VigiFlow

Introduction and basic features

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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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What is VigiFlow?

VigiFlow is a web-based ICSR data management system

It is your country's own national pharmacovigilance database which supports the collection, processing, analyzing and sharing of ADR and AEFI reports.
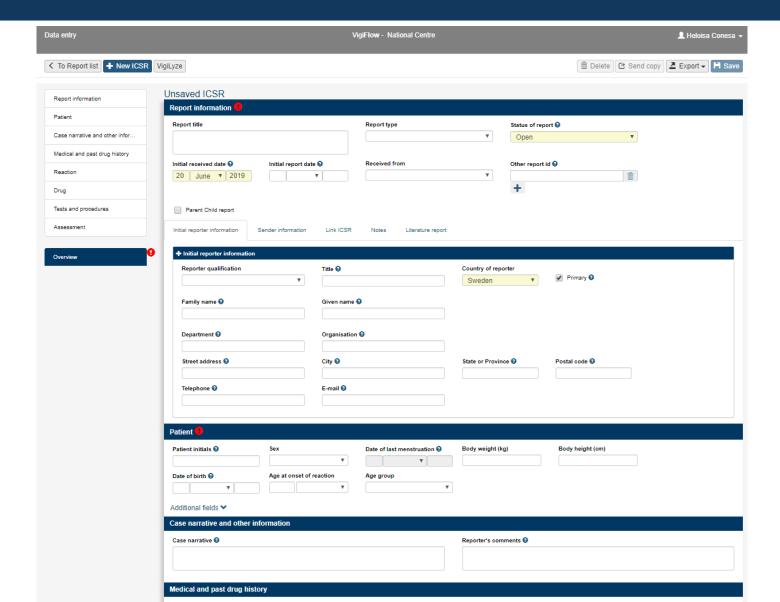
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Transitioning from the old VigiFlow…

… to VigiFlow

Main features of VigiFlow

- Compatible with updated international standards (ICH-E2B(R3))
  - *MedDRA is the medical terminology*

- Improved data entry options for ADR and AEFI reports
  - *e.g. enter multiple dosage info for same drug or vaccine*
  - *Possible to capture 25 AEFI core variables*

- Possible to capture causality assessment results from different methods:
  - *WHO-UMC causality; Naranjo; WHO AEFI; The French method*

- Direct access to VigiLyze

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Additional features in VigiFlow

Phase 1

Manual data entry

Direct reporting for patients and healthcare professionals (eReporting)

Phase 2

Interface and medical terminology in English, French, Portuguese and Spanish

Phase 3

Import and export of xml files for exchange of ICSRs between the NC and other stakeholders (e.g. pharmaceutical industries)

Phase 4

Different access levels that will enable multiple PV centers to report ICSRs directly into the national database

Phase 5*

Online form for data entry for pharmaceutical industries and public health programs

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* Features are under development and will be implemented in the upcoming months

Standardized terminologies in VigiFlow

MedDRA is the only medical terminology available in VigiFlow. It can be used to add adverse reactions, drug indication, medical history, cause of death, test names and diagnosis. For further information about MedDRA, go to https://www.meddra.org/.

WHODrug is the dictionary embedded in VigiFlow for finding drug names or active substances. For further information about WHODrug, go to https://who-umc.org/whodrug/whodrug-portfolio/.

Both terminologies are automatically updated whenever a new version is released.

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How to access VigiFlow

- Recommended web browser: **Google Chrome**

- Web address: https://vigiflow.who-umc.org

- Questions: vigibase@who-umc.org

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Login page

Terms and Conditions for the use of VigiFlow

At the first login, the user will be prompted to read and accept the Terms and Conditions for using VigiFlow to be able to use the system.

