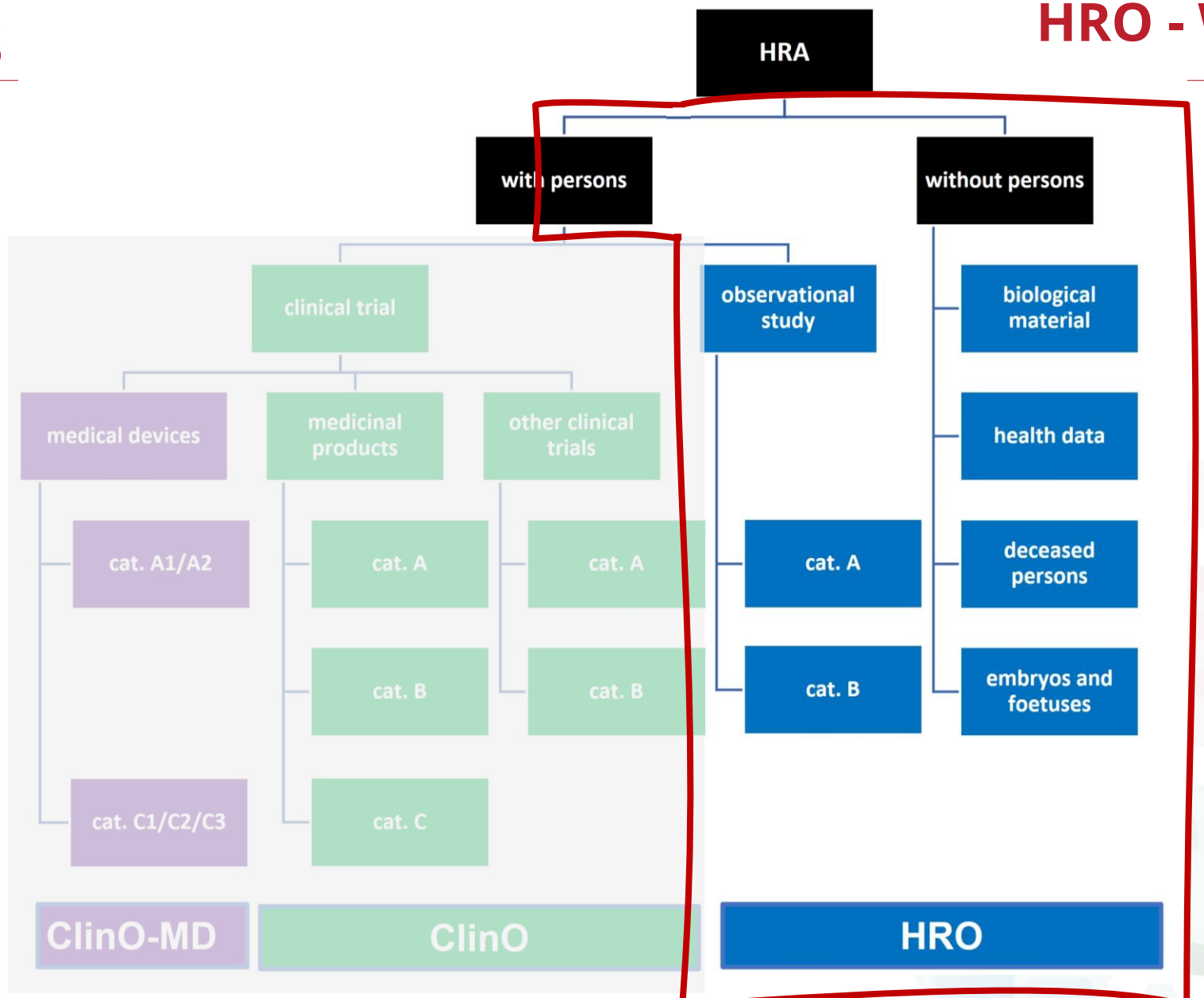

SCTO
PLATFORMS
4 December | 12h00 - 13h00 | online seminar
Facts and pitfalls of observational studies
Sample management and biobanking
Registration and more information:
sctoplatforms.ch/HRO-training-series

HRO - Where are we?



according to Ch. Seiler, EC Bern

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General information

- **Questions**:
  - **during presentation**: in the chat (→ for Q&A session at the end)
  - **during Q&A at the end**: also by raising hand/unmuting
- Presentation recorded
- Video, slides & Q&A provided after the session
- Feedback poll at end → please fill in!
- HRO lunch team:
  - Samia Abed-Maillard (CRC Lausanne)
  - Claudia Fila (CTC Zürich)
  - Simone Kälin (CTU St. Gallen)
  - Verena Golz (DKF Basel)

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Presentation

Dr. med. Michael Weisskopf

Head Research Biobanking Service Center, Universitätsspital Zürich (USZ)

Michael.Weisskopf@usz.ch

Sabine Bavamian, PhD

Chief Scientific Officer, Swiss Biobanking Platform (SBP)

Sabine.Bavamian@swissbiobanking.ch

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HRO Lunch Session - Part I

Sample management and biobanking

Dr. med. Michael Weisskopf

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Sample Management in Human Research

Dr. med. Michael Weisskopf, Msc Biobanking

Directorate Research and Education USZ

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The practical viewpoint…

Why bother, just store biological material a low temperatures?!

Pre-sampling | Post-sampling | Analysis

Consent | Collecting / Sampling | Transport | Processing | Storing | Access / Use

Pre-Analytical Phase

- Patient treatment, sampling procedure → impact on specimen
- After sampling, specimen is still „alive“ and biologically (re-)active!
- Analysis outcomes potentially altered by pre-analytical changes

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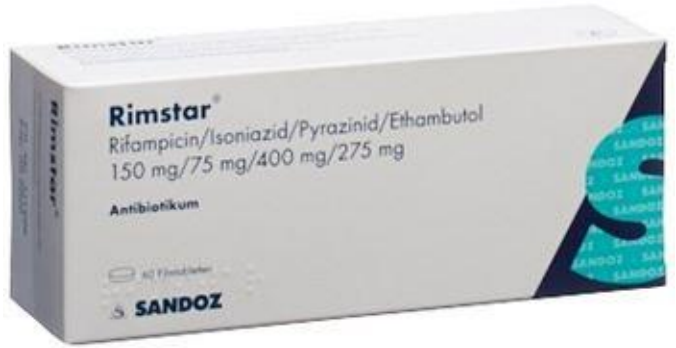
Use Case: Swissmedic Inspection

A clinical study conducted at the CTU USZ



Drug-drug-interaction
Endpoint: pharmacokinetics of Rifampicin, Isoniazid and Ethambutol

