

Decentralisation in VigiFlow



– Building a global safety culture

Disclaimers

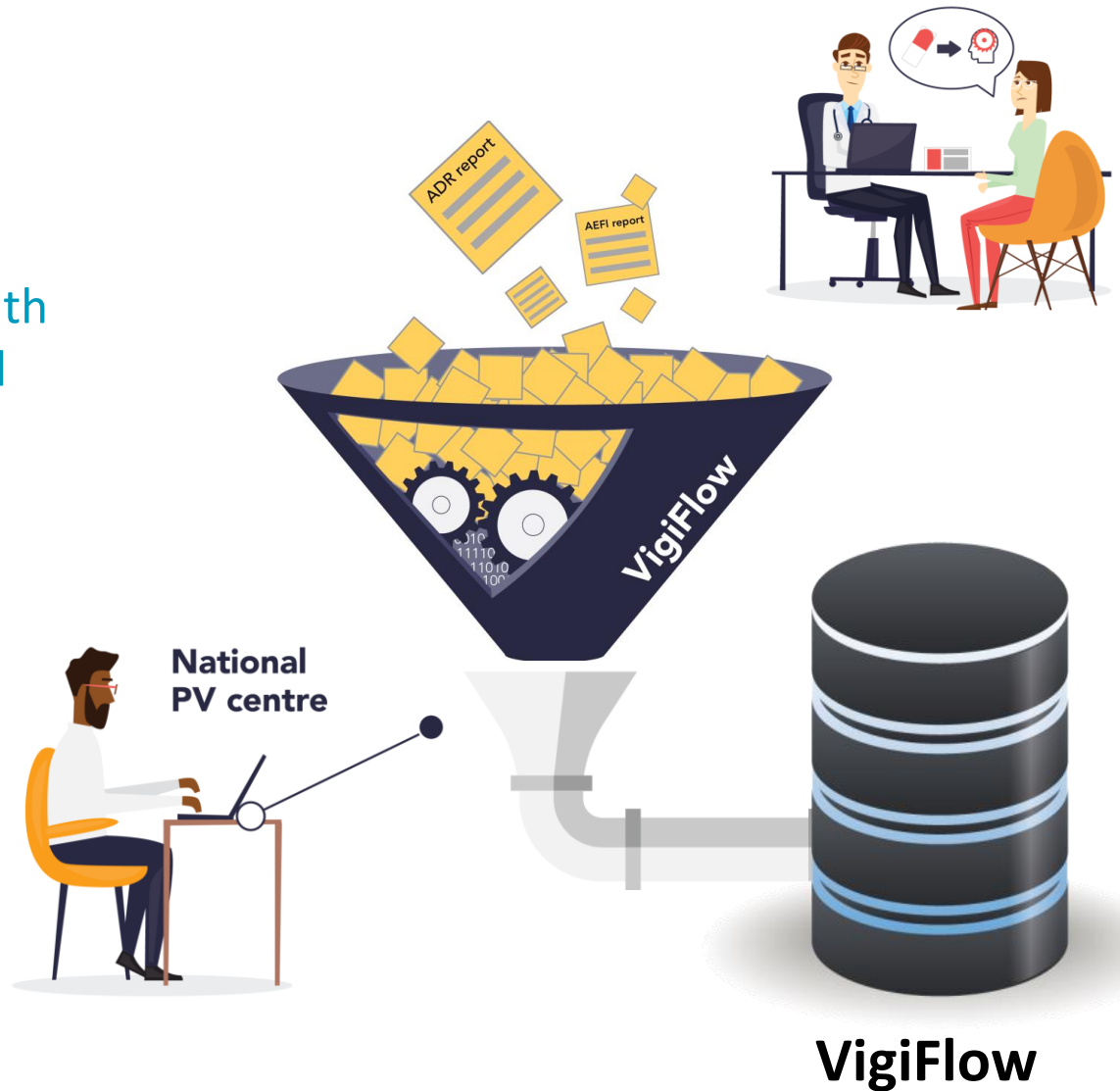
This material is based on the latest version of VigiFlow, released in May 2020. Some features are still under development, therefore the system appearance might differ from the slides included in this package.

