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**Change history**

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**1 Terms, definitions, abbreviations**

**Glossary**

|         |   |
|---------|---|
| ACK-Log | Acknowledgment Log. Automatically by receiver generated receipt in after uploading an E2B into the Drug Safety System or VigiFlow |
| ADR     | Adverse Drug Reaction   |
| AERS    | Adverse Event Reporting System  |
| E2B     | Electronic to Business - ICH Standard for electronic transmission of adverse drug reactions in XML format                         |
| EIViS   | Electronic Vigilance System   |
| EMA     | European Medicines Agency   |

|          |   |
|----------|---|
| ICH      | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) |
| ICSR     | Individual Case Safety Report   |
| ISCS     | Informatics Service Center Swissmedic   |
| MAH      | Marketing Authorization Holder  |
| PDF      | Portable Document Format  |
| PV       | Pharmacovigilance   |
| SUSAR    | Suspected Unexpected Serious Adverse Reactions  |
| VigiFlow | ADR data base used by Swissmedic  |
| XML      | Extended mark-up language   |

## 2 Introduction

This guidance intends to assist all MAHs in preparing the electronic exchange of Individual Case Safety Reports (ICSRs) with Swissmedic via the Swissmedic **Electronic Vigilance System** (EIViS). It will be regularly updated to reflect the development and the experience gained.

## 3 Objective

This guidance stipulates the conditions for MAHs to participate in E2B electronic exchange of ICSRs with Swissmedic (bi-directional) and describes some key features for the use of the Swissmedic ICSR reporting platform named EIViS (**Electronic Vigilance System**). It is not intended to be a training manual.

## 4 General Information

This note for guidance does currently not address SUSAR (suspected unexpected serious adverse reactions) reports from at Swissmedic notified Interventional Clinical Trials. For more details please refer to [MU101\\_21\\_012e\\_MB\\_Drug Safety Reporting Duties in Switzerland](#)

## 5 What is EIViS?

Swissmedic has implemented a new adverse event reporting tool and encourages the stakeholders to use the new **Electronic Vigilance System**, called EIViS, which allows the reporting of ICSR by direct insert of data or by upload of xml files in a two-way process.

This reporting platform is an alternative function to the Swissmedic PV Gateway to exchange ADRs. If requested, Swissmedic can assist in figuring out which option may be the best for your requirements.

During the registration process, interested MAHs have the option to choose between

- direct data insert, or
- upload of E2B files.

The combination of both options is not possible.

Note that by using the upload option, MAHs get a quick and easy solution for ADR reporting to Swissmedic. Before starting the reporting by file upload, compatibility testing has to be done.

For both options the submission of the CIOMS form is no longer required, as well as the backing form which is currently attached to any report.

