User Guide
for version 5.2
Consult release notes for updates in 5.3
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**Definitions and abbreviations**

ADR  Adverse drug reaction

Amend / Amendment  To update a committed report without adding new information about the case.

ATC-code  Anatomical Therapeutic Chemical classification system code

CIOMS  Council for International Organizations of Medical Sciences

Committed  A committed report is considered complete (for that version) and is available in the search and statistics database.

Drug code  A code used in WHO-DD to identify and group products according to their active ingredient(s).

E2B  The current international standard for ADR reporting developed by ICH, current version is E2B(R2).

eReporting  Web interface for primary reporters to submit ICSRs to VigiFlow

Follow-up  To update a committed report with new information about the case.

High Level Group Term (HLGT)  Used in MedDRA terminology.

High Level Term (HLT)  Used in WHO-ART and MedDRA terminology. Group terms of related or similar conditions, which are used for easy retrieval of information.

ICD  International Classification of Diseases

ICH  International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

ICSR  Individual Case Safety Report

Included Term (IT)  Used in WHO-ART terminology. Terms closely related to preferred terms. They are used to assist in finding the corresponding preferred term for proper coding of the adverse reaction reported.

Lowest Level Term (LLT)  Used in MedDRA terminology. Principal terms used for describing drug adverse reactions. The main terms used at the input side, but may also be used for output purposes.

MA holder  Marketing authorization holder

Mandatory field  A field where it is necessary to enter a value before the report can be committed. Note that several fields are only mandatory under certain circumstances.

MedDRA  Medical Dictionary for Drug Regulatory Affairs

NC  National Centre (for pharmacovigilance)

PDF  Portable Document Format, an open standard for electronic documents used by e.g. Acrobat Reader from Adobe Systems.

Preferred Term (PT)  Used in WHO-ART and MedDRA terminology. Principal terms used for describing drug adverse reactions. The main terms used at the input side, but may also be used for output purposes.

Primary source  The primary source is the person who reports the facts on an ICSR; the primary source is often called ‘reporter’.

PV Centre  Pharmacovigilance Centre

Reporter  See primary source.

RC  Regional Centre (for pharmacovigilance). In this document RC mainly refers to regional centres connected to VigiFlow.
| Sender | The sender is an entity that transmits the ICSR, it can be the same as the primary source (e.g. a doctor who sends a case to a National Centre) or different from the primary source (e.g. Pharmaceutical company that receives a case from a doctor and then sends it to the National Centre). The sender can also be the National Centre. In VigiFlow, the sender on the report information page refers to the entity that sent the case to the National Centre, and the sender on the assessment page is the National Centre itself. |
| Submission | A submission is a PDF or E2B export of one or several reports with an intended receiver. |
| System Organ Class (SOC) | Used in WHO-ART and MedDRA terminology. Groups of adverse reaction preferred terms pertaining to the same system-organ, and are for some purposes used at the output side. |
| UMC | Uppsala Monitoring Centre |
| VigiBase | The WHO global ICSR database. |
| VigiBase Online (VBO) | Former name of VigiFlow |
| WHO | World Health Organization |
| WHO-ART | WHO Adverse Reaction Terminology |
| XML | Extensible Markup Language, an open standard for information systems to share structured data, especially over the Internet. |
1 Introduction

VigiFlow is an Individual Case Safety Report (ICSR) management system developed and hosted by Uppsala Monitoring Centre (UMC). It is compatible with the ICH-E2B standard for electronic transmission of ICSRs.

1.1 System requirements

No client installation is needed to use VigiFlow since the system is web based and accessible over the Internet via an encrypted (https) connection.

The only requirement is a web browser, preferably Mozilla Firefox and a connection to the Internet. It is recommended to have an Internet connection of at least 1 Mbit/s, otherwise the system may be slow to use.

There are some additional requirements on the local computer to use the print report function and to export search and statistics results as PDF or Excel files. To view PDF files, Adobe Acrobat Reader is recommended and can be downloaded for free from Adobe (www.adobe.com). To view and analyse the Excel outputs, Microsoft Office Excel 2003 (or later) is needed.

1.2 VigiFlow user categories

Users of VigiFlow have different access rights depending on both the organization category and the user level.

<table>
<thead>
<tr>
<th></th>
<th>National PV org. Complete version</th>
<th>National PV org. Limited version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary level</td>
<td>Primary reporter</td>
<td></td>
</tr>
<tr>
<td>Intermediate level</td>
<td>Regional Centre</td>
<td>Regional Centre</td>
</tr>
<tr>
<td>Central level</td>
<td>National Centre</td>
<td>National Centre</td>
</tr>
</tbody>
</table>

The descriptions in this User Guide primarily describe the functionality for National Centres (NC) with the complete version, and their Regional Centres (RC; these terms are used by UMC and may differ from country to country). The limited access version is described below.

1.2.1 Limited access version of VigiFlow

The VigiFlow limited access version has been set up to facilitate for candidates and members of the WHO Programme of International Drug Monitoring to send reports to UMC even if they are not interested in the full report management
capabilities of VigiFlow. The following functionality is not included in the limited version of VigiFlow:
- the expanded filters of the list of reports (both reports under assessment and listing of committed reports)
- the Search and statistics tools (list of committed reports is available)
- the Administrative information chapter
- the Submission manager
- the Address book
- the E2B handling modules (both import and generate E2B)
- the eReporting system

As an example the top menu of the complete version (top) and the limited version (bottom) is shown here:

```
report handling  search and statistics  tools  exit
search and statistics  admin statistics  list reports
report handling  search and statistics  exit
list reports
```

### 1.3 New accounts

The contact person at each organization using VigiFlow can apply to UMC for new user accounts within that organization. Remember to also inform UMC about accounts that should be closed when staff leaves.

To find information on how to start using VigiFlow, prices etc, go to the UMC homepage at: [www.who-umc.org](http://www.who-umc.org)

### 1.4 Log in

Log in is done with a personal user name and password from the secure web-page: [https://adr.who-umc.org](https://adr.who-umc.org)

For security reasons, if a user fails to enter the correct password on five consecutive tries, he or she will be locked out of the system for one hour. If you have forgotten your password, talk to the person responsible for VigiFlow at your organization.

To log out, click the exit button in the top menu. A user that is inactive for 3 hours is automatically logged out.
1.4.1 Change password

At log in, it is possible for the user to change the personal password. To change the password, check the box change password and enter your user name and the original password, then click the button login or press enter.

On the page 'Change password' the original password should be entered again together with the new password you wish to use.

![Change password form]

The new password should be between 8 and 20 characters long and contain both non-numeric (e.g. a, b, c, #, !) and numeric (e.g. 1, 2, 3) characters to be accepted. Passwords are not case-sensitive (e.g. a, A are considered the same).

If you click on cancel, normal log in will continue and you should use the original password to log in next time. If you have entered a correct new password and click on change password, a confirmation will be given that your password has been changed. You will then continue normal log in and next time you log in the new password should be used.

The user name and the short name of the organization are always shown in the top right corner in the VigiFlow interface after log in.

1.4.2 Retrieve unsaved report

If a report was open when you last logged out or if your Internet connection failed while entering a report, the next time you log in, you will be asked if you want to retrieve the unsaved report.

![Welcome to VigiFlow]

If you click on retrieve, the unsaved version of the report will open. The backup of the report is made when you change between different pages in VigiFlow so any changes on the last page open will not be included. If you do not want to retrieve the report, you can click on skip and the list of reports page will open.
1.4.3 Language

Default language in VigiFlow is English and other available languages are Spanish, French and Russian. It is recommended to change the language directly after log in. It is possible to do at any time, but the user will be returned to the first page shown at log in after the change. The language is changed from the drop-down menu in the top left hand menu in the interface (see also Appendix 2 on page 113). The translations have mainly been made by VigiFlow users and have not been checked by professional translators.

1.5 Quick start

This section introduces the main functions of VigiFlow, including the menus and help functions in the system, how to enter a new report, how the flow of reports goes in the system and an overview of the search and statistical capabilities. The quick start section describes the menus for National Centre users. If you are a Regional Centre user or have the limited version of VigiFlow, not all of the options described here will be available for you (see section 1.2).

1.5.1 Menu overview and built-in help

The top row of the top menu is constant and contains report handling, search and statistics, tools and exit. In the example below report handling is chosen:

Under report handling it is possible to enter new reports and work with reports under assessment. To see reports under review choose list reports; choose send report to send an open report to another centre; and new report to add a new case. A version of a report is finalized by ‘committing’ it.

In the next example search and statistics has been chosen:

The committed reports will appear in this section. Choose list reports to find a specific committed report for e.g. follow-up, or viewing nullified and history marked reports. Choose search and statistics to perform more advanced searches and statistical analyses on the committed reports. The admin statistics section shows administrative information like profiles for counting number of reports with particular data and submission statistics.
Sometimes also a third row will appear in the top menu, as in the example below when a new report is started:

```
report handling    search and statistics    tools    exit
new report    send report    list reports
standard case    parent-child case
```

The top part of the left hand menu is always shown. The drop down menu to change language and the buttons for `contacts` and `user guide` are available for all users. The `give feedback` button is available for users at National Centre level. The rest of the contents of the left hand menu will vary depending on what is chosen in the top menu. The example on the left is from `search and statistics` ➔ `search and statistics`.

Note the possibility to `return to report` which will be shown when a report is open for editing while other tasks are performed.

The appearance of the left hand menu while a report is entered or edited is shown e.g. under section 1.5.2 Enter a new report.

There is a built in help function next to some fields; move the cursor over the icons in the interface to read the information:

- 🟢 – provides field specific help,
- ⚠️ – warns of e.g. mandatory fields, indicate serious reports
- ✔️ – an error in entered data has been found, the user will not be allowed to continue entering the report until the error has been corrected.

On some pages there is an expand/hide function. This is located as a button at the bottom of the section that can be expanded.

```
expand  ✄️ hide  ✄️
```

When the ‘expand’ button is clicked, additional fields are shown which will be hidden again if ‘hide’ is clicked. The button text will be shown in **bold text** if any of the hidden fields contain information and in **bold and red text** if there are errors in the hidden information.

### 1.5.2 Enter a new report (ICSR)

From the top menu, choose `report handling` ➔ `new report`; you will then be given the choice between entering a `standard case` or a `parent-child case` (the latter used primarily when a foetus has suffered the reaction after the mother has taken the drug).

The left hand menu while entering a new report is shown to the left. To move to the next page as shown in the menu, either click in the menu or click on `next` at the
The bottom of the page. The first page shown is the report info page. Enter known data in the fields given here and on the following pages; it is important to capture all known data into the correct fields, but if there is no information regarding a specific section – for instance tests and procedures – this can be skipped completely.

The page overview shows the entered data and if there are any errors on the report or missing information in mandatory fields. This page is also a good place to check that all information on the case has been captured correctly.

Do not forget to save the report regularly. While saving, it is also possible to add or edit the report comments and to generate a report Id (unless the report already has an Id).

When a report has been opened for editing, it will be seen as checked out for all other users on the list reports page. To make the report available for everyone again, choose report handling → list reports in the top menu. Find the report in the list and click on the check in icon next to the report.

Until all mandatory fields in the report are filled in, it is considered incomplete and cannot be committed to the Search and Statistics database. Note that some mandatory fields can appear or disappear at certain conditions, e.g. patient initials are mandatory on spontaneous reports but not on literature reports or if the sender is a pharmaceutical company.

The minimum information you have to enter on a spontaneous report for it to be considered ‘complete’ by VigiFlow is the following six mandatory fields:

- report title
- patient initials
- patient age (either date of birth, age at time of onset or age group)
- onset date of reaction (year only)
- a reaction term
- a drug name

Two more fields are mandatory (three on parent-child cases); these are automatically filled by VigiFlow, but should be edited if they do not agree with the case being entered:

- date first received (i.e. received at the National Centre) is pre-filled with “today’s date”.
- one of the primary source fields family name, institution, postal code, country of reporter, reporter qualification, literature reference or study name; of these country of reporter is pre-filled with country of user
• on parent-child cases one of the parent characteristics fields: **parent date of birth**, **parent age**, **parent initials** or **parent sex**; of these, parent sex is pre-filled as “female”.

For overviews of the VigiFlow interface, see Appendix 2 starting on page 113.

1.5.3 The report flow

New reports can be entered by all user levels (see section 1.2). The only necessary level is the National Centre, which can enter reports, commit them and perform Search and Statistics. Sending an ICSR to UMC is optional.

Below is a description of the steps numbered in the figure.

The Regional Centre can create a new ICSR and send (1) it to the National Centre. When the National Centre considers the report to be complete they can (2) commit the report to the Search and Statistics database. National and Regional Centres can (3) make statistical analyses and advanced searches of committed reports. While committing a report the National Centre can also choose to send (4) a copy of the ICSR to UMC to be included in the WHO global ICSR database, VigiBase. (5) Further searches and comparison with international data can be made using VigiLyze.

Steps (1) and (2) can also be performed in reverse, with e.g. a report sent from the National Centre to a Regional Centre or when new information makes it necessary to follow-up a committed report.

As mentioned above, only the National Centre level is necessary since also National Centres as well as Regional Centres can enter new reports. The Primary Reporter level mentioned in section 1.2 is not shown – it is a separate module and ICSRs entered by e.g. patients in this module will appear at the National Centre level in VigiFlow.
1.5.4 Send reports between Regional and National Centres

To send a report to another centre within the national VigiFlow organization either click on send report in the top menu of the open report or click on the send icon in the list of reports (the latter is only available for Regional Centres). First you will be taken to the Result from verification page, where information about missing information in mandatory fields may be given together with the report Id and report title. You can send incomplete reports to other centres. If you send a report without a report Id, one will be generated for the report. Secondly, you will see a list of all available centres within your organization – Regional Centres has the option to “send the report to central assessment” which is the National Centre. When a report has been sent to another centre it will not be available for editing at the centre it was sent from, unless it is sent back. Tip: use the report comments field to communicate with the recipient about the report.

1.5.5 Commit reports

Only National Centres can commit reports. A committed report will be included in Search and Statistics, therefore only complete reports can be committed. To commit a report, click on send report \(\rightarrow\) commit report in the top menu of the open report, or click on the commit icon in the list of reports. The Result of verification page will first appear, and on this page the choice to Send the report to the Uppsala Monitoring Centre when committed will also be given for National Centre users.

1.5.6 Edit a committed report

If a committed report needs to be updated, select search and statistics \(\rightarrow\) list reports in the top menu and find the report in the list of committed reports by searching for the report (see section 5.1). When the report is found, click on the follow-up/amend link to open the report for editing (only National Centres can do this). When the updated report is committed again, you will be asked to answer if the update is a follow-up or an amendment. See section 5.2 for more information.

1.5.7 Search and statistics

Only committed reports will be included in the Search and Statistics tools.

Under search and statistics the following profiles for advanced searches and statistical analyses are available:

- Report listing
- CIOMS line listing
- Summary tabulation
- Drug reaction profile
- Summary of products
- Summary of reported ADRs
- Summary of reported drugs

See section 8 for more information.

Under **admin statistics** the following profiles are available:

- Count profiles
- Submission statistics

See section 8.4 for more information.

### 1.5.8 Tools – exchange reports with external contacts

The top menu **tools** collects the main functions to send and receive reports with external contacts (see section 7 for more information).

Under **E2B handling** it is possible to export and import reports in E2B format, and uploaded files are listed in an upload statistics module. In the **address book**, information about the external contacts is kept; these are the organizations sending or receiving reports. The **submission manager** tracks all submissions of reports to external contacts both by E2B files and PDF file/paper.
Enter a new report

This chapter contains instructions on how to create a new Individual Case Safety Report (ICSR) and make an assessment of the case.

Follow the left hand menu, from report info to overview, to enter a report. Any time during the process you can save (see section 2.12) or print (6.1) the report. A saved report will be found in the list of reports (4.1) next time you log in. If you forget to save, or your Internet connection fails in the middle of entering a report, next time you log in you will be asked if you want to retrieve (1.4.2) your unsaved report.

Open a new report

A new report can either be standard or parent-child case. The differences between these types of cases are explained in section 2.1.2. If the user is working at a Regional Centre, a few fields look different; these are described in section 2.1.3.

Standard case

Select new report → standard case in the top menu. The first page that opens is the report info page (see section 2.2).

Parent-child case

A parent-child case is mostly the same as a standard case (see sections 2.2 to 2.12), except for the fact that there are two persons involved, which require additional fields. The most common parent-child case is when a mother takes a drug and her foetus or child experiences the adverse drug reaction. Below, the differences to a standard case are explained.

1) To open a new parent-child case, select new report → parent-child case from the top menu.

