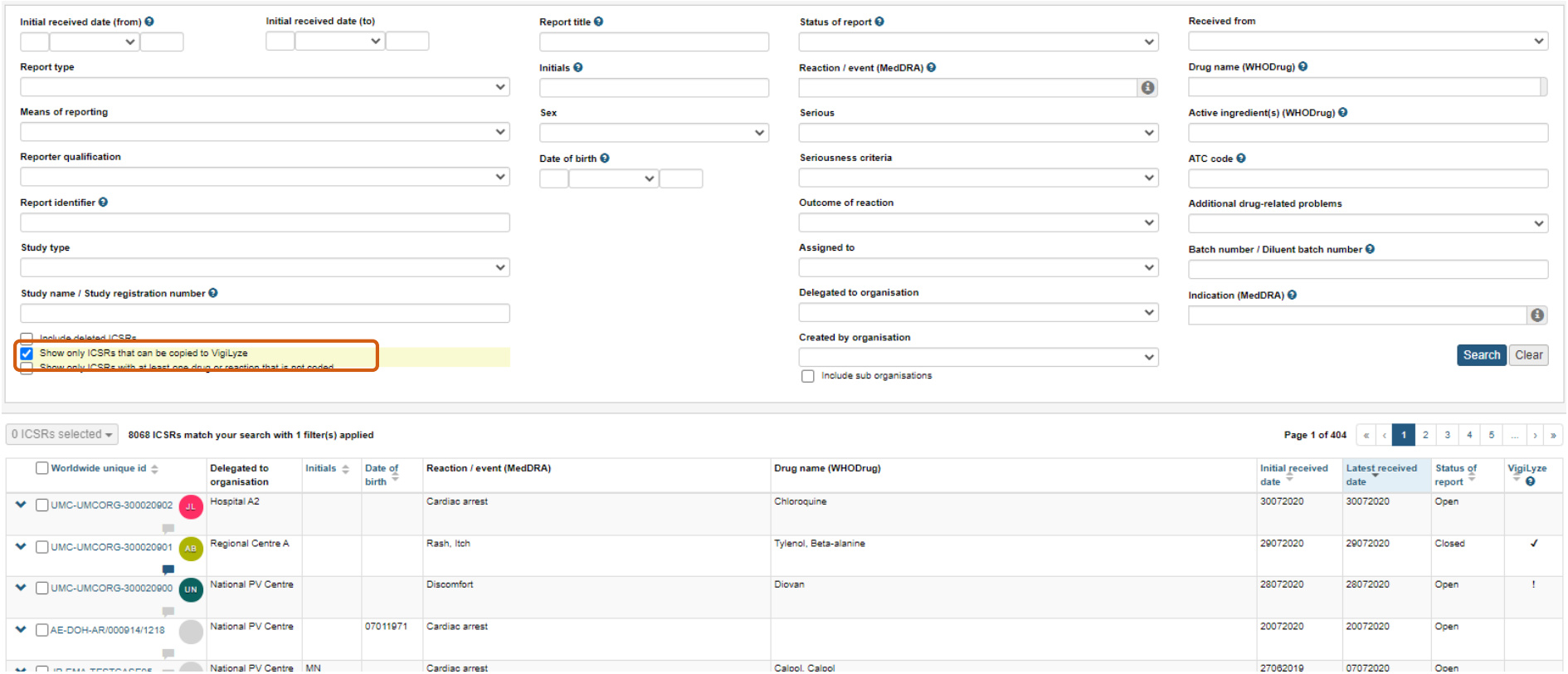
The VigiLyze column indicates if the ICSR has been shared with VigiBase and therefore visible in VigiLyze for analysis:

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

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			Cardiac arrest	Chloroquine	30072020	30072020	Open	
UMC-UMCORG-300020901	Regional Centre A			Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Closed	✓
UMC-UMCORG-300020900	National PV Centre			Discomfort	Diovan	28072020	28072020	Open	!
UMC-UMCORG-300020899	National PV Centre			Hypotension	Lamictal	27072020	27072020	Open	
AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
LV-EMA-Testcase08-nullifyme	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
EE-EMA-Testcase07-followmeup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27062019	07072020	Open	
JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27062019	07072020	Open	
SE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
NO-VHC-5678	National PV Centre	ABC	30062000	Pregnancy, Lack of drug effect		01072020	01072020	Closed	!
MX-002147023_T-NVSC2020MX076824	National PV Centre	POP	08051950	Angina pectoris	Oxcarbazepine	26062020	26062020	Closed	
UMC-UMCORG-300020894	National PV Centre					15062020	15062020	Closed	
UMC-UMCORG-300020893	National PV Centre			Rash gum	Ipamol	10062020	10062020	Closed	✓
UMC-UMCORG-300020892	National PV Centre				Paracetamol	09062020	09062020	Closed	
UMC-UMCORG-300020891	National PV Centre				Ursofalk	08062020	08062020	Under assessment	
UMC-UMCORG-300020890	National PV Centre			Abdominal pain	Diovan	05062020	05062020	Closed	

Knowing which ICSRs can be shared with the WHO Programme

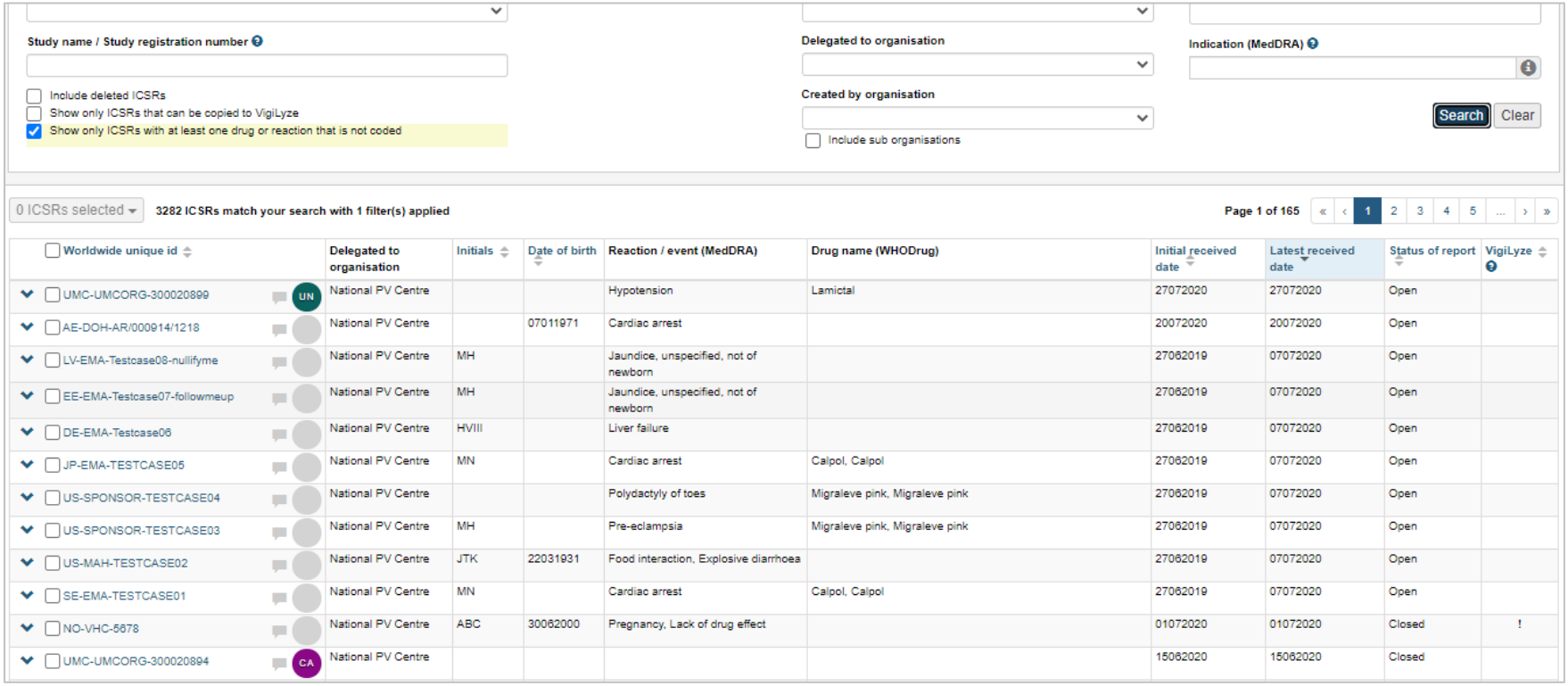
Use the search filter **Show only ICSRs that can be copied to VigiLyze**, to know which reports contain at least the minimum information to be shared with the WHO Programme of International Drug Monitoring.



