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Change history

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3.0	16.10.2019	Document updated	bop
2.0	04.09.2018	Document adapted formally, new address in footer	lc
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2.0	02.07.2015	Modification in chapter 9 (Training)	lc
1.0	29.09.2014	New document	lc, kch, sgu

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
ElViS	Electronic Vigilance System
EMA	European Medicines Agency

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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 **El**ectronic **Vi**gilance **S**ystem (ElViS). 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 ElViS (**El**ectronic **Vi**gilance **S**ystem). 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 ElViS?

Swissmedic has implemented a new adverse event reporting tool and encourages the stakeholders to use the new **El**ectronic **Vi**gilance **S**ystem, called ElViS, 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.

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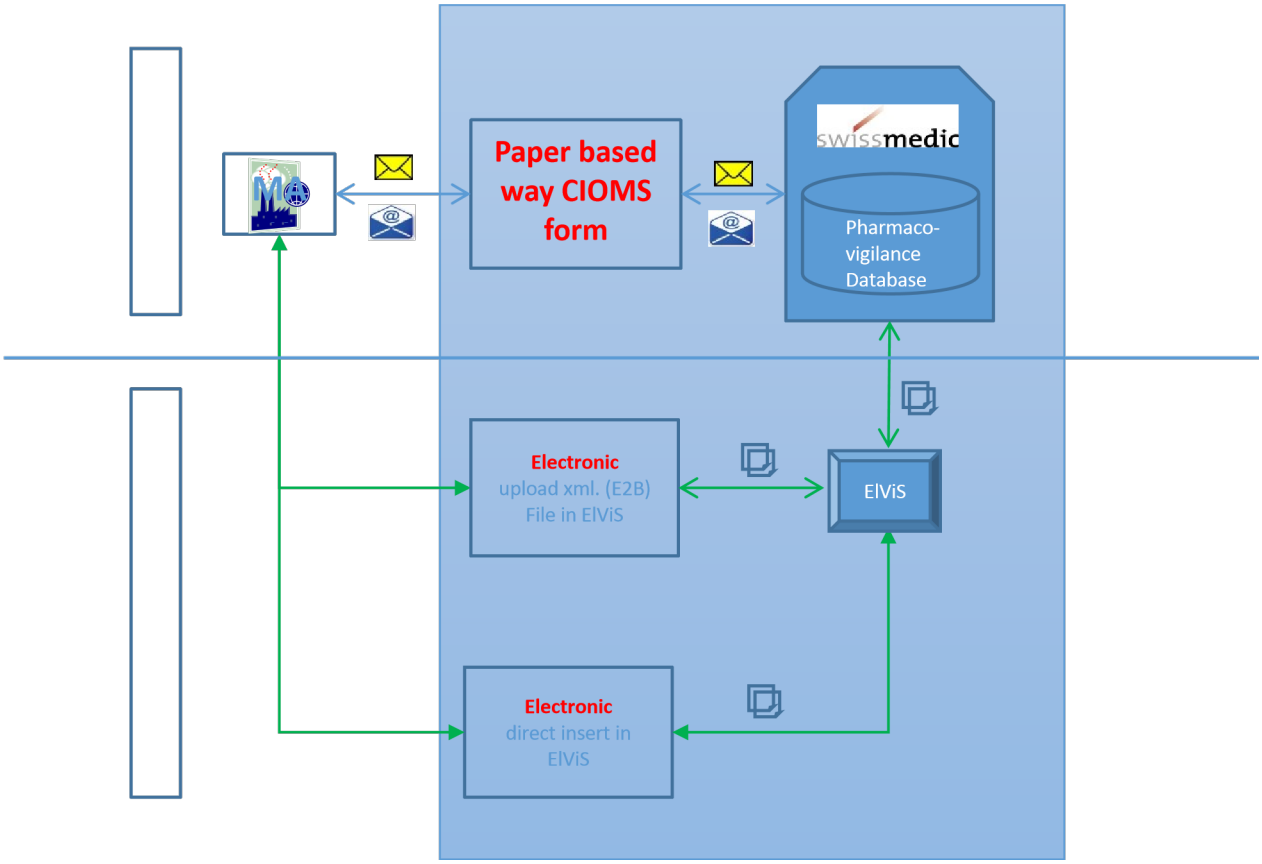
EIViS is not only capable of receiving but also of sending electronic reports compliant with ICH standards as detailed in E2B.
After the setup of the electronic exchange process between the MAH and Swissmedic, any other reporting routes will only be accepted as an exception.

