Decentralisation in VigiFlow
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.

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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.

- **Level 1**: National PV Centre
- **Level 2**: Affiliated centre A, Affiliated centre B, Affiliated centre C
- **Level 3**: Affiliated centre AA, Affiliated centre AB, Affiliated centre AC, Affiliated centre CE, Affiliated centre CF
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.
Example 3

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 to support workflow in VigiFlow
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
How to “delegate”

- 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”

- The national PV centre can find ICSRs delegated to them from a specific sub-organisation by using the filters “Delegated to organisation” and “Created by organisation”
“Status of report” in Report information

The status of report:
- is found in **Data entry page** in Report information
- can be set for each report from a drop down menu
- 3 options are available: - Open
  - Under Assessment
  - Closed
```
<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>
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<tbody>
<tr>
<td>UMC-UMCORG-113</td>
<td>Regional Centre</td>
<td>Z</td>
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<td>Felt like a zombie</td>
<td>Zomel</td>
<td>03052019</td>
<td>Closed</td>
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<td>Aximycin</td>
<td>14062019</td>
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<td></td>
<td>Device rejection</td>
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<tr>
<td>SE-BAYER-2018-12345</td>
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<td></td>
<td></td>
<td>Palpitation</td>
<td></td>
<td>10062019</td>
<td>Under assessment</td>
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VigiFlow feature: “Comments” option

To write short messages which pertain to the report
Can be used for communication with other users and for documentation of the report assessment process/workflow

Comments for UMC-UMCORG-117

Report ready for review - DA - 12/07/2019
### “Comments” option in Report list

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- **Comments** option in the report list allows for the addition of comments to recorded events.
VigiFlow feature: “Assigned to” option

- Everyone within an organisation can use the “assigned to” option
- You can assign reports to yourself
- You can assign reports to other users within own organisation
- Reports cannot be assigned outside of own organisation
There are 5 main features which can be used to support your PV workflow

1. “created by” filter
2. “delegated to” filter
3. “assigned to” filter and option in Report list
4. “status of report” filter and option in Report list
5. “comments box” field in Report list
### Display of VigiFlow features in Report list

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- **Comments box**
- **Assigned to**
- **Delegated to**
- **Status of report**
Questions:
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– Building a global safety culture

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