

ICSR Mgmt Tool: VigiFlow

UMC Pharmacovigilance course 2013

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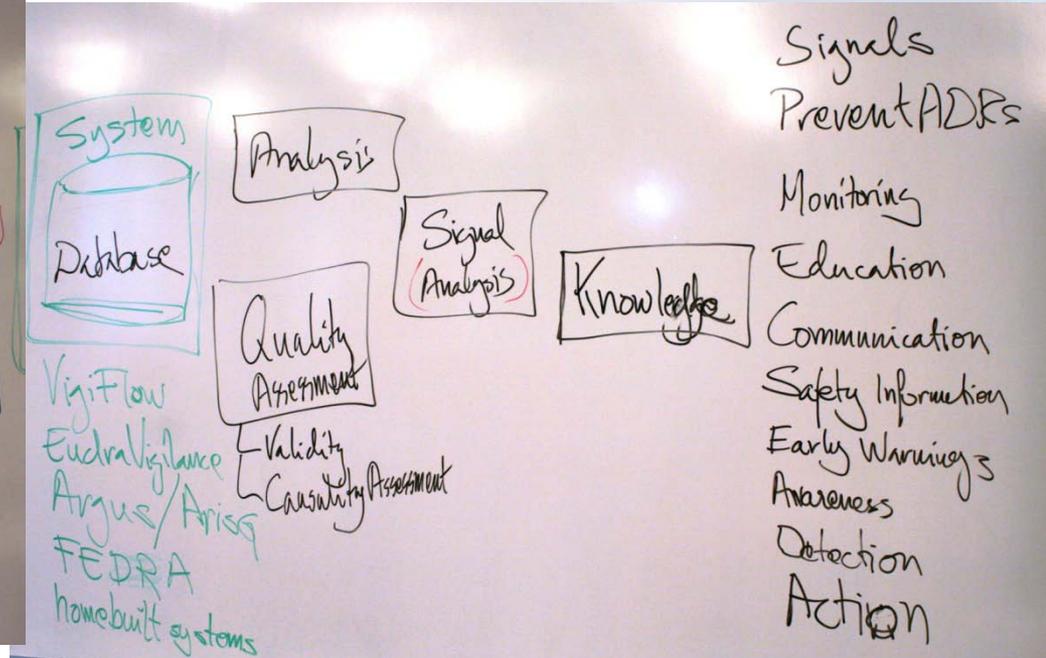
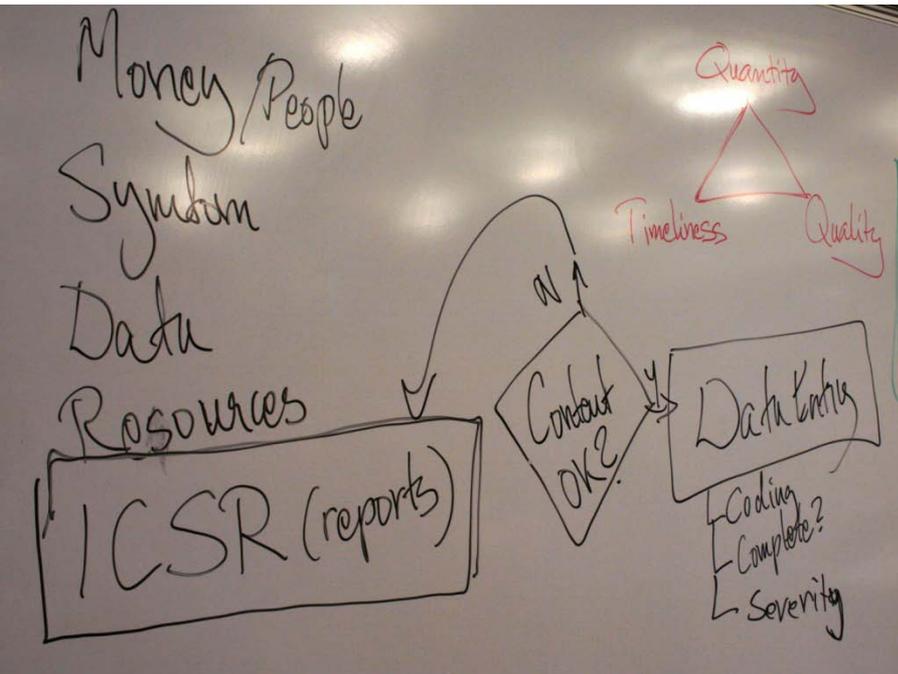