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.

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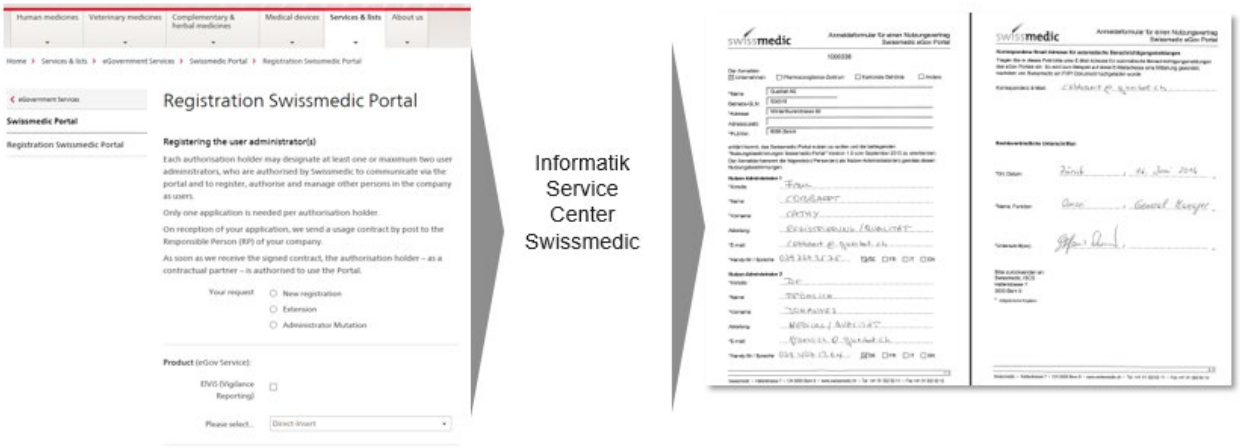
See below the steps for **MAH registration**:

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



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 ElViS, a direct link can be used via the homepage 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 ElViS participant obtains all reports from Swissmedic via ElViS. 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).

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7 Short description of main ElViS functionalities

ElViS 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 ElViS (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 ElViS 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 ElViS Hotline for any problem related to the access or use. The ElViS Hotline is available Mon – Fri from 07:30 – 17:30.
Telephone: +41 58 462 06 00
Email: IT@swissmedic.ch)

