

New VigiFlow

Release 1.8.2

August 2019



– Building a global safety culture

Report list

New column

Initial received date has been added to Report list

0 ICSRs selected 98 ICSRs match your search with 1 filter(s) applied Page 4 of 5

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
UMC-UMCORG-33	National Centre			Rash NOS	GEMOX	08092018	08092018	Open	✓
UMC-UMCORG-30	National Centre	Unknown	16121980	Black hairy tongue, Arrhythmia	Diflucan	04092018	04092018	Open	
UMC-UMCORG-97	National Centre	MLV	21052005	Fever, Myalgia, Appetite lost	Engerix	12052018	052018	Open	
UMC-UMCORG-98	National Centre					12022018	022018	Open	
UMC-UMCORG-32	National Centre			Rash NOS	Hajjeverolja	12012018			!
UMC-UMCORG-15	National Centre	JD	1967	Depression	Aerius, Hydrocortisone	02102017			✓
UMC-UMCORG-14	National Centre	JD	1967	Depression	Aerius, Hydrocortisone	02102017			!
UMC-UMCORG-23	National Centre		02011988	Urticaria	Alveca	02062017			✓

The report list can be sorted by Initial received date by using the arrows

New assessment method

French method

French method has been added as a new causality assessment method

The screenshot shows a web interface for causality assessment. At the top, there is a header '+ Causality assessment'. Below it, there are two main sections: 'Method' and 'Source'. The 'Method' dropdown menu is open, showing several options: 'WHO-UMC Causality', 'Naranjo', 'WHO AEFI', and 'French method'. The 'French method' option is highlighted with a green box. A green callout box points to this option with the text: 'When French method is selected these values can be used'. The 'Source' field contains 'Uppsala Monitoring Centre'. Below the 'Method' dropdown, there are two more dropdown menus. The first one is labeled 'Action(s)' and is currently empty. The second one is labeled 'Beta-alanine' and is open, showing a list of values: 'C0 or S0 - I0', 'C1S1 - I1', 'C1S2 - I2', 'C2S1 - I2', 'C2S2 - I3', 'C1S3 - I4', 'C3S1 - I4', 'C2S3 - I5', 'C3S2 - I5', and 'C3S3 - I6'. The first value, 'C0 or S0 - I0', is highlighted in blue.

Method

Source

WHO-UMC Causality

Uppsala Monitoring Centre

WHO-UMC Causality

Naranjo

WHO AEFI

French method

When French method is selected these values can be used

Beta-alanine

C0 or S0 - I0

C1S1 - I1

C1S2 - I2

C2S1 - I2

C2S2 - I3

C1S3 - I4

C3S1 - I4

C2S3 - I5

C3S2 - I5

C3S3 - I6

Import of E2B-xml files

E2B(R2) – Patient Initials

If *Patient Initial* is UNKNOWN or PRIVACY when importing an E2B(R2) file, the report is accepted and the values are saved as nullflavors.

Nullflavors are not yet implemented in the GUI so these values are not shown when looking at the reports in Data Entry.

<patientinitial>PRIVACY</patientinitial>

<patientinitial>UNKNOWN</patientinitial>

Import – acknowledgement message

The R2 acklog has been modified to include:

- *Encoding*
 - `<?xml version="1.0" encoding="UTF-8"?>`
- *Doctype element*
 - `<!DOCTYPE ichicsrack SYSTEM "http://eudravigilance.ema.europa.eu/dtd/ichicsrack11xml.dtd">`
- *Authoritynumb and Companynumb*
 - `<authoritynumb>SE-ZZZ-TESTFLOOW</authoritynumb>`
 - `<companynumb/>`
- *Receiptdate*
 - `<receiptdate>20150302</receiptdate>`
- *Errormessagecomment*
 - `<errormessagecomment>Patient identification missing.</errormessagecomment>`