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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

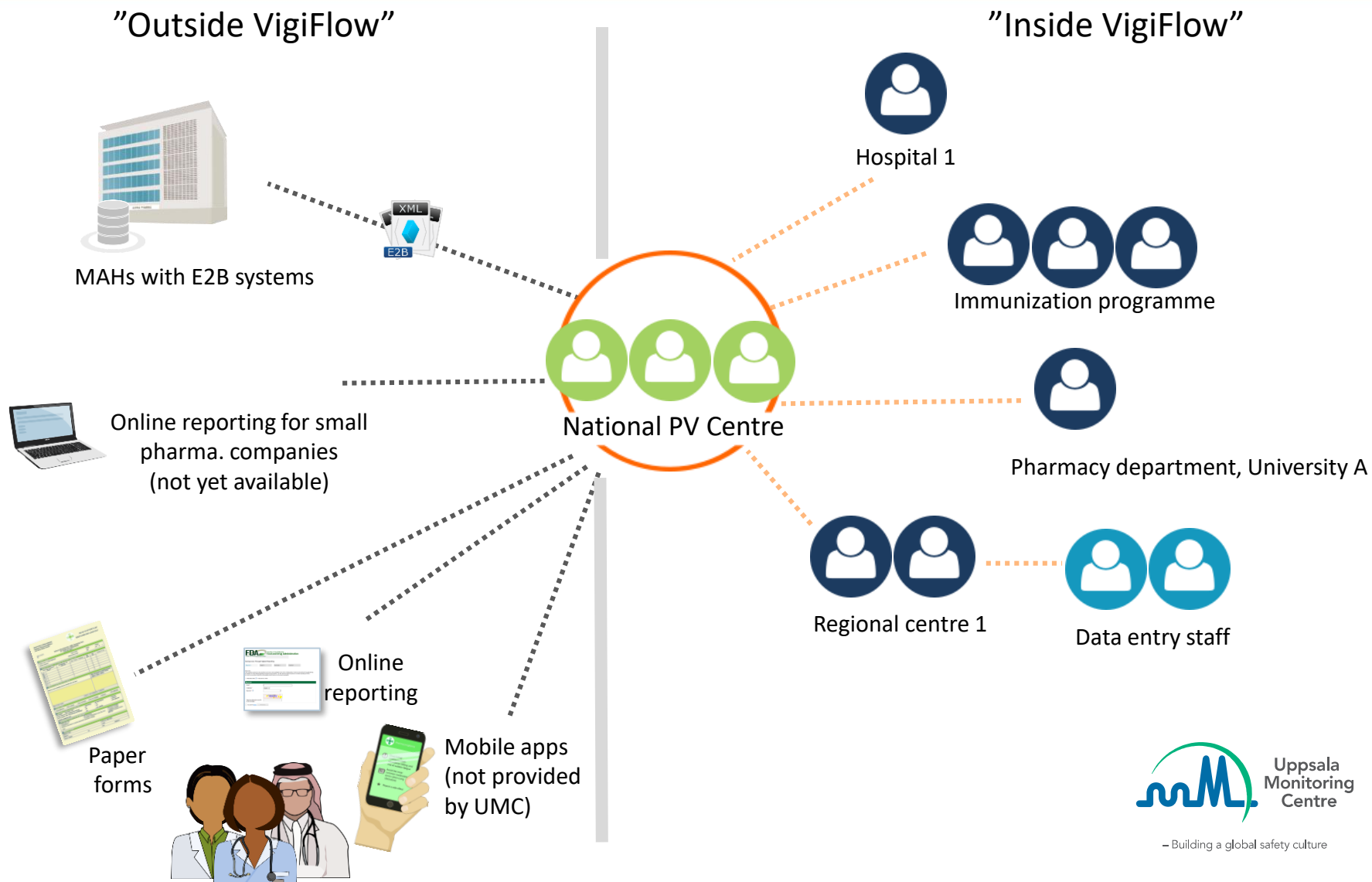
Autonomy to the national PV centre

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



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*
- Hierarchical 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 hierarchical 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

