SWISS
BIOBANKING
PLATFORM
BBMRI.ch

ANNUAL REPORT 2023

2023
A YEAR IN REVIEW

BBMRI

- Change of status from Observer to **Full member**
- SBP has been mandated to **evaluate BBMRI.at**
- Development of **a film on biobanking** with BBMRI.at and BBMRI.de in English.
- Active collaboration on development of the **cost calculator** template with BBMRI.de and BBMRI.be.
- **Quality manual** used as the **template for Europe** in collaboration with BBMRI.
- **Proficiency testing** for sample quality

New tool

Release of a Cost Calculator to help the biobank infrastructures determine the costs associated with the pre-analytical services they provide and invoice the interested party in a transparent and harmonized manner.

SBP SMPL (BIMS)

- Prototype development
- Presentation in Bern
- Selection of pilot biobanks
- Business Analysis and User Requirement Specification

Education

CAS in biobanking

- Expert recruitment
- Content development

Easy-GCS

Publication of the Easy-Guide for Clinical Studies

Social media

+293

Newsletter opening rate

42%

SBP Labels progression

74 (+13) VITA — 6 of which are the new VITA^{IT} label

33 (+6) NORMA

9 OPTIMA

Annual review KPIs

For how many research projects have your samples been used	How many samples have been used	Have you been contacted by researchers through SBP or BBMRI directory?
66	24'321	Yes : 33%

New support document

Data Quality SOP

Datasets

CORE Datasets — *published*

Veterinary Liquid
Veterinary Tissue

Extended Datasets — *ongoing*

Human Liquid
Veterinary Liquid
Vererinary Tissue

Genome of Switzerland

The Genome of Switzerland project has been developed to create a national reference dataset for genomic medicine and research. SBP is soliciting the biobanks from its network to collaborate in order to gather a first set of samples of 1'000-2'000 individuals.

Introduction

Swiss Biobanking Platform (SBP) is the national coordination platform for biobanks from the human and non-human biobanking fields.

It is an initiative of the Swiss National Science Foundation (SNSF), which responds to the increasing needs of researchers in biomedical and biological sciences in terms of quality, access, transparency, and interconnectedness of biobanks for research purposes. SBP's vision is to foster research by facilitating access and optimal usage to high-quality samples and data while our mission is to create a network of biobanks promoting FAIR (findable, accessible, interoperable, and reusable) samples. This report covers the activity period 2023 as delineated in the agreement 2021-2024 between the SNSF and SBP with the following goals to reach:

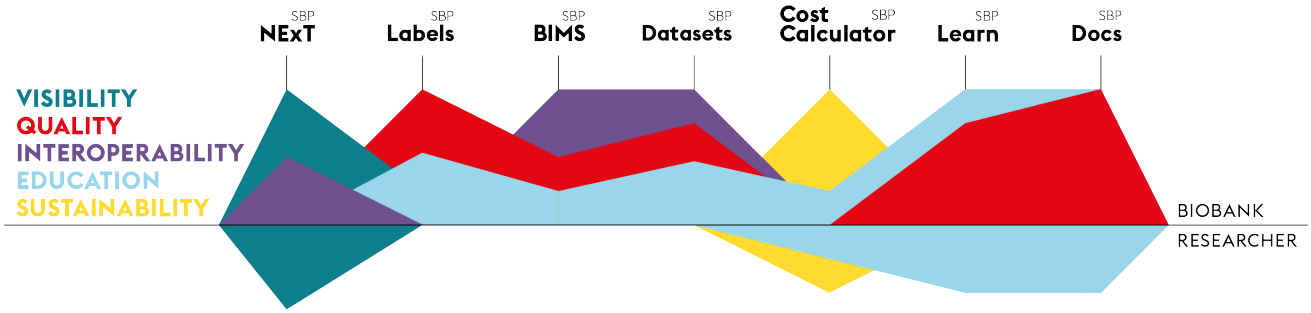
1. SBP promotes a quality strategy for biobanks.
2. SBP develops guidelines and IT advice to facilitate access to biobanking samples.
3. SBP drives the quality management of biobanking activities.
4. SBP consolidates the collaboration with the European networks of biobanks.
5. SBP provides a concept for its sustainable funding.

A budget of 4 Mio for four years has been allocated to achieve these objectives. SBP aims at consolidating its position providing additional tools and services to fulfill the needs of its biobanking community and to raise more awareness of the researchers. Its position has also been reinforced in the non-human biobanking community with new members in its governance.

In 2023, SBP major achievements were focused on:

- the development of a biobank information management system,
- the integration of the microbiology and natural history museum in its governance,
- the development of tools and services within the two new pillars "education", and "sustainability".
- an external evaluation of SBP by two independent groups of stakeholders.

Swiss Biobanking Platform offers specialized services and tools to support a growing network of biobanks and researchers, while also expanding its strategy to include education and sustainability.



SBP Governance

SBP enlarges its governing board to support new research fields.

Swiss Biobanking Platform (SBP) is an independent association initiated by Swiss National Science Foundation (SNSF) in 2016 as defined in its bylaws. https://swissbiobanking.ch/about-us/

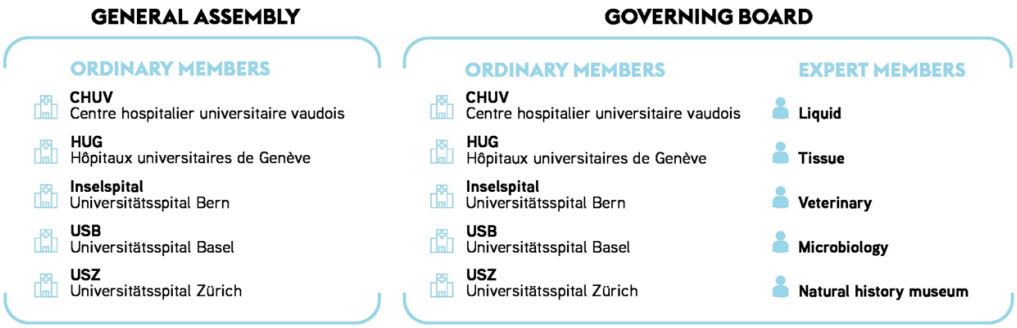


Figure 1: SBP governance according to statues

On 17th November 2022, SBP governance has been enlarged with two new expert members, representing the microbiology and the natural history museum fields to reinforce its position in the non-human biobanking environment.

For the next three-year period (November 2022 to October 2025), SBP president, Pr Antoine Geissbühler, as the representative from Geneva University Hospital, has been reelected unanimously for a second and last mandate. Pr Carlo Largiadèr succeeds Pr Aurel Perren as vice-president, who finished the second mandate. Pr Largiadèr brings expertise in the liquid biobanking domain.

ORDINARY MEMBERS

Basel
Prof. Christian Müller
Head of Clinical Research and Stationary Cardiology, USB

Bern
Prof. Thomas Geiser
Director of Education and Research, Insel Group Bern

Geneva
Prof. Antoine Geissbühler
SBP President
Vice-rector, UNIGE
Director of eHealth and telemedicine, HUG

Lausanne
Prof. Mauro Oddo
Vice-medical Director of Research, Education and Innovation, CHUV/UNIL

Zürich
Prof. Gabriela Senti
Director of Research and Education, USZ

EXPERT MEMBERS

Liquid
Prof. Carlo Largiadèr
SBP Vice-President
Head of Liquid Biobank Bern, Inselspital, Bern University Hospital

Tissue
Prof. Aurel Perren
Director of the Institute of Pathology, University Hospital Bern

Non-human – Veterinary
Prof. Tosso Leeb
Director of the Institute of Genetics
Vetsuisse Faculty, University of Bern

Microbiology
Prof. Adrian Egli
Director of the Institute of Medical Microbiology, University of Zurich

Natural history museum
Prof. Nadir Alvarez
Head of Natural Sciences Museum of Lausanne

Figure 2: SBP ordinary and expert members elected 17th November 2022

The creation of a strategic advisory board has been postponed to 2024, and, in the meantime, a user-oriented board has been put in place with the task to evaluate SBP tools, services and communication, as described in the chapter below. The user board evaluation will serve as a guide across this report to show the future strategic developments that could be useful to the research community.

Executive Office

SBP Executive Office is responsible for implementing the objectives agreed in the Service Level Agreement (SLA) as well as those agreed by the Governing Board. The SBP Executive Office has a broad expertise in various domains of biobanking enabling to advise biobanks in the SBP network, to manage different projects, and to be aligned with other research infrastructures nationally and at the European level. This strategy and composition of the team is planned to be continued in 2024 and the following years in order to respond to the growing interest of the network.

