Description of the research infrastructure

Summary report of the period 2021-2024

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

This initiative of the Swiss National Science Foundation (SNSF) 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 2021-2024 as delineated in the agreement between the SNSF and SBP with the following goals to reach:

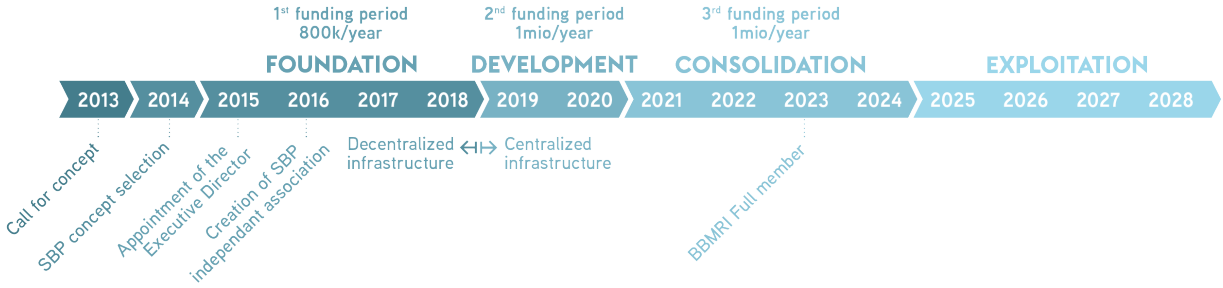
1. SBP promotes a quality strategy for biobanks.
2. SBP develops guidelines and IT advice to facilitate access to biobanking samples.
3. SBP drives the quality management of biobanking activities for human and non-human fields.
4. SBP consolidates the collaboration with the European networks of biobanks.
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 by providing additional tools and services to fulfil 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 novel expertise represented by new members in its governance. SBP offers specialized services and tools to support a growing network of biobanks and researchers, while also expanding its strategy to include education and sustainability as new pillars.
SBP values help approach and serve biobanks' interests.

1. Management and Governance

1.1 History

In 2013, after consultation of national and international experts in the field, the SNSF has launched a competitive call for concepts for constituting a national biobanking platform. The SBP concept was selected in 2014 by an international panel of experts in biobanking activities and starts its construction under the supervision of the five University Hospitals and the Vetsuisse faculty, in close collaboration with the SNSF.



A first funding period from 2015 to 2018 has been released by SNSF with a first instalment of CHF 800'000 per year. In November 2015, the SBP executive director has been hired and the new SBP executive office recruited to establish SBP according to the aims and milestones defined in the agreement between the SNSF, the University Hospitals and Vetsuisse faculty.
In June 2016, the SBP independent association has been established with a governance in place (see chapter 1.2). A first decentralized organization enabled SBP to get a good overview of the University Hospitals needs in terms of biobanking support to be developed. From 2018, this decentralized organisation setup rapidly turned into a centralization of human resources to be more effective and focused on the development of a support infrastructure counselling any biobank in Switzerland in the human and non-human domains.
During the second funding period of 2 years (2019-2020) with 1mio CHF per year, SBP was ready to provide its first services to biobanks, with a focus on human biobanking. This was the premises of the establishment of SBP biobank network and the first collaborations with BBMRI-ERIC, SBP taking part of the network as an observer member.
The third funding period of 4 years from 2021 to 2024 enabled SBP to consolidate its services while expanding them to other fields learning from the expertise gained from the human biobanking field. In June 2023, SBP became a full member of BBMRI-ERIC consolidating its position in the field.
SBP is now ready to provide biobanks with a concrete and complete strategy for the next period to come and then become a sustainable research infrastructure.

1.2 Legal status and organisation

SBP is an independent association from 2016 initiated by SNSF. SBP governance is composed of ordinary and expert members from non-profit and publicly funded institutions active in the biobanking field as defined in its bylaws[1]. The ordinary members constitute the SBP General Assembly and are represented by the founding members, the five Swiss University Hospitals. SBP Governing board is

[1] https://swissbiobanking.ch/2022/wp-content/uploads/2022/03/SBP_BYLAWS_ENG.pdf

composed of the ordinary members together with expert members as individuals highly recognized in specific biobanking domains (i.e. liquid, tissue and non-human biobanking)[2].

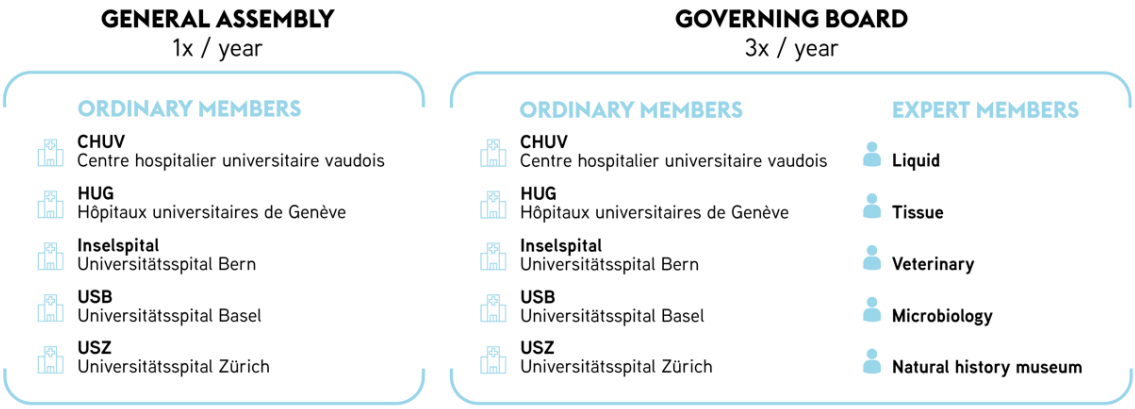


Figure 1: SBP governance according to bylaws

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.

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
Dean, Faculty of Medicine, UniGe
Director of Education and Research, 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

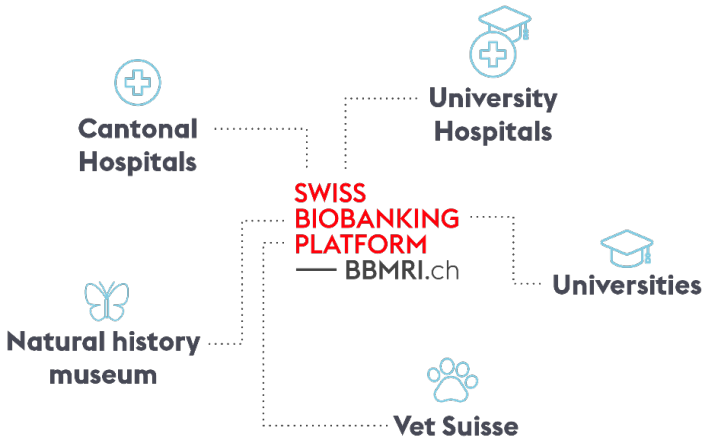
Figure 2: SBP ordinary and expert members elected 17th November 2022

A flexible appointment of three years enables the Governing Board to gather expertise for proper decision making in a fast-moving field and environment. For the three-year period from November 2022 to October 2025, SBP president, Pr Antoine Geissbühler, as the representative from Geneva University Hospital, has been re-elected unanimously for a second and last mandate. Pr Carlo Largiadèr succeeds Pr Aurel Perren as vice-president, bringing his expertise in the liquid biobanking domain.

[2] https://swissbiobanking.ch/about-us/

1.3 Host institution and localisation

SBP is an independent association working as a centralized organization currently based in the Biopôle (Epalinges, Canton de Vaud). The Biopôle hosts innovative life sciences companies and research groups offering SBP a stimulating environment in various medical and scientific disciplines. While located centrally in Lausanne, SBP serves the whole biobanking community in Switzerland. Indeed, SBP has been founded by the five University hospitals represented in the SBP governance as the SBP ordinary members. Those five institutions were the privileged partners for building up the network from scratch as they are hosting many biobanks in the human domain. Being mandated not only to coordinate the human, but also the non-human domain, Vetsuisse was part of the SBP governance as the first representative for non-human biobanking.
In the following years, other key institutions were integrated as SBP partners to get a better representation of biobanking activities in the SBP network with the Swiss Universities, the Cantonal Hospitals and the Natural history museums, some partners being represented in the SBP governance. SBP acts as an independent service provider to support the biobanks hosted in these institutions.



1.4 Human resources

SBP Executive Office is responsible for implementing the objectives as defined by the Governing Board and SNSF in various domains of biobanking enabling to:

- advise biobanks part of the SBP network on quality, interoperability and sustainability issues,
- develop key projects to position SBP as an innovative infrastructure for researchers,
- collaborate with other research infrastructures nationally on specific fields of expertise to avoid redundancies,
- collaborate with the BBMRI organisation, being a full member from 2023 on.

SBP Executive Office is a multidisciplinary team of 9 employees with different backgrounds from biologists, biobank specialists, UX/UI designers and communication specialists.

SBP Executive Office acts as an independent and autonomous association with expertise in the necessary domains to provide researchers with the tailored support they need.
SBP employees mainly work part-time in a productive and collaborative spirit being able to switch from a project to another, depending on their expertise. The number of persons remains quite stable along the years with slight differences in terms of FTEs (5.5 in 2021, 5.3 in 2022, 5.8 in 2023 and 6 in 2024). When necessary, SBP Executive Office rely on consultants in specific domains such as IT specialists often paid by additional funds depending on the scope and ambition of the projects. SBP is an agile association enabling the development of innovative projects having demonstrated its added value and efficiency over time.

