**SWISS
BIOBANKING
PLATFORM**

REPORT
2019-2020

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INTRODUCTION

Swiss Biobanking Platform (SBP) is the national coordination platform for biobanks in human and non-human domains. It is an initiative of the Swiss National Science Foundation (SNSF), which responds to the increasing needs of researchers in biomedical sciences in terms of quality, access, transparency and the interconnectedness of biobanks and their basic data for research purposes.

In Switzerland, biobanks operate with heterogeneous processes, are not registered, making the search for and comparability of samples difficult and their use critical due to compatibility issues of the different sampling methods applied. Moreover, biobanking practice has greatly evolved over the last years, from the individual collection of biological material to professional infrastructures dealing with ethical and legal issues, accessibility and data sharing, reproducibility, data protection and quality leading to a dramatic increase in the costs of biobanking activities. SBP has been created to respond to the needs of the Swiss research community facing these challenges.

In 2013, the SNSF launched a competitive call for concepts for constituting a national biobanking platform. SBP concept was selected by an international panel of experts in biobanking activities. Founded in 2014, SBP is presently in its consolidation phase. The initial funding period was ruled under the SNSF-SBP agreement 2015-2018 with a budget of CHF 3.2 Mio for 4 years. Funding for the years 2019 and 2020 in the same range is available and, the SNSF and SBP have elaborated and agreed on a new agreement and aims and milestones for this period.

The agreement for the period 2019-2020, detailed in Appendix 1, is focused on three major issues:

1. SBP structure and management are consolidated. SBP is positioned as the quality reference in the Swiss human and non-human biobanking community and as the national node of BBMRI-ERIC.
2. SBP develops guidelines to facilitate access to biobanking samples by establishing a Swiss biospecimen catalogue at the sample level in collaboration with SPHN.
3. SBP drives the quality management of biobanking activities.

Based on the previous SBP achievements, this agreement aims at consolidating SBP position as the reference for biobanking activities in the Swiss research landscape with the implementation and use of its documentation and related services.

In summary, and in accordance with the SNSF vision, SBP is centralizing information on human and non-human biobanks, which have been established for serving specific scientific questions and ensuring broad access to these biobanks for research purposes. It holds a register of biobanks in Switzerland. It provides up-to-date technical know-how and support for biobanking and IT management (e.g. "good biobanking practices", know-how on sampling, samples conservation and information processing), and counselling on legal and ethical aspects, quality and interoperability of biobanking. Moreover, SBP links Swiss biobanks or networks of biobanks with the European Biobanking and Biomolecular Research Infrastructure (BBMRI-ERIC) as the Swiss national node. It ensures the harmonization of biobanking practices with international and EU standards, provides information on biobanks networks abroad and the related activities.

This report is the closing report of the activity period 2019-2020 as delineated in the agreement 2019-2020 between the SNSF and SBP.
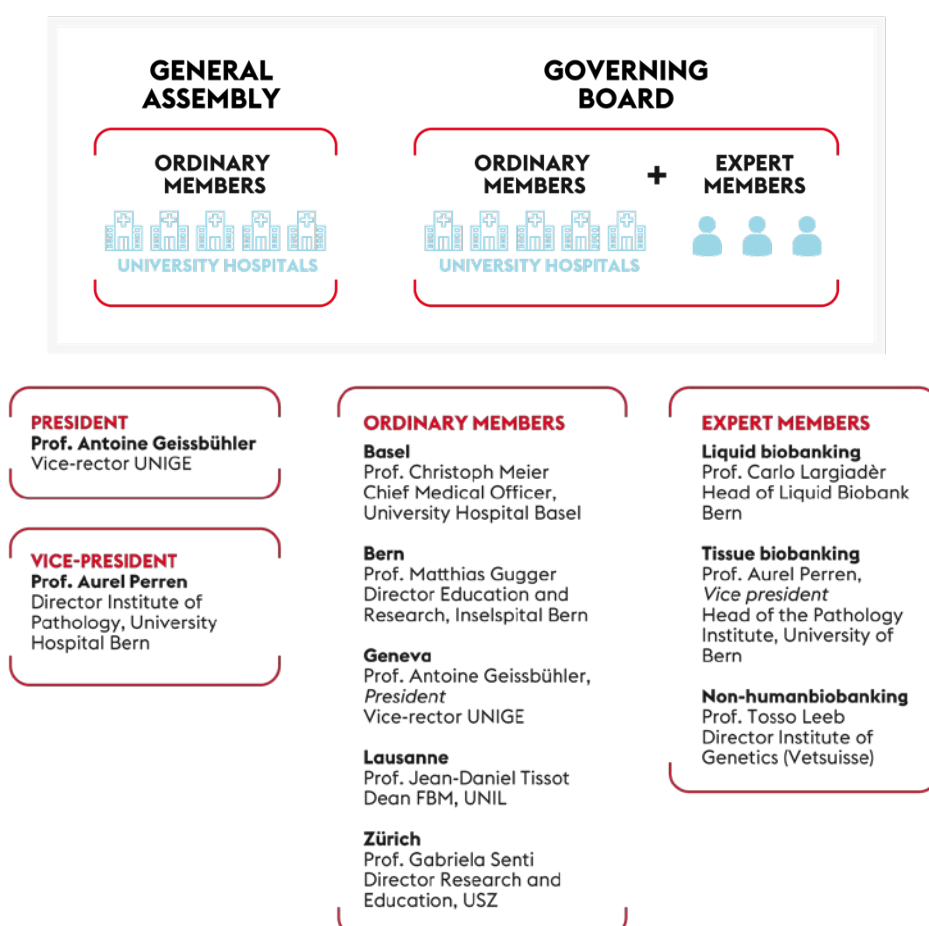
GOVERNANCE

Swiss Biobanking Platform (SBP), as the national coordination and reference platform for biobanking activities in all fields of research, is an independent association with a governance defined in SBP bylaws (https://swissbiobanking.ch/sbp-boards/).

Since September 2019, the new SBP governance structure is in place: Ordinary members are part of the General Assembly and of the Governing Board, and expert members are part of the Governing Board. Pr Antoine Geissbühler, Geneva University Hospital, assumes the presidency and Pr Aurel Perren, Bern University Hospital, the vice-presidency for a three year period (2018 to 2021).

The ordinary members are the University Hospitals of Basel, Bern, Geneva, Lausanne and Zürich. Each ordinary member appoints an individual member of the general management to act as its representative in the General Assembly and in the Governing Board.

The experts are chosen by the General Assembly according to the development and positioning of SBP. This flexible appointment enables the Governing Board to gather expertise for proper decision making in a fast moving field and environment.

In the last two years and according to the bylaws, the General Assembly met twice and the Governing Board seven times.

GENERAL ASSEMBLY

ORDINARY MEMBERS
UNIVERSITY HOSPITALS

GOVERNING BOARD

ORDINARY MEMBERS   +   EXPERT MEMBERS
UNIVERSITY HOSPITALS

PRESIDENT
Prof. Antoine Geissbühler
Vice-rector UNIGE

VICE-PRESIDENT
Prof. Aurel Perren
Director Institute of Pathology, University Hospital Bern

ORDINARY MEMBERS

Basel
Prof. Christoph Meier
Chief Medical Officer, University Hospital Basel

Bern
Prof. Matthias Gugger
Director Education and Research, Inselspital Bern

Geneva
Prof. Antoine Geissbühler, *President*
Vice-rector UNIGE

Lausanne
Prof. Jean-Daniel Tissot
Dean FBM, UNIL

Zürich
Prof. Gabriela Senti
Director Research and Education, USZ

EXPERT MEMBERS

Liquid biobanking
Prof. Carlo Largiadèr
Head of Liquid Biobank Bern

Tissue biobanking
Prof. Aurel Perren, *Vice president*
Head of the Pathology Institute, University of Bern

Non-humanbiobanking
Prof. Tosso Leeb
Director Institute of Genetics (Vetsuisse)

SBP EXECUTIVE OFFICE (from September 2019)

In 2019, SBP executive office has restructured and consolidated its expertise on specific biobanking domains with specialized collaborators. These domains are governance, interoperability, visibility and quality of biobanks.

