VIGIFLOW LEGACY DATA MIGRATION

VigiFlow is an ICSR management tool offered to national pharmacovigilance centres of the member states in the WHO Programme for International Drug Monitoring (WHO PIDM). VigiFlow is a software delivered as a service (SaaS) hosted and owned by the Uppsala Monitoring Centre.

The software is now upgraded to a new version and when moving to new VigiFlow, the ICSRs in old VigiFlow will be migrated to the new system. This document describes the migration process and highlights some changes of how data is presented in the two systems.

If you have any questions, or want more detailed information of the data migration, please contact vigibase@who-umc.org

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1 ICSR information

When your organization starts to use the new version of VigiFlow, the ICSRs available in the old version of VigiFlow will be migrated into the new system. The migration process will also include some of the administrative information related to the ICSRs.

This document gives an overview of how the data will be handled in the migration process.

The ICSRs in old VigiFlow will be extracted and then imported into new VigiFlow. Each field is assigned a mapping destination and if there is no exact match for the field, mostly free text fields will be used to capture the values. Since the systems are based on different versions of the E2B standard, (R2) vs (R3), some changes have to be made in how data is presented in new VigiFlow.

1.1 Version and statuses

The latest version of an ICSR will be migrated, meaning that if an ICSR has several follow-ups, only the active (latest) version will be migrated.

The statuses of the reports are named differently in the new system compared to the old. The report status in old VigiFlow will be reflected in the new VigiFlow according to the below table:

<table>
<thead>
<tr>
<th>Old VigiFlow status of report</th>
<th>New VigiFlow status of report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committed</td>
<td>Closed</td>
</tr>
<tr>
<td>Nullified</td>
<td>Deleted</td>
</tr>
<tr>
<td>Reports under central assessment</td>
<td>Open (delegated to the National Centre)</td>
</tr>
<tr>
<td>Reports under regional assessment</td>
<td>Open (delegated to the sub-organisation)</td>
</tr>
</tbody>
</table>
1.2 Fields moved from case level to event level
The following information is recorded on event level instead of case level in new VigiFlow, and can therefore be provided for each reaction/event instead of just for the full case:
- Seriousness
- Medical confirmation by healthcare professional
- Country where reaction/event occurred

When your data is migrated this information will be displayed on each reaction on the ICSR. Please see picture below for clarification:

![Example of how information will move from case level to event level.](image)

1.3 Tests and procedures
New VigiFlow structures tests and procedures in a somewhat different way than old VigiFlow. Because of this, all test information from old VigiFlow will be transferred to free text fields in new VigiFlow.

1.4 Time interval between administration and reaction onset
Time interval between administration and reaction onset (i.e. First dose and Last dose) is present under both ‘Reactions’ and ‘Drugs’ sections in old VigiFlow, but only in the ‘Drug’ section in new VigiFlow.

Because of this, the information in these fields will be migrated to the Case narrative field in new VigiFlow.

1.5 Drug and active substance information
Both coded and uncoded drugs will be migrated from old VigiFlow. However, please be aware that for coded drugs, the information associated with WHODrug will only be transferred if it has been copied into the interface. Please see example below for clarification:
• Artemax, tablets 50 mg from Haemotech Pvt Ltd, Zimbabwe is picked from WHODrug dictionary:

By clicking the icon , information about pharmaceutical form, obtain country, authorization country and authorization holder is copied into the corresponding fields (see picture below). In this case, this information will be transferred to new VigiFlow.

If the icon has not been clicked, the information about pharmaceutical form, obtain country, authorization country and authorization holder is not copied into the corresponding fields (see picture below). In this case, this information will not be transferred to new VigiFlow (only the drug name and active substance(s) will be transferred):

Please note that if the information in about pharmaceutical form, obtain country, authorization country and authorization holder has been manually entered/edited, the information visible in the interface will be transferred.