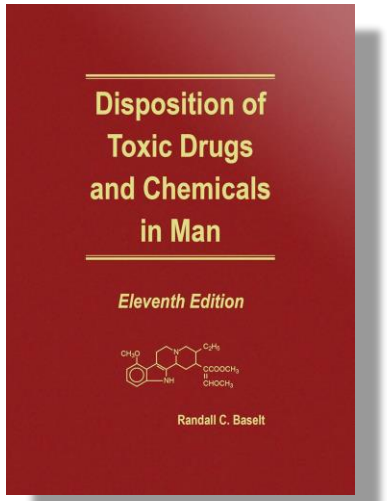
Swissmedic Inspection

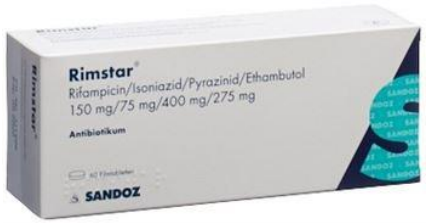
Finding / questions regarding sample management

Handling of the blood samples right after blood drawal:

- UV/light protection of blood sample
- room-temperature vs on ice after sampling
- delay between sampling / centrifugation / storage -80°C

Workup / reply to Swissmedic findings





Compound	Sample stability in whole blood at room temperature (20-25°C) in hours
Rifampicin	24h
Ethambutol	48h
Pyrazinamide	24h
Isoniazid	1 h
Chloroquine	24h

Samples not compromised in two cases of protocol deviations (delayed sample processing: 15mins / 20mins) UV protection, ice-bath necessary in case of longer delays.

The Swissmedic finding is highlighting the importance of diligent sample management

Use Case: how to do sample mangement right

Abnahme Datum: (Beispiel: 01 JAN 2001)	_ _ / _ _ _ / _ _ _ _

Lab - Probe vor IMP-Gabe			
Nach Absprache mit Studienteilnehmer Einlage von peripherer Verweilkanüle (PVK rosa/grün) durch Study Nurse. Danach 1. BE PK predose und Safety Lab. Danach kontinuierliche Gabe von NaCl 0.9% mit Verlängerung und Dreiweghahn via IVAC – 10ml/h, nachspülen nach PK-Entnahme, Zusatz-Röhrchen verwerfen vor PK-Entnahme			
Abnahme Zeit (Blut):	_ _ : _ _ (hh:mm)	**Abgenommen durch:** (Initialen)	

PK predose Predose = 5 bis 15 min. vor IMP Gabe von Rimstar		**Blut Volumen:** 10.0mL Lithium Heparin (**schwenken 8-10x**) **Empfehlung: Vacutainer grün mit Blut für PK Abnahme in Alufolie packen (Lichtschutz)**
Zentrifuge Eppendorf: 2800 x g, 10 min., bei 4°C, mit soft stopp (Programm 2) innerhalb von 10min, max 30min nach Abnahme Sollte die Zentrifugation erst 10-30min nach Abnahme stattfinden, Blutröhrchen mit Eiswasser kühlen! ☐		**Start Zentrifugation:** _ _ : _ _ (hh:mm) Ohne Alufolie zentrifugieren!
Lagerung: ☐ Transport / Transfer der Aliquots **in lichtgeschütztem Aliquot Behälter und Alu gepackt!** Danach in vollautomatisiertem Freezer -80°C im Raum: AUFN A 24		_ _ : _ _ **hh:mm** Zeitpunkt der Einlagerung der Aliquots in den vollautomatisierten Freezer AUFN A 24 Proben vor Einlagerung im CentraXX erfassen nach «Clear TB_Handout CentraXX_Lithium Heparin_PK»
Kommentar: Aliquots = FluidX Krvo Röhrchen		

Pre-sampling instructions

- to avoid dilution of blood sample
- correct timing and documentation

Post-sampling instructions

- light-protection (aluminium foil)
- Ice-water bath if centrifugation delayed
- sample transport instructions
- automated freezer system
- sample registration in BIMS
- labware definition