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 <u>at least one uncoded drug or reaction</u> so you can prioritize the coding.



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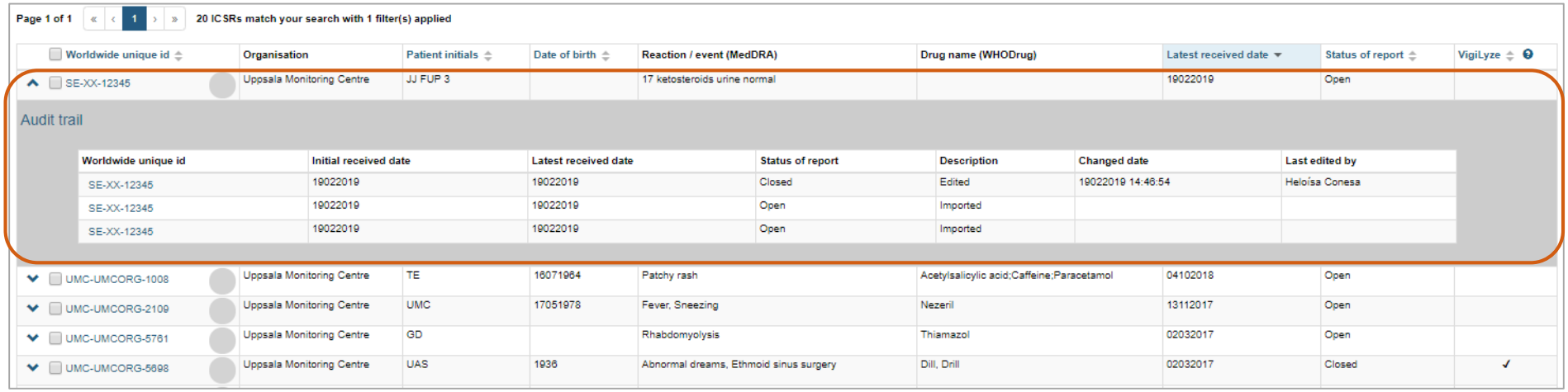
EE-EMA-Testcase07-followmeup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27062019	07072020	Open	
DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27062019	07072020	Open	
JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27062019	07072020	Open	
US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27062019	07072020	Open	
SE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27062019	07072020	Open	
NO-VHC-5678	National PV Centre	ABC	30062000	Pregnancy, Lack of drug effect		01072020	01072020	Closed	!
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

Worldwide unique id	Organisation	Patient initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report	VigiLyze
SE-XX-12345	Uppsala Monitoring Centre	JJ FUP 3		17 ketosteroids urine normal		19022019	Open	
UMC-UMCORG-1008	Uppsala Monitoring Centre	TE	16071964	Patchy rash	Acetylsalicylic acid;Caffeine;Paracetamol	04102018	Open	
UMC-UMCORG-2109	Uppsala Monitoring Centre	UMC	17051978	Fever, Sneezing	Nezeril	13112017	Open	
UMC-UMCORG-5761	Uppsala Monitoring Centre	GD		Rhabdomyolysis	Thiamazol	02032017	Open	
UMC-UMCORG-5698	Uppsala Monitoring Centre	UAS	1936	Abnormal dreams, Ethmoid sinus surgery	Dill, Drill	02032017	Closed	✓

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	Heloísa Conesa
SE-XX-12345	19022019	19022019	Open	Imported		
SE-XX-12345	19022019	19022019	Open	Imported		

Features for workflow support

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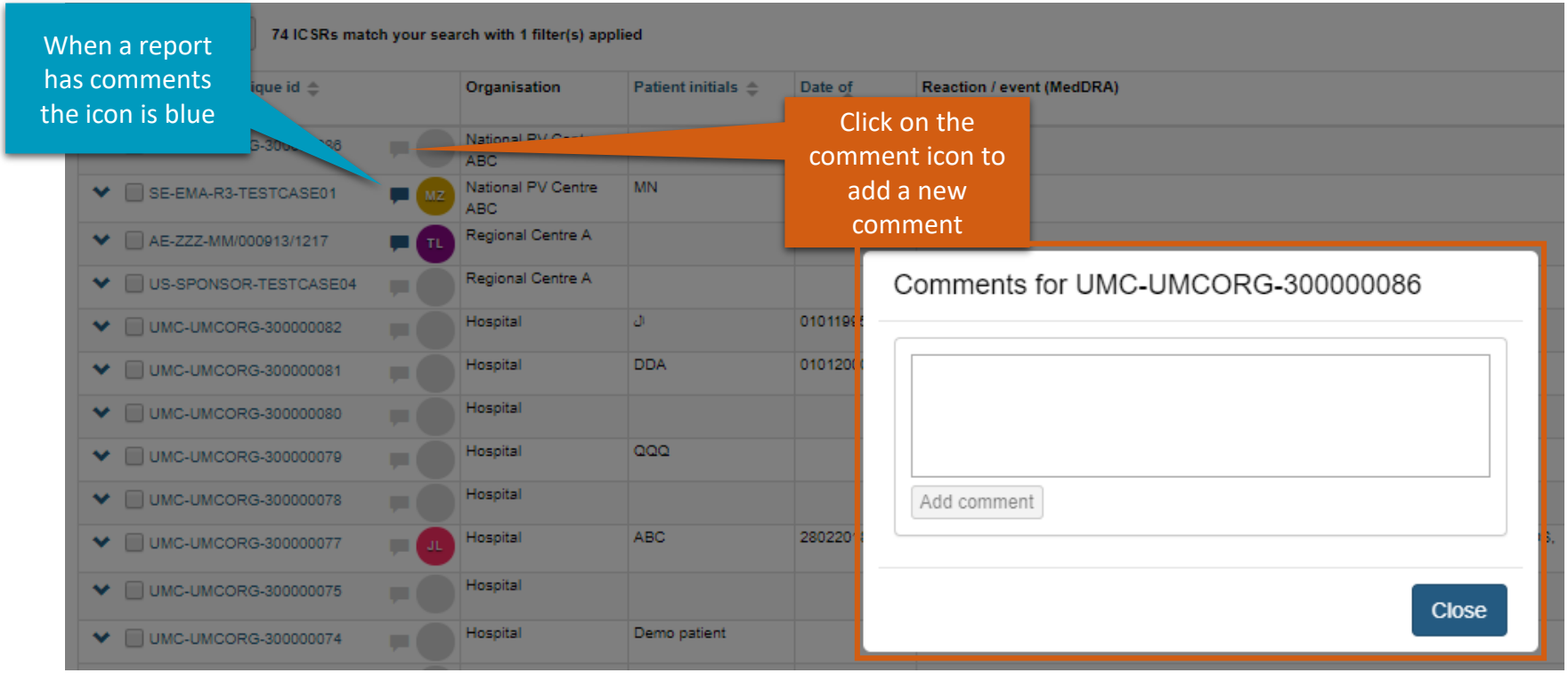
Add a comment to an ICSR

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.