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                        CHRISTINE CURRAT
                        Executive Director

                                              MARINE VALLOTTON
                                              Assistant Manager

        SABINE BAVAMIAN
        Chief Scientific Officer
                                              LOUISE ROY
                                              Communication Officer


JOSÉPHINE ULDRY     DOROTHÉE CAMINITI      RIAD GACEM        KHALIL KLOUCHE
Quality Officer     Legal and Ethical      IT Engineer       Data Visualization Engineer
                    Officer
```
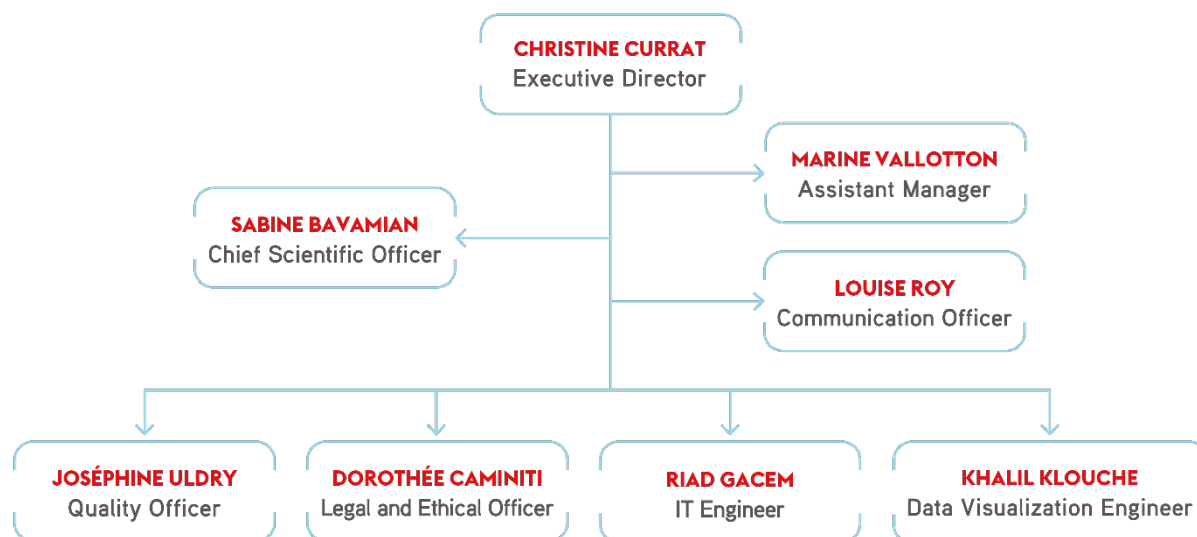
In 2020, the SBP executive office has been enlarged with IT specialists in order to develop the interoperability strategy and the dedicated SBP e-catalogue to foster visibility, access and sharing of samples for research purposes. SBP also appointed an IT solution architect as consultant, with a former experience within the SPHN network, to ensure a comprehensive and easier integration of the SBP e-catalogue with the data-related interoperability solutions developed at SPHN.

Globally, SBP executive office is thus in the position to offer specialized and competent advice and services to professionally advise biobanks and researchers on scientific, quality, governance and interoperability issues, as described in the present report.

SBP GOVERNANCE in summary

> SBP adopted major modifications in its bylaws in September 2019 approved by the SNSF Presiding Board.
> New members were integrated in the SBP governance :
>> ordinary members, representatives of the five University Hospitals general management
>> expert members, part of the Governing board.
> SBP executive office provides state-of-the-art services to support biobanks on governance, interoperability and quality issues.

COMMUNICATION

(measures 1.1, 1.2, 1.3, and 1.4)

As defined in the first aim of the 2019-2020 Agreement, SBP has reinforced its communication strategy with a clear positioning of the platform in the Swiss research landscape and with the identification of the main SBP stakeholders.

SBP POSITIONING

SBP is the reference research infrastructure supporting human and non-human biobanks harmonizing their practice and promoting high-quality research using biobanked samples.

SBP vision is to contribute to position Switzerland at the forefront of biomedical and biological research by facilitating access to and optimal usage of high quality biobanked specimens.

SBP mission is the coordination and harmonization of biobanking activities by increasing visibility, high quality, transparency, accessibility and interoperability of biobanks.

SBP clients are not only the biobanks and the biobank infrastructures, but also the biobanks' users (researchers, clinical research units, quality managers) that will benefit from the biobanks' harmonization, accessibility to samples and/or to biobank infrastructures to facilitate the setup of their research and even allow new research venues.

SBP STAKEHOLDERS' MAPPING

The stakeholders were classified in five major categories as presented in the scheme below.
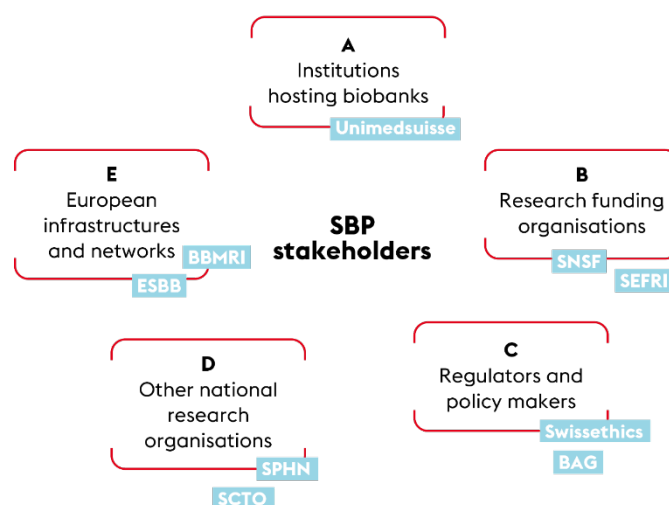
A.   Unimedsuisse

Unimedsuisse recognizes SBP as the national research infrastructure fostering biobank harmonization. The committee was convinced by the crucial role of SBP as the reference for biobanks to adhere to the governance and quality requirements, helping them with a set of services and preparing them to the new ISO norm.

B.   Swiss National Science Foundation (SNSF)

SNSF is the founder and funder of SBP as well as the funder of the Biolink projects in collaboration with SBP. In 2020, some Biolink projects could be used as pilot projects for the development of the new SBP e-catalogue called the SBP NExT.

C.   Swissethics and Federal Organization of Public Health (FOPH/BAG)

Swissethics has endorsed the Material Transfer Agreement (MTA) and the biobank regulation that SBP has developed. Swissethics advises biobanks and researchers to use them as the national templates.

SBP collaborates actively with the Federal Office of Public Health (FOPH) in the development of the Swiss Health Study Pilot project.

D. Swiss Personalized Health Network (SPHN) and Swiss Clinical Trial Organisation (SCTO) (measure 1.2)

A meeting to better coordinate Swiss research infrastructures in the biomedical field took place at SNSF on 9 April 2019 with the presidents and directors of SCTO, SPHN and SBP, organized by SNSF. They decided that representatives of the three organizations should participate as guests in their respective steering boards to promote collaborations where it is necessary and to avoid overlaps in the future.

E. BBMRI and ESBB (measure 1.3)

As the Swiss node in the BBMRI network, SBP attended regular management committee meetings and participated in the implementation of different common services and developments in the ELSI, quality and IT domains.

SBP also participates in the European and Middle Eastern Society for Biopreservation and Biobanking (ESBB), to enlarge its expertise with other working groups from the non-human field.

WEBSITE

SBP website (https://swissbiobanking.ch) is the central communication tool and is regularly updated to highlight the major changes and progresses of SBP (e.g. biobank SQAN, new elected Governing Board members) as well as key information on the biobanking field (announcement of international meetings, news from BBMRI, etc.).

In 2020, SBP has launched a redesigned website that proposes a more structured information on SBP services through streamlining menus and a simplified navigation. This new content includes an easier and facilitated access to SBP practical documentations (e.g. SBP SOPs, guidelines, recommendations) to support biobanks in the harmonization of their practices. Through the new login process, a more accurate monitoring on the visitors is done to better understand the needs of SBP clients and stakeholders.

SINCE THE NEW WEBSITE LAUCH
May 15th to August 15th / 3 months

72 REGISTRED USERS

262 DOWNLOADED DOCUMENTS

SBP MTA MOST DOWNLOADED DOCUMENT

SOCIAL MEDIA

SBP experienced the use of social media with the relay of each newsletter on LinkedIn enterprise page and used Twitter to highlight and share important information on SBP mainly followed by BBMRI partners and Swiss researchers.