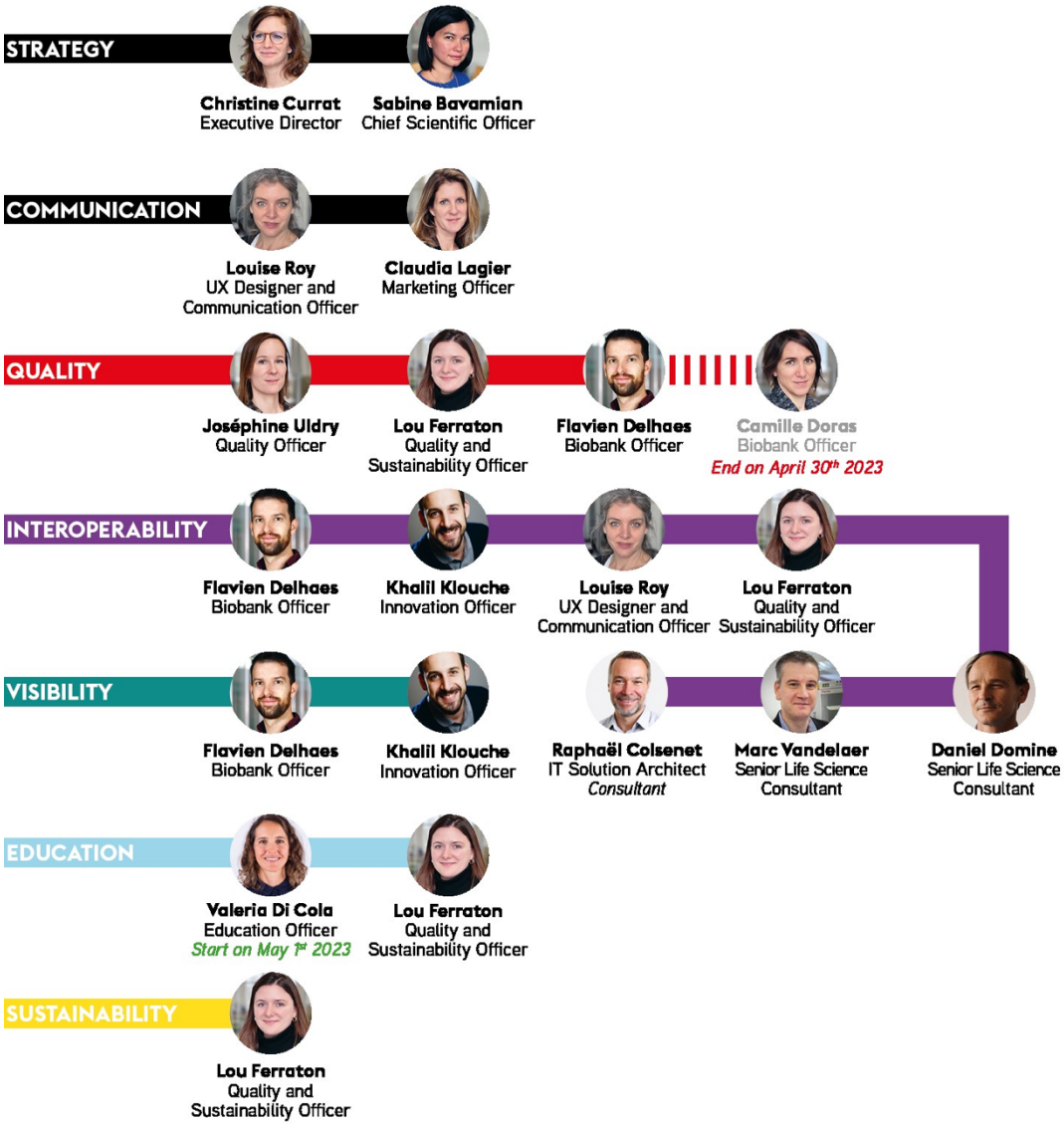


Figure 3: SBP Executive Office team

Swiss node in the BBMRI organization

SBP gains in visibility and influence at the EU level by becoming an ordinary member of the European network BBMRI-ERIC (measure 3.2 and 4.1)

Since December 2015, Switzerland had been an observer country in the Biobanking and BioMolecular Resources Infrastructure (BBMRI-ERIC). On June 6, 2023, the BBMRI-ERIC General Assembly of Members approved Switzerland as a full member following the membership request of Switzerland.

The process of Switzerland becoming a member of BBMRI-ERIC

On 13 April 2022, the Federal Council submitted to Parliament a Dispatch on Switzerland joining six international research infrastructure networks with the ERIC legal form and on amending the Federal Act on the Promotion of Research and Innovation (RIPA) to do so. The Parliament adopted the dispatch in December 2022. The Federal Council is thus enabled to apply to the 6 ERICs, for which Swiss participation was deemed to be important in the 2019 Roadmap process: BBMRI, CESSDA, DARIAH, ECRIN, EPOS and ICOS. This will allow the scientific communities involved to actively contribute to and benefit from the ERIC research infrastructures over the long term. By joining these ERICs, Switzerland (represented by SERI) will also be able to promote its interests given the right to vote as part of the governance of ERICs.

Switzerland is represented in the BBMRI-ERIC Assembly of Members (AoM) by the State Secretariat for Education, Research and Innovation (SERI), a representation formerly assumed by Swiss National Science Foundation. Dr. Christine Currat, the Executive Director of the Swiss Biobanking Platform (SBP), represents Switzerland as the National Node Coordinator within the BBMRI-ERIC Management Committee (MC).

Full membership enables the Swiss Node to reinforce Switzerland's position and SBP's position in the biobanking field. It also provides Swiss researchers with access to a large variety of samples and facilitate their integration in European projects. In 2023, SBP focused its work on building direct interaction or specific projects with other nodes:

- Regular meetings and alignment of strategies with the German Biobank Node, BBMRI.de
- After SBP evaluation of Charité Biobank in Berlin, SBP has been mandated to evaluate the Austrian node, BBMRI.at; this role allows SBP to have an in-depth vision of other nodes governance and organisations, and to find, together, strategies to overcome some issues and challenges.
- Development of a film on biobanking with BBMRI.at and BBMRI.de
- Active collaboration on the sustainability pillar and the development of the cost calculator template with BBMRI.de and BBMRI.be.
- Quality manual used as the template for Europe in collaboration with BBMRI.

In parallel, BBMRI-ERIC initiated strategic meetings with a first workshop on April 25th in Brussells, Belgium to agree on 10-year vision together with the AoM and MC representatives; the second workshop is planned October 24th and the last in January 2024.

Coordination Platform Clinical Research (CPCR)

SBP plays an active role in the building of the future of clinical research in Switzerland (measure 5.1 and 5.2)

Upon recommendation of the White Paper on Clinical Research and publication in 2021, SERI has setup the Coordination Platform for Clinical Research (CPCR) under the SAMS lead to strengthen the institutional dialogue and coordination between the key public stakeholders of clinical and health research.

SBP is one of the stakeholders and participated in the three 2023 CPCR meetings.

Working group "Map of services"

More specifically, SBP is contributing to one of the CPCR working groups called «map of services» aligned on the White Paper goal 1, measure a1 «reduction of redundancies through a clear distribution of tasks and responsibilities». This working group (WG) consists of the managing directors of the SAKK, SBP, SCTO and SPHN-DCC, accompanied by the CPCR officer. Since each organization uses its own vocabulary to describe its activities and services, the WG throve to understand the nature of the services offered, and to agree on categories and labels that encompasses all four organizations' services and all types of services considered. The aim was to offer researchers a map of services that is understandable with sufficient granularity to differentiate the services.

The CPCR decided to first map the services related to the handling of data and samples offered by national stakeholders (and their local branches) and focused on the services SAKK, SBP, SCTO and SPHN-DCC. The map, to be published on the websites of all involved organizations, should increase transparency, and make the distribution of tasks between organizations more comprehensible – both for the research community and for the organizations themselves. Besides bringing its own contribution to the discussion, SBP co-lead the WG and the interactions with SAKK, SCTO and SPHN - DCC. SBP also provided expertise in data visualization to transform the list of services into an interactive map.

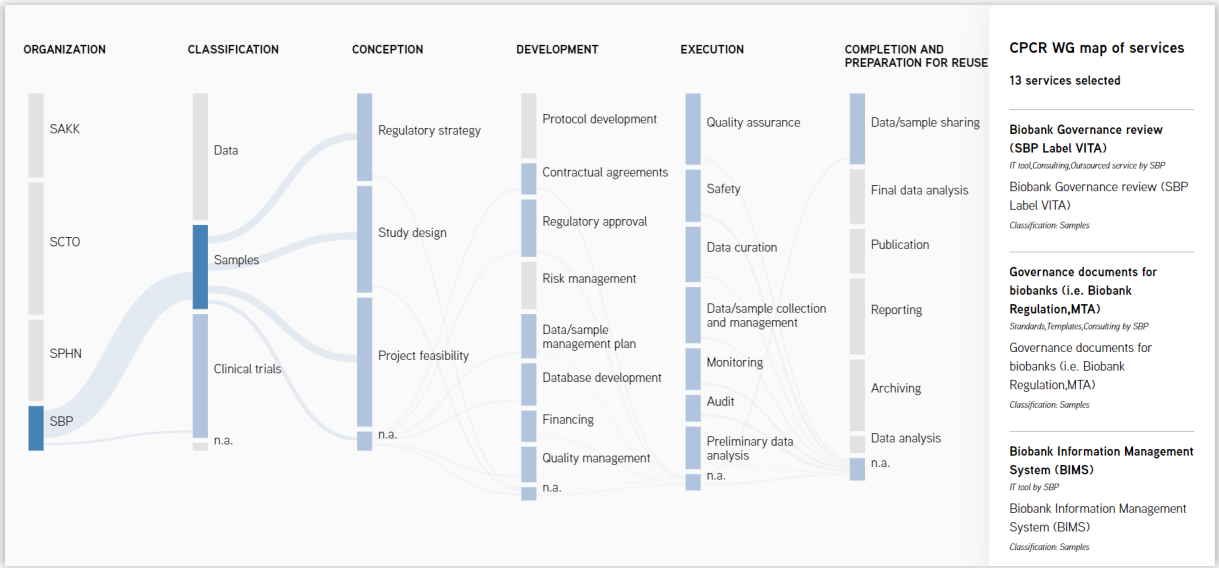


Figure 4: Prototype of the interactive map designed by SBP for the CPCR WG "map of services"

SBP external evaluation

SBP integrates the outputs of its users to shape, with its governing board, the future of SBP.