2. Users and impact

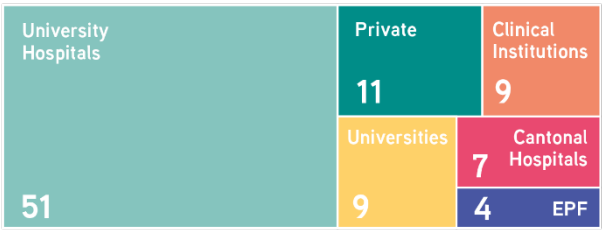
2.1 Users' communities

SBP first users are the **Swiss biobanking community** with biobanks collecting and providing samples for research purposes, as well as biobank infrastructures providing operational services to biobanks such as storage facilities, sample processing, transport, etc.

As a secondary user once the SBP network of biobanks reached a certain number, researchers will benefit from the biobanks' harmonization of practice by accessing high-quality samples. These users represented as the **research community** can come from Switzerland or abroad.

SBP reliable network of biobanks

Very concerned by the quality of the infrastructure and the services provided to its users' community, SBP developed a process enabling biobanks to join the network. A structured review helps SBP to support biobanks comply with the minimal ethical and legal requirements to fulfil before making them visible at the Swiss and European levels.
As shown in the figure below, the Swiss biobanking community has greatly increased with 91 biobanks (as of March 2024) constituting the Swiss reliable network of biobanks.

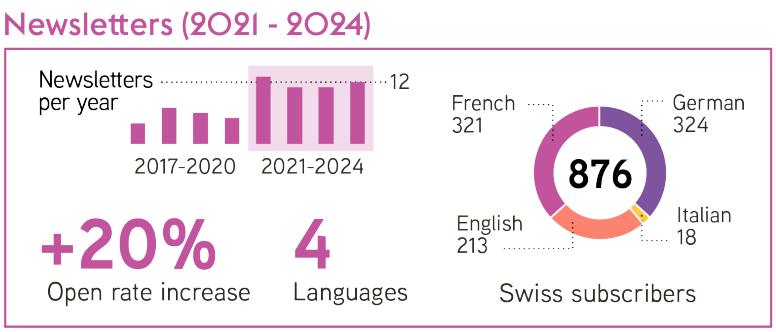


These biobanks, users of SBP services, are spread all over Switzerland, and are hosted by different types of institutions. The majority comes from the University Hospitals, which were the first SBP target, but over time, we noticed a diversification of the interested partners including private partners.
Indeed, from 2021, SBP opened its services to private biobanks as a paying service described in a specific collaboration agreement, with the limitation of complying with SNSF requirements in terms of publications and sharing their samples with the academic research community.

SBP virtual community

In addition to the network that SBP has created and developed over the years, there is also a "virtual" community made up of people inherent to the research field, via the SBP newsletters and the social medias Linkedin and X. There is a very different pattern of the community via these two channels:

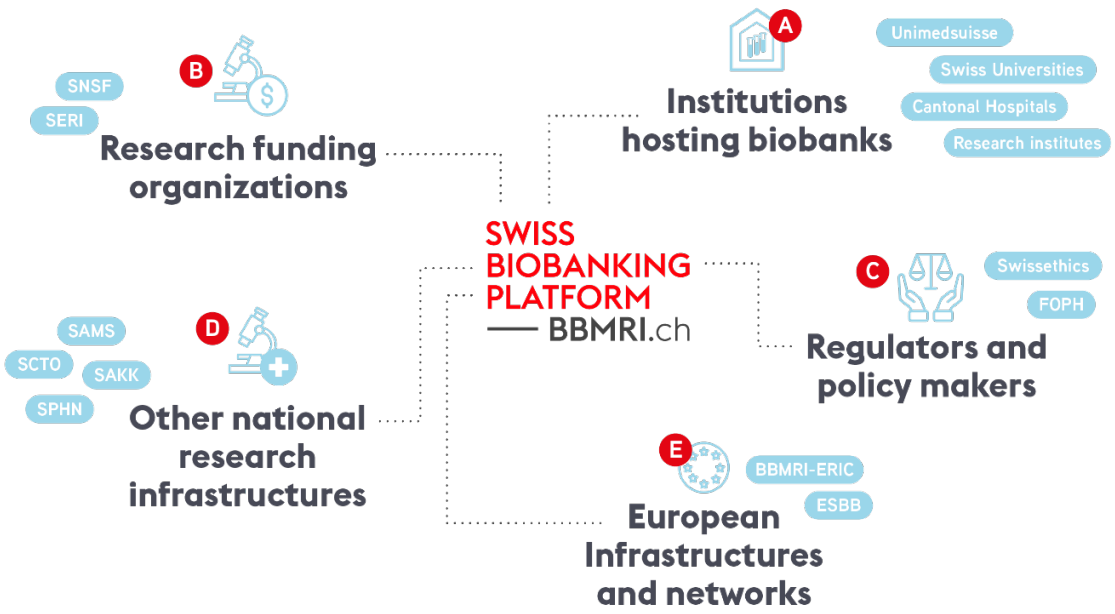
- The visibility generated by bi-weekly social media posts targeting the global research community is more active and engaging compared to newsletters, and it has attracted a significant number of followers.
- The monthly newsletter draws in fewer subscribers, but the audience is gaining in quality as a result of the growing open rate.



SBP stakeholders' mapping

Apart from the users' community, SBP is working within an environment of multiple key stakeholders that will help SBP to position its services at a strategic and operational level and maximize their implementation and awareness at the Swiss and International levels.
The stakeholders were classified in five major categories as presented in the scheme below:

A. Institutions hosting biobanks : Unimedsuisse (University Hospitals), Swiss universities, Cantonal Hospitals, Research institutes, …
B. Research funding organizations : Swiss National Science Foundation (SNSF), Secretariat of (SERI)
C. Regulators and policy makers : Swissethics, Federal Office of Public Health (FOPH), …
D. Other national research infrastructures : Swiss Clinical Trial Organization (SCTO), Swiss Personalized Health Network (SPHN), Swiss Academy of Medical Science (SAMS), Swiss Group for Clinical Cancer Research (SAKK), ..
E. European Infrastructures and networks: European research infrastructure for biobanking (BBMRI-ERIC), European Society for Biopreservation and Biobanking (ESBB)



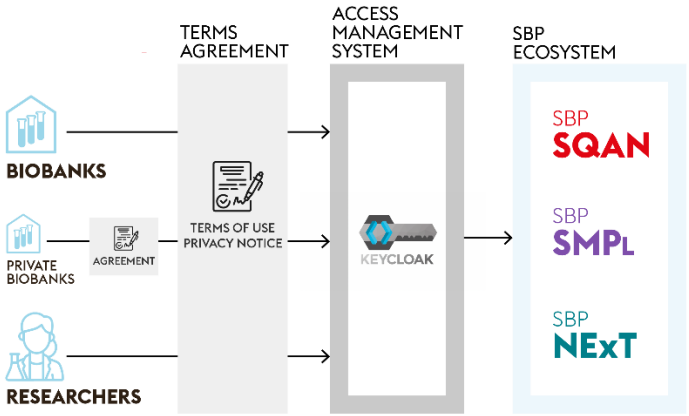
2.2 User access policy and fees

Potential users can easily find and access SBP for their research and biobanking needs through various channels:

- The main portal is the SBP website describing the different services with access to each tool, resources and contact details.
- Relay by key national organizations (e.g. Swissethics, SPHN) of some SBP main documents (e.g. SBP biobank regulation or MTA templates) on their websites to help researchers get access to these resources and SBP specific services.
- SBP presence on social media platforms like Linkedin and X to update the SBP network on its main achievements shall also attract additional users.
- Last but not least, word of mouth from the biobanks having used SBP services, especially the Label compliance process, attract other users to be part of the SBP network.

The services are provided for free, and the biobanks can access the different SBP supports on a voluntary basis. Up to now, the institutions don't contribute financially to the SBP association. In contrast to other research activities, no specific legal requirements oblige the biobanks to follow the standards, thus SBP had to find innovative ways and build trust to attract biobanks and convince institutions to partner with SBP and use its support services. The word of mouth has been an efficient one to enable attracting more partners and getting SBP services known in the Swiss community.

Once interested in any of SBP services, users get access to a unified security layer called Keycloak that manages authentication, authorization and single sign-on. Trusted users from other security networks such as SPHN and Switch Edu-ID will then have facilitated access to SBP tools with the same identification information. The registration system is only valid once users have agreed to the SBP privacy notice and terms of use as required by the Data Protection Law.