SOCIAL MEDIA

255 TWITTER FOLLOWERS

262 LINKEDIN FOLLOWERS

NEWSLETTERS

The newsletters in form on SBP deliverables and activities. They are sent to the SBP network and included in the BBMRI newsletters. In 2019 and 2020, eleven newsletters announced important steps at SBP:

2019

Newsletter N°17 — 10.01.2019 — SBP is looking for beta testers!
Newsletter N°18 — 15.02.2019 — Invitation to SBP Workshops **MOST OPENED AND CLICKED IN 2019**
Newsletter N°19 — 28.05.2019 — MTA and DTUA templates are available for researchers
Newsletter N°20 — 22.08.2019 — SBP at the Europe Biobank Week 2019
Newsletter N°21 — 14.11.2019 — BIMS guidelines are published!
Newsletter N°22 — 17.12.2019 — Happy Holidays!

**2
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2
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Newsletter N°23 — 19.03.2020 — SBP new expertise and deliverables
Newsletter N°24 — 20.04.2020 — Research on COVID-19: What can we do to help the research community? **MOST OPENED IN 2020**
Newsletter N°25 — 18.05.2020 — SBP new website and innovative exploration tool **MOST CLICKED IN 2020**
Newsletter N°26 — 10.08.2020 — Intellectual property and research
Newsletter N°27 — xx.09.2020 — *Planned on the quality control strategy*
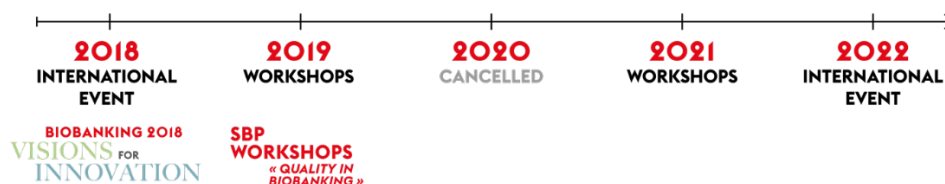
NEWSLETTERS

704
SUBSCRIBERS

EVENTS

SBP organized two main events, an international conference to strengthen its position as the Swiss node of BBMRI and a workshop day on quality for the Swiss biobanking community in 2018 and 2019. Both events dealt with the challenges the scientific community has to tackle, especially the implementation and usage of harmonized procedures, high quality standards or sustainability issues including ethical, legal and social dimensions.

In 2020, a workshop on biobank interoperability in collaboration with SNSF was planned to setup the features of the next BioLink call taking into account the changes in the Swiss biobanking landscape. This event was postponed to 2021 due to the COVID-19 situation.

Within the next four years, SBP plans to organize each year, and in alternation, a national workshop and an international symposium on specific biobanking topics. The aim of such events is to share updated information and knowledge on the biobanking field with the scientific community

In November 2020, SBP will take part to the online annual Europe Biobank Week 2020 and will present 4 posters on quality strategy, intellectual property, SBP e-catalogue and the SBP NExT tool.

SBP EVENTS

| 2018 INTERNATIONAL EVENT | 2019 WORKSHOPS | 2020 CANCELLED | 2021 WORKSHOPS | 2022 INTERNATIONAL EVENT |

BIOBANKING 2018 VISIONS FOR INNOVATION

SBP WORKSHOPS « QUALITY IN BIOBANKING »

SBP COMMUNICATION in summary

> SBP website is updated to promote its services, and to provide the research community with the essential documents to set up or run a biobank.
> Regular newsletters to update the SBP network on relevant activities
> SBP will organize a biobanking event every year in the coming years on a regular basis.

SBP ACHIEVEMENTS

Unique set of services

SBP provides a unique set of services for the research community at large and is focused on operational and easy to use tools and documentations. These services are regularly updated according to international and national standards on biobanking.

In order to support human and non-human biobanks in the harmonization of their practices and to promote high quality standards, SBP developed the tool SQAN in 2019 and the NExT tool in 2020. This latter enables biobanks' users to access samples and/or to biobank infrastructures for research purposes.
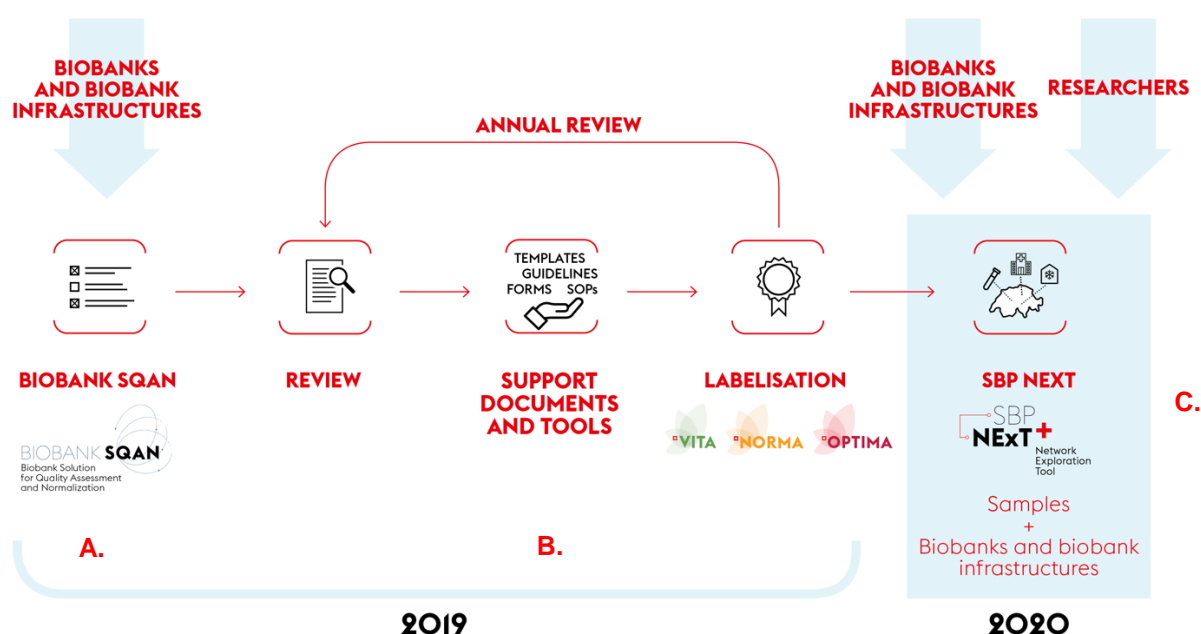
A.   BIOBANK SQAN

An interactive tool to help biobanks get compliant with the minimal requirements in terms of governance, process and quality management. Through SBP Biobank SQAN, different labels validate their compliance with minimal governance (VITA), process (NORMA) and quality (OPTIMA) requirements.

B.   SBP HARMONIZED DOCUMENTATIONS, TOOLS AND CONSULTING SERVICES

Harmonized documentations (e.g policies, SOPs, templates) providing the foundation for the Swiss biobanking guidance in accordance with the European and international requirements. Specific consulting services allow SBP to tailor these products to the clients' needs and interests.

C.   SBP NExT

To give visibility to biobanks through a directory and a request portal for researchers to access high-quality samples.

BIOBANK SQAN

(measures 3.1, 3.2 and 3.4)

BIOBANK **SQAN**
Biobank Solution
for Quality Assessment
and Normalization

CONCEPT

To support biobanks in the development of their governance and quality strategies, SBP developed an interactive tool in collaboration with VITAL-IT, called the Biobank Solution for Quality Assessment and Normalization – "the Biobank SQAN". It helps biobanks get compliant with the minimal requirements in terms of governance, process and quality management issues, through an innovative process to educate biobanks and harmonize their practice by providing specific support and documentations.

The Biobank SQAN integrates the critical factors a biobank should face to evaluate and monitor its practice. It not only addresses 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. These infrastructures are very important for biobanking since they facilitate an efficient biobank development and allow economies of scale for institutions hosting biobanks and also need to reach high quality biobanking standards.

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.

1	2	3	4	5
QUESTIONNAIRE ~ 250 QUESTIONS	**SCORE**	**REVIEW AND REPORT**	**LABELISATION**	**VISIBILITY IN THE SBP NEXT**

ANNUAL REVIEW

Three levels of compliance have been developed according to their degree of compliance:

Ethical and legal issues
for the VITA label
(governance)

Operational issues
for the NORMA label
(process)

Quality issues
for the OPTIMA label
(QMS).

Once the biobanks fulfill at least the VITA label, they become visible at a national level through the SBP directory. If interested, SBP also offers the possibility for the biobank and the biobank infrastructures to appear in the BBMRI directory, by managing the data capture and follow-up within the European network.