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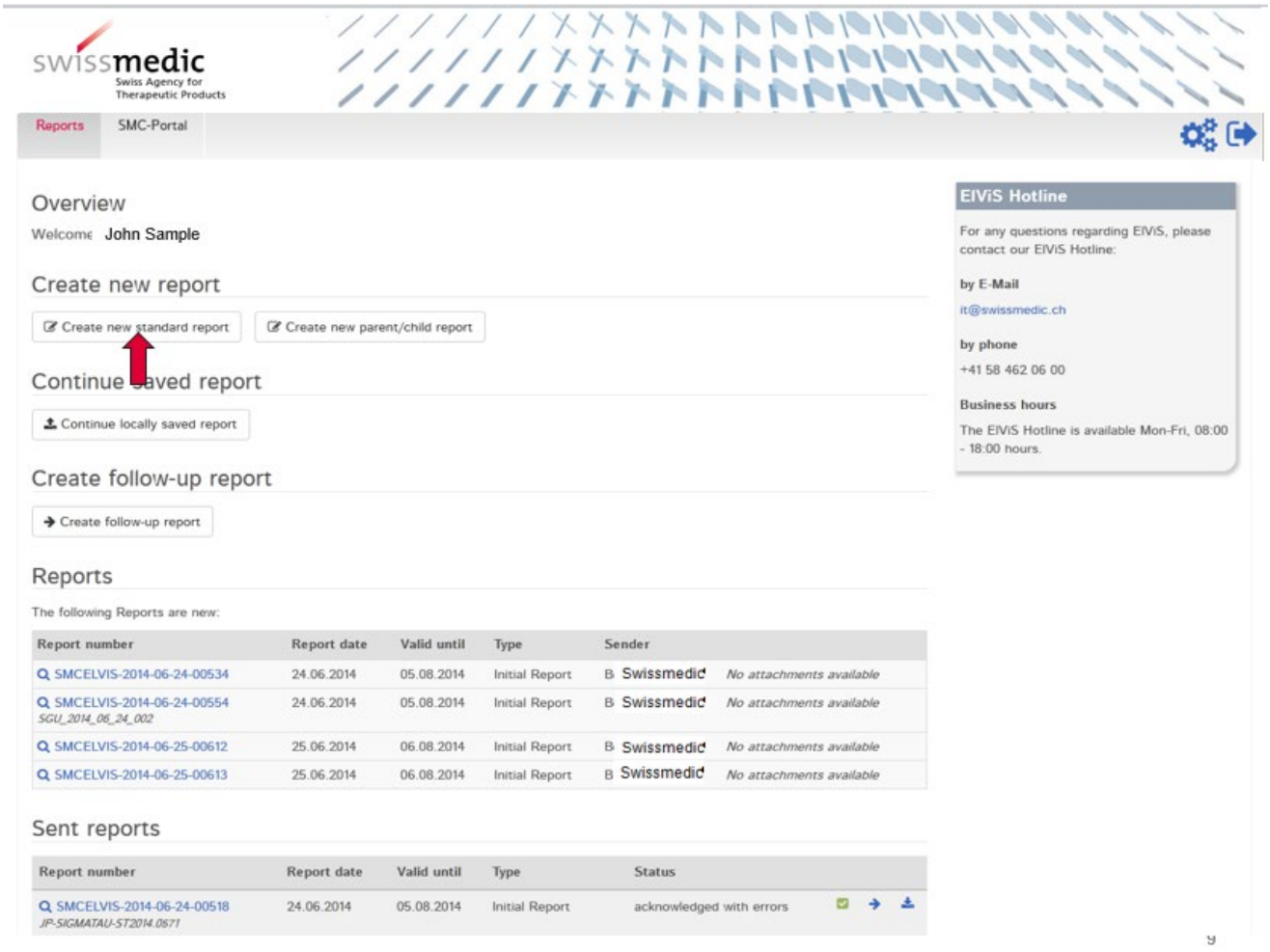
9 Working with ElViS - Training