Main screen – Report List

After logging into VigiFlow, you get directly into the **Report List**

Information displayed at the top bar

The name of the page in which you are current located

The name of your country´s national pharmacovigilance centre

The name of the person logged into VigiFlow

Report list

VigiFlow - National Centre

Heloísa Conesa

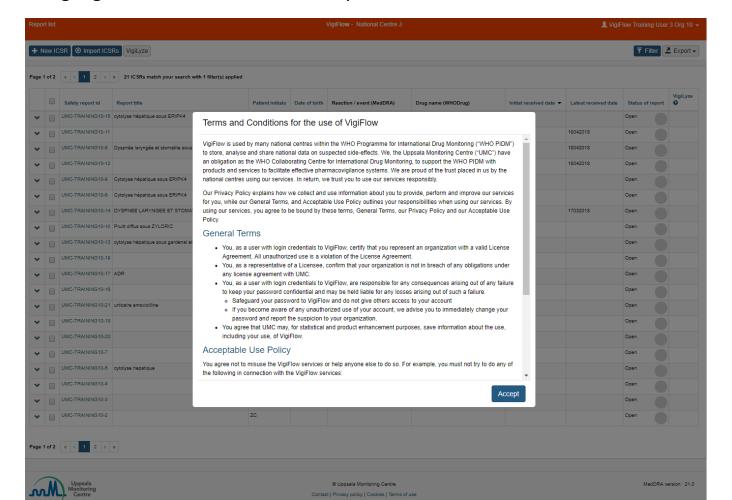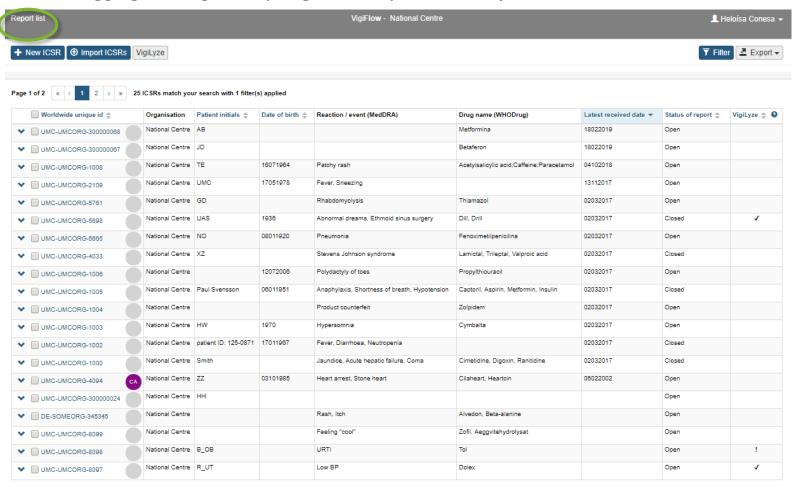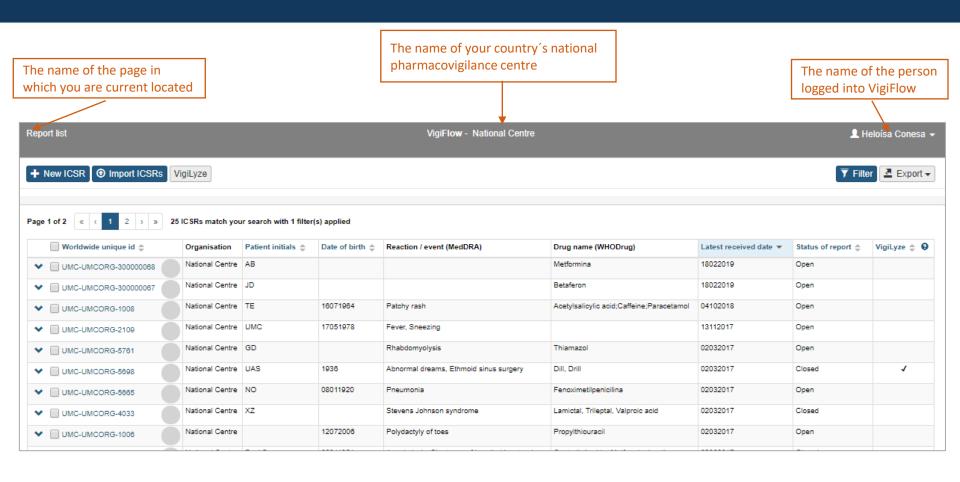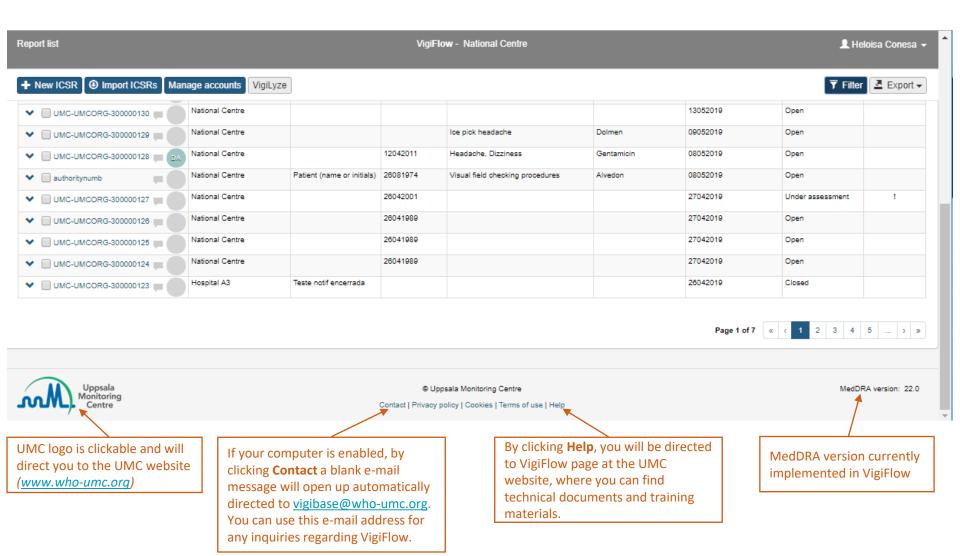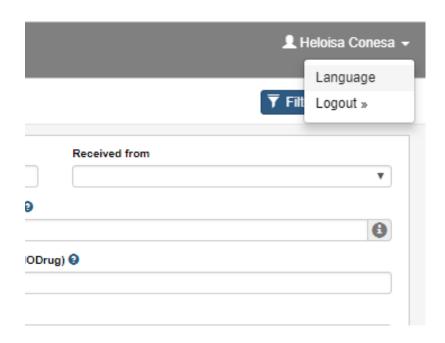+ New ICSR   ⊕ Import ICSRs   VigiLyze   ▼ Filter   ⊿ Export ▾

