EDUCATION PLATFORM

Seminar Series:

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

Q&A from the session

"Sample management and biobanking"

Dec 04, 2024

- Taipei declaration WMA, application. Do we need to adhere to the Declaration of Taipei?
    - Answered in presentation of Michael Weisskopf: It is mandatory by law to consult nationally and internationally recognised guidelines; however, the Declaration of Taipei is not legally binding and also not in all points fully compatible to Swiss law (at the moment).
    - Background: The Declaration of Helsinki (DoH) 2008/2013 was revised to specify the ethical framework for biobanks. In view of the complexity of the issues involved, a declaration separate from the DoH was necessary. This is the Taipei Declaration whose scope is to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In concordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks.
- Which BIMS do you use, is it commercially available?
    - USZ has CentraXX (Iqvia/Kairos) in use. It is commercially available.
    - Licence costs are several hundred CHF per year per clinic independent of the number of projects (biobanks, cohorts, registries). It is deeply implemented into the hospital IT landscape, e.g. having all patients and their general consent status mirrored, making the regulatory-wise necessary documentation efficient and safe.
    - SBP solution will also be available in 2025 (in collaboration with DiData) --> aims at providing an affordable, user-friendly solution. The solution also integrates SBP datasets as the backbone of the form the biobank has to fill in at each step. This will help improving the documentation of sample-related data and increasing data quality and interoperability.
- If we use stickers on tubes, what precaution should we use to avoid them falling off at -80°C ?
    - We do not recommend to use stickers, they have several issues: falling off, not readable anymore, stick to robotics…
    - However if you use such, then focus on commercially available dedicated Cryolabels (best with GTIN numbering)
    - Good practice would be to have dedicated racks and boxes (commercially available), to guarantee sample traceability and the proper organization in the storage unit.
- What are the minimum requirements for biobanking regulations? Acceptable if simpler than the Swiss biobanking platform model, or external sponsor model (different from SBP)?

    - This document has been developed by SBP with the expertise of its Governance Advisory Board members and was submitted to public consultation in Spring 2018. The template is endorsed by Swissethics.
    - SBP templates have been designed to address regulatory requirements --> also summarises activities needed on governance and process level, and how you address and safeguard participant's rights (incl. consent, return of results, confidentiality, etc)
    - Difficult to say what is the minimum, but in general you should show how you perform governance activities, which standards you use, and how you safeguard participant's rights

- What are the features of ethical review in biobanking?
    - Sample management plan, protocol, safeguarding participant rights (consenting, withdrawing, right for information), …
- @Sabine Bavamian: Could you say more about the cost calculator?
    - The tool was developed in collaboration with the Biobank infrastructures of the Universitätsspital Basel, Inselspital Bern, University of Bern, CHUV Lausanne, HUG Geneva, and Universitätsspital Zürich.
    - It reflects the costs associated with the biobank work and preanalytical services – processing, storage, manpower --> calculates how much biobanks can charge for sharing their samples to researchers (recovery cost)
- Biobanks: re-use of data: how specific does the upcoming question have to be related to the primary question one did collect the material for (and have consent for)?
    - That depends on the consent: if the consent is narrowed to certain conditions, one is limited to exactly these conditions; but if the consent is a general one, you are not restricted
    - Recommendation: endorse a specific consent for the sampling project and a general consent for the further use of these samples
    - In general: each research question has to be approved by ethics committee
- If you have experience with the biobanks, is there a user friendly document/video that explains which document to use, where to find the resources to create tutorials for the staff (preanalytic, etc.)?
    - SBP has a quality manual which points to which documents are essential for each step. This document will help you build your Quality strategy and implement the necessary documents to ensure a proper conduct of your biobanking activities.
    - European quality manual will be available 2025 (Collaboration with BBMRI).
- Are quality control protocols for liquid human samples available on the Swiss biobanking platform?
    - SBP provides guidance on Quality Control in its SOP template (SOP for quality control implementation, see "sample-related QC" tab). Though, QC to put in place depends on the intended use of the samples. For a specific application, please contact the Swiss Biobanking Platform.

- On the ISO website (https://www.iso.org/committee/54916/x/catalogue/p/1/u/0/w/0/d/0), there are standards developed for sample processing aspects and quality controls of liquid specimens. These Technical Specifications provide recommendations for the handling, documentation and processing of liquid specimens to prepare high-quality DNA, RNA, proteins, etc.

- What is it like to have a career in biobanking with a PhD in Biology and Stem Cell Biology?
    - Depends a lot on the setting you are in: academic vs. industry, pharmaceutical or basic research, human vs. non-human samples
- What signatures are required on the regulations?
    - What seen in practice is at minimum the signatures from the designated person representing the Legal Entity in other words the Institution and the Biobank Responsible person.
- Do you offer a professional bio banking management service, or just the review of data to determine quality?
    - Yes, SBP developed a comprehensive service using an online tool to evaluate biobank practices in terms of governance, process and quality management. This service called SBP Labels focuses on biobanking activities at the process level, providing a comprehensive evaluation of the biobank at the infrastructure level evaluating structural and operational activities.
    - SBP Labels are grounded in legal frameworks such as HRA/HRO, alongside professional standards mainly the ISO 20387 on biobanking, and for soft laws integrates requirements from the Taipei Declaration, and the Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin.
    - Once fulfilled, three distinctive labels can be awarded: the VITA label (governance), and the NORMA and OPTIMA labels (Quality) to demonstrate the minimum requirements in terms of process standardization and quality assurance, respectively. The compliance review also provides harmonized documentations “SBP Docs” developed in accordance with Best Practices and international standards and includes the review of the preanalytical data documented by the biobank.