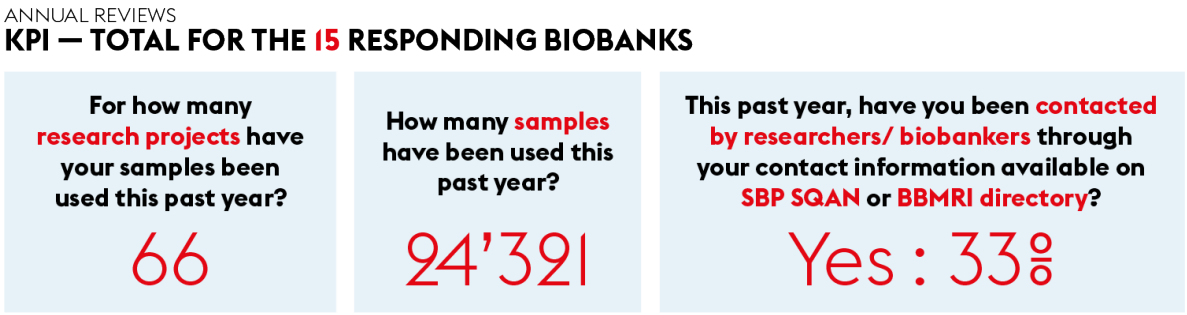
Private biobanks will only be allowed to register after having signed a specific agreement with SBP if they accept to share their samples with academic partners.

2.3 User approaching and training activities

As described in 2.1 "User's communities", SBP two main users are the biobanks and the researchers. To approach them, various communication channels are used to engage with each group effectively.
SBP aimed first at enhancing the network by supporting the biobank's practice improvement through SBP compliance process. This compliance review using the Biobank SQAN tool was the first educational support to raise awareness among SBP biobank partners to address key questions related to governance and quality aspects. Based on their valuable feedback, SBP has customized its communication strategy via newsletters and social media to attract more biobanks and make SBP network attractive to the research community by increasing the biobanks' visibility and showcasing available samples in the SBP Sample Catalog (SBP NExT).
While SBP has initially focused on biobanks, the recent user surveys performed in 2023 (see part 2.5 for more details) highlighted the need for better communication with researchers. To address this, a tailored communication strategy is under development, including a dedicated webpage on SBP website. SBP will also use channels such as factsheets, events, and social media to reach researchers effectively.
Additionally, offers in terms of training activities have been developed (see part 3.2 on Education for more details). Collaborations, such as with the Swiss Clinical Trial Organization (SCTO), have led to the development of an educational module on biobanking within the online platform called the Easy Guide for Clinical Studies (Easy-GCS). Moreover, SBP is currently developing a Certificate of Advanced Studies on Biobanking with the University of Geneva University, further expanding the educational outreach to a broader audience.

2.4 User research enabled by the infrastructure

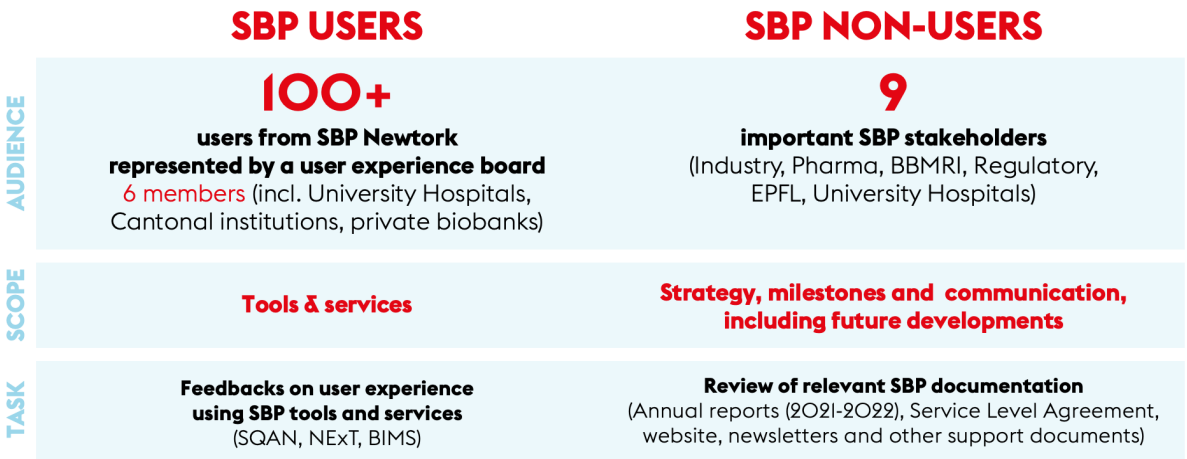
Very recently, as the biobank network has grown efficiently, Key Performance Indicators have been implemented to evaluate how many researchers looked for samples using the SBP network as an entry point.



This was the first time SBP could have an overview on the number of samples used in research projects and how useful the SBP network has been to promote access to samples for research purposes. This gives a first success to measure and work on impact improvement.

2.5 Impact

To evaluate its infrastructure, 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.



Overall, the feedback from SBP users highlighted the positive impact of SBP at national level. SBP is seen as a professional organization that has brought awareness about the specific need for dedicated knowledge and expertise in biobanking. Through its mission to increase access and visibility as well as quality and interoperability of biobanks, SBP serves as an important central contact point for biobanks to get support and to facilitate coordinated development and organization of biobanks in Switzerland, leading to an increasing number of biobanks working according to best practices or other international quality standards. The ongoing efforts to harmonize practices among biobanks are noted as promising for research advancement, and the label approach is considered as key in this overall quality process.

Importantly, through its network of Swiss biobanks connected to the European network through BBMRI Directory, SBP also improves the recognition of biobanks in Switzerland, by enhancing their visibility and advocates for their national and international representations. The network organization is identified as crucial for research enabling access to high-quality samples and supporting data-driven innovation, precision medicine, and patient engagement.

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

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.

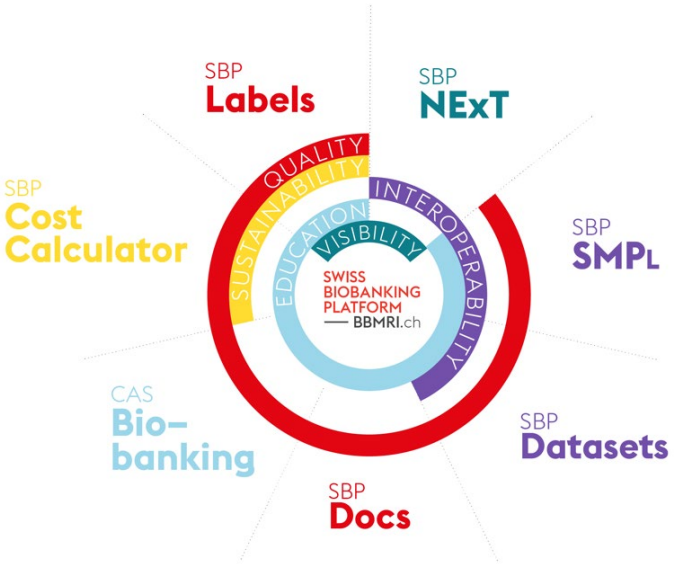
The results of this external evaluation will be of great support to shape the future of SBP. These results provided to the governing board valuable insights to tailor the roadmap for the next funding period, guiding strategic decisions and investments (see proposal 2025-2028). By aligning SBP's efforts with the identified strengths and opportunities, SBP will maximize its impact and contributions to the biobanking and scientific community.

3. Activities in the period 2021-24

3.1 Summary of main activities 2021-2024

SBP services

SBP strategy and position rely on the development of tools and services based on five key pillars ranging from quality, interoperability, visibility, sustainability to education. Those pillars help biobanks implement Good Biobanking Practice as described in detail in chapter 3.2 of this document.



QUALITY

To improve or get compliant with the minimal requirements in terms of governance, process and quality management, SBP developed a comprehensive service using an online tool to evaluate biobank practices. Once fulfilled, three distinctive labels can be awarded: the VITA label (governance), and the NORMA and OPTIMA labels (Quality) to demonstrate the minimum requirements in terms of process standardization and quality assurance, respectively. The compliance review also provides harmonized documentations “SBP Docs” developed in accordance with the European and international requirements.

VISIBILITY

To promote visibility, the SBP labeled biobanks are registered in the Network Exploration Tool (SBP NExT) combining both a directory and a request portal for researchers to access well-annotated samples. The NExT is also the link with the BBMRI directory and is the first step in the construction of a future national one-stop shop model for researchers.

INTEROPERABILITY

To facilitate sample sharing and increase sample quality, biobanks should document their practice using harmonized datasets. Implementation of these datasets is supported with the development of a dedicated Biobank Information Management System helping biobanks working on excel sheets switching to professional integrated tools.

SUSTAINABILITY

To maximize their use, visibility and efficiency, biobanks must develop a self-sustainable business model and apply a proper recovery cost for the activities they carry out. To support this approach, SBP

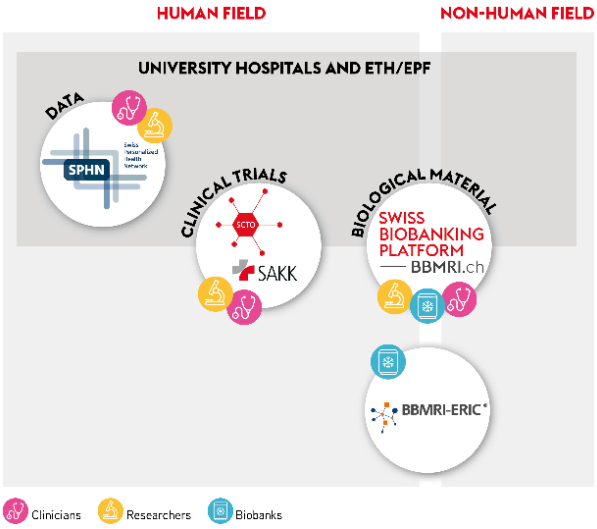
has developed a cost calculator to help them determine the costs associated with their pre-analytical activities and to invoice interested parties (e.g. researchers) in a transparent and harmonized manner.

