VigiFlow - introduction and data entry

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Agenda

- Module I
  - VigiBase – recapture
  - VigiFlow
    - General information and background
    - Data entry

- Hands on...

- Module II
  - VigiFlow – advanced concepts
    - Advanced report handling
    - Search and Statistics
Spontaneous reporting and the UMC - VigiBase

• the WHO global ICSR database
  - the WHO database
  - VigiBase
  - (INTDIS database)
• Core of the UMC operation
• Repository for spontaneous reports
Growth of the WHO Global ICSR database since start
2009-04-24

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Reporting formats

INTDIS – (International Drug Information System)
- 41 countries

E2B – (ICH standard)
- 53 countries
  - whereof 28 actively are using VigiFlow

So – how does it work?
What is VigiFlow?

- Complete ICSR (Individual Case Safety Report) Management System
- Can be used by both national authorities and companies for management of their own reports
  - Data entry
  - Assessment
  - Storage
  - Retrieval (e.g. for follow-ups)
  - Communication with other parties
- It is web-based
- It is E2B compatible
History

- 2001 – Swissmedic needed a new pharmacovigilance system
  - Support for primary notifier reporting
  - 7 regional centres
  - 4 languages

- A project was started – “ADR Pilot”:
  - Version 0.1 – Summer 2003
  - Version 1 – Autumn 2003
    - E2B compatible version complying with international standards
    - With this version the first report was entered – by Alex in Ghana
Swissmedic usage

- As mentioned Swissmedic has been using VigiFlow for all their report management since summer 2004
  - They have connected 7 regional centres, including one specialized centre
  - There is no more paper based reporting from physicians directly to Swissmedic
    - But companies are still sending reports on paper…
  - They are today managing twice the amount of reports compared to 2004 without increase in staff
Countries using VigiFlow

- Andorra
- Argentina
- Barbados
- Botswana
- Brazil
- Croatia
- Ethiopia
- Ghana
- Kazakhstan
- Lithuania
- Madagascar
- Montenegro
- Morocco
- Mozambique
- Namibia
- Nepal
- Nigeria
- Romania
- Saudi Arabia
- Senegal
- Serbia
- Sierra Leone
- Sudan
- Suriname
- Switzerland
- Tanzania
- Togo
- Turkey
- Uganda
- Uzbekistan

PMS Network
- Albania
- Iran
- Kazakhstan
- Senegal
- Sri Lanka
- Tunisia
- Uganda
Flexibility of VigiFlow

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Flow of reports in VigiFlow

External organizations

Regional Centre 1

Report repository

Regional Centre 2

E2B (XML)

Regulatory Authority

E2B (XML)

WHO database - VigiBase

PDF

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Pros and cons with VigiFlow

**Pros**
- Combination of structured and free-text fields to encourage complete data entry
- Integrated dictionaries and terminologies ensures correct coding
- Easy communication between national and regional centres
- No need for local server upkeep and back-ups
- Seamless transmission of reports to WHO/UMC

**Cons**
- Server (with national data) in another country might be against national regulations
- Needs Internet access - at least 0.5 Mbit/s for a good experience
- Not 100% adaptable to local ideas of how it “should work”
Terminologies used

- Terminology for coding reactions and indications
  - WHO-ART / ICD
    - Easy reporting and analysis

- Dictionary for coding drugs
  - WHO Drug Dictionary
    - Products from many countries as well as herbal products
Main parts: report handling

- Create new reports
- Data entry and editing of reports
- Only “open” reports
  - Reports that are in the process of getting new information added
- Communication between National and Regional centres
- Commit reports
  - Finalize a version of the report
Main parts: search & statistics

- Will be covered later…
Main parts: tools

- Will be covered later…
Main parts: report handling

With this button you create a new report

This button lists all reports that are “under assessment”
List of reports “under assessment”

Use these filters to find the reports to work on.

Select the reports to print and press the print button.

Advanced filter options.
Actions on reports available from the report list

- Open an existing report for edit
- Open a report for viewing it only
  - All report information on one page
- Commit a report
  - Report will be available for search and statistics
  - Report “can” be sent to the UMC
- Delete a report
  - Result of action depends on report “status”
- Open the administrative chapter
  - More information tomorrow
- Check in the report
  - Someone else can open the report to edit it
Report
input module
Create a new report

- **Standard case:**
  - A normal report with one patient taking a drug and suffering from an ADR

- **Parent-child case:**
  - A report where a parent has taken a medicine and the child is suffering from the ADR

Click this button to create a new report
Sections of the report input module

- General report information
- Patient information
- Drugs
- Reactions
- Tests and procedures
- Medical history
- Past drug therapy information
- Assessment fields
- If “parent-child case” also parent information
General report information

• The first section of the report
• Collects information about
  – General report data
  – Sender of the report
  – Primary source(s)
General report information

- Type of report
  - Spontaneous, study, literature ref…

- Seriousness criteria
  - Death, life-threatening, disabling, hospitalization, congenital-anomaly, other
## General report information