2) On patient page there are different tabs representing the two persons for the section patient characteristics.
3) When you have entered Patient characteristics (see section 2.3.1), click on the parent tab and add information under Parent characteristics. Note that one of the fields year in date of birth, parent age, parent initials or parent sex are mandatory, one of them has to be filled in.

4) The relevant medical history page (see section 2.5) and the relevant past drug therapy page (see section 2.6) also have different tabs for patient and parent.

5) On the drugs page (see section 2.8), it is possible to enter information both about the patient route of administration and the parent route of administration to the drug information.

6) Complete the report by following the instructions for a standard case as instructed in section 2.2 to 2.12.

2.1.3 Regional Centre

Regional Centre users do not see the date first received or the date receipt most recent info at the top of the report info page the way it is described in section 2.2.1. Information regarding the specific Regional Centre and when the report was received at the Regional Centre is found in the section Information on sender. What this section looks like for a user at a Regional Centre is shown below.
1) The **type of sender** is pre-filled.

2) The **date first received at regional centre** will be prefilled with “today's date” but this should be edited if the report arrived earlier.

3) The **sender** is the Regional Centre and the **person responsible** will be pre-filled with the name of the VigiFlow user.

4) The **regional centre report Id** can be used if another Id system is used at the Regional Centre; entering the local Id could then make it easier to identify cases.

The rest of the data entry is the same as described in section 2.2 to 2.12.

### 2.2 Report info page

#### 2.2.1 Report information section

1) The **date first received** is a **Mandatory field**. This date should be the date the ICSR arrived at the National Centre. Note: the date cannot be edited after the report has been committed the first time. Below is how the date fields look on a report that has been opened for editing after it has been committed:
Date receipt most recent info can be edited when the report is committed again, see section 5.2.1.

2) Fill in a report title of choice. (This is a Mandatory field.) It is recommended to have a standard for the report titles; however, this is for the National Centre to decide since the titles are only used within VigiFlow.

3) Select the appropriate type of report.

Mandatory field

4) Enter if the reaction was serious or not. If you select 'yes', it is mandatory to also select one or more reason for seriousness to explain why the report is serious.

5) The country of occurrence (where the adverse drug reaction occurred) and the country of primary source are given automatically as country of user, but can be changed if needed.

6) If 'yes' is selected for additional documents held by sender, the free text field list of documents will appear.

2.2.2 Information on sender

The sender in VigiFlow is the organization or person that sent the ICSR to the National Centre; so a Regional Centre is a sender when they enter an ICSR in VigiFlow. Market Authorization Holders, health professionals etc that send paper (or other format) cases to the National Centre are also senders. Note that the sender can be the same as the primary source if the primary source sent the case directly to the National Centre. Other sender information can also be added on the administrative information page, see section 3.2.

1) Select type of sender.
2) The **date first received at sender** is the date the ICSR arrived at the sender. This field is differently named for Regional Centres, see section 2.1.3.

3) If **type of sender** is ‘regional pharmacovigilance centre’, the fields **sender**, **person responsible** and **regional centre report Id** will also be available:

![Image](image)

This is what the same fields look like at the National Centre when the report was created at a Regional Centre:

![Image](image)

Fill in the name of the **sender** if not given automatically. The **person responsible** is given automatically as the name of the user that created the case report in VigiFlow, but can be changed if needed. The **regional centre report Id** can only be filled in by a Regional Centre (see 2.1.3) and cannot be edited by the National Centre.

4) To provide **Other case identifiers in previous transmissions**, click the **add new identifier** button. The fields **source** and **case identifier** will appear. See figure
5) A worldwide unique number will be generated automatically (when a report Id is generated) unless one is entered. See the helptext (the ? icon by the field) for further instructions.

2.2.3 Information on primary source(s)

The primary source is the person that first reported the facts; it can be the consumer (patient) or the doctor of the consumer for instance. Different countries allow reports from different primary sources. In this section the primary source’s contact information should be entered. A field for literature reference is also available here; this should only be used if the literature article is the primary source.

If a literature article is used for supporting information, it can instead be entered in the references or the sender’s comments fields on the assessment page. It is possible to enter more than one primary source by clicking on the add primary source button. It is possible to sort added primary sources; only the top primary source is included on PDF printouts. (For each primary source it is mandatory to add information on one of the fields family name, institution, postal code, country of reporter, reporter qualification, literature reference or study name.)

It is possible to save primary sources so that the entered information can be reused on other reports with the same primary source. To be able to save as primary source, the minimum information needed is either given name, family name and institution or literature reference, or study name. Click on the save primary source button when the information has been entered.

To reuse a saved primary source click the find primary source button and add the relevant source. Note that saved primary sources are personal and not available to other users.
If the **type of report** (see point 3) in section 2.2.1 is a ‘report from study’ there will also be fields about the study to fill in under the primary source section:

When the **report info** page is filled in with the information you have, click the **next button** or on **patient** in the left hand menu to continue to the **patient page**.
2.3 Patient page

2.3.1 Patient characteristics

The patient page contains fields about patient characteristics and death related information (see section 2.3.2).

![Patient characteristics](image)

**Mandatory field**

1) The patient age can be entered as either date of birth, age at time of onset or age group. *(This is a mandatory field. You have to enter either patient birth year, age at time of onset or age group.)* The age at time of onset will be calculated automatically if date of birth and onset date of reaction (on the reactions page) are completely filled in. Age group will be calculated automatically, when age at time of onset is filled in. Otherwise it can be entered manually. If no information about patient age is known, it is possible to enter age group 'unknown'.

**Mandatory field**

2) Enter the patient initials. *(This is a mandatory field.)* Tip: instead of entering the initials it is possible to write ‘privacy’ or ‘unknown’.

*Note: These fields are not mandatory if type of report is ‘literature’ or if sender is ‘pharmaceutical company’.*

3) If the patient is female, the date of last menstruation can also be entered.

4) The additional patient info button should only be used by participants in the WHO Post-Marketing Surveillance Network on Pre-Qualified vaccines. When the button is clicked, additional fields for vaccine report data are added. Data entered in these fields will not be exported to the external E2B file or to VigiBase; it will only be visible in the internal E2B file and the PDF print. The fields are not E2B compatible and should be removed by clicking on the trash icon in the section if they are not used.
5) The patient characteristics section can be expanded to show more fields.

2.3.2 **Death related information**

*Death related information* is primarily entered for serious cases when the patient died (filled in on report info page under reason for seriousness; see point 4) under section 2.2.1).

To fill in *death cause* you have to click on the link *search term* to enter a term. For more information on how to search for ICD-10 term (by word or by code) see section 9.2; MedDRA users see section 9.4. The same is valid for the field *death cause after autopsy* which will appear if ‘yes’ is selected for was an autopsy performed.
2.4 Tests and procedures page

Data about tests can be added as free text, structured information in tests or both.

2.4.1 Results from tests and procedures – free text

The free text field for tests and procedures is a common field for all tests.

<table>
<thead>
<tr>
<th>Results of tests and procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>results of tests and procedures - free text</td>
</tr>
</tbody>
</table>

2.4.2 Tests

To add structured information about a test, click on the add new test button. Each added test can contain test results from many dates. To add a new test with the same test dates as another test, click on copy dates in that test. It is also possible to edit or delete added tests. Test results that are outside the specified range are shown in italic text (see figure below).

Mandatory field

1) For test type you have a choice to either:
   a) Select the test type from the drop down menu.
   b) Or, if the test type in not included, write the name of the test in field test type (free text).
MedDRA users will have a search field to add a MedDRA term as test type instead, see section 9.4 for information on how to search for MedDRA terms.

(This is a Mandatory field. You have to give a test type for all added tests.)

2) For the low/high range of normal values for the test type you have a choice to either:

a) Check the box use default values and the low/high range values and test unit will be given automatically for some of the tests included in the test type drop-down list. The default values have been provided by Swissmedic. This function is not available for MedDRA users.

b) Or, enter low/high range manually. If there is only one normal value, enter it in both fields. If the normal value is ‘higher than’ or ‘lower than’ a specific value, enter the value in the left or right field, respectively and leave the other field blank. Select test unit from the drop-down list or write a test unit of choice in the free text field.

3) If you need to add more results to the same test, enter number of results to be added in the field at the bottom and click on add new result. (A result is a Mandatory field for all added results.) Note that it is possible to write the text values ‘positive’ and ‘negative’ in the result field.

2.5 Relevant medical history page

Relevant medical history can be entered as free text, structured data or both.

2.5.1 Relevant medical history – free text

The free text field for relevant medical history is a common field for all relevant medical histories.

2.5.2 Relevant medical history – structured

Click on the add relevant medical history button for each medical history you want to add structured information about. Each added medical history will appear in a list. From this list it is possible to sort, edit and delete the added medical histories.
errors or warnings on a particular medical history will be shown as a warning icon in the list.

1) When the button *add relevant medical history* is clicked, the field for adding structured information opens.

![Relevant medical history form](image)

2) Fill in the **Relevant medical history**. To enter a term, click on the link *search term*. For more information on how to search for ICD-10 term (by word or by code) see section 9.2; MedDRA users see section 9.4. *(Terms are mandatory fields on all added Relevant medical history.)*

After clicking on the *search term* link here it is also possible for ICD-10 users to select a term from a *Often used terms* list. This is not a complete list; it will only display terms that have occurred frequently until today’s date. Click on the *add to report* link to add a term.

3) If *continuing* is ‘no’, there will also be an option to fill in *end date*.

### 2.6 Relevant past drug therapy

A relevant past drug therapy is added by clicking on the button *add past drug therapy*. Several past drug therapies can be added and they will all appear in a list. In this list it is possible to sort, edit and delete all added relevant past drug therapies. Any errors or warnings on a particular past drug therapy will be shown as a warning icon in the list.
2.6.1 Therapy

Mandatory field

1) The drug name is added as free text. *(The drug name is a mandatory field for each added relevant past drug therapy.)*

2) The indication is entered as an ICD (or MedDRA) term. See section 9.2 on how to search for ICD-10 term; MedDRA users see section 9.4.

3) The reaction is entered as a WHO-ART (or MedDRA) term. See section 9.3 on how to search for WHO-ART term; MedDRA users see section 9.4.

2.7 Reaction page

More information about the reactions page can be found in Appendix 2, see page 115.

The reaction page is divided into a free text section for all reactions and a repeatable section for structured information on each reaction.

2.7.1 Reaction(s)/event(s) – free text field

The free text field reporter's comments is a common field for all added reactions/events. This field should be used for comments from the primary source that are relevant for all reactions.

2.7.2 Reaction / event

Mandatory field

Click on add new reaction for each reaction or event for the case. It is mandatory to have at least one reaction added to each report. Each added reaction/event will be shown in a list. In this list it is possible to sort, edit and delete added reactions/events. The delete icon in this list will delete the reaction and all information added with the reaction, compare with the delete icon by an added
reaction term, see point 1) below. Any errors or warnings on a particular reaction will be shown as a warning icon in the list. The reaction that is shown in bold text is open for editing below the list.

The primary reaction should be moved to the top of this list. (The primary reaction is used in e.g. CIOMS line listing, see section 8.3.2.)

To add a new reaction with the same information as an already added reaction, click on copy in the upper right corner when the relevant reaction is displayed. All information entered about the reaction (except for relatedness) will then be copied into a new entry.

1) A reaction term is a Mandatory field for each reaction on the report. Use the search functions to find and select a reaction term. See section 9.3 on how to search for WHO-ART term; MedDRA users see section 9.4.

An added term can be removed by clicking the trash icon next to the term, note that all other information added (like dates and outcome) will not be affected.

For WHO-ART users there is also a possibility to suggest new WHO-ART term if the dictionary does not contain a term that matches the described reaction, for instructions see section 9.5.1.
2) The field **reaction/event as reported by primary source** is a free text field to add the original wording about the specific reaction (See section 2.7.1 for other comments from the primary source).

**Mandatory field**

3) Enter **onset date**. *(Year is a Mandatory field except if the type of report is ‘literature’ or the sender is ‘pharmaceutical company’)*. It is also possible to enter the exact time of the reaction by using the fields for hours and minutes. If complete **onset date and end date** are entered, but no hours and minutes, the **duration** will be calculated automatically; click on the calculator icon to fill the field. If **onset date and end date** are incomplete or identical, a known **duration** can be entered manually (e.g. 1 day, continuing, 20 minutes).

4) Other fields are **treatment of reaction, outcome of reaction** and highlighted. Note that some non-E2B compatible values for outcome of reaction were removed with the release of VigiFlow 5.0 in November 2012. Reports entered before this can keep the old values (‘fatal – reaction may be contributory’ and ‘fatal – unrelated to reaction’) unless the report is manually edited to one of the other values.

5) The **vaccine data section** button should only be used by participants in the WHO Post-Marketing Surveillance Network on Pre-Qualified vaccines. When the button is clicked, the additional field **AEFI category** is added. Data entered in this field will not be exported to the external E2B file or to VigiBase; it will only be visible in the internal E2B file and the PDF print. The field is not E2B compatible and should be removed by clicking on the trash icon in the section if it is not used.

6) Under the expand button there are fields for **time interval between suspect drug administration and reaction onset**.

### 2.7.3 Relatedness of drug(s) to reaction(s)

The section **Relatedness of drug(s) to reaction(s)** will appear on the reactions page as well as on the drugs page. This is where the actual causality assessment is performed. It is described in section 2.9.
2.8 Drugs page

More information about the drugs page can be found in Appendix 2, see page 116.

Both suspected and concomitant drugs can be added to the report. It is mandatory to add at least one suspected drug (or two interacting drugs) on each report.

All added drugs are listed at the top of the page. In this list it is possible to sort, edit or delete all added drugs. The delete icon in this list will delete the drug and all information added with the drug, compare with the delete icon by an added drug name, see point 1) in section 2.8.1 below. Any errors or warnings on a particular drug will be shown as a warning icon in the list. The list of suspected drugs also includes interacting drugs. The drug that is shown in bold text is open for editing below the lists.

To add a new drug click on the button add new drug under list of suspected drugs or list of concomitant drugs. It is possible to later change an added drug, from suspected drug to concomitant drug, or vice versa by clicking on the link change to concomitant/suspected next to the field characterization.

To add a new drug with the same information as an already added drug, click on copy in the upper right corner when the relevant drug is displayed. All information entered about the drug (except for the relatedness) will then be copied into a new entry.
### 2.8.1 Suspected drug

1) A **drug name** is a *Mandatory field* for each drug on the report. Clicking on *search drug* will take you to the *Search for drug* page where you can use several search criteria to find a drug name to add to the report. See section 9.1 on how to search for drug. On the Search for drug page there is also the possibility to suggest a new drug by clicking on the button *suggest new drug* if there is no drug in the WHO Drug Dictionary that matches. See section 9.5.2 for instructions.

2) After a drug name has been added from the WHO Drug Dictionary, it is possible to populate drug information fields with data from the WHO-DD by clicking on the icon. The following five fields will be populated (if data is unavailable for these fields in WHO-DD for the chosen drug, the fields will be cleared or entered with ‘not specified’/ ‘unspecified’):

---

**Mandatory field**

- **drug name**: This is a mandatory field for each drug on the report. It can be searched for using the *search drug* button.
- **characterization**: Options include: *Suspect, Interacting, Change to concomitant*.
- **suspected ingredient**: This field is mandatory and must contain the name of the suspected ingredient.
- **pharmaceutical form**: Options include: *LIQUIDS, DROPS*.
- **obtain country**: Options include: *Netherlands*.
- **batch number**: This field can be filled in if available.
- **authorization number**: This field can be filled in if available.
- **authorization country**: Options include: *Netherlands*.
- **authorization holder**: Options include: *Allergan BV*.

---

32 (120)
Note that if the drug name is removed by clicking on the trash icon next to the name, only the field active substance(s) will be cleared, the other fields will have to be cleared manually or overwritten by adding a new drug and clicking the populate drug information fields icon again.

3) Select characterization. If interacting is chosen there must be at least one more drug added to interact with.

4) To enter an indication, click on the search term link. See section 9.2 on how to search for ICD-10 term (by word or by code); MedDRA users see section 9.4. If no suitable term is found, write the indication in the free text field additional information.

5) If a rechallenge was performed, fill in the field did reaction recur after rechallenge. To specify which reaction recurred, see section 2.9 on Relatedness of drug(s) to reaction(s). If no rechallenge was performed (or if you do not know), leave the field blank.

6) In field is the ADR adequately labelled, select ‘Yes’ if the reaction linked to the drug is adequately described in the product information for the reporting country, otherwise choose ‘No’. If you do not know – leave blank. More information on the labelling can be entered in the free text field additional information.

7) The vaccine data section button should only be used by participants in the WHO Post-Marketing Surveillance Network on Pre-Qualified vaccines. When the button is clicked, additional fields for vaccines are added to the report. Data entered in these fields will not be exported to the external E2B file or to VigiBase; it will only be visible in the internal E2B file and the PDF print. These fields are not E2B compatible and should be removed by clicking on the trash icon in the section if they are not used.