Page 1 of 2 « ‹ **1** 2 › »   25 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 ⇕ ❓
⌄ ☐ UMC-UMCORG-300000068	National Centre	AB			Metformina	18022019	Open	
⌄ ☐ UMC-UMCORG-300000067	National Centre	JD			Betaferon	18022019	Open	
⌄ ☐ UMC-UMCORG-1008	National Centre	TE	16071964	Patchy rash	Acetylsalicylic acid;Caffeine;Paracetamol	04102018	Open	
⌄ ☐ UMC-UMCORG-2109	National Centre	UMC	17051978	Fever, Sneezing		13112017	Open	
⌄ ☐ UMC-UMCORG-5761	National Centre	GD		Rhabdomyolysis	Thiamazol	02032017	Open	
⌄ ☐ UMC-UMCORG-5698	National Centre	UAS	1936	Abnormal dreams, Ethmoid sinus surgery	Dill, Drill	02032017	Closed	✓
⌄ ☐ UMC-UMCORG-5665	National Centre	NO	08011920	Pneumonia	Fenoximetilpenicilina	02032017	Open	
⌄ ☐ UMC-UMCORG-4033	National Centre	XZ		Stevens Johnson syndrome	Lamictal, Trileptal, Valproic acid	02032017	Closed	
⌄ ☐ UMC-UMCORG-1006	National Centre		12072006	Polydactyly of toes	Propylthiouracil	02032017	Open	

Information displayed at the bottom bar

UMC logo is clickable and will direct you to the UMC website (*www.who-umc.org*)

If your computer is enabled, by clicking **Contact** a blank e-mail message will open up automatically directed to vigibase@who-umc.org. You can use this e-mail address for any inquiries regarding VigiFlow.

By clicking **Help**, you will be directed to VigiFlow page at the UMC website, where you can find technical documents and training materials.

MedDRA version currently implemented in VigiFlow

Language settings

By clicking in the username, it is possible to change the language in VigiFlow.
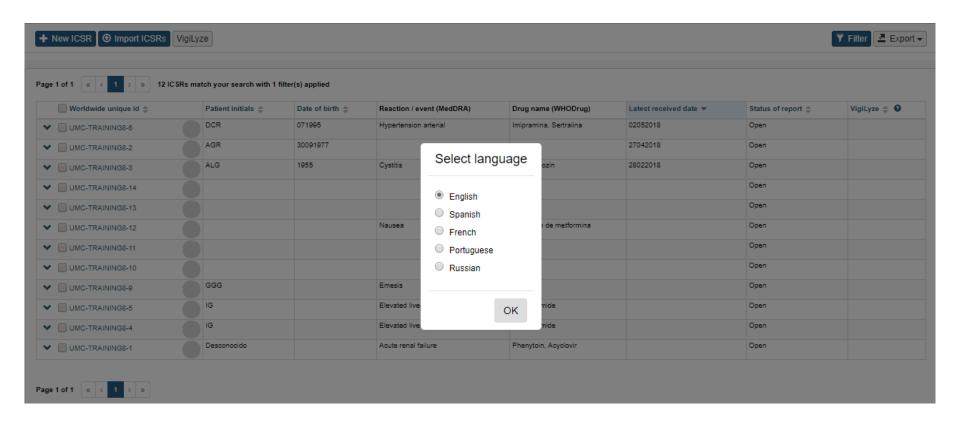
Choosing the language

