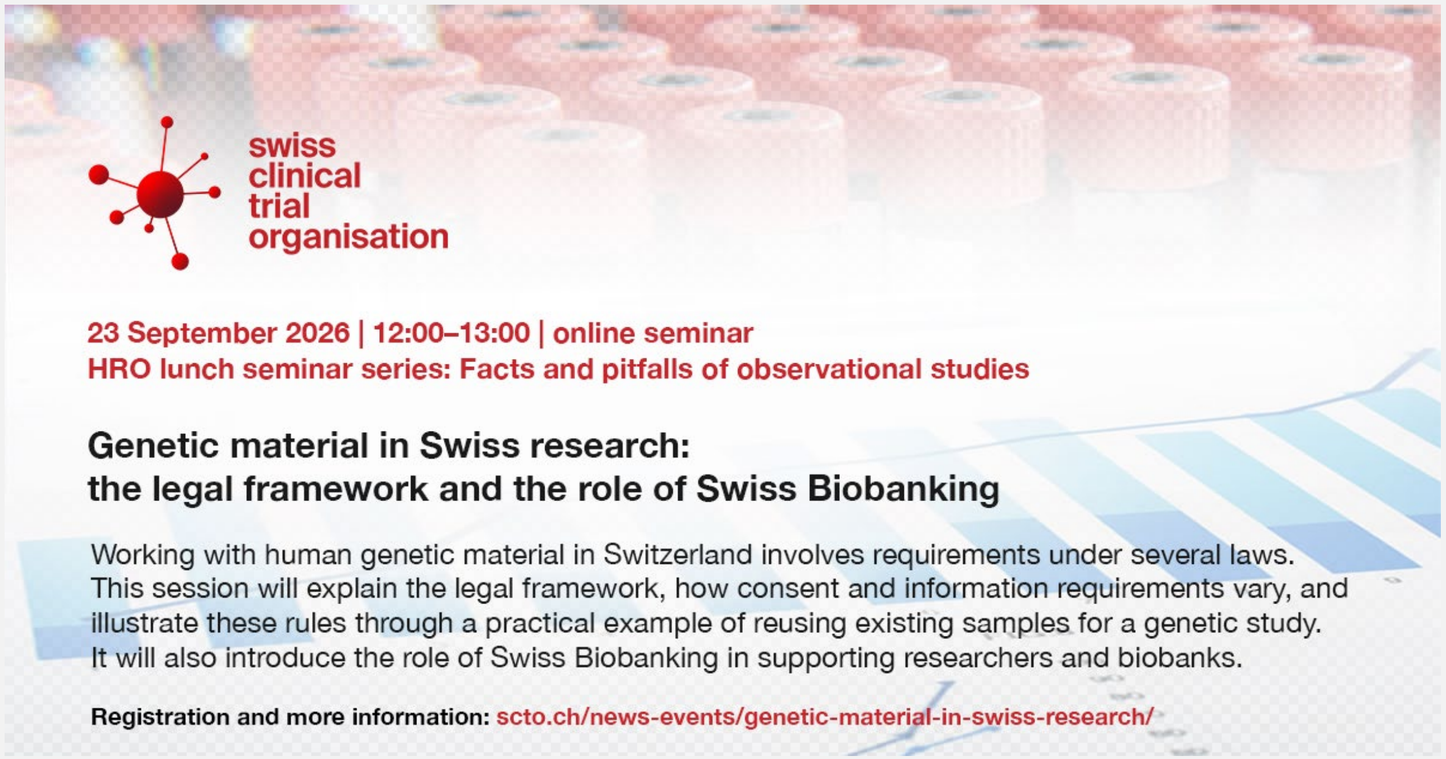
swiss clinical trial organisation

HRO Lunch Seminar Series

Session 3, 2026

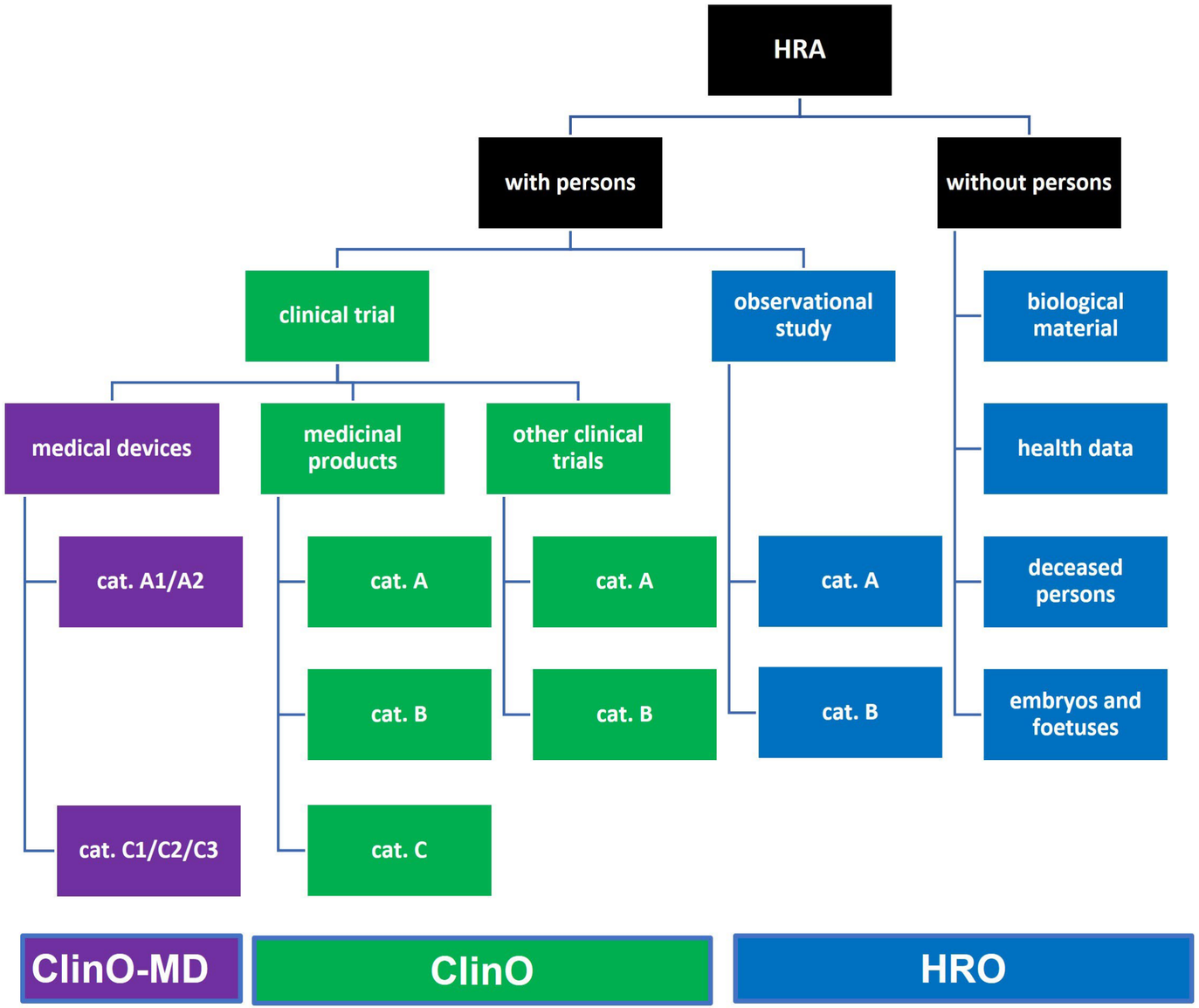


SCTO EDUCATION PLATFORM

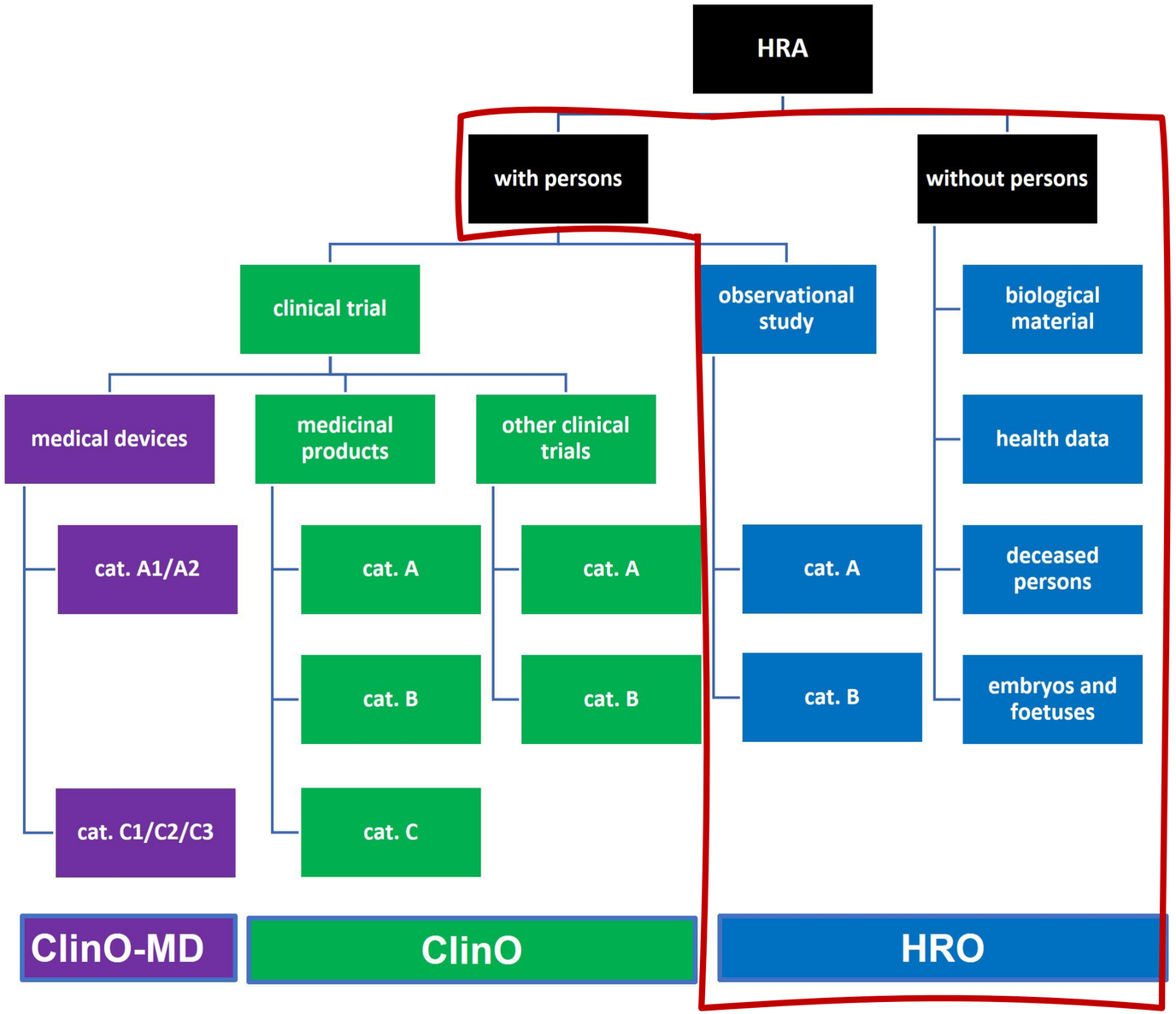
Introduction

swiss clinical trial organisation

Introduction

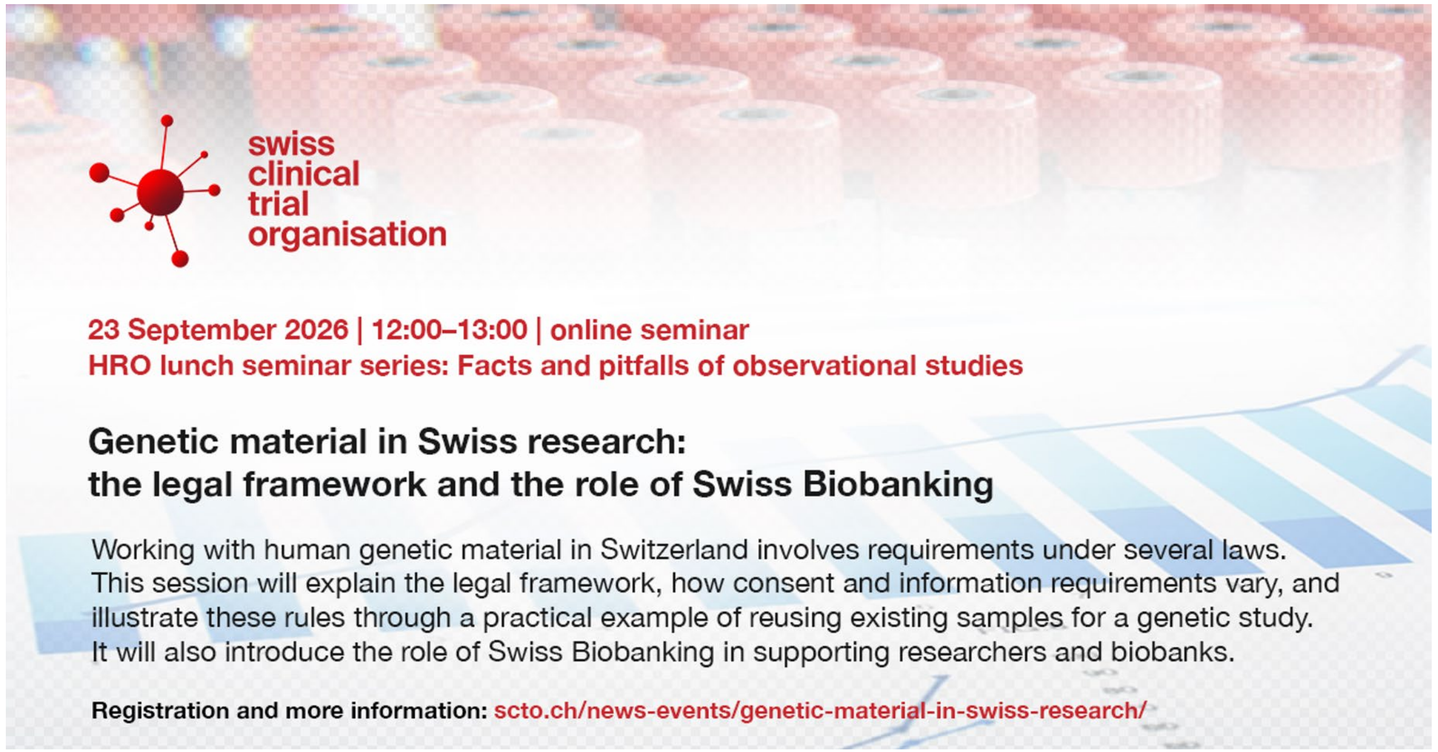


Introduction



General information

- If your require a certificate please login with your correct full name!
- Questions:
  - ➢ during presentation in the chat → for Q&A part at the end
- Presentation recorded
- Video, slides and Q&A document provided after the session on the website
- Feedback poll at end → please fill in!
- HRO lunch project team:
  - Claudia Fila (CTC Zurich)
  - Antoine Poncet (HUG)
  - Stephanie Maissen (SCTO)



Dr. Adam Strobeyko

Ethics, Legal and Social Implications (ELSI) Officer

Swiss Biobanking

adam.strobeyko@swissbiobanking.ch



SCTO HRO LUNCH

Genetic material in Swiss research: legal framework and role of Swiss Biobanking