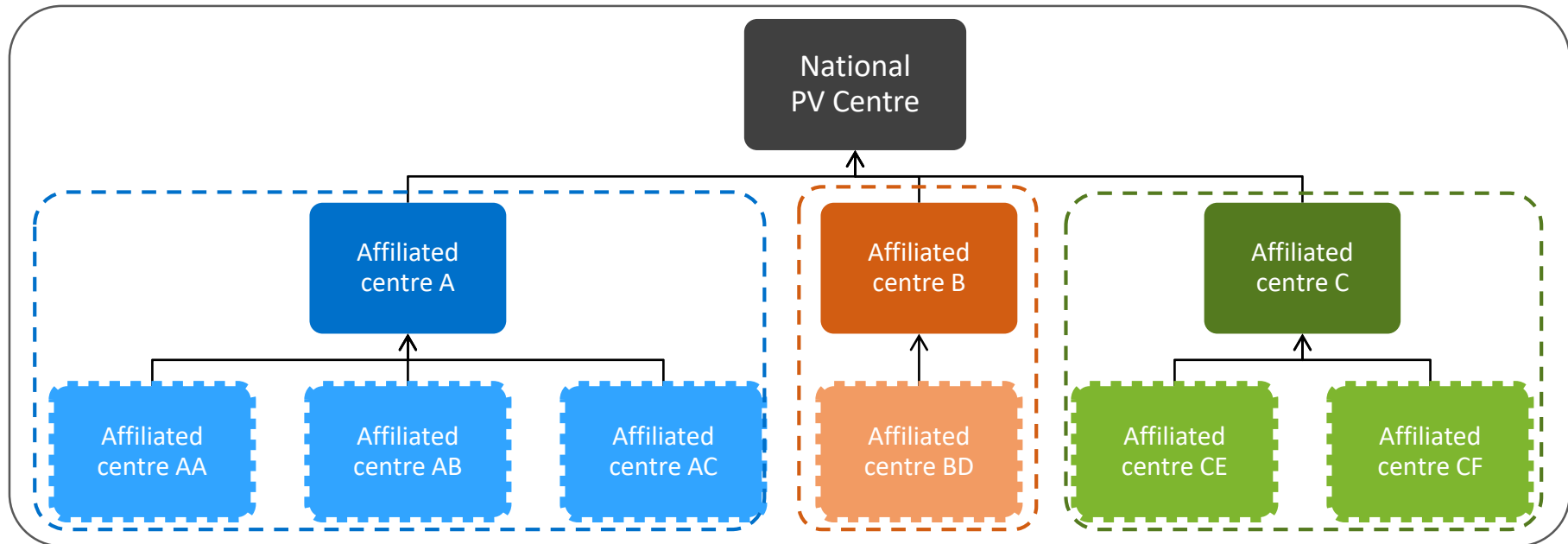
Affiliated
centre AC

Affiliated
centre CE

Affiliated
centre CF

Default setting for viewing / editing ICSRs

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



Default setting for viewing / editing ICSRs