Choose the language you want to use

NOTE! The same language is set for the interface and medical terminology, which means that it is not possible to have the system in one language and use MedDRA in a different language.
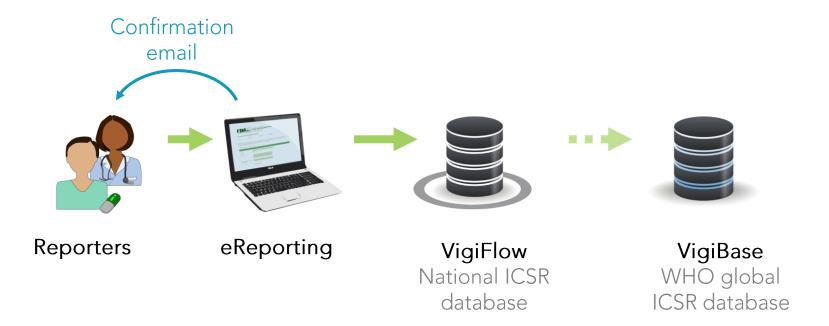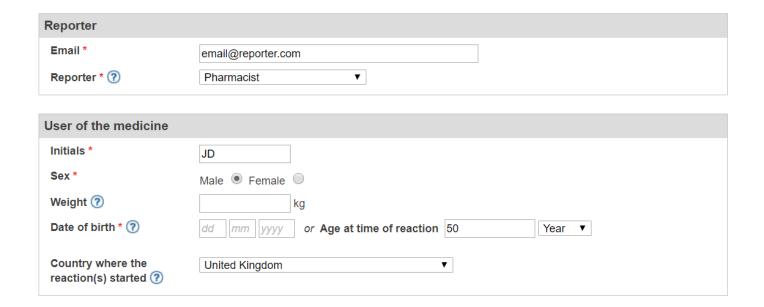
eReporting

eReporting: add-on to VigiFlow

eReporting is a standardized online ADR reporting form developed by the UMC to facilitate electronic reporting from patients and healthcare professionals

- *Reports go directly into VigiFlow without delay*
- *Information is automatically placed in the corresponding fields*
- *Minor manual data entry left for the PV centre*

Confirmation
email

Reporters eReporting **VigiFlow**
National ICSR
database

VigiBase
WHO global
ICSR database

eReporting fields (1/3)

Reporter

Email *	email@reporter.com
Reporter * ?	Pharmacist ▼

User of the medicine

Initials *	JD
Sex *	Male ⦿ Female ◯
Weight ?	___ kg
Date of birth * ?	dd mm yyyy *or* **Age at time of reaction** 50 Year ▼
Country where the reaction(s) started ?	United Kingdom ▼

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eReporting fields (2/3)

Describe what happened

* Describe what happened in your own words, any symptoms or side effects you suspect were caused by your medicine, and what happened since then.

Other specific details about each medicine and relevant dates can be entered below, but please include enough information here to connect to the Reactions/Symptoms section below.

Remaining: 19986

```
Case narrative
```

Reactions/Symptoms

Enter a short description (headache or diarrhoea for instance) for each reaction that you suffered and the relevant details. Click on the "Add another reaction/symptom" button for each new reaction you need to describe.

1 **Reaction/Symptom ***   Remaining: 183

```
Flu-like symptoms
```

⑦   **Start date ***   **End date**   **Duration**

dd 10 2018   dd mm yyyy   *or* [   ] [▼]

Outcome of reaction

○ Recovered/Resolved   ○ Reaction ended, but with after effects
○ Recovering/Resolving   ○ Fatal
○ Not recovered/Not resolved   ○ Unknown

⊕ Add another reaction/symptom

Did the reaction(s) lead to any of the following

Tick those that apply or leave blank

☐ Caused/prolonged hospitalization ⑦   ☐ Life threatening
☐ Disabling/Incapacitating   ☐ Results in death
☐ Congenital anomaly/birth defect   ☐ Other medically important condition

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eReporting fields (3/3)