Purpose of a PV unit

Possible inputs

Process between input and output

Main output





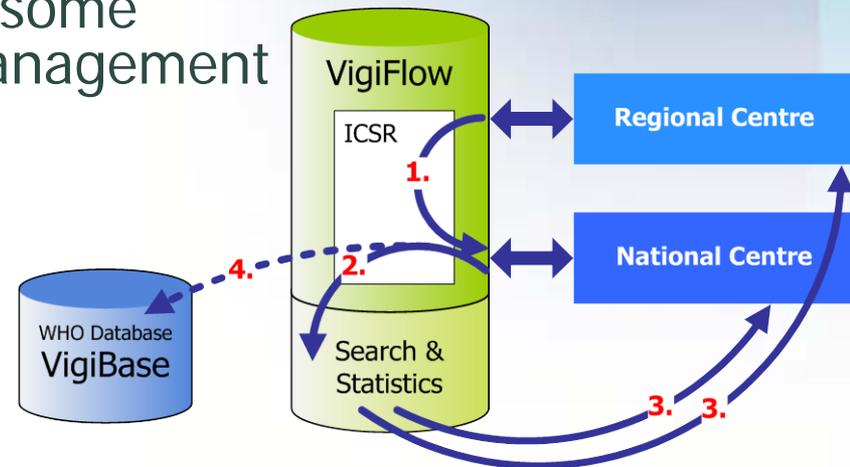
Presentation outline

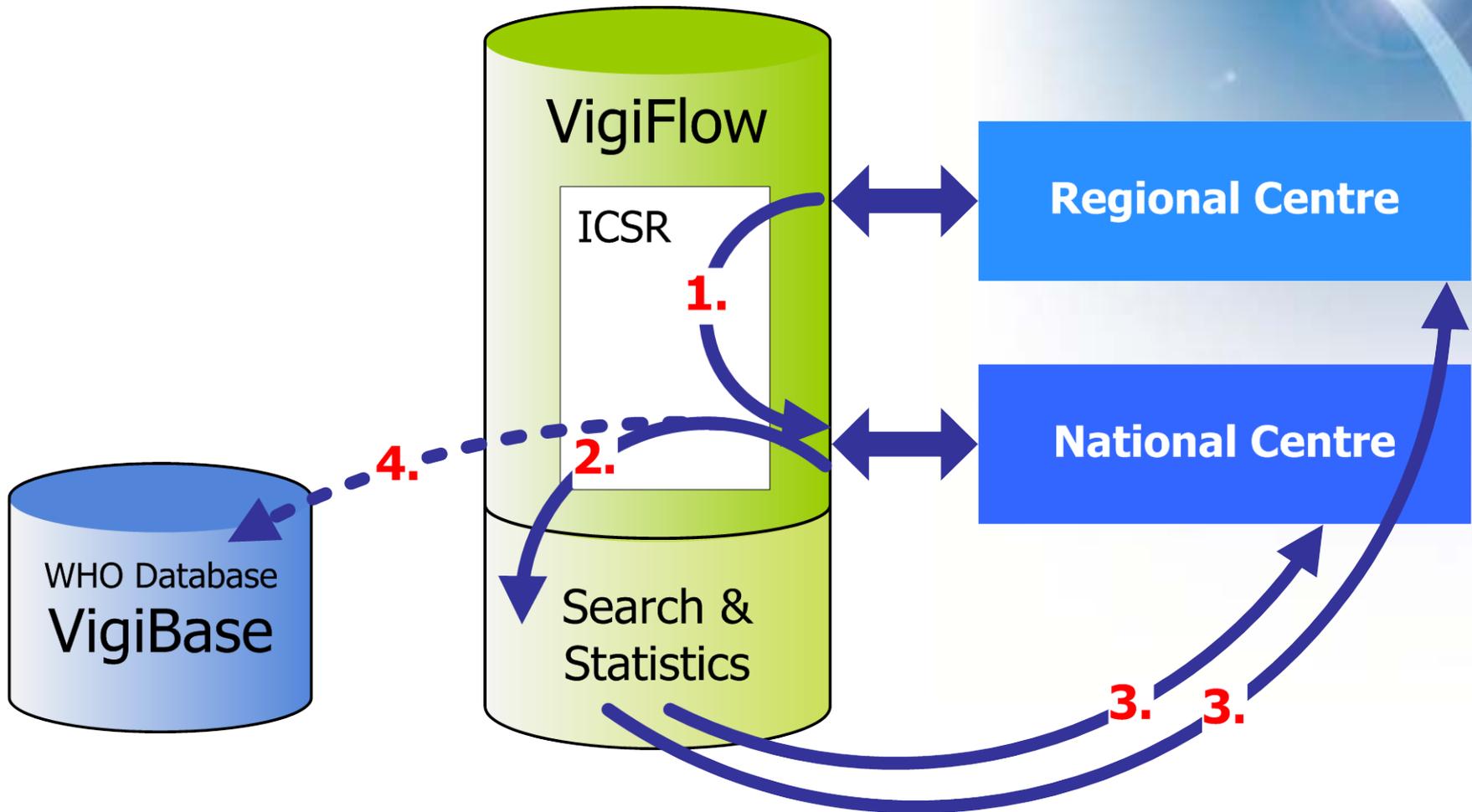
- Basic facts
- Choices, possibilities and process support
- Demo
- Extra: E2B information and demo

