SWISS
BIOBANKING
PLATFORM

ANNUAL REPORT 2019

This public version has been approved by the SBP Governing Board 21st November 2019 and by the SNSF presiding board 10th December 2019

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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 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 and data collections, which have been established for serving specific scientific questions and ensuring broad access to these data for research purposes. It holds a register of biobanks and data collections in Switzerland. It provides up-to-date technical know-how and training for biobanking and IT management (e.g. “good biobanking practices”, know-how on sampling, samples conservation and information processing), information 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.

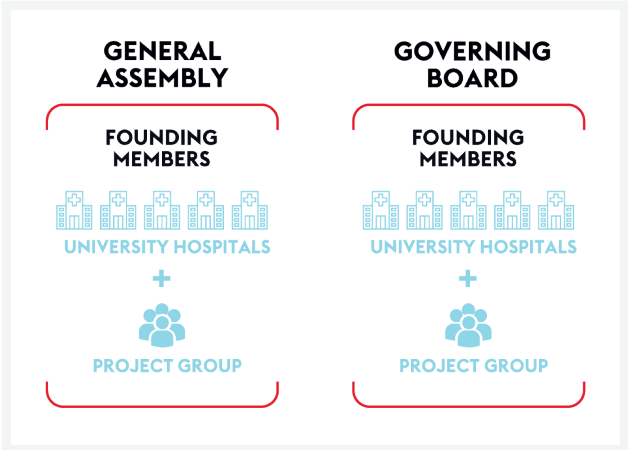
ACHIEVEMENTS 2019

SBP ASSOCIATION

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/*).

From April 2016 to April 2019, the SBP association was constituted by founding members acting on both the General Assembly of members and the Governing Board. These members were representatives of the general management of the five University Hospitals as well as the SBP project group, consisting of the four investigators who proposed the concept selected to become SBP. They represented different fields of biobanking (pathology, clinical chemistry, veterinary and public health) and were part of the Govening Board to ensure the construction of the platform. They had assumed its presidency and vice-presidency until 2018. From September 2018, Pr Antoine Geissbühler from the Geneva University Hospitals assumes the presidency.

2016 — SEPTEMBER 2019



PROJECT GROUP

Prof. Vincent Mooser
President
Head Laboratory
Department at CHUV

Prof. Tosso Leeb
Head Institute of Genetics,
Vetsuisse Faculty, Bern

Prof. Aurel Perren
Vice-President
Director Institute of Pathology,
University Hospital Bern

Prof. Nicole Probst-Hensch
Head Unit Chronic
Disease Epidemiology,
Swiss TPH Basel

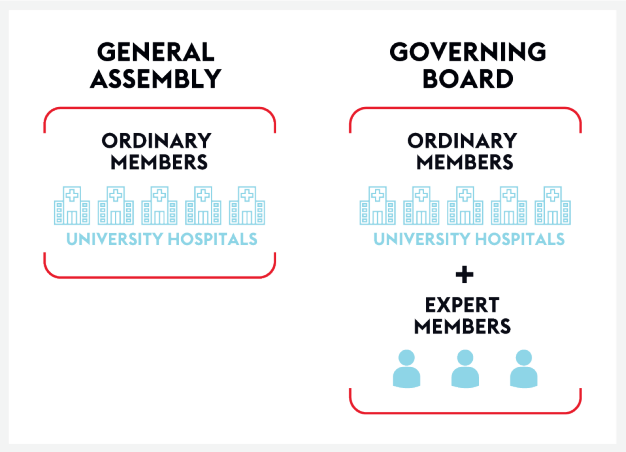
In its general assembly in May 2019, the Governing Board agreed on strategic changes in its structure to face adequately the growing demand on SBP services and the quickly evolving biobanking landscape in Switzerland and abroad, in particular since the foundation of the Swiss Personalized Health Network. In this respect, and since SBP is established, the Governing Board decided that the project group should be dismissed and replaced by new experts in biobanking, each one having one vote. The number of these experts is limited to three, elected for the next three years. They represent different domains of biobanking in complement to the expertise of the Governing Board members. This decision was approved by the SNSF Presiding board in its session of 20th August 2019.

Since September 2019, the new SBP governance structure is in place with ordinary members being part of the General Assembly and the Governing Board, and expert members being only part of the Governing Board.

The ordinary members are representatives of the University Hospitals of Basel, Bern, Geneva, Lausanne and Zürich, considered as non-profit institutions and organizations active in the biobanking field. 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 according to the development and positioning of SBP by the General Assembly. With this change, the Governing Board aims at gaining expertise and ensuring flexibility for proper decision making in a fast moving field and environment.