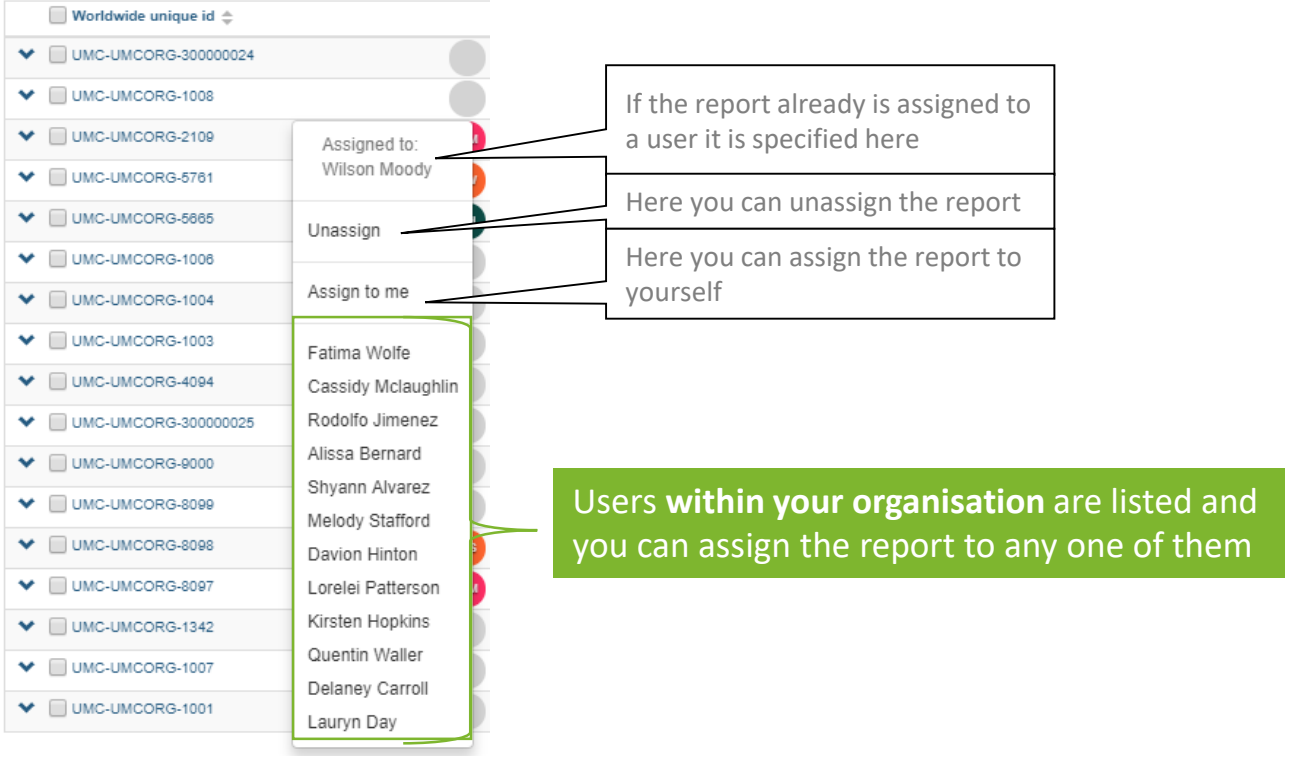


Assign reports to users

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

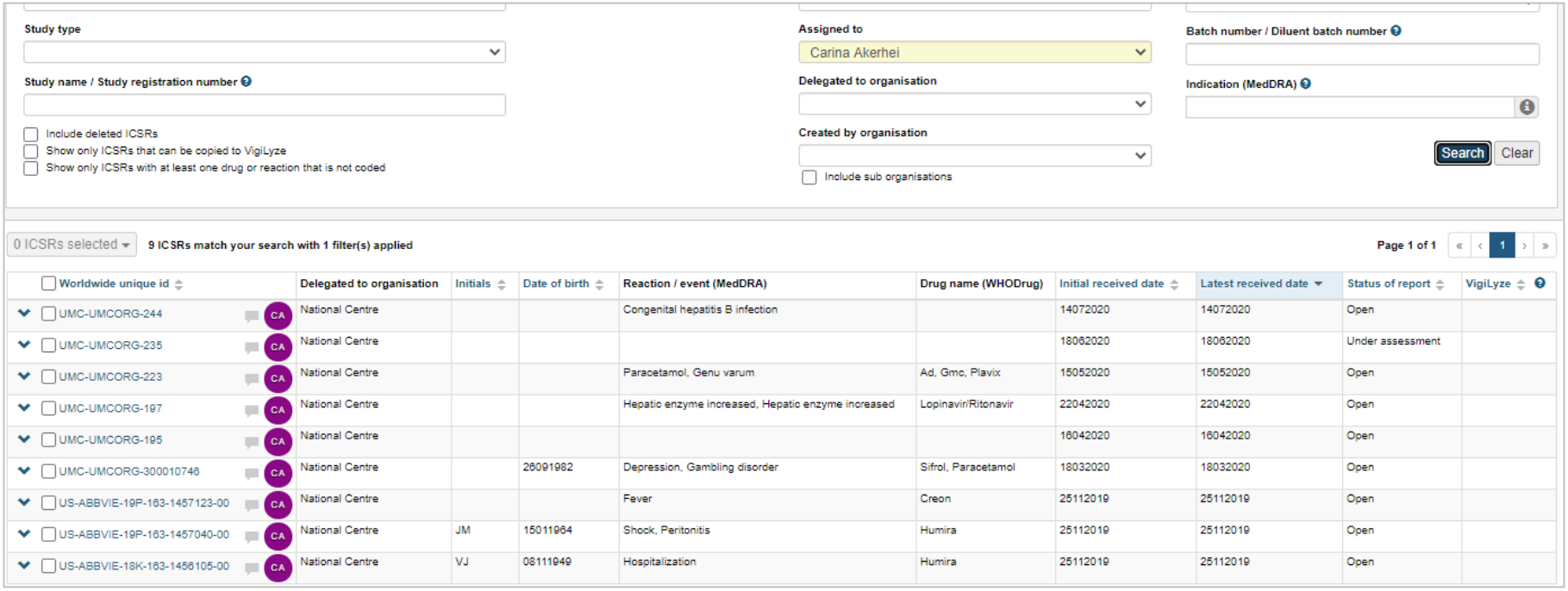
Click on the grey circle near the worldwide unique id to open the menu below.