EDUCATION

To raise awareness on the importance of biobanking, SBP collaborates with the University of Geneva in the development of a Certificate of Advanced Studies (CAS) in Biobanking. This advanced program addresses the critical need to equip individuals and institutions interested in biobanking and research, with essential knowledge and proficient skills for effective biobank establishment and management.

National collaborations

SBP strategy needs to be very well structured and scattered to the needs of biobanks. As some activities are transversal and some pillars are also key for other research infrastructures of national importance (i.e data interoperability managed by the Swiss Personalised Health Network (SPHN) or quality for clinical trials managed by the Swiss Clinical Organisation (SCTO)), bridges need to be built to make synergies, avoid redundancies and highlight uniqueness of each research infrastructure. This will enable each infrastructure to concentrate on its field of expertise and rely on the other infrastructures where needed. This map shall be very understandable by the researchers, being the users in this complex system.



Swiss node in the BBMRI-ERIC organization

SBP gains in visibility and influence at the EU level by becoming an ordinary member of the European network BBMRI-ERIC. 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.

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 should facilitate their integration in European projects. In 2023, SBP focused its work on building direct interaction or specific projects with other nodes such as Germany, Austria and Belgium. SBP tools or documents are highly recognised at the European level such as the Cost calculator or the SBP Quality manual used as the reference template for Europe.

SBP pillars and developments are aligned with the BBMRI strategy, with efficient collaborations even if Switzerland is not able to take an active part in European projects due to specificities limiting the funding of such projects.

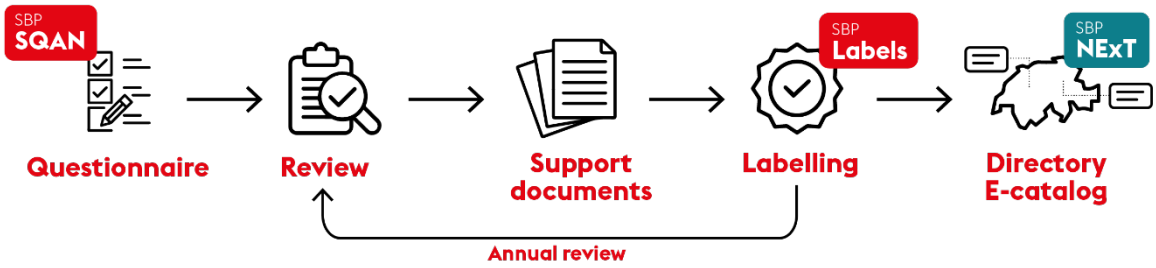
3.2 Research & Development activities 2021-2024

QUALITY

The collected, processed and stored biological samples are important research tools used to perform efficient and high-quality investigations. Sample quality is a wide concept, which should be understood as a whole to establish standard control criteria and foster good biobanking practices.
The entry into force of the new ISO norm 20387 in October 2018 gives biobanks incentives to follow these high-quality standards. As the gap between the law requirements and their implementation is important, SBP developed a step-by-step approach using an innovative tool and the SBP Labels as a service to help biobanks reach these standards.
Quality was the first concern SBP was dealing with and the best field to support and build trust with the biobanks. In terms of quality, SBP offers different services to support biobanks in the development of a state-of-the-art practice. In addition to standardized support documents available on SBP website, a compliance review leading to three SBP Labels helping biobanks get compliant with the minimal requirements on governance, process and quality management.
This conformity check with the obtention at minimum of the VITA label (Governance) has been decided as a mandatory step to enter the Swiss and European networks of biobanks.

SBP Labels

SBP developed an interactive tool, the Biobank Solution for Quality Assessment and Normalization – (Biobank SQAN), integrating the critical factors a biobank should address to evaluate and monitor its practice. It helps biobanks get compliant with the minimal requirements in terms of governance, process and quality management issues by providing specific support and documentation (SBP Docs).
The Biobank SQAN not only targets the biobanks which collects and provides samples for research purposes, but also biobank infrastructures which provide services to biobanks such as storage facilities, sample processing, transport, etc.
The Biobank SQAN compliance process is based on a five-step approach for biobanks to reach the minimal levels of requirements, integrating the main principles of the new accreditation norm ISO 20387: 2018.



Upon assessment, three different labels can be awarded to confirm the biobank compliance with the minimal requirements in terms of Governance (label VITA) and Quality (labels NORMA and OPTIMA) and depending on the biobanks' objectives and strategy. The obtention of the VITA Label is a prerequisite to be visible in the SBP Network Exploration Tool (NExT) and the BBMRI-ERIC directory.

Compliance with legal and ethical standards

The VITA Label guarantees a proper Governance of the biobank in line with the applicable regulatory framework.

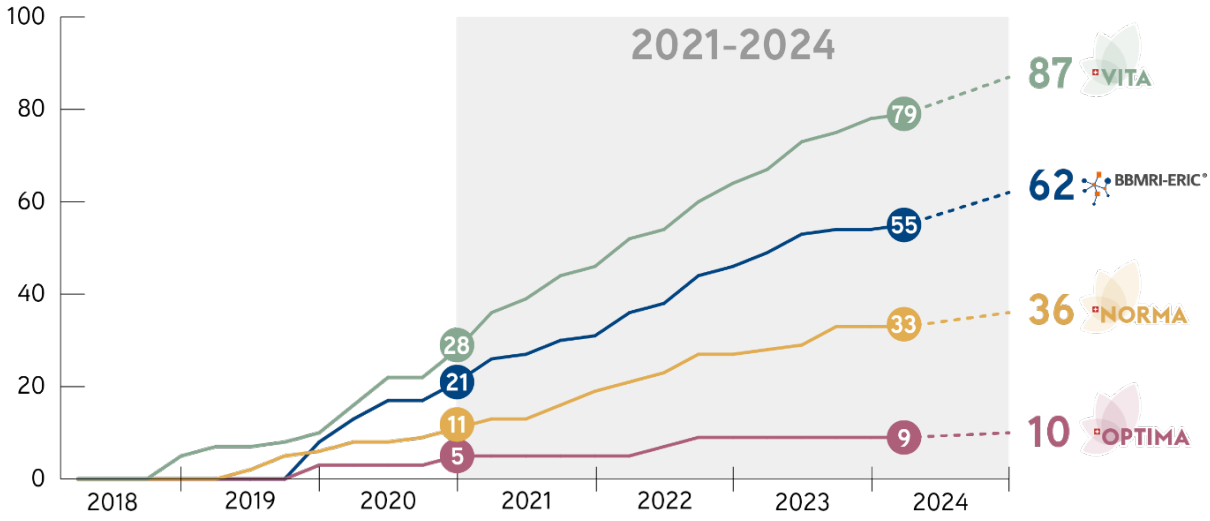
Standardization of the operational processes of a biobank

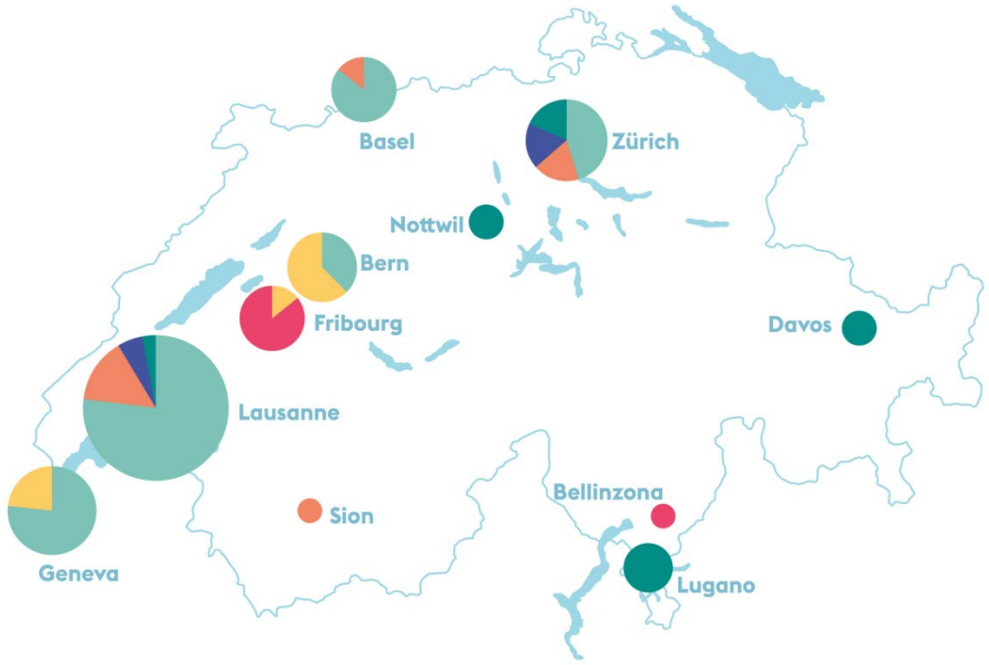
The NORMA Label guarantees the quality of the operational processes and the harmonization of practices at the Swiss level.

