Decentralisation in VigiFlow
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.
VigiFlow – the national database

- An internet based ICSR management system
- Supports the workflow with collection, processing and sharing of reports with stakeholders
- Data is structured to facilitate analysis
Definitions

Centralised system: only the national pharmacovigilance (PV) centre has access to VigiFlow

Decentralised system: the national PV centre grants access to VigiFlow to other organisations in the country
Autonomy to the national PV centre

Other pharmacovigilance centres in the country can also have access to VigiFlow

In VigiFlow, the national PV centre is responsible for:

• Granting access to VigiFlow to other PV centres in the country
• Managing user accounts
Getting data into VigiFlow

"Outside VigiFlow"

- MAHs with E2B systems
- Online reporting for small pharma. companies (not yet available)
- Paper forms
- Online reporting

"Inside VigiFlow"

- Hospital 1
- Immunization programme
- Pharmacy department, University A
- Regional centre 1
- Data entry staff
- Mobile apps (not provided by UMC)
Decentralise data entry / case assessment to other organisations

- Data entry / case assessment can be done by other organisations
  - *Decrease workload at the national PV centre*

- Hierarchial structure: the national PV centre will always have full oversight of all reports in the database
  - *Only the national PV centre can send reports to the WHO global database of ICSRs*

- Flexibility to restrict access to information according to the hierarchial level

- Reports are always editable

- All organisations can upload ICSRs as E2B XML files
Setting up a decentralised system
VigiFlow allows to setup a hierarchical structure of up to three levels to decentralise data entry.
Default setting for viewing / editing ICSRs

By default, each centre will only view / edit the ICSRs created by itself and all centres below it.
By default, each centre will only view / edit the ICSRs created by itself and all centres below it, which implies that:

**Level 1 (National PV centre=NC)**

National PV centre views and edits ICSRs created by all centres (NC + A + AA + AB + AC + B + BD + C + CE + CF)

**Level 2**

- Centre A views and edits ICSRs created by centres A + AA + AB + AC
- Centre B views and edits ICSRs created by centres B + BD
- Centre C views and edits ICSRs created by centres C + CE + CF

**Level 3**

Each Level 3 centre will only view and edit ICSRs created by its own centre
Examples of decentralised systems
Example 1

Hospitals collect reports and send them directly to the national PV centre
Example 2

Hospitals and regional PV centres collect reports and send them directly to the national centre
Hospitals report to the state PV centres, who do an initial assessment of the reports and are responsible for sending them to the national PV centre.
Example 4

- Hospitals report to the state PV centres, who do an initial assessment of the reports and are responsible for sending them to the national PV centre.
- The clinics enrolled in the TB Programme are responsible for reporting to a centralised group that collects reports from all the clinics and is responsible for sending them to the national PV centre.
- The vaccine programme also has a centralised group that is responsible for sending the AEFI reports to the national centre.
- Finally, there is also a poison centre that sends the drug-related reports to the national PV centre.
Features for workflow support in VigiFlow
VigiFlow features

There are 5 main features which can be used to support the workflow for collection and assessment of ICSRs within an organisation and even between organisations. The features are:

1. **Delegate ICSRs** to other organisations and “Delegated to” filter
2. **Created by** filter
3. **Assign ICSRs** to an user from your organisation and “assigned to” filter
4. Change **status of report** and corresponding filter
5. Add **comments** to an ICSR an view it in Report list
VigiFlow feature: “Delegated to” option

• If you need to assign a report outside of own organisation, then the report can be “delegated to” another organisation

• This can also indicate to the other organisation that the report is ready for review

• Reports are delegated upwards and downwards, but not across to other organisations
Delegate ICSR to another organisation

VigiFlow allows to create a hierarchical structure of up to 3 levels to decentralise pharmacovigilance activities, being the national PV centre the only organisation on the highest hierarchical level.
How to delegate ICSRs from the Data Entry page

Organisations on levels 2 and 3 of the hierarchy can delegate ICSRs to other organisations above or below their hierarchy.

On the example below, the ICSR created by Regional Centre A (level 2) can be delegated to the national centre (level 1) or to one of the hospitals below Regional Centre A in the hierarchy, but not to other organisations (see hierarchy on the previous slide).
How to delegate ICSRs from the Report List

- Select the report(s) you want to delegate by ticking the check box for each report
- Click the button “XX ICSRs selected” and
- Choose which organisation to delegate to
How to filter on “delegated reports”

With the **Delegated to** filter it is possible to select the name of an organisation to identify which ICSRs are currently delegated to it.
View ICSRs created by an organisation

The filter Created by allows to search for the ICSRs created by the organisation selected on the list, even if the ICSRs are delegated to another organisation.