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

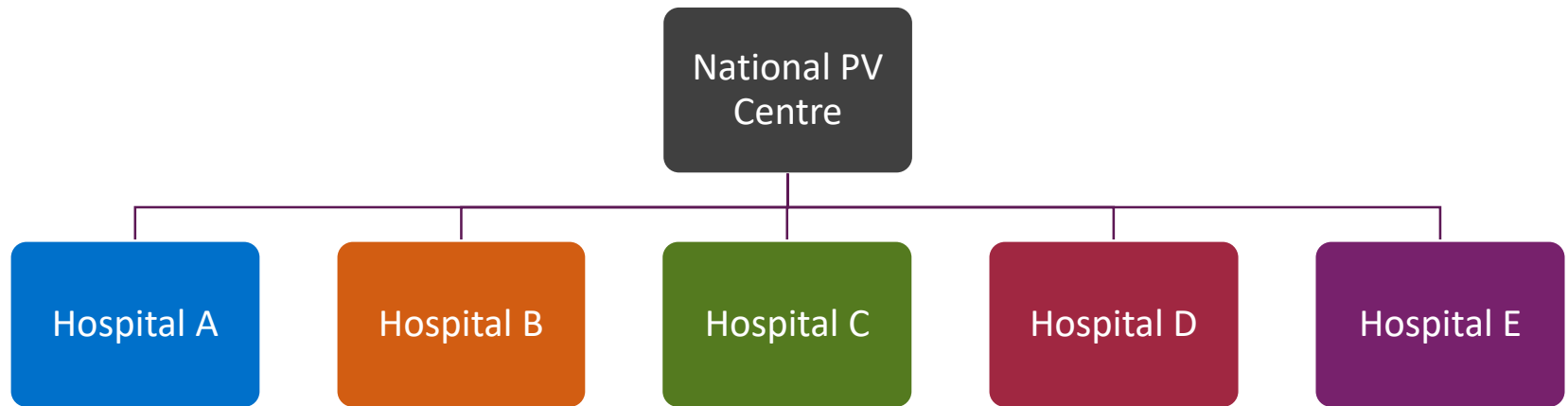
Level 3

Each Level 3 centre will only view and edit ICSRs created by its own centre

Examples of decentralised systems