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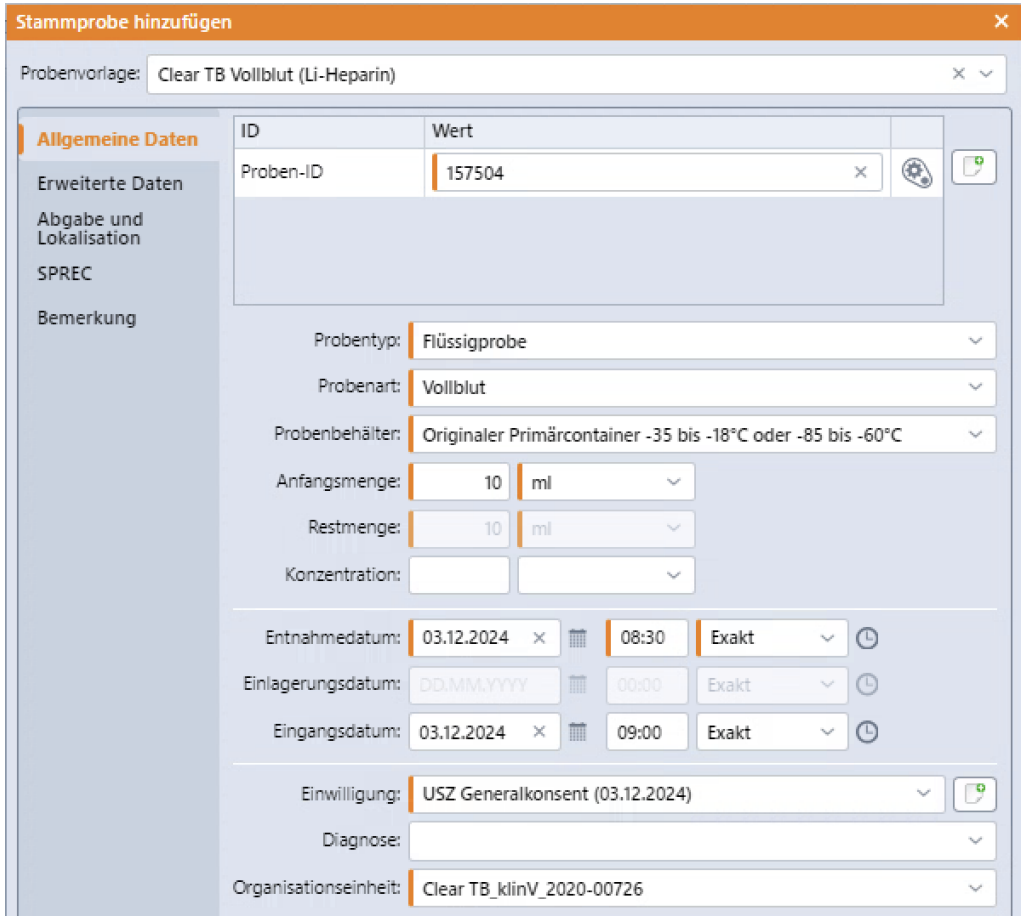
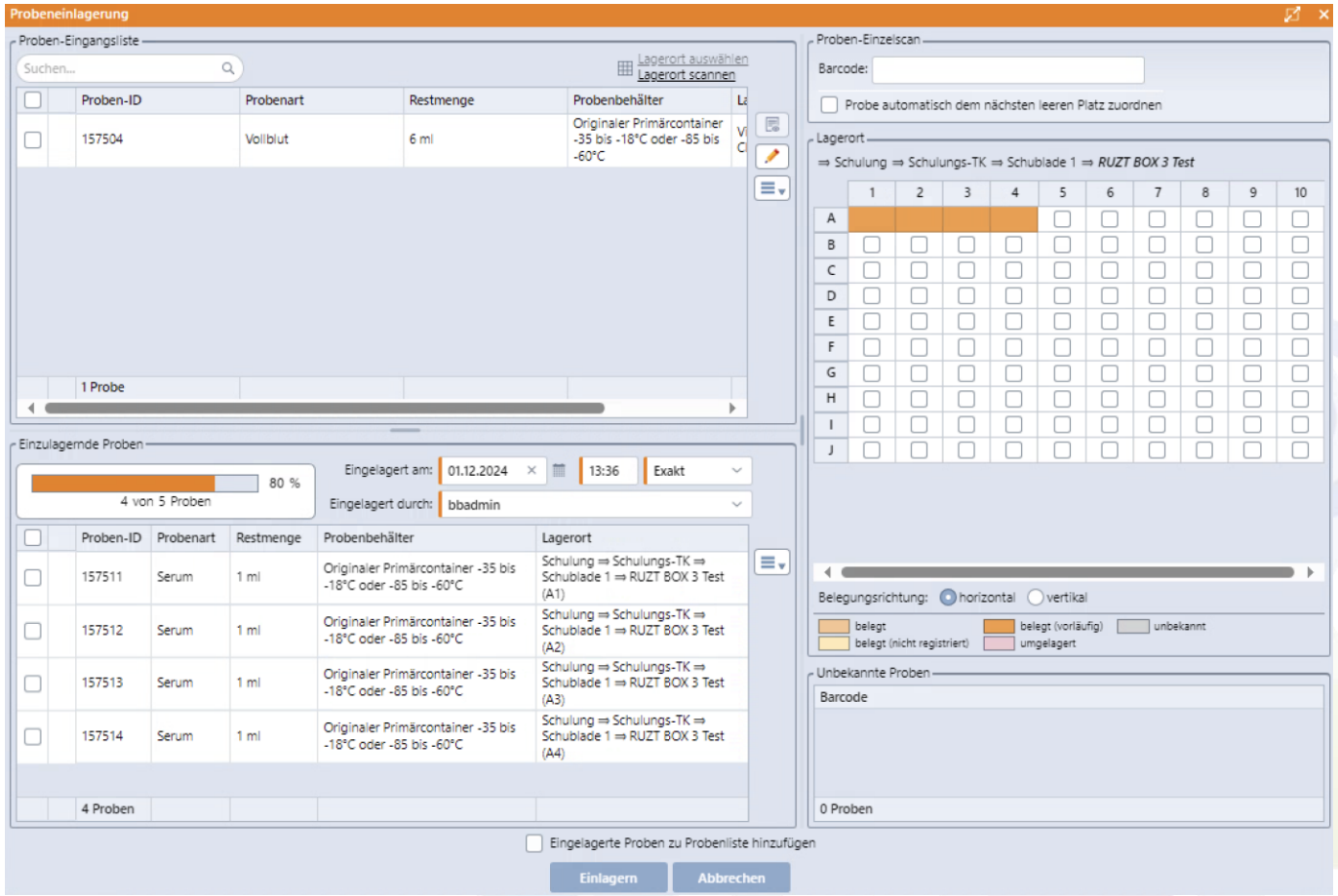
Sample Management in Human Research

Documentation according to (inter-)national standards

→ Evaulation of sample quality, comparability, FAIR-principle

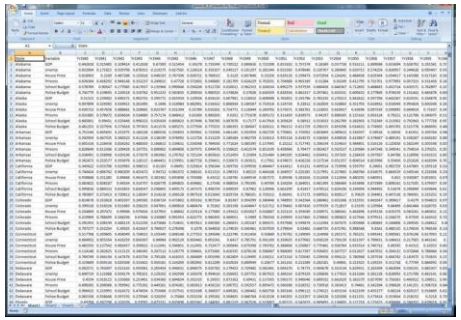




Sample Management in Human Research

- Data protection issues, avoid sticky labels

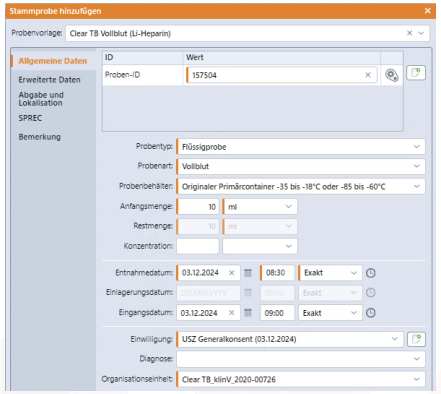
- Ice building, exposure to room temperatures, high energy consumption, unauthorized access, …



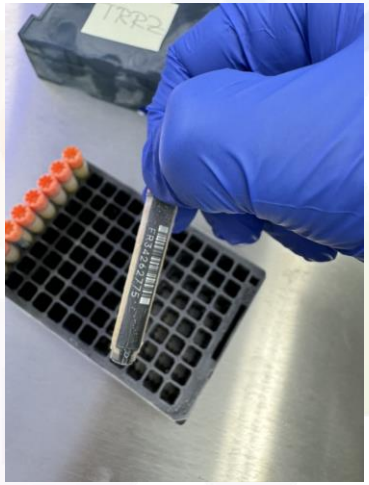
- Excel sheets with manual data entry
- Non-standard documentation
- unfit-for-purpose numbering systems

- Scanning

- Structured safe storage
- Temp monitoring (cf. Swissmedic findings)



- Sample Management Software (BIMS)
- Standard documentation
- Barcoded labware



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The regulatory viewpoint…

Human Research Act on sample mangement

- «biological material» → sampled from living humans*
- «appropriate measures» for storage and management
- connection to data (meta-data / clinical data) «a biobank is a registry with samples»
- availability for (yet undefined) research projects

Reminder: the key difference

Sampling of specimens for the build-up of a biobank (**HRO Art. 6b / ClinO**)

- *PIC & EC approval required*

Collecting of otherwise being generated samples for the build-up of a biobank (**HRO Art. 24**)

- *GC & no EC approval necessary (but EC advice recommend)*

* in contrast to autopsy material! Regulated separately in own HRA chapter

Human Research Act on sample mangement

HRA Art. 43 Storage

[1] Anyone who stores biological material or health-related personal data for research purposes must take appropriate technical and organisational measures to prevent unauthorised use thereof, and fulfil the operational and professional requirements.