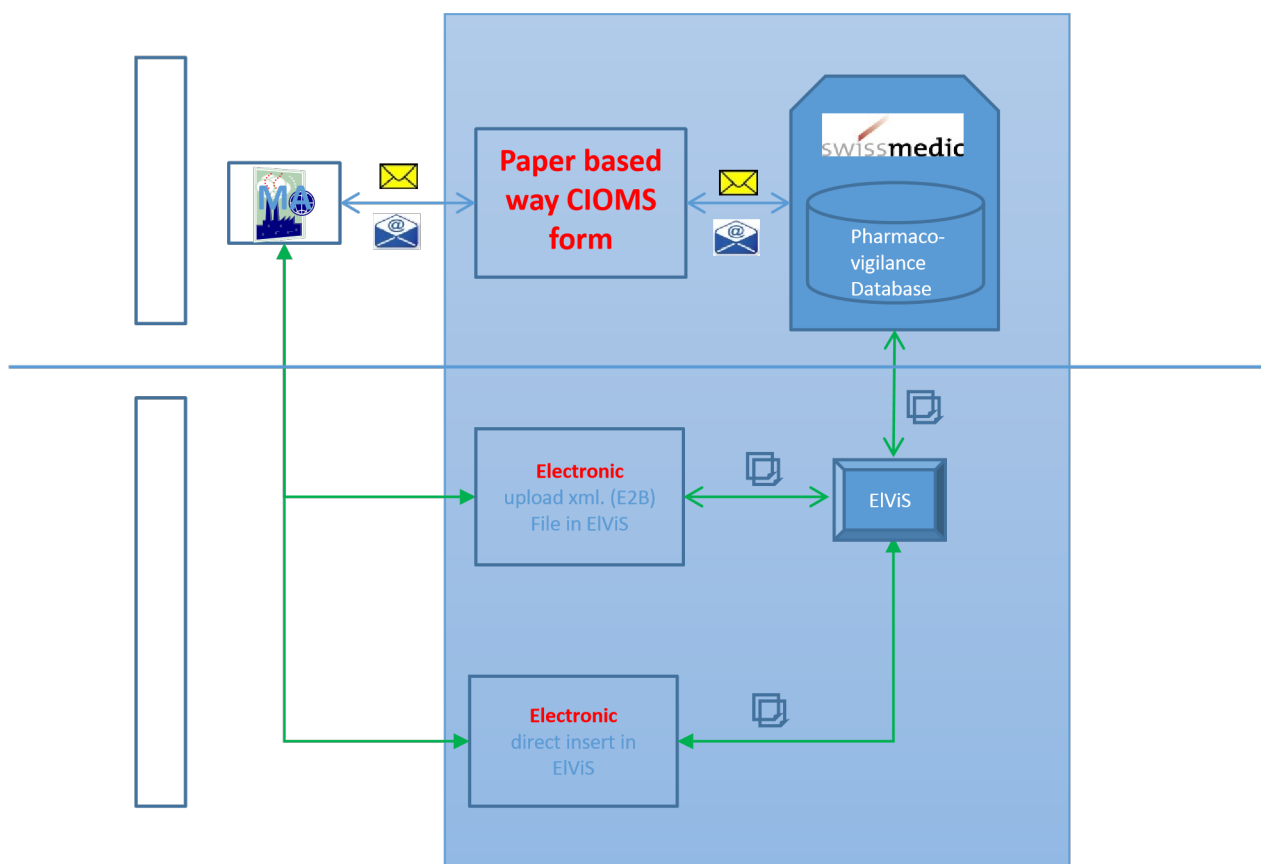
EIViS is not only capable of receiving but also of sending electronic reports compliant with ICH standards as detailed in E2B.

After the setup of the electronic exchange process between the MAH and Swissmedic, any other reporting routes will only be accepted as an exception.

EIViS allows the exchange of attached documents such as laboratory reports, X-rays, or pictures, regardless of the format. Furthermore, queries and answers to submitted ICSR will also be exchanged by EIViS.

EIViS forms are in English, but free text (e.g. narrative or sender comment) and attachments could also be submitted in German, French or Italian.

The technology behind EIViS complies with the highest security standards in data protection.



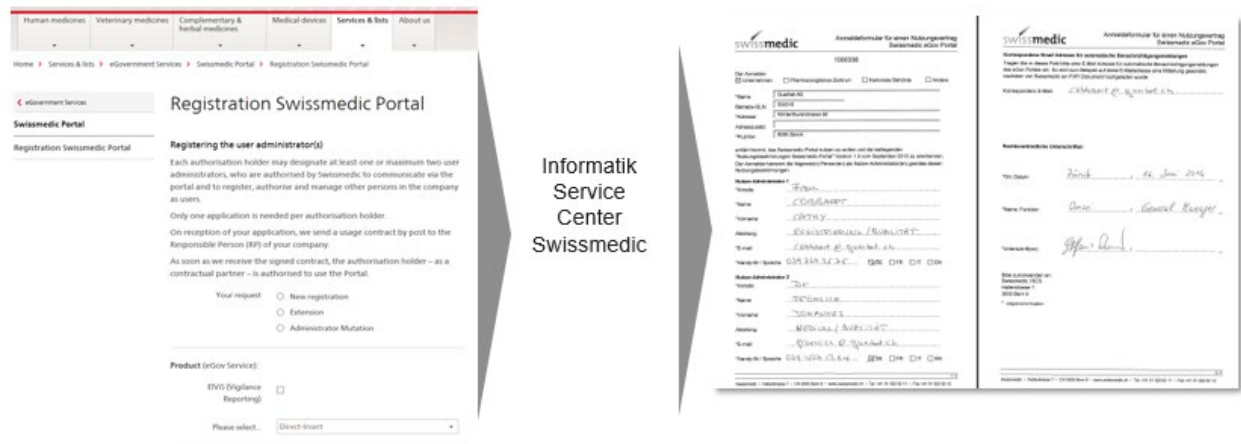
## 6 Conditions for the use of the Swissmedic Portal and EIViS

