Decentralisation / Regional Centres: Key differences in old versus new VigiFlow
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.

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Decentralisation functionality in new VigiFlow

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

• For a description of available options and how to get started with using this functionality, please see the training materials “Decentralisation in VigiFlow” and “Management of user accounts in VigiFlow”.

• This slide deck describes the key differences in how the functionality of decentralisation (e.g. VigiFlow access to regional PV centres) is implemented in the new version of VigiFlow.
Key differences

All ICSRs immediately accessible to national PV centre (NC)

In new VigiFlow, all ICSRs entered by sub-organisations are visible and editable to the NC immediately. This gives better overview of reported issues, even when the report is still in draft version.

The NC should set up routines with sub-organisations on how to collaborate in the system.

The "Delegated to" functionality can be used for flagging when the ICSR is ready for any action by the NC.
Sub-organisations can always edit their own ICSRs

In new VigiFlow, sub-organisations are able to view and edit any ICSR they have entered, even after delegating the report to the NC or the report has been closed.

This simplifies follow-up handling compared to old VigiFlow. Sub-organisations can find and edit a closed ICSR directly, without having to contact the NC to send the report to them.

The NC should set up routines with sub-organisations on how to collaborate in the system. The "Delegated to" functionality can be used for flagging when the ICSR is ready for any action by the NC.

Sub-organisations can import E2B XML files

In new VigiFlow, sub-organisations are able to upload E2B XML files, which was not possible in the old VigiFlow.
Two levels of sub-organisations

New VigiFlow allows one or two levels of sub-organisations. In old VigiFlow only one level was possible.

Please see further information in the training material “Decentralisation in VigiFlow” and “Management of user accounts in VigiFlow”
Two access levels available

In new VigiFlow two access levels are available. Each sub-organisation will have full access or restricted access:

- **Full access** means the sub-organisation can view and edit all reports in the database.
- **Restricted access** means that the sub-organisation can only view and edit their own reports (i.e. reports created or imported by them).

This allows for flexibility and different types of sub-organisations to be connected.

Please see further information in the training materials “Decentralisation in VigiFlow” and “Management of user accounts in VigiFlow”
Manage your own sub-organisation set-up

In new VigiFlow, the NC will manage sub-organisation set-up and decide on the structure directly in the system. This will give better control and overview of the centres, as well as quick access to an updated list of users accessing VigiFlow.
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