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



Find the reports assigned to an user

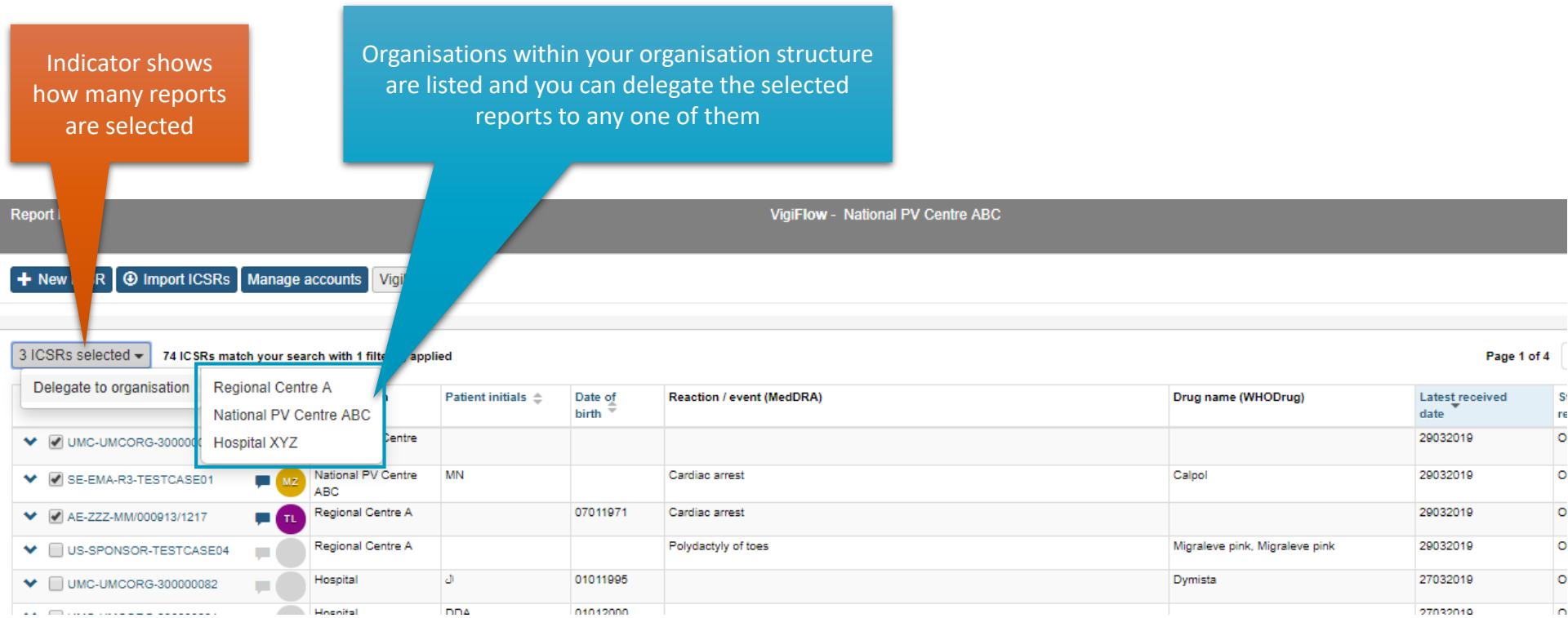
Use the search filter **Assigned To** to easily see the list of reports that have been assigned to you or someone else at your organisation and know who is working with a specific set of reports.



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-244	National Centre			Congenital hepatitis B infection		14072020	14072020	Open	
UMC-UMCORG-235	National Centre					18062020	18062020	Under assessment	
UMC-UMCORG-223	National Centre			Paracetamol, Genu varum	Ad, Gmc, Plavix	15052020	15052020	Open	
UMC-UMCORG-197	National Centre			Hepatic enzyme increased, Hepatic enzyme increased	Lopinavir/Ritonavir	22042020	22042020	Open	
UMC-UMCORG-195	National Centre					16042020	16042020	Open	
UMC-UMCORG-300010746	National Centre		26091982	Depression, Gambling disorder	Sifrol, Paracetamol	18032020	18032020	Open	
US-ABBVIE-19P-163-1457123-00	National Centre			Fever	Creon	25112019	25112019	Open	
US-ABBVIE-19P-163-1457040-00	National Centre	JM	15011964	Shock, Peritonitis	Humira	25112019	25112019	Open	
US-ABBVIE-18K-163-1456105-00	National Centre	VJ	08111949	Hospitalization	Humira	25112019	25112019	Open	

Delegate reports to other PV centres

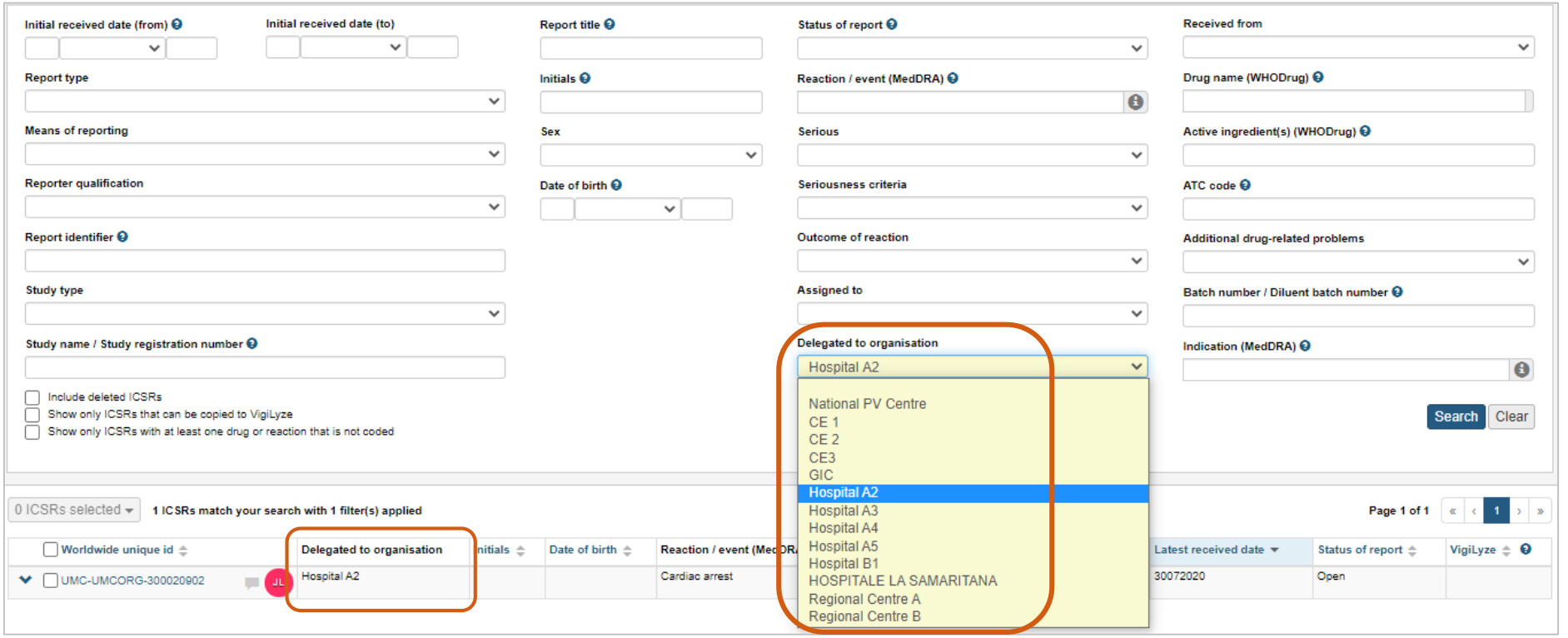
If the national centre setup a decentralized system in VigiFlow, you can delegate reports to other PV centres.



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.