For quality reasons, SBP asks the labelled biobanks and biobank infrastructures to update annually their answers in the Biobank SQAN, which will be reviewed by SBP to ensure accuracy of the information provided to the biobank users and to reflect up-to-date practice of the biobank.

RESULTS

SBP network is increasing over time with new biobanks as well as biobank infrastructures. A large number of biobanks has registered spontaneously after having heard from already labelled biobanks, or through the Ethics Commission of Canton de Vaud requiring that biobanks have at least the VITA label to be used in a research project.

Biobanks

In 2019 and 2020, the activity has increased, with 22 VITA labelled biobanks, while 15 are still in the evaluation process. As the NORMA and OPTIMA labels require on-site visits, this activity has not increased as much as expected due to the COVID-19 restrictions, but the interest of the majority of the VITA labelled biobanks is to reach, at least, the NORMA label, as soon as possible.
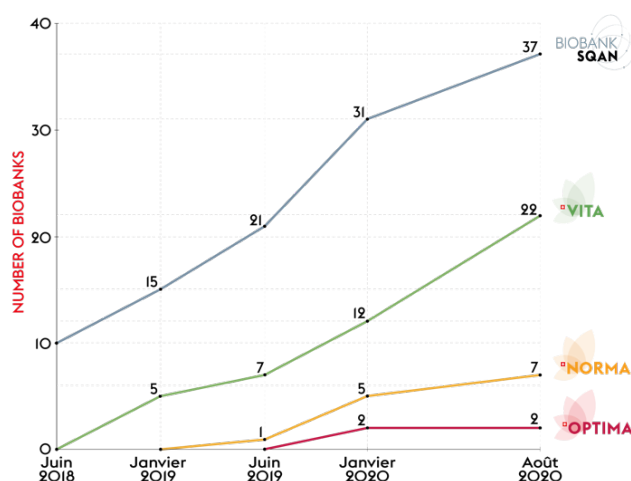
During the evaluation process, the large majority of biobanks are using one or the other of the harmonized documentation provided by SBP; as an example, 9 out of 22 biobanks already use the SBP harmonized biobank regulation.

Biobank infrastructures

In terms of biobank infrastructures, the number of registration has increased which is a great asset as they will encourage biobanks to use them. One biobank infrastructure has reached the OPTIMA label this year, the others being planned in 2021 for the NORMA, and the OPTIMA labels.

As Appendix 2, a detailed list of the biobanks and biobank infrastructures part of the SBP network highlights a well-distributed interest towards Switzerland, with increasing demands from biobanks hosted outside of the University Hospitals and from private biobanks. These will be integrated in the near future, to complete the SBP vision and mission as the reference platform for Switzerland.

Biobanks and biobank infrastructures in the SBP directory

This is a general view of the SBP network with labelled biobanks distributed all over Switzerland.

Biobanks and biobank infrastructures in the BBMRI directory

(measure 1.3)

In 2020, SBP registered officially Swiss biobanks in the BBRMI directory with 10 biobanks and 2 biobank infrastructures (https://directory.bbmri-eric.eu/menu/main/app-molgenis-app-biobank-explorer/biobankexplorer).

This achievement is important for SBP as the Swiss node of BBMRI, since it gives Swiss researchers the opportunity of creating new partnerships and collaborations within the European network and with other BBMRI nodes.

PUBLICATION OF SWISS BIOBANKS AND BIOBANK INFRASTRUCTURES IN BBMRI DIRECTORY

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

BIOBANKS

1.	Covid-19 Ticino Biobank	Fondazione Epatocentro Ticino, Ticino
2.	Geneva Brain Bank	HUG, Geneva
3.	Swiss Pediatric Haematology and Oncology Biobank Network	Kinderspital Zürich, Zürich
4.	Liquid Biobank Bern	Inselspital - Universitätspital Bern, Bern
5.	SHeS-Unisanté Pilot Phase biobank	Liquid Biobank Bern Infrastructure - Biobank Services, Bern
6.	VetSuisse Biobank, VET_GEN_BERN	University of Bern, Bern
7.	AILD biobank	Fondazione Epatocentro Ticino, Ticino
8.	Biobanque Génomique du CHUV	CHUV, Vaud
9.	SwiSCI biobank	Swiss Paraplegic research, Notwill
10.	Tissue Bern Biobank	University of Bern, Bern

BIOBANK INFRASTRUCTURES

11.	Liquid Biobank Bern Infrastructure - Biobank Services	Inselspital - Universitätspital Bern, Bern
12.	Laboratoire Pré-Analytique	CHUV, Vaud

BIOBANK SQAN in summary

> The Biobank SQAN is a five-step process allowing biobanking to get compliant with minimal requirements, helping biobanks improve their processes and quality.
> The Biobank SQAN is the entry point for biobanks to integrate the SBP network, which then gives access to the BBMRI European network.
> The number of registered biobanks and biobank infrastructures is increasing
> The future objective is to enlarge the scope to any Swiss biobanks and to integrate a better representation of the Swiss landscape in the catalogue.

SBP DOCUMENTS, TOOLS AND CONSULTING SERVICES

The entry into force of the new ISO norm 20387 in October 2018 gives biobanks incentives to follow high quality standards. As the gap between the law requirements and their implementation is important, SBP developed a systematic approach to help biobanks reach these standards.

Biobank quality is based on documented information at every step of the biobanking processes. To that end, SBP quality strategy is to provide 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.

SBP guidance provides different types of documents (policies, procedures, templates and datasets) covering crucial aspects biobanks should follow in terms of governance, quality and interoperability and delineates a responsibility gradient between SBP and biobanks.
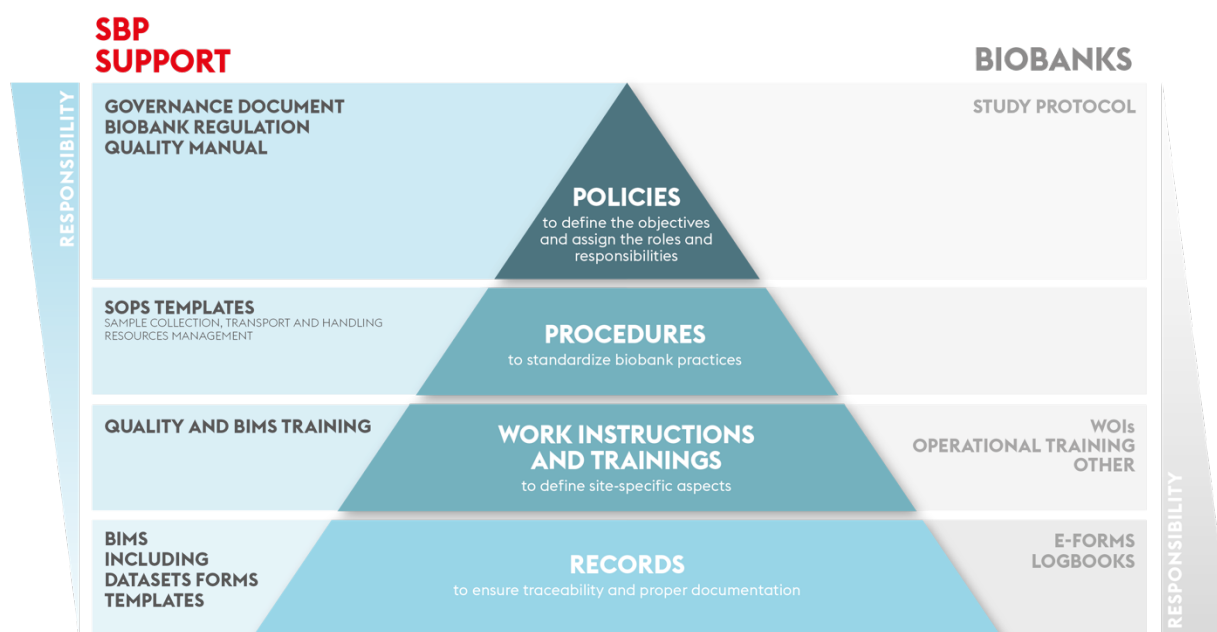
SBP policies rely on the legal and ethical framework in Switzerland and in Europe, have been discussed with experts in these specific fields, and submitted to a public consultation Before publication on SBP website.

SBP procedures (SOPs) are based on Good Biobanking Practices, the new ISO norm 20387 and international standards, and should serve as a reference guidance for biobanks to develop site-specific work Instructions. SBP can provide, on demand, support and training on specific questions as for the Swiss Health Study Pilot project presented in the chapter "partner projects" of this report.

SBP datasets were developed and discussed by different national working groups, based on the international recommendations on preanalytics. They list preanalytical factors impacting sample quality, which shall be documented along the process to ensure an evidence-based approach.

SBP guidance with the related-documents is provided on a fit-for-purpose through the Biobank SQAN review or is accessible in the documents library on SBP website (https://swissbiobanking.ch/which-document-do-i-need/).

To help find the most suitable documents depending on the status of your biobank, SBP provides different use cases and packages described below. The main documents are presented in the next sections divided into SBP governance documentation, SBP quality documentation, SBP interoperability documentation and finally SBP consulting services.