SINCE SEPTEMBER 2019



From November 2018 to October 2019, the General Assembly met twice and the Governing Board four times under the presidency of Pr Antoine Geissbühler.

The President, the Vice-president and the SBP members listed are elected for a three year period.

SBP GOVERNING BOARD (FROM SEPTEMBER 2019)

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

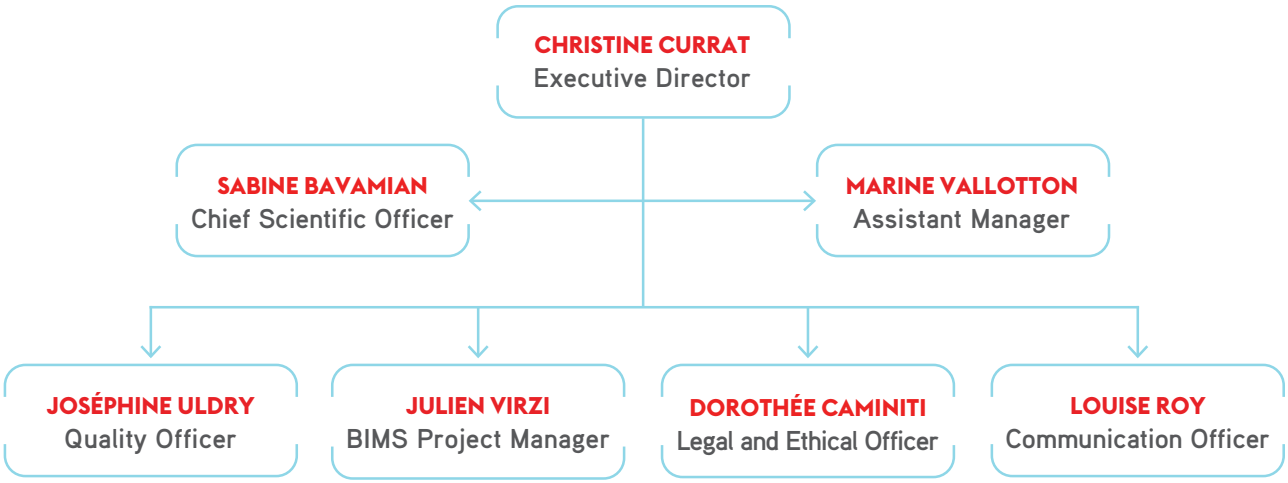
Liquid biobanking
Prof. Carlo Largiadèr
Head of Liquid Biobank Bern

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 issues of biobanks.



SBP ASSOCIATION 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, only part of the Governing board.
- SBP executive office is operational and provides support to biobanks on governance, interoperability and quality issues.

SBP VISIBILITY

EVENTS

SBP organized two 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. Both events discussed the challenges the scientific community have to tackle, especially implementation and usage of harmonized procedures, high quality standards or sustainability issues including ethical, legal and social dimensions.

INTERNATIONAL BIOBANKING CONFERENCE 2018

SBP organized its first international biobanking conference on February 1st 2018 featuring international and national experts sharing their vision of the "Biobanking of the future". Three panels of experts discussed new directions in state-of-the-art biobanking research.

This event was a great success in terms of positioning SBP as the reference infrastructure for biobanking activities in Switzerland and

as the Swiss node in the European context, through BBMRI. This event welcomed more than 200 attendees mainly from Switzerland (52% from the French part, 36% from the German part and 2% from the Italian part) with 10% from Europe. The audience was diverse and mainly composed of persons from the academic sector such as researchers, biobank managers, as well as representative of private companies.

A specific website was created for the conference with a dedicated visual identity; the day was recorded on video, shared on Twitter, moderated by a scientific journalist and animated with interactive tools trying to promote more exchanges with the public.

WORKSHOP ON «QUALITY IN BIOBANKING»

SBP organized its first workshop on «Quality in Biobanking» on March 11th 2019 in Bern with the support of SNSF. A plenary session opened the workshop with an update on SBP and SNSF expectations in terms of quality biobanking in Switzerland. Three parallel thematic workshops followed on quality (session 1), interoperability (session 2) and governance (session 3). SBP members moderated the discussions in the workshops.