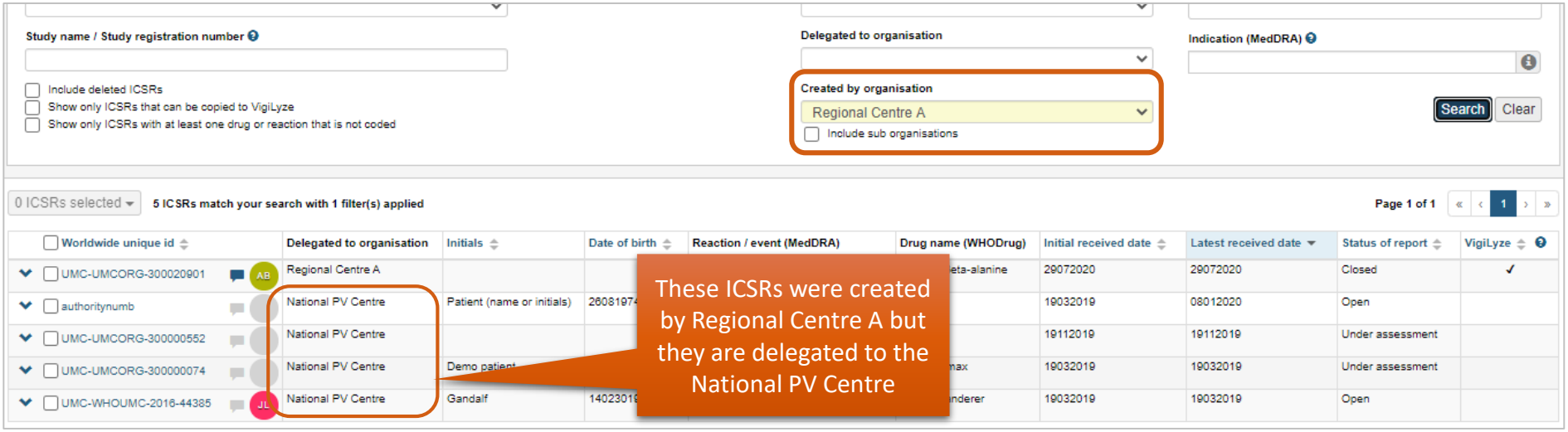
Your PV centre will always be able to view all the reports that have been either created by or delegated to your PV centre.



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.



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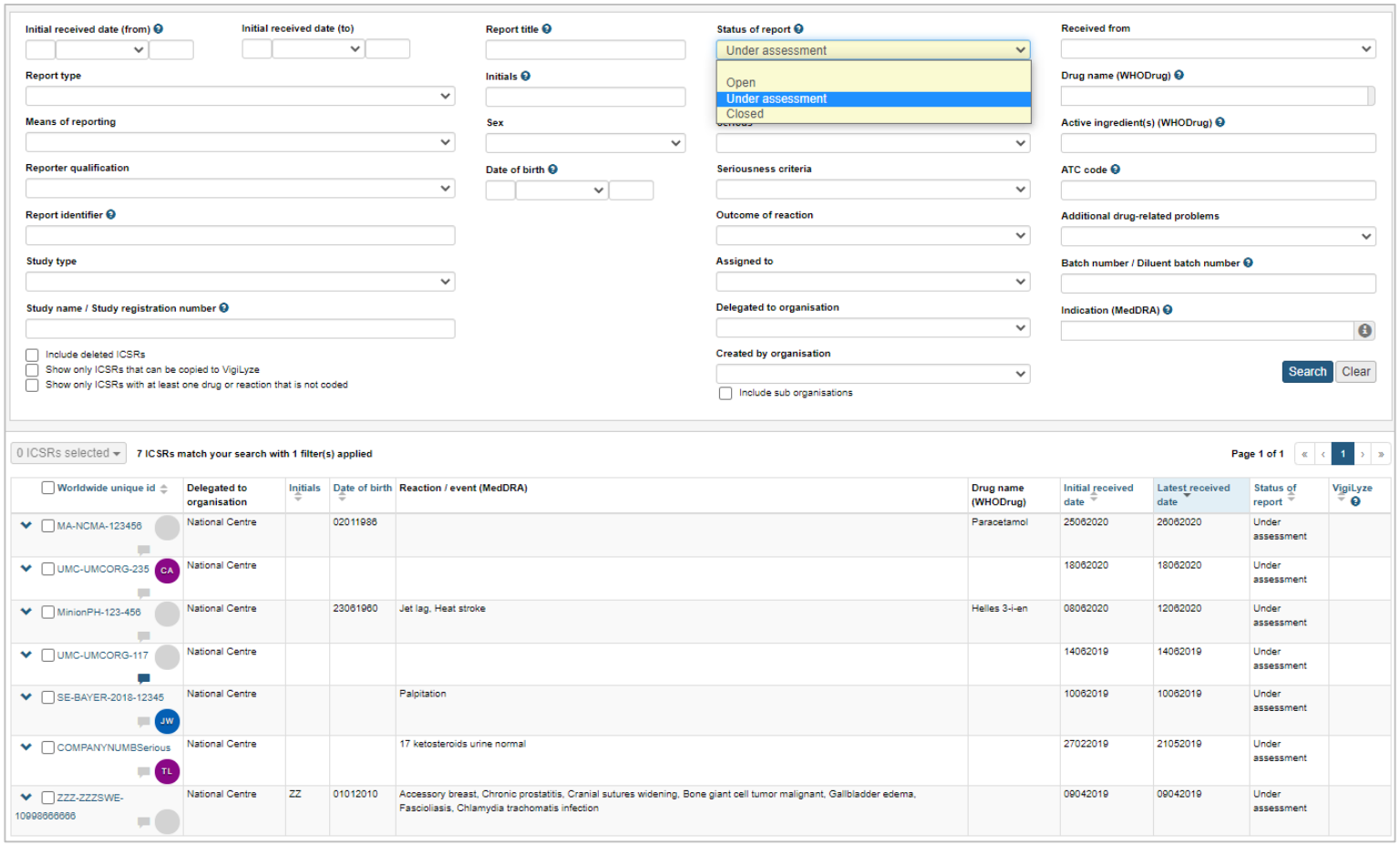
Search report by status

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



Exporting ICSRs

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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

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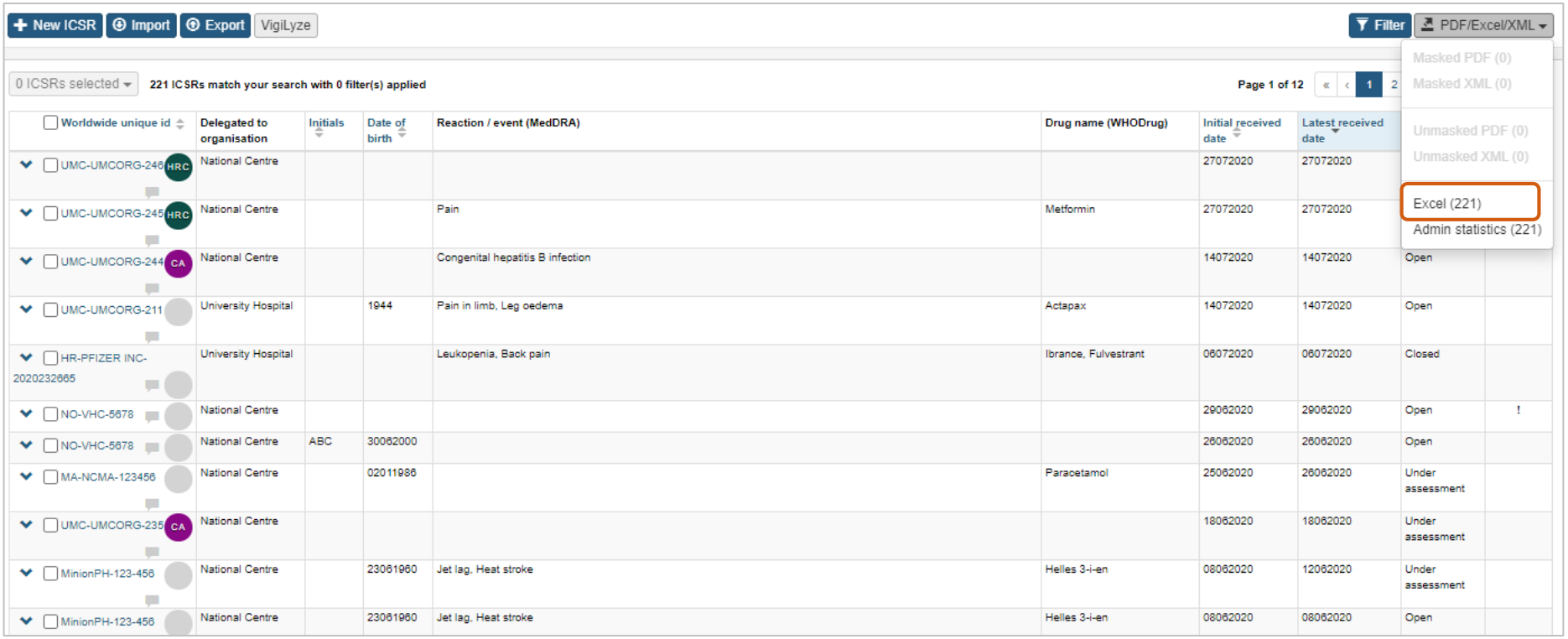
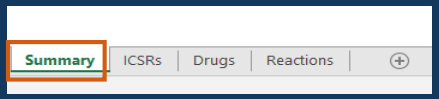
Export to Excel