Besides SBP's annual evaluation by the SNSF, SBP was very interested to collect feedback and vision from SBP network and other key stakeholders through an external evaluation. The feedback will provide to the governing board valuable insights to tailor the roadmap for the next funding period, guiding strategic decisions and investments. By aligning SBP's efforts with the identified strengths and opportunities, SBP will maximize its impact and contributions to the biobanking and scientific community.

To evaluate Swiss Biobanking Platform (SBP) structure, SBP has mandated two groups to conduct a comprehensive assessment of SBP's performance and impact, focusing on different aspects of its organization including its tools and services, communication strategy and added value.

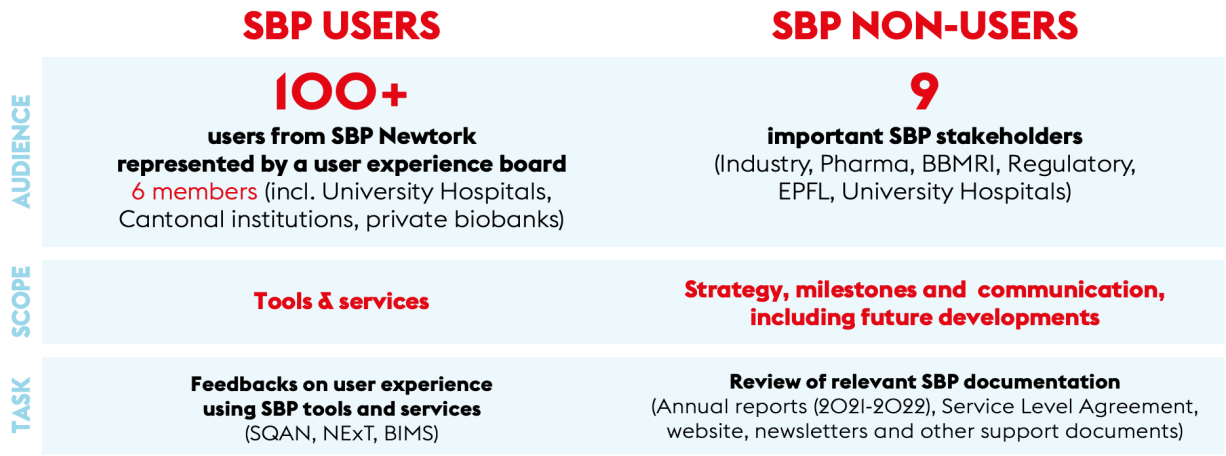


Figure 5: Evaluation process, scope and audience

The first group involved active users of the SBP network who were familiar with its tools and services. Their primary focus was to evaluate the efficiency and overall support provided by SBP by answering a tailored questionnaire, concentrating on user satisfaction, resource, and the impact of SBP's services to support them in the management of their daily operational biobanking activities.

The second group, referred to as the Non-User Board, was composed of eight stakeholders with a strong interest in the biobanking domain and with a multidisciplinary expertise in biobanking, research, regulatory compliance, and industry. They received a questionnaire based on the understanding of SBP important documents, such as annual reports, the Service Level Agreement between SBP and the Swiss National Science Foundation (SNSF), SBP Newsletters, and the SBP website. Their primary objective was to evaluate the broader impact of SBP on a national level based on these documents and to conduct a comprehensive assessment of SBP's achievements, effectiveness, and alignment with strategic goals during the previous and current funding period.

USER BOARD
LEAD: Alexander Leichtle

Alexander Leichtle — Bern University Hospital, Inselspital, Bern
Stephen Leib — University of Bern
Elodie Ristorcelli — CHUV, Lausanne
Jean Paul Rivals — CHUV DO, Lausanne
Tatiana Terrot — Ente Ospedaliero Cantonale, Ticino
Maurizia Bissig — Fondazione Epatocentro Ticino

Figure 6: List of members in the user and non-user boards

NON-USERS BOARD
Stakeholders' applicants

Franziska Bosshard — Swiss Federal Office for the Environment, Bern
Fabienne Maurer — CHUV, Lausanne
Annarita Nicoletto — EPFL, Blue Brain project, Lausanne
Angelina Rau — VISCHER AG, Zurich
Steffen Zeisberger — University of Zurich and ETH of Zurich
Paul Schroeder — Novartis Pharma AG, NIBR, Basel
Patrick Segu — BrainGenetics, Lausanne

BBMRI and European partners

Annelies Debucquoy — BBMRI, Belgium
Cornelia Specht — BBMRI, Germany

The feedback was collected by SBP then reviewed and discussed within a subgroup of users known as the User Board which reported to SBP and discussed the needs and possible solutions from a user perspective. SBP received 38 answers out of the more than hundred questionnaires that were sent out.

In general, the users are satisfied to very satisfied of the support they received and provided very positive feedback. 95% of the users appreciated the easy contact with the SBP team. Overall, the view of the non-user group aligns with the positive evaluations given by SBP users (see boxes).

The findings and actions agreed by the Evaluation boards are highlighted in this report for each pillar and distributed in each corresponding chapter in the document.

As a summary, the survey highlighted the strengths and weaknesses of SBP presented below.

Survey feedbacks

Description of the observations.

Action plan

☑ Point already implemented
☐ Point to be discussed

STRENGTHS

+ **Centralized Organizational Structure**
National-wide and centralized operating (financially and legitimately) organizational structure for the overall promotion of biobank activities, ensuring coordinated efforts across the Swiss landscape.
+ **Collaborations with national research organizations** SBP has a strong network within Switzerland and benefit from the support of the most important research organizations.
+ **Comprehensive Capture of the national landscape**
SBP has a very comprehensive and structured capture of biobank features, understanding well their needs and tailoring its support accordingly.
+ **Strategic Tool Development**
SBP provides robust support through tool development for Quality and IT, supported by qualified staff with a strong expertise in diverse biobank domains.
+ **Harmonization of practice**
SBP supports a national effort of standardization activities, focusing on Quality, Visibility, and Interoperability.
+ **Effective Communication**
SBP's communication strategy is disseminated through clear and extensive outreach via various channels (e.g., newsletters, LinkedIn, website).

WEAKNESSES

– **SBP Sustainability**
Waste of both national funds and individual efforts if sustainability of SBP is not guaranteed.
– **Governance imbalance**
The imbalance in governance representation, particularly the underrepresentation of Zurich region in comparison to Bern region at the governance level needs to be re-evaluated.
– **Lack of collaboration with the private sector**
The link with the private sector needs to be encouraged and additional efforts have to be made to develop such collaborations and make bridge with the public sector.
– **Sustainability of biobanks**
There is a lack access to substantial funding for biobanks, which can hinder ambitious initiatives and increase the risk that research efforts may not be translated into tangible outcomes.
– **Patient and Public Communication**
The absence or insufficient planned communication directed towards patients and the general public could hinder public engagement and awareness.

Communication

SBP aims to better engage with the research community to promote its tools and services.

Newsletter and social media posts

Newsletters are sent once a month, in four languages, according to subscriber preference, with an opening rate of 42%, well above the industry average. These are relayed on LinkedIn and X (Twitter), which remain the main distribution channels for our various communications.

LINKEDIN
715 → 962
+35%

TWITTER
381 → 427
+12%

09.23 - 🧪 Get your first Swiss biobanking Cost Calculator!
08.23 - 📊 Here's how SBP is progressing
06.23 - 🎉 Switzerland becomes BBMRI-ERIC member country
05.23 - 📖 Education is the cornerstone of biobanking
04.23 - ❗ WORKSHOP 11.05: registration still possible!
03.23 - ✍️ Register for the WS: new BIMS product SBP SMPL
02.23 - 📈 Our 2022 performance and the importance of Labels
01.23 - 🎉 Here is our new brochure to start the year!
12.22 - 🎂 New MTA 3.0 document available
11.22 - ⏳ Sustainability: what we do to advance
10.22 - ❗ Our Annual Report is available!

