VigiFlow

Importing E2B XML files

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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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Content

In this presentation you will find:

- How to import XML files

- Validation rules

- Receipt acknowledgment to sender

- Search for ICSRs imported in a XML file

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Considerations

VigiFlow allows the import of XML files according to both the **ICH E2B(R2)** and **ICH E2B(R3)** standards.

To guarantee the system performance, the UMC recommends a maximum of **100 ICSRs per XML file**.

How to import XML files

How to import XML files

From the Report list, click on **Import**.

Main screen for handling imports

The screen for handling XML imports is divided in three parts

Filters to search for imported files

Select the XML file from your computer to import in VigiFlow

List of imported files

Select file to import

Remember to save the XML file somewhere on your computer

1. Click on the **Choose File** button to search for the XML file on your computer

2. **Validated import** is default and should always be used for ICSRs from Marketing Authorisation Holders (MAHs)

3. Click on **Import ICSRs** to conclude the import

Validation rules

All imported XML files will be validated according to the technical requirements for a valid ICH E2B XML file; ICH DTD, encoding, date formats and lexicon values established in the ICH E2B standard.

➤ The **Validated** import requires that the ICSRs in the file capture some administrative and basic information. For example;

• Report type

• Reporter identifier - *Designation/Qualification of the reporter*

• Patient identifier

• At least one reaction/event - *MedDRA code*

• At least one suspect drug

➤ The **Non-validated** import has no requirements for administrative and basic information to be captured in the ICSR

    ➤ *Should only be used for ICSRs originated from a source not compatible with ICH E2B*

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List of imported files

When the import is done, it is immediately shown in the list of imports with a summary of the status and number of ICSRs succesfully imported in VigiFlow

Sender	Source of import	Import date	Import status	Import format	Number of ICSRs	E2B acklog
HW	Manual	20072020 14:32:49	Ok	R2	1	Download
EVTESTWT	Manual	07072020 10:07:12	Ok	R2	8	Download
	Manual	07072020 10:06:07	Fail	Unknown	0	Download
BIP	Manual	01072020 22:36:15	Ok	R3	1	Download
VULCANHC	Manual	01072020 12:16:48	Ok	R3	1	Download
002147023T	Manual	26062020 09:33:14	Ok	R3	1	Download
VULCANHC	Manual	25062020 14:30:34	Fail	R3	0 (1)	Download
VULCANHC	Manual	25062020 14:30:15	Fail	R3	0 (1)	Download
	Manual	09062020 14:20:59	Fail	R2	0	Download
ZZLILLY	Manual	04062020 10:23:52	Ok	R3	1	Download
UMC	Manual	28052020 13:20:15	Fail	R3	0	Download
UMCPRS	Manual	28052020 10:31:34	Ok	R2	1	Download
SAAVTEST	Manual	27052020 09:35:35	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:35:09	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:34:33	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:34:12	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:33:48	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:33:28	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:32:56	Ok	R3	1	Download
SAAVTEST	Manual	27052020 09:32:23	Ok	R3	1	Download

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Import status

There are 3 possible status for an imported file:

- **Ok**: All ICSRs contained in the file were successfuly imported

- **Partial**: Some ICSRs were successfully imported but others did not fulfill the minimum requirements of the validation rules

- **Fail**: None of the ICSRs were imported

Sender	Import date	Import status	Number of ICSRs	E2B acklog
SpecFlow	05122018 16:12:44	Ok	1	Download
UMCPRS	05122018 15:52:34	Partial	1 (2)	Download
	05122018 15:52:23	Ok	1	Download
SpecFlow	05122018 15:52:05	Ok	1	Download
TestDB	05122018 15:51:55	Fail	0 (1)	Download

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Import format

The Import format shows if the specific XML files follows the E2B (R2) or (R3) version

Unknown is used when the system cannot recognise a file as neither E2B(R2) nor E2B(R3)

Sender	Import date	Import status	Import format	Number of ICSRs	E2B acklog
	01042019 16:14:21	Fail	Unknown	0	Download
EVTESTWT	01042019 16:13:25	Partial	R2	32 (40)	Download
Zaar Pharma	01042019 16:12:46	Ok	R3	1	Download

Number of ICSRs

One XML file can contain several ICSRs

If all ICSRs are successfully imported (Status = Ok), the total number of ICSRs contained in the file will be displayed

If the file has been partially imported or failed to import, the number of ICSRs will be displayed according to the following standard:

Number of ICSRs: A (B)

A = Number of ICSRs successfully imported

B = Total number of ICSRs contained in the file

Sender	Import date	Import status	Number of ICSRs	E2B acklog
SpecFlow	05122018 16:12:44	Ok	1	Download
UMCPRS	05122018 15:52:34	Partial	1 (2)	Download
	05122018 15:52:23	Ok	1	Download
SpecFlow	05122018 15:52:05	Ok	1	Download
TestDB	05122018 15:51:55	Fail	0 (1)	Download

Acklog

- The ICH E2B standard establishes that for each imported file there must be an receipt confirmation, which is known as the *acknowledgement log* (or **acklog**)

- In VigiFlow, it is possible to download the *E2B acklog* in XML format to send back to the sender

Select file to import

Choose file | No file chosen

Type of import ❓
◉ Validated ○ Non-validated

Import ICSRs

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Sender	Import date	Import status	Number of ICSRs	E2B acklog
RU-RZN	21022019 08:51:22	Fail	0 (1)	Download
UMCPRS	19022019 15:47:11	Ok	1	Download
UMCPRS	19022019 15:45:56	Ok	1	Download
UMCPRS	19022019 15:45:38	Ok	1	Download

Import details

By clicking on a specific row on the list of imported files, you will see additional details about the import

Import details – ICSRs not imported

If the import was partial or failed, the "**Import Details**" specify the error message for the ICSRs not imported.

In that way, it is possible to identify the cause of the error and communicate it back to the sender.

Import details

Sender	DOH
Import date	17102018 12:00:30
File name	PharmaAR_1092018.xml
Import status	Fail
Message	Could not persist all information
Number of ICSRs	0 (2)
ICSRs imported	
ICSRs not imported	AE-DOH-AR/000913/1217 Incomplete reaction event information. A valid ICSR must contain at least one medDRA coded reaction. AE-DOH-AR/000900/1217 Incomplete reaction event information. A valid ICSR must contain at least one medDRA coded reaction.

Import details

Sender	UMCPRS
Import date	17102018 13:20:43
File name	PartialSuccess.xml
Import status	Partial
Message	Could not persist all information
Number of ICSRs	1 (2)
ICSRs imported	UMC-UMCORG-43
ICSRs not imported	INVALID Property icsr.IdentificationOfTheCaseSafetyReport.TypeOfReport has an invalid value: 123!

Close

Search for imported files

Click on **Filter** to open the search section. It is possible to search for imported files based on:

- Date when file was imported

- Name of the organisation that sent the file (Sender)

Identifying reports received via E2B XML import

In the Report List, use the search filter **Means of reporting** to search for ICSRs received via import:

- Import – validated: ICSRs from Marketing Authorisation Holders (MAHs)

- Import – non-validated: ICSRs from a source not according to ICH E2B

To identify if the import is a follow-up or initial report, compare the initial and latest receive date

This is a follow-up report (latest receive date is later than the initial received date)

Follow-up handling

Identification of follow-ups

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

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

Identified follow-ups are *automatically merged* 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

Questions:
vigibase@who-umc.org

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