Optimization of the Quality Management System

The OPTIMA Label acknowledges the biobank has established a QMS with proper documentation management and implementation of Quality Indicators to monitor and optimize its operational processes.

To date, 91 biobanks out of which 12 are biobank infrastructures are registered in the SBP directory, and 55 are searchable within the BBMRI-ERIC Directory. One third of the biobanks reached the NORMA Label while few at the moment have reached the OPTIMA Label.





UNIVERSITY HOSPITALS — 51
- Universitätsspital Zürich 5
- USB — Universitätsspital Basel 6
- Inselspital — Universitätspital Bern 3
- CHUV — Centre Hospitalier Universitaire Vaudois 27
- HUG — Hôpitaux Universitaires Genève 10

CANTONAL HOSPITALS — 7
- HFR - Hôpital Fribourgeois 6
- Ente Ospedaliero Cantonale 1

CLINICAL INSTITUTIONS — 9
- UKBB: Universitäts-Kinderspital beider Basel 1
- Kinderspital Zürich 2
- Fondation Asile des Aveugles 1
- Unisanté — Lausanne 4
- Unisanté — Sion 1

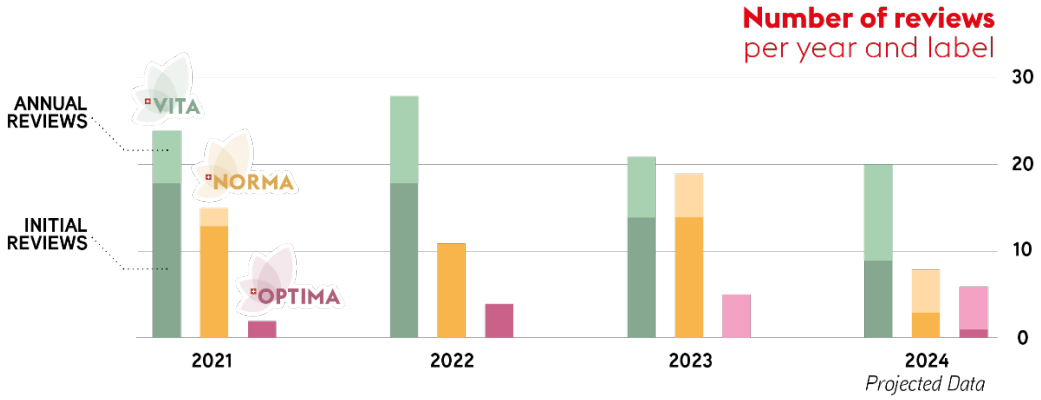
UNIVERSITIES — 9
- University of Bern 5
- University of Geneva 2
- University of Fribourg 1
- Fondation Campus Biotech Geneva 1

EPF — 4
- EPFL 2
- ETH Zürich 2

PRIVATE — 11
- Fondazione Epatocentro Ticino 4
- DOPPL SA 1
- CK-CARE 1
- Davos Biosciences AG 1
- Swiss Paraplegic Research 2
- Balgrist Campus AG 2

The biobanks are well spread within Switzerland covering the majority of districts, and are hosted by different types of institutions. Efforts have to be made to increase this number, but the approach built up by SBP has demonstrated its efficiency so far and will be further developed to extend its network.

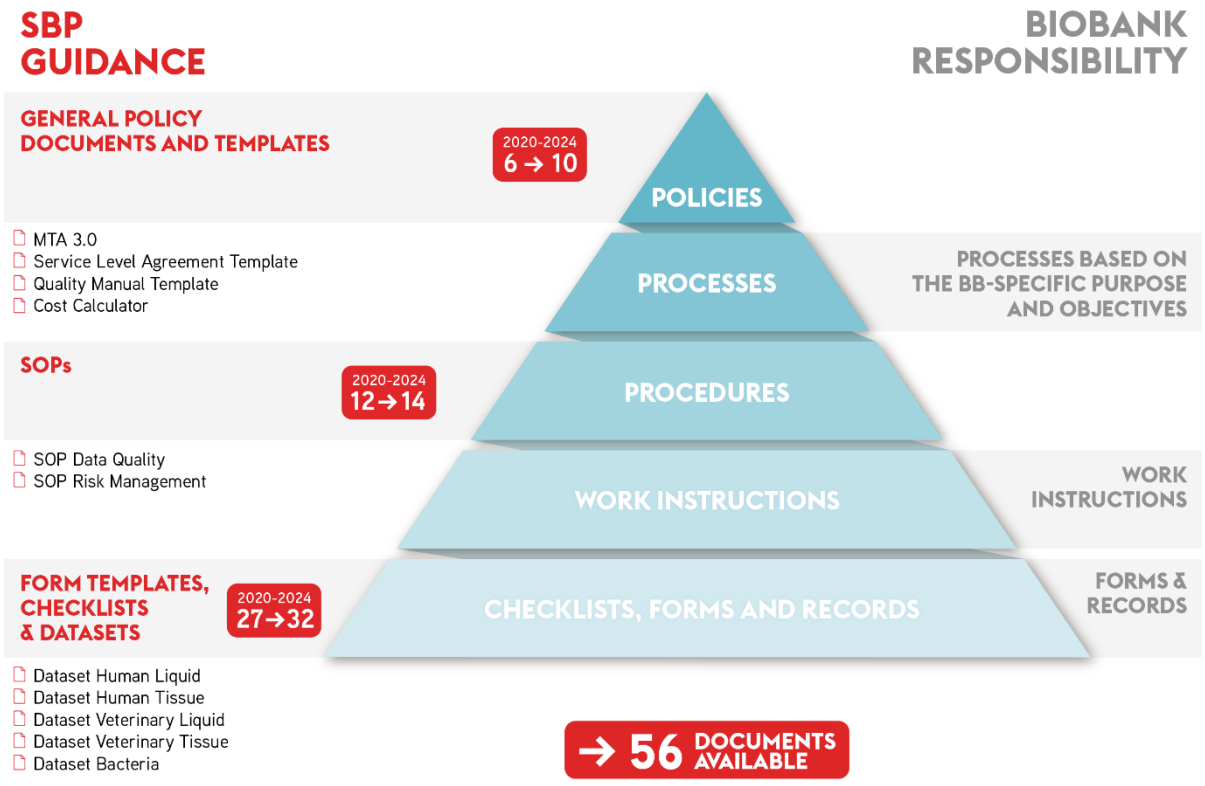
To maintain trust and foster collaboration, each partner biobank is contacted yearly for an annual review to ensure accuracy of the information provided to the biobank users and to reflect up-to-date practice of the biobank. During this update, SBP collects some Key Performance Indicators, that are reported at the European level, on the organization of the biobanks but also on the research activity that is performed with the stored samples.



SBP Docs

Along the evaluation process, SBP provides biobanks with the necessary documentations to build up and maintain state-of-the-art biobanks organized into a SBP guidance described in the figure below. Biobank and sample quality is based on documented information at every step of the biobanking processes.

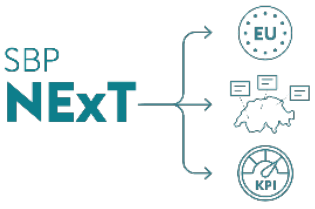
SBP provides guidance with a large set of documents including policies, procedures, templates and datasets covering crucial aspects biobanks should follow in terms of governance, quality and interoperability. This guidance is accessible in the document library on SBP website[3] and should be considered as the national standards supporting harmonization and interoperability within the Swiss biobanking community.



The provided documents represent a consensus between the Swiss field experts and are based on the applicable professional standards including the new ISO norm 20387. On demand, SBP can provide additional support and training on specific questions, or if necessary, develops new documents relevant for the biobanking community.

VISIBILITY

SBP tries to tackle one of the biggest challenge biobanks face: the under-used and sharing of biobanked samples. To overcome this challenge and to respond to the increasing demand for sample visibility, access and interconnectedness, SBP has developed a Swiss e-



[3] https://swissbiobanking.ch/documents/

catalogue directory that offers the possibility for researchers to easily connect with biobanks and search for samples of interest based on a personalized set of search criteria.
This centralized national e-catalogue, called SBP Network Exploration Tool (SBP NExT), combines the features of a directory (search at the biobank level) with the ones of a catalogue (search at a sample level) using visualization aspects to facilitate the ergonomy and the user experience.

NExT is a monitoring, exploration and communication platform for biobanks and researchers as an innovative and interactive instrument provided by SBP to

- foster visibility of biobanks and biobank infrastructures in the SBP network,
- enable search and exploration of biobanking entities as well as biological samples,
- help biobank administrators and researchers to find a mutual agreement facilitating the transfer of biological material with key documents (e.g. MTA) uploaded in the system.

NExT has then been developed to maximize visibility through a network, where connections between biobanks and researchers are enabled not only on a national level but throughout Europe via the BBMRI Directory.

The e-catalogue (SBP NExT), officially launched in 2021[4] is featured in its initial version the SBP directory only.

For biobankers, it is a monitoring platform to upload samples, choose their visibility level (for the research community at large or for a selected community) and manage access policy at a later stage. For researchers, it is an exploration platform to search for biobanks and samples integrating pre-analytical data as well as a communication platform with the biobank once the samples of interest have been selected.