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

9.1 Overview



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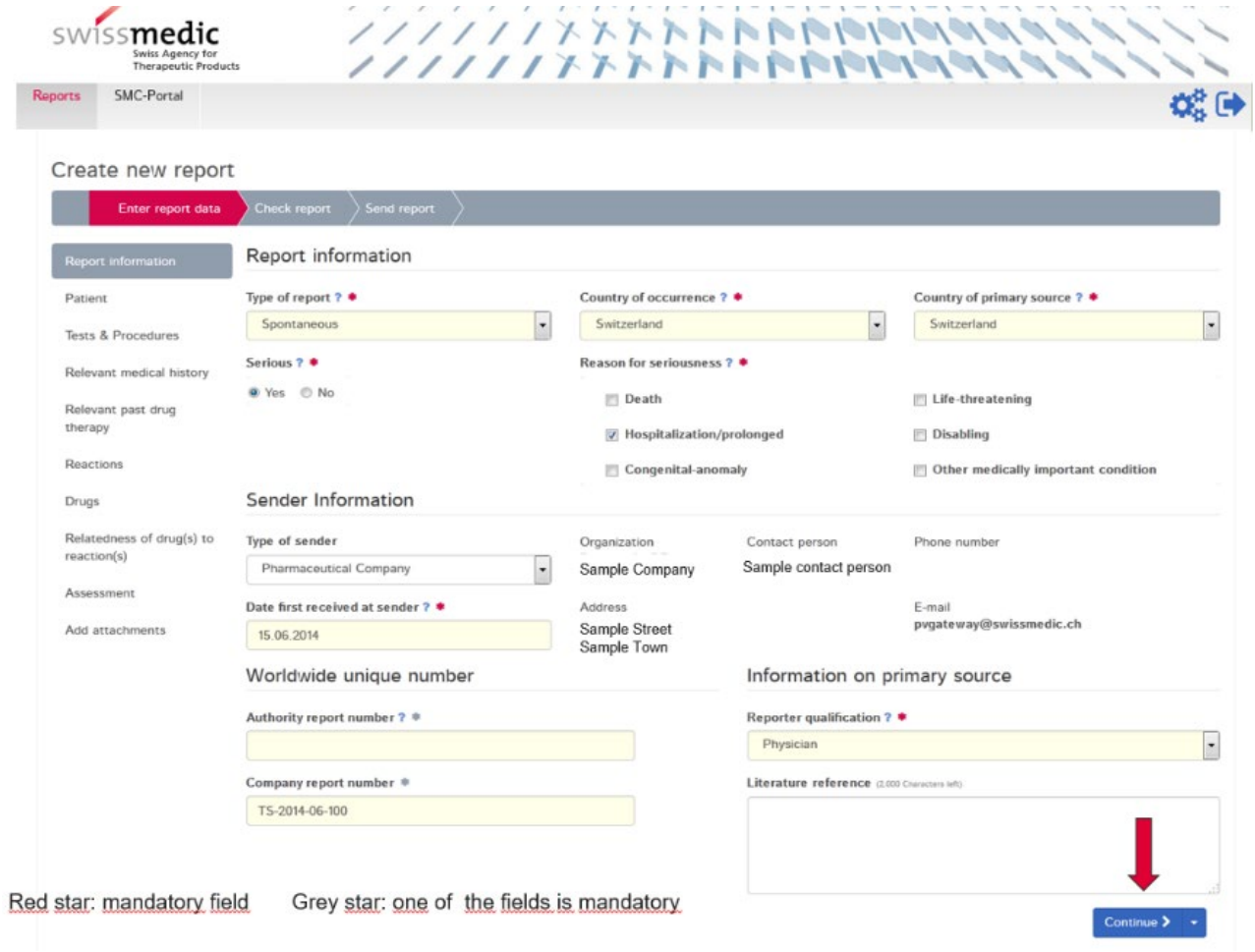