8) A specific frame collects drug information fields like batch number and authorization holder.
9) All the dosage and duration fields are also collected in a frame. The administered **dose** can be entered here. In the example below, the patient has taken 500 milligrams 2 times per day.

One dose every second day, is entered as: ‘1’ in **doses in interval** and ‘2 day(s)’ in **definition of interval**.

More fields about the dosage can be found under the **expand** button at the bottom of the page. These include a free text field for dosage information that is impossible to enter in the structured fields.

10) If complete **start** and **end of administration** dates are entered, **duration** will be calculated automatically. Click on the **calculator icon** to fill the field. If start and end dates are incomplete or identical, you can manually enter a known **duration** (e.g. 1 day, 5 months, long term, treatment continued).

### 2.8.2 Concomitant drug

The fields for entering a concomitant drug are almost the same as for a suspected drug. The only fields that differ are **suspected ingredient** and **did reaction recur after rechallenge** which are **not** present for concomitant drugs.

### 2.8.3 Relatedness of drug(s) to reaction(s)

The section **Relatedness of drug(s) to reaction(s)** will appear on the **drugs** page as well as on the **reactions** page. This is where the actual causality assessment is performed. It is described in section 2.9.

### 2.9 The causality assessment

The **Relatedness of drug(s) to reaction(s)** section is where the causality assessment is entered. The section appears on both the **reactions** and **drugs** page and will reflect the reactions and drugs entered on those pages. In the made-up example below the reactions ‘Dyspepsia’ and ‘Nausea’ and the drugs ‘Acetylsalicylic acid’ and ‘Paracetamol’ have been added.
In this section, there are fields for causality and rechallenge (the field for rechallenge will only appear if you have answered ‘yes’ for did reaction recur after rechallenge on the drugs page). You have the possibility to remove and add relations between drugs and reactions. To remove a relation, click on the trash icon.

How likely is it that the reaction occurred due to the patient taking this drug?

This is the actual causality assessment!

1) Select the appropriate causality, from the drop-down list. VigiFlow is using the WHO causality assessment.

Note that the values for causality assessment differed slightly before the release of VigiFlow 5.0 in November 2012*; reports entered before this will keep the differing values unless the value is manually changed into one of the current values.

2) Select ‘Yes’ if the specified reaction recurred after a rechallenge of the drug, otherwise select ‘No’. (This field only appears if you have answered that the reaction recurred after rechallenge on the drugs page.)

* Comparison of old and new causality assessment values:

<table>
<thead>
<tr>
<th>Until VigiFlow 4.3</th>
<th>From VigiFlow 5.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain</td>
<td>Certain</td>
</tr>
<tr>
<td>Probable</td>
<td>Probable/Likely</td>
</tr>
<tr>
<td>Possible</td>
<td>Possible</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Unlikely</td>
</tr>
<tr>
<td>No relationship</td>
<td>–</td>
</tr>
<tr>
<td>Not (yet) assessed</td>
<td>–</td>
</tr>
<tr>
<td>–</td>
<td>Conditional/Unclassified</td>
</tr>
<tr>
<td>Not assessable</td>
<td>Unassessable/Unclassifiable</td>
</tr>
<tr>
<td>Unknown</td>
<td>–</td>
</tr>
</tbody>
</table>
If the report is an import, the sender's relatedness will also be displayed:

### Relatedness of drug(s) to reaction(s)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rash</th>
<th>Red eye</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image" alt="" /></td>
<td><img src="image" alt="" /></td>
</tr>
</tbody>
</table>

**2.10 Assessment page**

The actual causality assessment takes place on the **reactions page** or on the **drugs page** under the heading **Relatedness of drug to reaction** (see section 2.9). On the **assessment page** you can add additional information about the case:

1) **Case narrative**: this is the field for the detailed description of the case as received from the **primary source**.

2) **Sender's comments**: enter any discussion or alternative diagnoses from the sender; note that in this section, the National Centre (as well as Regional Centres) is considered a sender. If more than one sender has added comments, it is important to specify who entered which comment. The field is included in line listings (see section 8). If the case is a patient safety report*, you can enter the text [PATIENT SAFETY] (including the square brackets) to this field.

3) **Sender's diagnosis**: enter the sender's diagnosis by clicking on the **search term** link. For this field also, the National Centre is considered a sender. Regional Centres can add their diagnosis as a suggestion to the National Centre. See section 9.3 on how to **search for WHO-ART term**; MedDRA users see section 9.4. Note that WHO-ART users entered **sender's diagnosis** using ICD-10 terminology before the release of VigiFlow 4.3 in April 2012; reports entered before this will keep their entered ICD term unless the report has been manually updated and the ICD term changed into a WHO-ART term.

4) **Imported sender's comments and diagnosis**: this field is only available on imported reports. Here the sender's comments and sender's diagnosis from the entity that sent the report to the National Centre will be found.

5) **References**: here you can enter any references or similar cases that you know of.

* **Explanation of 'Patient Safety report’**: Patient Safety reports generally have some aspect of the way a drug has been used as the most likely reason for causing an adverse event. Overdoses, inadvertent re-exposure and interactions are a few examples of immediate causes, but some
method of root-cause analysis to determine contributory causation (e.g. unclear labels, wrong route of administration, lack of training, distraction) is necessary. Such information should be included as free-text narrative. A WHO Programme Patient Safety Pilot study has been conducted, with the aim of gaining more information on avoidable drug related events. Several Programme member countries have expressed their interest in continuing to register reports that have a ‘patient safety focus’.

2.11 Overview page

To see an overview of all information entered in the report, click on overview in the left hand menu.

If there is information missing in mandatory fields or errors in the report, text in red will appear to the right on the page.

2.12 Save report

You can save a report at any time during the process of entering information, and resume later. The report does not have to be complete in order to be saved. If you have forgotten to save the report before exiting VigiFlow, see section 1.4.2 on how it can be retrieved next time you log in.

1) Select save from the left hand menu. In the field Report comments you can write your comments on the case (optional). This information can later be found in a green note (the comment icon) next to the report title, in the list of reports (select report handling \(\rightarrow\) list reports in the top menu). The report comment will also be included on internal PDF printouts of the report (see section 6.1). Note that the comment will be deleted when the report is committed and cannot be restored.

2) There is an option to Generate report Id by checking the box. An Id will be generated automatically if the report is sent to another centre or committed.

Note! It is not possible to completely delete a report after generating a report Id, but a National Centre can nullify the report (see section 4.5 for more information).
3) Click the **save** button. A message saying *The report was successfully saved* should be shown together with the **Report Id** if an Id has been generated. On the confirmation page there are also links to go back to the report, go to report listing (see section 4.1) and to go to the administrative information (see section 3) for the report.

4) Next time you log in you can find the report in the list of reports under assessment (see section 4.1). Find the report in the list and click on the **edit** icon to open and continue working on the report.

5) If the report should be made accessible for other users you have to **check in** the report after saving it. Go to the list of reports under assessment (see section 4.1), find the report and click on the **check in** icon.
3 Administrative information page

The administrative information page is an extra separate chapter for each report. 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 (both ‘under assessment’, see 4.1 and ‘listing of committed reports’, see 5.1).

3.1 Administrative and report data

The administrative and report data section gives the status of the report (regional assessment, assessment, committed, historical, nullified). It also shows the receive date (date first received) and the receipt date (date receipt most recent info). These two dates will usually be the same unless a follow-up has been made of the case. If the report has been imported (see section 7.1.2), the sender’s receive and receipt dates from the imported file will also be shown. Reports set under close surveillance can be searched for in the lists of reports pages (see section 4.1 and 5.1). Changes to the administrative comment and close surveillance tick box are saved by clicking on save this section.

![Administrative and report data](image)

3.2 Sender information

The sender is the organization that sent the report to the VigiFlow user. Reports can only have one sender. On imported reports the sender will be added automatically and the field will not be editable.

![Sender information](image)

On manually entered reports, a sender can be added. Senders already in the Address book (see section 7.2) can be added to the report. Note that reports with a sender added cannot be deleted, only set as historical or nullified (see section 4.5).
To add a sender manually:

1) Either click on *get sender* to get a list of all contacts in the Address book, or write the name or part of the name in the field before clicking on *get sender*.

2) Press the link for the wanted sender in the list.

3) You will then be prompted to enter the *sender's report number*. This number will be used to look for pre-existing reports (see section 4.1.1).

4) Click *save this section* to save the sender and the added report number.

When a sender has been manually selected and saved, the field will look like the example below. The sender can be removed by clicking on the trash icon 🗑️.

---

3.3 Information about external report receivers

External report receivers are added from the Address book (see section 7.2). A report can have many receivers, and a report with a receiver added will appear in the Submission manager (see section 7.3.1) for sending to the added receiver. To add a receiver, either click on *get receiver* to get a list of all contacts, or write the name or part of the name in the field before clicking on *get receiver*. Then press the link for the wanted receiver in the list.

In the example above, the report has three receivers added and the report has been submitted to the first receiver. The other receivers can be removed from the report e.g. if they have been added by mistake, by clicking on the trash icon 🗑️.

Any receiver that has received a report once will reappear as receiver again (on the administrative information page and in the submission manager) if the report is updated as a follow-up, amendment—to be resent, or if the report is nullified.

However, if the report was sent by mistake the first time it is possible to make the
report not reappear by clicking the disable future submissions icon. When the function to send future updates of a report is disabled, this icon will be shown instead:

### 3.4 Linked reports

A report can be linked to other reports within VigiFlow, and this information will be included in E2B exports of the report. An added link will point from that report to the added report. In the list all linked reports will appear, both those pointing from the report and those pointing to the report.

In the example below, the first report in the list (2008-00059) has been linked from the current report (2008-00063), the arrow in the list points to the report Id. The other reports (2008-00062 and 2008-00003) have been linked to the current report from those reports, and the arrow in the list points from the report Ids. These two reports have also been linked to each other, which is also visible in the list.

![Linked reports](image)

To link a report, write the report Id of the report you wish to link to in the field and click on get report. If the report Id is valid, it will appear with a link to select the report. The link will appear under “Linked reports” on both reports.

Information about linked reports will also appear on the view page of the reports (see section 4.1.2 and 5.1.1).

### 3.5 Duplicate and replacement information

This section will only appear on reports that have this kind of information and it is not editable. In the example below, the report 2008-00064 has been nullified (see section 4.5.3) and the current report (2006-00062) has been set as a replacement. The arrow points from the report Id.

![Duplicate and replacement information](image)

In the nullified report the opposite is shown; the arrow points to the report Id:
Note that the status of the report and the reason for nullification is shown in the Administrative and report data section (3.1) in the nullified report:

This information will be shown for all types of nullifications and history markings.

For information on how to nullify (or history mark) a report, see section 4.5.

3.6 Replaced reports

This section is only available if there are replaced reports to view.

Replaced reports are other versions of the same case that have been imported and replaced from Updates of previously received cases described in section 5.3. It is possible to view the replaced reports from the list of Replaced reports. Note that if each version of the case has its own audit trail accessible from the view.

The title of reports imported after the release of VigiFlow 5.2, will have the format "Import: [first reaction], [first drug]."
4

Manage reports under assessment

This section describes functions available for handling reports under assessment, i.e. reports that are currently being worked with.

4.1

List reports (under assessment)

The list of reports (under assessment) page is also shown in overview on page 113.

The List reports (under assessment) page is the first page that opens at log in (unless a report was open at log out from the previous session; see section 1.4.2).

To find the page from anywhere else in the system, choose report handling  list reports in the top menu. Note that there are two list reports in the top menu, one under report handling (for reports under assessment, described in this section) and one under search and statistics (for committed, nullified and history marked reports, see section 5.1).

The list reports (under assessment) page consists of several sections and the functionality differs between National Centres and Regional Centres. What the page looks like for Regional Centres is shown in section 4.1.6. The section Reports under regional assessment is only available if there are Regional Centres connected to the national VigiFlow organization. Here National Centres can see the list of reports located at the Regional Centres, without accessing them in any way.

For the National Centres Reports under central assessment is the main section, here all reports that are in the process of data entry and assessment at the National Centre are listed. There are two more sections only available for National Centres, but these are only shown if they contain any reports. First, there is a section for Reports with suggested ADRs and/or drugs from the UMC, where reports with uncoded drugs or WHO-ART terms will appear with suggestions from UMC.

For more information on how to accept or reject these suggestions see section 4.2. Second, is the section Updates of previously received cases, which lists reports that need to be updated since a sender has sent a new version in E2B format of the same case. This section will only show updates that have been imported (see section 7.1.2). A description of the functionality is found in section 5.3.

National Centres may also apply search criteria to find specific reports. In the figure below, all search criteria are not shown since the expand button has not been clicked:
1) To get an overview of all reports under assessment, leave the search fields blank or click clear form to reset the filters, select include reports under regional assessment ‘yes’, change rows to display to ‘all’ and click the refine button.

2) To find a specific report, enter relevant search criteria and click the refine button. Possible search criteria above the expand button are:
   a) The receive date of the reports (this is the date first received as specified on the report information page on the report, see section 2.2.1).
   b) Multiple report Id(s) can be separated by using either: comma (,), semi-colon (;), space ( ), dollar sign ($), tab-mark, or line break.
   c) To be able to specify which regional centre the reports should originate from, there has to be one or more Regional Centres using VigiFlow connected to the National Centre.
   d) The search criteria type of sender is the field type of sender on the report information page.
   e) It is possible to not include updates of previously received cases by selecting ‘no’. This section will otherwise always be seen if it contains any cases regardless of the other search criteria.
   f) If reports under assessment at the Regional Centres should be included, choose to include reports under regional assessment.

3) It is possible to have the resulting list sorted by 'receive date', 'change date', 'report Id' or 'regional centre'.

4) The rows to display sets the number of reports shown in the section Reports under central assessment, it is also possible to see all reports. A text below the listed reports states how many reports are shown and how many there is in total.
Under the expand button in the List of reports search section there are more search criteria and a possibility to include more information about the reports in the list. Note that if all the possible information is included at the same time, the list of reports will be very wide!

a) Reports under close surveillance are set on the report administrative information page (see section 3.1).

b) Patient safety reports are reports with the text [PATIENT SAFETY] (including the square brackets) in the field sender's comments on the assessment page (see section 2.10 for an explanation).

c) Sender information is data entered on the administrative information page except the world wide unique number from the report info page. The sender's report number is 'exact match' search while the world wide unique number search will find anything that 'begins with' the entered characters.

d) Patient information is the data entered on the patient page. The search for initials only needs to 'contain' the entered characters while the specialist record number is an 'exact match' search.

e) Literature reference is the primary source field on the report info page. The search is a 'contains' search.

f) Reporter family name is the primary source field on the report info page. The search is a 'contains' search.

An overview and explanation of all icons is found in Appendix 3, on page 119.

Some of the functions available from this list will be described in the following sections. However, it is also possible to get PDF printouts (see section 6.1), commit reports (see section 4.4), delete reports (see section 4.5), and go to the Administrative information page for reports (see section 3). Regional Centres can send reports directly from the list (see section 4.3).

The title of reports imported after the release of VigiFlow 5.2, will have the format "Import: [first reaction], [first drug]".
4.1.1 Pre-existing reports function

When a report is entered (either by E2B import or manually) the sender + sender's report number (found on the Administrative information page, see section 3) and the worldwide unique number will be compared with all previously entered reports. If a match is found with either of the above, this will be seen in the list of reports as a + sign and the text Pre-existing reports. If the + sign is clicked, information about the pre-existing report(s) will be displayed.

<table>
<thead>
<tr>
<th>Report ID</th>
<th>Report title</th>
<th>sender's report number</th>
<th>worldwide unique number</th>
<th>Report status</th>
<th>Sender's version</th>
<th>Sender's receive date</th>
<th>Sender's receipt date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Import: SE-GETC-CompletePC, version: 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A pre-existing report can be a simple mistake (the same report has been both imported and entered manually or the wrong number entered in sender's report number or worldwide unique number). Another possible explanation is that the report is a duplicate report.

When a report shows up with a pre-existing reports warning it is important to investigate what has happened starting with comparing the reports. If it is a duplicate you need to decide which one of the reports needs to be deleted and if any information on this report should be moved to the report that is kept.

See section 4.5 for instructions on how to delete reports.

4.1.2 View a report

Find the report you wish to view in the list of reports. Click on the view icon for that report. The view includes all information entered on the report (except for the fields in the vaccine data section see for example 2.8.1 point 7). There is a print button for easy printout of the frame containing the report information from the view.

From the view page it is also possible to continue to the audit trail for the report and from there view previous versions of the report (see section 4.1.3).