Engagement with our various posts has helped SBP understand which topics and formats and reach researchers with tips and stories on biobanking: informative, entertaining "Did You Know?", educational (Q&A) and feedback with testimonials. From the simple question "How has SBP been helpful to you?" we created a new post concept (peer to peer communication), which is also aimed to engage researchers.

BBMRI-ERIC Task Force Outreach and Communications

The interaction with BBMRI-ERIC became more intensive especially since we became full members (BBMRI-ERIC press release, revised logo design). The sharing of information about the BBMRI-ERIC network and National Node communications has increased with our participation to its newly launched Communications and Outreach Task Force.

Survey feedbacks

In terms of communication, SBP should focus on collaborative efforts between biobanks and researchers by integrating and communicating specifically with researchers. Promoting the biobanking field with webinars or publications of best practices, know-how, efficient usage of samples could be a way to communication with the community. Collaborations with the industry should be envisioned to expand SBP Network, as well as communication with the patients and the public at large.

Action plan

- ☐ Create a website page within SBP website dedicated to researchers.
- ☐ Better integrate the research community into the SBP network by emphasizing two crucial aspects – improving communication strategies and providing educational resources for researchers.
- ☐ Communicate with patients and the public at large.
- ☐ Link with the industry sector by fostering collaborations with private biobanks.

Quality

In terms of quality, SBP is offering different services to help our expanding network of biobanks develop state-of-the-art practices.

Main achievements

- 33% of biobanks from SBP network have been contacted through SBP Directory to participate in research projects
- The VITA Label has been updated with data interoperability and data quality requirements.
- The SBP Quality manual serves as a reference document at the European level
- The SOP on data quality aligned with the FNS Data Management Plan is published
- SBP provides access to a first European pilot proficiency test developed by BBMRI.de to check sample quality stored in biobanks

SBP network (measure 1.2, 1.3 and 3.1)

The SBP network is currently composed of 86 entities, 74 Biobanks and 12 Infrastructures (+11%). The identification of Biobank Infrastructures is important at the Network level, as they should help Biobanks in the management of their daily routine activities and allow economies of scale, higher quality, centralized systems, and increased efficiency at operational level.

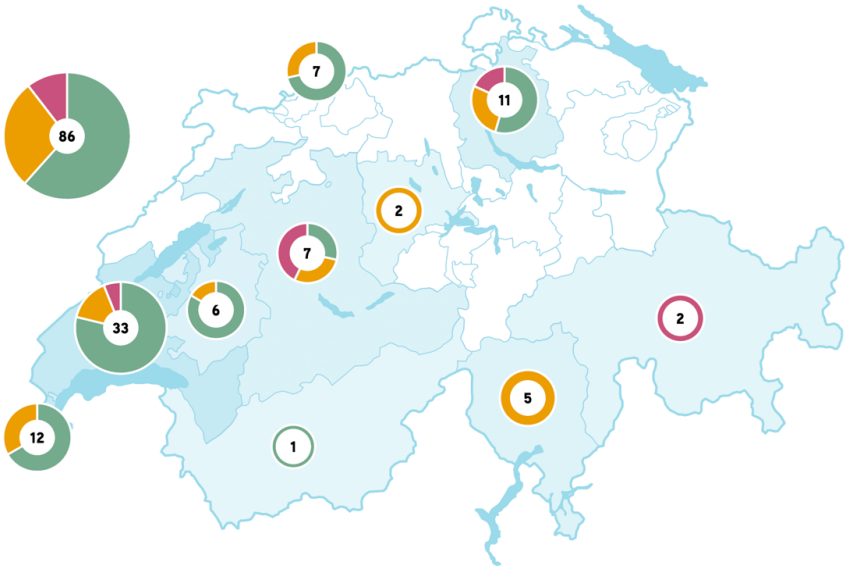


Figure 7: SBP network with the number of biobanks with the VITA, NORMA and OPTIMA labels

Once a biobank obtains the quality label and is part of SBP network, SBP organizes follow-up interviews with labelled biobanks on an annual basis. This so-called "annual review" helps SBP to measure biobank's accountability by collecting Key Performance Indicators (KPIs) on research activities as shown in figure 8.

In 2023, SBP organized 14 annual reviews and noticed that, among others, 33% of biobanks from SBP network have been contacted through the SBP and BBMRI Directories with the interest of developing research projects. Practically, 66 research projects have used samples from SBP network biobanks, with more than 24K samples shipped to researchers.

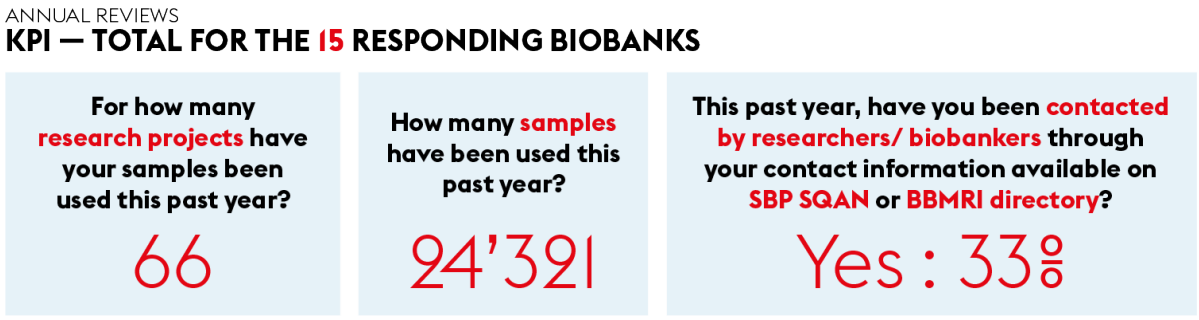


Figure 8: Key performance indicators of biobanks within SBP network

The picture below presents the support provided by SBP in 2023 to biobanks. Biobanks that are part of the SBP network are mainly within University hospitals but the number of biobanks hosted in other hospitals, universities and private institutions is increasing over time.

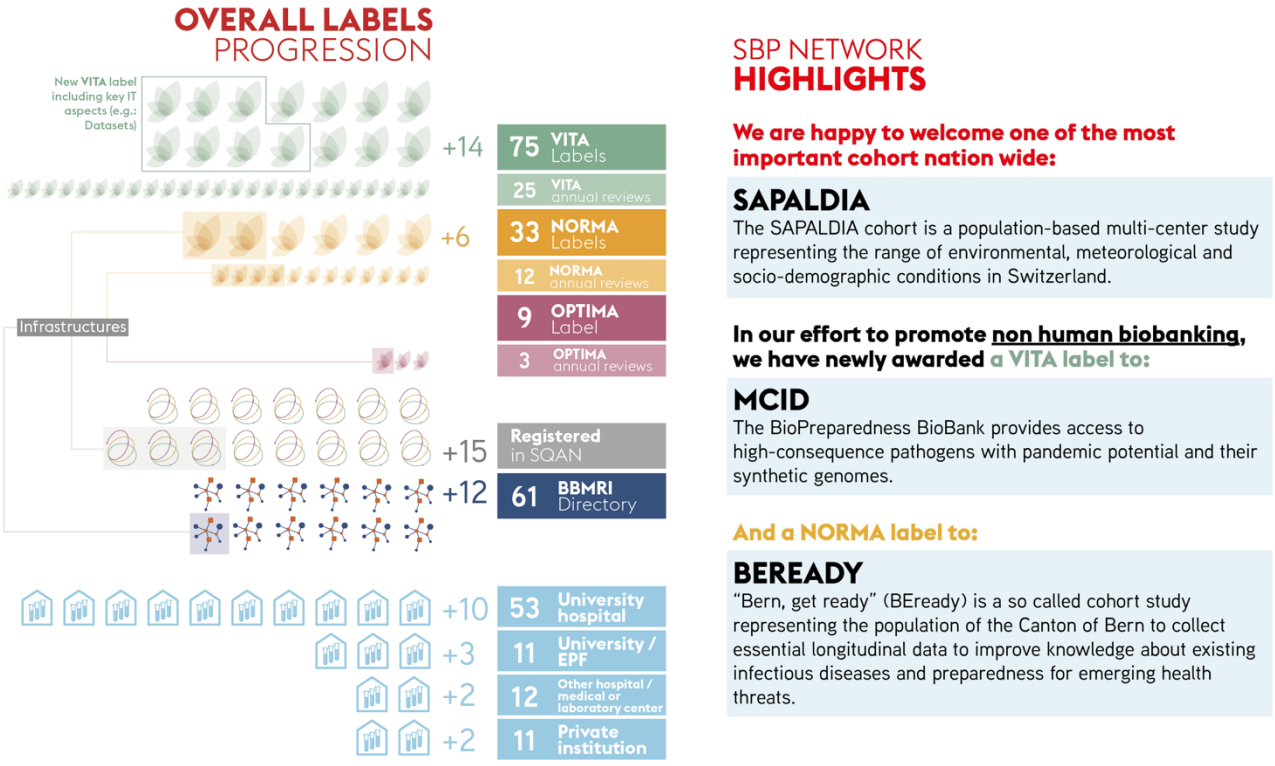


Figure 9: SBP quality support and activities in 2023

The VITA Label has been updated: the new VITA Label integrates new requirements on data quality and interoperability with a check on the implementation of the SBP core datasets in the biobanks daily practice. This is a step forward for those willing to share samples at national level ensuring that their samples are interoperable in terms of preanalytical data.