Connection between eReporting and VigiFlow

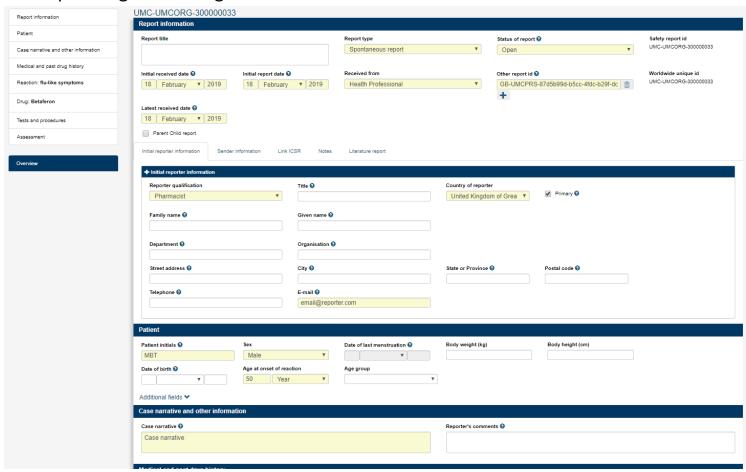When a new case is reported in eReporting, it automatically shows in the list of reports as seen below.

If the drug names are recognized by the WHODrug dictionary, they are automatically coded.

Page 1 of 2 « ‹ 1 2 › »   24 ICSRs match your search with 1 filter(s) applied

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UMC-UMCORG-2109	National Centre	UMC	17051978	Fever Sneezing		13112017	Open	

Reaction is blank
Drug name is auto-mapped

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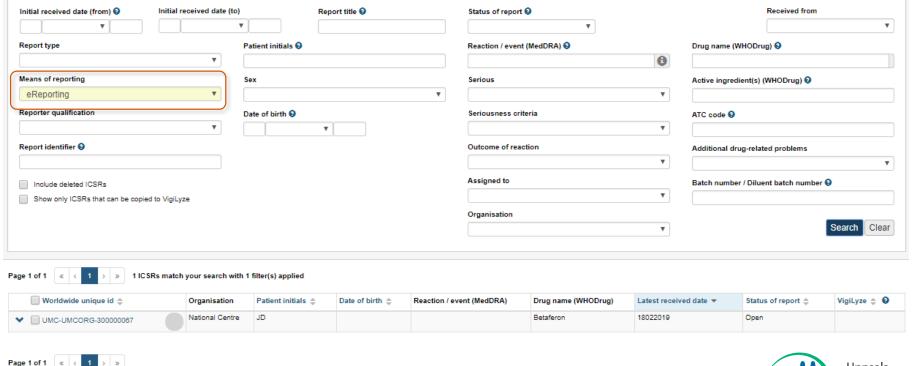– Building a global safety culture

Auto-mapping of information entered in eReporting

Reports received through eReporting require less manual data entry because information entered in the eReporting online form are automatically transferred to the corresponding field in VigiFlow.

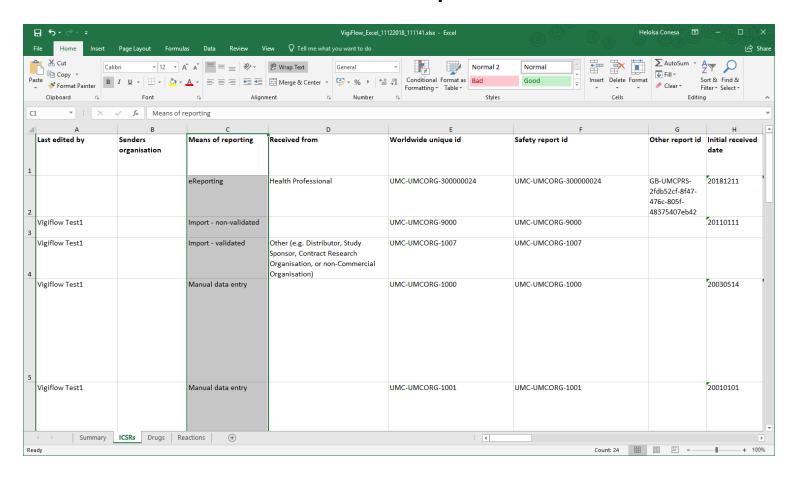# Identifying reports received via eReporting – Search filters

These reports are also identifiable through the **Means of reporting**, available as a **search filter** and a column in the Excel export.

Identifying reports received via eReporting – Excel export

These reports are also identifiable through the **Means of reporting**, available as a search filter and a **column in the Excel export**.

Questions:
vigibase@who-umc.org

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