Before providing biobanks with the possibility to import their sample data in the NExT and based on the results of a risk analysis, SBP has proposed and implemented measures to enhance Data Security and Data Privacy and to safeguard the interests of all stakeholders including the research participants. To test the system, two pilot biobanks agreed to import their sample data, the Swiss Health Study (SHeS) and the Tissue Biobank Bern (TBB). The NExT is planned to be fully operational in 2025.

INTEROPERABILITY

To promote the exchange and the use of biological samples, the sample-related data from different biobanks needs to be comparable and searchable by researchers to assess the sample suitability for their projects. To that end, relevant sample data needs to be documented in a standardized way and implemented in professional systems. In this effort to standardize associated data and increase the

[4] https://swissbiobanking.ch/next-biobanks/

quality of data recording, SBP has worked with experts from various biobanking domains to establish datasets.

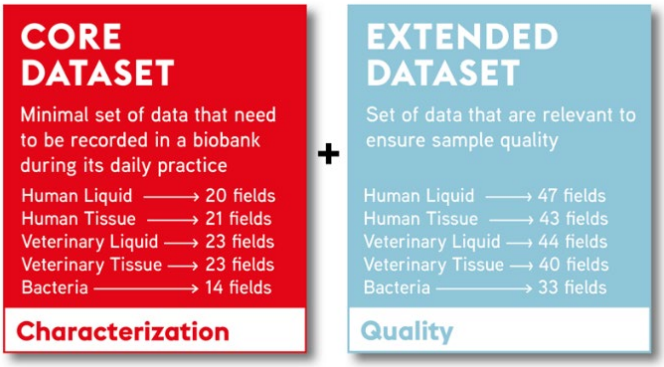
SBP Datasets → SBP SMPL → SBP NExT

This development is aligned with current SBP interoperability activities aiming at:

- Engage biobanks in the documentation of sample-related data by identifying the minimum information to be documented for their internal activities;
- Provide a step-by-step approach to facilitate the implementation of these datasets;
- Support the future development of a SBP BIMS by integrating these datasets (Core and Extended) into the biobank sample workflow;
- Be integrated in SBP Labels to be checked during the SBP VITA Label process to help their implementation in the biobanks' daily practice.

Datasets

The publication of our first 5 datasets (DS) for tissue and liquid samples derived from human and animals (in 2018), as well as for bacteria (in 2019) was the first step to provide guidance to biobanks on sample-related documentation and towards biobank interoperability. This important achievement was the result of the involvement of national experts who agreed on a list of data that need to be documented for each sample (SBP DS v1.0). To facilitate their implementation by the biobanks, SBP has revised the v1.0 version of its Datasets introducing a segmentation into a Core dataset and an Extended dataset. The Core dataset contains a minimal set of data a biobank shall document to characterize the samples, whereas the Extended dataset list the other variables that need to be documented to ensure sample quality.



In 2023, the Core Datasets for human liquid (20 variables) and tissue (21 variables), for bacteria (14 variables), and for veterinary liquid (23 variables) and tissue (23 variables) were published.
In 2024, the other variables defined in the Extended Datasets have been published for human liquid (47 variables) and tissue (43 variables), for bacteria (33 variables), and for veterinary liquid (44 variables) and tissue (40 variables).
The interest of generating datasets in other fields has led to start a new collaboration with EPFL and a development is currently on-going to create new datasets for organoids and iPS cells.

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

Biobanks are under ever growing pressure to improve the documentation of their sample-related data and activities. The complexity and sheer amount of data to record makes it necessary to use dedicated systems that will facilitate traceability as required by the Human Research Act (HRA) and interoperability to promote sample exchange and comparability.

Such systems called Biobank information management systems (BIMS) have become a necessary tool towards proper documentation and traceability of biological samples. Unfortunately, deploying such a solution is often prohibitively complex, time consuming and expensive for the biobanks, explaining why many biobanks are using excel sheets.

Another challenge is the simultaneous complexity and uniqueness of processes used in each biobank protocol, which prevents availability of off-the-shelf solutions, resulting in the need to externalize many hours of custom development. Thanks to its large network, SBP is in the unique situation of understanding specific needs of biobanks and translate them into a professional Biobank Information Management System (BIMS) that will respond to the aforementioned challenges.

A new BIMS Concept

SBP is working on a new Biobank Information Management System (BIMS) concept that will offer a common basis for harmonization and sharing of information across Swiss biobanks, in complement to the already available BIMS in the University Hospitals and on the market.

This new concept should provide biobanks with an affordable, adaptive, interoperable, and interconnected solution:

- **Affordable** in terms of cost and operation
- **Adaptive** to almost any biobanking use-case in both human and non-human applications
- **Interoperable** with the SBP Datasets integrated in the solution
- **Interconnected** with the SBP e-catalogue (NExT) to enable the seamless integration of sample-related data that will be made available for sharing

SBP BIMS concept is under development using the DiData company, a LIMS provider chosen in June 2022 by an independent panel of experts through an official public tender. A security assessment of DiData with penetration tests demonstrated a well-constructed solution particularly permeable to data segregation and aligned with security requirements. At the end, DiData has been selected as the perfect candidate to collaborate with for the co-development of the new SBP BIMS concept.

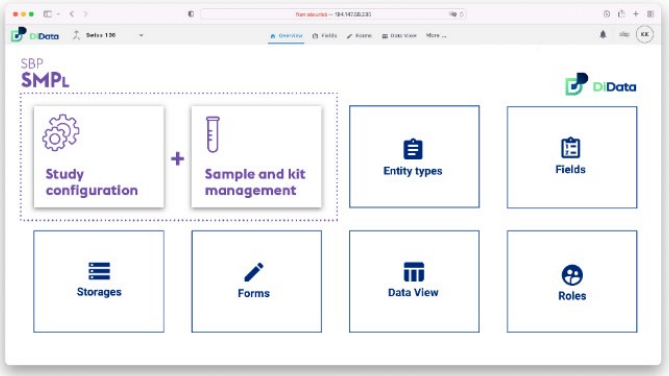
This development is also aligned and supported by the University Hospitals being interested in a complementary tool to the other BIMS already in place. To that end, the CHUV University Hospital already working with DiData has been identified as a privileged partner to help SBP develop and test this new BIMS concept.

SBP Sample Management Plugin (SMPL)

The new BIMS concept consists in the integration of a specific plugin developed by SBP, the so-called SBP Sample Management Plugin (SMPL) into any BIMS compatible solution such as DiData.

This Plugin (SMPL) has two modules:

- a Study configuration module to help biobanks configure their workflows;
- a Sample and kit management module to manage their day-to-day operations.

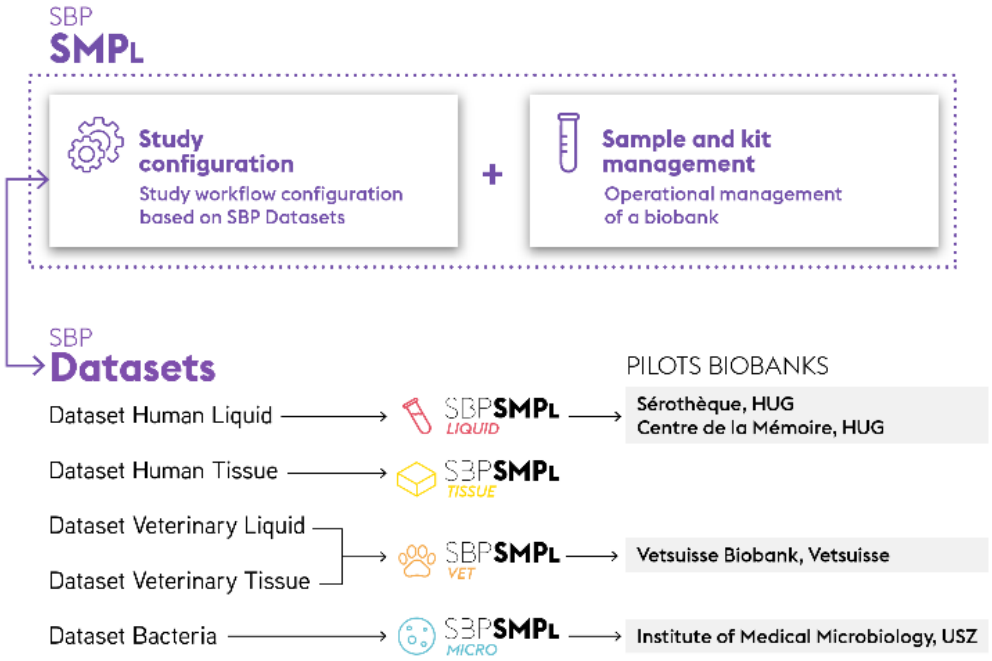


The SMPL modules are using an innovative event-based method for accurately modelling any biobanking workflow through visual building blocks. This method provides biobanks with preconfigured systems integrating the SBP Core and Extended Datasets in different biobanking environments.

