VigiFlow release 17 May 2022
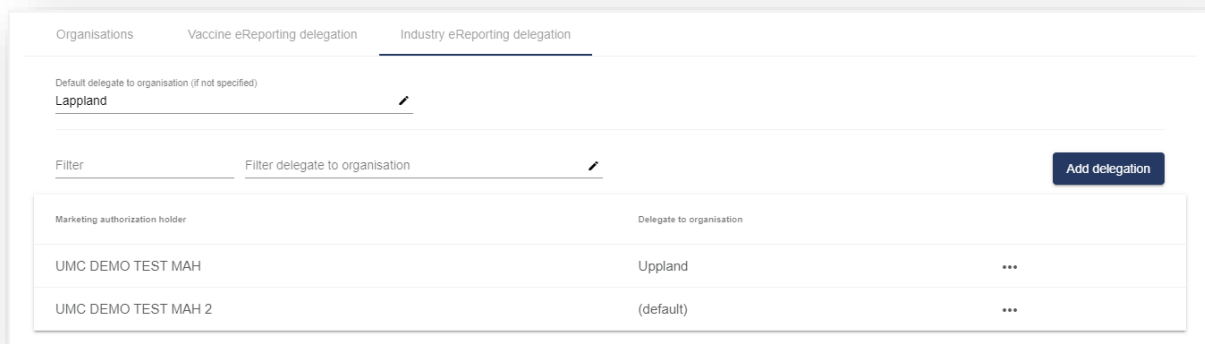
What's new?

Custom fields

"Identification number" is available as an optional field in ICSR and AEFI manual data entry.

- When activated the field will be displayed in the Patient section and added to Excel, AEFI Excel and PDF printouts.
- The field will not appear in Masked PDF or Masked xml printouts.
- This UMC extension of the ICH E2B (R3) standard can be imported and exported for both unidentified and identified receivers in VigiFlow.

To activate the field, contact us at vigibase@who-umc.org.

Delegating ICSRs in VigiFlow

Users can delegate ICSRs submitted by marketing authorisation holders via VigiFlow Industry eReporting to sub-organisations in VigiFlow.

EDQM Standard Terms

VigiFlow now accepts EDQM Standard Terms for routes of administration and pharmaceutical dose forms for use in electronic exchange of ICSRs.

What does that mean?

Pharmaceutical dose form concept classes

EDQM Standard Terms for pharmaceutical forms are structured into several concept classes. All classes are recognised in the import and export of ICSRs. You can find more information about EDQM Standard Terms on the EDQM web page here.

BDF = Basic dose form   Generalised version of the pharmaceutical dose form, used to group together related pharmaceutical dose forms.

PFT = Patient friendly terms   Generally shortened term that may be used for labelling only, in case of space limitation, where justified and authorised.

PDF = Pharmaceutical dose form   Physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient.

CDF = Combined pharmaceutical dose form   Single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product.

Transition to EDQM Standard Terms

Existing ICSR data for routes of administration has been updated to ensure compliancy with ICH E2B (R3) guidelines.

- Routes of administration structured according to ICH code list 14 have been mapped to corresponding EDQM Standard Terms.
- If no match is found the term is entered as free text.

Import of ICSRs in ICH E2B (R3)

- Routes of administration reported with EDQM Standard Terms in ICH E2B (R3) are accepted automatically.
- Routes of administration reported with ICH code list 14 in ICH E2B (R3) are mapped to EDQM Standard Terms.
- Pharmaceutical dose forms can be reported as EDQM Standard Terms or in free text.

Import of ICSRs in ICH E2B (R2)

- Routes of administration reported with ICH code list 14 in ICH E2B (R2) are mapped to EDQM Standard Terms automatically.
- Pharmaceutical dose forms are always reported as free text in ICH E2B (R2).

Mapping exceptions

For existing ICSRs and imports with ICH code list 14 the following terms are always entered as free text:

1. 025 Intrahepatic
2. 050 Other
3. 051 Parenteral
4. 065 Unknown

Export of ICSRs in ICH E2B (R3)

EDQM Standard Terms for routes of administration and pharmaceutical dose forms are included in the export file.

Manual data entry

Users can either structure routes of administration and pharmaceutical dose forms according to EDQM Standard Terms or as free text for manual data entry of ICSRs or AEFIs.

Input language
EDQM Standard Terms for routes of administration and pharmaceutical dose forms are available in several languages. VigiFlow supports EDQM Standard Terms for all VigiFlow languages. Terms are displayed in English if no translation is available.

What's improved?
Drug history for patient or parent
If you fill in any of the fields under drug history, you will be prompted to enter information about "Previous medication".

Additional documents
.png attachments are accepted in both ICSR and AEFI manual data entry for file uploads up to 15MB.

Import of ICSRs
Time out issue resolved for large ICH E2B (R2) xml files.

Export of ICSRs
Initial reporter information "Reporter qualification" is no longer a mandatory value in the export of ICSRs for electronic exchange.

Time out issue is resolved for large ICH E2B (R3) files.

Export enabled for nullified ICSRs that are not compliant with the ICH E2B (R3) standard referred to non-valid reports in VigiFlow.

Manual data entry
To make it easier to see where a nullFlavor value has been reported the nullFlavor icon's placement and appearance have been updated.

PDF printouts
PDF printouts also include structured "Test result" qualifier information.