VigiFlow

Introduction and basic features
Disclaimers

This material is based on the latest version of VigiFlow, released in September 2019. 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

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
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](https://vigiflow.who-umc.org)

• Questions: vigibase@who-umc.org
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.
After logging into VigiFlow, you get directly into the Report List.

<table>
<thead>
<tr>
<th>Worldwide unique Id</th>
<th>Organisation</th>
<th>Patient initials</th>
<th>Date of birth</th>
<th>Reaction / event (MedDRA)</th>
<th>Drug name (WHODrug)</th>
<th>Latest received date</th>
<th>Status of report</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Beteferon</td>
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<td>Patient initials</td>
<td>Date of birth</td>
<td>Reaction / event (MedDRA)</td>
<td>Drug name (WHO/Drug)</td>
<td>Latest reserved date</td>
<td>Status of report</td>
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<td>Rash</td>
<td>Propylthiouracil</td>
<td>09-02-2019</td>
<td>Open</td>
</tr>
</tbody>
</table>
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

Confirmation email

Reporters -> eReporting -> VigiFlow

VigiFlow
National ICSR database

VigiBase
WHO global ICSR database
**eReporting fields (1/3)**

### Reporter

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

### User of the medicine

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initials *</td>
<td>JD</td>
</tr>
<tr>
<td>Sex *</td>
<td>Male</td>
</tr>
<tr>
<td>Weight *</td>
<td>kg</td>
</tr>
<tr>
<td>Date of birth *</td>
<td>dd mm yyyy</td>
</tr>
<tr>
<td>Age at time of reaction *</td>
<td>50 Year</td>
</tr>
<tr>
<td>Country where the reaction(s) started *</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.

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
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. Please also describe any herbal preparations, recreational drugs or other alternative medicines you were taking.

1. **Name on medicine**: Betaferon
   - Medicine producer
   - **Probably causing the reaction**

2. **Strength**
   - Dosage: alternate days

3. **Route**
   - Place where medicine was obtained

4. **Start date**: 10/01/2018
   - **End date**
   - **Duration**

5. **Reason for taking the medicine**: Multiple sclerosis

6. **What else did you do?**

7. **Has the medicine caused a similar reaction before?**: Yes

8. **Action taken with medicine**

9. **Add another medicine**

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.
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

– Building a global safety culture