The SMPL method offers the following benefits:

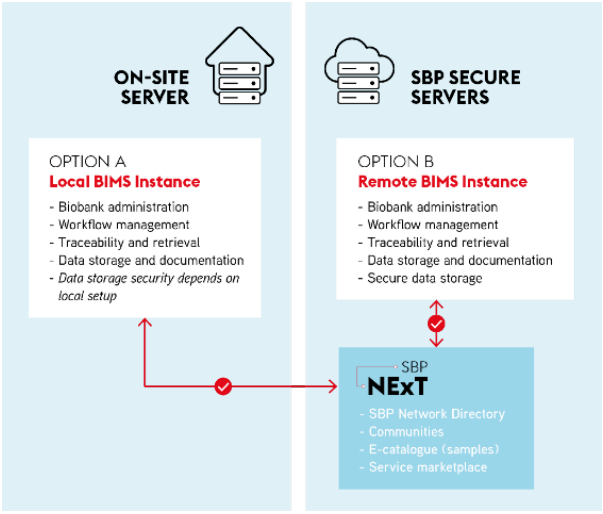
- It allows biobank administrators to make the most custom changes themselves such as add biobank specific datasets, without relying on dedicated IT services.
- It facilitates day-to-day operations and reduces the need for dedicated training.
- It readily integrates SBP's harmonized datasets and recommendations for improved data quality.

Depending on the biobank organization, SBP can also support or customize the workflow as an additional service, instead of the biobank doing it by itself.



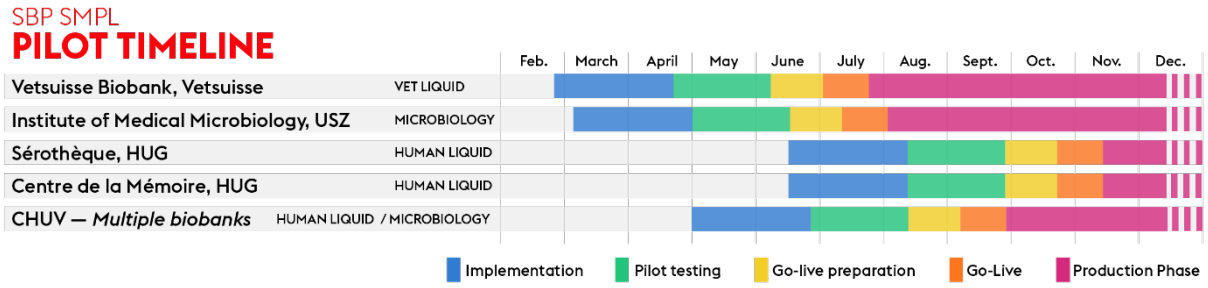
Pilot biobanks

The SBP SMPL first prototype raised a lot of interest when presented at SNSF 11th May 2023 to biobank specialists coming from different Swiss regions and biobank environments (human liquid, human tissue, veterinary, microbiology, from the public and private sectors). On this occasion, SBP identified eight pilot biobanks interested to help shaping the SMPL plugin to their needs.



SBP organized first business analyses for each pilot to to understand their sample life cycle and workflows. For six of them, the process continued with regular operational meetings to integrate their workflows into the SMPL environments. A last meeting before the implementation phase was organized to present the business model, the cost to have the DiData solution hosted, either on a local instance within institutions (Option A) or on a remote instance at BioMedIT (Option B) and the timelines.
The SBP BIMS is, in any option, integrated in the SBP Ecosystem and will have the sample information further linked with the SBP e-catalogue, SBP NExT.

At this stage, four pilot biobanks are on their way to test the SMPL workflow integrated within the DiData BIMS solution. The future steps are described below with Go-Lives planned in Q3-Q4 2024.



The CHUV University Hospital, hosting many biobanks working on excel sheet and having already on site the DiData system, decided to apply as an institutional pilot. The strategy is to test the potential for an institution to implement the new BIMS concept including the SMPL plugin and scale up to a high number of biobanks, which will benefit from the SBP standardization. For SBP, this model will be a good opportunity to convince the other University hospitals to trust SBP strategy.

Business model and next steps

The affordability of the new BIMS concept integrating SBP SMPL has been extensively discussed and negotiated with DiData. For SBP, the pricing model shall not only be accessible and economically interesting for the biobanks, but also envisioned as a return on investment to SBP for the SMPL plugin development, support and maintenance.
A first agreement was made between SBP and DiData specifying that for each contract DiData signs with a biobank interested in the SMPL plugin, a percentage is paid back to SBP on licence fees:

- 25% for Swiss biobanks,
- 15% for biobanks part of the BBMRI network,
- 10% for biobanks outside of these two networks.

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 in 2024 with a robust business model to contribute to SBP long-term sustainability.

In parallel, SBP is looking for other LIMS provider where SBP SMPL could be integrated. A first candidate already implemented in Universities and cantonal hospitals has been identified and interests from these Institutions have been expressed to collaborate with SBP to develop a suitable solution. SBP is thus almost ready to open the new BIMS concept as a paying service.

SUSTAINABILITY

"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.

SBP Cost calculator

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

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.

The cost calculator is an excel file the biobanks can fill in, based on the user guide instructions. This tool has been reviewed by European experts and will serve as an example at the European level.

EDUCATION

There is a gap in Switzerland around biobank education with a large target audience starting with general interests in biobanking concepts to detailed interests in biobanking processes. This raises the importance of developing a learning strategy that responds to these different needs. For some stakeholders, biobanking is still just a question of storing samples for research ignoring the complexity of biobanking related issues.
After having contributed to a first education program in a "SBP dedicated Biobanking" module within the Easy-Guide for Clinical Studies (Easy-GCS) in collaboration with the Swiss Clinical Trial Organization (SCTO), SBP is very interested in setting up the foundation of biobanking by creating a

harmonized education program. In that context, SBP added a new pillar, education, to reinforce its strategy with the development a first online CAS in Biobanking in collaboration with the University of Geneva, Institut Pasteur and Health Sciences and Training Foundation (HSeT).

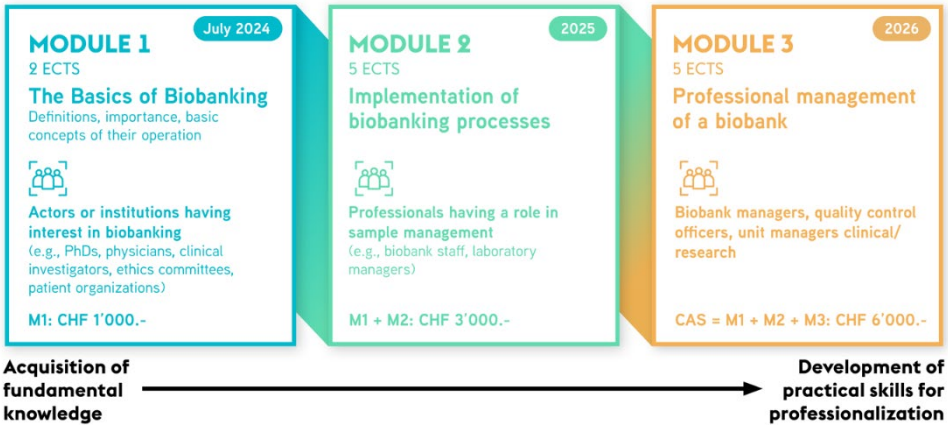
The Certificate of Advanced Studies (CAS) in Biobanking of the Faculty of Medicine at the University of Geneva is an innovative and unique training course developed in Switzerland. The purpose of the CAS is to train worldwide individuals or institutions with an interest in biobanking and research (e.g. PhDs, physicians, clinical investigators, ethics committees, patient organizations) and to give participants the indispensable knowledge and proficient skills critical for the successful establishment and management of a biobank.

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 skills for professionalization.
With this design, the modules target a large audience in a step-by-step approach:

Module 1 provides to any interested stakeholder harmonized training, for laying the foundations of biobanking and to bring everyone up to a common language. It is designed for actors (e.g. PhDs, physicians, clinical researchers, ethics committees, patient organisations) having an interest in learning about the basics of biobanking (Beginner)

Module 2 describes the operational processes for harmonized and efficient sample management, as well as quality storage and personnel management. It is oriented to participants having followed Module 1 or professionals dealing with biological sample management (Intermediate).

Module 3 helps biobank managers to follow up the optimization of the Quality Management System and the ISO accreditation. It targets professionals having followed the previous modules, such as biobank managers, quality control officers, clinical unit managers (Advanced).



SBP contribution to the CAS

SBP is responsible to coordinate the CAS content development and was granted with a financial support from the Loterie Romande for this purpose. SBP will also identify and propose experts in the various fields from the Swiss and European networks that will bring value to this CAS in addition to the experts proposed by the Geneva University and the Pasteur Institute.
In summary, SBP will contribute to this CAS by:

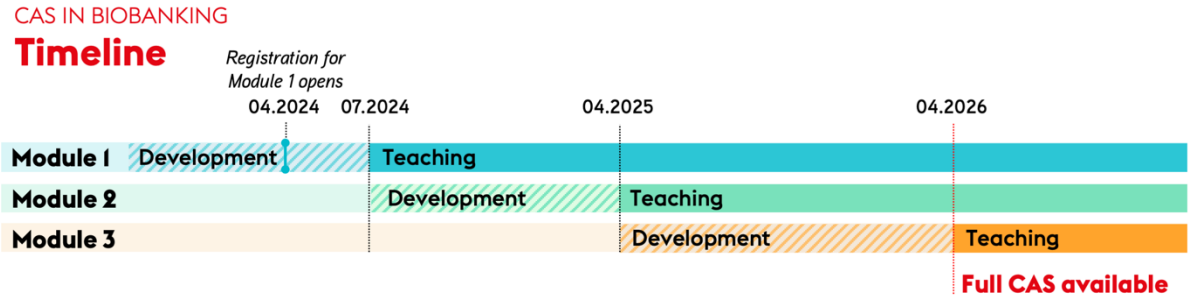
- Developing content and structure of the CAS in collaboration with all other partners
- Offering access to its national and European network for identifying experts
- Promoting the CAS through its website and finding potential students interested in taking one or more CAS modules
- Participating in the evaluation of the candidates during the analysis of the application files.