[2] The Federal Council shall specify the requirements for storage.

What are these «appropriate technical and organisational measures»?
→ HRO Art. 5 and ClinO Art. 18

Human Research Act on sample mangement

HRO Art. 5 = ClinO Art. 18 (identical wording!)

[1] Any person who stores health-related personal data for research must take appropriate operational and organisational measures to protect it, and in particular:

a. restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties;
b. prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data;
c. document all processing operations which are essential to ensure traceability.

- Data Protection
- Audit Trail
- Documentation

[2] Any person who stores biological material for research must, in particular:

a. comply with the principles set out in paragraph 1 *mutatis mutandis*;
b.[6] ensure that the technical requirements are met for appropriate storage of the biological material; here, nationally and internationally recognised guidelines must be consulted;
c. make available the resources required for storage.

Nationally and internationally recognised guidelines?

- Declaration of Tapei 2016

WMA DECLARATION OF TAIPEI ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002
and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016

PREAMBLE

1. The Declaration of Helsinki lays down ethical principles for medical research involving human subjects, including the importance of protecting the dignity, autonomy, privacy and confidentiality of research subjects, and obtaining informed consent for using identifiable human biological material and data.

2. In health care provision, health information is gathered by physicians or other members of the medical team to record health care events and to aid physicians in the on-going care of their patient.

3. This Declaration is intended 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.

Legally non binding in CH and not fully compatible. E.g. *“19. An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes.”*

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Nationally and internationally recognised guidelines?

- ISBER Best Practices 5th Edition December 2023

ISBER
INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSITORIES

- SPREC 3.0

Standard PREanalytical Code Version 3.0

Fay Betsou,[1] Roberto Bilbao,[2] Jamie Case,[3] Rodrigo Chuaqui,[4] Judith Ann Clements,[5] Yvonne De Souza,[6] Annemieke De Wilde,[7] Jörg Geiger,[8] William Grizzle,[9] Fiorella Guadagni,[10] Elaine Gunter,[11] Stacey Heil,[12] Michael Kiehntopf,[13] Iren Koppandi,[14] Sabine Lehmann,[1] Loes Linsen,[15] Jacqueline Mackenzie-Dodds,[16] Rocio Aguilar Quesada,[17] Riad Tebbakha,[18] Teresa Selander,[19] Katheryn Shea,[20] Mark Sobel,[21] Stella Somiari,[22] Demetri Spyropoulos,[23] Mars Stone,[24] Gunnel Tybring,[25] Klara Valyi-Nagy,[26] and Lalita Wadhwa;[27] and the ISBER Biospecimen Science Working Group

- CEN Standards
- BBMRI / ESBB / SBP Guidelines
- SPHN Data Standards
- ISO

cen

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ESBB
European, Middle Eastern & African Society for Biopreservation and Biobanking

BBMRI-ERIC

SPHN
Swiss Personalized Health Network

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The scientific and ethical viewpoint…

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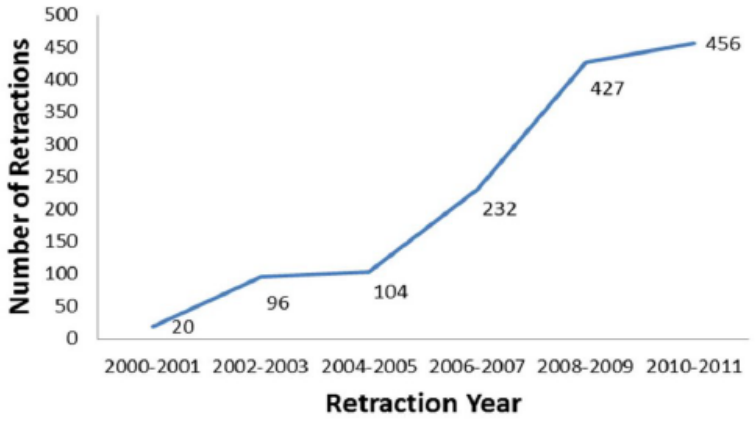
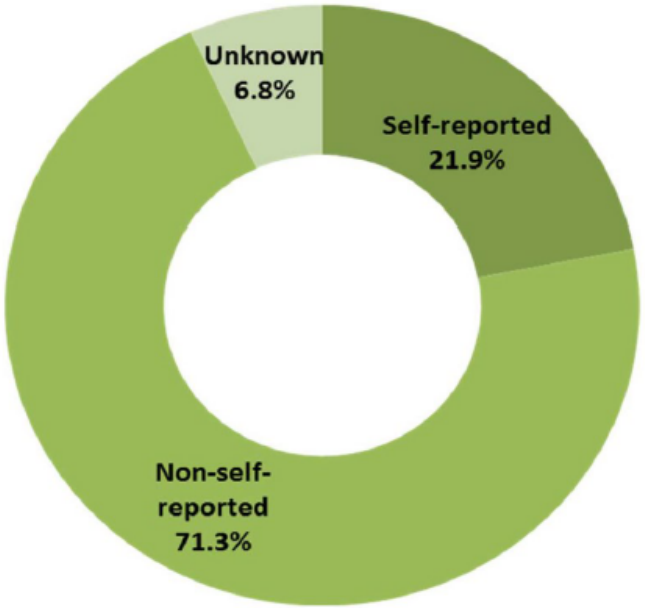
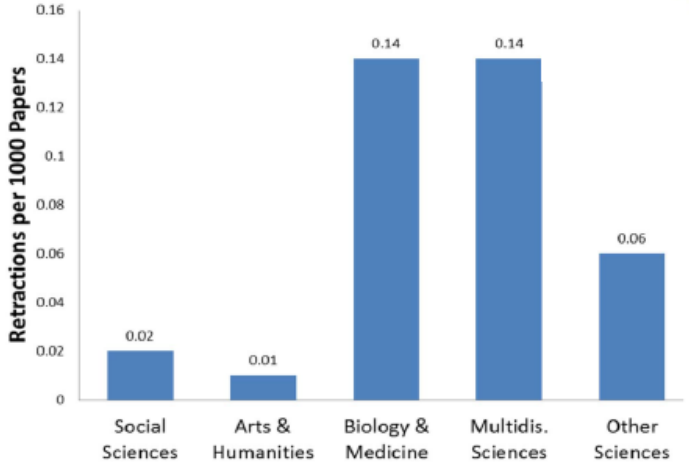
Pre-analytics and impact on science







