



Seminar Series:

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

**Q&A from the session**

**“Registries and biobanks: Background, obstacles, and practical views”**

**Topic: international projects**

- How to find out about regulations in other countries? Who can you contact?
  - In some countries you find information at the ethics committees or the authorities, study sites often know where to find something, but really helpful are also CROs (keep in mind that they might be specialized towards ClinO studies, but they help with language and often also with HRO projects)
  - Recommended: make phone call to ethics committees or authorities in case of doubt
  - In Germany: “Arbeitskreis der Deutschen Ethikkommissionen»
  - ECRIN website: <https://ecrin.org/>
  - TRREE course: <https://elearning.treee.org/> "Regulatory frameworks"
  
- In case of an international study with ICFs in different languages, does each little change in an ICF of one language have to be adapted in every other ICF-language as well?
  - It depends --> but check if the changes have to be approved by EC, keep track of every version and store in TMF
  - General amendment that applies to all sites: adapt each ICF
  - If it's just an improvement of language only that one ICF can be adapted (no change to the content)
  - If change is site-specific: adapt only that ICF
  - Very important: you have to be able to track back for each sample/data which version of which ICF was signed and what you are allowed to use the sample/data for
  
- What about a study specific consent form where consent for a study/project can be given, but not for further use consent?
  - You can give a specific consent for a specific project/study and at the same time withdraw your consent for further use -> important to write a clear ICF!



- Side note: special consent and general consent are then signed separately on two separate pages.
- This could be the same situation for a withdrawal General Consent, but a given further use consent. If so, routine data couldn't be used but study specific data could be further used.

### Topic: registries

- Regarding the registry and the Swissmedic clarification of no approval needed when registry is related to an intervention, e.g. the stent performance example. The results are relevant for Post market and Periodic Safety Updates for either device / generic group or specific devices / interventions. Could we discuss the reporting to Swissmedic obligations?
  - Materiovigilance reporting -> standard procedure for every physician in Switzerland in routine work (since product is already on the market)
  - If the registry is about a pharmaceutical product -> standard procedures of pharmacovigilance will apply (since product is already on the market)
  - Same as for clinical trials of Cat A
  - In case that you discover e.g. bad effects in the scope of your registry, it would make sense to report it as well
- What measures do you recommend to implement in order to build quality into your registry projects?
  - Important aspects: eCRF
  - Provide worksheets to sites to make data/sample collection as easy as possible for the individual sites
  - Check data entry regularly, check in with sites regularly
  - Think about standardisation in the means of Central Lab or providing of equipment to site, a biosampling manual, guidance for other important procedures (photographs for example)
  - See last slides of presentation
  - Do a feasibility check and check for things that are important to you
- It seems that large, national cohort studies (such as the MS or the Swiss HIV Cohort Study) transitioned over time from a strict cohort design (with clear defined research questions) to a more open registry format (with many questions to be investigated). Is this, from a regulatory perspective, problematic? Does a registry have regulatory requirements other than those covered by a cohort study?
  - Data protection always applies



- Recommended: submit your registry to the ethics, even if it does not have a research question yet -> they give "advisory opinion" with feedback (= "Unbedenklichkeitsbescheinigung")
  - Comment: On submission of registry/biobank WITHOUT a research question to Ethics Committee: in BASEC, this needs to be submitted on the form "Advice on ethical questions/comments on research projects not subject to the HRA", NOT on the regular submission form for research projects. Ethics Committee will then make an advisory opinion on registry/biobank (fees based on working time). There are guidelines and templates for submission of registries/biobanks on swissethics website (>Topics>Biobanks and data registries) on which the evaluation will be based.
- Often one question to start with, which results in many more questions --> important to always ask for further use or for prospective prolongation of data collection in your ICFs (every research questions needs approval)
- Do you need patient consent for a retrospective (cohort) study using routinely collected data?
  - You need a signed informed consent -> in many hospitals, this is the general consent
  - If you do a feasibility check and plan how much data there will be in one center, you only get a number of how many data sets there are, and this does not need consent
  - Exception: Article 34 application -> in case you cannot ask the patient for consent
    - Comment: For such very rare cases when consent is waved, that is in the approval, so the consent process is waved and should be thoroughly justified.
- How to deal with registry data governance?
  - Always adhere to general data protection requirements -> see data session for details
  - Oblige everyone involved in a DTUA, especially regulate the requirements for data transfer

**Topic: biobanks**

- In general: swiss biobanking platform (SBP) very useful
  - <https://swissbiobanking.ch/>
  
- Necessity of material transfer agreement with biobanks
  - Always necessary!
  - For storage: biobanking regulations
  
- What requirements for HRO study with reuse of data and at the same time prospective HRO study (= use of a registry + data added in the registry)?
  - Same requirements (ethics approval, keeping track, quality assurance, ...) as in other projects
  - Important: study-specific ICF for the prospective part, check consent to re-use/further use of data for the retrospective part, cover additional further use in newly signed consent if needed
  
- Advisory opinion of the Ethics Committees on registries: advantages/disadvantages compared to a multicenter study and procedure, incl. for research
  - The advisory opinion can also be obtained for multicenter registries and is then particularly recommended.

**Topic: general**

- What are best practices to link data with samples?
  - Have clear procedures
  - Keep track of procedures
  - Recommended: use templates and procedures that are required for GCP -> this way, all crucial processes are covered systematically and keeping track in the long run is easier
  - Ensure standardised labelling of the samples