```
                                                        I manage a biobank
  I want to create a biobank                            and I want to...

                              Improve/Labelize                                     Share samples
                              a biobank

   to be compliant with the   to improve samples quality    to implement quality
   law and ethical standards   and operational processes     assurance measures
```

«GOVERNANCE»
To support biobanks to be compliant with the law and ethical standards, SBP provide the following documents.

Governance
- BB regulation
- Responsibilities SOP
- Developing Consent Form SOP
- Best Practices for general consent
- Obtaining consent SOP
- Safety and Complaint SOP
- MTA 1.0 template
- MTA 2.0 template **NEW**
- Ethical, legal and professional compliance list for human research biobanks applicable in Switzerland

IT
- Datasets (Tissue & Liquid / Veterinary / Bacteria)
- BIMS guidelines **NEW**
- Data Protection SOP

«QUALITY»
To support the biobanks performing their daily activities according to the applicable Best Practices and improve the quality of their samples and operational processes, SBP provides the following documents.

RESOURCES
- **Equipment Management SOP**
  - Equipment calibration record
  - Equipment maintenance/repair record
  - Critical Consumables Inventory
  - Equipment Inventory
- **Personnel Management SOP**
  - Personnel File

PROCESSES
- **Biological Material Management SOP**
  - Sample tracking form
  - Shipping Log
  - Sample Acceptance Criteria
- **Data and sample traceability SOP**
  - Participant iD log template
- **Quality Control Management SOP** **NEW** *(planned for septembre 2020)*
  - Quality Control Results
- **Validation of methods SOP**
  - Validation method record
  - Method List

«QMS»
To support the biobanks setting up a Quality Management System including proper documentation and implementation of quality assurance measures, SBP provides the following documents.

- Quality Manual
- **Non-conformity management SOP**
  - Non-Conformity Report
  - Non-Conformity Log
- **Improvement Management SOP**
  - Management Review Report
  - Quality Policy
- **Documentation management SOP**
  - Standard document
  - Standard SOP
  - List of essential documents
- **Internal audit SOP**
- Risk Management SOP (in preparation)
- Internal Communication Document (not provided)
- Business model and cost recovery document (not provided)
- Service Level Agreement Template (in preparation)
- Satisfaction survey (not provided)
- Risk-biosafety check-list (not provided)

«SHARING»
To support the biobanks wishing to share their samples, SBP provides the following documents.
- MTA 1.0 template
- MTA 2.0 template **NEW**
- SBP NEXT (directory)
- Datasets (Tissue & Liquid / Veterinary / Bacteria)
- IP Guidelines (in preparation)
- Shipping Log
- Sample tracking form template
- SBP e-catalogue (in preparation)

SBP governance documentation

1. *"Biobank regulation"*

The Biobank regulation is the mandatory policy defining the biobank purposes, activities, organisation and reflects the daily practices in terms of biobanking. Beyond the compliance with legal and ethical requirements and professional standards, the regulation promotes transparency on the governance of the biobank towards researchers, and thus increase public trust.

This document, published by SBP at the end of 2018 has been endorsed by Swissethics in 2019. In 2020, half of the VITA labeled biobanks use the SBP template as their biobank regulation

2. *"Material Transfer Agreement" (MTA)*

In 2019, SPHN and SBP published, respectively, a Data Transfer and Use Agreement (DTUA) and a Material Transfer Agreement (MTA) in order to facilitate research collaboration in Switzerland and as part of a national harmonization effort to exchange samples and data for research projects between academic institutions.

Upon its publication in 2019, the MTA template (MTA 1.0), endorsed in 2020 by Swissethics, is the most requested and downloaded document on the SBP website. As this template is restricted to the exchange of biological material with preanalytical data only, SBP developed in 2020 the MTA 2.0 that responds to the increasing demands from cohorts or biobanks having not only biological material but also personal data associated. It will be published in October 2020, after consultation by some stakeholders (SPHN, SIB, Swiss Transplant Cohort Study),
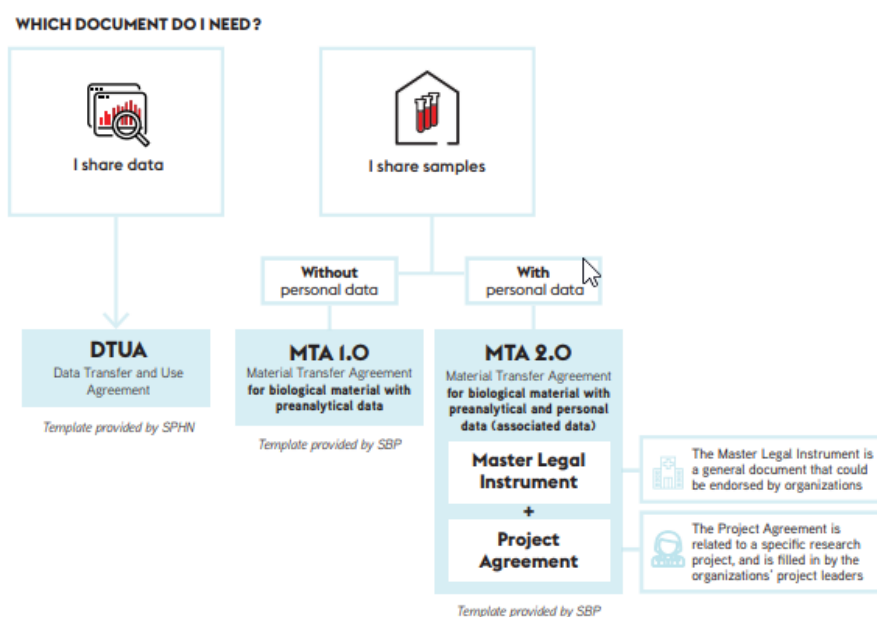
For non-human biobanks, the SBP MTA 1.0 was adopted by Vetsuisse faculty with minor adaptations to allow exchange of biological material for research purposes.

3. *"IP guidelines" – work in progress*

In collaboration with SPHN, SBP is preparing IP guidelines to clarify the personal data and biological material "ownership" question, deliver guidelines on IPR in the Swiss research context, further develop and harmonize the IPR regimes and options offered by the current DTUA, MTA 1.0, and MTA 2.0, and provide IPR related training to researchers.

SBP quality documentation (measure 3.3)

Biobanks have to document preanalytics across all processes and implement adequate sample and process quality controls in accordance with ISO 20387 standard requirements and other international guidelines (e.g."Biotechnology – Biobanking – General requirements for biobanking", ISBER, IARC).

SBP thus developed different documentations in a step-by-step approach: a quality strategy describing the overall quality objectives of the biobank, a procedure focused on the sample quality evaluated throughout a quality control process, and datasets that document each step of the biobank process.

1. *Quality manual – work in progress*

   A quality manual for Swiss biobanks is under development at SBP and will be published in 2021.

2. *"SOP on quality control" (measure 3.3)*