ICSR Management: VigiFlow

What is VigiFlow?

- **Complete ICSR Management System**
 - Used by over 50 countries
- **National PV authorities** and some vaccine units use it for ICSR management
 - Data entry
 - Assessment
 - Storage
 - Retrieval (e.g. for follow-ups)
 - Line listings and statistics
 - Communication with other parties
- **Web-based**
- **ICH-E2B compatible**





Choices at VigiFlow set up



- Regional Centres
- WHO-ART or MedDRA
- Complete version or Limited access

Advantages with Regional Centres



- The RCs will be more “involved”
- Data entry is done at the RCs
 - Less need for data entry work at the NC
 - Paper forms are handled and archived at RC
 - Finalization/last check of ICSRs done by NC
- Search and Statistics available for the RCs

Regional Centres can be added (or removed) at any time!

Two versions of VigiFlow

Complete version

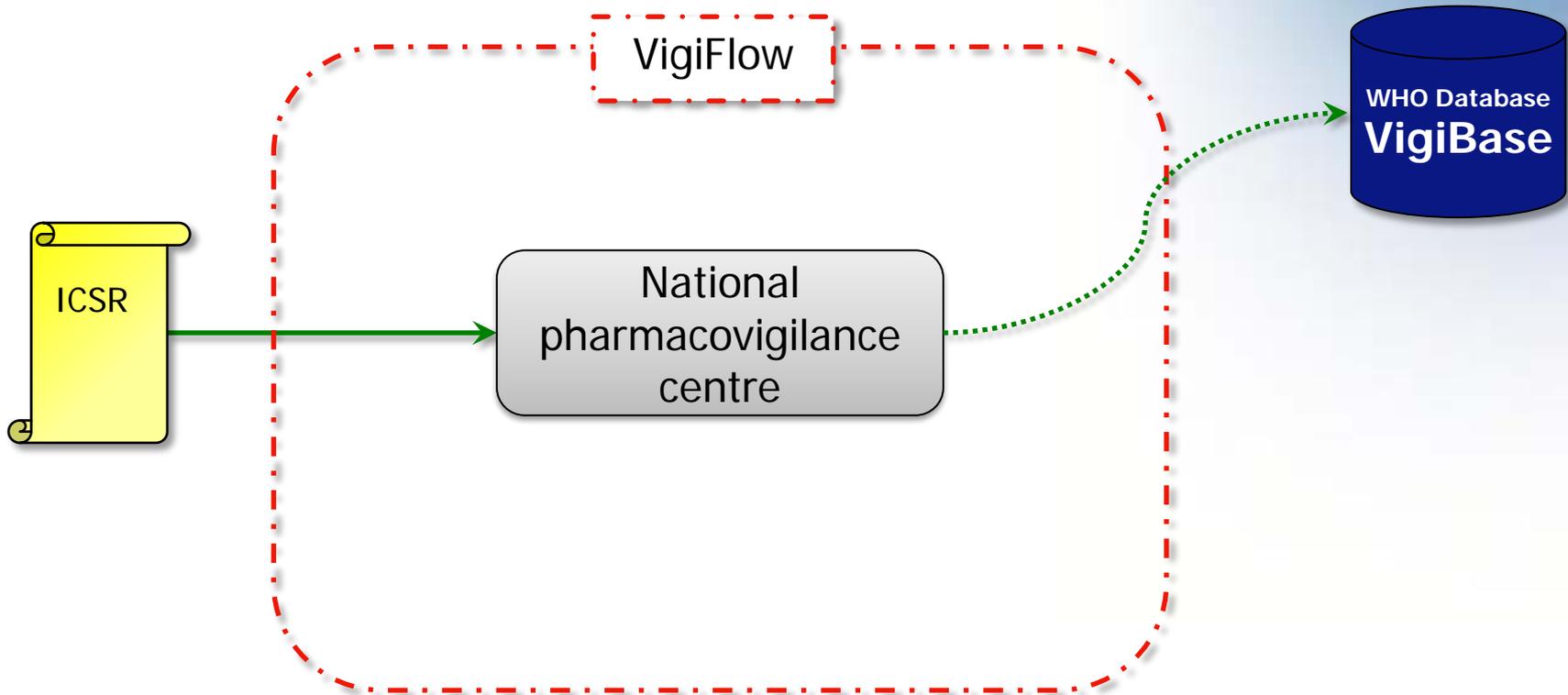
- **Complete ICSR Management System**
- Search & Statistics on national cases
- Yearly fee