Adam Strobeyko
ELSI Officer — Swiss Biobanking

23 September 2026

Who

Swiss Biobanking

The national research infrastructure harmonizing and connecting biobank resources for the benefit of biomedical research

Created in 2016 as an independent association called Swiss Biobanking Platform

An initiative launched by Swiss National Science Foundation with the five Swiss University Hospitals as the founding members

Swiss node of BBMRI-ERIC, the "*European Research Infrastructure for biobanking and biomolecular resources*" established in 2013



SWISS BIOBANKING

Swiss National Science Foundation

BBMRI·ch
The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Why

Too many valuable samples sit unused in fragmented biobanks — a missed opportunity for advancing research

National biobanks need support to become a structured and professional infrastructure

Switzerland’s competitiveness in research and innovation depends on biobanks being high-quality, visible, accessible, and interoperable

Fostering collaboration, sharing expertise, and participating in European projects through the BBMRI-ERIC community is vital for Swiss biobanks

We position CH at the forefront of research by facilitating access to high-quality samples and promoting their optimal use.



SWISS BIOBANKING

Swiss National Science Foundation

How

10 years of Swiss Biobanking:
From fragmented biobanks to connected research

Platform

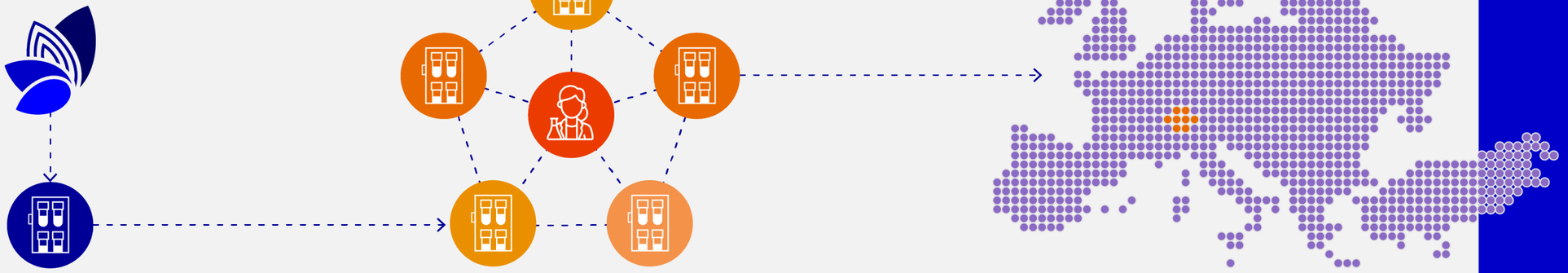
One-to-one

Network

Peer-to-peer

Node

Bridge to Europe



Provide common tools for harmonised practices

Promote, showcase & share samples

Collaborate & build bridges with European research

SWISS BIOBANKING

Building trusted, connected, and interoperable biobanks

Connecting biobanks and researchers through trusted digital tools and services

HOW TO STRENGTHEN AND EMPOWER BIOBANKS THROUGH GOVERNANCE, INFRASTRUCTURE, AND QUALITY?