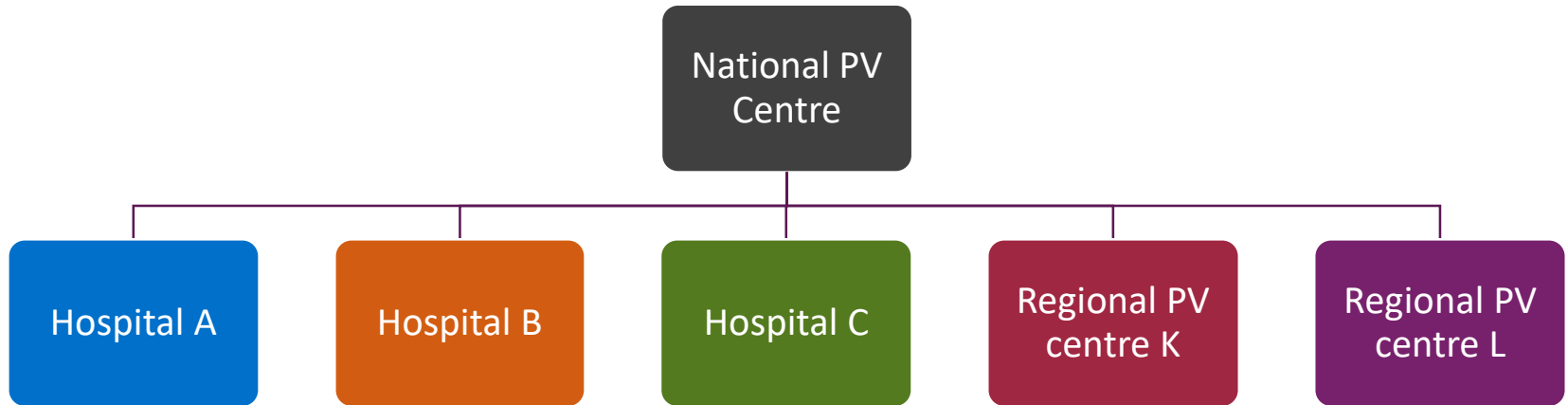
Example 1

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



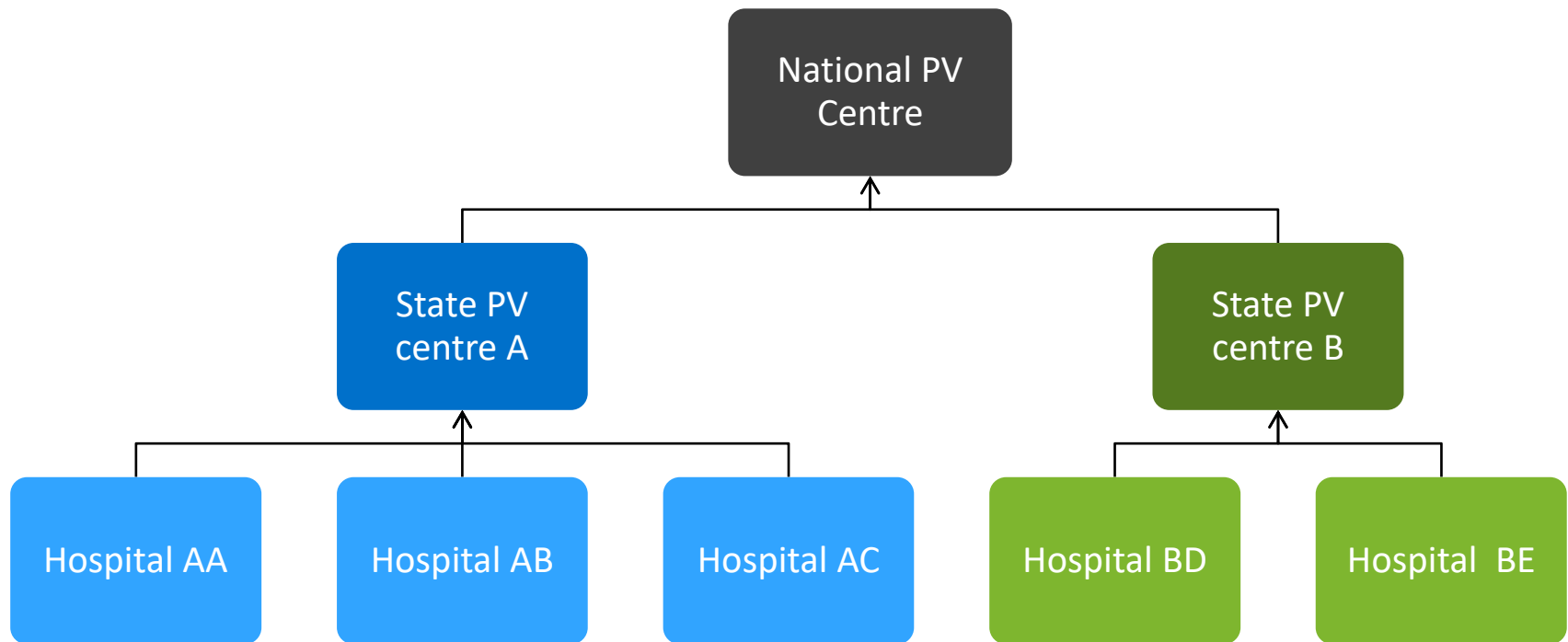
Example 2

Hospitals and regional PV centres collect reports and send them directly to the national centre