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

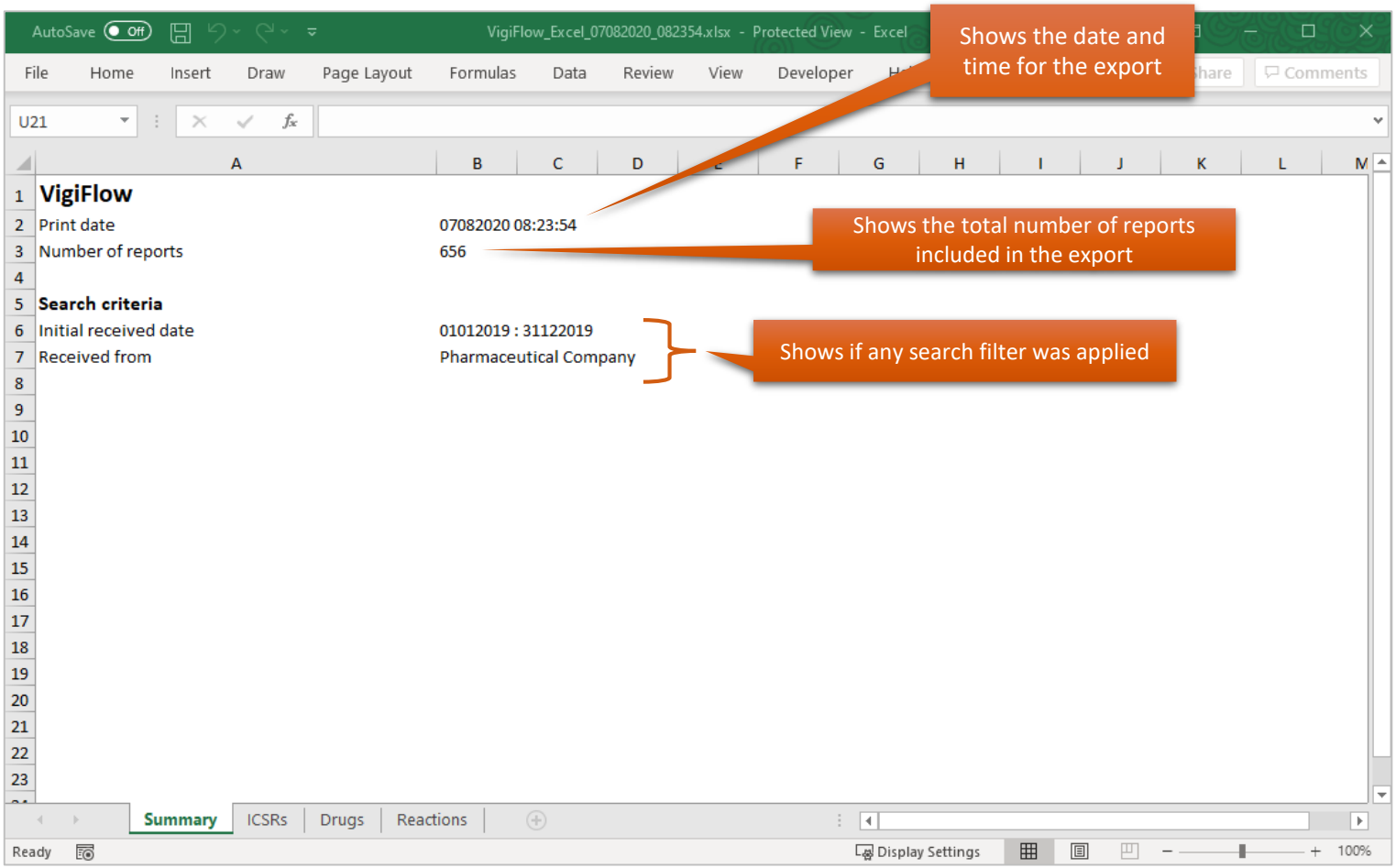
The number in brackets shows the amount of reports which will be included in the list. The Excel export allows a maximum of 3000 ICSRs per file.



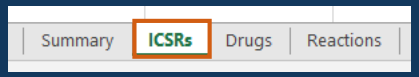
Summary sheet in the Excel



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



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	Captoril Aspirin Metformin Insulin

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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	Domeridone		
UMC-UMCORG-1005	UMC-UMCORG-1005	Interacting	Captoril	Captoril	Captopril

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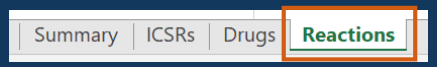
Reactions sheet in the Excel



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

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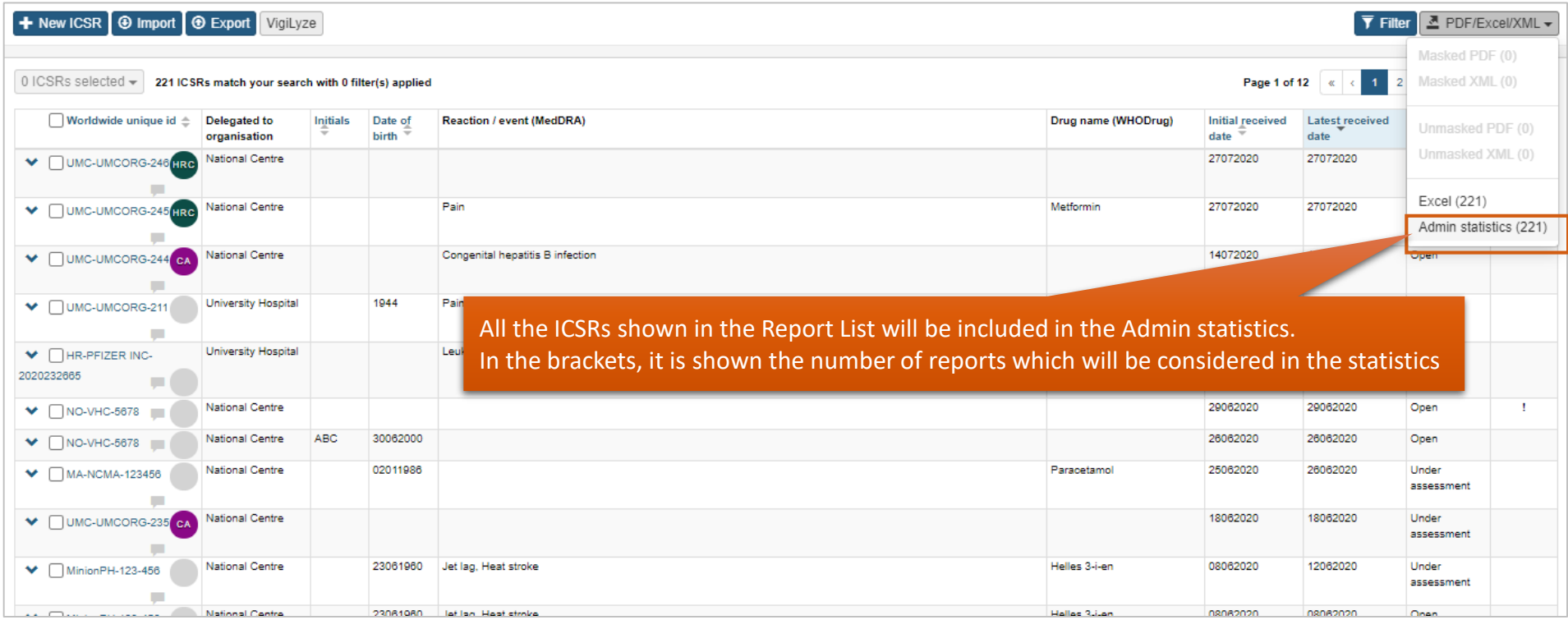
Admin statistics

