Disclaimers

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

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

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

*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.
How to access VigiFlow

- Recommended web browser: Google Chrome

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

- Questions: vigibase@who-umc.org
Login page

someone@example.com

Keep me signed in

Sign in  Back

Can't access your account?

Please keep in mind that the availability of our services might be affected the third Wednesday of every month, between 19:00 and 22:00 Swedish time (GMT +1 hour), due to scheduled maintenance. For any questions please contact us at helpdesk@who-umc.org.
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.
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 currently located

The name of your country’s national pharmacovigilance centre

The name of the person logged into VigiFlow
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: 22.0.
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
### eReporting fields (1/3)

<table>
<thead>
<tr>
<th><strong>Reporter</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Email</strong> *</td>
<td><a href="mailto:email@reporter.com">email@reporter.com</a></td>
</tr>
<tr>
<td><strong>Reporter</strong> ?</td>
<td>Pharmacist</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>User of the medicine</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initials</strong> *</td>
<td>JD</td>
</tr>
<tr>
<td><strong>Sex</strong> *</td>
<td>Male [Select] Female [Select]</td>
</tr>
<tr>
<td><strong>Weight</strong> ?</td>
<td>[ ] kg</td>
</tr>
<tr>
<td><strong>Date of birth</strong> * ?</td>
<td>[ ] dd [ ] mm [ ] yyyy or [ ] Age at time of reaction [ ] 50 [ ] Year</td>
</tr>
<tr>
<td><strong>Country where the reaction(s) started</strong> ?</td>
<td>[ ] United Kingdom</td>
</tr>
</tbody>
</table>
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: 10000

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 *

Flu-like symptoms

Start date *

End date

Duration

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
- Life threatening
- Disabling/incapacitating
- Results in death
- Congenital anomaly/birth defect
- Other medically important condition
eReporting fields (3/3)

Medicines

Enter the name and details for each medicine you were taking before the reaction occurred. Click on "Add another medicine" for each new medicine you need to describe. Please also describe any herbal preparations, recreational drugs or other alternative medicines you were taking.

1. Name on medicine *  
   Medicine producer
   Betaferon
   Strength  
   Dosage
   Probably causing the reaction
   Route  
   alternate days
   Place where medicine was obtained
   Injection into skin
   Start date   
   End date
   Duration
   Reason for taking the medicine
   Multiple sclerosis
   What else did you do?  
   Action taken with medicine
   Has the medicine caused a similar reaction before? Yes  
   No  
   Unknown  

Additional information

Please give a short description of your medical history. This is important since some reactions only appear with a combination of previous or ongoing disease, special diets, recreational drugs, smoking habits, alcohol intake or allergies. You can also enter other comments you feel are important.

Current and previous illnesses

Additional comments
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.
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.
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**.

![Excel spreadsheet showing means of reporting](image-url)
Questions:
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