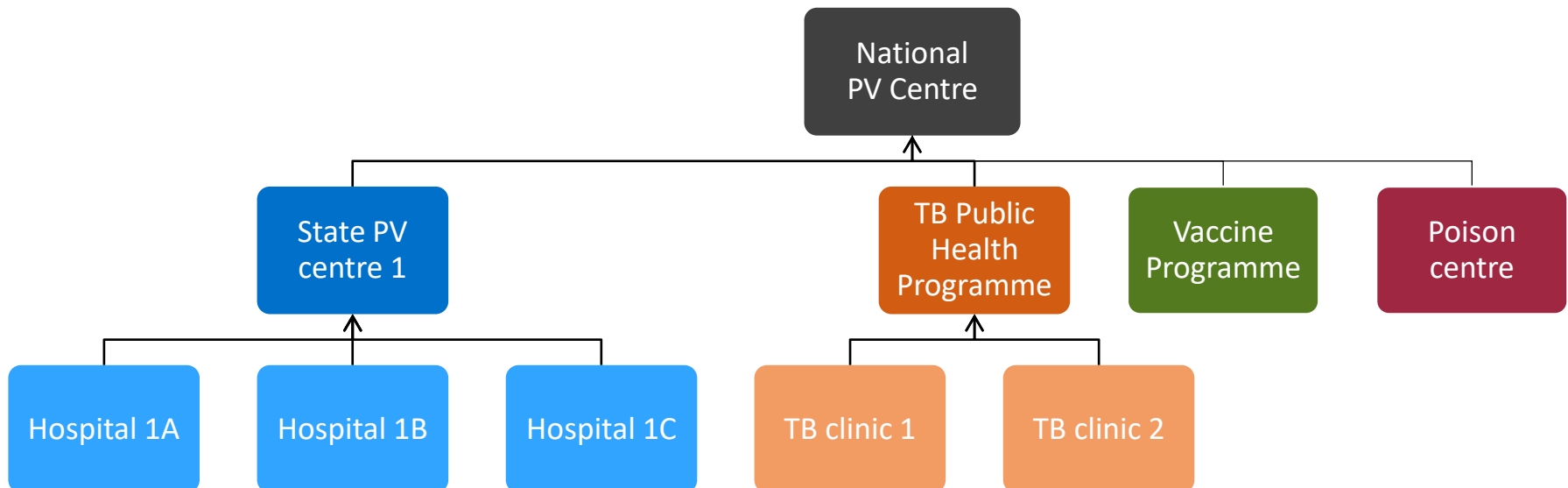
Example 3

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 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 and view it in Report list

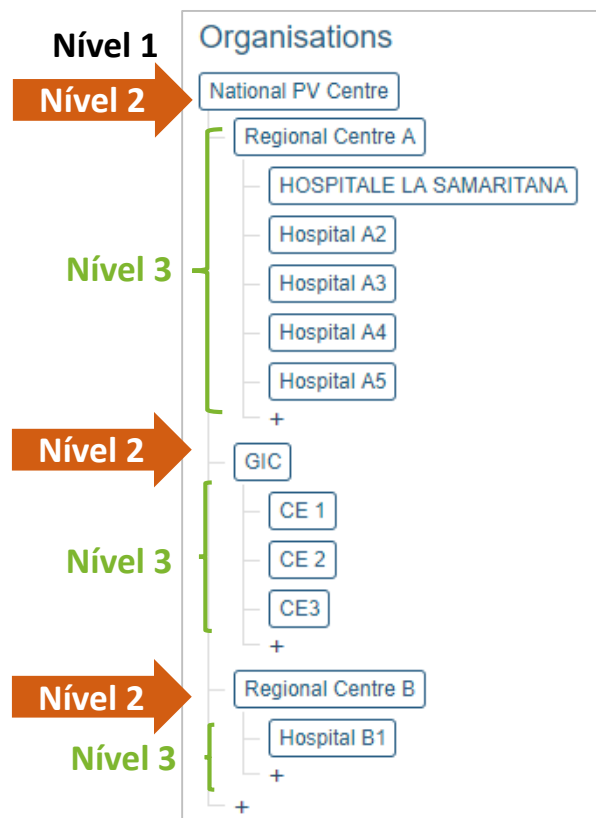


VigiFlow feature: “Delegated to” option

- 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 (level2) 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).

The screenshot displays the Uppsala Monitoring Centre's ICSR Data Entry interface. At the top, there are navigation buttons: '< To Report list', '+ New ICSR', and 'VigiLyze'. A 'Delegate to organisation' dropdown menu is open, showing a list of options: 'Regional Centre A ✓', 'National PV Centre', 'Hospital A2', 'Hospital A3', 'Hospital A4', 'Hospital A5', and 'HOSPITALE LA SAMARITANA'. The main form area shows the report ID 'UMC-UMCORG-300020901' and 'Created by organisation: Regional Centre A'. The form includes fields for 'Report title', 'Report type' (set to 'Spontaneous report'), 'Initial received date' (29 July 2020), 'Initial report date', and 'Received from' (Health Professional). A sidebar on the left contains 'Report information' tabs for Patient, Case narrative and other information, Medical and past drug history, and Reaction: Rash.

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

The screenshot shows the 'Report list' interface in the Vigiflow system. At the top, there are buttons for '+ New ICSR', 'Import', 'Export', and 'VigiLyze'. Below these, a dropdown menu indicates '3 ICSRs selected' and '15 ICSRs match your search with 1 filter(s) applied'. The dropdown menu is open, showing a list of organisations to delegate to, including 'Regional Centre A', 'National PV Centre', 'Hospital A2', 'Hospital A3', 'Hospital A4', 'Hospital A5', and 'HOSPITALE LA SAMARITANA'. The background shows a table of ICSR reports with columns for 'Initials', 'Date of birth', and 'Reaction / event (MedDRA)'. The table contains several rows of data, including one for 'Cardiac arrest' and another for 'Rash, Itch'.