Quality — frameworks, labels & standards

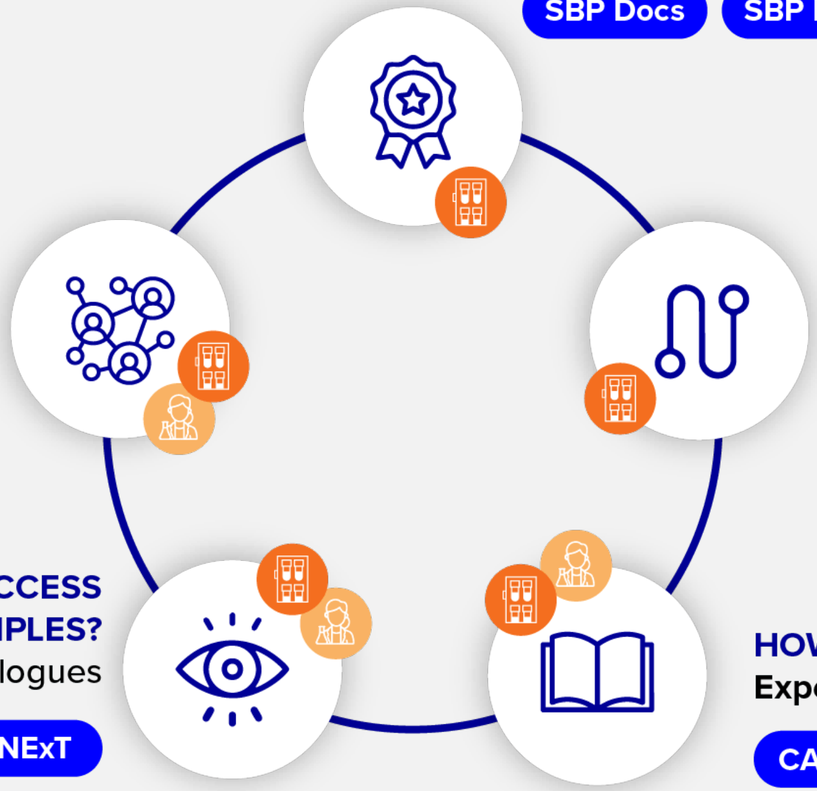
SBP Docs | SBP Labels

Vita | Norma | Optima

HOW TO BREAK OUT OF SILOS AND BUILD BRIDGES?

Collaboration — a connected community of practice

SBP Community



HOW TO MAKE SAMPLES AND DATA INTEROPERABLE?

Traceability — structured workflows & datasets

SBP Datasets | SBP SMPL

Dataset LIQUID | Dataset TISSUE | Dataset VET LIQUID | Dataset VET TISSUE | Dataset BACTERIA

HOW TO GIVE RESEARCHERS ACCESS TO FAIR SAMPLES?

Access — visible, FAIR samples via catalogues

SBP NExT

SBP Sample Cost Calculator

HOW TO UPSKILL BIOBANK PROFESSIONALS?

Expertise — training & resources

CAS in Biobanking

SWISS BIOBANKING

Biobanks | Researchers

Positioning

SBP CLIENTS

A **biobank** is an organized entity with a governance in place, responsible for the management of biological resources.

Biobanks

A **biobank infrastructure** in an organized facility that offers services to biobanks.

Biobank infrastructures

A **researcher** is interested in accessing high-quality samples for their research.

Researchers

SWISS BIOBANKING

SBP STAKEHOLDERS

Institutions hosting biobanks

- Unimedsuisse
- Swiss Universities
- Cantonal Hospitals
- Research institutes

Research funding organizations

- SNSF
- SERI

Regulators and policy makers

- Swissethics
- FOPH

Other national research infrastructures

- SAMS
- SCTO
- Swiss Cancer Institute
- SPHN

European Infrastructures and networks

- BBMRI-ERIC
- ESBB

SWISS BIOBANKING

A national network, with a stepwise quality approach

— The SBP Label programme is a stepwise path to improving and demonstrating quality, and governance

— Evaluating your biobank's practices and enhancing harmonization

— Preparation for the requirements of the ISO 20387 biobanking standard

— 3 labels to showcase compliance with SBP's minimum requirements



Compliance with legal and ethical standards



Standardization of the biobanking processes

From consent presentation to sample shipment, including personnel and equipment management