Quality documents (measure 1.1)

Data quality SOP
This SOP on "Data Quality" provides guidance to guarantee sample data quality, integrity, protection, and security. Before its final release in March 2023, the SOP has been reviewed by IT experts identified by the SBP Governing Board members and validated by the latter. The proposed measures are fully aligned with the SNSF strategy and its requirements for researchers to develop a Data Management Plan (DMP). They are also integrated into the revision of the SBP VITA Label aimed at supporting biobanks and researchers.

Development of a Registry Regulation template
Swiss Clinical Trial Organization (SCTO) launched a working group to develop a medical registry regulation template. SBP actively takes part in this initiative, together with representatives from CHUV, HUG, H+, SBP, SCTO platforms from Basel, Zürich, and St-Gallen, SAKK, SPHN and Unimedsuisse. Based on the biobank regulation template developed by SBP and endorsed by Swissethics, this new document will include the joint recommendations issued by Unimedsuisse, FMH, H+ and SAMS. The final Registry Regulation template will be published in Q1 2024 on the Swissethics website.

Development of an overarching Quality Manual (QM) in collaboration with other BBMRI National Nodes
SBP has published in 2022 a first Quality Manual template as a reference deliverable guiding the biobank in the development of their quality strategy. The template is easily adaptable to the different biobank practices to set up and document their quality management system (QMS) as a requirement of the ISO 20387 on Biobanking and the SBP OPTIMA Label.

At this stage, BBMRI-ERIC is willing to harmonize the existing documents with a European overarching quality manual. using the SBP template as the European reference model. The project planning is ongoing, and the writing phase to come up with this common and harmonized development will start Q1 2024.

Strategy to biobanks towards the ISO 20387 accreditation (measure 1.4, 1.5 and 3.3)
Biobank accreditation is strongly encouraged to increase the visibility of a biobank and to harmonize practices at national and international level. SBP already provides a step towards the ISO 20387 with the SBP OPTIMA Label which paves the way for getting accredited or helps biobanks getting awareness on the essential quality requirements to reach. In 2023, SBP integrated two additional biobanking norms to support biobanks in these specific topics for animal (ISO 20388) and bacteria (ISO 24088).

As accreditation can only be delivered by the Swiss Accreditation Service (SAS) in Switzerland but has not yet integrated the ISO 20387 in its portfolio, SBP is in close contact with the SAS to see how an active collaboration could be envisioned to serve biobanks' interests. Being part of the Belgium node Advisory Board, SBP works closely with the BBMRI National Nodes to align the SBP accreditation strategy with the European developments around the ISO 20387 accreditation.

Proficiency testing for sample quality
A good quality management system does not completely ensure the quality at the sample level to ensure reproducibility of research results. This could be done through a so-called proficiency testing as Germany has organized by a dedicated and specialized laboratory where samples can be shipped following a harmonized procedure and analyzed in batches.

Being part of BBMRI, SBP had the opportunity to participate in a pilot proficiency test for liquid biobanking launched by the German Biobank Node and led together with the Belgian and Polish Nodes of BBMRI. This pilot will allow to check sample quality of the biobanks through the evaluation of their biobanking processes having an impact on the sample quality. SBP has invited liquid biobanks from its network to take part to the pilot phase and the five who accepted are: CK-Care Biobank, Davos Biosciences AG, Davos, Laboratoire Préanalytique, CHUV Lausanne, Liquid Biobank Bern (LBB), Inselspital Bern, Biothèque SML, HUG Geneva, and SwiSCI biobank, Swiss Paraplegic Research, Notwill.

Survey feedbacks

The survey highlights that SBP has gained a clear recognition for providing quality support through its Labels, comprehensive documentation, and expertise in the field. Interest to obtain additional support for the ISO 20387 accreditation has been expressed together with the development of a quality strategy at the sample level (e.g., quality controls (QCs), preanalytics), the support to implement a Quality Management System (QMS) and the practice harmonization.

Action plan

- ☑ Encourage biobanks willing to get the accreditation (ISO 20387) to reach the SBP OPTMIA requirements.
- ☐ Develop a preanalytical sample quality strategy to ensure sample fitness for purpose (proficiency testing in collaboration with BBMRI.de).
- ☐ Develop and implement a peer review by quality experts from different institutions.
- ☐ Organize on-site presentations, workshops, or webinars around different topics.
- ☐ Develop a network of ELSI partners instead to answer the diversity of questions around the topic.

Interoperability

SBP promotes implementation of Datasets into existing or the future SBP ready-to-use Biobank Information Management System.

Main achievements

- Core Datasets for human, veterinary and bacteria are published
- Extended Datasets are revised for human liquid samples as well as Veterinary liquid and tissue samples
- Workshop in Bern to present the SBP ready-to-use BIMS prototype
- Development of the SBP BIMS in 8 pilot biobanks
- A business model for the SBP BIMS is almost ready

Datasets (measure 2.1)

Datasets are the essential variables a biobank shall document to characterize a sample and to promote interoperability. To help biobanks adhere to these standards, a segmentation into a Core dataset and an Extended dataset was very useful and closer to the practice. The Core dataset contains a minimal set of data a biobank shall document to be closer to practice, in contrast to the Extended dataset that a biobank shall document to ensure sample quality.

SBP CORE Datasets	Case	Collection	Processing	Storage	Distribution
HUMAN LIQUID	6	3	4	5	2
HUMAN TISSUE	6	4	6	3	2
BACTERIA	4	6	1	1	2
VETERINARY LIQUID	8	4	5	4	2
VETERINARY TISSUE	8	5	4	4	2

Figure 10: SBP Core Datasets distribution in the sample life

In 2023, after publication of the Core Datasets for human liquid (20 variables) and tissue (21 variables), as well as for bacteria (14 variables), the Core Datasets for veterinary liquid (23 variables) and tissue (23 variables) were published. The interest of generating Datasets in new fields stimulates SBP to develop new datasets for organoids and IPS cells in collaboration with EPFL researchers. These Datasets will be available in 2024.

The already published Core Datasets are integrated and checked during the SBP VITA Label process to help their implementation in the biobanks' daily practice. Then, the Core Datasets will be implemented in Biobank Information Management Systems (BIMS), and the SBP BIMS as the backbone of standardized workflows developed for each specific biobanking environment. All the other variables will be further defined in the Extended Datasets revision that has begun in 2023 for liquid biobanking (human and vet) and for tissue biobanking (vet).

Development of a ready to use Biobank Information Management System (BIMS) (measure 2.2)

SBP is providing biobanks working on excel sheets the opportunity to switch to a professional Biobank Information Management System (BIMS) with its new product called SBP BIMS. SBP BIMS is developed in close collaboration with DiData, the LIMS provider chosen by an independent panel of experts through a public tender. SBP BIMS is also developed in close collaboration with the University Hospitals to be positioned as a complementary tool to the other BIMS already in place.

In 2023, as advised by the independent panel of experts, an external security audit of DiData has been performed by ELCA. The CHUV was interested to take part in the audit process, having already implemented DiData for the registries.

DiData security audit by ELCA

To guarantee a solid foundation and the highest security standards for our new BIMS application based on DiData, we mandated ELCA, among four service providers, to conduct penetration tests on the DiData solution. ELCA is one of Switzerland's largest independent IT providers and has a dedicated cybersecurity subsidiary with over 15 years' experience. The security assessment analysis targeted few vulnerabilities, from code injection to privilege escalation, using OWSAP and CEH methodologies. Overall, the results were good, with a solution well-constructed and particularly permeable to data segregation. Multifactor authentication (MFA) is also well implemented, and the team was unable to bypass it during testing. The few vulnerabilities with medium and low impact were found during testing were corrected by DiData, such as data breaches, confidentiality violations or intrusions. A new version of the solution is now available with all fixes.

As described, the ELCA report confirmed that the Di-LIMS solution is a solid tool, aligned with security requirements for building up SBP BIMS in partnership with DiData.

SBP BIMS Prototype Development

The SBP BIMS prototype has been extensively developed in 2023 with two modules that will be integrated within the DiData solution. A first module for study configuration that should be easily managed by the biobank staff once trained by SBP. The second module, called the SMPL module for Sample Management Platform, is a visual representation of the day-to-day operations of a biobank design shown as an interactive and intuitive workflow.