The MAH must be registered on the Swissmedic Portal. The access is possible for all companies holding an establishment licence for the manufacture and distribution of medicinal products on the Swiss market. MAHs interested to use EIViS are requested to fill out the application for a user account under <https://www.swissmedic.ch/swissmedic/en/home/services/egov-services/portal/egov-portal-registration.html> and to sign a user agreement to access the system.

Both Mozilla Firefox (at least version 24) and Microsoft Explorer (at least version 9) browsers can be used.

See below the steps for **MAH registration**:

1. Webform on <https://www.swissmedic.ch/swissmedic/de/home/services/egov-services/portal/egov-portal-registration.html>
2. ISCS (Informatik Service Center Swissmedic) creates contract for the Swissmedic-Portal
3. Company signs the contract and delegates a Partner-Administrator
4. ISCS creates the Partner-Administrator Account



Informatik  
Service  
Center  
Swissmedic

### To use the ELVIS application, you will need

- A CH-LOGIN user account to verify your identity/authorisation
- You will receive an email with your onboarding code to associate your CH-LOGIN user account with the applications released in the eIAM portal (such as ELVIS)
- Short instruction for your registration and onboarding [here](#)
- Read [here](#) more about how an administrator can set up a new ELVIS user in eIAM Portal

The Swissmedic Portal is accessed via the link <https://www.portal.swissmedic.ch>. On this page, the user is required to enter his CH-Login data (User account e-mail address and Password). Once these are entered correctly, the user will each time receive an SMS with the mobile transaction number (mTAN) on his personal cell phone (or a dedicated one). This numerical code must be entered on the screen coming after.

At the first time users login, and also after software updates, the terms of use will be displayed during the login process. The user needs to accept the terms of use in order to be able to continue. For the following connections to EIViS, a direct link can be used via the homepage [www.swissmedic.ch](http://www.swissmedic.ch).

Two User Administrators have to be appointed by the MAH (administrator and deputy). The user administrators are the primary contact persons within the company, and are responsible to manage/administrate all other users in the company (self administration).

The EIViS participant obtains all reports from Swissmedic via EIViS. Two file formats are provided

- XML to upload the information directly into the own AERS
- PDF to see all the information directly

If a company decides to exchange the reports via file upload, a compatibility test needs to be conducted with Swissmedic. To do so the company needs to hand in a ICSR 2.1 XML file beforehand. The file needs to be compliant to the EMA Business rules. It is recommended to do the compatibility testing on the company side (with the Swissmedic XML files) as well to ensure the correct upload into the own system (if wanted).

## **7 Short description of main EIViS functionalities**

EIViS is not a database, but a reporting platform to transmit and receive ADRs to and from Swissmedic. All reports, including attachments and queries, are stored in the system during a limited period of 6 weeks. It is the responsibility of each company to handle and administrate the reports (ICSRs, acknowledgements, etc.) by downloading all information locally on its own systems.

An automatic confirmation of different actions fulfilled by users is provided by email. Therefore a unique email address is requested from the MAH.

The Swissmedic pharmacovigilance database is E2B compatible according to the EMA Business rules. Therefore, no major difficulties regarding E2B interpretation are expected. Safety and acknowledgement messages have to follow the content and format of the respective ICH guidelines.

MedDRA coding is required for some data fields in EIViS (e.g. diagnoses, reactions or indications). Swissmedic will not provide the MAHs with a pull down or a popup displaying the MedDRA terms. The user needs to insert the MedDRA terms copied from its own MedDRA browser. Further information is available under <http://www.meddra.org/>

### **Contingency plan**

If case transmission problems arise (missing or error code in the ACK-log), the EIViS Hotline has to be contacted. If the problem cannot be solved within reasonable time, cases must be submitted the traditional way (backing form and CIOMS form).

## **8 Support – Point of contact**

Users are recommended to contact the EIViS Hotline for any problem related to the access or use. The EIViS Hotline is available Mon – Fri from 07:30 – 17:30.