9.2 Create and submit a new report



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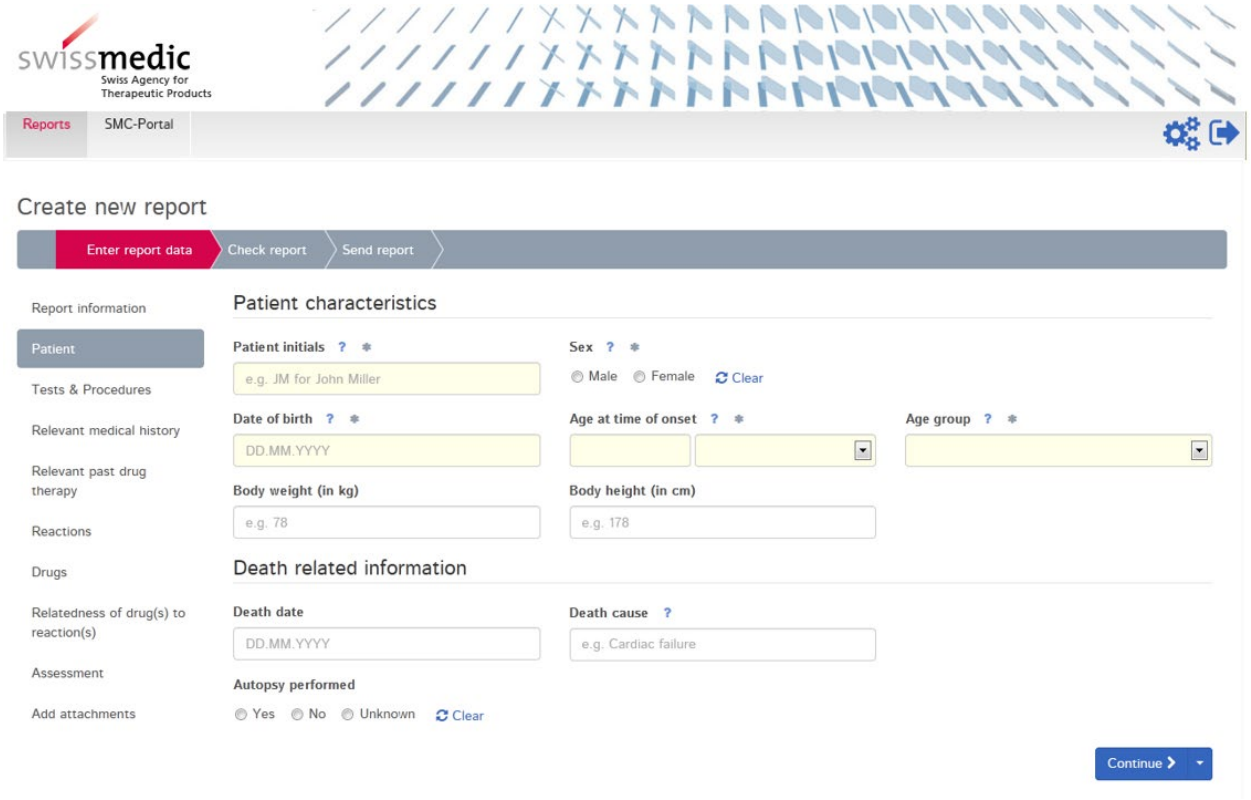

