

VigiFlow

Importing E2B XML files



– 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.

This PowerPoint presentation has been developed by the UMC for training purposes. This material may be passed on to other users of VigiFlow.

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Content

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- [How to import XML files](#)
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- [Receipt acknowledgment to sender](#)
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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**.

Report list VigiFlow - National PV Centre User name

New ICS **Import** Export Manage accounts VigiLyze Filter PDF/Excel/XML

0 ICSRs selected 20500 ICSRs match your search with 1 filter(s) applied Page 1 of 1025

<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	VigiLyze
<input type="checkbox"/> UMC-UMCORG-300020903	National PV Centre	UN		Urinary retention, Vomiting	Metformina	31072020	31072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020902	Hospital A2	TJ		Cardiac arrest	Chloroquine	30072020	30072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020900	National PV Centre	TJ		Discomfort	Diovan	28072020	28072020	Open	✓
<input type="checkbox"/> UMC-UMCORG-300020899	National PV Centre	UN		Hypotension	Lamictal	27072020	27072020	Open	
<input type="checkbox"/> AE-DOH-AR/000914/1218	National PV Centre		07011971	Cardiac arrest		20072020	20072020	Open	
<input type="checkbox"/> LV-EMA-Testcase08-nullifyme	National PV Centre	MH		Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> EE-EMA-Testcase07-followmeup	National PV Centre	MH		Jaundice, unspecified, not of newborn		27082019	07072020	Open	
<input type="checkbox"/> DE-EMA-Testcase06	National PV Centre	HVIII		Liver failure		27082019	07072020	Open	
<input type="checkbox"/> JP-EMA-TESTCASE05	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE04	National PV Centre			Polydactyly of toes	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-SPONSOR-TESTCASE03	National PV Centre	MH		Pre-eclampsia	Migraleve pink, Migraleve pink	27082019	07072020	Open	
<input type="checkbox"/> US-MAH-TESTCASE02	National PV Centre	JTK	22031931	Food interaction, Explosive diarrhoea		27082019	07072020	Open	
<input type="checkbox"/> SE-EMA-TESTCASE01	National PV Centre	MN		Cardiac arrest	Calpol, Calpol	27082019	07072020	Open	
<input type="checkbox"/> UMC-UMCORG-300020888	National PV Centre	SA				03082020	03082020	Open	
<input type="checkbox"/> MX-SA-2020SA000185	National PV Centre			Gastrointestinal toxicity, Drug toxicity NOS, Neutropenia, Hypertension arterial	Zaltrap, Irinotecan, Calcium folinate, Fluorouracil, Levothyroxine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030943	National PV Centre			Lack of drug effect, Product use issue	Apidra solostar	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030944	National PV Centre			Pentonsillar abscess	Oxaliplatin, Calcium folinate, Fluorouracil	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030938	National PV Centre			Flu like symptoms	Influenza vaccine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030946	National PV Centre			Influenza, Vaccination failure	Influenza vaccine	27052020	27052020	Open	
<input type="checkbox"/> MX-SA-2019SA030939	National PV Centre		01011950	Cardiovascular symptom, Urinary incontinence	Insulin glargine, Humalog mix25, Humalog mix50	27052020	27052020	Open	

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

Import ICSRs | VigiFlow - National PV Centre | User name

< To Report list | Filter

Import date (from) | Import date (to)

Sender

Source of import

Search | Clear

Select file to import

Choose file | No file chosen

Type of import

Validated Non-validated

Import ICSRs

Page 1 of 30 | 587 imports match your search

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 10:08:07	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	26082020 09:33:14	Ok	R3	1	Download
VULCANHC	Manual	25082020 14:30:34	Fail	R3	0 (1)	Download
VULCANHC	Manual	25082020 14:30:15	Fail	R3	0 (1)	Download
	Manual	09082020 14:20:59	Fail	R2	0	Download
ZZLULLY	Manual	04082020 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