Limited version

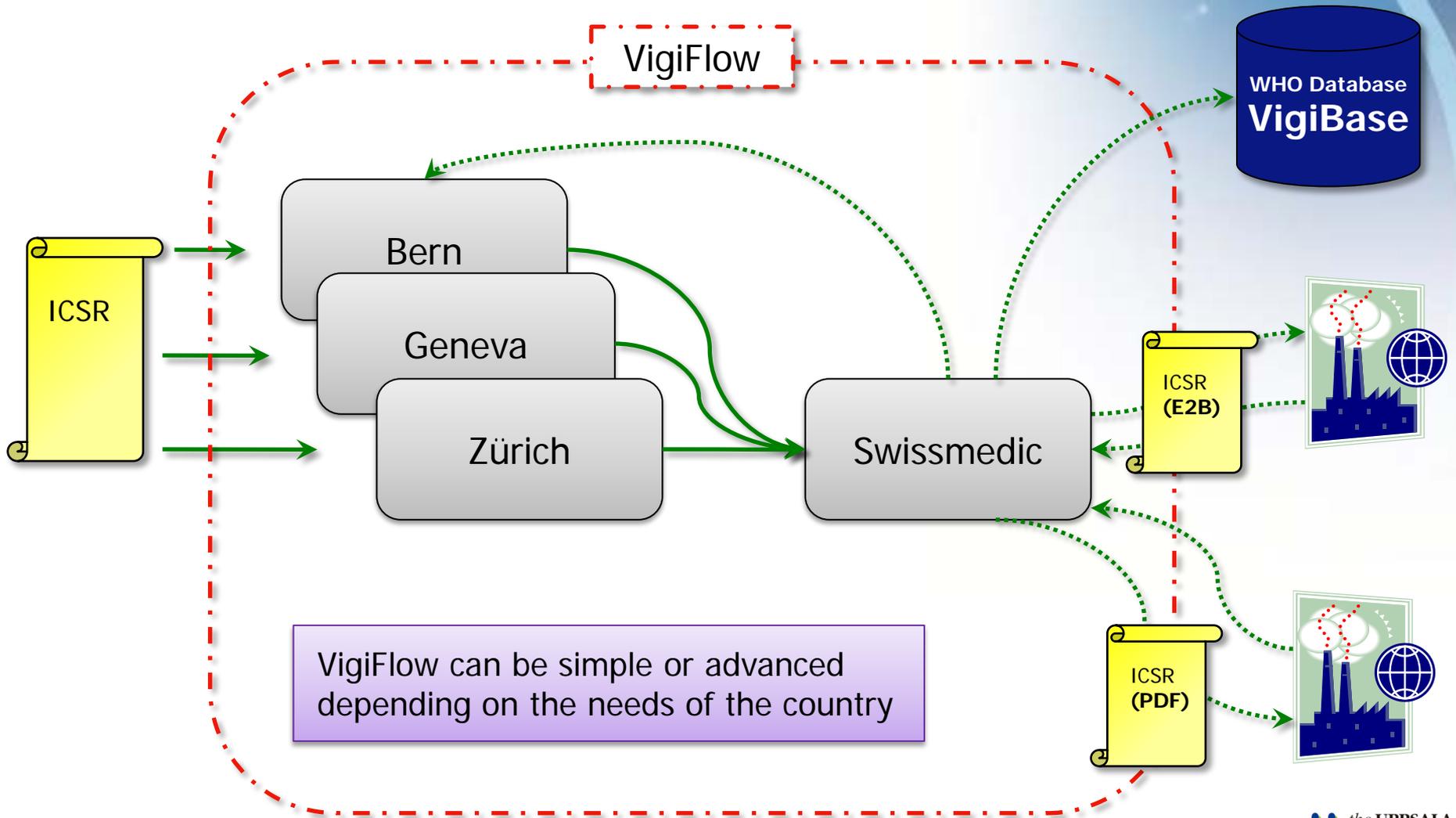
- Only for creation of and sending ICSR
- Free of charge

It is possible to switch between Complete and Limited version.

An example of using VigiFlow

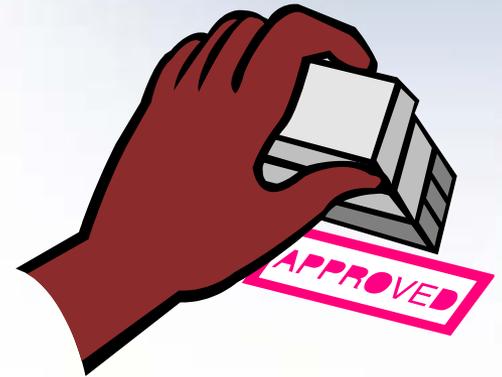


Example from Switzerland



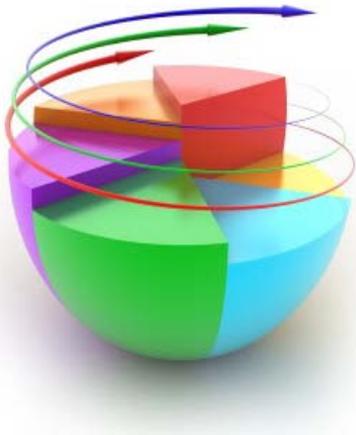
Built in quality

- Support (help pop-ups, user guide)
- Mandatory fields
 - Receive date
 - Age at onset + patient initials
 - Drug
 - Reaction + start year of reaction
- Terminology and dictionary look up tools
 - WHO Drug Dictionaries
 - ICD-10 + WHO-ART or MedDRA
- Data entry overview page and audit trail
- Encrypted access (<https://>) via internet
- Training available online and in person