   This procedure provides a guidance on the developments to be implemented by the biobank to assess the quality of its biological material and related activities. This strategy focuses on measuring the performance of a biobank operational processes related to the objectives described in the future Quality Manual.
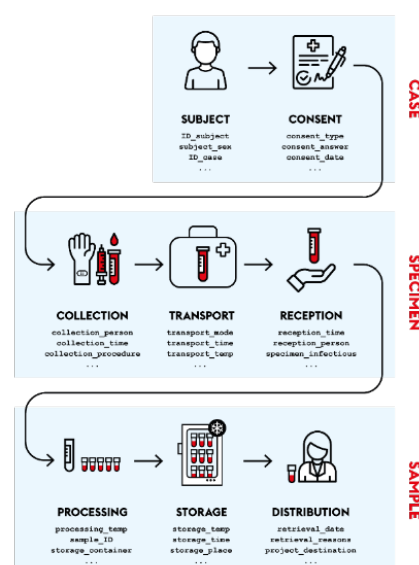
   This procedure has been developed with the support of an SBP expert member and has been submitted to the NORMA-labeled biobanks to gather their feedback on the utility and practicability of the SOP. The publication is planned in October 2020.

3. *"SBP datasets"*

   SBP recommends biobanks to integrate SBP datasets in every step of the sample life cycle to minimize variations and provide researchers with high-quality biological material. SBP datasets represent the minimal data to be documented for each sample to define its quality, focused on the preanalytical data.

   Different SBP datasets are available on SBP website :

   > Liquid and the Tissue datasets:

   https://swissbiobanking.ch/tissue-and-liquid-data-sets/

   > Veterinary datasets :

   https://swissbiobanking.ch/dataset-veterinary

   > Bacteria datasets :

   https://swissbiobanking.ch/dataset-bacteria/

SBP interoperability documentation

1. *"BIMS guidelines" (measures 2.2 and 2.3)*

   The SBP Biobank Information Management System (BIMS) guidelines have been published in late 2019 to support biobanks who wish to acquire a BIMS to manage their biological resources. These guidelines do not favor any commercial solution, but shall be used as a support to biobanks in their software choice by ensuring that the implementing software meet their needs and facilitate their long-term operational management.

   A BIMS should be designed mainly to ensure the traceability of samples and their associated data, ensure the quality of samples, host sensitive data (e.g. personal data and/or clinical data) and preanalytical data, integrate research data and information from other systems (e.g. patient records, laboratory systems, equipment).

SBP consulting services

Besides supporting biobanks and biobank infrastructures through the Biobank SQAN compliance process, SBP is facing an increasing demand for additional specific SBP thus developed internal checklists on several themes to provide specific answers and consulting. Consulting is provided through reports and eventually, to SBP recommendations on the website.

Consultancy reports

SBP provides a professional service, similar to a helpdesk, to guide biobanks, institutions and researchers around key biobanking topics as a way to educate and enlarge its activities. Each demand is documented, analyzed and formalized into consultancy reports with the description of the issue raised and the time for SBP executive office to return the appropriate advice.

As listed in Appendix 3, 37 consulting services were received from February 2020, 51% dealing with governance, 27% with ELSI, 17% with IT and 6% with quality issues. 35% of the requestors are coming from the private sector, a topic that need to be encountered and answered adequately in the near future.

SBP recommendations

SBP issues from its consultancy reports SBP recommendations to make the wider biobanking community benefit from the delivered consulting service. Those recommendations are published on the SBP website (https://swissbiobanking.ch/sbp-recommendation/).

Two first recommendations addressing ELSI-related issues on the retention of original consent forms and the consequences of consent withdrawal were published this year. The third deals with the issue of investing into a specific Biobank Information Management System (BIMS) instead of using Excel to manage their biological samples.

SBP checklists for internal use

SBP regularly updates the necessary documentations to provide up-to-date services to researchers. The COVID-19 pandemics triggered SBP to analyze and advise researchers on Covid-19 biobank creation and sample management. To that end, a specific service was communicated on SBP website.

COVID-19 checklist

To help tackling the immediate need for research and gaining a better understanding of the SARS-CoV-2 to improve the clinical and public health response, SBP offers the research community a "Covid-19 Biobank Biosafety Check" to evaluate biobanking processes and practices around Covid-19 sample handling. The goal is to ensure compliance with the legal requirements as well as with the national and international standards (e.g. WHO and CDC guidelines, and FOPH recommendations).

The biosafety check of Covid-19 biobanks includes an evaluation of the risk management, personnel, biobanking processes, cleaning and waste handling, as well as of the legal aspects.

SBP Network Exploration Tool (SBP NExT)

(measure 2.1)

Promoting biobank visibility and sample sharing being a central task, SBP developed an innovative and interactive tool, called SBP Network Exploration Tool (SBP NExT), combining the features of a directory (search at a macro level) with the ones of a catalogue (search at a micro level) using visualization aspects to facilitate the search.
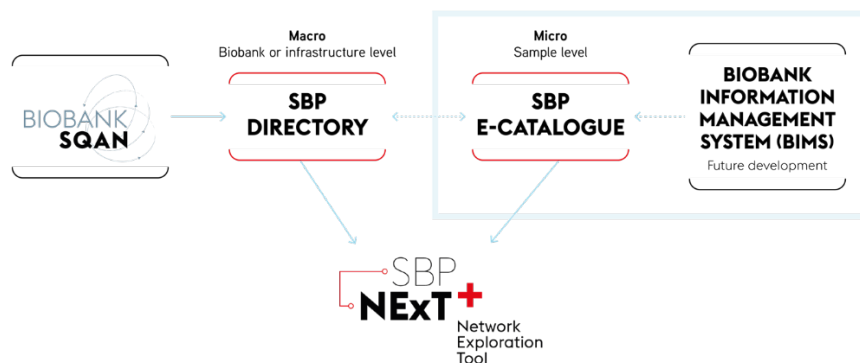
SBP NExT addresses several stakeholders:

- biobanks willing to increase their biobank visibility
- biobank infrastructures willing to promote their services
- researchers looking for samples and related data or for infrastructures offering specific services
- patients or research participants who are interested in knowing which biobanks store specific samples or in obtaining general information about certain biobanks

SBP NexT is already accessible on SBP website in an initial version only featuring the SBP directory, the e-catalogue being integrated in 2021 (https://swissbiobanking.ch/sbp-next/).

SBP directory

In 2019, a first version of the SBP Directory was published on SBP website with a fixed Swiss map labelled biobanks were clickable to see specific information on them. This achievement was appreciated by the stakeholders since it allows them to have an overall view of the existing biobanks and biobank infrastructures.