Feng Lu et al. Sci Reports 2013

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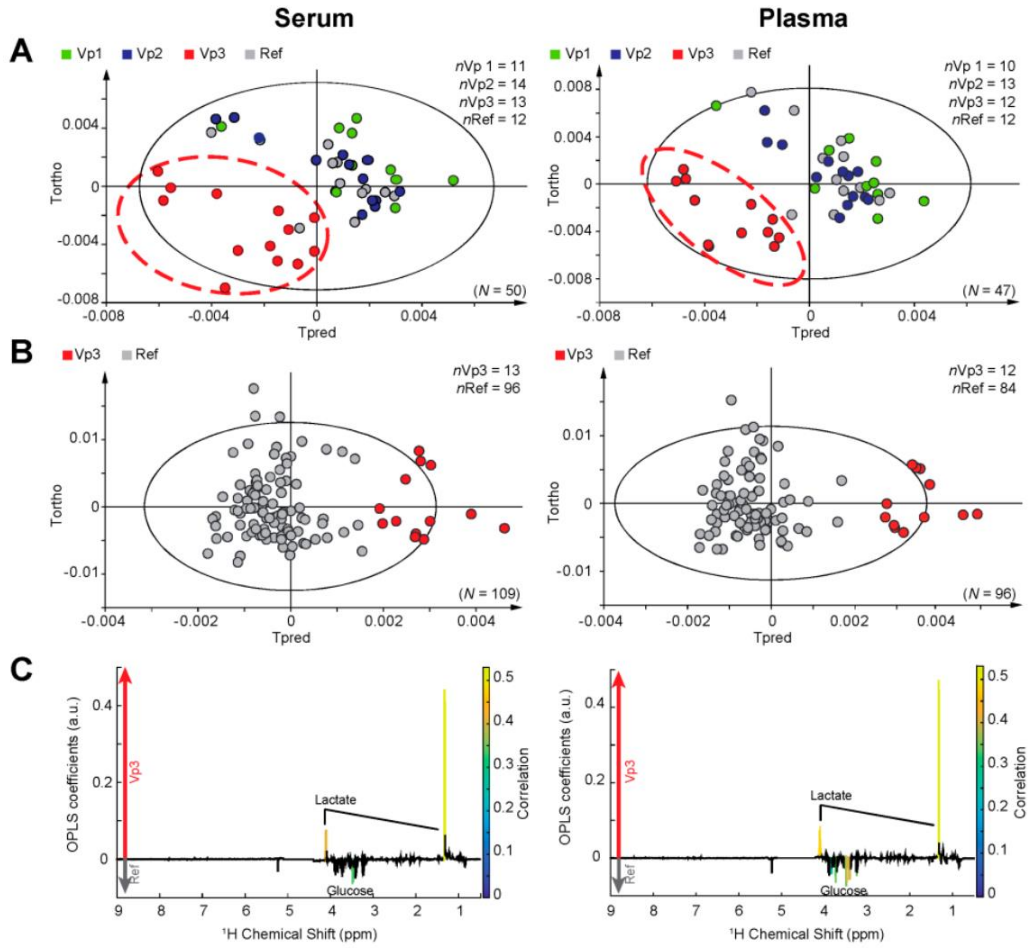
Pre-analytics and impact on science



Jobard E et al. A systematic evaluation of blood serum and plasma pre-analytics for metabolomics cohort studies. Int J Mol Sci 2016;17:2035.

- You may miss the effect you are looking for
- Even worse, you may missinterpret pre-analytic artifacts as biomarkers!

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Pre-analytics and impact on science

Table 1. Overview of the study protocol. Fasting blood samples are obtained and handled according to the reference protocol or one of eight variant protocols.

		Processing				Freezing & Storage	
Protocol	Delay of Incubation	Temperature of Incubation	Centrifugation Parameters			Delay between Sample Preparation & Freezing at −80 °C	Time at −80 °C
			Speed	Temperature	Time		
Reference (Ref)	**1 h**	**22 °C**	**2000 g**	**20 °C**	**10′**	**15′**	**3 months**
Variant 1 (Vp1)	1 h	**4 °C**	2000 g	20 °C	10′	15′	3 months
Variant 2 (Vp2)	**6 h**	**4 °C**	2000 g	20 °C	10′	15′	3 months
→ **Variant 3 (Vp3)**	**6 h**	22 °C	2000 g	20 °C	10′	15′	3 months
Variant 4 (Vp4)	1 h	22 °C	2000 g	20 °C	**20′**	15′	3 months
Variant 5 (Vp5)	1 h	22 °C	2000 g	**4 °C**	10′	15′	3 months
Variant 6 (Vp6)	1 h	22 °C	**3000 g**	20 °C	10′	15′	3 months
→ **Variant 7 (Vp7)**	1 h	22 °C	2000 g	20 °C	10′	**1 h**	3 months
Variant 8 (Vp8)	1 h	22 °C	2000 g	20 °C	10′	15′	**48 h**

Jobard E et al. A systematic evaluation of blood serum and plasma pre-analytics for metabolomics cohort studies. Int J Mol Sci 2016;17:2035.

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Ethics and Economy of pre-analytics

Preanalytical Quality Improvement: In Quality We Trust

Giuseppe Lippi [1], Kathleen Becan-McBride, Darina Behúlová, Raffick A Bowen, Stephen Church, Joris Delanghe, Kjell Grankvist, Steve Kitchen, Mads Nybo, Matthias Nauck, Nora Nikolac, Vladimir Palicka, Mario Plebani, Sverre Sandberg, Ana-Maria Simundic

The Cost of Poor Blood Specimen Quality and Errors in Preanalytical Processes

Sol F Green [1]

The Economics of Reproducibility in Preclinical Research

Leonard P. Freedman, Iain M. Cockburn, Timothy S. Simcoe

There is growing evidence that the pre-analytical phase of liquid samples for biomedical research as well as patient care accounts for up to 75% of errors.

Insufficient description accounts for about one-third of the 28.2 billion US dollars spent annually in the US on research resulting in irreproducible research data.