Search and Statistics

- Committed reports are available in the Search and Statistics module
- Predefined output types (profiles)
 - Line listings
 - Statistics
 - Administrative statistics
- Possible to save queries
- Export to Excel for further analysis



Communication with MAHs

- Fully compatible with the ICH-E2B format
 - VigiFlow is based on E2B (R2)
- Integrated tools for communication with MAHs
 - Either PDF or E2B format
 - “Submission manager”





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Additional information

General E2B info

- E2B standard is set up by the ICH (EU, USA, Japan)
- An E2B file is in a standardized XML file structure
- Transmissions of E2B files follow a standardized protocol
- One E2B message 1 ≤ 100 ICSR (or ack logs)

```
<patientmedicationhistoryext/>
<resultstestsprocedures/>
+<patientdeath></patientdeath>
-<reaction>
  <primarysourcereaction/>
  <reactionmeddraversionlt>WHO-ART</reactionmeddraversionlt>
  <reactionmeddrallt>APPETITE SUPPRESSION</reactionmeddrallt>
  <reactionmeddraversionpt/>
  <reactionmeddrapt/>
  <termhighlighted/>
  <reactionstartdateformat>102</reactionstartdateformat>
  <reactionstartdate>20101010</reactionstartdate>
  <reactionenddateformat>102</reactionenddateformat>
  <reactionenddate>20101014</reactionenddate>
  <reactionduration>5</reactionduration>
  <reactiondurationunit>804</reactiondurationunit>
  <reactionfirsttime/>
  <reactionfirsttimeunit/>
  <reactionlasttime/>
  <reactionlasttimeunit/>
  <reactionoutcome>3</reactionoutcome>
</reaction>
+<reaction></reaction>
+<drug></drug>
+<drug></drug>
+<drug></drug>
-<summary>
  <narrativeincludeclinical/>
  <reportercomment/>
  <senderdiagnosismeddraversion/>
  <senderdiagnosis/>
```



Additional information

E2B Import

Import	VigiFlow automatic process	Manual process
Manual E2B import "standard"	<ol style="list-style-type: none">1. Address book updated (unless manually changed)2. Upload statistics updated (including link to ack log)3. ICSRs listed in <i>list of reports under assessment</i>	<ul style="list-style-type: none">▪ Check result page (for error messages)▪ Download ack log (and send manually)▪ Check ICSRs and commit them

**Additional
information**

E2B Export

Export	VigiFlow automatic process	Manual process
Manual export via Submission manager or "external"	<ol style="list-style-type: none">1. File is generated (external E2B/PDF)2. Submission manager updated (moved from unsubmitted to submitted)3. Administrative information page updated4. When ack log is received, update submission manager with ack log	<ul style="list-style-type: none">▪ Download file (and send manually)▪ Receive and upload ack log (result of upload page shows error messages in ack log)

Additional
information

Pros and cons with VigiFlow

Pros

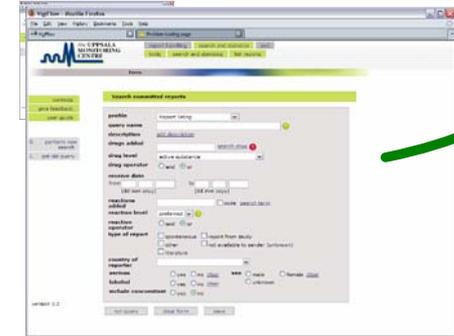
- Fast set-up; no need for local server installation and back-ups
- Improved report quality with built in error checks and help texts
- Integrated terminologies supports correct coding
- Easy communication between regional and national centres
- Communication with external organisations (paper or E2B)
- Available in English, French, Russian and Spanish
- Seamless transmission of reports to VigiBase™ possible