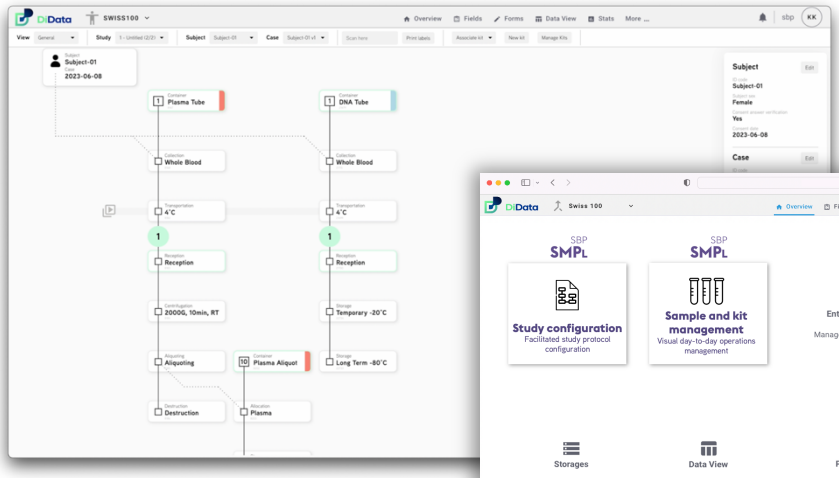


Figure 12: SBP pre-configured workflows

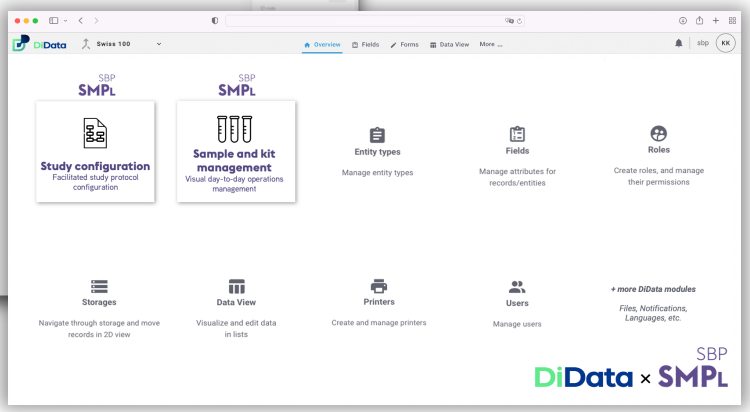


Figure 11: SBP modules integration in Di-LIMS → Di-BIMS

To facilitate the study configuration, SBP provides pre-configured workflows on specific environments (i.e. liquid, tissue, bacteria, …). These workflows integrate the Core and Extended Datasets for each environment, with the possibility to enrich them with biobank specific data. This strategy and the SBP BIMS prototype were successfully presented to the research community at SNSF 11th May.

Workshop on SBP BIMS on May 11th at the SNSF in Bern (measure 4.3)

SBP BIMS Prototype and call for pilot biobanks

SBP BIMS first prototype has been presented at the Workshop 11th May to an audience of 50 persons with diverse backgrounds coming from different Swiss regions and biobank environments (human liquid, human tissue, veterinary, microbiology, from the public sector and from the private sector).

At this workshop, SBP opened a call for pilot biobanks interested in implementing the SBP BIMS.

Pilot biobanks

The call for biobanks was successful with eight biobanks in the liquid and bacteria environments willing to implement and choose the newly developed BIMS. The interest for SBP was to shape the product to biobanks' needs, define the next steps with the pilot biobanks, and in parallel define the business model with DiData.

Biobank		Business Analysis
Vetsuisse Biobank, collection VET_GEN_BERN	**Vetsuisse, Bern**	13.06.2023
Microbiologie (IMUL)	**CHUV**	27.06.2023
Institute of Medical Microbiology (IMM)	**USZ**	22.08.2023
Sérothèque	**HUG**	28.08.2023
Centre de la Mémoire	**HUG**	31.08.2023
Service Médecine Intensive Adulte (SMIA)	**CHUV**	11.09.2023
Swiss Salt Study 2 (SSS2)	**Unisanté**	14.09.2023
Biobanca EOC	**EOC Ti**	09.10.2023

Figure 13: List of SBP pilot biobanks for the BIMS

SBP organized a first meeting to setup the conditions for the pilot biobanks, and once approved, planned a Business Analysis (BA) with each of them. The eight BA were organized from June to October, and successfully resulted in the development of specific workflows. The future steps are described below with a Go-Live in Q2 2024,

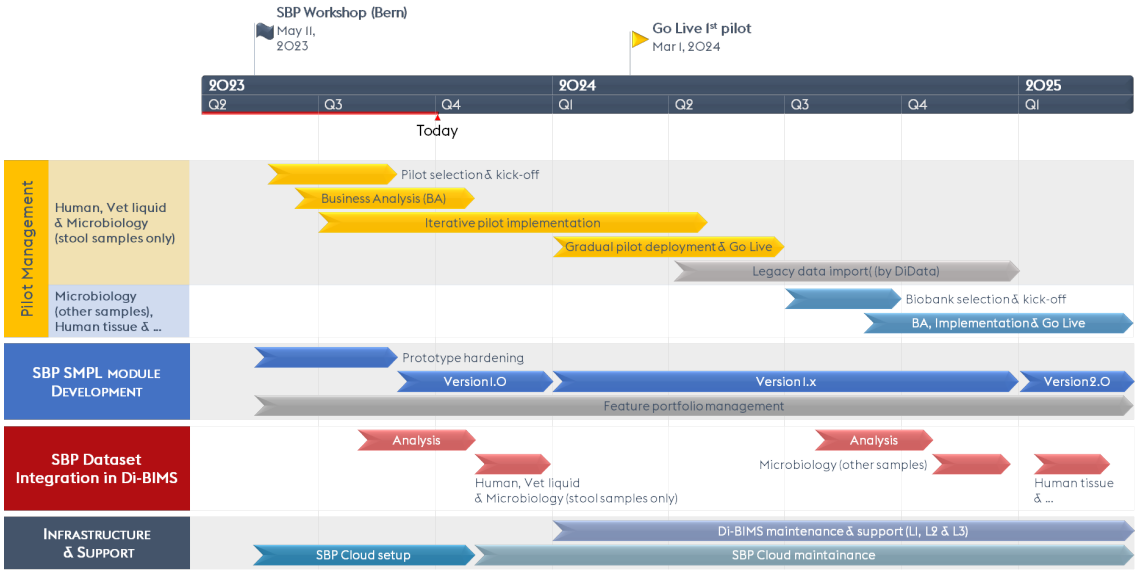


Figure 14: Timeline for the SBP BIMS development

Business model (measure 4.2 and 5.3)

With the development of the SBP BIMS, the interest is to provide SBP network biobanks with an affordable system. To that end, SBP is negotiating a price that makes the system economically interesting and accessible for the biobanks, and that allows SBP have a return on investment for the modules developed.

On SBP side, it has been agreed that for each contract Di-Data signs with a biobank from SBP network, or BBMRI network, a percentage is paid back to SBP: 25% for Swiss biobanks, and 15% for biobanks part of the BBMRI network. This concerns services provided as a starter pack, and also annually for licenses. This will help SBP to support further the development of the SBP BIMS, and to provide training to the different biobanks. The negotiation about the price of the license fees is still ongoing and shall be finalized at the end of the year.

Survey feedbacks

The survey highlights the awareness for SBP datasets (85%) as well as the interest in developing new datasets, in areas like oncology, organoids, virus, microbiome or tumor cell lines. There is also an interest in SBP Biobank Information Management System (BIMS) solution, for biobanks using Excel. The solution should be cost-effective, easy to configure and with access to prompt support when needed.

Action plan

- ☑ There is an interest in developing new datasets particularly in the areas of oncology, organoids, virus, microbiomes, or tumor cell lines.
- ☐ The BIMS solution developed should be interesting in terms of cost, should require minimal training for user and an efficient support.
- ☐ Since many partners already have acquired a BIMS, a strategy should be developed to make these systems compatible and interoperable.

Visibility

SBP is ready to promote research by using the SBP Sample catalog.

Main achievements

- SBP NExT has been renamed in SBP Sample Catalog
- 87 biobanks appear in the Directory and 26034 samples in the Sample Catalog
- A risk analysis has been performed and corrective measures implemented
- A unique identification system for SBP tools (Keycloak system in collaboration with SPHN)

SBP sample catalog

(measures 2.3 and 2.4)

SBP has developed a sample catalog offering both a Swiss directory of biobanks and a query system at the sample level using visualization aspects to facilitate the search. To promote biobanks and their samples to European researchers, SBP connects them to, both the BBMRI Directory and the newly BBMRI Federated Query System.

The Swiss Health Study (SHeS) and the Tissue Biobank Bern (TBB) have imported their samples information in the system, while others are in the pipeline waiting for the publication of a risk analysis that was performed with the CHUV (The Liquid Biobank Bern, the Swiss Transplant Cohort Study and the Biobank Genomic CHUV).

SBP sample catalog risk analysis

To be fully functional and get used by researchers, SBP has conducted a risk analysis to evaluate if the security measures and safeguards are in place to guarantee the integrity and confidentiality of sample-related data within the SBP NExT. This is essential to warrant data security and maintain data confidentiality, safeguarding the interests of all stakeholders including the research participants. SBP applied diverse approaches including 1) the use of the "Data De-Identification" tool developed by the SPHN Data De-Identification Task Force to address data privacy concerns and enhance confidentiality; 2) Expert Opinions with expertise in IT but also in legal compliance and data security.

Based on the results of this risk assessment, SBP has proposed and implemented measures to mitigate these risks and enhance Data Security and Data Privacy.