4.1.3 Audit trail (report history)

This function gives the user a possibility to see what has happened to a report during the process. Information such as changes in status, user and date checked in can be found. The audit trail is updated e.g. when the report is checked in, sent to another centre or committed.

You can also choose to view different versions of the report to be able to trace changes that have been made.
1) Click on list reports in the top menu (under report handling for reports that you are working on or under search and statistics for committed reports).

2) Click on the view icon 📋 to view a report in the list.

3) Click the audit trail button. The report history page is shown.

4) Click on the view icons 📊 to study different versions of the report. Return to the report history page by clicking the back button.

4.1.4 Edit a report

If you want to edit a committed report, see section 5.2.

1) Under report handling, click on list reports in the top menu.

2) Click on the edit icon 📊 to open and edit the specific report. See the section about report entry, 2, for instructions.

3) Save the report (section 2.12).

4) When you have finished updating the report and want to make it available to others for editing or assessment you have to check in the report (section 4.1.5).

4.1.5 Check out and check in reports

A report will automatically be checked out when you open it for editing by clicking on the edit icon 📊 or choose to perform a follow-up or amendment (see section 5.2) of a committed report.

When you have entered or edited a report, it has to be checked in to make it available for other users. This function prevents two users from making changes on the same report at the same time.

To check in a report, go to the list of reports (under assessment) by choosing report handling → list reports in the top menu. Find the report you want to check in and click on the check in icon 📊. The report will also be automatically checked in when you send (4.3) or commit (4.4) the report.

4.1.6 List reports (under assessment) at a Regional Centre

Regional Centres have a reduced set of functionality compared to the National Centre. There is filter function to search for particular ICSRs and for reports reported as serious, for the two lists Reports under regional assessment and Reports under central assessment. The section Reports under regional assessment is the main section, here all reports that are in the process of data entry and assessment at the Regional Centre are listed. Reports under central assessment lists the reports from that Regional Centre that are under assessment at the National
Centre, the regional Centre can view and print these, but not access them in any other way.

The Regional Centre users can do the following from this list:

1) Edit the report comment or – see section 2.12.
2) Open reports for editing – see section 4.1.4.
3) View reports – see section 4.1.2, and look at the audit trail – see section 4.1.3.
4) Send reports to another centre – see section 4.3.
5) Delete reports that do not have a report Id – see section 4.5.1.
6) Check in reports to make them available to other users at the Regional Centre – see section 4.1.5.
7) Regional Centres can also print selected reports – see section 6.1.
8) The icon indicates that the report is labelled serious,

9) As an option on request: a time alert marker to visualize when it is due time to send the report to the NC.
Accept or reject suggested ADRs and/or drugs from the UMC

When a report is committed, uncoded WHO-ART terms or drugs will be sent to UMC for consideration (for uncoded drugs, see option send drug request to the UMC in section 9.5.2). UMC personnel will then suggest a newly entered or similar term from WHO-ART, or drug from the WHO Drug Dictionary, for use on the report. Note that the UMC personnel will only see the information given for the suggested drug or term, nothing else on the report. National Centres have the option to accept or reject the suggested terms and drugs. They can also view the whole report by clicking on the view icon.

National Centres can find a list of Reports with suggested ADRs and/or drugs from the UMC under report handling list reports if there are reports with uncoded drugs or terms that have been handled by UMC personnel. To review a suggestion:

1) Click on the accept/reject suggestion link of the report of interest to open the Update drugs and reactions by UMC suggestions page. In the example below, both a drug and a reaction had been entered as uncoded on the report. For the drug, a suggestion is given by UMC personnel that can be accepted or not. For the term, more information is requested.
2) Depending on the response from UMC personnel there are three alternatives:
   
a) If a suggested drug or term is accepted, click ‘yes’ in accept suggestion.
   
b) If a suggested drug or term is not satisfactory, click ‘no’ in accept suggestion. When ‘no’ is chosen, the comment field is a mandatory field; information on why the suggestion was rejected and other relevant information must be given.
   
c) If more information is requested, enter your answer in the more info field, which is a mandatory field.
   
3) Click on the update button to send the entered updates.
   
a) If all suggestions have been accepted the report will appear at once in the search and statistics database.
   
b) If there are unresolved drugs or terms on the report, the entered comments and information will be resent to UMC for renewed consideration. The report will then reappear under Reports with suggested ADRs and/or drugs from the UMC on the list reports page.
   
Note that a report with uncoded drugs or terms can still be found in the listing of committed reports (see section 5.1) and it is possible to open and edit the report from there (but a UMC suggestion that has not been accepted will not be seen in the report itself). Tip: copy the report Id to easy find the report in the list of committed reports!
4.3 Send report

A saved report can be sent to another centre even if it is not complete, and a list of available receivers is shown during the process. Regional Centres can send a report to the National Centre, or to other Regional Centres (if available). A National Centre can send a report to Regional Centres (if available) e.g. for questions or comments.

1) To send a report, you can either:
   a) Select report handling → send report → send report in the top menu when the report is open for editing.
   b) Or, for Regional Centres, there is also an option to click on the send icon in the list of reports (found under report handling → list reports in the top menu; see section 4.1.6).

2) The page Result from verification opens, stating the Report Id and Report title. You will also receive a warning if mandatory information is missing on the report. You can choose to go back and enter the missing parts or send the report as it is.

3) If you are satisfied with the report, click the send report button. The Report comments page opens. Write your comments on the case (optional). Below the Report comments you will find the Send the report to another centre list.

4) Click on the send icon for the Centre you want to send the report to. If the report has no report Id one will be generated automatically.
   a) A Regional Centre sends reports to the National Centre by using the option send the report to central assessment. They can also send reports to other Regional Centres belonging to the same VigiFlow organization.
b) National Centres can only send reports to Regional Centres belonging to their VigiFlow organization.

A message saying ‘The report was successfully sent’ should be shown together with the Report Id. On this page there is also an option to print the report, see section 6.1. For National Centres there is also an option to go to the Administrative Information chapter for the report, see section 3.

### 4.4 Commit report

Only National Centres can commit reports to make them available for search and statistics. To be able to commit a report, the report has to be complete and correctly filled in.

1) To commit a report either:
   a) Click on the commit report icon in the list of reports (found under report handling → list reports in the top menu).
   b) When the report is open for editing select report handling → send report → commit in the top menu.
2) Information about the report is shown on the Result from verification page. If the report is incomplete, i.e. there is information missing in Mandatory fields, you have to go back and enter the missing information before you can commit the report.

3) If the report is complete, National Centres can choose to check the box ‘Send the report to the Uppsala Monitoring Centre when committed’.

4) Click the commit report button. If the report has been committed before you will be asked if the report is a follow-up or an amendment. See section 5.2 for more information. Click on commit report again when you have selected one of the choices.

5) A message saying ‘The report was successfully sent’ should be shown together with the Report Id when the commit is completed. On this page there is also an option to print the report, see section 6.1, and to go to the Administrative Information chapter for the report, see section 3.

A committed report will no longer appear under report handling ➔ list reports, instead it can be found under search and statistics ➔ list reports (see section 5.1). Committed reports are included in search and statistics queries (see section 8). However, reports with uncoded drugs or WHO-ART terms (see section 4.2) will only appear if the uncoded drug or term is not part of the search query. The uncoded drug or term will not appear in the search result.

4.5 ‘Delete’ a report

Reports that have been deleted in any way cannot be restored again. There are three different levels of deletion depending on the report (see table below). The system will automatically set the type of deletion. All deletion types start with clicking on the trash icon in the list of reports. Reports that have been history marked or nullified can be viewed after deletion (see section 5.1). Note that reports that have been deleted will not be included in the Search and Statistics module (see section 8).

<table>
<thead>
<tr>
<th>Applicable reports</th>
<th>Status after deletion</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Delete’</td>
<td>Manually entered reports without Report Id and sender information. This is the only type of deletion that Regional Centres can do.</td>
</tr>
<tr>
<td>Table entries</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>'History mark'</strong></td>
<td>Imported reports without Report Id. Manually entered reports without Report Id, but with sender information. History marked – the report is saved in the database (status=0).</td>
</tr>
<tr>
<td><strong>'Nullify'</strong></td>
<td>Reports with Report Id. Nullified – the report is saved in the database (status=1).</td>
</tr>
</tbody>
</table>

See instructions in the following sections for details.

### 4.5.1 Delete

A report fulfilling the following three criteria can be completely deleted. There will be no trace of the report in the database.

- It does not have a report Id (see section 2.12).
- It has been manually entered (and not imported, see section 7.1.2).
- It does not have a sender (on the Administrative information page, see section 3.2).

To delete a report:

1) Find the report that should be deleted in the list of reports (under assessment; under report handling ➔ list reports in the top menu).
2) Click on the trash icon 🗑️ for that report (the word delete pops up).
3) Confirm that you want to delete the report (“remove item”).

### 4.5.2 History mark

History marking can be done to reports that fulfil the criteria below. History marking is similar to nullification. The report will be left in the database and can be viewed (see section 5.1), but not restored.

- It does not have a report Id (see section 2.12).
- It does have an added sender (on the Administrative information page, see section 3.2, either entered manually or because the report is imported, see section 7.1.2).

To history mark a report:

1) Find the report that should be deleted in the list of reports (under assessment; under report handling ➔ list reports in the top menu).
2) Click on the trash icon 🗑️ for that report (the word history mark pops up).
3) Enter a **reason for history marking** (this is a **mandatory field**).

4) Set the **type of history mark**.
   
   a) If ‘replacement’ is chosen, it is **mandatory** to select the report replacing the history marked report. Write the report Id in the field, click on **get report** and then on **select** for the report.

5) Click on **set as historical** to complete the history marking. A confirmation that the report has been history marked will appear. Make a choice in the top menu to leave the **Set a report as historical** page.

6) A report that has been set as historical can be found under **search and statistics** ➔ **list reports** (see section 5.1).

### 4.5.3 Nullify

A report that **has a report Id** (see section 2.12) can be nullified. The report will be left in the database and can be viewed (see section 5.1), but not restored.

To nullify a report:

1) Find the report that should be nullified in the **list of reports** (under assessment; see section 4.1; or, if the report is committed, from the **listing of committed reports** see section 5.1).

2) Click on the **trash icon** 🗑️ for that report (the word **nullify** pops up).
3) Enter a **reason for nullification** (this is a **mandatory field**).

4) Set the **type of nullification**.
   a) If 'duplicate' or 'replacement' is chosen, it is **mandatory** to select the master report for the duplicate or replaced report. Write the report Id in the field, click on **get report** and then on **select** for the report.

5) Click on **nullify** to complete the nullification. A confirmation that the report has been nullified will appear. Make a choice in the top menu to leave the **Report nullification** page.

6) A report that has been nullified can be found under **search and statistics → list reports** (see section 5.1).

   **NOTE:** if a nullification report arrives as an E2B file and is imported, see section 5.3 on how to proceed.

### 5 Manage committed reports

When a report has been committed, it will no longer be available in the **list of reports (under assessment)**. Instead it will be found in the **listing of committed reports** (section 5.1). Committed reports can be viewed, printed in PDF format or exported in E2B format. They can also be nullified or have their Administrative information pages edited (see section 3). For submission of committed reports, see section 7.3.2. A committed report can also be opened for editing as a **follow-up** or **amendment** (see section 5.2).
5.1 Listing of committed reports

This section covers listing of committed reports. For more advanced searches and statistical analyses, go to section 8 Perform search and statistics.

In this list committed reports will be displayed. However, it is also possible to see reports that have been history marked or nullified, whether they have ever been committed or not by changing the type of listing. All types of reports can be printed (see 6.1), and committed and nullified reports can also be exported in E2B format (see 6.2).

Only National Centres have the full functionality described here, Regional Centres can only search for and view reports. If a Regional Centre needs to update (follow-up/amendment) a committed report, they have to ask the National Centre for assistance, see section 5.2.2. The functionality as seen at a Regional Centre is found in section 5.1.4.

In the top menu, choose search and statistics ⇒ list reports.

To search for a committed report, enter relevant search criteria. Possible search criteria are:

1) The receive date (this is the date first received as specified on the report information page on the report, see section 2.2.1).
2) Multiple report Id(s) can be separated by using either: comma (,), semi-colon (;), space ( ), dollar sign ($), tab-mark, or line break.

3) The report title (name or part of the name/title).

4) In type of listing you have the following choices:
   a) ‘Committed reports’ lists all reports that have been committed (shown in the figure above).
   b) ‘Historical reports’ lists reports that have been set as historical; the reason for history marking is available as a comment icon in the list.
   c) ‘Nullified reports’ lists nullified reports; the reason for nullification is available as a comment icon in the list.

5) Under the expand button there are more search criteria and a possibility to include more information about the specific reports in the list. These are described in section 4.1 about the list of reports under assessment.

6) Click the search button to perform the search. It is also possible to click the search button without entering any search criteria or clicking clear form to reset the filters first. This will display the latest 100 committed reports.

When you have found your report(s) of interest see the following chapters for what tasks can be performed from the list! However, PDF printouts (see section 6.1) and E2B generation (see section 6.2) are not further described here.

5.1.1 View a committed report.

Find the report you wish to view in the listing of committed reports (see section 5.1). Click on the view icon for that report. The view includes all information entered on the report (except for the fields in the vaccine data sections see for example 2.8.1 point 7). There is a print button for easy printout of the page containing the report information from the view.

From the view page it is also possible to continue to the audit trail for the report and view previous versions of the report (see section 4.1.3).

5.1.2 Nullify a committed report

A nullification is performed e.g. to remove duplicate reports in the database. If the report that is nullified has been submitted (section 7.3.2) to an external contact, it will automatically reappear in the Submission manager for resubmission to the same contact (section 7.3.1).

Follow the instruction in section 4.5.3 also to nullify committed reports.
5.1.3 Administrative information page

Find the report for which you wish to edit the Administrative information page in the listing of committed reports (see section 5.1). Click on the administrative information icon for that report. For more information see section 3.

5.1.4 Listing of committed report for Regional Centres

Regional Centres have a reduced set of functionality compared to the National Centre. They can still search for and list all committed reports, but they cannot follow-up/amend reports that they find. Neither can they look at nullified nor history marked reports.

All filters described in section 5.1 (except for the type of listing) are available for the Regional Centre, as well as the possibility to view a report – see section 5.1.1. They can also print selected report from the list – see section 6.1.

5.2 Follow-up/amend

When a committed report needs to be changed, a follow-up or an amendment should be done. Follow-up is made when new information has arrived from the primary source; it can also be used if a correction of the case data significantly changes the case, for instance if the age of the patient is changed from 8 decades to 8 months. Amendment is meant to be used for corrections and for instance if the causality assessment is changed due to a re-evaluation of the existing data. The
workflow when making a follow-up or amendment differs depending on for instance if the new information arrives to the National Centre or to a Regional Centre (see section 5.2.2) or if the update arrives as an E2B file (see section 5.3).

5.2.1 Follow-up/amend a report at the National Centre

This is the workflow when the National Centre wants to update the case and any new information has arrived on paper, e-mail or phone for instance.

To update a committed report click on the follow-up/amend link in the listing of committed reports (see section 5.1). The report will open for editing and you can enter the new or changed information in the report. When the follow-up/amend link has been clicked, the report can be found in the list of reports under assessment (report handling → list reports; see section 4.1) and the report needs to be committed again to finalize the new version.

The choice between making a follow-up or an amendment is made when the report is committed:

1) Commit the updated report (see section 4.4 on how to commit reports).
2) On the Result from verification page click on commit report.
3) The Follow-up or amendment? page will open; on this page it is mandatory to choose between follow-up, amendment or amendment – to be resent (also read the last paragraph below about resubmissions):

<table>
<thead>
<tr>
<th>Follow-up or amendment?</th>
</tr>
</thead>
<tbody>
<tr>
<td>report Id: 2010-00015</td>
</tr>
<tr>
<td>report title: Title of test report (follow-up)</td>
</tr>
<tr>
<td>The report has previously been committed. Please select one of the options below.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>commit report</td>
</tr>
<tr>
<td>back to report</td>
</tr>
</tbody>
</table>

a) Choose follow-up if more information on the case has become available, e.g. addition of a drug or reaction or a change of outcome. The official report version number (seen on PDF printouts and E2B exports) will be increased and it will be possible to set the date receipt most recent info (today’s date is given as default).
**5.2.2 Workflow if new information arrives at a Regional Centre**

*For organizations/countries using VigiFlow with Regional Centres.*

A Regional Centre cannot by themselves open a report for editing once it is sent to the National Centre. Therefore, the following workflow is suggested if a Regional Centre receives new information (or the report needs changing by the Regional Centre for another reason):

1) The Regional Centre identifies the correct report (report Id) e.g. from the listing of committed reports (see section 5.1). The Regional Centre then contacts the National Centre (by e-mail or phone) and asks the National Centre to send the report.