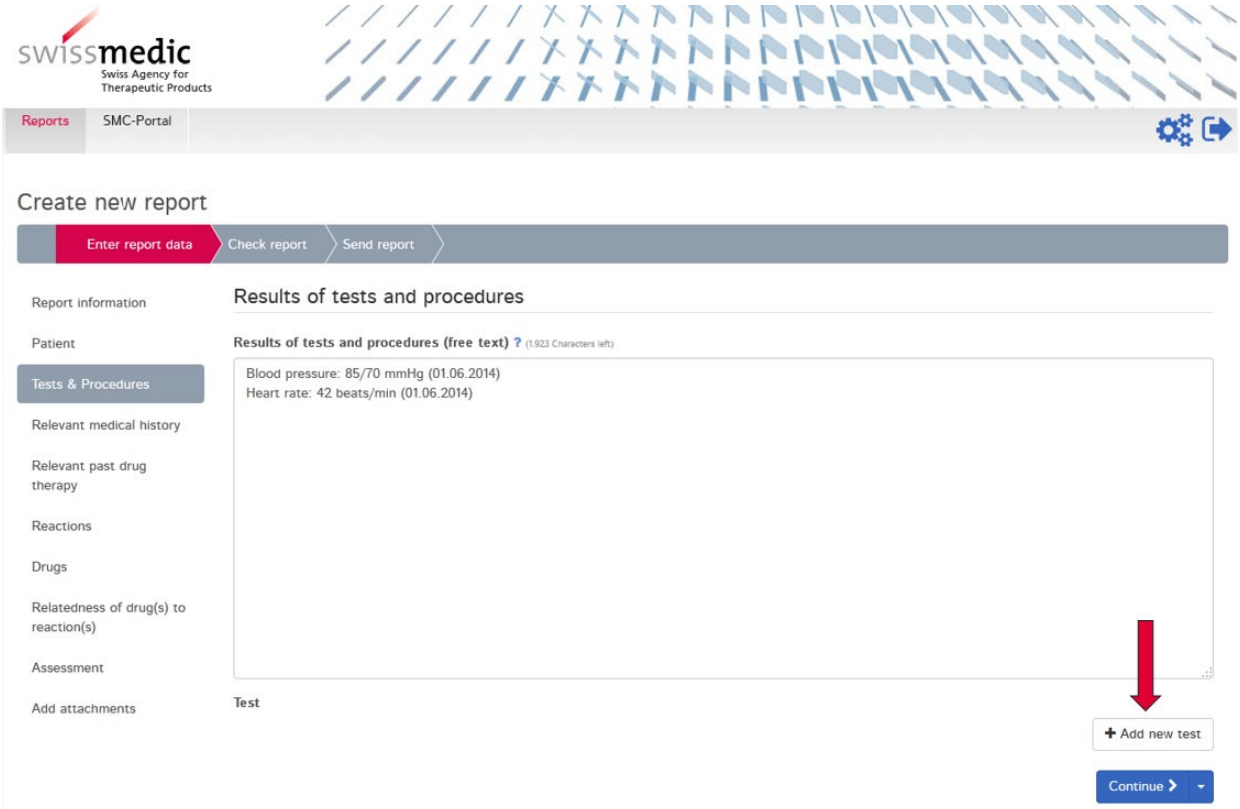

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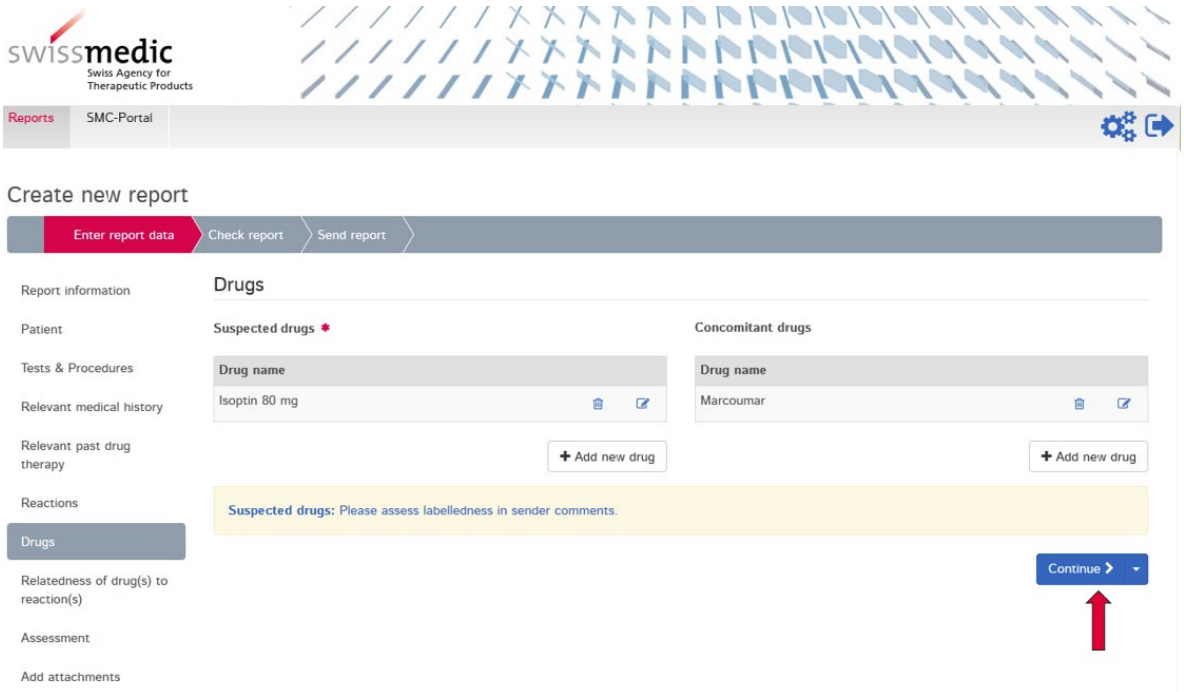