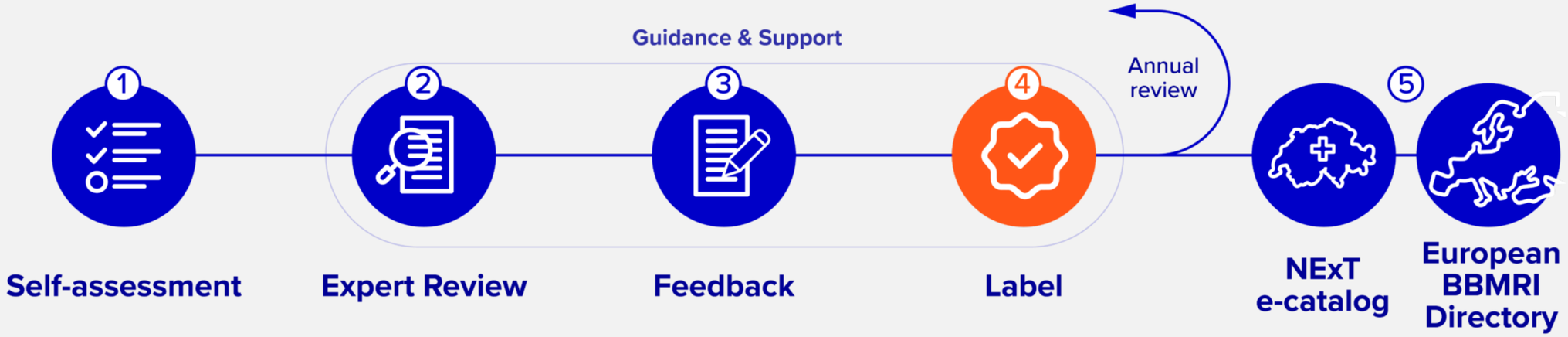


Implementation of quality assurance measures of the overall biobanking system



SWISS BIOBANKING

SBP Labels
a guided step-by-step approach



SWISS BIOBANKING

Network

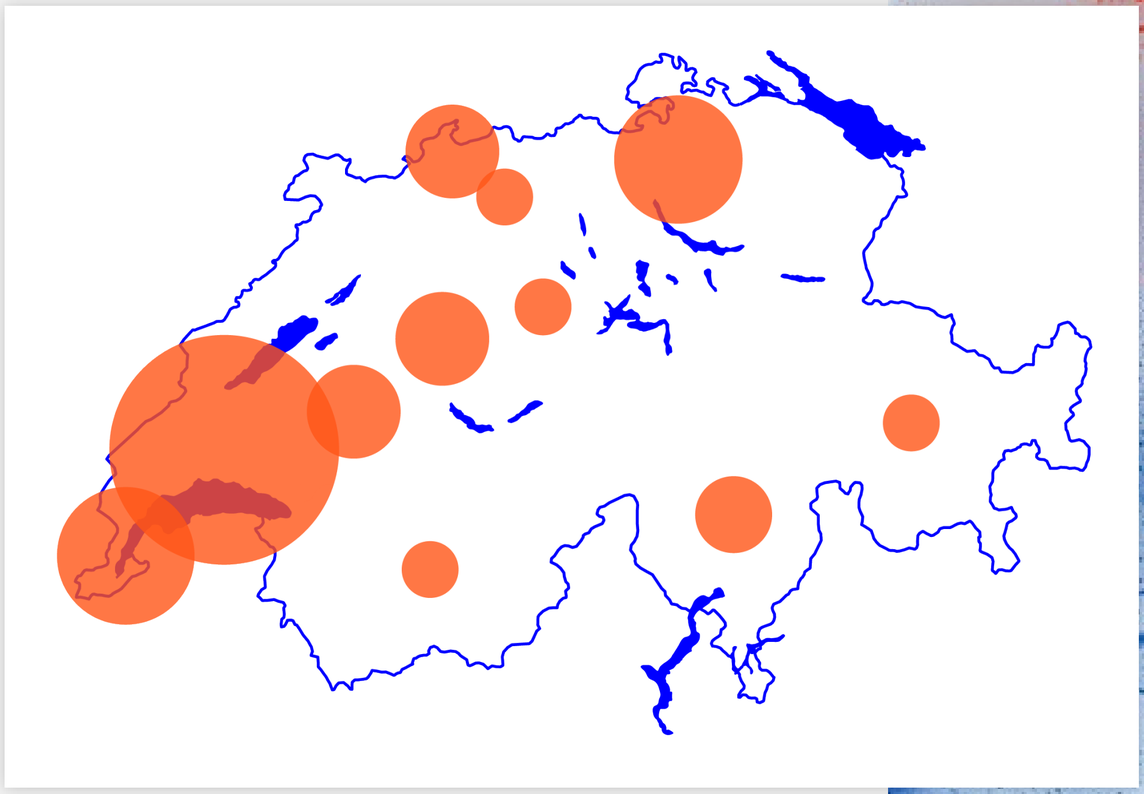
Biobanks which want to improve quality and share samples with the research community

107 Vita

43 Norma

11 Optima

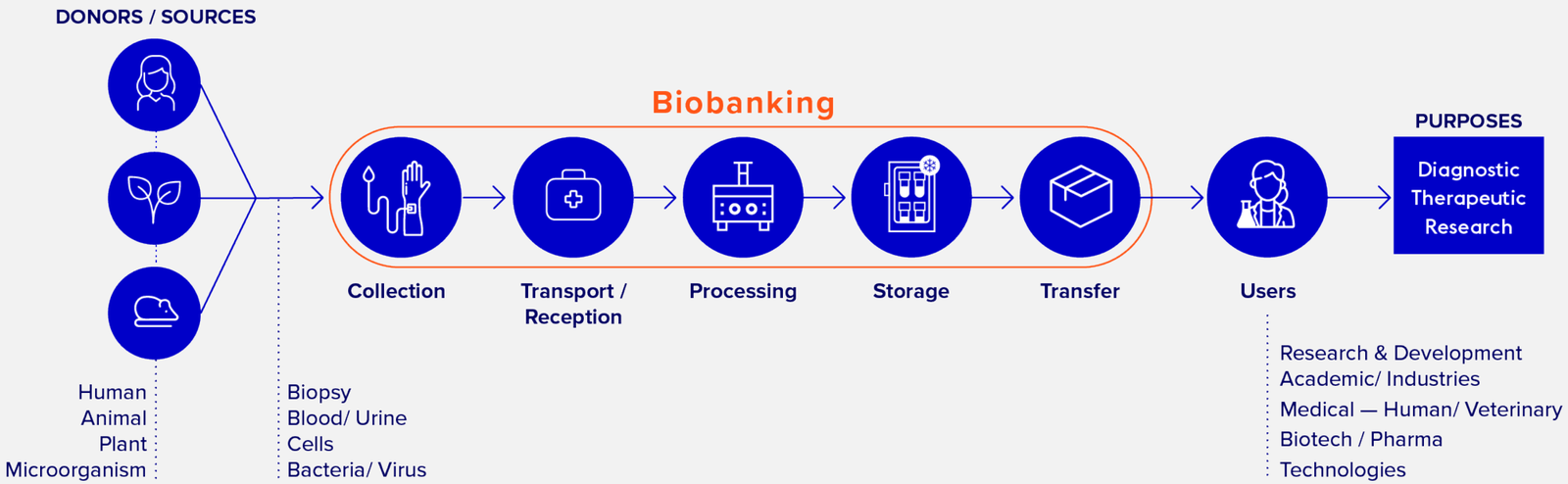
55 BBMRI-ERIC Directory



SWISS BIOBANKING

Reference Guide: Biobanking process

Developed in collaboration with SCTO



Systematically maps operational, regulatory, and quality documentation to each phase of the biobanking workflow.