2) The National Centre finds the report in the listing of committed reports (see section 5.1), and clicks the link follow-up/amend to open the report. When the report is open for editing, the National Centre user sends the report to the Regional Centre by selecting **report handling → send report → send report** in the top menu (see section 4.3 for full description on how to send reports).

3) The Regional Centre edits the report to for example add the follow-up information and sends the report back to the National Centre (as described in section 4.3).
4) The National Centre commits the report, and selects if the update was an amendment or follow-up (see section 5.2.1; this information can be added in the report note from the Regional Centre). Note that if it was a follow-up, the date receipt most recent info should be filled with the date the updated report was received at the National Centre (not necessarily the same date the report is committed again).

5.3 Follow-up/amend/nullify when the update is an E2B import

This is the workflow when for instance a company sends an E2B file containing a follow-up, amendment or nullification of a previously entered report.

This section will cover the functionality and workflow for handling follow-ups, amendments or nullifications that have been imported. For information regarding how to do the E2B import, go to section 7.1.2 first.

At E2B import, VigiFlow checks the sender and the sender’s report number of the imported reports against all other reports entered in VigiFlow. If a match is found, the new report is considered an update (follow-up, amendment or nullification) of the previously entered report. The update is then listed in the list of Updates of previously imported reports (which is one section of the list of reports under assessment – see section 4.1).

<table>
<thead>
<tr>
<th>Updates of previously received cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report title</td>
</tr>
<tr>
<td>2012-00D31</td>
</tr>
<tr>
<td>2012-00D32</td>
</tr>
</tbody>
</table>

To describe this functionality, four new definitions are used:

- **case**: The case is the individual patient suffering an adverse event or reaction, it is possible to receive several ICSRs on the same case, these are either duplicates (reports from different senders) or updates of the initial report (reports from the same sender)
- **initial report**: The first version of a report that has been received from a particular sender
- **primary report**: The version of a report that is active in VigiFlow when several versions have been imported from the same sender
- **replaced report**: A version of a report that has been replaced with a newer version or discarded

5.3.1 General functionality

In the list of updates, each case will only be listed once, regardless of how many updates have arrived. The report id, title and status of the primary report (the initial version of the case will be the primary report until an update replaces it) is given in
the list. The receive date (date first received) will be the initial receive date, but the receipt date (date receipt most recent info) is the receipt date of the most recent update. If more than two weeks¹ has passed since the last update arrived a red clock icon will appear. This icon warns that the case needs to be handled. To view the received updates, click the icon to view updates and the page List of follow-up reports will appear. Note that if the primary report is checked out (or sent to a Regional Centre), it will not be possible to do anything except view the updates on this page until the report is checked in (or sent to the National Centre). Depending on if the received update is a follow-up/amendment or a nullification, different alternatives will be possible on the page.

<table>
<thead>
<tr>
<th>Report title</th>
<th>Report status</th>
<th>Receive date</th>
<th>Sender’s version</th>
<th>Sender’s receive date</th>
<th>Sender’s receipt date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Import: SE-ENC-2012-00017, version: 2</td>
<td></td>
<td>20121116 2</td>
<td>20121101</td>
<td>20121113</td>
<td></td>
</tr>
<tr>
<td>2012-00210 Exemplar report - Import: SE-ENC-2012-00017 committed</td>
<td></td>
<td>20121112 1</td>
<td>20121101</td>
<td>20121110</td>
<td></td>
</tr>
</tbody>
</table>

5.3.2 Promote or discard update

Normally it is recommended to always promote the latest arrived version of a case to become the new primary report. Before that is done, you can however view the current primary report and the received update(s). TIP: open the views in new windows by right-clicking on the icons and selecting “Open link in new window” or similar. When you continue working with the case, it can also help to keep the view of the current primary report open in its new window.

Discard update

If the decision is to not update the case with the new information, it is possible to discard the update by clicking the discard version icon. No change will then be made to the primary report except that the date receipt most recent info will be updated with the date the update arrived and the sender’s receipt date (seen on the administrative information page, see section 3.1) will also be updated. The discarded update can be viewed on the administrative information page of the primary report (see section 3.6).

Promote update

When the received update should replace the primary report, the icon promote to primary report should be clicked. The following will then happen:

¹ The time between last update and the appearance of the red clock icon may change depending on input from users.
The primary report is removed from the Search and statistics database if it has been committed and it will also disappear from any list of reports (list of reports under assessment or the list of committed reports, depending on its status). The new primary report will appear in the list of reports under assessment. This report will have all the information from the promoted update except the following fields which will be copied from the former primary report:

a. Report Id
b. Report title
c. Receive date
d. Report version (the new VigiFlow report version is set when the report is committed)
e. Any extra duplicate report numbers
f. Terms and drugs that were manually coded on the primary report (described in section 5.3.3)
g. Sender’s diagnosis
h. Sender’s comment
i. Content of green note (only if primary report is under assessment)

From the Administrative information page:

j. Linked reports
k. Receiver(s) including all submission data
l. Administrative and report data (fields administrative comment and if report is under close surveillance)

The updated report now needs to be checked. New terms or drugs may have been added or changed, and new data may change the causality assessment – step 5) in section 7.1.2 describes how to check a report after import.

When the new update has been checked, it should be committed.

If the case has been committed before it is important to note that this case will not be included in the Search and Statistics tools until the new update is committed. (Normally a previously committed version is part of the Search and Statistics tool until the new version is committed.) At commit, the page Follow-up or amendment? (see section 5.2.1) will appear and when ‘follow-up’ is chosen the date receipt most recent info will be pre-filled with the date the update was imported.

If the case has not been committed before, the report may still have different receive and receipt dates (the date first received from when the initial report was imported and the date receipt most recent info from when the latest update was imported). The version number will also be ‘2’ even though the report has not been committed before.
If several updates have arrived and the latest update is promoted as the primary report, the versions in between will automatically be discarded.

### 5.3.3 Manually coded drugs and terms

As explained in section 7.1.2, VigiFlow will not always be able to auto code received entries with WHO-ART, ICD-10, MedDRA or WHO Drug Dictionary. To keep the manual workload to a minimum on these reports, VigiFlow has a function that will transfer a manually coded entry from a former primary report to its successor. This function will compare the original value that was uncoded and if the same value is used again in the same field on the update, the uncoded value will be automatically replaced with the coded value when the update is set as the new primary report.

The users do not need to do anything for this to happen, and it is always possible to see if it has happened by looking in the audit trail of the new primary report.

**Fields with this function**

<table>
<thead>
<tr>
<th>VigiFlow field</th>
<th>Terminology</th>
<th>E2B tag name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug name</td>
<td>WHO Drug Dictionary</td>
<td>medicinalproduct</td>
</tr>
<tr>
<td>Active substance(s)</td>
<td>N/A</td>
<td>activesubstancename</td>
</tr>
<tr>
<td>Authorization holder</td>
<td>N/A</td>
<td>drugauthorizationholder</td>
</tr>
<tr>
<td>Reaction term</td>
<td>WHO-ART or MedDRA</td>
<td>reactionmeddralit</td>
</tr>
<tr>
<td>Indication</td>
<td>ICD10 or MedDRA</td>
<td>drugindication</td>
</tr>
<tr>
<td>Relevant medical history</td>
<td>ICD10 or MedDRA</td>
<td>patientepisodename</td>
</tr>
<tr>
<td>(Parent) Relevant medical history</td>
<td>ICD10 or MedDRA</td>
<td>parentmedicalepisodename</td>
</tr>
<tr>
<td>Relevant past drug therapy – indication</td>
<td>ICD10 or MedDRA</td>
<td>patientdrugindication</td>
</tr>
<tr>
<td>Relevant past drug therapy – reaction</td>
<td>WHO-ART or MedDRA</td>
<td>patientdrugreaction</td>
</tr>
<tr>
<td>Parent relevant past drug therapy – indication</td>
<td>ICD10 or MedDRA</td>
<td>parentdrugindication</td>
</tr>
<tr>
<td>Parent relevant past drug therapy – reaction</td>
<td>WHO-ART or MedDRA</td>
<td>parentdrugreaction</td>
</tr>
<tr>
<td>Test type</td>
<td>N/A (drop down list or free text) or MedDRA</td>
<td>testname</td>
</tr>
</tbody>
</table>

The entered causality assessment in the section **relatedness of drug(s) to reaction(s)** will also be inherited from the previous primary report as far as the same drug-reaction pairs can be found on the follow-up version of the report. It is very important for the user to check that the new information does not make it necessary to change the causality assessment inherited from the previous version.
Exceptions

Some fields are excluded from this function:

<table>
<thead>
<tr>
<th>VigiFlow field – comment</th>
<th>Terminology</th>
<th>E2B tag name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sender’s diagnosis – see section 5.3.2</td>
<td>WHO-ART or MedDRA</td>
<td>senderdiagnosis</td>
</tr>
<tr>
<td>death cause – technically not possible</td>
<td>ICD10 or MedDRA</td>
<td>patientdeathreport</td>
</tr>
<tr>
<td>death cause after autopsy – technically not possible</td>
<td>ICD10 or MedDRA</td>
<td>patientdetermineautopsy</td>
</tr>
</tbody>
</table>

Other exceptions are:

1) If anything differs in the uncoded value (e.g. spelling), the coding decision will not be inherited.

2) When a coding decision relating to a medical product is inherited, three fields need to be the same as on the previous primary report: **drug name, active substance(s)** and **authorization holder** (see section 2.8). When these fields match, all of them will be inherited.

3) If the same uncoded value is repeated in the same type of field (e.g. same medical product, or same reaction is repeated with different start and stop dates) on an ICSR the coding decision for the first instance will be inherited for all instances. However, for the indication field on the drug page and reaction and indication fields on the past drug therapy pages, an uncoded value will only be inherited if the corresponding drug name is the same. That means that if the same indication is used on two different suspected drugs, they can be coded differently without loss of data. But if the same drug name is reported on both suspected drugs both indications will inherit the coded indication from the first drug name.

4) ICSRs where the initial report arrived before the release of VigiFlow 5.1 in June 2013 will not have this function since the original uncoded values were not saved before this release.

Documentation of inherited coding decisions

When the audit trail of the new primary report is opened, the audit trail will contain both the imported version and the promoted version where the coding decisions have been inherited.

```
<table>
<thead>
<tr>
<th>user</th>
<th>status</th>
<th>date checked in</th>
<th>centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>e2import</td>
<td>12. 03. 2013 - 20:32:14</td>
<td>Testcentre</td>
</tr>
<tr>
<td>2</td>
<td>promotion</td>
<td>12. 03. 2013 - 20:33:52</td>
<td>Testcentre</td>
</tr>
<tr>
<td>Current</td>
<td>5</td>
<td>12. 03. 2013 - 20:33:52</td>
<td>Testcentre</td>
</tr>
</tbody>
</table>
```
The first row, **c2bimport**, contains the original values from the sender, and the second row, **promotion**, is the version VigiFlow has created. See section 4.1.3 for more information regarding the audit trail, and section 5.3.5 for information on where to find the audit trail of the replaced reports of the same case.

### 5.3.4 Nullification

If a nullification report is sent, it will be possible to nullify the case by approving the nullification by clicking the trash icon. The primary report (in the example below 2012-00031) will then be nullified (see section 4.5.3). If you decide for some reason you do not want to nullify the case, it is instead possible to click on the icon to discard the nullification. The nullification will then be treated as a discarded update.

#### List of follow up reports

<table>
<thead>
<tr>
<th>Report title</th>
<th>Report status</th>
<th>Receive date</th>
<th>Sender's version</th>
<th>Sender's receive date</th>
<th>Sender's receipt date</th>
</tr>
</thead>
<tbody>
<tr>
<td>nullification</td>
<td>Import: NOL-LRR-030252675, version: 1</td>
<td>20120827 1</td>
<td>20100930</td>
<td>20120658</td>
<td></td>
</tr>
<tr>
<td>2012-00031</td>
<td>Import: NOL-LRR-030252675, version: 1 assessment</td>
<td>20120827 1</td>
<td>20100930</td>
<td>20120658</td>
<td></td>
</tr>
</tbody>
</table>

### 5.3.5 Documentation of received updates

All discarded and replaced versions of a case will be listed on the Administrative information page in the section Replaced reports (see section 3.6).
6 Output

If you wish to save created reports on a local computer or to make paper copies of cases, there are two options: PDF printout or E2B generation (committed reports). If you want to submit a report to an external contact (PDF or E2B submission), see section 7.3.2 instead.

6.1 PDF printout

A report can be printed at any time during the process of entering information; click on print report in the left hand menu, and continue from step 3) below. The same is valid for the print report button that appears when a report has been successfully committed or sent to another centre. These two ways of printing will generate a PDF file with the single report. However, following the instructions from step 1) below can generate a PDF file containing many reports. The generated PDF file can be saved to disk or printed on paper.

To make PDF printouts:

1) Find the relevant report(s) in the list of reports (under assessment; see section 4.1; or, from the listing of committed reports see section 5.1). If you create printouts of reports that are history marked or nullified (see section 4.5) a watermark with the text ‘nullified’ will be shown across each page in the PDF file.

2) Tick the checkbox(es) next to the report(s) you want to print and click the print selected reports button.

3) The page Create document from ADR-report will open. Select the type of printout to make under report type (for information, point the cursor on the help icon next to the field in the interface).

4) Click the ok button. A link to the created PDF file will appear under Created documents. Click on this link to open and print the file; or, right-click to save the file on the local computer.
6.2 Generation of E2B report

Only National Centres can generate E2B files.

1) You can select reports for E2B generation in two ways:
   a) Check the boxes for the relevant report(s) in the listing of committed reports (see section 5.1; note that it is not possible to generate E2B files when type of listing is ‘historical reports’). Click on the generate E2B button. The chosen reports will be pre-selected on the Generate E2B page – skip to point 3) below.
   b) Select tools → E2B handling in the top menu; E2B export in the left hand menu with the Generate E2B section is opened.

2) Enter receive date (this is the date first received as specified on the report information page on the report, see section 2.2.1) or the report Id(s) of the reports you want to include in the E2B generation. Note that only committed or nullified reports will be included in the E2B file. At least one search criterion must be entered.
   a) If only year is entered in receive date, the from field will use 1st of January and the to field will use 31st of December of the entered year. The same logic applies if month and year are entered.
   b) Multiple report Id(s) can be separated by using either: comma (,), semi-colon (;), space ( ), dollar sign ($), tab-mark, or line break.

3) In the field type you can choose from (both will generate xml files):
   a) ‘External E2B’: includes only E2B standard information; VigiFlow specific data will not be included and information like the name and address of the primary source will be withheld and the patient initials will be changed to
‘PRIVACY’ (for more details see Appendix 1). ‘External E2B’ is mainly intended for submissions to external contacts such as companies and/or authorities.

b) ‘Internal E2B’: includes all information entered on a report. This will not be a correct E2B standard format. This extract is intended to use as a local copy of the data and not for submission of reports to external contacts.

4) Do not select a receiver unless you want it to be a submission (see section 7.3.2). If you add a receiver, it is only possible to generate an ‘External E2B’.

5) Click the generate button.

6) When generation is done, right-click on the link (name of file, in the example above TST-999999.xml) under Result from generation and save the selected report(s) on your local computer.
Tools menu — external report exchange

Only National Centres have access to the functions in the tools menu described in this section.

This menu handles report exchange with external contacts; for sending reports between a National Centre and its Regional Centres see section 4.3; for sending reports to UMC see section 4.4.

7.1 E2B handling

VigiFlow has the capability of both import and export of E2B reports. Select tools → E2B handling in the top menu. The left hand menu will appear as the figure to the left.

7.1.1 E2B export

The E2B export is described in the Output section (see 6.2). E2B files can also be exported as submissions (see section 7.3.2).

7.1.2 E2B import

Select E2B import in the left hand menu to import a file. Only correct E2B files in xml format can be imported. If the file is incorrect an error message will appear.

1) Write the location and file name in the field file, or click the Browse... button to find the file to upload. Note that this function might differ depending on your internet browser and settings.

The following import settings can be made:

a) The type of import should normally be “standard E2B”. If “incomplete E2B” is chosen a number of exceptions from the normal E2B import process are made: the fields sender (and other sender information fields), sender's report Id,
report type (this will be set to “spontaneous” in VigiFlow if not present), and the worldwide unique number (which is either authority number or company number) are not mandatory. Also no connection to the address book will be made, the import will not be listed in the upload statistics page (see point 4) below) and no acknowledgment file will be generated (see point 3) below).

b) There is also an option to generate report Id(s) during import. The generated report Id(s) will then be included in the acknowledgment file (for follow-up reports report Id of the already existing report will be included instead). If not generated now, Report Ids can be generated later during report handling, but it is recommended to generate the report Ids at import.