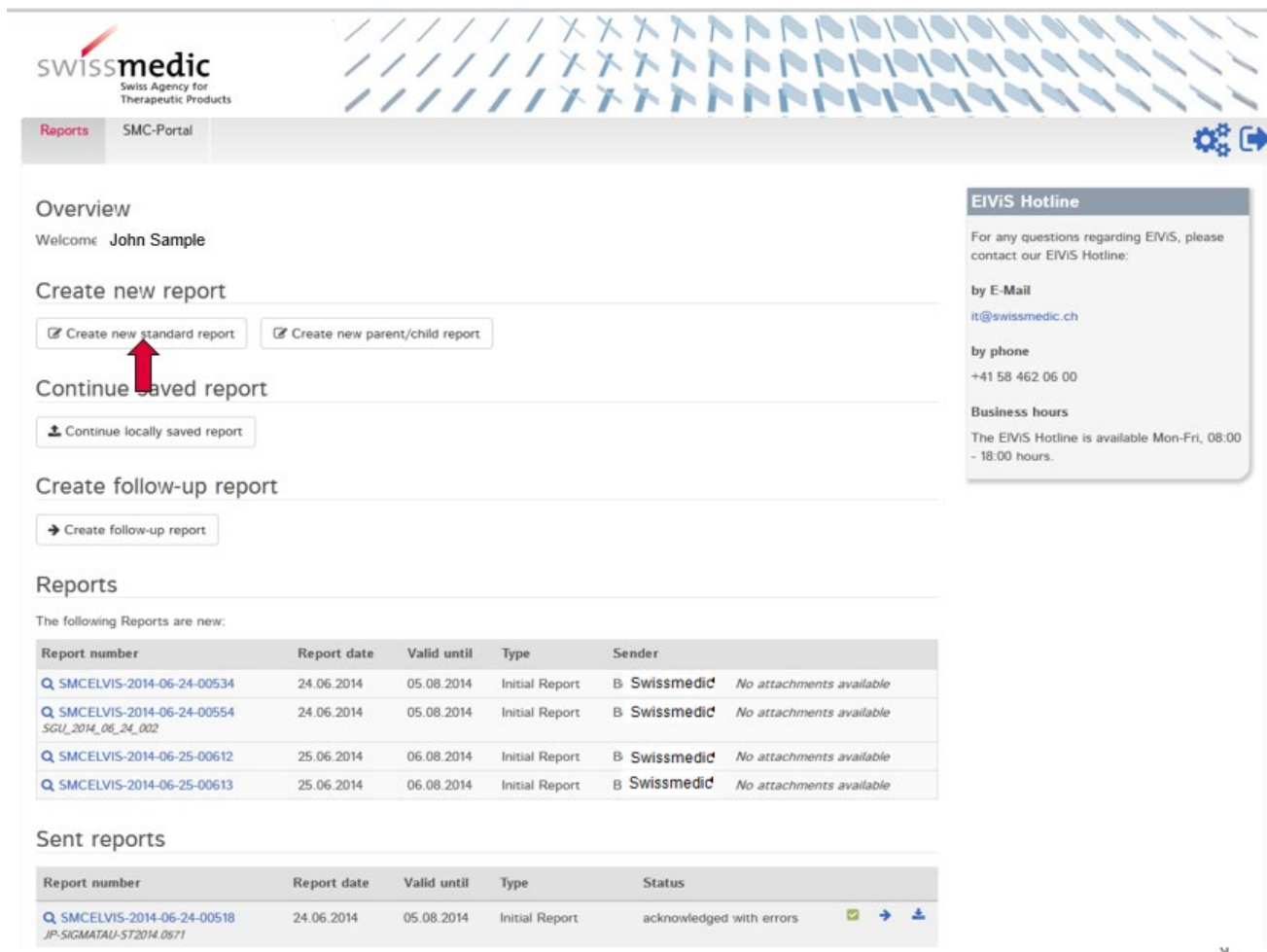
Telephone: +41 58 462 06 00

Email: [IT@swissmedic.ch](mailto:IT@swissmedic.ch))

## 9 Working with EIViS - Training

The following screenshots are proposed to give an overview of how EIViS looks like, and about some features it offers.