SWISS BIOBANKING

How clinical researchers can work with SBP

- **Find samples & partners:** search biobanks and samples on SBP NExT; join or create research communities.
- **Set up collaborations:** SBP acts as a neutral coordinator between biobanks, researchers and institutions (national and European level through BBMRI).
- **Governance & contracts:** VITA Label, support in developing your main Governance documents (i.e. Biobank Regulation, MTA or questions around consent).
- **ELSI support:** Consulting and guidance on ethical, legal and social issues.
- **Training:** the CAS in Biobanking and targeted governance and quality education.

One entry point to compliant, high-quality samples and data.



SWISS BIOBANKING

SWISS BIOBANKING

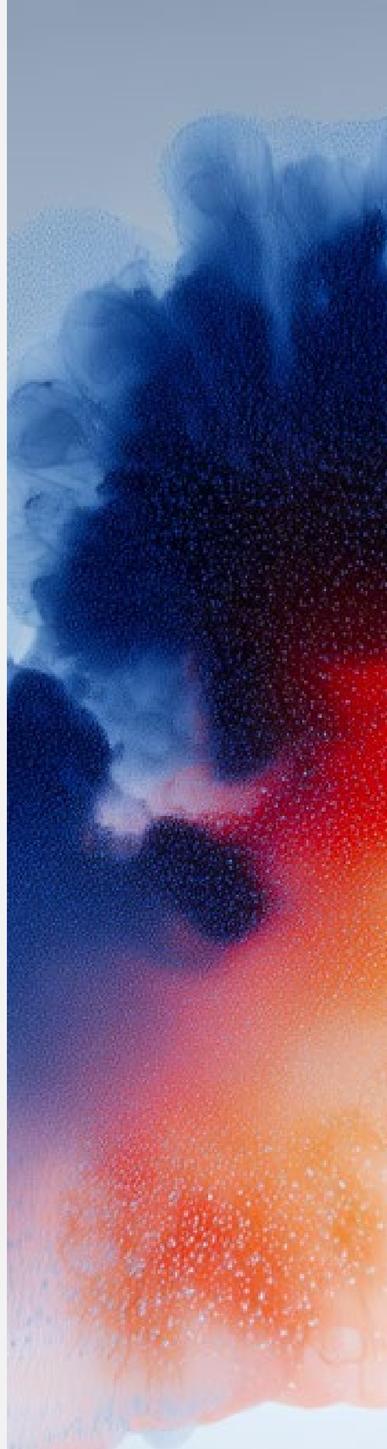


Part 2

Swiss legal framework: the example of human genetic material

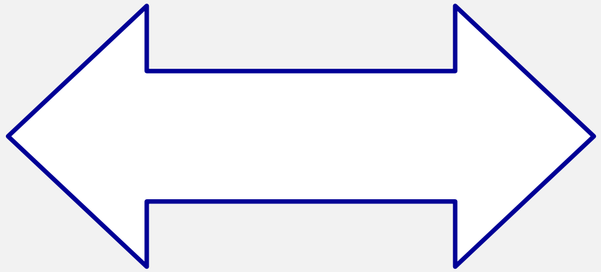
Why genetic material and data are treated differently

- **Pseudonymized/coded data —** difficult to speak of anonymization in the context of genetic material
- **Shared with relatives —** findings can reveal information about biological family members who never consented.
- **Predictive and lifelong —** it can indicate future disease risk and cannot be changed.
- **Sensitive by law —** genetic data are treated as sensitive personal data, attracting heightened protection.
- **Consequence —** the law sets a higher bar for using genetic material and data.



SWISS BIOBANKING

Growing pressure to access health data…



a need to safeguard the rights of data subjects, especially over sensitive data, and public trust in health and research institutions

Example of guidelines: WHO, 'Guidance for human genome data collection, access, use and sharing' World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO, https://www.who.int/publications/i/item/9789240102149



SWISS BIOBANKING

The Swiss legal landscape is layered

Human Research Act (LRH / HRA)
constitutional basis: art. 118b Cst

Clinical Trials Ordinances (OClin / OClin-Dim)
→ clinical trials

Human Research Ordinance (ORH / HRO)
→ research projects, incl. reuse of samples & data

General data-protection law applies underneath everything:
Federal Act on Data Protection (FADP / LPD) + cantonal laws

Scope note — the Federal Act on Human Genetic Testing (GUMG / LAGH) governs genetic testing in clinical, insurance and employment settings. Genetic analysis for research is governed primarily by the HRA

Human Research Act (HRA): Scope

Art. 2 Scope

[1] This Act applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

a. persons;
b. deceased persons;
c. embryos and foetuses;
d. biological material;
e. health-related personal data.

[2] It does not apply to research which involves:

a. IVF embryos in accordance with the Stem Cell Research Act of 19 December 2003;
b. anonymised biological material;
c. anonymously collected or anonymised health-related data.



SWISS BIOBANKING

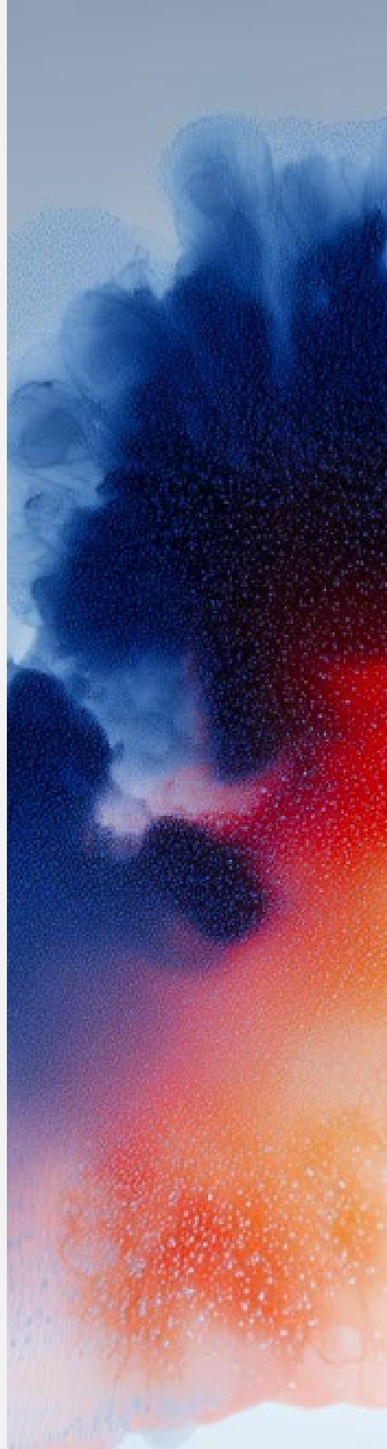
Human Research Act (HRA): to consider

- Art. 17 HRA: **obtaining consent** for the further use at the time the data is collected
- Art. 32-34 HRA: **conditions for the further use** for the purpose of research involving human beings (see also art. 24 et seq. HRO, 17 ClinO)
- Art. 43 HRA: **conditions for the storage of data and biological material** (see also art. 5 HRO)
- Art. 45 HRA: the **authorisation** regime for carrying out a research project or the further use



