

# Import ICSRs: Key differences in old versus new VigiFlow

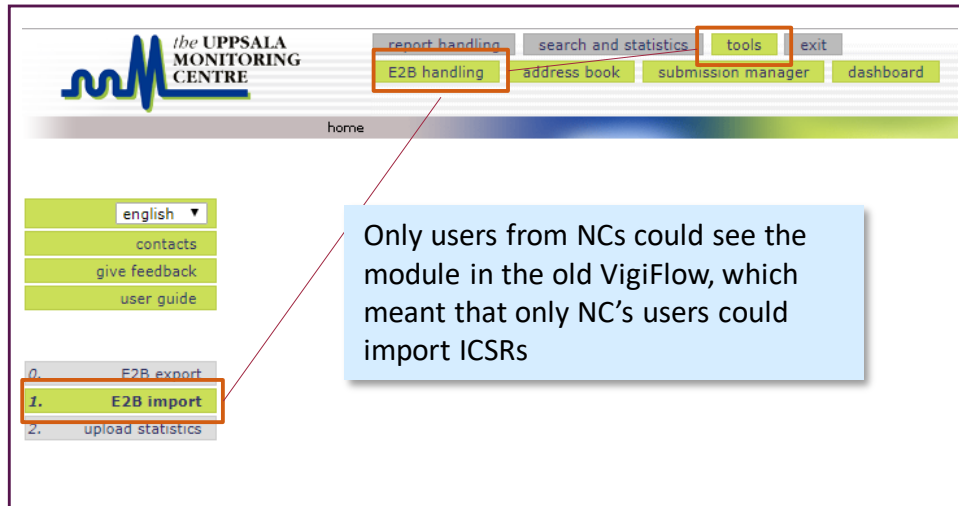


– Building a global safety culture

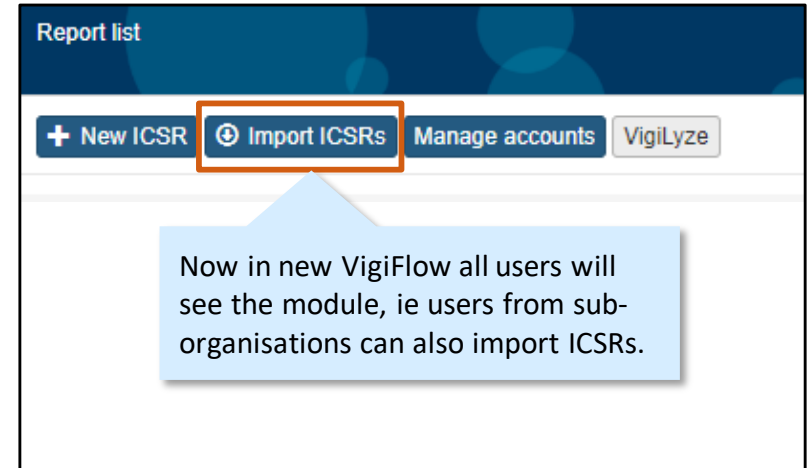
# Key differences – Access to import module

## All users can import ICSRs, not only National PV Centre (NC) users.

In new VigiFlow, sub-organisations are able to import E2B-xml files. This was not possible in the old VigiFlow, where only National PV Centres could import.



The screenshot shows the 'the UPPSALA MONITORING CENTRE' interface. A navigation bar at the top contains 'report handling', 'search and statistics', 'tools', and 'exit'. Below this, a secondary bar includes 'E2B handling', 'address book', 'submission manager', and 'dashboard'. A 'home' link is visible below the navigation. On the left, there is a language dropdown set to 'english' and links for 'contacts', 'give feedback', and 'user guide'. A list of menu items is shown at the bottom: '0. E2B export', '1. E2B import', and '2. upload statistics'. The 'E2B import' item is highlighted with an orange box. A blue callout box with a red arrow pointing to the 'E2B handling' link contains the text: 'Only users from NCs could see the module in the old VigiFlow, which meant that only NC's users could import ICSRs'.



The screenshot shows the 'Report list' interface. A navigation bar at the top contains '+ New ICSR', 'Import ICSRs', 'Manage accounts', and 'VigiLyze'. The 'Import ICSRs' button is highlighted with an orange box. A blue callout box with a white arrow pointing to the 'Import ICSRs' button contains the text: 'Now in new VigiFlow all users will see the module, ie users from sub-organisations can also import ICSRs.'

# Key differences – Import formats

Old and new VigiFlow are based on different versions of the ICH E2B standard, **(R2)** vs **(R3)**. Imports in new VigiFlow can be done with both formats while the old only handled **E2B (R2)**.



## Conversion of formats

When importing **E2B(R2)** files to new VigiFlow the reports will be converted to **E2B(R3)** format when saved in the database.

This means that some of the error messages will be expressed referring to **E2B(R3)**. However, a Q&A will be compiled to clarify the error messages.

# Key differences – Type of imports

## Type of imports

In both old and new VigiFlow there are two options when uploading E2B files, one where strict rules apply and one with looser rules.

In old VigiFlow they are named '*standard E2B*' and '*incomplete E2B*', and in new VigiFlow '*Validated*' and '*Non-validated*'.