Initials	Date of birth	Reaction / event (MedDRA)
		Cardiac arrest
		Rash, Itch
		Cardiac arrest
	26081974	Visual field checking procedures

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.

+ New ICSR Import ICSRs Vigilyze Filter Export

Report identifier

Outcome of reaction

Assigned to

Delegated to organisation

Created by organisation

Additional drug-related problems

Batch number / Diluent batch number

Search Clear

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilyze
 Show only ICSRs with at least one drug or reaction that is not coded

3 ICSRs selected 114 ICSRs match your search with 1 filter(s) applied Page 1 of 6

Delegate to organisation	Report identifier	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilyze
<input checked="" type="checkbox"/> UMC-UMCORG-135		National Centre Regional Centre University Hospital	kkkss		Elderly	Elderm	03092019	03092019	Open	
<input checked="" type="checkbox"/> UMC-UMCORG-134		National Centre	kkkss		Elderly	Elderm	03092019	03092019	Open	
<input checked="" type="checkbox"/> UMC-UMCORG-133		National Centre	GGYYGY		Frustration tolerance decreased	Frusin	03092019	03092019	Open	
<input type="checkbox"/> UMC-UMCORG-132		National Centre	GGYYGY	01022016	Frustration tolerance decreased	Frusin	03092019	03092019	Open	
<input type="checkbox"/> UMC-UMCORG-131		National Centre	JO		SPEP	Spel	03092019	03092019	Open	

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.

Include deleted ICSRs
 Show only ICSRs that can be copied to Vigilize
 Show only ICSRs with at least one drug or reaction that is not coded

Created by organisation
Regional Centre A
 Include sub organisations

Search Clear

0 ICSRs selected 6 ICSRs match your search with 1 filter(s) applied Page 1 of 1

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	Vigilize
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	TJ		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020901	Regional Centre A			Rash, Itch	Tylenol, Beta-alanine	29072020	29072020	Open	✓
<input type="checkbox"/> authoritynumb	National PV Centre	Patient (name or initials)	29081974	Visual field checking procedures	Alvedon	19032019	08012020	Open	
<input type="checkbox"/> UMC-UMCORG-300000552	National PV Centre			Chills	Dil	19112019	19112019	Under assessment	
<input type="checkbox"/> UMC-UMCORG-300000074	National PV Centre	Demo patient		Caffeine consumption	Caffeine max	19032019	19032019	Under assessment	
<input type="checkbox"/> UMC-WHOUMC-2016-44385	National PV Centre	Gandalf	14023019	Dermatophytosis of scalp and beard	Happy wanderer	19032019	19032019	Open	

Assigned ICSRs to users

0 ICSRs selected

98 ICSRs match your search with 1 filter(s) applied

Page 1 of 5

« < 1 2 3 4 5 > »

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Patient initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> UMC-UMCORG-116	National Centre	BASYAS		Skin rash	Aximycine	14062019	Open	✓
<input type="checkbox"/> UMC-UMCORG-115	National Centre			Device rejection		14062019	Open	✓
	National Centre			Palpitation		10062019	Open	