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Sample Management Plan

Before you start a research project involving the collection and handling of biological material, address all critical steps in the whole sample life cycle

Sample Management Plan Template (USZ)

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HRO Lunch Session - Part II

Sample management and biobanking

Sabine Bavamian, PhD

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Swiss Biobanking Platform
HRO Lunch

Sabine Bavamian, PhD
Chief Scientific Officer

04.12.2024

QUALITY | VISIBILITY | SUSTAINABILITY | INTEROPERABILITY | EDUCATION

Vision and Mission

SBP is the research infrastructure of national importance supporting both human and non-human biobanking activities

An independent association funded by the Swiss National Science Foundation (SNSF)

Swiss National Science Foundation

GENERAL ASSEMBLY

ORDINARY MEMBERS

UNIVERSITY HOSPITALS

GOVERNING BOARD

ORDINARY MEMBERS + EXPERT MEMBERS

CHUV HUG Insel USB USZ

UNIVERSITY HOSPITALS

- Liquid
- Tissue
- Veterinary
- Microbiology
- Natural history museum

- Position CH at the cutting edge of research by facilitating access to high-quality samples and their optimal usage
- Improve the quality, visibility, accessibility and interoperability of biobanks

BBMRI national node

Positioning

SBP is the reference research infrastructure in supporting and counselling on high quality biobanking

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

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SBP STAKEHOLDERS

Institutions hosting biobanks
Unimedsuisse
Swiss Universities
Cantonal Hospitals
Research institutes

Research funding organizations
SNSF
SERI

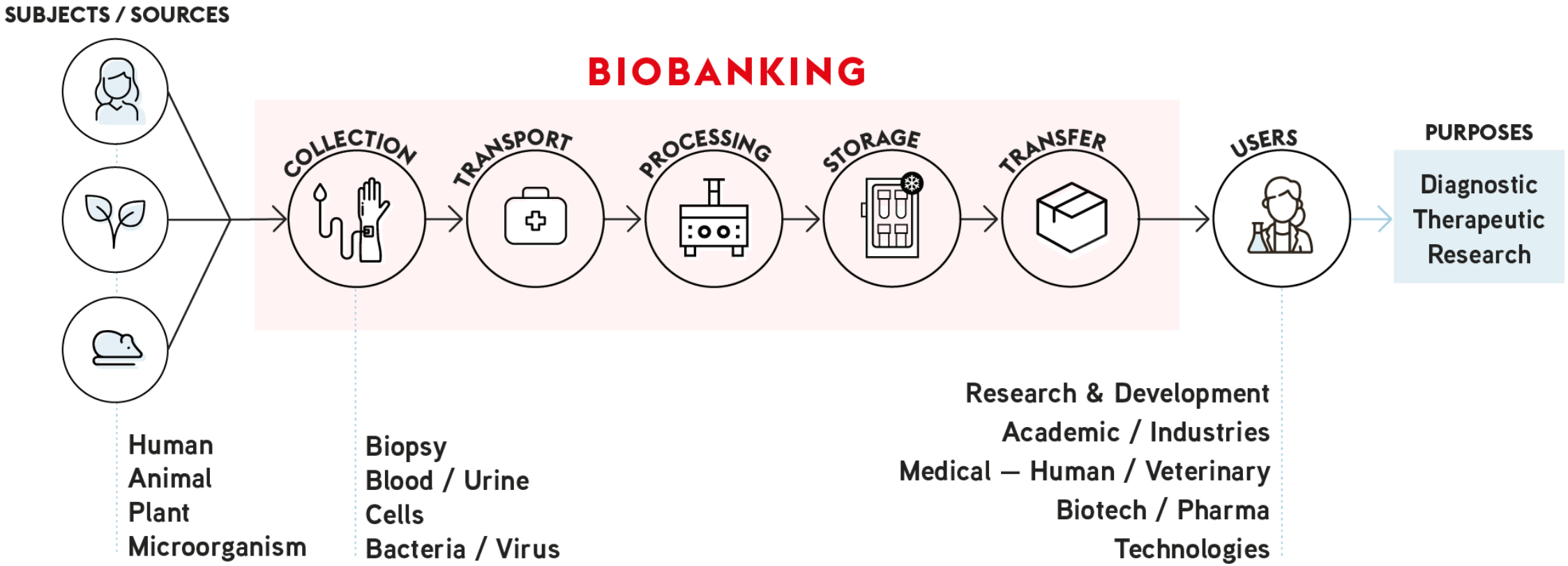
Regulators and policy makers
Swissethics
FOPH

Other national research infrastructures
SAMS
SCTO
SAKK
SPHN

European Infrastructures and networks
BBMRI-ERIC
ESBB

Biobanks and “biobanking”

Misconception
A biobank is just a sample in a freezer



Strategy

How SBP supports researchers and biobanks

➡ **A combined approach with innovative tools and services based on 5 pillars and their related tools and services**

1 Documentation

SOPs, datasets, Quality Manual, Biobank Regulation, etc.