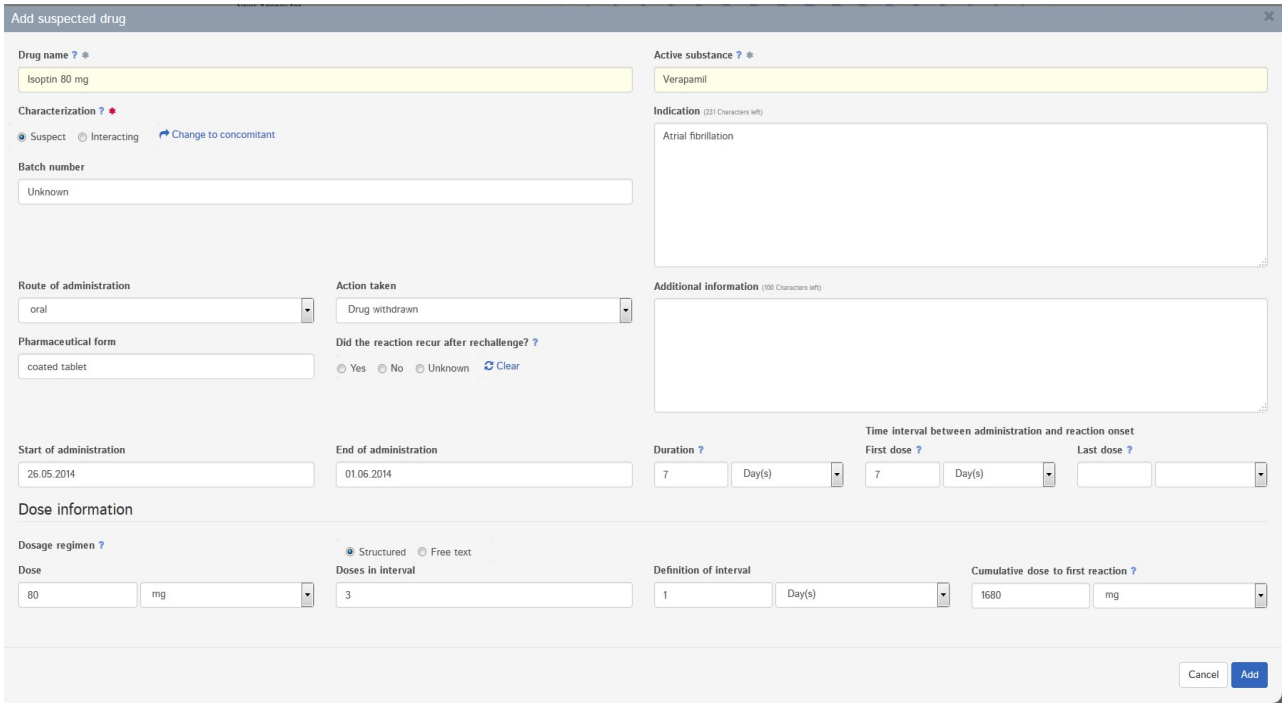

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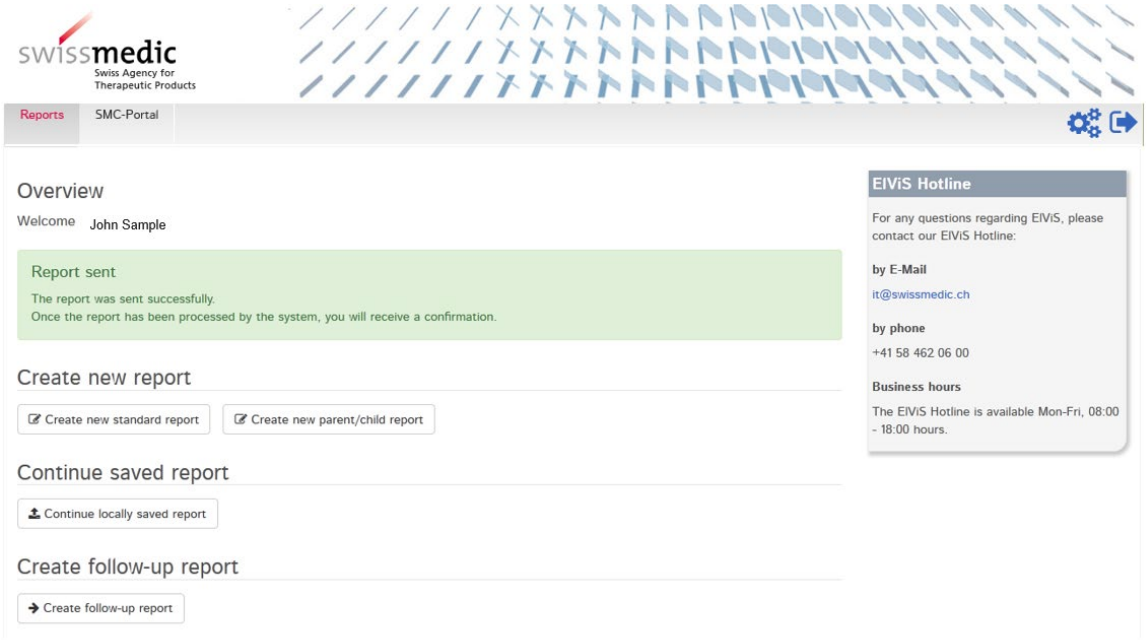