In 2020, SBP developed an interactive map with the possibility to make comparison between biobanks or to group biobanks around defined criteria. The list of criteria contain the following information and can be enlarged at any time : biobank type, species, canton, hosting organization, type of organization, purpose, research scope, SBP label, professional standards, services provided and type of entity.
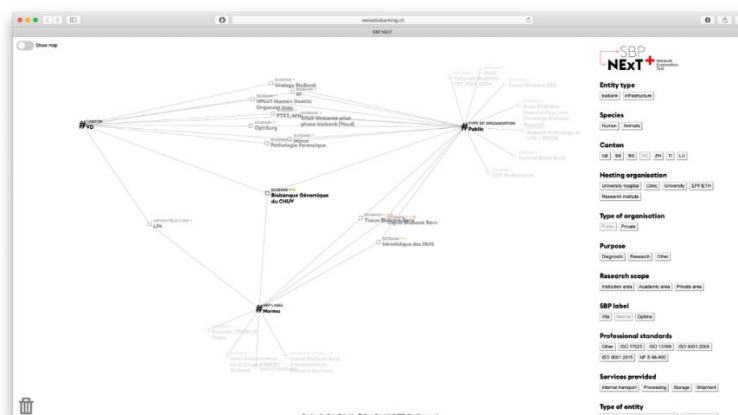

The biobank information shown in the SBP NExT is directly imported from the Biobank SQAN, giving a real time representation of the SBP network. A search result is presented in the figure below showing in the middle in black of the SBP NExT, the biobanks fulfilling all the criteria selected, while in grey, the biobanks fulfilling only some of the criteria.

SBP e-CATALOGUE

SBP is developing a concept for a centralized national e-catalogue at the sample level with different access rights.

CONCEPT
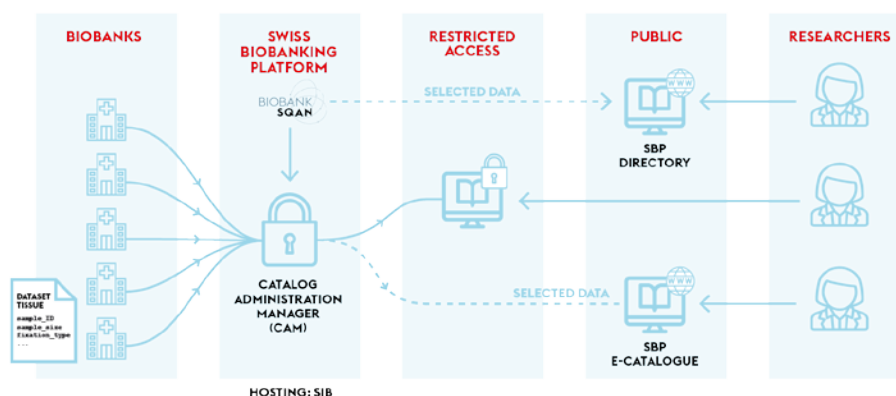
The SBP e-catalogue concept, approved by the SBP governing board 14th May 2020, has been discussed and approved by key stakeholders to secure its feasibility and integration with the data infrastructure developed at SPHN, the local developments within the University Hospitals, but also the developments in the non-human field :

> SPHN : Katrin Crameri (PHI), Christian Lovis (HUG), Nicolas Rosat (CHUV) and Alexander Leichtle (Inselspital Bern)
> SBP expert members and president : Aurel Perren, Carlo Largiadèr and Antoine Geissbühler
> Vetsuisse : Franco Guscetti and Sven Rottenberg (Biolink project)

PILOT BIOBANKS **(measure 2.5)**

The pilot biobanks to enter the e-catalog were selected to give a overview of different biobanking fields among Biolink projects: tissue biobanks, veterinary biobanks and liquid biobanks. The pilot biobanks are several BioLink biobanks,, a biobank infrastructure, and a Swiss cohort. The pilot biobanks will challenge and test the solution until the end of 2020.

E-CATALOGUE PILOTS

Vetsuisse
Patholink (GE, BE, ZH)
Bern Liquid
STCS

TIMELINES

The SBP e-catalogue details specifications with critical features (including advanced search capabilities, follow-up on samples requests and restricted catalogues) were defined as well as theSBP e-catalogue dataset the biobanks will have to document and push into the e-catalogue regularly.
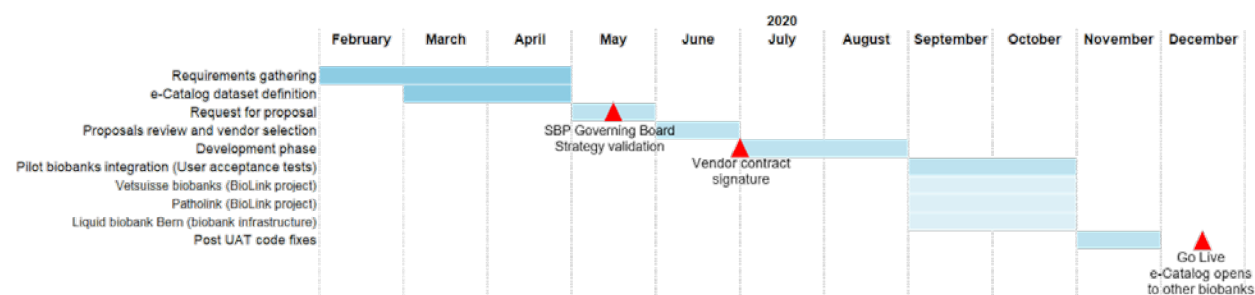
In May 2020, Sigmalis, the best provider selected, has been appointed to build up the e-catalog between July and October 2020. A test phase will begin end of September with the pilot biobanks providing sample data to test the e-catalog with pre-defined use cases.

The SBP e-catalogue is planned to be open to researchers in 2021. Besides this important development, SBP is exploring the needs and interests to propose a BIMS strategy to ensure sample quality and traceability and to allow direct transfer from the BIMS into the SBP e-catalogue **(measures 2.3 and 2.4)**.

STRATEGY 2021-2024

A new convention between SNSF and SBP, approved by SBP governing board, defining the main objectives SBP executive office should develop :

1. SBP shall promote a quality strategy for biobanks that serves both quality management issues and sample quality.
2. SBP shall promote access and sharing of biobanked samples for high-quality research.
3. SBP shall support non-human biobanks with specific guidelines and services.
4. SBP shall consolidate the collaboration with the European networks of biobanks.
5. SBP shall provide a concept for its sustainable funding.

For each of the following aims, measures, milestones and deliverables are defined and presented in the Appendix 4.

Pr Antoine Geissbühler   DrSc Christine Currat
President   Executive Director

APPENDIX 1
Table of deliverables and milestones 2019-2020

Aims	Measures and deliverables 2019-2010	Timing	Status
1. The SBP structure and management are consolidated. The SBP is positioned as quality reference in the Swiss human and nonhuman biobanking community and as national node of BBMRI-ERIC.	1.1 — a communication strategy is developed between the bodies of SBP and with SBP stakeholders (e.g. SPHN, UnimedSuisse, universities, university hospitals).	05.2019	Achieved
	1.2 — the unique value proposition of the SBP is defined and the collaboration with national or international initiatives is established, especially with SPHN on sample-related issues.	05.2019	Achieved
	1.3 — the SBP provides updated information and fosters an efficient collaboration with BBMRI-ERIC as Swiss node and other human and nonhuman biobank consortia.	10.2020	Achieved
	1.4 — the SBP establishes a communication strategy for promoting itself as intermediate in the access to international biobanks (Swiss node).	10.2019	Achieved
	1.5 — strategies for sustainable funding are available.	10.2020	In progress
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 — SPB collaborate with SPHN to establish the Swiss biospecimen catalogue: SBP provides know-how on preanalytics and sample related issues.	10.2020	Achieved
	2.2 — the minimal requirements regarding BIMS are defined and available BIMS solutions are known.	10.2019	Achieved
	2.3 — guidance on available BIMS and BIMS minimal requirements is developed as service.	05.2020	Achieved
	2.4 — A strategy for the future development of a SBP BIMS or a BIMS accreditation via SBP is developed.	10.2020	In progress
	2.5 — SBP guides BioLink projects in the choice of IT solutions and their implementation and their integration to the Swiss biospecimen catalogue.	10.2020	Achieved
3. The SBP drives the quality management of biobanking activities.	3.1 — the SBP informs regularly on the SBP BiobankSQAN and auditing services	10.2020	Achieved