1.6 Other specific data field mapping
Some information from old VigiFlow will not have a matching field in new VigiFlow. This information will be transferred to different free text fields in new VigiFlow, according to the below list. An example of what it will look like is shown in the image below.
<table>
<thead>
<tr>
<th>Old VigiFlow section</th>
<th>Old VigiFlow field</th>
<th>New VigiFlow field where the data is transferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>additional information (on drug)</td>
<td>Additional information on drug</td>
</tr>
<tr>
<td>Drugs</td>
<td>is the ADR adequately labelled (when Yes)</td>
<td></td>
</tr>
</tbody>
</table>
| Drugs                | Vaccine specific information:  
- expiry date  
- site of administration  
- diluent authorization holder  
- diluent expiry date  
- vaccination session |  |
| Report info          | case narrative | Case narrative |
| Reactions            | time interval between suspect drug administration and reaction onset:  
- first dose  
- last dose |  |
| Drugs                | time interval between administration and reaction onset:  
- first dose  
- last dose |  |
| Drugs                | treatment of reaction |  |
| Patient              | Vaccine specific information:  
- hospitalization date  
- discharge date  
- birth weight (gram)  
- gestational age  
- treatment details  
- details about pregnancy |  |
| Reactions            | Vaccine specific information:  
- AEFI category |  |
| Drugs                | Dosage (free text) | Dosage |
| Drugs                | dosage regimen - doses in interval (when invalid, i.e. not a number) |  |
| Relevant past drug therapy | drug name | Previous medications |
| Relevant past drug therapy | indication (when not a MedDRA code, i.e. ICD-10) |  |
| Relevant past drug therapy | reaction (when not a MedDRA code, i.e. WHO-ART) |  |
| Relevant past drug therapy (for parent) | drug name | Previous medications (for parent) |
| Relevant past drug therapy (for parent) | indication (when not a MedDRA code, i.e. ICD-10) |  |
| Relevant past drug therapy (for parent) | reaction (when not a MedDRA code, i.e. WHO-ART) |  |
| Reactions            | reaction/event as reported by primary source | Reaction / event as reported by initial reporter |
| Reactions            | reaction term (when not a MedDRA code, i.e. WHO-ART) |  |
Example of how information will be transferred from different fields in old VigiFlow into the same field in new VigiFlow (field ‘Case narrative’ in this case).

1.7 Information migrated from old VigiFlow but not yet shown in new VigiFlow
A few fields are not yet visible in the new VigiFlow user interface. The following information is migrated from old VigiFlow to new VigiFlow and will be stored but not visible in the interface for the time being:

<table>
<thead>
<tr>
<th>Old VigiFlow section</th>
<th>Old VigiFlow field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report info</td>
<td>additional documents held by sender (yes/no)</td>
</tr>
<tr>
<td>Test and procedures</td>
<td>more info available (yes/no/unknown)</td>
</tr>
<tr>
<td>Reactions</td>
<td>highlighted</td>
</tr>
</tbody>
</table>
2 Administrative and supportive information

2.1 Administrative information page

The administrative information page is an extra separate chapter for each report in old VigiFlow. It is accessed from the button administrative information that appears when a report is saved, sent or committed and from the administrative information icon in the list of reports. The administrative information is divided in different parts:

<table>
<thead>
<tr>
<th>Area of administrative information</th>
<th>Migration information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative comment</td>
<td>Migrated to Notes in new VigiFlow</td>
</tr>
<tr>
<td>Report is marked as ‘report under close surveillance’</td>
<td>This information will not be migrated</td>
</tr>
<tr>
<td>Information about external report receivers</td>
<td>External receivers for a report will not be migrated</td>
</tr>
<tr>
<td>Linked reports</td>
<td>Links between reports will be migrated</td>
</tr>
</tbody>
</table>

2.2 E2B import/export related information

Under the top menu ‘Tools’ tab in old VigiFlow, it is possible to import and export E2B-xml files. In this tab, information in the Upload statistics section and the Submission manager section, including uploaded acknowledgement logs, will not be migrated to new VigiFlow. Please contact the UMC you need access to this information after migration to the new VigiFlow.

The address book contains contact information of those who sent or received reports to/from your VigiFlow organization. An address book functionality is not yet available in new VigiFlow, but it is planned to be developed. Only sender/receiver information that is present on a report will be migrated to new VigiFlow. Any manually changed addresses or addresses connected to obsolete reports will not be migrated.
2.3 Other

Saved queries
In the *Search and Statistics* section in old VigiFlow, there was a possibility to save old queries in order to re-run the same query several times. The saved queries are not migrated to new VigiFlow.

Duplicate and replacement information
Nullified reports and the replacement reports will be migrated separately.
The link between them that informed about which was the current report and which was the replacement report will not be migrated.

Report note
Before ICSRs are committed there is a possibility to add a temporary Report note which was displayed as an icon next to the report. Any information saved in this Report note will not be migrated.