The workshop welcomed 86 attendees, mainly SBP clients and stakeholders (called partners at large).The discussions were very rich highlighting the expectations SBP partners could have towards the association. Mainly, the importance of developing guidelines around governance and quality issues has been stressed together with the need for biobanks to be accompanied in those processes. The link to BBMRI is seen as an important asset for a better SBP positioning towards its partners. Finally, the interest of having a BIMS strategy was heavily debated since the interoperability of biobanks is not achieved and some biobanks already have bought different BIMS.

SBP is thus recognized as the infrastructure supporting the biobanking community and providing tools to harmonize biobanking practice and improve sample quality and accessibility. SBP is also expected to play a central role between BBMRI and the Swiss biobanking community, which in fact would only be built once SBP has consolidated its position in Switzerland, and once BBMRI has clearly defined its collaboration with its national nodes.

WORKSHOP 1
BIOBANK SUSTAINABILITY AND SAMPLE QUALITY

Prof. Carlo Largiadèr
SBP Working Group Liquid Biobanking head

The aim of panel 1 on Biobank quality was to brainstorm SBP services and discuss specific quality-related issues on biobank sustainability and sample quality, as well as to better understand the expectations of the new ISO standard ISO 20387:2018 – General requirements for biobanking. The biobanking 2.0 visions from an international perspective was also raised.

WORKSHOP 2
BIOBANK INTEROPERABILITY AND DATA QUALITY

Prof. Antoine Geissbühler
SBP President

The aim of panel 2 on Biobank interoperability was to brainstorm SBP services and discuss specific interoperability-related issues on sample and data sharing. The question on the specific use and implementation of Biobank Information Management Systems (BIMS) in Switzerland was also raised.

WORKSHOP 3
BIOBANK GOVERNANCE AND INTERACTION WITH OTHER RESEARCH PARTNERS

Prof. Aurel Perren
SBP Vice-President

The aim of panel 3 on Biobank governance was to brainstorm SBP services and discuss specific governance-related issues on biobank sustainability and sample price as well as better understand the expectations of the biobanking community regarding national and European networks. The question on the governance of such networks was also raised.

BOOTH AT THE "EUROPE BIOBANK WEEK 2019"

(measure 1.3)

Besides the event organized in Switzerland, SBP also presented its activities abroad with the participation to the annual international congress, "Europe Biobank Week" organized by the two major biobanking networks, BBMRI (Biobanking and BioMolecular resources Research Infrastructure) and ESBB (European and Middle Eastern Society for Biopreservation and Biobanking), in Lübeck Germany from 8 to 11 October 11th 2019.

This year, SBP took an active part in the congress with posters presenting SBP activities, with the chairing of a session and with a booth as the Swiss national node among other national nodes from the BBMRI network.

The four posters presented by SBP raised the following issues:

- sustainability with the concept that funding mechanisms could give incentives to biobanks to promote high-quality samples
- quality strategy as a support to biobanks and a mechanism promoting biobanks to get compliant with minimal requirements
- access and visibility of samples with an efficient process to serve researchers
- cross-border exchange with ethical and legal challenges, mainly focused on the compliance with the new General Data Protection Regulation (GDPR) and the update Switzerland should give to its law on data protection.

SBP co-chaired the session on "How do biobanks support clinical trials and precision medicine?" where Carlo Largiadèr was selected as the key-note speaker presenting the construction of the Liquid Biobank Bern.

Overall, the participation in the international meeting was very constructive and raised the interest of the attendees. SBP received requests for tighter collaborations, in particular from several BBMRI national nodes (e.g. Italy, Poland and Germany).

Finally, SBP gained visibility being among the five largest participating nations in terms of number of attendees (Germany (24%), Austria (10%), Switzerland (5%), The UK (5%), and The Netherlands (5%)).

COMMUNICATION TOOLS

WEBSITE

Our website, https://swissbiobanking.ch, is the central communication tool for the SBP and is regularly updated to highlight the major changes and progresses of SBP (e.g. biobank SQAN, new elected Governing Board members).

NEWSLETTERS

The newsletters are regularly sent to the SBP network to inform on the SBP deliverables and activities. These newsletters are relayed into the BBMRI newsletters. In 2019, five newsletters announced important steps at SBP:

- Newsletter N°17 — 10.01.2019
  SBP is looking for beta testers!
- Newsletter N°18 — 15.02.2019
  Invitation to SBP Workshops
- 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 — Planned November 2019
  BIMS guidelines are published!

SOCIAL MEDIA

SBP experienced the use of social media with the relay of each newsletter on LinkedIn enterprise page.

During the events organized by SBP, highlights or important information of the day were reported via the SBP twitter account. These tweets were mainly followed by BBMRI partners and Swiss researchers.