Click on the upload button when the correct file is identified and you have chosen your import settings.

2) The result of the upload is shown with information about e.g. the number of reports in the file and the number of imported reports. Reports in the file that are not correct will not be imported; instead an error message will appear in the acknowledgment file.

3) To send an acknowledgement file to the sender:
   a) Click on the get acklog icon.

   b) Right click on the file name and save it.
   c) Send the file (by e.g. e-mail) to the sender of the imported file.

4) The import will be listed in the upload statistics section (see 7.1.3).

   The imported reports can be found in the list of reports (under assessment; see section 4.1, for follow-up reports see section 5.3). All imported reports get the title "Import: [first reaction], [first drug]"
5) Each imported report needs to be checked before it is committed. To perform the check, open the report for editing. The overview page (see section 2.11) will give an overview of the whole case before a page by page check is made.

a) Any errors or missing mandatory fields need to be handled.

b) Fields that are coded using one of WHO-ART, MedDRA, ICD-10 or the WHO Drug Dictionary need to be checked. If the import process could not auto code the information, manual coding is needed – most important not to leave uncoded are the suspected (and concomitant) drugs and the reaction terms. If these are uncoded, the case will not be found properly in the Search and Statistics tool after it is committed. See also section 5.3.3 for information regarding coding on follow-up reports.

If a drug name (or reaction term) does not exist in the WHO Drug Dictionary (or WHO-ART, respectively) and you want UMC staff to add them, leave the entry uncoded at commit; for the drug name it is important to then fill in as much other information as possible and tick the checkbox as described in section 9.5.2 (for WHO-ART terms see section 9.5.1).

c) It is also recommended to do the causality assessment (see section 2.7.3; the sender’s causality assessment will be shown as well on imported reports), and, if wanted, also to fill in the fields sender’s comments and sender’s diagnosis (see section 2.10; the previous sender’s comments and diagnosis will be available as well). It is also possible to change the title to match your preferred title structure.

NOTE:

If one of the imported reports is a follow-up, amendment, or nullification of a case that was received previously see further information in section 5.3.

If the imported report is a nullification, and you have not received the case before, this will be indicated in the list and the reason for nullification will be displayed. This should however not happen unless the sender has made a mistake. Such an imported nullification report should be deleted (i.e. history marked – see section 4.5.2) to remove it from the list of reports under assessment.

7.1.3 Upload statistics

Uploaded files are listed under upload statistics in the left hand menu. The list includes information like the message number, included reports and the ack log. The ack log can be viewed or downloaded as an xml file (see point 3) in section 7.1.2). The icons indicate the status of the submission. See appendix 3 for description.
There is a search function above the list of imported files to make it easier to find information about a specific upload. Search fields include date of the upload and sender. Several senders can be included in a search and they are selected from the contacts in the Address book. Click on refine to perform the search. The filter is pre-filled with a from date two weeks before current date. If you want to list all uploaded files this date needs to be manually removed before clicking on refine.

**Upload statistics**

The following list contains information on all files imported in the system.

<table>
<thead>
<tr>
<th>import date</th>
<th>sender(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>from 10 11 2011 to 28 01 2013</td>
<td>get sender</td>
</tr>
</tbody>
</table>

The filter is pre-filled with a from date two weeks before current date. If you want to list all uploaded files this date needs to be manually removed before clicking on refine.

### 7.2 Address book

The Address book stores contact information of those who send or receive reports to/from your VigiFlow organization.

E2B imported reports (see section 7.1.2) will automatically have their senders added to the Address book. The contacts can be viewed in a list of contacts (see 7.2.1) where they also can be manually added or updated (see 7.2.2).

#### 7.2.1 List of contacts

To go to the Address book select tools ➔ address book in the top menu. The list of contacts will be displayed. It is possible to search for a specific contact and to add or edit contacts. The contacts are listed below the search fields:
It is possible to view details on a contact by clicking on the -sign on the left side of the list. On the right there are icons for editing ( ) and deleting ( ) the contact. It is possible to view, edit and restore ( ) deleted contacts. However, it is not possible to delete contacts that have active links to the submission tables (see section 7.3).

To search for a specific contact, use the search fields at the top of the list of contacts section:

1) The organization name field will search for names that contain the entered text.
2) The field status decides if deleted contacts should be included in the search.
3) Click on refine to start the search.

### 7.2.2 Add or edit contacts

From the page list of contacts (7.2.1) it is possible to add new contacts or edit existing ones. The same page is used both to add and edit contacts (see figure below). To add a new contact, click on the button add new contact below the search fields. To edit an existing contact, click on the edit contact icon for the specific contact.

**Note:** If an automatically entered contact is updated manually, it will not be automatically updated at subsequent imports.
1) The fields organization name and identifier are mandatory for all contacts. Organization name is used in the contact (sender/receiver) look-up fields in e.g. the Administrative information page and Submission manager (see section 3 and 7.3.2, respectively).

2) The type is the same as the type of organization shown in the search for contact.

3) The preferred transmission type (manual E2B or PDF) can also be selected.

7.3 Submission manager

The Submission manager keeps track of all submissions sent to external contacts and the acknowledgment files returned. Select tools → submission manager in the top menu. The submission manager is divided in three pages, one for unsubmitted reports (see 7.3.1), one for submitted reports (see 7.3.3) and the third used for uploading received acknowledgment files (see 7.3.4). Choose between the pages in the left hand menu of the submission manager.

7.3.1 Unsubmitted reports

On the page for Unsubmitted reports, all reports that have had a receiver added in the Administrative information page (see section 3.3) will be listed. Also read about resubmissions as specified in section 5.2. However, only reports with status ‘committed’ or ‘nullified’ can be part of a submission. Other reports will stay as unsubmitted reports until they are committed/nullified (and included in a subsequent submission) or the receiver is removed from the Administrative Information page (see section 3.3).
The reports are sorted by receiver on the Unsubmitted reports page. If the receiver's preferred transmission type is specified in the address book (see section 7.2.2), this will be shown in brackets next to the name. The date when the receiver was last added to a report (selection date) is shown, and if the report has been submitted earlier (submission status) the previous submission date (previously submitted) is also shown. The status column shows the status of the report, as described earlier, only committed or nullified reports can be included in a submission.

![Unsubmitted reports table]

### 7.3.2 Make a submission

Submissions can be in E2B or PDF format, and it is also possible to make submissions in both formats. (Note that E2B submissions can also be made from the Generate E2B page, see section 6.2.) Regardless of which format you want, follow these steps to make a submission from the Unsubmitted reports page:

1) Click on one of the submit as E2B file/PDF/E2B and PDF buttons in the list of Unsubmitted reports.

![Generate E2B and PDF]

* - Only committed and nullified reports will be exported!

2) On the Generate E2B/PDF/E2B and PDF page it is possible to remove reports by clicking the trash icon. However, it is not possible to remove the last report in the list.
3) Click the *generate* button to generate the submission. It will be registered in VigiFlow as a submission and have a message number after this step.

**Result from generation**

The following file(s) contains the result of your generation request.

- Text.db-PMARM-50005191.xml
- Text.db-PMARM-50005191.pdf

4) Right-click on the link to the generated file to download it to the local computer. The file name contains your organization identifier, the organization identifier of the receiver and the message number for the submission.

5) Send the generated file to the receiver (by e.g. e-mail).

### 7.3.3 Submitted reports

On the *Submitted reports* page all created submissions are listed. To facilitate finding specific submissions it is possible to filter for a specific report *Id*, *message number*, *submission date*, or *receiver*. In the list below the filter, the submissions are listed by receiver. From this list, it is possible to retrieve old submissions by clicking the link (*PDF submission* or *E2b submission*) in the submission information box. Note that for submissions made before the release of VigiFlow 4.11 it will only be possible to retrieve old E2B submissions, not PDF submissions. Any uploaded acknowledgments can also be viewed (不懈) or downloaded as an XML file (不懈) by clicking on the icons. See section 7.3.4 on how to upload acknowledgment files.

The icon shows the status of the ack log, if OK不懈, the 不懈 indicates that not all reports were loaded in the transmission and 不懈 indicates that no reports were loaded in the transmission.

```java
Submitted reports
```

<table>
<thead>
<tr>
<th>report Id</th>
<th>message number</th>
<th>receiver(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Receive information* | *Reports* |
7.3.4 Upload received acknowledgment file

When an E2B submission is sent to a receiver, they should return an acknowledgment file. These files will automatically be connected to the relevant submission when uploaded into VigiFlow and can then be viewed from the list of submitted reports in the submission manager (see 7.3.3).

Select tools ➔ submission manager in the top menu, then select upload ack log in the left hand menu to upload an acknowledgement file.

1) Write the location and file name in the field file, or click the Browse... button to find the acknowledgment file to upload. Note that this function might differ depending on your internet browser and settings.

2) Click the upload button when the correct file is identified. The result of the upload will then be shown with a view of the contents of the acknowledgement file.
### Upload ack log file

- **message**: The file was successfully uploaded
- **file name**: ACK-000056.xml

### acknowledgement

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ack log number</td>
<td>edktes020</td>
</tr>
<tr>
<td>sender</td>
<td>SETA</td>
</tr>
<tr>
<td>receiver</td>
<td>VFORG</td>
</tr>
<tr>
<td>date</td>
<td>20100404111111</td>
</tr>
<tr>
<td>sender message number</td>
<td>00000025</td>
</tr>
<tr>
<td>local message number</td>
<td>testing020</td>
</tr>
<tr>
<td>message sender</td>
<td>Test db</td>
</tr>
<tr>
<td>message receiver</td>
<td>SETA</td>
</tr>
<tr>
<td>message date</td>
<td>20100920134187</td>
</tr>
<tr>
<td>acklog code</td>
<td>01</td>
</tr>
<tr>
<td>error message</td>
<td></td>
</tr>
<tr>
<td>safety report id</td>
<td>SE-VFORG-2010-00001</td>
</tr>
<tr>
<td>safety report version</td>
<td>2</td>
</tr>
<tr>
<td>local report number</td>
<td>SE-SETA-2010-00011</td>
</tr>
<tr>
<td>authority number</td>
<td>SE-VFORG-2010-00001</td>
</tr>
<tr>
<td>company number</td>
<td></td>
</tr>
<tr>
<td>receipt date</td>
<td>20100914</td>
</tr>
<tr>
<td>acklog code - report</td>
<td>01</td>
</tr>
<tr>
<td>error message - report</td>
<td></td>
</tr>
<tr>
<td>safety report id</td>
<td>SE-VFORG-2010-00003</td>
</tr>
<tr>
<td>safety report version</td>
<td>1</td>
</tr>
<tr>
<td>local report number</td>
<td>SE-SETA-2010-00012</td>
</tr>
<tr>
<td>authority number</td>
<td>SE-VFORG-2010-00003</td>
</tr>
<tr>
<td>company number</td>
<td></td>
</tr>
<tr>
<td>receipt date</td>
<td>20100913</td>
</tr>
<tr>
<td>acklog code - report</td>
<td>01</td>
</tr>
<tr>
<td>error message - report</td>
<td></td>
</tr>
</tbody>
</table>

This is the number of the submission the acknowledgment belongs to.

This is the VigiFlow report Id of the (first) report acknowledged.
8 Search and statistics

This section describes the Search and statistics module (below until page 93) and the Administrative statistics module (section 8.4); for information about the listing of committed reports, please see section 5.1.

The Search committed reports page allows you to perform advanced searches and statistical analyses of the committed reports within your VigiFlow organization. It is possible to save a query to be performed again later.

There are several profiles available for different types of searches. An overview of the profiles is given in the table below. Values not mentioned in the table are the same for all profiles. For differences in search result, see section 8.3 for descriptions of each profile.

<table>
<thead>
<tr>
<th></th>
<th>Report listing</th>
<th>CIOMS line listing</th>
<th>Summary tabulation</th>
<th>Drug reaction profile</th>
<th>Summary of products</th>
<th>Summary of reported ADRs</th>
<th>Summary of reported drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of drugs allowed</td>
<td>0–n</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0–1</td>
<td>1</td>
<td>1–n</td>
</tr>
<tr>
<td>Drug operator</td>
<td>●</td>
<td>_ †</td>
<td>_ †</td>
<td>_ †</td>
<td>_ †</td>
<td>_ †</td>
<td>_ †</td>
</tr>
<tr>
<td>Receive date</td>
<td>● ²</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Reaction level</td>
<td>●</td>
<td>● ³</td>
<td>● ³</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Reaction operator</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>_ †</td>
<td>_ †</td>
<td>_ †</td>
<td>_ †</td>
</tr>
<tr>
<td>PDF output of result</td>
<td>–</td>
<td>●</td>
<td>●</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Excel output of result</td>
<td>●</td>
<td>–</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Print selected reports</td>
<td>●</td>
<td>●</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

1 The drug/reaction operator for these is ‘or’.
2 Receive date is mandatory if no drug has been entered here.
3 SOC level not allowed.

It is possible to switch between the different profiles while keeping the already entered search criteria. If an entered search criterion is not available for the new profile it will be ignored and if an entered search criterion is not allowed for the new profile an error message will appear.

More information on PDF and Excel output of results and Print selected reports is given in section 8.2, below.
8.1 Getting started

For an overview of the Search committed reports page see Appendix 2, page 117.

1) Select search and statistics → search and statistics from the top menu. The Search committed reports page is displayed.

2) Choose the profile for the query (see table of profiles above and description of profiles in subchapters below).

3) If you intend to save the query, enter a query name and if you wish also a description of the query. These fields are optional and should be filled only if you wish to save a query for future use. For more information see section 8.1.1 Saved queries.

4) Enter a drug name in drugs added and click the search drug link or leave blank and click on the search drug link (see search for drug in section 9.1 for more information). Note that a drug has to be added on all profiles except Report listing and Summary of products. The drug operator (only available when doing a Report listing) lets you choose if all added drugs should be present (drug 1 ‘and’ drug 2), or if only one of the entered drugs is needed (drug 1 ‘or’ drug 2), for a report to be included in the search results.

5) You can choose on what drug level the search should be performed. The level ‘active substance’ will include the most number of reports, while the others will restrict the search result to include only the trade name or medicinal product specified in the query.
6) If desirable, enter the **receive date** (called **date first received** at data entry; see section 2.2.1) as a specific date, a month and year, or only as a year. You can also enter an interval of dates.

7) If desirable, use the search functions to find and add reaction term(s). See section 9.3 on how to search for WHO-ART term; MedDRA users see section 9.4. The **reaction operator** lets you choose if all added terms should be present (term 1 ‘and’ term 2), or if only one of the entered terms is needed (term 1 ‘or’ term 2), for a report to be included in the search results. (The reaction operator is available for profiles Report listing, CIOMS line listing, and Summary tabulation.)

8) You can choose to specify the entered reaction by changing the **reaction level**. Reaction level is connected to the hierarchies for WHO-ART and MedDRA, respectively. Generally, the lower value chosen the narrower the search will be. The highest level (‘SOC’/’system organ class’) is not allowed for profiles CIOMS line listing and Summary tabulation.

9) **Type of report**, **country of primary source**, **serious** and gender (sex) information can be added as search criteria. Also, you can select if the reaction on the report should be set as adequately labelled in the product information. (How to enter these values on a report is described in sections 2.2 to 2.11.)

10) If you chose to include concomitant also reports or reactions where the entered drug is set as concomitant will be listed in the search result.

11) Click the **run query** button to run the query. The results will be shown under **Results from search**. If your query did not match anything in your database, a message saying that no result was found will appear instead.

### 8.1.1 Saved queries

A saved query can be opened and used again whenever you want. To save a query, enter the search criteria the query shall contain and a **query name**. It is also
possible to enter a description of the query. Click on the button save at the bottom of the page.

To open and run a saved query:

1) Click on get old query in the left hand menu to open the page List of old queries.

![List of old queries](image)

On the List of old queries page all saved queries are listed. A description added to a query will appear as a green note next to the query name. Move the cursor to the note to see the entered description. To remove a query, click on the trash icon for the query in question.

2) Click on the edit icon to open a saved query. The query will open with the saved search criteria. Click on run query to get the search results displayed. It is also possible to edit the search criteria and save the query again.

### 8.2 Results from search and statistics

The result of a query will be given below the search fields under the heading Result from search. Depending on the profile chosen there are different options while viewing the result. Report Ids are given as links to an overview of the report. There is an option to go back to the search (the entered search criteria will remain and the result will be seen again after clicking on run query again) from the report overview.

#### 8.2.1 PDF print of reports

For the profiles Report listing and CIOMS line listing there are check-boxes by each report Id in the search result; then it is possible to generate a PDF file for printing the chosen report(s) by clicking on the button print selected reports found above and below the result. It is also possible to select all or clear selected. The Create document from ADR-report page will open when clicking print selected reports. See more information about printouts of reports in section 6.1.