Data security measure : Keycloak Installation

To improve SBP user experience within the SBP ecosystem, a complete redesign of the security access management system is ongoing. The number of applications owned and offered by SBP is growing and it's important to have a unified security layer. The new architecture based on Keycloak will simplify users' access and strengthen security for the SBP ecosystem. Keycloak is a security framework that manages authentication, authorization and single sign-on. This framework is widely used, including SPHN. The new SBP Keycloak instance is on SIB infrastructure and managed by SPHN which will ensure expert skills, as well as other possible synergies. Trusted users from other security networks such as SPHN and Switch Edu-ID will then have facilitated access to SBP tools.

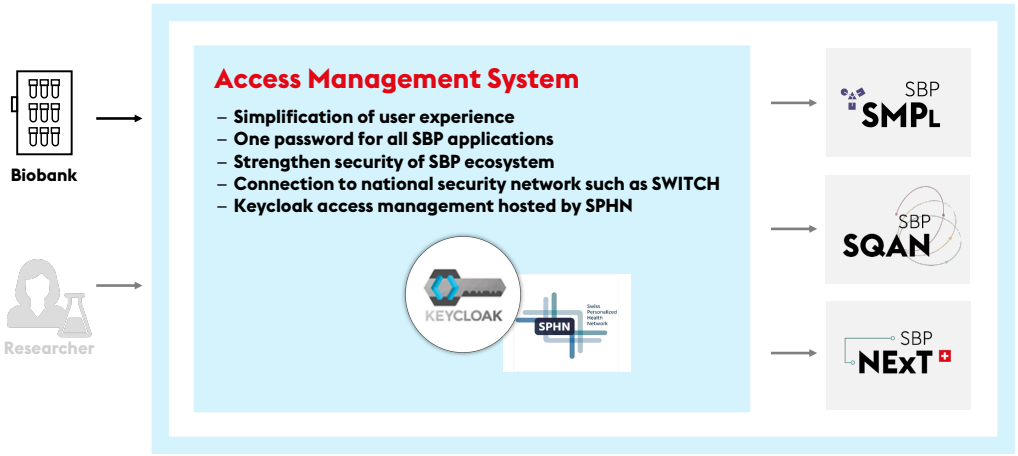


Figure 15: Access management system using KeyCloak

Data sensibility measures to avoid re-identification

No ID (neither Donor-ID nor Sample-ID) from a biobank is visible, Collection date: Only the years will be indicated, Age of the participant indicated as age categories e.g. [0-9]; [10-19]; etc, Diseases: Allow search for a disease but hide the disease-sensitive column in the display list, Rare criteria: The measure of k-anonymity<10 is applied.

The SBP Sample Catalog is now ready to be advertised and promoted to the research community.

Survey feedbacks

The survey highlights that SBP NExT is not well known and its name is not explicit enough to make it visible. Enhancing biobank visibility is key, and SBP is well positioned with the dedicated tool (such as NExT) enabling researchers to efficiently search for samples. They pointed out the importance to integrate the NExT platform with other national and European databases and with the BIMS systems used by the biobanks to enable automatic and standardized data import. Furthermore, non-users also stress the importance of providing through the tool conditions for sharing (availability of funding to support sample preparation, MTA, ..).

Action plan

- ☑ Propose a more user-friendly and intuitive name for the SBP NExT platform to make its purpose clearer and easier to understand;
- ☐ Enhance the promotion of SBP NExT through communication channels and strategies to engage with researchers effectively
- ☐ Plan integration strategies with other national (e.g., SPHN data warehouse) and European exchange platform (e.g., BBMRI Negotiator) to enable efficient search, and with the BIMS used by the biobanks to automatize and standardize the data import.

Education

SBP triggers professionalization by developing a first CAS in Biobanking in collaboration with the University of Geneva.

After having contributed to the Easy-GCS education program of the Swiss Clinical Trial Organization in 2022, SBP is working on a second education program. This triggers SBP to add a new pillar to its portfolio in response to a growing need for knowledge in the biobanking field and to reinforce its strategy.

Easy-GCS

SBP has collaborated to a first education program within clinical studies, the "SBP dedicated Biobanking" module, with the release of Swiss Clinical Trial Organization (SCTO) Easy-Guide for Clinical Studies (Easy-GCS). This is a comprehensive tool that provides all professionals involved in clinical studies answers and guidance on how to proceed with the set up and implementation of their study (https://www.easy-gcs.ch/grid/yecs.html). Biobanking is of great importance in the clinical studies which often deals with human biological material storage but does not integrate SBP practice.

CAS in Biobanking

Together with the University of Geneva, Institut Pasteur and Health Sciences eTraining Foundation (HSeT), SBP began the development of the first module of the future Certificate of Advanced Studies (CAS) in Biobanking. To develop this project which was not originally identified in the Aims and milestones 2021- 2024, SBP received a separate financial support of the Loterie Romande. A collaboration agreement, setting the rights and responsibilities of the four partners, is still under negotiation and shall be finalized before the end of the year.

The CAS in biobanking is planned as a 3-module education program, mainly online with contents and learning activities from basic knowledge acquisition to the development of practical and usable competencies. This strategy allows each module to be followed independently and to target specific audiences. Swiss and International experts, through the BBMRI network, will be invited to provide testimonials or perspectives on specific topics.

With this support from Loterie Romande, SBP hired a dedicated collaborator to coordinate the development of this CAS with the redaction of the chapters as well as the recruitment of a large panel of Swiss and International experts.

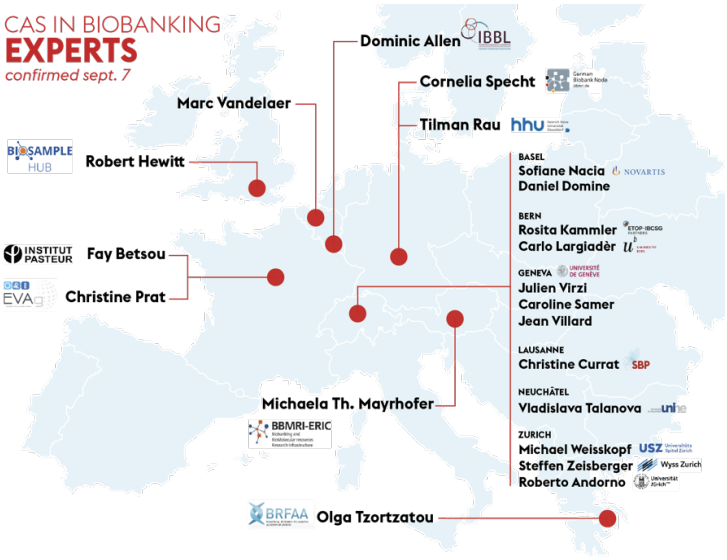


Figure 16: Experts having agreed to be part of the CAS Program

Module 1

The development of the CAS starts with the release of module 1 planned Q2 2024. Advertising begins in January 2024 with a descriptive brochure, focusing on Module 1, being only available next year. Module 1 called "The Basics of Biobanking" is presented below with a representation of experts contacted within the Swiss and European networks and Pasteur Institute network.

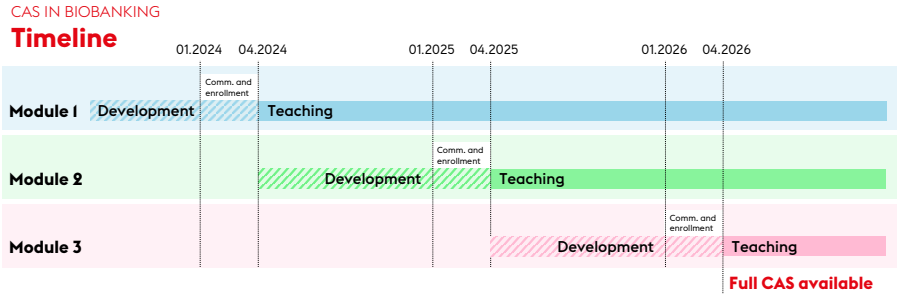


Figure 18: Timeline for the development of the CAS

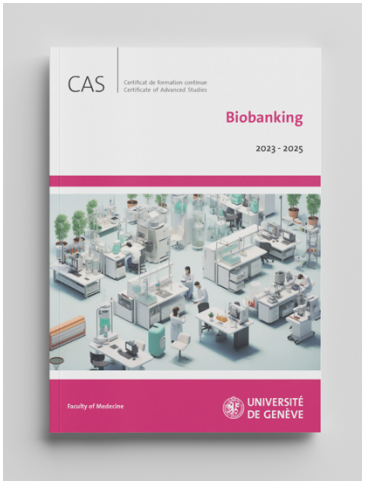


Figure 19: CAS brochure

CAS — MODULE 1
PROGRAM

1. WHAT IS BIOBANKING

1.1 **Why Biobanking is important**

1.2 **Scope, type and functions of biobanks**

1.3 **Biobank vs Biobank Infrastructures**

1.4 **Biobanking Networks**
Importance of networks, International (BBMRI, ISBER), National (SBP), IP-EVAg

2. GOVERNANCE

2.1 **Regulations**
Legal instruments, Ethical instruments, Professional standards

2.2 **Regulatory Affairs**
Responsibilities, Governance Documents

2.3 **Data Management**
Confidentiality and Privacy, Traceability

2.4 **Accountability**
Return of results, External Communication, Complaints

2.5 **Sustainability**
Social, Economic, Environmental

3. OPERATIONAL MANAGEMENT OF A BIOBANK

3.1 **Resources**
Infrastructures involved in Biobanking, Equipment and Material, Personnel

3.2 **Processes**
Workflow overview, Specific workflows: tissue biobanks, liquid biobanks, microbiology, etc.