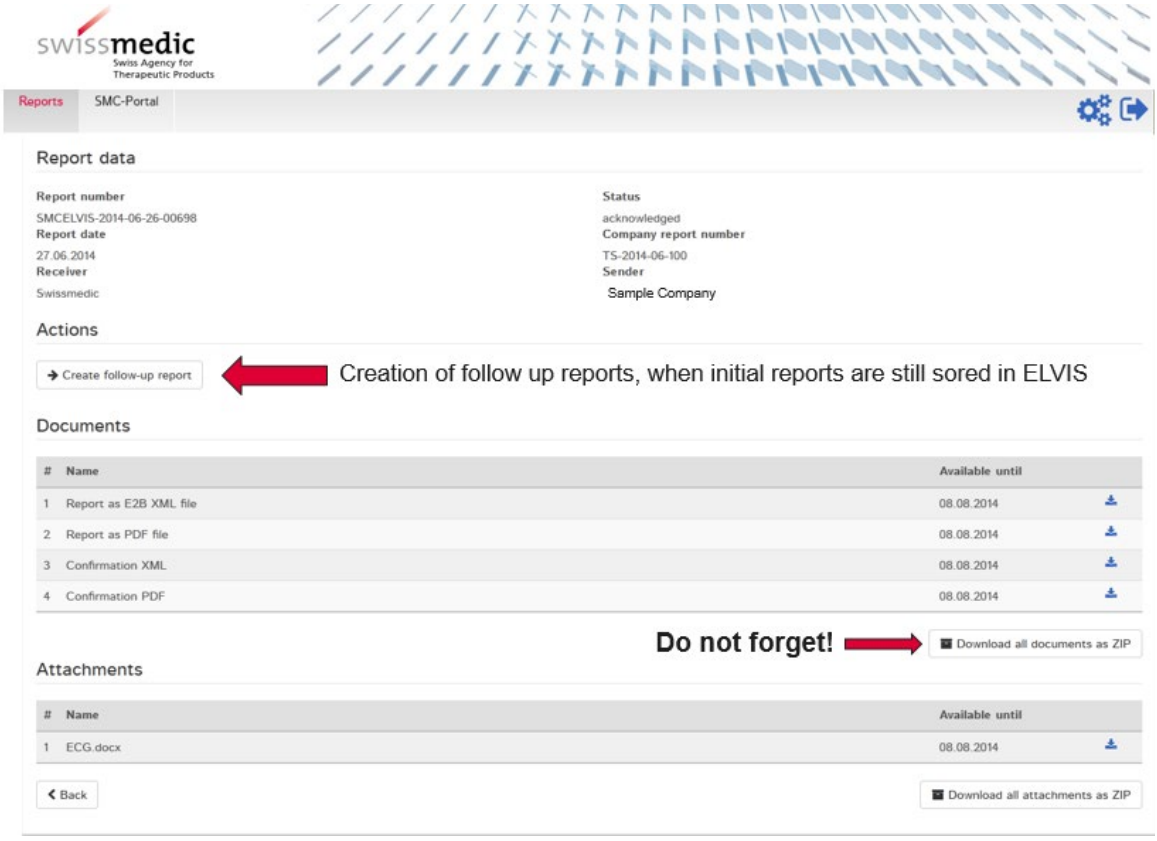


9.3 Download of documents



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