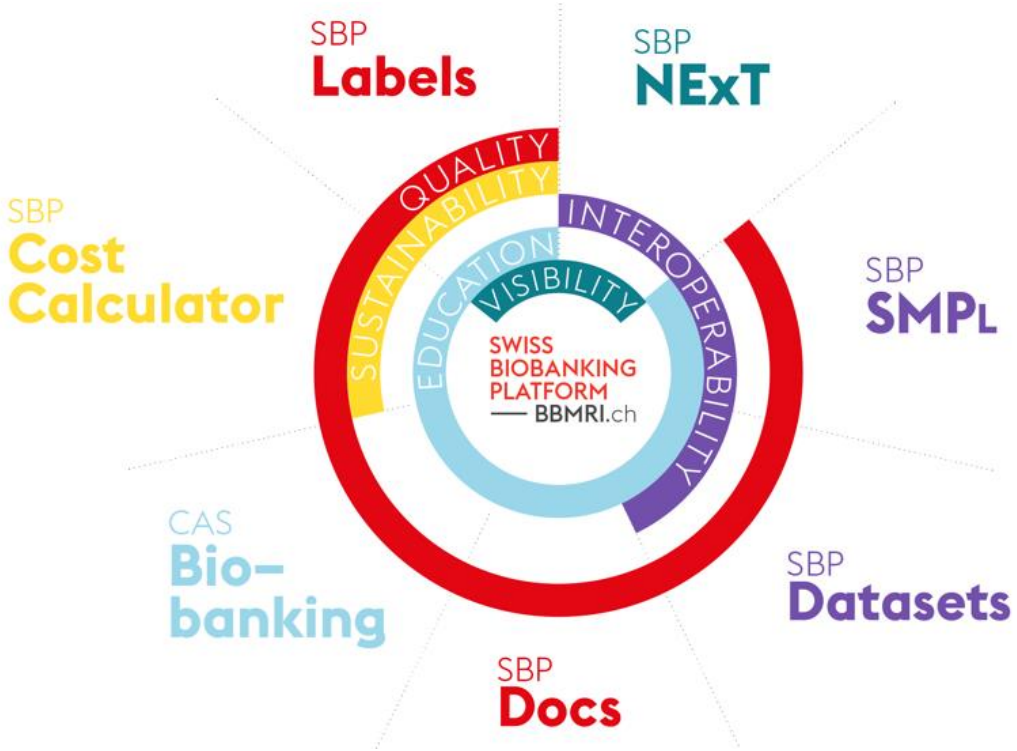
2 Innovative tools

Easy-to-use and ergonomic tools

SBP SQAN SBP SMPL SBP NExT

3 SBP services

Professional support in Governance, Quality, Visibility and Interoperability



SBP Labels

- A **preparation to the ISO 20387** on biobanking
- Aligned with **BBMRI Quality programme (Q-label)**
- A **resource to increase biobank's education** on governance and quality issues
- An **innovative way to harmonize biobanks' practices**
- **3 Labels** to feature your conformity with SBP minimal requirements

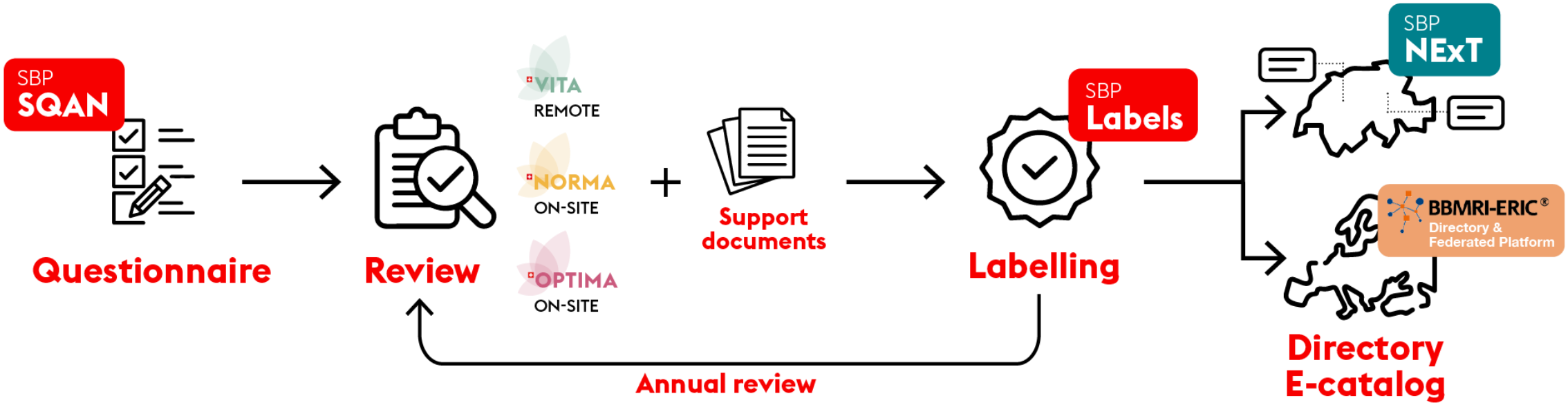
1.
Compliance with legal and ethical standards

2.
Standardization of the biobanking processes
From consent presentation to sample shipment, incl. personnel and equipment management

3.
Implementation of quality assurance measures of the overall biobanking system

A stepwise compliance review

To evaluate and monitor your biobank's processes

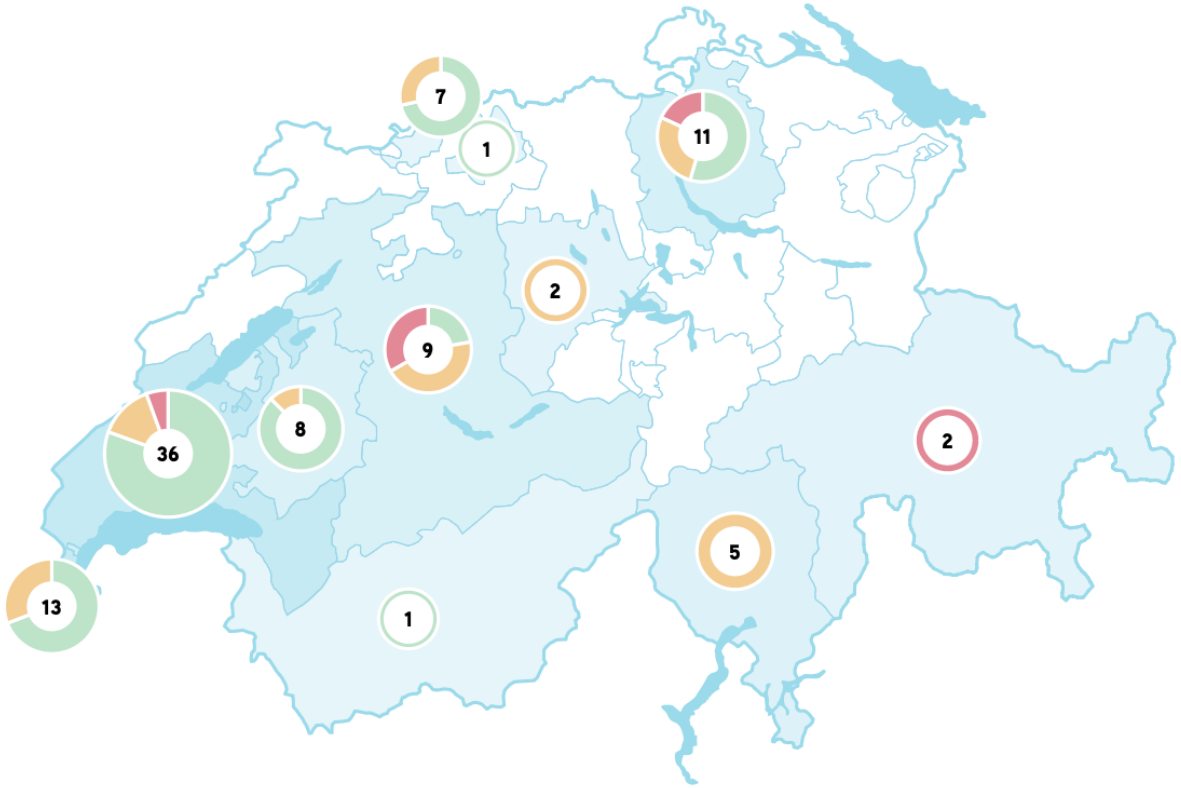


To help biobanks reach the minimal level of requirements (Governance and Quality)

