Dear VigiFlow user,

VigiFlow is updated with some new features!

1. The PDF-output of the ICSR is now available in two formats:

    a. The existing PDF is renamed to **Unmasked PDF** and is still marked with *Internal use only*
    b. **Masked PDF** has been added as a new option, marked with *Masked*. It creates a PDF for external use with sensitive data replaced with 'MSK' instead of the original value. The following fields are masked:
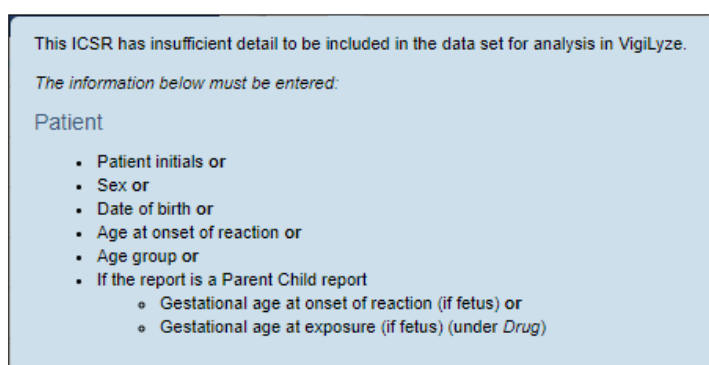
    Patient information:
    *   Patient initials
    *   Parent initials (if parent-child case)
    *   Specialist record number/GP medical record number/Hospital record number/Investigation number

    Initial reporter information:
    *   All information is masked <u>except</u> *reporter qualification* and *country of reporter*

2. When a PDF is created from a deleted report you can now read the **Reason for deletion of ICSR** in the PDF.

3. A change is made to the minimum requirements needed for an identifiable patient, where the information about **Test date together with Test result** has been removed.

    From this release the minimum requirements for patient identification are:

    This ICSR has insufficient detail to be included in the data set for analysis in VigiLyze.

    The information below must be entered:

    Patient

    *   Patient initials or
    *   Sex or
    *   Date of birth or
    *   Age at onset of reaction or
    *   Age group or
    *   If the report is a Parent Child report
        *   Gestational age at onset of reaction (if fetus) or
        *   Gestational age at exposure (if fetus) (under *Drug*)

4. You can now capture the following information in VigiFlow *(new fields/checkboxes)*:

    a. Report information: **Source** for 'Other report id'

    When an 'Other report id' is added you need to also specify the source that assigned the id to the report.
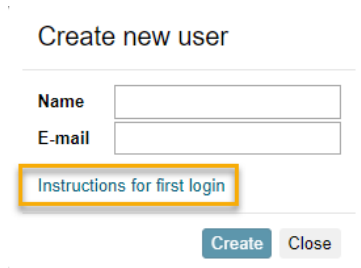
b. Report information: **Does this case fulfil the local criteria for an expedited report?**
Yes or No can be selected.

c. Report information: **Additional documents**
Any relevant documents you have for an ICSR can be described here, in free text.

d. Case narrative and other information: **Concomitant therapies** (checkbox)
Used to indicate that there were concomitant therapies at the time of the reaction. The concomitant therapies should be described in the 'Case Narrative'.

e. Reaction**: Language of reaction / event as reported by initial reporter**
Undetermined is shown as the default language. Another default language (country language) can be set by the UMC upon request.

f. Tests and procedures: **Test result (code)**
This field has 4 fixed values: *Positive, Negative, Borderline* and *Inconclusive*

g. Medical and past drug history: **Family history** (checkbox)
Used to indicate that the reported medical history is also present in another family member (e.g. hereditary diseases).

5. Additions and updates have been done to the **French translations** of the interface.

6. New warnings are added in the following circumstances:

a. When **Country of reporter** is not selected for the Initial reporter marked as *Primary*

b. When **Test date** exists but no **Test name** (neither coded nor free text) is populated and the other way around.

c. Other report ID source (see section 4a)

For VigiFlow countries using the xml-import functionality:

1. When importing ICSRs this information is also shown in the interface if it was present in the imported xml:

a. Translated reaction / event as reported by initial reporter

b. Imported 'additional documents' (free text description)

c. Authorization/application number

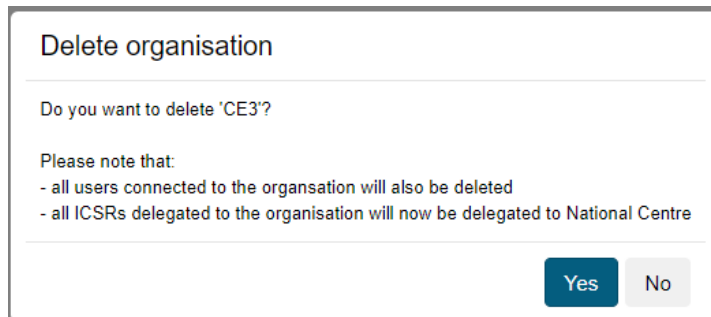d. 'This investigational product is blinded'

For VigiFlow administrators:

1. A link to *'Instructions for first login'* has been added when creating a new user to facilitate communications with the new users

2. An extended warning is shown when sub-organisations are to be deleted.

If you have any questions or comments, please contact vigibase@who-umc.org