

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.

The screenshot displays the VigiFlow interface for managing ICSRs. At the top, there are buttons for '+ New ICSR', 'Import ICSRs', and 'VigiLyze'. On the right, there are 'Filter' and 'Export' buttons. The main area is a form with various fields for data entry, including dates, report titles, patient information, and drug details. A 'Delegated to organisation' dropdown menu is highlighted, showing 'Centre National de Pharmacovigilance' and 'Centre Régional de PV 2'. A callout box explains that the NC can find ICSRs delegated to them from a specific sub-organisation by using the filters "Delegated to organisation" + "Created by organisation".

Initial received date (from) [] Initial received date (to) [] Report title []

Status of report [Open]

Report type [] Patient initials []

Reaction / event (MedDRA) []

Means of reporting [] Sex []

Serious []

Reporter qualification [] Date of birth []

Seriousness criteria []

Report identifier []

Outcome of reaction []

Assigned to []

Received from []

Drug name (WHODrug) []

Active ingredient(s) (WHODrug) []

ATC code []

Additional drug-related problems []

Batch number / Diluent batch number []

Delegated to organisation [Centre National de Pharmacovigilance]

Created by organisation [Centre Régional de PV 2]

2 ICSRs selected 30 ICSRs match your search with 1 filter(s) applied

Delegate to organisation

- UMC-TRAINING10-30
- UMC-TRAINING10-29
- UMC-TRAINING10-28
- UMC-TRAINING10-27

Patient initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report	VigiLyze
				04062019	Open	
				04062019	Open	
		Persistent dry cough	Amlodipine:Lisinopril, Amoxicilline/Acide Clavulanique	13052019	Open	
AB	042013			25042019	Open	

Key differences cont.

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

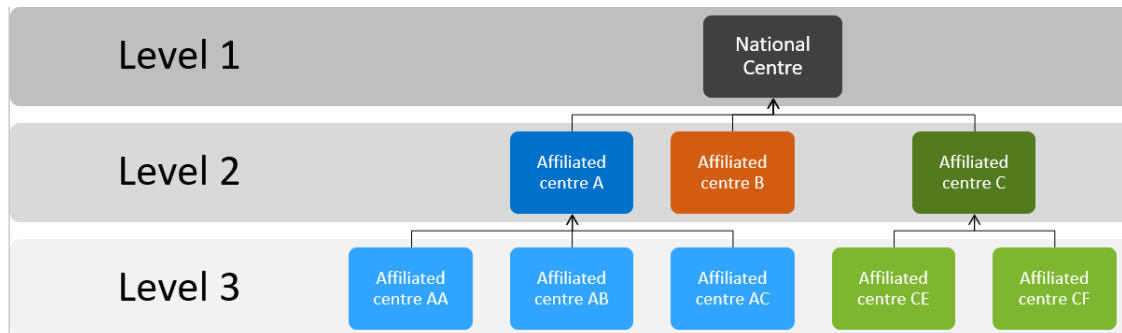
In new VigiFlow, sub-organisations are able to upload E2B XML files, which was not possible in the old VigiFlow.

Key differences cont.

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”*



Key differences cont.

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*”

Key differences cont.

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.

Manage accounts and organisations VigiFlow - National Centre Therese Lundin ▾

[← To Report list](#) [VigiLyze](#)

Organisations







- National Centre
 - Regional centre A
 - Hospital A1
 - Hospital A2
 - Hospital A3
 - National TB Programme
 - TB clinic 1
 - TB clinic 2
 - Vaccine Programme
 - Poison centre

National Centre

Name

View / Edit

Users

Name	Email	Administrator 	
<input type="text" value="A3 test"/>	a3@test.com	<input type="checkbox"/>	 Delete
<input type="text" value="A6 Test"/>	emil.wall@consid.se	<input type="checkbox"/>	 Delete
<input type="text" value="Anna Anderson"/>	anna.anderson@test.org	<input type="checkbox"/>	 Delete
<input type="text" value="Anna Baumgarten"/>	anna.baumgarten@who-umc.org	<input type="checkbox"/>	 Delete
<input type="text" value="Another test user"/>	hasnoemail@test.se	<input type="checkbox"/>	 Delete

Questions:
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– Building a global safety culture

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