VISIBILITY

Network

Biobanks willing to improve their quality and to share samples with the research community



95 VITA

35 NORMA

9 OPTIMA

55 BBMRI-ERIC Directory

SBP Biobank Information Management System (BIMS)

A new concept

Common basis for biobank harmonization, sample documentation and information sharing across Switzerland… but not only

SBP BIMS AIMS TO BE:

- **Affordable** – Cost & operations
- **Adaptive** – Wide variety of biobanking use-cases
- **Interoperable** – SBP Datasets integration
- **Interconnectable** – SBP sample e-catalogue (NExT) & other
- **Secured** – Relying on state-of-the art tool

SBP BIMS — SBP Datasets

The minimal data the biobank should document to ensure sample quality

Developed with SBP Working Groups and still evolving

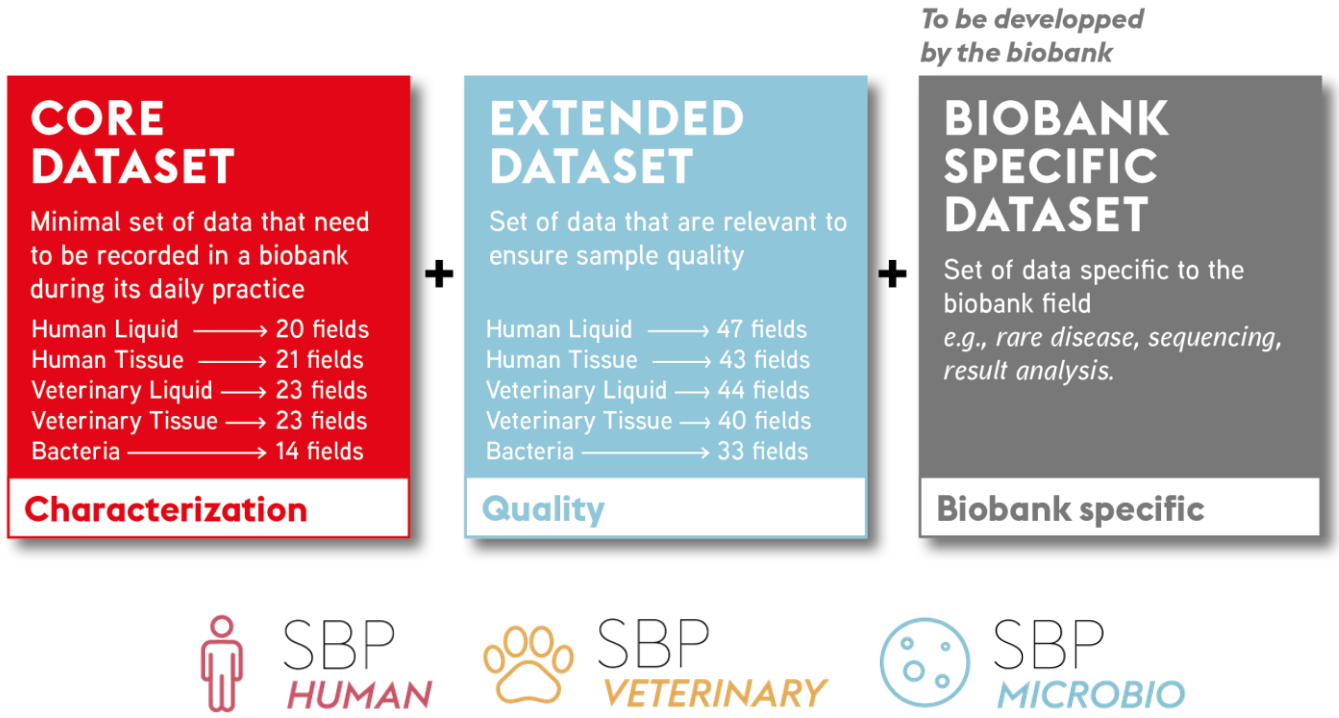
References

- CEN/ISO specifications
- SPREC 3.0 (ISBER)
- Aligned with MIABIS 3.0 (BBMRI)

Ontologies

- ICD-10, ICD-O3, SNOMED CT

The Core Datasets evaluation is integrated in SBP VITA Label.



EASY-GCS - Biobanking module www.easy-gcs.ch

swiss clinical trial organisation

STUDY	Basic	Concept	Development	Set-Up	Conduct	Completion
Protocol						
Management						
Ethics and Laws						
Documents						
Safety						
Data Management						
Statistic Methodology						
Quality and Risk						
Monitoring						
Drug or Device						
Biobanking	Definition Donor The Swiss Law Ethics Principles Biobanking Standards Swiss Biobanking Platform	Biobanking in Studies Management of a Biobank	Biobank Set-Up Donor Consent Handling of Biological Material Documentation Safety Quality Control	Regulatory Affairs Staff Management Sample Management Biobanking in Studies Data Integrity	Biobanking Operation	Leftover Biological Material Publication

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CAS in Biobanking

SBP has develop a new service to help creating bridges between Swiss biobanks, researchers, other national research infrastructures, ethics committees and society.

Launch January 2025

MODULE 1
2 ECTS

The Basics of Biobanking

Definitions, importance, basic concepts of their operation

Actors or institutions having interest in biobanking
(e.g., PhDs, physicians, clinical investigators, ethics committees, patient organizations)

M1: CHF 1'000.-

MODULE 2
5 ECTS

Implementation of biobanking processes

Professionals having a role in sample management
(e.g., biobank staff, laboratory managers)

M2: CHF 2'000.-

MODULE 3
5 ECTS

Professional management of a biobank

Biobank managers, quality control officers, unit managers clinical/ research

M3: CHF 3'000.-

Acquisition of fundamental knowledge → **Development of practical skills for professionalization**

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EDUCATION

The crucial role of professional biobanks in advancing scientific research

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Thank you!

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Flavien Delhaes
Biobank Officer


Valeria Di Cola
Education Officer


Lou Ferraton
Quality and Sustainability Officer


Claudia Lagier
Marketing Officer


Khalil Roy
Innovation Officer


Louise Roy
Designer


Joséphine Uldry
Quality Officer

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End of session

Thank you for participating!

Information on **HRO lunch series 3** will follow next year – looking forward to seeing you again!

Further questions:

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Verena.Golz@usb.ch