

VigiFlow Release 02 March 2022

## General introduction

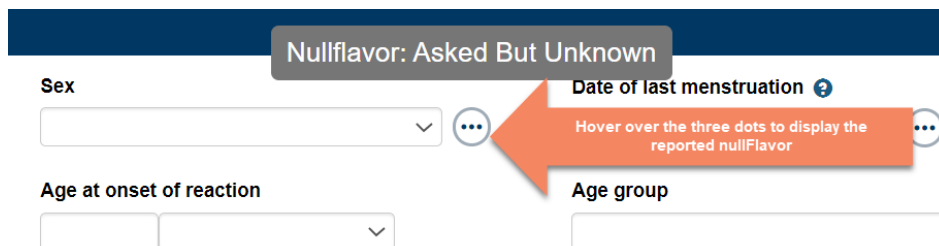
This release of VigiFlow contains updates mainly to support and harmonise with the launch of Industry eReporting.

### Listing the updates:

- **nullFlavor**

The concept of nullFlavor is introduced. nullFlavors are a set of values that can be used in the ICSR message to describe the reason for missing data/information in a field.

Currently you will only be exposed to nullFlavors, shown as three dots, in VigiFlow if they were included in an imported ICH E2B(R3)-XML. Different sets of nullFlavors applies for the various fields where nullFlavors are allowed.



The screenshot shows a form with several fields. A dark blue header bar contains the text "Nullflavor: Asked But Unknown". Below this, there are four fields: "Sex" (a dropdown menu), "Date of last menstruation" (a date field with a help icon), "Age at onset of reaction" (a range selector), and "Age group" (a dropdown menu). Each of these fields has a three-dot menu icon to its right. A red arrow points from the "Date of last menstruation" field to the "Sex" field, with a tooltip that says "Hover over the three dots to display the reported nullFlavor".

It is possible to edit a field and replace a nullFlavor.

With the inclusion of nullFlavors, it also implies that a nullFlavor is accepted as a value “minimum criteria” when included in following elements: Reporter qualification, Patient/parent initials, Patient/parent date of birth, Patient/parent sex and Patient medical record numbers.

- **Coding to WHODrug in Industry eReporting**

Companies can now code to WHODrug in Industry eReporting when they create reports using manual data entry. This will decrease manual coding in VigiFlow since the information will be available automatically.

- **Updates to Medical and past drug history**

Past drug history for “Patient” and “Parent” (if Parent Child report) can now be coded according to WHODrug dictionary.

The information is also included in VigiFlow PDF printouts.

- **Updates to “Drug” section**

**Dechallenge-Rechallenge**

“Not applicable” is added as a value in “*Did reaction recur on re-administration?*” With this update VigiFlow will also accept imported E2B XML-files with this value.

**Units**

With further adaptation to ICH E2B (R3), some additional options have been added for duration and dosing interval units.

The “Dosing interval” unit and “Time interval between administration and reaction onset” unit have been updated to include the value “Decade”. The “Duration” unit has been updated to include the values “Second” and “Decade”.

**Imported active ingredients**

For ICSRs in E2B (R3) XML format; if active ingredients have been specified with strength and strength unit, this information will also be shown in the user interface as non-editable information.

- **Increased precision for “Time”**

With further adaptation to ICH E2B (R3), increased precision has been added;

“Start and end of administration/reaction” and “Time for date of reconstitution” can now be specified with increased precision down to seconds.

- **Bug fixes**

Default routing of reports that was set-up for Vaccine eReporting that unintentionally also affected Primary reporter eReporting has been permanently resolved.

If you have any questions or comments, please contact us at [vigibase@who-umc.org](mailto:vigibase@who-umc.org).