Cons

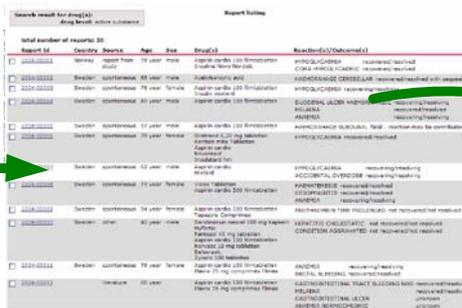
- Server (with national data) in another country might be against national regulations
- Needs Internet access, 1 Mbit/s recommended
- Not 100% adaptable to local ideas of how it “should work”
- More complex than needed for some countries

Additional information

Example of using Excel export from Search and Statistics module

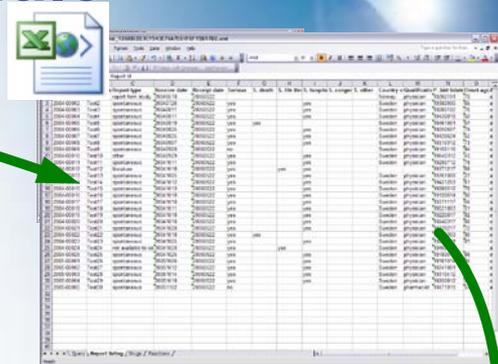


1 Search via VigiFlow Search and Statistics

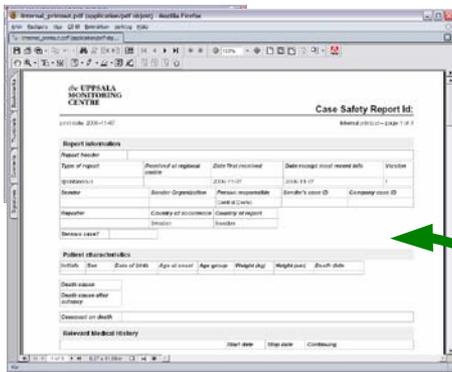


Report ID	Country	Report	Age	Sex	Reaction(s) (Preferred)
2009-00001	Sweden	ageless from 2007	18 year male		HYPOCALCAEMIA; thrombocytopenia; thrombocytopenic purpura
2009-00002	Sweden	cardiomyopathy	78 year female		HYPOCALCAEMIA; thrombocytopenia; thrombocytopenic purpura
2009-00003	Sweden	cardiomyopathy	67 year male		HYPOCALCAEMIA; thrombocytopenia; thrombocytopenic purpura
2009-00004	Sweden	cardiomyopathy	62 year male		HYPOCALCAEMIA; thrombocytopenia; thrombocytopenic purpura
2009-00005	Sweden	cardiomyopathy	78 year female		HYPOCALCAEMIA; thrombocytopenia; thrombocytopenic purpura

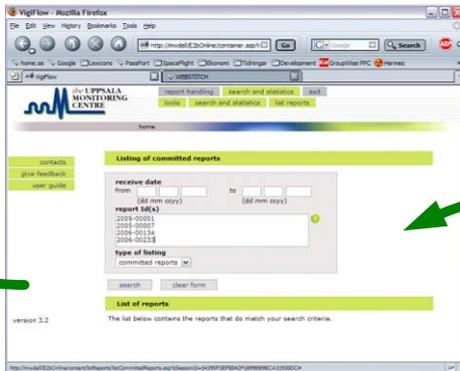
2 Result as report list



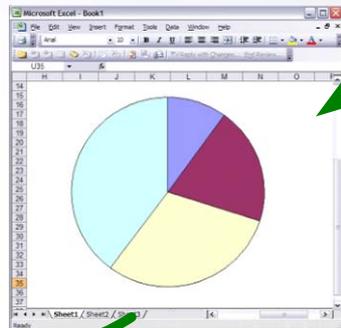
3 Export as Excel



6 Print reports as PDF



5 Retrieve reports from VigiFlow via IDs



4 Analyse and identify interesting reports