What kind of data are you using?

- **Anonymized / anonymous data —** no link to a person; the HRA does not apply (art. 25 HRO).
  - However, true anonymization or feasibility of true anonymization may be particularly difficult for genomic data
- **Genetic or non-genetic data**
  - **Non-coded data:** always linkable to a person
  - **Coded (pseudonymized) —** linkable to a person only through a key (art. 3 HRA; art. 26 HRO).
- **Genomic —** Whole Genome Sequencing (WGS) requires sufficient level of information for informed decision/consent.



Consent depends on data type — and genetics raises the bar

DATA REUSED IN RESEARCH		CONSENT REQUIRED
Non-coded personal data	genetic	Project-specific consent
	non-genetic	General consent
Coded personal data	genetic	General consent
	non-genetic	Right to object (in practice: general consent)
Anonymous data		Right to object to anonymization → HRA does not apply

Underlying reuse regime: art. 32–34 HRA.
A person's refusal to take part in research is always binding (art. 118b Cst).



SWISS BIOBANKING

Example — reusing existing samples for a genomic study

Scenario — You want to perform whole-genome sequencing on existing coded blood samples held in a hospital biobank and analyse the resulting coded genomic data.

Ask, in order:

1. **What biological material and data are involved?** Whole blood -> DNA -> human genomic data.
2. **Is the material/data coded, uncoded or intended to be anonymized?** Coded.
3. **What consent exists?** Project-specific or general?
4. **Will genetic or genomic analyses be performed?** Check whether the consent and participant information adequately address genomic research and the intended data use.
5. **Does the ethics approval cover this study, including sequencing, data linkage and planned sharing?**



SWISS BIOBANKING

DATA REUSED IN RESEARCH		CONSENT REQUIRED
Non-coded personal data	genetic	Project-specific consent
	non-genetic	General consent
Coded personal data	genetic	General consent
	non-genetic	Right to object (in practice: general consent)
Anonymous data		Right to object to anonymization → HRA does not apply

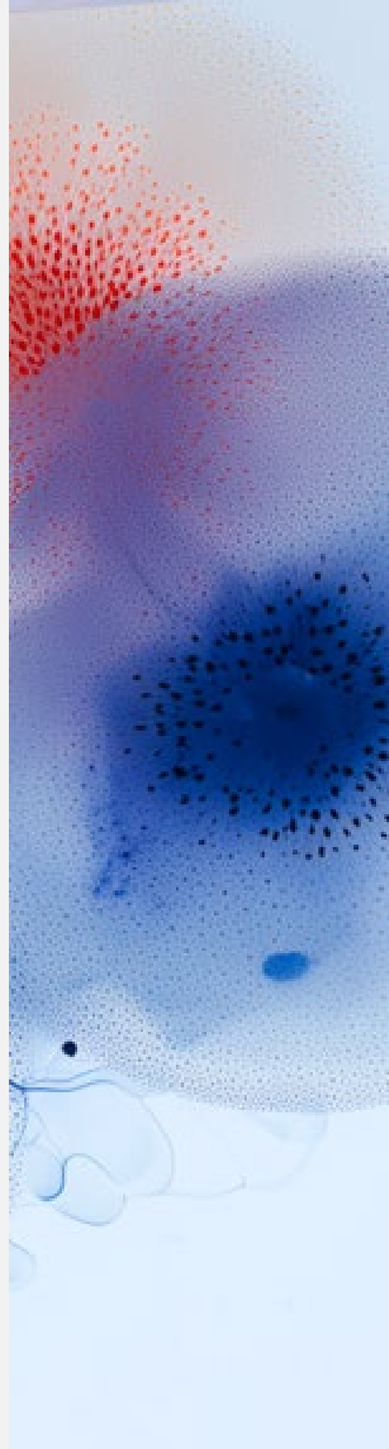
Result: genetic + coded needs general consent (art. 32–33 HRA); genetic + non-coded needs project-specific consent. In practice, WGS usually requires adequate specific information.

Reuse without required consent: reuse only possible via the exceptional route of Art. 34 HRA, with authorization from the competent ethics committee.

Conclusion: Existing coded samples and genetic data can be reused when valid general covers the proposed research. For WGS assess the adequacy of genomic information. If consent is missing, seek consent where feasible. Reuse without it requires an authorized Art. 34 exception.

Data protection framework

- **Sensitive data:** health and genetic data qualify as *sensitive* personal data under data-protection law, which triggers heightened safeguards (art. 5(c) FADP).
- **Define roles —** controller (decides purposes and means) vs. processor (acts on the controller's behalf); engaging a processor itself requires a contract (art. 9 FADP).
- **MTA/DTA —** a Material or Data Transfer Agreement sets out the purpose, roles, responsibilities and conditions of the exchange
  - DTA is what binds the recipient to purpose limitation, use restrictions and accountability.
- **Cross-border —** disclosure abroad permitted only if the destination ensures an adequate level of protection; otherwise added safeguards or a statutory exception are required (art. 16–17 FADP).
  - Export of biological material or genetic data for research additionally requires informed consent (art. 42 HRA).



HRA reform: key issues

- Facilitating access to samples and data
- Anonymization: is it possible for genetic data?
  - Add odds with current logic that genetic data = coded data
- Notification-based system instead of Ethics Commission approval for low-risk project?
  - The role of SBP labels
- Streamlining procedures through a lead-commission model for multi-site projects?
- Alignment with the revised FADP and EU developments (notably EHDS).