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



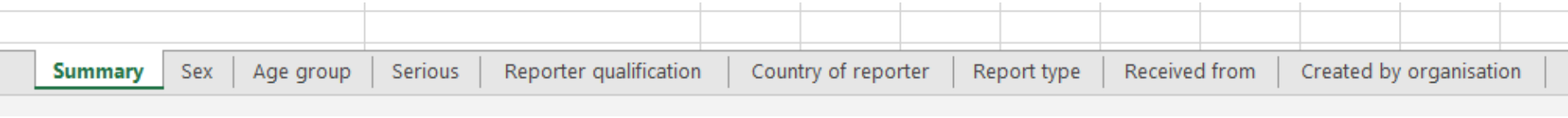
Admin statistics in Excel

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*



Admin statistics in Excel

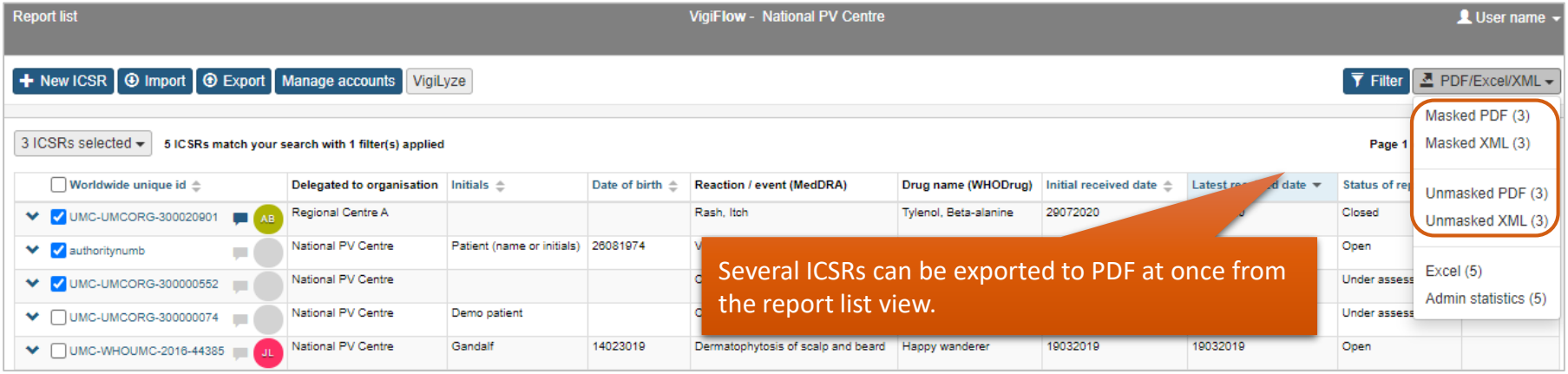
The statistics are presented by Year, Month and values in respective sheet, for example:

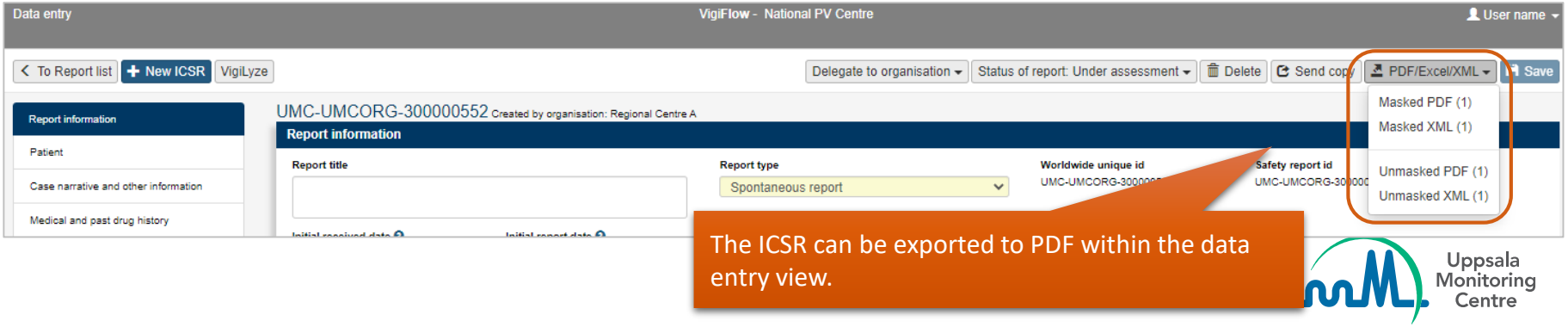
from sheet Serious:

	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.





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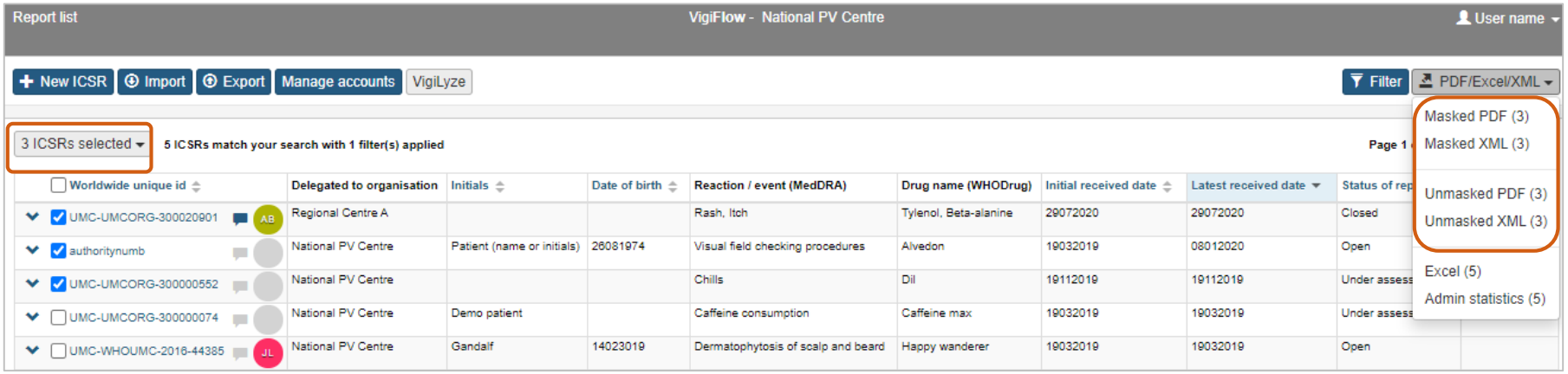
PDF-export from the report list

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.