#### 8.2.2 PDF output of search result

To create a PDF output of the search result, click on the button generate pdf found above and below the result (available for profiles CIOMS line listing and Summary tabulation). The page Created documents will open with a link to the created PDF
file; right-click on the link to download the file and save it on your local computer. The file will contain one page specifying the query and the rest will correspond to the query result as shown on the screen.

8.2.3 Excel output

To export the result in a format readable by Microsoft Office Excel (version 2003 or later is needed), click on the button generate excel found above and below the result (available for most profiles). The page Created documents will open with a link to the file. To open the file in Excel:

1) Save the file on your local computer by right-clicking on the link and choosing 'Save as...', 'Save target as...', 'Save link as...' or similar.

2) Open Excel and choose 'Open...' and find the file saved on your computer.

The file will contain several sheets where the first sheet specifies the query and the others contain the query result data.

Which of the profiles have these options for PDF and Excel output of the results is found in the table above (section 8) and in the descriptions of the profiles found below (sections 8.3.1 to 8.3.7). The Excel output is as far as possible translated into the language chosen in the VigiFlow interface, note that this does not apply to the contents of free text fields.

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8.3 Search and statistics profiles

8.3.1 Report listing

The profile Report listing is a tool to find reports of interest. The total number of reports included in the search result is given above the result table. In this profile a report will only appear once, and the result is sorted by report Id; the report Id is also a link to the view page of the report. The comment that can be shown or hidden is from the field sender's comments (see section 2.10; only the first 255 characters will be shown in the list; the whole text can be seen on the view page).

Above is a result from a search of made-up reports; from the profile Report listing it is possible to print selected reports and to generate an Excel file of the result. The Excel file from Report listing contains much more data regarding each report than is shown in the interface. Note that the first tab of the Excel file has one row for each report, but on the tabs for reactions and drugs each reaction or drug has its own row; which report they belong to is then identifiable by the report Id on each row.

8.3.2 CIOMS line listing

The profile CIOMS line listing will group reports by SOC. Only one drug can be used in the query and each report found will only appear once in the list. The reports will be sorted by the SOC of the primary reaction on the report (see section 2.7.2). The report Id is a link to the view page of the report and the comment is the first 255 characters from the field sender's comments (see section 2.10; the whole text can be seen on the view page). The column duration of treatment
shows the duration of treatment before reaction if onset date of reaction and start of administration are both completely filled in (day-month-year) on the report.

Above is shown a CIOMS line listing of the same made-up reports used before. The primary reaction on each report is shown in bold text. For this profile it is possible to print selected reports and to get a PDF file of the result.

**NOTE:** The daily dose calculation on the CIOMS line listing contains an error and does therefore not give the correct dose!

### 8.3.3 Summary tabulation

The profile Summary tabulation gives a summary of reactions per SOC/preferred term and report type for a chosen drug. A report with multiple reactions can appear several times in the result. The column 'Total' gives the total number of reactions per SOC/preferred term, while the last row 'TOTAL' gives the total number of reactions per report type.
Above is shown a summary tabulation of the same made-up reports used before, note that it is not possible to count the number of reports included in the result, only the reactions. (Tip: change to profile Report listing and repeat the same search to get the number of reports). For profile Summary tabulation it is possible to generate both PDF and Excel outputs of the result.

8.3.4 Drug reaction profile

The Drug reaction profile shows information on the reports and reactions for one chosen drug (combined with specified reaction(s), if added to the query). At the top of the results list the total number of reports included in the result is shown.

In the figure above a Summary tabulation of the previously used made-up reports is shown. The reactions on the reports are divided into three categories (see table below) depending on the entered causality on the report (see section 2.9).
Causality categories used in search and statistics profiles:

<table>
<thead>
<tr>
<th>Category</th>
<th>Causality:</th>
</tr>
</thead>
<tbody>
<tr>
<td>possible related reactions</td>
<td>– certain</td>
</tr>
<tr>
<td></td>
<td>– probable/likely</td>
</tr>
<tr>
<td></td>
<td>– possible</td>
</tr>
<tr>
<td>unlikely reactions</td>
<td>– unlikely</td>
</tr>
<tr>
<td>unclassified reactions</td>
<td>– conditional/unclassified</td>
</tr>
<tr>
<td></td>
<td>– unassessable/unclassifiable</td>
</tr>
<tr>
<td></td>
<td>– no relationship, old value</td>
</tr>
<tr>
<td></td>
<td>– not assessed, old value</td>
</tr>
<tr>
<td></td>
<td>– unknown, old value</td>
</tr>
<tr>
<td></td>
<td>– blank (no causality has been chosen)</td>
</tr>
</tbody>
</table>

The total number of reports with ‘death’ entered as reason for seriousness (see section 2.2.1) is also shown in the result as ‘fatal reports’. The result will also show the total number of unique drugs reported, and how many of them are marked as generic (i.e. the substance name and not a trade name has been used on the report). Since the generic drug ‘paracetamol’ has been used on all the reports in the example shown in the figure above, only one reported drug is shown in the result.

8.3.5 Summary of products

The profile Summary of products lists all drugs sorted by active ingredient (preferred name). This is the only profile where no search criteria are necessary; it is possible to get a list of all drugs on the reports in the search and statistics database (this can be a long list!). Each report can appear as many times as the number of entered drugs on the report. (Only drugs entered as suspected or interacting will appear in the result unless concomitant drugs are included in the query.)

Above is shown a Summary of products on the five made-up reports shown before and a sixth report with paracetamol entered as a concomitant drug; in the search criteria include concomitant is set to ‘yes’. Click on the link view details to expand the result as shown below. In this view each trade name is expanded into a group
with all reports containing that trade name listed. Each trade name group is still sorted under its active ingredient (preferred name).

In the search result, drugs on a report are shown in different typesetting: drugs belonging to the specific group are shown in bold text, other drugs are shown in regular text, and concomitant drugs are shown in italic text. For example, ‘Paracetamol’ on report 2008-00100 above, is in bold because it is in the group for Paracetamol and in italics because it is a concomitant drug on the report.

It is possible to export the result as an Excel file. The file will contain information corresponding to the expanded view.

### 8.3.6 Summary of reported ADRs

The profile Summary of reported ADRs lists reactions by year, relatedness and gender. The reactions are sorted by reaction level; it is possible to expand the SOC level to show preferred terms and included terms (lowest level term for MedDRA users) by clicking on the ☑-signs (close a group by clicking on a ☐-sign). Reports can appear multiple times in the list if they contain more than one reaction. In the first tab, summary by year, reports will be sorted by the year received (field date first received, see section 2.2.1). Each included year will have a column for suspected ADR(s) which corresponds to the category ‘possible related reactions’ in the table on page 89.
The second tab, summary by relatedness, shows the same suspected ADR(s), and also unlikely (category ‘unlikely reactions’), unknown (category ‘unclassified reactions’) and Total.

<table>
<thead>
<tr>
<th>Reaction code</th>
<th>2007 Total</th>
<th>suspected</th>
<th>unlikely</th>
<th>unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0600 - Gastro-intestinal system disorders</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>00205 - DIARRHOEA</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0279 - DYSPEPSIA</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0308 - NAUSEA</td>
<td>3</td>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>1820 - Application site disorders</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0047 - APPLICATION SITE REACTION</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0047004 - APPLICATION SITE RASH</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

The third tab shows summary by gender, with all reactions included (suspected, unlikely and unknown) and summarised by gender of the patients.

<table>
<thead>
<tr>
<th>Reaction code</th>
<th>male</th>
<th>female</th>
<th>other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0600 - Gastro-intestinal system disorders</td>
<td>3</td>
<td>1</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>00205 - DIARRHOEA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0279 - DYSPEPSIA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0308 - NAUSEA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1820 - Application site disorders</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>0047 - APPLICATION SITE REACTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0047004 - APPLICATION SITE RASH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It is possible to export the result as an Excel file; the information on the tabs in the result will appear on separate sheets in the file.

### 8.3.7 Summary of reported drugs

The profile Summary of reported drugs lists the drugs by relatedness, gender and reaction. It is possible to expand the shown active ingredients (preferred names) to show the trade names by clicking on the - signs (close it again by clicking on the

91 (120)
The first tab, relatedness by product, shows the included drugs with number of reactions sorted by suspected (category 'possible related reactions' in the table on page 89), unlikely (category 'unlikely reactions'), unknown (category 'unclassified reactions') and Total number of reactions.

The second tab, summary by gender, shows all reactions (suspected, unlikely and unknown) by gender of the patients.

In the third tab, reaction by product, only suspected ADR(s) are included and they are shown by the drugs included in the search (columns) and by the reaction level (rows).

Excel files can be generated with results from Summary of reported drugs queries; the information on the tabs in the result will appear on separate sheets in the file.
8.4 Administrative statistics

The Administrative statistics contains types of statistics that are more of use for yearly reports or to get a quick overview of the ICSRs in the database. Depending on the feedback regarding these statistics, they may be developed further.

8.4.1 Count profiles

The count profiles give a quick count of number of reports per the values of the selected profile(s) for a selected time period (receive dates; called date first received at data entry; see section 2.2.1). The last year is always shown including months; it is also possible to show months for all years. An example of how a search may look is given below. The generated result can also be exported in a Microsoft Office Excel compatible format (see section 8.2.3 for instructions).
8.4.2 Submission statistics

Submitted reports are those sent (using the Submission manager see section 7.3) to a receiver. The statistics show how many reports have been sent (including follow-ups within parentheses) to each receiver. It is possible to filter for submissions between specific dates and to add the number of amendments or nullifications to the follow-up number within parentheses. The generated result can also be exported in a Microsoft Office Excel compatible format (see section 8.2.3 for instructions).

<table>
<thead>
<tr>
<th>Submission statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission date</td>
</tr>
<tr>
<td>from: 01 01 2012</td>
</tr>
<tr>
<td>to: 16 04 2012</td>
</tr>
<tr>
<td>(dd mm yyyy)</td>
</tr>
<tr>
<td>include amendments and nullifications</td>
</tr>
<tr>
<td>show months for all years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Submissions per year and month</th>
</tr>
</thead>
<tbody>
<tr>
<td>generate excel</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Company Tester Inc. Sweden</td>
</tr>
<tr>
<td>Organization Sweden</td>
</tr>
<tr>
<td>Pharma Inc. Sweden</td>
</tr>
<tr>
<td>SE testing company Sweden</td>
</tr>
</tbody>
</table>
9  Search for drugs and terms

VigiFlow provides access to updated dictionaries and terminologies. These are provided from the UMC and other sources.

Note that VigiFlow can be set up to use either WHO-ART or MedDRA as reaction terminology; this is chosen at set up of a new VigiFlow organization/country. If WHO-ART is chosen, some fields are filled using ICD-10 (e.g. indication and death cause). If MedDRA is chosen, all these fields (as well as the field for test type) will use MedDRA. The WHO Drug Dictionary is used for entering the drug name for all users.

9.1  Search for drug

The WHO Drug Dictionary is used to enter drug names. The WHO Drug Dictionaries are continuously updated and maintained by the UMC. More information about the WHO Drug Dictionary can be found on the UMC Products and Services homepage: www.umc-products.com

1)  The actual search for a drug is performed on a separate page from the one where the drug name should be added. You can enter your search text in the field before you click on search drug to go to the search page.

2)  The Search for drug page opens. If you had entered a drug name the search result will also be displayed.

3)  On the Search for drug page you have the following options:

   a)  Enter the whole or part of the name of the drug you want to find in the drug name field. It is possible to specify in the drop-down list if the search result should begin with, contain or equal the entered text.
b) It is also possible to search for the **substance** the drug should contain in the same way as for drug names.

c) If you know the **MA holder** you can add this to your search.

d) If you specify a country, you have the choice to:

i) ‘Include unspec.’ includes drugs where country is unspecified.

ii) ‘Only selected’ only includes those drugs where the country is the one chosen in the country drop-down list.

c) To add an **ATC-code** to the search, click on the **pick ATC-code** button. Browse for the code you want by clicking on the plus signs until you find it, then click on **add to search**.

4) It is possible to have the search result sorted by either drug name or substance.

5) Click **start search**. The search result will match all your entered search criteria. You can change your criteria and click on **start search** again to widen or narrow the search results.

6) The search result is presented on three levels with only the first one visible to begin with. You can drill down in the search result (click on the -signs) to find the result you want to add.

a) The top level shows the **drug name** and the **substance**. If you add a drug at this level, this is what you get.

b) The second level contains additional information on **name specifier**, **MA holder**, and **country**. A drug added at this level will also include this information.

c) The third level has additional information on **form** and **strength**; if the drug you are looking for exists at this level this information will also be included.
7) If the specific MA holder, country, form or strength does not exist, you can still add the drug on a higher, less specified level. When you have found the right drug (and level) click on add to add it and return to the page you were working on.

8) After a drug has been added to the page you can view the drug information by clicking on the drug name or remove the drug by clicking on the trash icon next to the drug name.

9) If no suitable existing drug is found in the WHO Drug Dictionary, it is possible to suggest a new drug if you have come to the Search for drug page from the drugs page, see section 9.5.2.

When searching for drugs from the Search committed reports page also drugs set as historical in the WHO Drug Dictionary will be shown in the result. These are marked with the text ‘historical’ in red.

<table>
<thead>
<tr>
<th>Results from search</th>
</tr>
</thead>
<tbody>
<tr>
<td>drug name</td>
</tr>
<tr>
<td>aspirin</td>
</tr>
<tr>
<td>aspirin</td>
</tr>
<tr>
<td>aspirin</td>
</tr>
</tbody>
</table>

### 9.1.1 Search tip

#### Wildcards

You can use the % sign as a ‘wild card’ in the fields drug name, substance, and MA holder. If for example you are unsure about the spelling you can use the wildcard to take the place of one or more letters.

#### More than one substance

Note that if you enter more than one substance in the substance field, the order of the substances is part of the search; ‘paracetamol%caffeine’ will give a different result than ‘caffeine%paracetamol’. If you do not find what you are looking for at first, try changing the order of the entered substances.

#### Contains – Begins with – Equals

Some drugs are very common and will result in a long list of results. For example, when searching for contains ‘aspirin’ you get more results than begins with ‘aspirin’; you get the fewest number of results with equals ‘aspirin’.
Drug name specifier

Some drugs have a so called name specifier, for example ‘Nasal’ in ‘Lomudal Nasal’. If you search for ‘Lomudal Nasal’ you will get a result on the first level for ‘Lomudal’; you need to drill down to the second level to see ‘Lomudal Nasal’.

Note that if you search for equals ‘Lomudal’ you will not find ‘Lomudal Nasal’ on the second level.

Difference between ‘Only selected’ and ‘Include unspecified’

One way to narrow down the search result is to specify the country. If you for example search for equals ‘aspirin’ and still find the number of choices on the second level too many, add your country to the search. For country, you can either choose to include unspecified or show only selected.

If you use only selected, you will only get a result if the drug is available for your country. For example, there are no hits for equals ‘aspirin’ with only selected country ‘Holy See (Vatican City State)’.

If you use include unspecified you will get a result if the drug exists in the WHO Drug Dictionary on the first level only, or with country ‘Not Applicable’ or ‘Unspecified’, even if it does not exist for your country.

9.2 Search for ICD-10 term

There are several places where ICD-10 terminology is used.

ICD is updated and maintained by WHO; more information regarding ICD can be found on the homepage: www.who.int/classifications/icd/

1) The actual search for an ICD-10 term is performed on a separate page from the one where the term should be added. You can enter your search term (or code if the code checkbox is ticked) before you click on search term to go to the search page.

2) The Search for ICD-10 term page opens. If you had entered a word or code, the search result will also be displayed.
3) To search (or continue searching) for a term on the Search for ICD-10 term page, either:
   a) If you know the full or partial code for the ICD-10 term, enter it in the code field and click on start search. The search result will display all terms beginning with the entered code.
   b) If you do not know the code for the ICD-10 term, you can enter a word in the text field and click on start search. The search result will display all terms containing the entered word.

4) When you have found the appropriate term, click on add to report to add it, and return to the page you were working on.

5) If you change your mind and do not want to add an ICD-10 term, click on back to return to the page you were working on without adding a term.

6) An added ICD-10 term can be removed by clicking on the trash icon next to the term.

9.3 Search for WHO-ART term

WHO-ART is used for adding reaction terms on several pages.

WHO-ART is updated and maintained by the UMC. More information about WHO-ART and its structure can be found on the UMC Products and Services homepage: www.umc-products.com
The search for a WHO-ART term is performed on the same page as the one the term should be added to. It is possible to use both text and code in the search and to browse through the WHO-ART structure.

1) The search function has three drop-down lists, a search field, and a search button. The drop-down lists decide which level the search is performed on, if the search result should contain, begin with or equal the entered text, and in which language the search should be performed in.