FLYERS

SBP developed flyers to present its infrastructure and the available tools to promote the harmonization of practice, the education of researchers and biobank owners and the compliance of biobanks with the minimal quality requirements.

SBP COMMUNICATION STRATEGY *(measures 1.1, 1.2 and 1.4)*

As defined in the first aim of the 2019-2020 Agreement, SBP has to collaborate more actively with existing national research infrastructures or initiatives. To that end, 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' categories (see below). The outcome is that SBP offers a unique set of services that will help not only biobanks and researchers identified as SBP users, but also SBP stakeholders to understand what SBP could offer and where SBP could add a significant value.

SBP POSITIONING IN SWITZERLAND AND ABROAD

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.

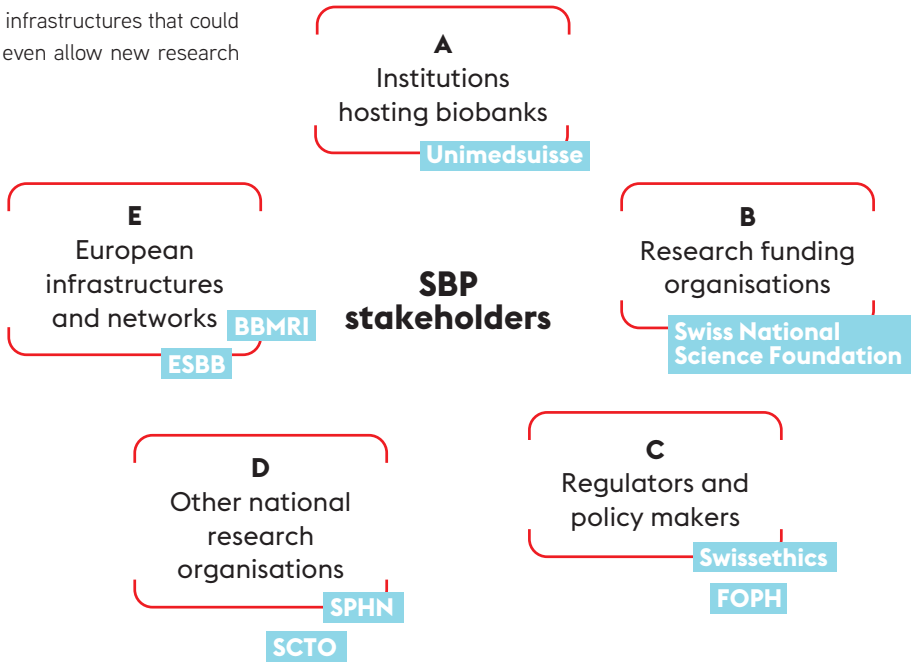
SBP mission is the coordination and harmonization of biobanking activities by increasing visibility, high quality, transparency, accessibility and interoperability of biobanks.

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 that could facilitate the setup of their research and even allow new research venues.

SBP STAKEHOLDERS' MAPPING

(measures 1.2, 1.3 and 3.2)

The stakeholder analysis and mapping will help SBP to adapt its communication strategy to consolidate its position as infrastructure offering peculiar services. The stakeholders were classified in five major categories as presented in the scheme below. The stakeholders in blue have already worked with SBP in 2019.



The outcomes of the ongoing collaborations with each identified stakeholder are depicted below:

A. UNIMEDSUISSE

SBP was invited to present its activities on 5 June 2019 at Unimedsuisse. Unimedsuisse recognizes SBP as the national research infrastructure fostering biobank harmonization. The committee was convinced by the role of SBP as a support 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. This role is considered as essential for the development of biobanks within hospitals. However, Unimedsuisse expects a closer collaboration of SBP with the other research national infrastructures, especially SPHN and SCTO.

B. SWISS NATIONAL SCIENCE FOUNDATION (SNSF)

(measure 3.2)

SNSF is the funder of SBP. Moreover, SNSF collaborates with SBP on a concept of a "Biobank Management Plan" (BMP) that could foster the quality of biobanks by reaching minimal requirements for samples and data. Following the open research data policy, the FAIR principles will be required (Findable, Accessible, Interoperable and Reusable). The BMP concept follows the SNSF Data Management Plan.

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, which is described in the section "partner project" of this report.