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

1
2
3

Select file to import

No file chosen

Type of import 

Validated Non-validated

Page 1 of 5 « < 1 2 3 4 5 > » 87 imports match your search

Sender	Import date	Import status	Import format	Number of ICSRs	E2B acklog
Zaar Pharmaceuticals	08042019 15:58:47	Ok	R3	1	<input type="button" value="Download"/>
Zaar Pharma	08042019 15:52:32	Ok	R3	1	<input type="button" value="Download"/>
HCOPOSTMARKET	08042019 12:54:22	Ok	R3	1	<input type="button" value="Download"/>
HEALTHCANVIG	08042019 12:20:52	Ok	R3	1	<input type="button" value="Download"/>
BAYER	05042019 11:30:02	Ok	R2	1	<input type="button" value="Download"/>
	05042019 11:28:19	Fail	Unknown	0	<input type="button" value="Download"/>

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*

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 successfully imported in VigiFlow

Page 1 of 30 << < 1 2 3 4 5 ... > >> 587 imports match your search

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

Import status

There are 3 possible status for an imported file:

- **Ok:** All ICSRs contained in the file were successfully 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

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

Page 1 of 1 « < 1 > » 4 imports match your search

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

The screenshot displays a web interface for importing files. At the top, there is a 'Select file to import' section with a 'Choose File' button and the text 'No file chosen'. Below this, the 'Type of import' is set to 'Validated' (indicated by a selected radio button). A blue button labeled 'Import ICSRs' is visible. The main area shows a table with two rows of imported files. The second row, for 'EVTESTWT', is selected. A modal window titled 'Import details' is open, showing the following information:

Field	Value
Sender	EVTESTWT
Import date	14022019 15:36:49
File name	Zs many test cases.xml
Import status	Ok
Number of ICSRs	40
ICSRs imported	UMC-UMCORG-300000026 UMC-UMCORG-300000027 UMC-UMCORG-300000028 UMC-UMCORG-300000029 UMC-UMCORG-300000030 UMC-UMCORG-300000031 UMC-UMCORG-300000032 UMC-UMCORG-300000033 UMC-UMCORG-300000034 UMC-UMCORG-300000035 UMC-UMCORG-300000036 UMC-UMCORG-300000037 UMC-UMCORG-300000038 UMC-UMCORG-300000039 UMC-UMCORG-300000040 UMC-UMCORG-300000041 UMC-UMCORG-300000042 UMC-UMCORG-300000043 UMC-UMCORG-300000044 UMC-UMCORG-300000045

The background interface also shows pagination controls for the table, indicating 'Page 1 of 1' and '2 imports match your search'. The Uppsala Monitoring Centre logo is visible at the bottom left of the interface.

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)

[← To Report list](#) **Filter**

Import date (from) **Import date (to)** **Sender**

Search

Select file to import
 Nenhum arquivo selecionado

Type of import ⓘ
 Validated Non-validated

Page 1 of 2 « < 1 2 > » 40 imports match your search

Sender	Import date	Import status	Number of ICSRs	E2B acklog
SpecFlow	05122018 16:12:44	Ok	1	<input type="button" value="Download"/>
UMCPRS	05122018 15:52:34	Partial	1 (2)	<input type="button" value="Download"/>
	05122018 15:52:23	Ok	1	<input type="button" value="Download"/>
SpecFlow	05122018 15:52:05	Ok	1	<input type="button" value="Download"/>
TestDB	05122018 15:51:55	Fail	0 (1)	<input type="button" value="Download"/>

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

0 ICSRs selected | 140 ICSRs match your search with 1 filter(s) applied | Page 1 of 7

<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 checked="" type="checkbox"/>	UMC-UMCORG-153	National Centre					30102019	05112019	Open	
<input checked="" type="checkbox"/>	UMC-UMCORG-152	National Centre					30102019	30102019	Open	
<input checked="" type="checkbox"/>	UMC-UMCORG-151	National Centre					30102019	30102019	Open	

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:

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, Magio 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		

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

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

Questions:
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– Building a global safety culture

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