<table>
<thead>
<tr>
<th>Report Information - Standard Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Report Id</strong></td>
</tr>
<tr>
<td>2008-00023</td>
</tr>
<tr>
<td><strong>Date first received at national centre</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Report title</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Type of report</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Serious</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Reason for seriousness</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Country of occurrence</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Country of primary source</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Does this case fulfill local criteria for an expedited report?</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Additional documents held by sender</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>List of documents</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Was the case medically confirmed?</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
General report information - sender details

• Information about the organization sending the report to you
  - Type of organization
  - Name of sender and senders report number to be entered in admin chapter

• World wide unique number
  - If you are the first receiver of the report this should be left blank. It will be automatically filled with your report number.
  - If you are not the first receiver, fill in the report number of the original sender of the case

• Information about other case identifiers in previous transmissions
General report information

Information on sender

- **Type of sender**
  - Pharmaceutical company
  - Regulatory authority
  - Other (clear)
  - Health professional
  - Regional pharmacovigilance center

Other case identifiers in previous transmissions

- **Source**: ACME
- **Case identifier**: SE-ACME-2008-1:

Add new identifier

Worldwide unique number

- **Authority report number**: SE-DPB-2008-00023
- **Company report number**: 

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General report information – primary source(s)

- Information about primary source
  - Name and details of for example physician
  - Literature reference
    - To be filled in if a literature case
  - Information about study details
    - To be filled in if report from study
- The entire section is repeatable if there are more than one primary source
- Possibility to save a reporter for later re-use
General report information

Information on primary source(s)

Given name

Family name

Institution

Department

Street address

State

Postal code

City

Telephone

Fax

E-mail

Country of reporter

Sweden

Reporter qualification

- Physician
- Lawyer
- Consumer or other non health professional
- Pharmacist
- Other health professional

Literature reference

Add primary source

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Patient information

• Birth date, age or age group
• Initials
• Weight
• Height
• Sex
• Information on patient death
  - Death date
  - Death cause
  - Autopsy information
Tests and procedures

- Allows for entry of test data
- Free text field
- Structured information
  - The preferred option
  - Test type entered as free text or by selection from a drop down

In appearance the test sections differs somewhat from the rest of the tool since there has been a wish to always see all information for comparison reasons.
### Results of tests and procedures

**results of tests and procedures - free text**

- **Free text entry**

**Tests**

- **Add another “coded” test**

<table>
<thead>
<tr>
<th>Test type</th>
<th>Test type (free text)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphocytes</td>
<td></td>
</tr>
</tbody>
</table>

- **Add test type as free text or from drop down**
  (Only MedDRA term if MedDRA is used as terminology)

<table>
<thead>
<tr>
<th>Low/high range</th>
<th>Test unit</th>
<th>Test unit (free text)</th>
<th>More info available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Units/l</td>
<td></td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

**Results**

<table>
<thead>
<tr>
<th>Date (dd mm ccyy)</th>
<th>Result</th>
<th>Date (dd mm ccyy)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 01 2008</td>
<td>12</td>
<td>13 01 2008</td>
<td>18</td>
</tr>
</tbody>
</table>

- **Add another test result, more than one can be added at the same time**

- **Copy dates if several tests have been done at the same date(s)**
Relevant medical history

- In this section medical history that might be of importance is recorded
- Free text field
- Structured information
  - Medical history term (ICD-10)
  - Start and stop date
  - Comment
Past drug therapy

- In the past drug therapy section information about previous medications is recorded
  - Drug name
  - Indication (if available)
  - Reaction (if applicable)
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>Y32 - CRASHING OF MOTOR VEHICLE, UNDETERMINED INTENT</td>
<td>Headache</td>
</tr>
</tbody>
</table>

2 past drug therapies entered

Name of drug (free text)

Reaction (coded with term lookup)

Indication (coded with term lookup)
Reactions

- Reporter’s comments
- List of coded reactions
- Details about each individual reaction
- Causality assessment
List of reactions

5 reactions added

Use the up arrow to move the most important reaction to the top

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Use the reaction lookup tool to add the correct term (described later)

Enter a new term **only** if you could not find an appropriate term in the term lookup tool
Comments provided from primary source (in free text)

Coded reactions
The reaction in bold is the “active” reaction below

Details about “active” reaction

Relatedness assessment – entered for each drug/reaction combination
Drugs

- List of coded drugs
- Details about each individual drug
- Causality assessment
List of drugs

List of suspected drugs

- Alvedon
- Aspirin
- Mangolol uncoded

List of concomitant drugs

- Magnecyl

Add new drug

Use the up arrow to move the most important drug to the top

Add one more drug to the report

3 suspected and 1 concomitant drug added

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Drug entry

Use the drug lookup tool to add the correct drug

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Coded drugs
The drug in bold is the “active” drug below

Details about “active” drug

Relatedness assessment – entered for each drug/reaction combination
Drug reaction relatedness (Relatedness assessment)

- Information on the relatedness of the drugs and reactions coded on a report
  - Relatedness information
    - In VigiFlow – WHO Causality
    - Information on recurrence
  - Information entered in a “simple” matrix