D. SPHN AND SCTO

(measure 1.2)

A meeting to better coordinate Swiss research infrastructures took place at SNSF on 9 April 2019 with the presidents and directors of SCTO, SPHN and SBP, organized by SNSF. It has been decided that the executive director of SPHN, Adrien Lawrence, the coordinator of the SPHN Data Coordination Center, Katrin Crameri, the executive director of SCTO, Annette Magnin and the executive director of SBP, Christine Currat, will meet to perform a gap analysis on how to better serve the interests of the research community. This initiative is supported by Unimedsuisse and will help to consolidate the needs and tasks of each infrastructure in the context of a future national research infrastructure.

The group met four times.One of the first outcomes of this collaboration is the distribution of tasks between the three organisations, SBP taking the lead for the development of Intellectual Property guidelines.

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 decided at EBW19 that an active participation with the other European organization for biobanks, the European and Middle Eastern Society for Biopreservation and Biobanking (ESBB), could enlarge its expertise with additional partners also in the non-human domains by integrating other working groups.

SBP UNIQUE SET OF SERVICES

To deliver a clear message to its clients and stakeholders, SBP will more precisely describe its tools and services and emphasize the value added they represent for biobanking activities and research

SBP services are based on three pillars, which are more precisely described in the next chapters of the report:

1. SBP HARMONIZED DOCUMENTATIONS

Harmonized documentations (e.g best practices, SOPs, templates) setting up the foundation for a Swiss biobanking guidance and promoting harmonized practice in accordance with the European and international requirements.

2. BIOBANK SQAN

An interactive tool to help biobanks get compliant with the minimal requirements in terms of governance, process and quality management, which integrates the different documentations presented below. Through Biobank SQAN labels are delivered as a recognition for compliance with the following minimal requirements:

a. Ethical and legal issues for the VITA label (governance)

b. Operational issues for the NORMA label (process)

c. Quality issues for the OPTIMA label (QMS).

BIOBANK SQAN
Biobank Solution
for Quality Assessment
and Normalization

3. SBP DIRECTORY

Visibility of biobanks at the Swiss and European levels through a directory and a request portal for researchers to access high quality samples.

SBP HARMONIZED DOCUMENTATIONS

Over the first funding period, SBP focused on the development of a set of documentations to promote biobank harmonization and interoperability. This work was done sequentially but was published as a package to provide a thorough support to biobanks.

SBP provides different types of documents, policies, procedures and templates, available on the SBP website, covering the important issues in biobanking activities

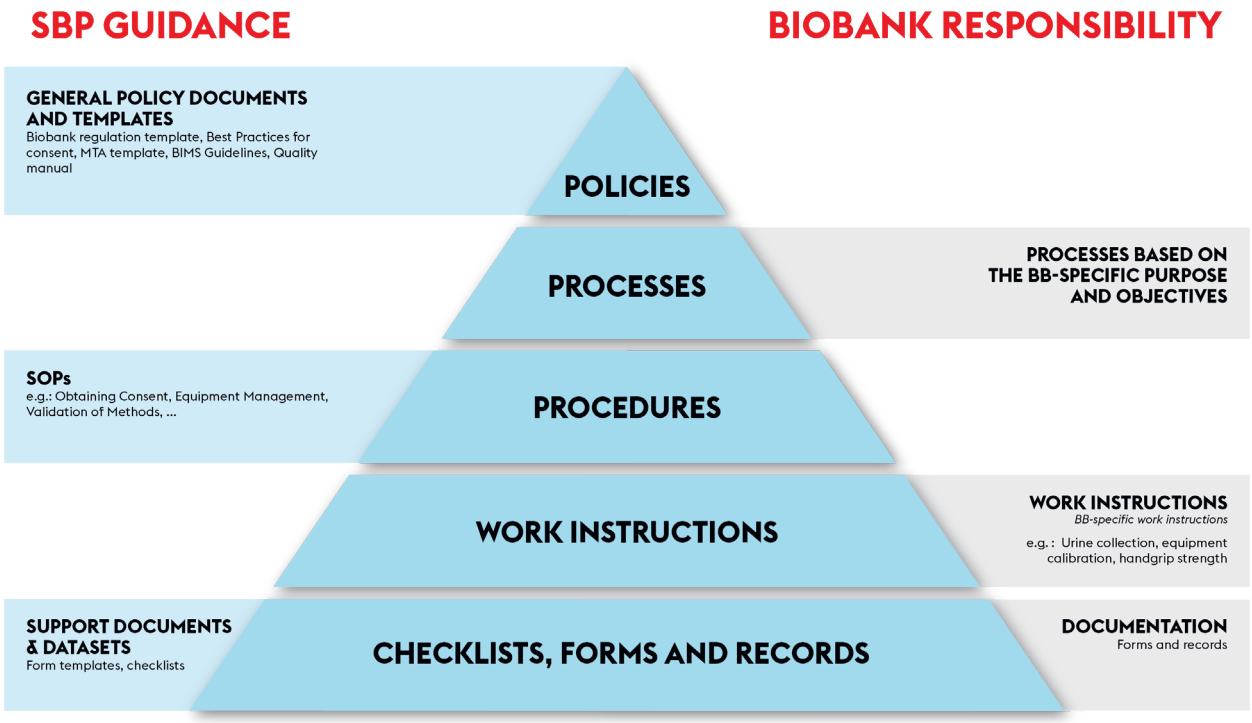
- Governance : three policies and two procedures
- Quality : eleven procedures and fourteen templates
- Interoperability: one policy, one procedure and four templates.