Assigned to:
Jennifer Wall

Unassign

Assign to me

UMC Developer
Per Nyberg

Helólsa Ricci Conesa

Carina Akerhei

Helena Wilmar

Hui Ling Lua

Jason Johansson

Martin Levin

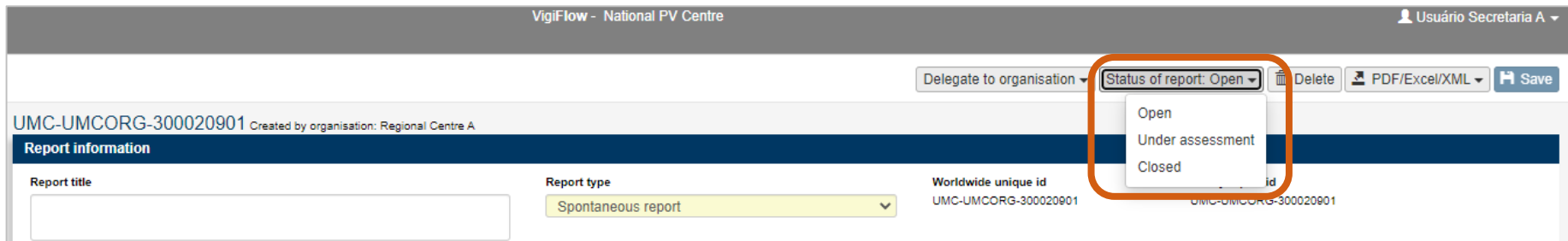
- You can assign ICSRs to yourself or to other users within your own organisation
- Click on the grey circle close to the worldwide unique ID to open the menu shown on the left side
- Reports cannot be assigned outside of own organisation

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



The screenshot displays the VigiFlow - National PV Centre interface. At the top, the user is logged in as 'Usuário Secretaria A'. The main content area shows a report entry form for 'UMC-UMCORG-300020901'. The 'Report type' is set to 'Spontaneous report'. A dropdown menu for 'Status of report' is open, showing three options: 'Open', 'Under assessment', and 'Closed'. The 'Open' option is currently selected. The interface also includes buttons for 'Delegate to organisation', 'Delete', 'PDF/Excel/XML', and 'Save'.

“Status of report” in Report list

0 ICSRs selected ▾ 111 ICSRs match your search with 0 filter(s) applied Page 1 of 6 « < 1 2 3 4 5 ... > »

<input type="checkbox"/> Worldwide unique id ▾	Delegated to organisation	Patient initials ▾	Date of birth ▾	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report ▾	VigiLyze ? ▾
▼ <input type="checkbox"/> UMC-UMCORG-113 	Regional Centre	Z		Felt like a zombie	Zomel	03052019	Closed	
▼ <input type="checkbox"/> UMC-UMCORG-116 	National Centre	BASYAS		Skin rash	Aximycine	14062019	Open	✓
▼ <input type="checkbox"/> UMC-UMCORG-115 	National Centre			Device rejection		14062019	Open	✓
▼ <input type="checkbox"/> SE-BAYER-2018-12345 	National Centre			Palpitation		10062019	Under assessment	

Status of report

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.

0 ICSRs selected | 111 ICSRs match your search with 0 filter(s) applied | Page 1 of 6

<input type="checkbox"/> Worldwide unique id	Delegated to organisation	Patient initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report	VigiLyze
<input type="checkbox"/> UMC-UMCORG-117	National Centre						Under assessment	
<input type="checkbox"/> UMC-UMCORG-116	National Centre	BASYAS		SK			Open	✓
<input type="checkbox"/> UMC-UMCORG-115	National Centre			Del			Open	✓

Comments for UMC-UMCORG-117





Report ready for review - DA - 12/07/2019

Add comment

Close

Summary of features for workflow support in VigiFlow

0 ICSRs selected ▾ 111 ICSRs match your search with 0 filter(s) applied Page 1 of 6

<input type="checkbox"/> Worldwide unique id ▾	Delegated to organisation	Patient initials ▾	Date of birth ▾	Reaction / event (MedDRA)	Drug name (WHODrug)	Latest received date	Status of report ▾	VigiLyze ? ▾
<input type="checkbox"/> UMC-UMCORG-113 	Regional Centre	Z		Felt like a zombie	Zomel	03052019	Closed	
<input type="checkbox"/> UMC-UMCORG-116 	National Centre	BASYAS		Skin rash	Aximycine	14062019	Open	✓
<input type="checkbox"/> UMC-UMCORG-115 	National Centre			Device rejection		14062019	Open	✓
<input type="checkbox"/> SE-BAYER-2018-12345 	National Centre			Palpitation		10062019	Under assessment	

Comments box

Assigned to

Delegated to

Status of report



Questions:
vigibase@who-umc.org



– Building a global safety culture

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