	3.2 — the SBP supports the SNSF in implementing a Sample Management Plan according to international quality standards.	10.2019	Achieved
	3.3 — the SBP develop a process for sample quality control.	10.2020	Achieved
	3.4 — the Biobank SQAN is adapted to the coming ISO norm on biobanking and follows BBMRI-ERIC quality strategy.	05.2019	Achieved
4. The SBP informs the SNSF on its advancement and operating according to the agreement.	4.1 — an annual business report is submitted to the SNSF	10.2019	Achieved
		10.2020	Achieved

APPENDIX 2

List of registered biobanks and biobank infrastructures in the Biobank SQAN

	Biobank	Institution	Registration	BBMRI directory	Public	Private	Label status	Interest for Norma label	Interest to register more BBs	Support documents	Services / Consulting
1	**Liquid Biobank Bern**	Inselspital	22.03.18				O			4	
2	**Biobanque IPA**	CHUV	22.03.18								
3	**USZ Bioresource**	Universitätsspital Zürich (USZ)	26.03.18				V			0	
4	**Biobanque Génomique du CHUV**	CHUV	27.03.18				O			0	
5	**Sérothèque HUG**	HUG	03.04.18				N			6	BB Regulation
6	**Vetsuisse Biobank**	University of Bern	03.04.18				V			4	BB Regulation
7	**Tissue Biobank Bern**	University of Bern	11.04.18				O			9	
8	**SwiSCI biobank**	Swiss Paraplegic research	13.04.18				N			7	
9	**BPUSB**	Universitatsspital Basel	24.04.18				V			2	
10	**Swiss Center for Musculoskeletal Biobanking**	Balgrist University Hospital - Zurich	24.04.18								
11	**Swiss Transplant Cohort Study**	Universitatsspital Basel	14.02.19				V pending			3	
12	**Swiss Pediatric Haematology and Oncology Biobank Network**	Kinderspital Zurich	05.06.19				V			3	
13	**Geneva Pathology Biobank**	HUG	07.06.19								
14	**Geneva Brain Bank**	HUG	21.06.19				V			3	BB Regulation
15	**Spitalhygiene Labor USZ**	Universitätsspital Zürich	24.06.19								
16	**PINIT**	Kinderspital Zurich	20.08.19				V			4	
17	**Biobank of the Swiss Health study - pilot phase, Vaud center**	Unisanté	10.09.19				V			1	BB Regulation, Quality Manual, BIMS service, WOIs development
18	**Tissue Biobank USZ**	Universitätsspital Zürich	22.10.19				V			2	
19	**Pathologie forensique**	CHUV	21.11.19				V			4	
20	**AILD Biobank**	Fondazione Epatocentro Ticino	06.12.19				N			11	
21	**Human Gastric Organoid lines**	EPFL	30.01.20				V			3	
22	**EF**	CHUV	13.02.20				V			4	BB Regulation
23	**Minco**	CHUV	13.02.20				V			4	BB Regulation
24	**Biobanque de recherche des humeurs en neuroiimunologie**	CHUV	18.02.20								
25	**PTX3_AML**	CHUV	20.02.20				V			2	BB Regulation
26	**BB OPTISURG**	CHUV	26.02.20				V			2	
27	**BB d'Urologie**	CHUV	24.03.20				V			3	
28	**PIPOVAP**	CHUV	01.04.20								
29	**BB COVID-19 Ticino**	Fondazione Epatocentro Ticino	03.04.20				N			4	
30	**BB_008_NLG _serum_LCR**	CHUV	11.06.20				V pending			3	
31	**Microbiome NEC**	ETH	26.06.20				V pending			4	BB Regulation
32	**Bioledger**	Sun bioscience	13.07.20				V pending			4	BB Regulation
33	**Microbiome IEM**	ETH	29.07.20								
34	**Biobanque EDM**	CHUV	20.08.20								
35	**Biomonitoring DSTE**	Unisanté	21.08.20								
36	**SWISS100**	HUG	25.08.20								
37	**MDS biobank**	Inselspital	26.08.20								

APPENDIX 3
List of SBP consulting services

	Date	Person	Biobank	Institution	Public	Private	Type of Consulting	Allocated time (h)
1	04.02.20	Laura Zimmermann (Master student)		Université de Lucerne	X		ELSI	0,25
2	07.02.20	Sydney Wijngaards (Master student)		Zürich Universität	X		ELSI	0,5
3	18.02.20	Arthur Zinn-Poget		CER-Vd	X		IT	2
4	24.02.20	Ramona Schaniel	SwiSCI biobank	Notwill		X	Governance	2
5	05.03.20	Michael Scheder, Antoine Meyer and J-L Magnin		Hôpital de Fribourg	X		Organisation	2
6	27.03.20	Smiljan Rakovic, Judith Haeberli		Merck		X	Governance	8
7	30.03.20	Stefano Ongarello		FIND		X	Organisation	1,5
8	09.04.20	Miriella Pasquier		Ichnos Sciences Biotherapeutics SA		X	Governance	3,5
9	15.04.20	Claudine Bommer		Universitätspital Basel	X		ELSI	5,5
10	28.04.20	Chloé Gay-Balmaz (student)		Bern University	X		ELSI	2
11	28.04.20	Prof. Nina Khanna		Universitätspital Basel	X		Governance	0,25
12	06.05.20	Noemi Meier	Microbiome_NEC, Microbiome_IEM	ETH	X		Quality	0,5
13	12.05.20	Ramona Schaniel	SwiSCI biobank	Notwill		X	Governance	5,5
14	12.05.20	Irina Banzola	SPHO	KISPI, USZ	X		IT	0,25
15	10.06.20	Christophe Lamy (Unige)		UniGe	X		IT	2
16	11.06.20	Laura Frangeul		UniGe	X		Organisation	1,5
17	10.07.20	Nathalie Brandenberg	Bioledger	Sunbioscience		X	Organisation	1,5
18	27.07.20	Nathalie Brandenberg	Bioledger	Sunbioscience		X	ELSI	1,5
19	24.08.20	Valérie Dutoit Vallotton	Geneva laboratory of tumor immunology	HUG	X		Organisation/ELSI	5
20	01.09.20	Sylvain Lengacher		UniGe (NCCR Synapsy)	X		Organisation	1
21	04.02.20	Laura Zimmermann (Master student)		Université de Lucerne	X		ELSI	0,25
22	07.02.20	Sydney Wijngaards (Master student)		Zürich Universität	X		ELSI	0,5
23	18.02.20	Arthur Zinn-Poget		CER-Vd	X		IT	2
24	24.02.20	Ramona Schaniel	SwiSCI biobank	Notwill		X	Governance	2
25	05.03.20	Michael Scheder, Antoine Meyer and J-L Magnin		Hôpital de Fribourg	X		Organisation	2
26	27.03.20	Smiljan Rakovic, Judith Haeberli		Merck		X	Governance	8
27	30.03.20	Stefano Ongarello		FIND		X	Organisation	1,5
28	09.04.20	Miriella Pasquier		Ichnos Sciences Biotherapeutics SA		X	Governance	3,5
29	15.04.20	Claudine Bommer		Universitätspital Basel	X		ELSI	5,5
30	28.04.20	Chloé Gay-Balmaz (student)		Bern University	X		ELSI	2
31	28.04.20	Prof. Nina Khanna		Universitätspital Basel	X		Governance	0,25
32	06.05.20	Noemi Meier	Microbiome_NEC, Microbiome_IEM	ETH	X		Quality	0,5
33	12.05.20	Ramona Schaniel	SwiSCI biobank	Notwill		X	Governance	5,5
34	12.05.20	Irina Banzola	SPHO	KISPI, USZ	X		IT	0,25
35	10.06.20	Christophe Lamy (Unige)		UniGe	X		IT	2
36	11.06.20	Laura Frangeul		UniGe	X		Organisation	1,5
37	10.07.20	Nathalie Brandenberg	Bioledger	Sunbioscience		X	Organisation	1,5

APPENDIX 4
Aims and milestones 2021-2024

Aims	Measures and deliverables 2019-2010	Milestone	Deliverables
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	