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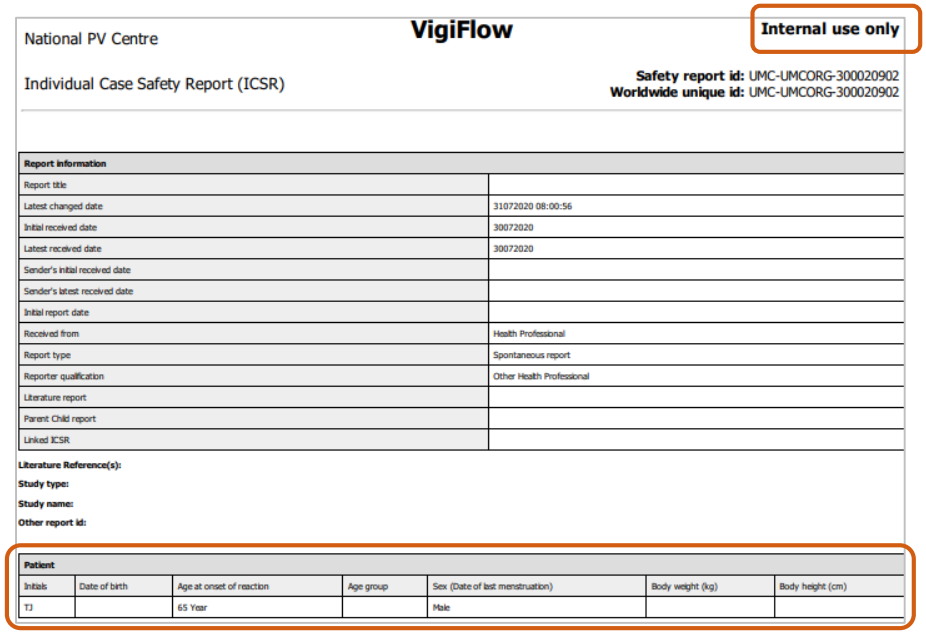
Examples of PDF exports

Unmasked PDF



National PV Centre

VigiFlow

Internal use only

Individual Case Safety Report (ICSR)

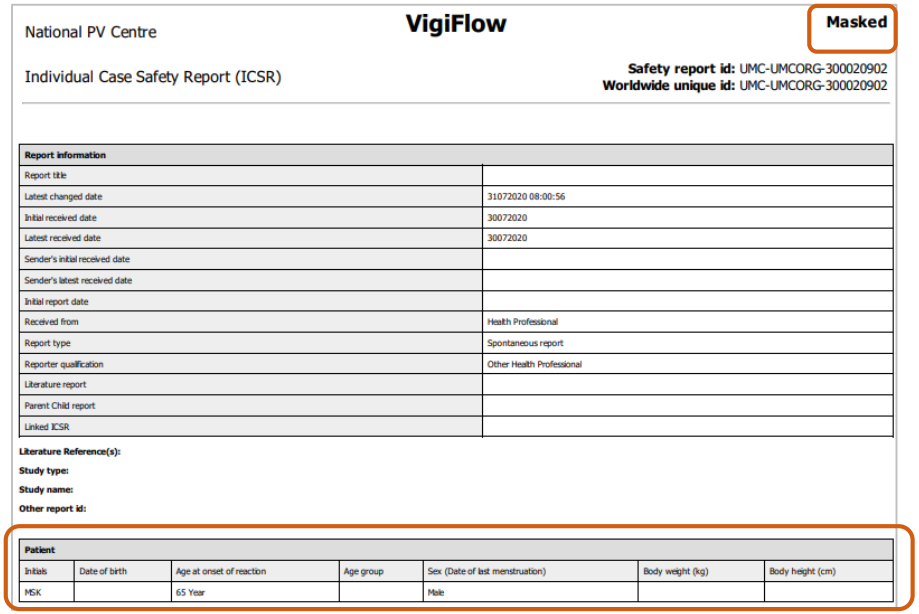
Safety report id: UMC-UMCORG-300020902
Worldwide unique id: UMC-UMCORG-300020902

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

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

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

Masked PDF



National PV Centre

VigiFlow

Masked

Individual Case Safety Report (ICSR)

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

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

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

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

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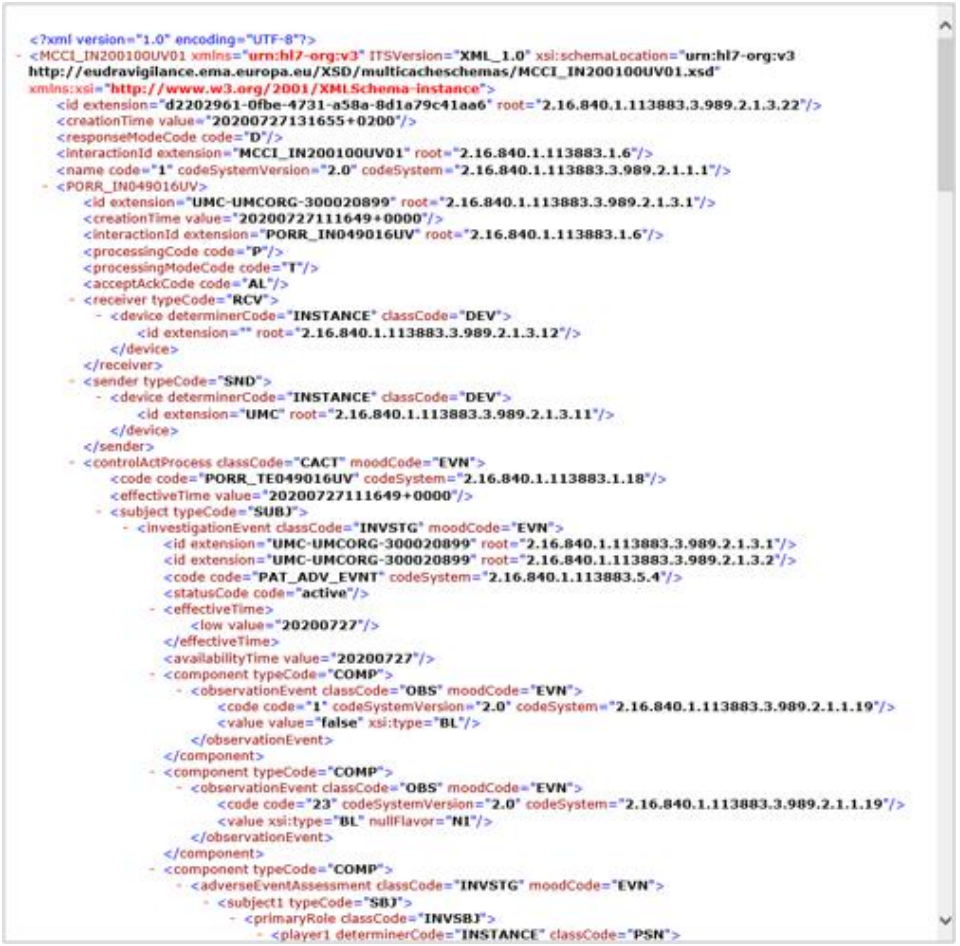
Export to xml

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

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



Questions:
vigibase@who-umc.org

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Tel: +46 18-65 60 60 **www.who-umc.org**