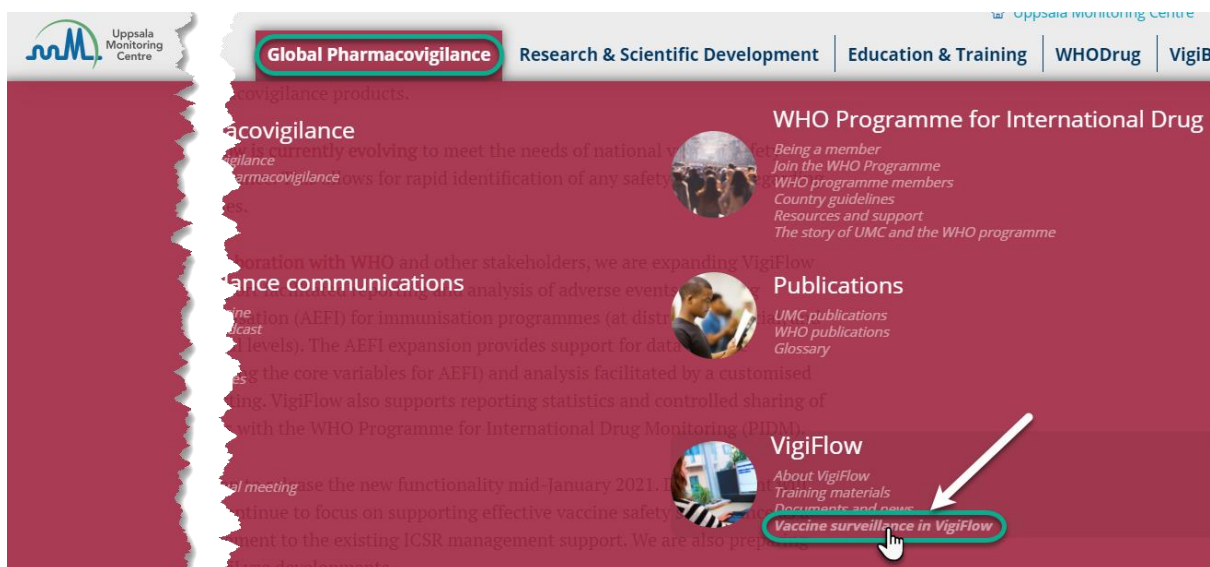


Dear VigiFlow user,

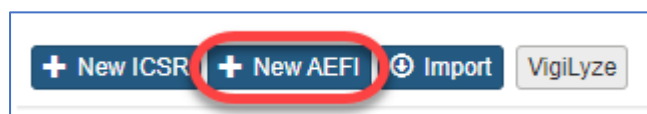
VigiFlow is updated with some new features related to capturing and analysing **Adverse Events Following Immunization (AEFIs)**.

The new functionality will be covered in **training webinars**, as well as **short video instructions**, all available through the UMC website [www.who-umc.org](http://www.who-umc.org):



### AEFI data entry form

A new AEFI data entry form tailored to support straight-forward digitalization of the existing WHO AEFI paper form is implemented. The new form can be found from the top menu of the report list page:



- **Data entry and specific fields**  
For general guidance on data entry, please see the [UMC website short videos](#) referred to above
- **Report type**  
Report type is automatically set to “Spontaneous report” for the AEFI reports, but this is not visible in the AEFI form

- **Workflow support**

Some actions can be performed directly from the AEFI data entry form (top menu):

- *Delegate* report to another organisation in the VigiFlow hierarchy (if implemented)
- *Change status* of the report
- *Delete (nullify)* report
- *Send report copy* to VigiLyze (only highest level organisation)

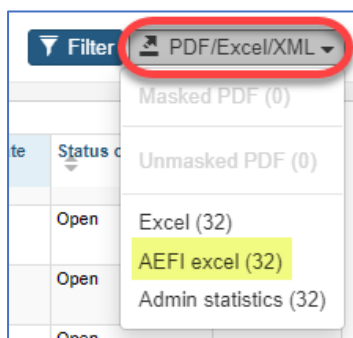
- **Adverse event pre-defined list**

To support an efficient data entry process a pre-defined list of common terms with both free text and mapping to MedDRA is present when entering adverse event information.

It is also possible to enter the reaction as free text and manually code the reaction to MedDRA.

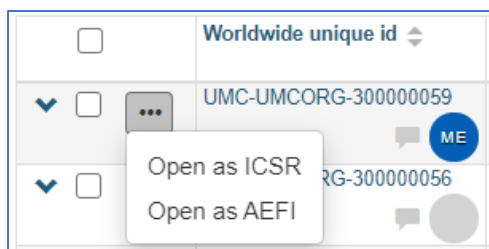
### **AEFI line listing**

Reports can be exported in a specific **AEFI line listing format** to make possible provincial and national analysis (e.g. finding of clusters) and reporting statistics for evaluation of the AEFI reporting process. The line listing is an Excel that presents some of the data added via the AEFI reporting form, and it is found from the top menu of the report list page:



### **Report list**

By default, a report is opened in **the data entry form it was created (AEFI or ICSR)**, when clicking on the 'Worldwide unique id' in the report list. However, you can also select in which form to open the report as illustrated below:



## ICSR data entry form

Some of the adaptations for the AEFI form also affects the ICSR form.

- **Drug section**

*Time* has been added to *Start of administration* and *End of administration* for drugs.



The screenshot shows a form with two main sections: 'Start of administration' and 'End of administration'. Each section has a date input field and a 'Time' input field. The 'Time' input fields are highlighted with red circles. The 'Time' input fields are labeled 'Time' and have a question mark icon next to them. The 'Start of administration' and 'End of administration' labels also have question mark icons.

- **Attachments**

Attachments can now be uploaded in two places in the ICSR form:

- For *Literature Reference(s)*
- For *Additional documents*

A warning is shown if an attachment is uploaded but no description has been filled in.

The total attachment size for one case report is 15 mega bytes (MB), with an exception that imported reports are accepted even if the attachment size is larger.

- **Causality assessment**

A new revision of the *WHO AEFI causality assessment method* has been implemented. Since the new version of the method is more granular than the old, it is not possible to map reports with assessments in the former version to the new. Therefore, you will see the old version's values when opening an older report. However, new assessments will only be possible to do with the new version.

The heading for assessment has been renamed to '*Relatedness of suspect/interacting drug(s) and reaction(s)*' to emphasize that only suspected and interacting drugs will be available for assessment.

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