When selecting the national centre or a level-2 organisation, it is also possible to view the ICSRs created by the organisations on the lower levels of the hierarchy by selecting the Include sub organisations checkbox.
Assigned ICSRs to users

You can assign ICSRs to yourself or to other users within your own organisation.

Click on the grey circle close to the worldwide unique ID to open the menu shown on the left side.

Reports cannot be assigned outside of your own organisation.
Status of report

The status of report can be used to differentiate the steps in the workflow for collection and assessment of the ICSR. There are 3 possible status for an ICSR:

- Open
- Under Assessment
- Closed

The status of report is changed from the Data Entry page.
### Status of report in Report list

<table>
<thead>
<tr>
<th>Worldwide unique id</th>
<th>Delegated to 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>
<th>VigiLyze</th>
</tr>
</thead>
<tbody>
<tr>
<td>UMC-UMCORG-113</td>
<td>Regional Centre</td>
<td>Z</td>
<td></td>
<td>Felt like a zombie</td>
<td>Zomel</td>
<td>03052019</td>
<td>Closed</td>
<td></td>
</tr>
<tr>
<td>UMC-UMCORG-116</td>
<td>National Centre</td>
<td>BASYAS</td>
<td></td>
<td>Skin rash</td>
<td>Aximcyne</td>
<td>14062019</td>
<td>Open</td>
<td>✓</td>
</tr>
<tr>
<td>UMC-UMCORG-115</td>
<td>National Centre</td>
<td>TL</td>
<td></td>
<td>Device rejection</td>
<td></td>
<td>14062019</td>
<td>Open</td>
<td>✓</td>
</tr>
<tr>
<td>SE-BAYER-2018-12345</td>
<td>National Centre</td>
<td>JW</td>
<td></td>
<td>Palpitation</td>
<td></td>
<td>10062019</td>
<td>Under assessment</td>
<td></td>
</tr>
</tbody>
</table>
Add a Comment to an ICSR

Click on the balloon icon to write short messages which pertain to the report, for example to communicate with other users or to document the steps of the report assessment process/workflow.

The comments are internal, which means that they will not be available when the ICSR is exported in PDF, Excel or xml.

<table>
<thead>
<tr>
<th>Worldwide unique id</th>
<th>Delegated to 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>
<th>VigiLyze</th>
</tr>
</thead>
<tbody>
<tr>
<td>UMC-UMCORG-117</td>
<td>National Centre</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Under assessment</td>
<td></td>
</tr>
<tr>
<td>UMC-UMCORG-116</td>
<td>National Centre</td>
<td>BASYAS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Open</td>
<td>✓</td>
</tr>
<tr>
<td>UMC-UMCORG-115</td>
<td>National Centre</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Open</td>
<td>✓</td>
</tr>
</tbody>
</table>

Comments for UMC-UMCORG-117

Report ready for review - DA - 12/07/2019
## Summary of features for workflow support in VigiFlow

<table>
<thead>
<tr>
<th>Worldwide unique id</th>
<th>Delegated to 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>
<th>VigiLyze</th>
</tr>
</thead>
<tbody>
<tr>
<td>UMC-UMCORG-113</td>
<td>Regional Centre</td>
<td>Z</td>
<td></td>
<td>Felt like a zombie</td>
<td>Zomel</td>
<td>03052019</td>
<td>Closed</td>
<td></td>
</tr>
<tr>
<td>UMC-UMCORG-116</td>
<td>National Centre</td>
<td>BASYAS</td>
<td></td>
<td>Skin rash</td>
<td>Atrimycin</td>
<td>14062019</td>
<td>Open</td>
<td>✓</td>
</tr>
<tr>
<td>UMC-UMCORG-115</td>
<td>National Centre</td>
<td>TL</td>
<td></td>
<td>Device rejection</td>
<td></td>
<td>14062019</td>
<td>Open</td>
<td>✓</td>
</tr>
<tr>
<td>SE-BAYER-2018-12345</td>
<td>National Centre</td>
<td>JW</td>
<td></td>
<td>Palpitation</td>
<td></td>
<td>10062019</td>
<td>Under assessment</td>
<td></td>
</tr>
</tbody>
</table>

- **Comments box**
- **Assigned to**
- **Delegated to**
- **Status of report**