Conclusions

- Genetic data is especially sensitive and necessitates stronger protection.
- Growing pressure to access health data, balanced against people's rights and public trust.
- A layered Swiss legal framework (HRA/HRO, ClinO, FADP).
- EU legal framework (GDPR, EHDS) increasingly relevant.
- Reuse for research follows the HRA: the consent you need depends on the data type, and genetics raises the bar.
- Data sharing framed by contracts (MTA/DTA), with stricter rules for cross-border transfers.
- HRA reform underway addresses some of the foundations of current legal framework.
- SBP will continue to support CH biobanks to navigate this environment.



SWISS BIOBANKING

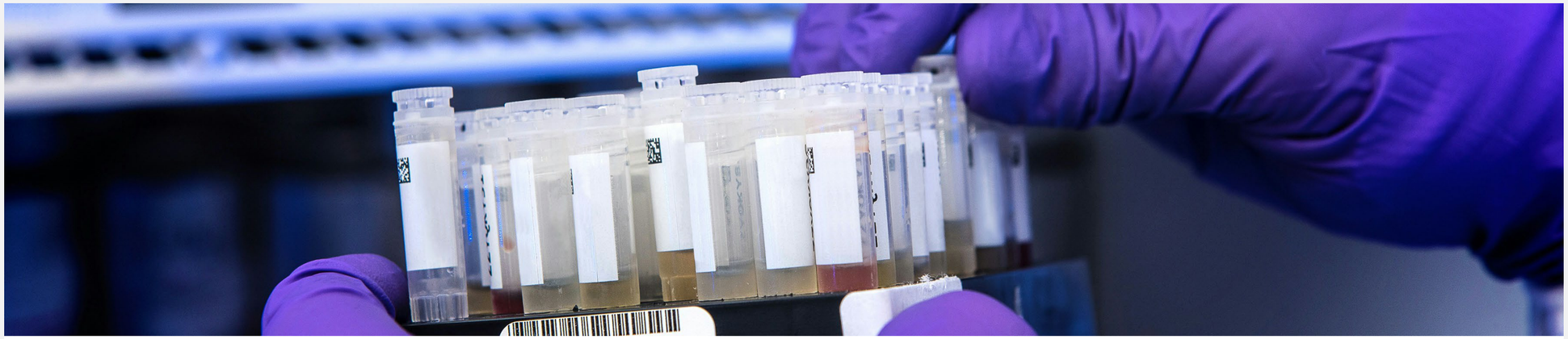
Microcertification
The Basics of Biobanking

100% e-learning
Flexible, and accessible worldwide

Advanced Expertise
State-of-the-art biobanking knowledge

Global Community
Connect with experts and peers worldwide

Registrations are open to start on 01 February 2027



SWISS BIOBANKING

UNIVERSITÉ DE GENÈVE

HSeT Health Sciences e-Training Foundation

INSTITUT Pasteur

SWISS BIOBANKING

SWISS BIOBANKING

BBMRI·ch
The European research infrastructure for biobanking and biomolecular resources in health and life sciences

Thank you

Adam Strobeyko
ELSI Officer
Swiss Biobanking

adam.strobeyko@swissbiobanking.ch

www.swissbiobanking.ch



Q&A part – Questions?

Adam Strobeyko

Coming soon: Reference Guide to Biobanking

Simplify your biobanking journey

A new practical tool by **Swiss Biobanking & SCTO**, bringing together:

- Key steps in the biobanking process
- Essential documents
- Further information & resources

➢ Published by the end of the year.

Thank you for participating!

Further questions to:

adam.strobeyko@swissbiobanking.ch

HRO lunch session 4

- 25 November 2026 –

Speaker: Swiss Cancer Research Institute



Registration possible soon under:

«Tools & Outcomes»

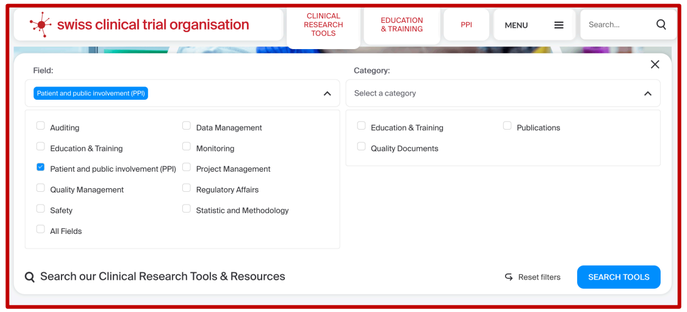
Don‘t miss out on events and training opportunities: Subscribe to the SCTO newsletter today

www.scto.ch/newsletter-signup/



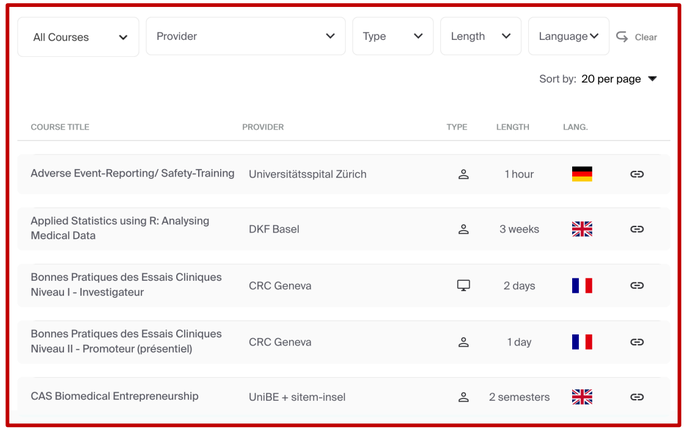
SCTO Tools & Resources Navigator: Explore and download free tools designed for the clinical research community

www.scto.ch/clinical-research-tools/



Course Finder: To discover courses for clincial reserachers

www.scto.ch/education-and-training/clinical-research-training/



Thank you!

Swiss Clinical Trial
Organisation Effingerstrasse 35
| 3008 Bern Switzerland
Tel +41 31 307 10 47

www.scto.ch

swiss
clinical
trial
organisation