3.3 **Quality Management**
ISO Standards (20387), Documentation Management, Risk Management, Quality Strategy (Quality Manual)

Figure 20: Module 1 description

Survey feedbacks

The survey highlights a great interest for educational content focused on quality and interoperability, addressing topics like sample handling, interoperable biobank setup, quality guidelines and accreditation. It also identifies gaps around regulatory/ELSI issues and guidance on the regulatory challenges and potential pitfalls inherent in biobanking, sustainability and funding strategies.

Action plan

☐ **Provide comprehensive educational content, including basic knowledge as well as practical or hands-on courses, on-site presentations, live webinars, and workshops targeting researchers covering practical aspects.**

Sustainability

SBP innovates by developing the first Swiss Cost Calculator for biobanks.

SBP Cost calculator

"Sustainability is the capacity of a research infrastructure to remain operative, effective, and competitive over its expected lifetime" as defined by the OECD at the Global Science Forum in 2017. Biobank infrastructures provide services (e.g. sample processing, sample storage) as well as trained personnel and adapted equipment to the biobank community. To maximize their use, visibility, and efficiency, they must develop a self-sustainable business model and apply a proper recovery cost for the activities they perform.

From a business perspective and to support this approach, SBP has developed a Cost calculator to help the biobank infrastructures determine the costs associated with the pre-analytical services they provide and invoice the interested party (e.g. biobanks or researchers) in a transparent and harmonized manner.

Figure 21: Scheme explaining the cost calculator strategy

The Cost Calculator was developed in collaboration with the main Swiss biobanking infrastructures from:

1) Universitätsspital Basel (representative: Andreas Loehrl);
2) Inselspital Bern (representative: Carlo Largiadèr);
3) University of Bern (representative: Aurel Perren);
4) CHUV Lausanne (representative: Elodie Ristorcelli);
5) HUG Geneva (representative: Pierre Lescuyer);
6) Universitätsspital Zürich (representative: Michael Weisskopf).

The cost calculator is an excel file the biobanks can fill in, based on the user guide instructions.

SBP Cost Calculator

→ User Guide (pdf)

① Cost Calculator (xls)

② Cost Calculator — Appendix (xls)

Exemples of indirect costs that a biobank infrastructure may encounter.

Key Performance Indicators

In response to the demand from various European member states and their respective monitoring authorities (ministries, research councils, funding agencies), BBMRI-ERIC's Assembly of Members (AoM) resolved in its June 2022 meeting to implement a standardized set of key performance indicators (KPIs) across its member states. A total of 14 KPIs were finalized.

SBP, as the Switzerland national node, was responsible for collecting data on 4 of the 14 KPIs.

1. Requests successfully handled for samples and data, and for data only
2. Number of publications involving biobanks
3. Number of events and of participants
4. Number of successful grants and total budget

Those data will help to better understand the actual situation regarding sample access, research collaborations at national and European level, the impact of communication and education as well as gather more information on the sustainability of biobanks. Out of the 103 biobanks contacted, 31 responded to the survey.

Responses by type of institutions

- 16 from university hospitals
- 7 from universities
- 3 from foundations
- 2 from ETH
- 2 from cantonal hospitals
- 1 from a private biobank

This is a first step towards biobank accountability as it has been shown previously through the annual review SBP is leading within its network.

Survey feedbacks

The survey indicates a critical need for support regarding sustainability of biobanks to better acknowledge and recognize their work and better support them (financially) in the long run. To address this need, SBP has decided to create a new pillar "Sustainability" and will propose as a first step towards biobank's work recognition a Cost calculator for biobank infrastructure services to help them estimate the cost of samples used in a project.

Action plan

- ☐ The SBP Governing Board should initiate contact with the Swiss National Science Foundation (SNSF) to explore the possibility of obtaining specific funding support for biobanks.
- ☐ SBP is currently working on the development of a first tool to create a cost calculator for biobanks' infrastructure services, aiming to provide a comprehensive and transparent tool for assessing expenses and financial planning of their activities.

Aims and milestones 2021 – 2024

Aims	Measures and deliverables 2019-2020	Milestone	Deliverables	Status
1. **SBP promotes a quality strategy for biobanks that serves both quality management issues and sample quality.**	1.1 — Provide biobanks with guidelines, support documentations and consulting services to improve their preanalytical process	10.2021	SOPs, a quality manual and specific trainings are developed	✓
	1.2 — Enlarge the SBP national network of biobanks to other hospitals, universities, public or private research organizations.	10.2021	Biobanks from University Hospitals are the main SBP partners	✓
		10.2022	Biobanks from Universities are part of the network	✓
		10.2023	Interest of other research partners is encountered	✓
		10.2024	Interest of private industries is considered and evaluated	↻
	1.3 — Develop and update guidance, know-how and consulting services in terms of quality on a regular basis	10.2022	The Biobank SQAN and its related labels are updated	✓
		10.2024	The Biobank SQAN and its related labels are updated	
	1.4 — Provide biobanks with guidance, support and consulting services to prepare the ISO accreditation	10.2022	Interest and needs of biobanks getting accredited by ISO norm is evaluated	✓
	1.5 — Develop and coordinate peer-review audits on specific fields of biobanking by SBP experts	10.2024	An expert panel is created and guidelines for audits are developed	↻
2. **The SBP develop guidelines to facilitate access to biobanking samples by establishing a Swiss biospecimen catalogue at the sample level. The SBP provides advice in IT systems for quality and networked biobanks.**	2.1 — Provide biobanks with solutions to implement SBP datasets promoting interoperability and ensuring quality documentation	10.2021	Datasets are endorsed by SBP partners and implemented in most biobanks	✓
	2.2 — Develop a ready-to-use Biobank Information Management System (BIMS) for biobanks in Switzerland and abroad	10.2021	SBP BIMS concept is developed with a business plan	✓
		10.2023	SBP BIMS is developed and implemented in interested biobanks	✓
	2.3 — Develop a catalogue at the sample level facilitating search, usage and turnover of samples for research purposes aligned to the Swiss Personalized Health Network Strategy (SPHN)	10.2022	SBP e-catalogue development is operational and its efficiency evaluated on a regular basis	↻

	2.4 — Setup counselling services and tools to facilitate national and cross border exchange	10.2022	Guidelines and services are developed and provided by an ELSI helpdesk
	2.5 — Facilitate access to samples for researchers through the development of guidelines, access policies and a defined process promoting efficient usage of biobanks	10.2023	Tools and processes such as a sample negotiator are developed with a one-stop-shop approach to efficiently connect researchers and biobanks
3. **The SBP drives the quality management of biobanking activities.**	3.1 — Adapt SBP quality labels with minimal quality and interoperability requirements to the non-human biobanks needs	10.2022	Non-human biobanks' specificities are integrated in the minimal requirements of the different labels
	3.2 — Identify an international non-human biobanking consortium or initiative to network Swiss biobanks as BBMRI for the human biobank	10.2022	The consortium or initiative is identified and the collaboration is defined
	3.3 — Analyze the needs for services and guidelines to be developed for bacteria/virus and veterinary biobanking field as well as for other animal, plant and other organisms, if applicable	10.2023	A list of services and guidelines are proposed and prioritized
	3.4 — Develop a concept or non-human biobanking in terms of processing and storage infrastructures based on the information gathered under 3.2 and 3.3	05.2024	A concept for the development of specific non-human biobank infrastructures is validated (type of storage, specific
4. **SBP consolidates the collaboration with the european networks of biobanks**	4.1 — Participate in BBMRI as well as ESBB and ISBER development and inform on a regular basis the Swiss biobanking community on the important achievements in biobanking	10.2022	Regular newsletters and analysis are provided to SBP partners
	4.2 — Provide a list of SBP services that could be developed for the European community or other interested stakeholders (Biobank SQAN, support documents,…) as paying services	10.2024	Interested services are provided and a price is calculated for each
	4.3 — Organize regular national and international conferences to promote knowledge-sharing on different biobanking aspects aligned with European guidance	10.2021	a national conference is organized
		10.2022	an international conference is organized
		10.2023	a national conference is organized
		10.2024	an international conference is organized

5. **SBP provides a concept for its sustainable funding**	5.1 — Maintain a coherent and efficient collaboration between research infrastructures of national importance in Switzerland by creating and intensifying synergies with other infrastructures (SPHN, SCTO, Swissethics,...)	10.2024	
	5.2 — Develop a concept to be integrated in the SERI list of research infrastructures of national importance	10.2023	
	5.3 — Develop a business plan with financing measures	10.2023	

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