2) You can find a term in three ways:
   a) Search text content by entering a term (or part of it), set the drop-down choices to reflect your preference and click on the search button. Note that you need to enter at least three characters in the text field to perform a search (unless the level is set to ‘SOC’).

   b) Enter a WHO-ART code, either the four digits of the adverse reaction record number or the seven digit full code and click on the search button.

   c) Browse for a term by setting the first drop-down list to ‘SOC’, leave the text field blank and click on search. All SOC terms will be displayed and you can browse down to the term you want by clicking on the plus signs.
3) In the search result, all levels down to the found result will be shown. In the search result you can:
   a) Select terms on 'PT' and 'IT' levels. (On the Search committed reports page you can select several terms together by checking the boxes to the left of the terms and clicking add selected.)
   b) Browse for other terms by clicking on the plus and minus signs.
   c) If you want to close the search for term result without adding a term, click on the check entries button at the bottom of the page.
4) After a term has been added to the page you can view the term information by clicking on the term name or remove the term by clicking the trash icon next to the term.
5) On the reactions page it is possible to suggest a new WHO-ART term if no suitable existing term is found, see section 9.5.1.

9.3.1 Search tip

Colours and highlighting

Note that the text string you use in the search is highlighted in blue in the result. In the result and while browsing, the different levels IT, PT, HLT and SOC also have their own colours:

Browse from SOC and browse your result

Most reaction terms will be found on the IT ('Included Term') level which is the default value in the first drop-down list. However, if you want to browse for a term,
change this drop-down list to ‘SOC’, leave the search field empty and click on search. The whole WHO-ART tree is then available for browsing. You can also browse from any search result. Use the \( \text{[X]} \)-signs (and \( \text{[ ]} \)) to discover other terms which might suit the described reaction better.

### 9.4 Search for MedDRA term

MedDRA is maintained by the MSSO (Maintenance and Support Services Organization) and updated twice yearly. Information about MedDRA can be found on the MSSO homepage at: [www.meddrarmsso.com](http://www.meddrarmsso.com)

The search for a MedDRA term is performed on the same page as the one the term should be added to. It is possible to both search for text and to browse through the MedDRA structure.

1) The search function has two drop-down lists, a search field and a *search* button. The drop-down lists decide which level the search is performed on and if the result should contain, begin with or equal the entered text.

2) You can find a term in two ways:

   a) Search *text* content by entering a term (or part of it), set the drop-down choices to reflect your preference and click on the *search* button. Note that you need three characters in the text field to perform a search (unless the level is set to ‘SOC’).
b) **Browse** for a term by setting the first drop-down list to ‘SOC’, leave the text field blank and click on search. All SOC terms will be displayed and you can browse down to the term you want by clicking on the plus signs.

3) In the search result, all levels down to the found result will be shown and the entered text will be shown in blue. In the search result you can:
   a) Select terms on ‘PT’ and ‘LLT’ levels. (On the **Search committed reports** page you can select several terms together by checking the boxes before the terms and clicking **add selected**.)
   b) Browse for other terms by clicking on the plus and minus signs.
c) If you want to close the search for term result without adding a term, click on the check entries button at the bottom of the page.

4) After a term has been added to the page you can view the term information by clicking on the term name or remove the term by clicking the trash icon next to the term.

9.4.1 Search tip

Bug in the search function

Regrettably, there is a bug in the search function that makes it impossible to perform searches containing an apostrophe (‘), letters with accents (é) and some other special letters (ì etc.). If you want to find the term “Bell’s palsy” for instance, you cannot include the apostrophe. You can either search for contains or begins with “Bell” or contains “palsy” or “s palsy”. (Wildcards are not possible when searching for WHO-ART terms.)

Colours and highlighting

Note that the text string you use in the search is highlighted in blue in the result. In the result and while browsing, the different levels LLT, PT, HLT, HLGT and SOC also have their own colours:

Browse from SOC and browse your result

Most reaction terms will be found on the LLT (‘Lowest Level Term’) level which is the default value in the first drop-down list. However, if you want to browse for a term, change this drop-down list to ‘SOC’, leave the search field empty and click on search. The whole MedDRA tree is then available for browsing. You can also browse from any search result. Use the -signs (and ) to discover other terms which might suit the described reaction better.
9.5 Suggest new drug or WHO-ART term

For all users it is possible to suggest new drugs to be included in the WHO Drug Dictionary, for WHO-ART users it is also possible to suggest new terms to be included in WHO-ART. These possibilities should only be used if a drug or term does not exist in WHO Drug Dictionary or WHO-ART respectively.

When a drug or term has been suggested on a report, the suggestions will be handled by UMC staff after the report is committed. (For drugs this will only happen if the checkbox send drug request to the UMC is ticked.) For more information on this process, see section 4.2.

9.5.1 Suggest a new WHO-ART term

The suggest new WHO-ART term button is located next to the reaction term field (see section 2.7.2) on the reactions page. The Suggestion for a new WHO-ART term page will open when the button is clicked.

Enter the suggestion for a new term and click the next button. You will return to the reactions page and can continue entering your report.
To remove a suggested term, click on the trash icon; to edit a suggested term you have to remove it and then re-enter a term by clicking on the *suggest new WHO-ART term* button. Suggested terms will have the text *uncoded* after the term name on the report until a UMC suggestion has been accepted and the term has been coded in WHO-ART (see section 4.2).

9.5.2 Suggest a new drug

To suggest a new drug, you first have to go to the *Search for drug* page (see section 2.8) from the *drugs* page. On the search for drug page click the button *suggest new drug* to open the page *Add drug that doesn’t exist in search*.

You should enter as much information about the drug as possible. (*The field name of product is a Mandatory field for added drugs.*)

It is optional to send drug request to the UMC. If the box is checked, it is mandatory to add a comment and UMC personnel will handle your request (see section 4.2). If not checked, the drug will remain as free text (uncoded) on the report. Reports with uncoded drugs are included, but not searchable by the uncoded drug name, in the Search and Statistics module. Note that for drug requests sent before the release of VigiFlow 4.2 this option is not available since all requests were then automatically sent to the UMC.

When you have entered the available information, click on the *next* button. You will return to the *drugs* page and can continue entering your report.
To remove a suggested drug, click on the trash icon, to edit a suggested drug, click on the name of the entered drug name. Suggested drugs will have the text *uncoded* after the drug name on the report until a UMC suggestion has been accepted and the drug has been coded into WHO Drug Dictionary (see section 4.2).
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## Appendix 1: E2B table

### Values from VigiFlow that will be excluded in external E2B reports

Sometimes a whole field (e.g. ‘date received at regional centre’) and sometimes only specific values from a field (e.g. ‘literature’ in ‘type of report’) will be excluded when a report is generated into external E2B. This is because extra fields have been added in VigiFlow in addition to E2B standard, due to special demands. Also some fields in VigiFlow allow more characters than the current version of E2B. When values are added in italic text, only the specified values from the field will be excluded.

### Report info page

date first received at sender (same field as date received at regional centre)
report title
application number (if report is from study)
type of report – authorities report, literature, product complaint (values will be converted into ‘other’)
person responsible
regional centre report Id
the primary source information fields: given name, family name, institution, department, street address, state, postal code, city, telephone, fax, e-mail

### Patient page

patient initials (will be converted into ‘privacy’)
parent initials (if parent–child case, will be converted into ‘privacy’)
date of birth (if not complete the value will be moved to the case narrative)
date of birth (parent, if parent–child case; if not complete the value will be moved to the case narrative)
age group – unknown
sex (patient) – unknown
sex (parent, if parent–child case) – unknown
date of last menstruation (parent, if parent–child case; if not complete the value will be moved to the case narrative)
GP medical record number
specialist record number
hospital record number
investigation number
comments (to death related information)
vaccine data section – all fields in the section

### Relevant past drug therapy (patient and parent)

import specific field for uncoded indication
import specific field for uncoded reaction

### Reactions page

duration (unit) – short term, long term, continuing
outcome of reaction – fatal - reaction may be contributory (will be converted into ‘fatal’), fatal - unrelated to reaction (will be converted into ‘unknown’)
treatment of reaction
vaccine data section – all fields in the section

### Drugs page

suggest new drug – name of product (drug suggested by user) Only the first 70 out of 80 characters will be included
suggest new drug fields: form, strength, MA-holder, active ingredient, obtain country, comments/references, ATC-code, indication (ICD-10)
suspected ingredient
vaccine data section – all fields in the section
dosage regimen (value and if unit is any of) – as necessary, cyclic, total
duration (value and unit if unit is any of) – second(s), short term, long term, continuing
is the ADR adequately labelled
additional information – only the first 100 out of 2000 characters will be included.

### Assessment page

sender’s comments – only the first 2 000 out of 20 000 characters will be included
imported sender’s comments and diagnosis references
Appendix 2: Interface Overviews

9.5.3 List of reports page (for National Centres)

To open a report in the list, click on the edit icon. To delete a report in the list, click on the trash icon. A deletion can be 'delete', 'history mark' or 'nullify', depending on the report.

To commit a complete report, click on the commit icon. (Not for Regional Centre.)

To view a report in the list, click on the view icon.

Click on the check in icon when you have finished editing a report, to make it available to others.

This icon opens the Administrative Information chapter for a report. (Not for Regional Centre.)

This code (year - five digits) is the report Id.

This icon indicates that the report is reported as serious.

To print reports in the list, check the relevant box(es) and click the print selected reports button.

To add comments to a report, click on the comment icon and edit.

To open a report in the list, click on the edit icon.

To display the reports that are to be assessed, choose report handling and then list reports in the top menu.

Only National Centres can search on List of reports page.

The rows to display will limit the number or reports shown in the section Reports under central assessment unless you set it to 'all'.

To change the language in the interface, use this drop-down menu.

To print reports in the list, check the relevant box(es) and click the print selected reports button.

To add comments to a report, click on the comment icon and edit.

This icon indicates that the report is reported as serious.

To delete a report in the list, click on the trash icon. A deletion can be 'delete', 'history mark' or 'nullify', depending on the report.
9.5.4 Report info page

These are the data entry pages.

To start entering a report, select new report from the top menu.

The warning icon indicates e.g. that a field is mandatory.

To give feedback to UMC at any time during the process, click on the give feedback link. (Not for Regional Centre users.)

The top menu contains general functions for handling reports, e.g. listing and sending reports.

The help icon will give you help with the field it is located next to.

The error icon will warn you of invalid entries, and keep you on the page.

To see or download the User Guide, click on the user guide link.

At any time during the process, you can choose to save or print report by clicking on any of these two links.

When you are working with a report, after completing a step, click the check entries button to refresh your information, generate or remove error messages, etc.

It is possible to save primary sources that you enter often. You can then find and add your saved source with the find primary source function.

The next button will take you to the next page according to the left hand menu, unless you have an unresolved error message on this page.

The link clear will remove your choice in the field it is located next to.

To give feedback to UMC at any time during the process, click on the give feedback link. (Not for Regional Centre users.)
9.5.5 Reactions page

To add a new reaction, click on **add new reaction**.

For WHO-ART users it is possible to suggest a new term by clicking on the **suggest new WHO-ART term** link, if an appropriate reaction is not found.

The reaction shown here is the one you have chosen in the list.

If you click on the **move up** arrow you can sort the terms in a specific order.

If you click on the **trash** icon, you will delete the term and corresponding information from the report.

In the list you can switch between reactions that you have entered, to e.g. add more information on a reaction.

This icon warns of a missing mandatory field or error for this reaction.

Enter a reaction by searching for a reaction term and selecting it.

Use the **expand/hide** button to reveal or conceal more fields.

This is the causality assessment. It is available on both the reactions and drugs page.
Here you can switch between suspected and interacting drugs that you have entered, to add more information on each drug.

If you click on the trash icon, you will delete the selected drug and corresponding information from the report.

To add a new suspected drug, click on add new drug here.

This drug has been added to the report, click on the drug name to view details, click on the trash icon to remove the drug.

Use the expand/hide button to reveal or conceal more fields.

This is the causality assessment. It is available on both the reactions and drugs page.
9.5.7 Search and statistics module

This is the view details view of the result. Click back to return to the original view.

Click on search and statistics then on search and statistics in the top menu.

Choose the profile here.

If you want to save a query, the fields query name and description are useful!

For most profiles it is mandatory to enter a drug.

Click on save if you want to save the query to be used again at a later date.

If you click on get old query all saved queries will be listed.

Start searching your database with the entered search criteria by clicking on run query.

Click on the Report Id to view a specific report.
9.5.8 Useful shortcuts

Shortcuts in the form of access keys have been created to facilitate switching between different pages without using the mouse. In the left hand menu all pages have a number (or letter). To switch to a specific page the access keys are $Alt + [key]$. The access keys for the buttons check entries and next, are $Alt + c$ and $Alt + n$, respectively. Please note that this function works differently in different web browsers. E.g, with Internet Explorer you have to also press enter after the access keys for the shortcuts to work, and with Mozilla Firefox you need to press $Shift + Alt + [key]$.

Also note that it is generally not recommended to use the ‘back’-function in the web-browser while navigating secure internet pages.

Access key: $Alt + c$.

Access key: $Alt + n$. 

To move to the next field on a page, press $Tab$. (To move in the opposite direction press $Shift + Tab$.)

To tick or un-tick radio buttons or checkboxes, press the spacebar on your keyboard.

Navigate in drop-down lists by typing the beginning of the word you want and/or use the up- and down-arrows.
# Appendix 3: Icons

<table>
<thead>
<tr>
<th>Icon:</th>
<th>Explanation:</th>
</tr>
</thead>
</table>
| ![Edit](edit_icon.png) | *Edit.* Opens a report for editing.  
When you have opened a report, it is ‘checked out’. This means that no one else can change the contents until you have closed it. Click on the *check in* icon to close the report when you have finished editing. |
| ![Administrative information](admin_info_icon.png) | *Administrative information.* Opens the Administrative information page for a report. |
| ![View](view_icon.png) | *View.* Opens a view of the report. You can only read the information on the report, not edit the report. |
| ![Send](send_icon.png) | *Send.* Click on the envelope to send the report to another centre (in list reports only available for Regional Centres). |
| ![Commit](commit_icon.png) | *Commit.* When the report is complete and correct, you can commit it (only for National Centres). |
| ![Check in](check_in_icon.png) | *Check in.* After a user has edited or entered a report it has to be checked in to be available for other users. |
| ![Trash](trash_icon.png) | *Trash.* Removes the report. It can be ‘delete’, ‘history mark’ or ‘nullify’ depending on the report. It can also remove a drug name, reaction or other added information from a report. |
| ![Comment](comment_icon.png) | *Comment.* This note contains comments on the report. To read the comment, point the cursor on the comment icon.  
To add or change a comment, click on the comment icon under *list reports* or, if the report is open, select *save report* in top menu and add the *Report comments* in the comments box. |
| ![Warning](warning_icon.png) | This icon has several meanings. Point the cursor on the warning icon to get a pop-up with context specific information.  
*Mandatory field / Warning.*  
Indicates a *Serious ICSR* in the List of reports under central or regional assessment  
See also the definition as a transmission acknowledgment code. |
<p>| <img src="help_icon.png" alt="Help" /> | <em>Help.</em> Point the cursor on the help icon to get a pop-up with context specific information. |
| <img src="error_icon.png" alt="Error" /> | <em>Error.</em> Point on the error icon to get a pop-up with context specific information. |
| <img src="calculator_icon.png" alt="Calculator" /> | <em>Calculator.</em> Click on the calculator when you have entered full onset/start and end dates. The calculator will calculate the duration (of reaction or administration). |
| <img src="drug_info_icon.png" alt="Populate drug information fields" /> | <em>Populate drug information fields.</em> If this icon is clicked, fields on the drug page will be filled with data from the WHO Drug Dictionary about the added drug. See section 2.8.1. |
| <img src="nullify_icon.png" alt="Nullification comment icon" /> | <em>Nullification comment icon.</em> This icon gives quick access to the nullification/history marking comment. |
| <img src="discard_icon.png" alt="Discard version icon" />, <img src="promote_icon.png" alt="Promote version icon" /> and the warning clock | The <em>Discard version icon</em>, <em>promote version icon</em> and the warning clock are used to handle updates of previously received cases, see section 5.3. |</p>
<table>
<thead>
<tr>
<th>Disable future submissions icon and the icon showing that future submissions have been disabled. Read more in section 3.3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission acknowledgment codes,</td>
</tr>
<tr>
<td>This icon informs that the transmission is OK.</td>
</tr>
<tr>
<td>This icon informs that not all reports were loaded in the transmission.</td>
</tr>
<tr>
<td>This icon informs that no reports were loaded in the transmission.</td>
</tr>
</tbody>
</table>