The image shows two side-by-side screenshots of web forms. The left form is titled 'Upload E2B file' and has a green header. It contains a 'file' field with a 'Choose File' button and 'No file chosen' text. Below this is a 'type of import' section with a question mark icon, containing two radio buttons: 'standard E2B' (selected) and 'incomplete E2B'. Below that is a 'report Id' section with a question mark icon and a checkbox labeled 'generate report Id at import'. At the bottom is an 'upload' button. The right form is titled 'Import ICSRs' and has a dark blue header. It contains a 'file' field with a 'Choose File' button and 'No file chosen' text. Below this is a 'Select file to import' section with a 'Choose File' button and 'No file chosen' text. Below that is a 'Type of import' section with a plus icon, containing two radio buttons: 'Validated' (selected) and 'Non-validated'. At the bottom is an 'Import ICSRs' button. A red line connects the 'type of import' section of the left form to the 'Type of import' section of the right form.

Note! when importing E2B(R3) files in new VigiFlow, the only option allowed is '*Validated*' import.

# Key differences – Type of imports

## Logging of imports

When using the *'incomplete E2B'* option in old VigiFlow no logging is made in upload statistics:

Upload statistics						
message number	sender identifier	sender message number	file name	type of import	import date	in (tot)
00001130	Leo Pharma	ZZ Testing 123	Import: Polydactyly of toes, Epilim SE-LEOPHARMA-99992293	manual E2B	06 05 2019	1 (1)
00001129	Leo Pharma	ZZ Testing 123	Import: Polydactyly of toes, Epilim SE-LEOPHARMA-0004495	manual E2B	06 05 2019	1 (1)
00001128	Zaar Pharma	ZZ Testing 123	Import: Polydactyly of toes, Epilim SE-ZAARPHARMA-0447511	manual E2B	06 05 2019	1 (1)

**NO** row is created in this list for *'incomplete E2B'* uploads

In new VigiFlow all uploads are logged, ie also *'Non-validated'* uploads will be shown in the import history:

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Sender	Import date	Import status	Import format	Number of ICSRs	E2B acklog
TestDB	14062019 10:01:02	Ok	R2	1	<a href="#">Download</a>
Zaar Pharmaceuticals	18042019 10:59:08	Ok	R3	1	<a href="#">Download</a>
Zaar Pharma	18042019 10:09:08				<a href="#">Download</a>

All uploads are logged regardless of the Type of import used

# Key differences – Follow-ups

## Identification of follow-ups

The two VigiFlow systems identify follow-ups for imported reports in slightly different ways.

New VigiFlow is slightly more strict due to the automatic handling of follow-ups; since no manual verification step is available, this is necessary to avoid incorrect report merging (see next pages).

Old VigiFlow

An imported ICSR is regarded as a follow-up when **these two id's are the same** as for an ICSR **already** in VigiFlow:

- Message sender identifier
- Sender's Safety Report Id

New VigiFlow

An imported ICSR is regarded as a follow-up when **these three id's are the same** as for an ICSR **already** in VigiFlow:

- Sender organisation
- Sender's Safety Report Id
- Worldwide Unique Id

# Key differences – Follow-ups

In old VigiFlow, follow-ups are shown in a separate list from which the user needs to **manually** *Promote* or *Discard* the update:

**Updates of previously received cases**

Report title	Report status	Receive date	Receipt date	Checked out by
2019-00044 Import: Feeling drunk, Feeling	assessment	17 06 2019	17 06 2019	
2019-00036 Import: Polydactyly of toes, Epilim	assessment	06 05 2019	06 05 2019	

**List of follow up reports**

Report title	Report status	Receive date	Sender's version	Sender's receive date	Sender's receipt date	
Import: Feeling drunk, Feeling		20190617	2	20190602	20190610	
2019-00044 Import: Feeling drunk, Feeling	assessment	20190617	1	20190601	20190609	

# Key differences – Follow-ups

In new VigiFlow, follow-ups *automatically updates* the follow-up reports with the original report that already exists in VigiFlow.

Older versions of the report can be viewed via the Audit trail:

The latest version updated with follow-up information is shown in the report list

Worldwide unique id	Delegated to organisation	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)				
SE-ZZZ-AUTHORITY1234	Uppsala Monitoring Centre	MN		Feeling drunk	Feeling, Alcohol stop, Magic mix	17062019	17062019	Open	

Audit trail

Worldwide unique id	Initial received date	Latest received date	Status of report	Description	Changed date	Last edited by
SE-ZZZ-AUTHORITY1234	17062019	17062019	Open	Imported		




To open earlier versions of the report click on a Worldwide unique id in the audit trail



# Key differences – Nullification of report

In old VigiFlow the user needed to **manually** *Discard nullification* or *Nullify case*:

List of follow up reports

Report title	Report status	Receive date	Sender's version	Sender's receive date	Sender's receipt date	
<b>nullification</b> Import: Feeling drunk, Feeling		20190617	3	20190602	20190610	 
2019-00044 Import: Feeling drunk, Feeling assessment		20190617	2	20190602	20190610	

Callouts: Discard nullification, Nullify case

In new VigiFlow the reports are **automatically deleted** (nullified):

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	VigiLyze
<input checked="" type="checkbox"/> SE-ZZZ-AUTHORITY1234	Uppsala-Monitoring-Centre	MN		Feeling-drunk	Feeling-Alcohol-step-Magie-mix	47082040	47082040	Open	

Audit trail

Worldwide unique id	Received date	Status of report	Description	Changed date	Last edited by
SE-ZZZ-AUTHORITY1234		Open	Imported		
SE-ZZZ-AUTHORITY1234	17082019	Open	Imported		

Callout: Automatically deleted reports can be seen in the report list when using filter 'Include deleted ICSRs'