### 9.1 Overview



The screenshot shows the EIViS SMC-Portal interface. At the top left is the Swissmedic logo. The main navigation bar includes 'Reports' and 'SMC-Portal'. A sidebar on the right contains the 'EIViS Hotline' contact information.

**Overview**  
Welcome **John Sample**

**Create new report**

- Create new standard report
- Create new parent/child report

**Continue saved report**

- Continue locally saved report

**Create follow-up report**

- Create follow-up report

**Reports**

The following Reports are new:

| Report number  | Report date | Valid until | Type           | Sender       |                          |
|--|-------------|-------------|----------------|--------------|--------------------------|
| <a href="#">Q SMCELVIS-2014-06-24-00534</a>                                      | 24.06.2014  | 05.08.2014  | Initial Report | B Swissmedic | No attachments available |
| <a href="#">Q SMCELVIS-2014-06-24-00554</a><br><small>SGU_2014_06_24_002</small> | 24.06.2014  | 05.08.2014  | Initial Report | B Swissmedic | No attachments available |
| <a href="#">Q SMCELVIS-2014-06-25-00612</a>                                      | 25.06.2014  | 06.08.2014  | Initial Report | B Swissmedic | No attachments available |
| <a href="#">Q SMCELVIS-2014-06-25-00613</a>                                      | 25.06.2014  | 06.08.2014  | Initial Report | B Swissmedic | No attachments available |

**Sent reports**

| Report number   | Report date | Valid until | Type           | Status                   |  |
|---|-------------|-------------|----------------|--------------------------|--|
| <a href="#">Q SMCELVIS-2014-06-24-00518</a><br><small>JP-SIGMATAU-ST2014.0971</small> | 24.06.2014  | 05.08.2014  | Initial Report | acknowledged with errors |  |

**EIViS Hotline**

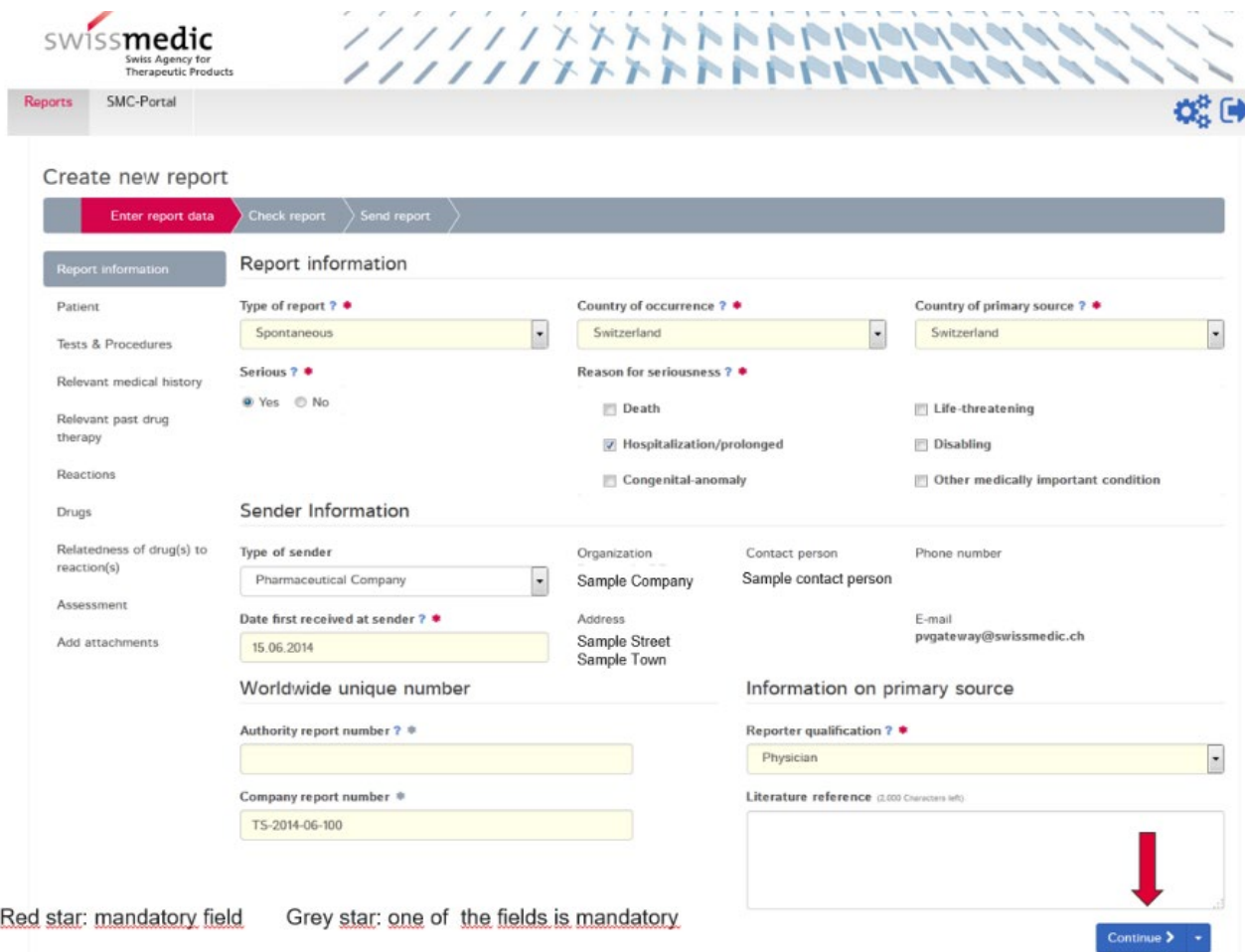
For any questions regarding EIViS, please contact our EIViS Hotline:

**by E-Mail**  
it@swissmedic.ch

**by phone**  
+41 58 462 06 00

**Business hours**  
The EIViS Hotline is available Mon-Fri, 08:00 - 18:00 hours.

## 9.2 Create and submit a new report



**SWISSmedic**  
Swiss Agency for Therapeutic Products

Reports SMC-Portal

### Create new report

Enter report data | Check report | Send report

**Report information**

Patient  
Tests & Procedures  
Relevant medical history  
Relevant past drug therapy  
Reactions  
Drugs

Type of report ? \*  
Spontaneous

Country of occurrence ? \*  
Switzerland

Country of primary source ? \*  
Switzerland

Serious ? \*  
 Yes  No

Reason for seriousness ? \*

Death  
 Hospitalization/prolonged  
 Congenital-anomaly

Life-threatening  
 Disabling  
 Other medically important condition

**Sender Information**

Type of sender  
Pharmaceutical Company

Organization  
Sample Company

Contact person  
Sample contact person

Phone number  
E-mail  
pvgateway@swissmedic.ch

Date first received at sender ? \*  
15.06.2014

Address  
Sample Street  
Sample Town

**Worldwide unique number**

Authority report number ? \*  
[Empty field]

Company report number \*  
TS-2014-06-100

**Information on primary source**


Reporter qualification ? \*  
Physician



Literature reference (2,000 Characters left)  
[Empty text area]

Continue >

**Red star: mandatory field    Grey star: one of the fields is mandatory**





Reports SMC-Portal  

### Create new report

Enter report data **Check report** Send report

Report information

**Patient**

Tests & Procedures

Relevant medical history

Relevant past drug therapy

Reactions

Drugs

Relatedness of drug(s) to reaction(s)

Assessment

Add attachments

#### Patient characteristics

**Patient initials** ? \*

**Sex** ? \*  Male  Female

**Date of birth** ? \*

**Age at time of onset** ? \*

**Age group** ? \*

**Body weight (in kg)**

**Body height (in cm)**


#### Death related information



**Death date**

**Death cause** ?

**Autopsy performed**  Yes  No  Unknown

[Continue >](#)



Reports SMC-Portal  

### Create new report

Enter report data **Check report** Send report

Report information

Patient

**Tests & Procedures**

Relevant medical history

Relevant past drug therapy

Reactions

Drugs

Relatedness of drug(s) to reaction(s)

Assessment


Add attachments

#### Results of tests and procedures

**Results of tests and procedures (free text)** ? (1,923 Characters left)

Blood pressure: 85/70 mmHg (01.06.2014)  
Heart rate: 42 beats/min (01.06.2014)

Test

 [+ Add new test](#)

[Continue >](#)



Create new report

Enter report data > Check report > Send report

Report information

Patient

Tests & Procedures

Relevant medical history

Relevant past drug therapy

Reactions

**Drugs**

Relatedness of drug(s) to reaction(s)

Assessment

Add attachments

**Drugs**

**Suspected drugs \***

| Drug name     |
|---------------|
| Isoptin 80 mg |

+ Add new drug


**Concomitant drugs**

| Drug name |
|-----------|
| Marcoumar |

+ Add new drug

Suspected drugs: Please assess labelledness in sender comments.

