

## EIViS FAQs

Version date: 01/09/2019

Question	Answer
<b>General</b>	
Why should I use EIViS to report adverse reactions?	Electronic reporting offers a large number of advantages. Your data are recorded in a structured fashion and checked to ensure they are complete and plausible before they are submitted. Furthermore, you can attach important documents such as laboratory reports, hospital letters, etc. to your report. Your report is then imported direct into Swissmedic's drug safety database, where the Regional Pharmacovigilance Centre can process it. This means that risks are identified earlier and more accurately. Further advantages include data security and the fact that all documents are electronically archived.
Why can I only store one unfinalised report in EIViS?	EIViS is primarily a reporting platform, not a database. That's why submitted reports are only stored in EIViS for a limited period of time. However, you can resume work on any unfinalised report that you store in EIViS whenever you want.
How long will reports that I submit be stored in EIViS?	No more than 6 weeks. It is the responsibility of each user to archive their reports and accompanying documents on their own computer.
Are my data really secure?	EIViS satisfies the most stringent data protection and security requirements.
Are reports submitted via EIViS also sent to the Regional Pharmacovigilance Centres?	Yes. Any reports you submit via EIViS will be sent to one of the Regional Pharmacovigilance Centres.

Question	Answer
Whom do I contact if I have questions or problems?	Please contact the EIViS hotline by e-mailing <a href="mailto:it@swissmedic.ch">it@swissmedic.ch</a> or by calling +41 58 462 06 00. The hotline is open from 7.30 a.m. to 5.30 p.m., Monday to Friday.
<b>Registration</b>	
Why do I have to register?	Once-only registration is required before you can use EIViS. This is to ensure that the data you submit are transmitted securely and to unequivocally link senders to reports. Registration doesn't take long and all the information you provide will be treated in strict confidence.
Where do I register?	<p><b>Registration for MAHs</b> MAHs should register for EIViS on the Swissmedic website <a href="#">here</a>. A ticket will automatically be created at Swissmedic and your request to use EIViS will be processed. Once we have reviewed the information you have provided, you will receive an EIViS user agreement.</p> <p><b>Registration for HCPs</b> Go to the <a href="#">EIViS</a> page of the Swissmedic website. Click <a href="#">HCP Registration</a> . You will find detailed instructions on how to register here <a href="#">(Insert link to "HCP self-registration for EIViS" here)</a></p>
What's the difference between a "direct insert" and a "file upload"?	If you want to type your report into an online entry mask, choose "direct insert". This is the standard option for most users. If you have an electronic system capable of generating E2B files and you want to upload these files to EIViS, choose "file upload". This option will normally only be available in specialised centres. You will have to contact the EIViS hotline before you can start a file upload. The same applies if you have chosen a file but then want to change it.
I've forgotten my password. What should I do?	You can reset your password yourself. Click the "Forgotten password" link on the login screen.

**Kommentiert [low1]:** Upload instructions to SMC website and insert link.

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<b>Entering a new report</b>	
What's the quickest way to get to the EIViS login page?	Go to the Swissmedic website and click "Log in EIViS" at the top right of the screen. Alternatively, you can add the login page to your favourites/bookmarks.
Do I have to enter data in a particular order?	No. EIViS will suggest a predefined order, but you can choose which screen you want to enter data on simply by clicking in the menu bar on the left-hand edge of the screen.
What should I do if I don't know the patient's exact date of birth or precisely when an ADR began, for example?	Enter the full date of birth or leave the field empty.
What's the difference between "Designation of the ADR" and "Description of the ADR"?	As the designation, enter a symptom or diagnosis, e.g. headache or rash. You can then describe the diagnoses, symptoms, findings, treatment and course in detail in the description section.
How do I save the data I have entered?	You can save any data you have entered without submitting it if you click the drop-down menu (i.e. the small white triangle) to the right of the "Next" button and click "Save". Please note that you can only save one report in EIViS and will therefore have to save that report on your own computer before you can start to enter another one.
What do I do if I want to resume work on a report I've saved?	If you have saved your report in EIViS, click "Edit" under "Continue report saved in EIViS". If you have saved your report on your own computer, click "Continue a locally saved report", choose the appropriate file and upload it to EIViS.

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What does "Add attachments" mean?	If you have test results (e.g. lab reports) or other documents (e.g. hospital letters) that are relevant to a report, you can send them with your report. You can add one or more attachments in any file format.
Will I receive confirmation that my report has been sent?	If your report has been successfully received by the RPVC and imported into Swissmedic's drug safety database, you will receive an e-mail. This e-mail will contain a link that you can click to download further documents, including confirmation of receipt.
I've clicked the link in the e-mail, but get a "Documents not found" error message.	You've probably already downloaded your report and associated documents. These are automatically deleted 24 hours after they have been downloaded and the link will cease to work.
There's a "Valid until" date with the reports I have sent and accompanying documents. What does that mean?	Reports and accompanying documents are stored in EIViS for six weeks. It is the responsibility of each user to archive their reports and accompanying documents on their own computer. Reports and documents are automatically deleted 24 hours after they have been downloaded. If you have not yet downloaded the relevant files, you will receive an e-mail about one week before the six-week deadline expires.
<p><b>Submitting follow-up reports</b></p>	
Can I attach files to a follow-up report?	Yes, you can attach one or more files in any format, just as you can for an initial report.

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Does it matter whether my initial report is stored in EIViS?	Yes. If your report is still stored in EIViS, click the report's EIViS case number in "Sent reports", then click "Write follow-up". The report number field will be automatically completed so that your follow-up report can be unequivocally linked to your initial report. If your initial report is no longer stored in EIViS, simply click "Write follow-up", then upload the E2B file for the initial report. The report number field will be automatically completed. Alternatively, you can also complete the report number field manually.
Why can't I choose a Regional Pharmacovigilance Centre to send my follow-up report to?	Your follow-up report will be automatically sent to the same RPVC as your initial report.
What should I do if my initial report is no longer stored in EIViS and I haven't archived either the E2B file or any other documents associated with the initial report?	You cannot submit a follow-up report without the original report number. Please contact the EIViS hotline.
Will I receive confirmation that my follow-up report has been sent?	You will receive an e-mail when your follow-up report has been successfully received by the RPVC. This e-mail will contain a link that you can click to download further documents, including confirmation of receipt.
Can I submit just one follow-up report or is it possible to send several?	There is no limit on the number of follow-up reports you can submit for a particular initial report.
<p><b>Receiving messages and answering queries</b></p>	
How do I know if there are any messages or queries for me?	You will receive e-mail notification if there are messages or queries concerning a report that you have submitted. You will see them under "Received messages" or "Queries" when you log into EIViS.

Question	Answer
What exactly is the difference between a message and a query?	A message from the Regional Pharmacovigilance Centre contains information on a report you have submitted. There is no need for any action on your part. If you receive a query, however, you will be asked to respond by downloading the relevant document to your own computer, processing it there and then uploading it once again to EIViS.
Can I also reply to queries by phone?	Certainly. The Regional Pharmacovigilance Centre may well contact you by phone. However, if you prefer to use e-mail, please remember that e-mail is not a secure way of transmitting sensitive data.