<table>
<thead>
<tr>
<th>Application site reaction</th>
<th>Alvedon</th>
<th>Aspirin</th>
<th>Mangolol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash</td>
<td>Unlikely</td>
<td>No relationship</td>
<td>No relationship</td>
</tr>
<tr>
<td>Headache aggravated</td>
<td>Unlikely</td>
<td>Unknown</td>
<td>Certain</td>
</tr>
<tr>
<td>Any term not found</td>
<td>Possible</td>
<td>Probable</td>
<td>Not assessable</td>
</tr>
</tbody>
</table>

Remove a relatedness with the trash if NO relatedness at all
### Relatedness of drug(s) to reaction(s)

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Alvedon</th>
<th>Aspirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>Unlikely</td>
<td>Unlikely</td>
</tr>
<tr>
<td>Stomach upset</td>
<td>Probable</td>
<td>Possible</td>
</tr>
</tbody>
</table>

(* = Yes - if reaction recurred after rechallenge)
Assessment

• A number of “mainly” free text fields
  - Case narrative
  - Sender’s comments
    • Your comments
  - Sender’s diagnosis
    • Coded in ICD10 or MedDRA with the term lookup tool
  - References
    • Any references to other sources, like literature
Overview

- Shows a summary of the report
  - All filled in fields
  - All fields with errors or warnings
  - Only to be used for a quick overview not “print or read friendly”!

If you are about to finalize/commit a report and it is reporting that it has errors… this is the place where to go!
# Report information - standard case

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>report version</td>
<td>1</td>
</tr>
<tr>
<td>date receipt most recent info</td>
<td>15.06.2008</td>
</tr>
<tr>
<td>report title</td>
<td></td>
</tr>
<tr>
<td>type of report</td>
<td>spontaneous</td>
</tr>
<tr>
<td>reason for seriousness</td>
<td></td>
</tr>
<tr>
<td>country of occurrence</td>
<td>Sweden</td>
</tr>
<tr>
<td>country of primary source</td>
<td>Sweden</td>
</tr>
</tbody>
</table>

## Information on sender

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>type of sender</td>
<td>Central Demo</td>
</tr>
<tr>
<td>person responsible</td>
<td></td>
</tr>
</tbody>
</table>

## Information on primary source(s)

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>country of reporter</td>
<td>Sweden</td>
</tr>
</tbody>
</table>

## Patient characteristics

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>date of birth</td>
<td></td>
</tr>
<tr>
<td>patient initials</td>
<td></td>
</tr>
</tbody>
</table>

## Death related information

## Reaction(s) / event(s)

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>reporter's comments</td>
<td>Reaction / event Application site rash</td>
</tr>
<tr>
<td>reaction term</td>
<td>Reaction / event Rash</td>
</tr>
<tr>
<td>onset date</td>
<td>Reaction / event Headache aggravated</td>
</tr>
<tr>
<td>reaction term</td>
<td>Reaction / event Any term not found</td>
</tr>
<tr>
<td>onset date</td>
<td>年 mandatory</td>
</tr>
<tr>
<td>onset date</td>
<td>年 mandatory</td>
</tr>
<tr>
<td>onset date</td>
<td>年 mandatory</td>
</tr>
<tr>
<td>new term</td>
<td>年 mandatory</td>
</tr>
<tr>
<td>onset date</td>
<td>年 mandatory</td>
</tr>
</tbody>
</table>

## List of suspected drugs

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>drug name</td>
<td>Alvedon</td>
</tr>
</tbody>
</table>
Reaction lookup tool

The reaction lookup tool has been rebuilt in version 4.1 of VigiFlow. New features are:

- The lookup is done without leaving the page where the term shall be added
- The entire search tree is displayed in the result
- Searches can be done with:
  - Begins with, equals and contains
- Searches can be done on specific levels
- Result tree can be expanded
Reaction lookup tool
Drug lookup tool

- With version 4.1 of VigiFlow one of the major changes is the tool to pick drugs from WHO-DD
- The aim is to:
  - Make it easier to find the appropriate drug and drug level
  - Make it more difficult to suggest new drugs!
Enter a new drug only if you could not find an appropriate drug in the drug lookup tool.

Select appropriate level depending on available information on report and details available in WHO-DD.
Comment on report entry

- VigiFlow contain a large number of data fields, filling them all in may be very time consuming.  
  *But*…

- There are **only 5 mandatory fields**
  - Header, initials, birth date, drug, reaction and onset date

  *On the other hand*…

- More data will improve the overall quality and simplify the causality assessment
VigiFlow – hands on

• Form groups of three or four
• One in the group must be a “experienced” VigiFlow user
  – But – someone else should do the hands on!
• Create one “made up” report with your “group name” in the report header and a small amount of data
  – Add at least two reaction
• Save and commit the report
  – Write down the report number
• Search for the report in the search and statistics tool and export the result set on excel format

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Practical details

- **Passwords**
  - edunc1  yete8r6s
  - edunc2  yete8r6s
  - edunc3  yete8r6s
  - edunc4  yete8r6s
  - edunc5  yete8r6s

- **URL**
  - https://adr.who-umc.org