[Continue >](#)



Add suspected drug

Drug name ? \*

Isoptin 80 mg

Characterization ? \*

Suspect  Interacting

Batch number

Unknown

Route of administration

oral

Pharmaceutical form

coated tablet

Start of administration

26.05.2014

End of administration

01.06.2014

Dose information

Dosage regimen ?

Dose

80 mg

Doses in interval

3

Definition of interval

1 Day(s)

Cumulative dose to first reaction ?

1680 mg

Active substance ? \*

Verapamil

Indication (231 Characters left)

Atrial fibrillation

Additional information (100 Characters left)

Did the reaction recur after rechallenge? ?

Yes  No  Unknown

Action taken

Drug withdrawn

Time interval between administration and reaction onset

Duration ?

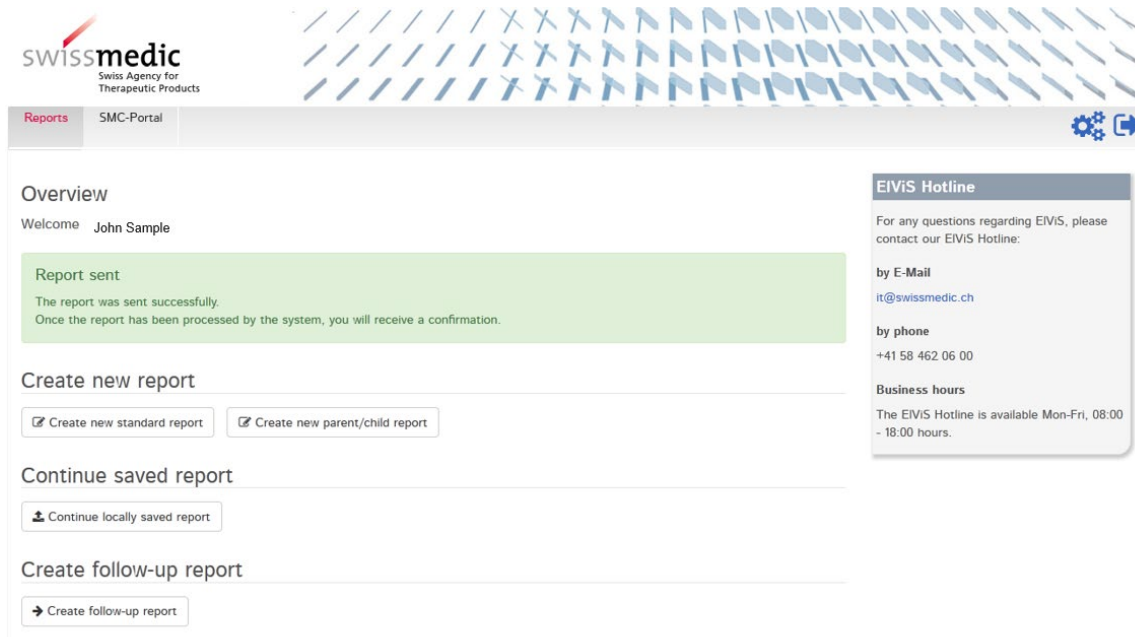
7 Day(s)

First dose ?

7 Day(s)

Last dose ?

Cancel Add



**Overview**  
Welcome John Sample

**Report sent**  
The report was sent successfully.  
Once the report has been processed by the system, you will receive a confirmation.

