



Seminar Series:

Facts and pitfalls of observational studies - How to plan and conduct HRO projects

Q&A from the session

“BASEC: A practical walk-through for HRO projects”

Sept 11 2024

Take-home messages:

- Always use the **current templates** from swissethics
- Choose the **right project category** and click through all sections
- Download the **summary PDF** at the end (AFTER submission – it contains all documents you handed in and the BASEC number)
- Be aware that **BASEC is no storage system** for your documents!
 - You have to store all versions of all documents yourself and be able to track everything
 - **BASEC is only for handing them in**
 - **Summary PDF** is very helpful here!
- Extra tipp: when making changes on your submission, use the **comment field at the end** and quickly describe what has been done → easier overview for everybody

Q&A:

- For further use projects: "start date" is always misunderstood:
 - the “start date” is the date where you have the first access to your samples.
- If we have a project with historical data (prior consent), prospective data (consent to be sought) and data with no consent, is it correct to tick all 3 boxes on page 3?
 - Yes, that is correct – as soon as you have only one participant who falls into one of those categories, you have to tick it.
- Do we need to have a PI confirmation for each site?
 - Yes, you have to tick the box for each site
- Is there a limit to the number of documents that can be submitted on BASEC portal?
 - Not really, you can upload loads of documents. Only when you have to adapt some of the documents and re-upload, it can be that there are too



many. But in this case you anyway delete the old ones, and then it fits again

- Does the billing address need to be in Switzerland?
 - In general, it's the PI or the sponsor representative in Switzerland if the sponsor is outside Switzerland.
- How to deal with additional projects for an existing approved protocol regarding a registry project. Should additional projects be added as Annex to the protocol, or should an own protocol "further use" be prepared and submitted?
 - If it's a registry for which you get an opinion from the EC, for every new project that reuse data from this registry, you must submit it to the EC for approval. If it's an already approved protocol, and you would like to reuse more data and the objectives are the same field that the approved protocol, then you can ask for an amendment.
- a contact person (as explained at the beginning) and a contributor (→ manage invitations) are different roles. correct?
 - yes
- Will the changes to the HRO be visible in BASEC on November 1, 2024?
 - Most changes are not on the BASEC portal itself, but rather on the templates. Swissethics will update all templates on time and upload them to their website. Some are already updated now. In addition, it might be that also additional training material will be provided.
- How durable and reliable is BASEC's IT support?
 - As far as we know, durable. BUT, IMPORTANT: BASEC IS NOT STORAGE FOR YOUR DOCUMENTS! It is just a portal with which you can send documents to the ethics committees, not more. You are responsible for storing all versions of the documents.
- Is another system than BASEC under consideration?
 - Not that we know, ethics committees are (as far as we know) happy with BASEC.
- Practical aspects difference between further use with and without consent
 - There is a difference. If you will reuse data of patients for whom you don't have a consent, you will use the protocol template for data reuse without consent in which you will ask perhaps for a waiver consent and justify it. In BASEC, in section 3, you need to tick on consent to be sought no consent-Art.34 HRA even if you have just one patient without consent.

If all patients have consent, then you will use data reuse with consent protocol template and you don't need to ask for any waiver of consent. In BASEC, in section 3, you need to tick on prior consent/general consent exists.