Release of Module 1

As of the end of March, Module 1 is planned to be promoted in cooperation with the University of Geneva through various channels and supports, including:

- SBP website
- Publication of a short interview with three specific questions about this module to generate interest
- UNIGE brochure and website
- Social media platforms (such as LinkedIn and X) with sponsored and native posts according to an editorial plan
- Targeted mailings, including the SBP Newsletters

The Module 1 is planned to start in July 2024 with opening of registrations in April 2024.
The idea of Module 1 is to give a good overview of the key factors biobanking is dealing with. These key factors will then be more extensively described in the next modules for biobanking specialists.



1.3 Unique selling proposition

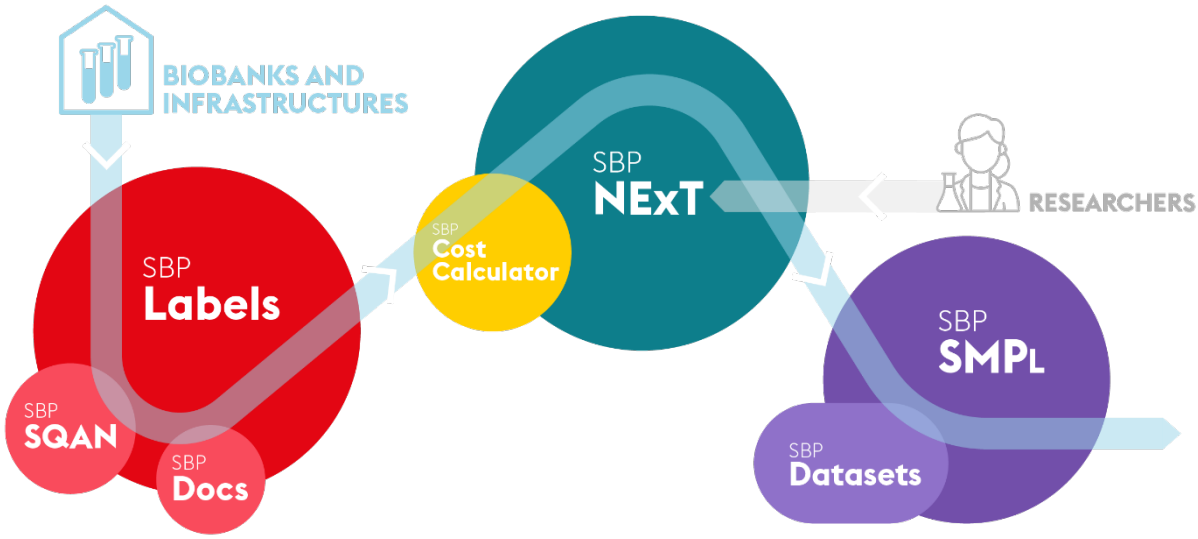
SBP is positioned as an independent professional organization supporting and counselling the Swiss biobanking community on specific needs while bringing awareness and expertise not only to the biobanking community but also to the research community interested in using biological material.
SBP has built up a stepwise strategy over the years to provide a coherent and integrated approach for biobanks and researchers as its unique selling proposition.

SBP serves as an important central contact point for biobanks to get support and to facilitate coordinated development and organization of biobanks in Switzerland.
To enter and be visible into the SBP Network, the collaboration begins with the quality strategy enabling biobanks to benefit from the quality master documents and a compliance review.

SBP provides support to the Swiss biobanks to improve their data/sample management and harmonize their practices through its label strategy. The ongoing efforts to harmonize practices among biobanks with the label approach are combined with a second focus on interoperability with datasets biobanks should document in their daily practice to have comparable samples for researchers.

Second, through its network of Swiss biobanks connected to the European network through BBMRI Directory, SBP also improves the recognition of biobanks in Switzerland, by enhancing their visibility and advocates for their national and international representations.

By offering quality master documents and IT tools (e.g., SBP BIMS) as well as educational support, SBP has the potential to address the limitations faced by numerous biobanks and increase the awareness of quality aspects to improve reproducibility in biomedical and biological research.



4. Data strategy

4.1 Data management and compliance with SNSF Open Research Data policy

SBP is not generating any data and has the only function of making biobank data visible for the research community through the SBP Sample catalog called the SBP NExT.
SBP provides the biobanks with the necessary support ensuring them to produce FAIR data and follow the SNSF ORD policy and requirements.
Among the tools and services, SBP offers its biobank partners to reach this goal

- Document the biobank practice by following the SBP standards (incl. SBP Core and Extended Datasets) as part of the standardization effort to promote data quality and interoperability.
- With a preconfigured BIMS already integrating these datasets to help their implementation in the daily practice.
- Use a communication and exploration tool, the SBP NExT to increase the visibility of biobanks and facilitate the access and sharing to well-annotated samples including pre-analytical data to researchers thereby promoting the FAIR principles.
- Be visible in the BBMRI-ERIC IT tools such as the Federated Platform, the Directory and negotiator.

4.2. National and international linkage

To guarantee the interoperability among different biobanks and across systems (e.g. between sample catalogs or between BIMS) it is crucial that the documentation of sample history follows common standards. This applies also to biobanks for which harmonizing the terminology and defining the minimum of common overlapping information is a prerequisite for the interoperability among biobanks and facilitates the exchange of samples. To continue its work supporting this effort in data standardization, SBP is collaborating with experts at national level to develop new datasets (e.g. DS on organoids and on iPSCs with experts from EPFL) or at European level in taking part to the MIABIS (MINIMUM INFORMATION ABOUT BIOBANK DATA SHARING) working group launched by BBMRI with a focus on the development of an OMICs dataset. For this important development, SBP has involved national experts (from the Genome Center in Geneva and Swiss Multi-Omics Center in Zurich) to take part of this WG with SBP and provide relevant input and feedback.

SBP has no direct link with the European Open Science Cloud, but through its involvement in BBMRI-ERIC, SBP can be informed on the major developments and foreseen collaborations where relevant.

4.3. Data access and sharing

As described in part 2.2 on User access and fees, users get access to a unified security layer called Keycloak that manages authentication, authorization and single sign-on on all the SBP ecosystem. Trusted users will have facilitated access to SBP tools with the same identification information. The registration system is only valid once users have agreed to the SBP privacy notice and terms of use of each tool as required by the Data Protection Law.
In terms of data access and sharing, researchers can connect to biobanks through SBP Sample Catalog (NExT) (see part 3.2 on Visibility). This platform enables an efficient search by researchers to look for samples of interest that can be used for their research projects. SBP NExT is hosted at Lausanne University in a secure environment administered by Swiss Institute of Bioinformatics (SIB). No dataset can be exported by the users, they only have the possibility to send an inquiry to the biobank for the samples that fulfilled their inclusion criteria.

Though SBP NExT is currently functional, 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.
As of March 2024, the Swiss Health Study (SHeS), the Liquid Biobank Bern (LBB) and the Tissue Biobank Bern (TBB) have imported their sample-related data in the system. Several other biobank partners are in the pipeline to pursue with the support of SBP this important task and make their samples visible to the research community.

5. Budget for the period 2021-24

5.1 Expenses on SNF budget

Activity of SBP in general	**2021**	**2022**	**2023**	**2024** *(projection)*	**TOTAL SNF**
Total Salaries *(incl. social security and contributions)*	**775’818.01**	**778’284.96**	**900’102.26**	**1’100’000**	**3’554’205.23**
Total Overhead	**-**	**-**	**-**	**-**	**-**
Total Operations	**239’942.48**	**220’503.69**	**117’057.13**	**164’000**	**741’503.30**
IT costs (cloud, server, licences, etc.)	115’414.50	69’288.04	16’764.98	37’000	
Other infrastructure costs (office, HR, finances, legal services, basic IT equipment for all staff, books, etc.)	75’707.12	94’652.67	95’188.60	112’000	
Events, travel, teaching, training	17’240.68	25’542.14	5’103.55	15’000	
Expenses for subcontracting	31’580.18 (BBMRI)	31’020.84 (BBMRI)			

5.2 Third party funding, additional income

Detail any additional expenses covered by additional income and funding (cash and in kind) according to the following table:

Activity on BIMS and CAS	**2021**	**2022**	**2023**	**2024** *(projection)*	**TOTAL**
Third party fund from Loterie Romande - BIMS Describe shortly the activity and the incurred costs		**10’701.34**	**158’901.82**	**69’930.86**	**239’534.00**
Third party fund from Loterie Romande - CAS Describe shortly the activity and the incurred costs			**17’989.45**	**42’476.55**	**60’466.00**