**Create new report**

- Create new standard report
- Create new parent/child report

**Continue saved report**

- Continue locally saved report

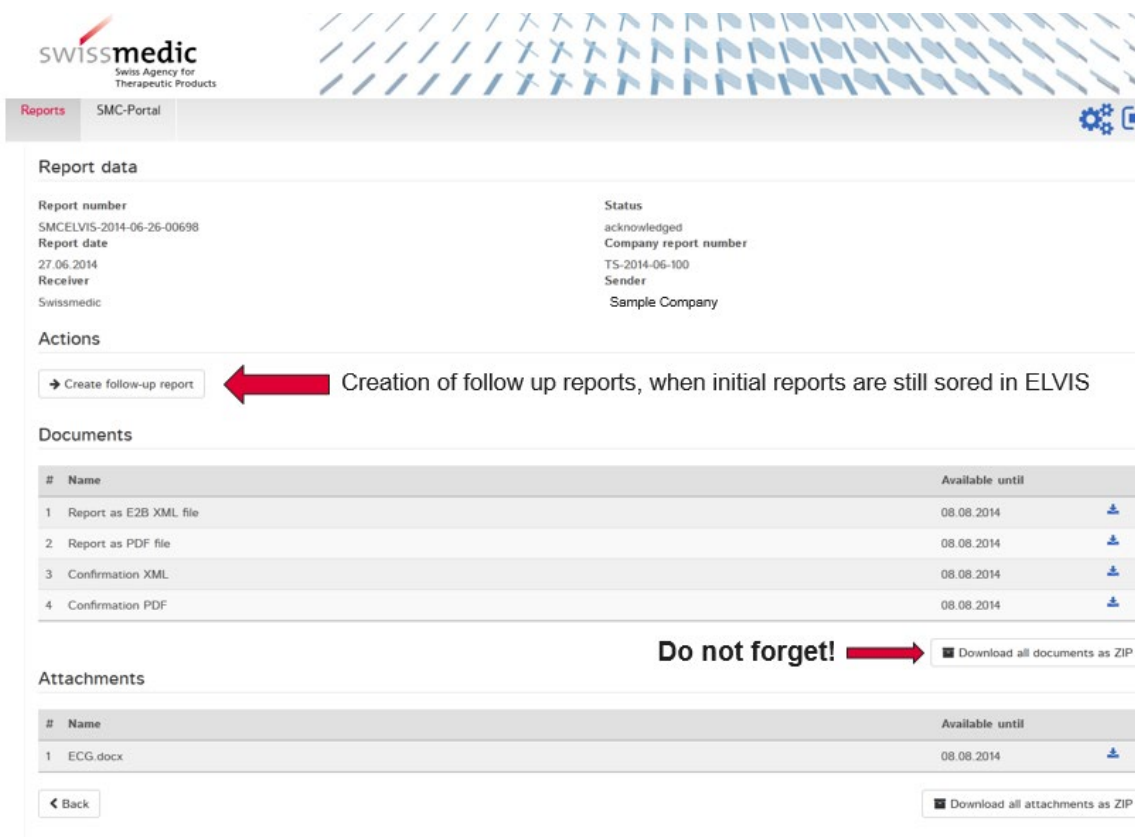
**Create follow-up report**

- Create follow-up report

**EIVIS Hotline**  
For any questions regarding EIVIS, please contact our EIVIS Hotline:

- by E-Mail**  
it@swissmedic.ch
- by phone**  
+41 58 462 06 00
- Business hours**  
The EIVIS Hotline is available Mon-Fri, 08:00 - 18:00 hours.


### 9.3 Download of documents



**Report data**

|   |  |
|---|--|
| <b>Report number</b><br>SMCELVIS-2014-06-26-00698 | <b>Status</b><br>acknowledged                  |
| <b>Report date</b><br>27.06.2014                  | <b>Company report number</b><br>TS-2014-06-100 |
| <b>Receiver</b><br>Swissmedic                     | <b>Sender</b><br>Sample Company                |

**Actions**


- Create follow-up report  Creation of follow up reports, when initial reports are still sored in ELVIS

**Documents**

| # | Name                   | Available until |
|---|------------------------|-----------------|
| 1 | Report as E2B XML file | 08.08.2014      |
| 2 | Report as PDF file     | 08.08.2014      |
| 3 | Confirmation XML       | 08.08.2014      |
| 4 | Confirmation PDF       | 08.08.2014      |

**Attachments**

| # | Name     | Available until |
|---|----------|-----------------|
| 1 | ECG.docx | 08.08.2014      |

**Do not forget!**  Download all documents as ZIP