The strategy developed at SBP is to provide biobanks with the necessary documentations to build up and maintain state-of-the-art biobanks, called the SBP guidance (on the left side of the pyramid below). This guidance consists of policies, procedures, and support documents such as templates of forms and datasets. This guidance should be considered as the national foundation allowing harmonization and interoperability of biobanks.

It is the biobanks' responsibility to adhere to the SBP guidelines, which should facilitate and relieve their administrative workload to ensure quality. First, the biobank should adapt and detail the objectives and processes specific to its activity, then produce Work Instructions detailing the specific requirements of the SBP procedures, and finally fill-in the necessary forms to adhere to the quality documenting requirements. Upon request, SBP can support the biobanks in the elaboration of these documents.

The SBP policies have been written based on the legal and ethical framework in Switzerland and in Europe, discussed with different experts depending on the topic, and finally submitted to a public consultation (SBP partners) whose comments were integrated into the final version published on the SBP website.

The procedures, support documents and datasets have been based on the new ISO norm 20387 and international standards. They have been discussed within different working groups and improved with a Swisswide pilot project, the Swiss Health Study of the Federal Office of Public Health (FOPH). The datasets have been submitted to a public consultation before their finalization.



POLICIES

SBP policy gives biobanks the framework for building up state-of-the-art biobanks.

This year, SBP published three main policies listed below:

1. "BIOBANK REGULATION"

The Biobank regulation defines 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 public trust.

This document has been developed by SBP with the expertise of Swiss experts and was submitted to public consultation in Spring 2018. This regulation is now recognized as a national guidance and is proposed to any SBP client. This regulation is also endorsed by Swissethics which will promote the SBP template on its website.

2. "MATERIAL TRANSFER AGREEMENT" (MTA)

Biological material and health data belong to citizens whose interests have to be protected. These individuals have given their consent for their samples and health data to be used for research. In order to be able to exchange samples and data for research projects between institutions, a Material Transfer Agreement (MTA) and/or Data Transfer and Use Agreement (DTUA) are required.

The MTA and DTUA are crucial regulatory requirements that define the rights, responsibilities and obligations of the Parties involved (e.g. Provider, Recipient, Processor) regarding permitted use, ownership, publications, intellectual property and liability when biological material and/or data are being transferred or accessed in the frame of a project.

So far, Swiss universities (Basel, Bern, Geneva, Lausanne, Zurich), ETH-Domain institutions (EPFL, ETHZ), and the five University Hospitals have been using their specific MTA and DTUA templates. In order to facilitate research collaboration in Switzerland and as part of a national harmonization effort, SBP and SPHN have, together with the legal representatives of the above-mentioned institutions, developed common templates for both documents.

The Material Transfer Agreement (MTA) template governs the transfer and use of human biological material made available by a provider to a non-profit third party wishing to use this research material for its own research purposes. This template will serve SBP clients and researchers. The use of this template is limited to exchanges between academic institutions and is not suitable for exchanges with for-profit organizations

A version for the veterinary context has been developed and needs to be validated by the Vetsuisse faculties in the first semester 2020.

3. "BIMS GUIDELINES"

(measure 2.2)

This guidance document is intended for SBP clients and stakeholders who wish to acquire a Biobank Information Management System (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)..

NEXT STEPS

> MTA for veterinary research

> Quality manual

PROCEDURES, TEMPLATES AND DATASETS

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

Biobanks need to be educated and accompanied to efficiently implement and monitor a new quality management system in their daily routine. The SBP documentation on quality is available to any biobank willing to develop a robust quality approach and to harmonize its practice. The SBP datasets are available to strengthen the quality of their biological resources

1. PROCEDURES AND TEMPLATES

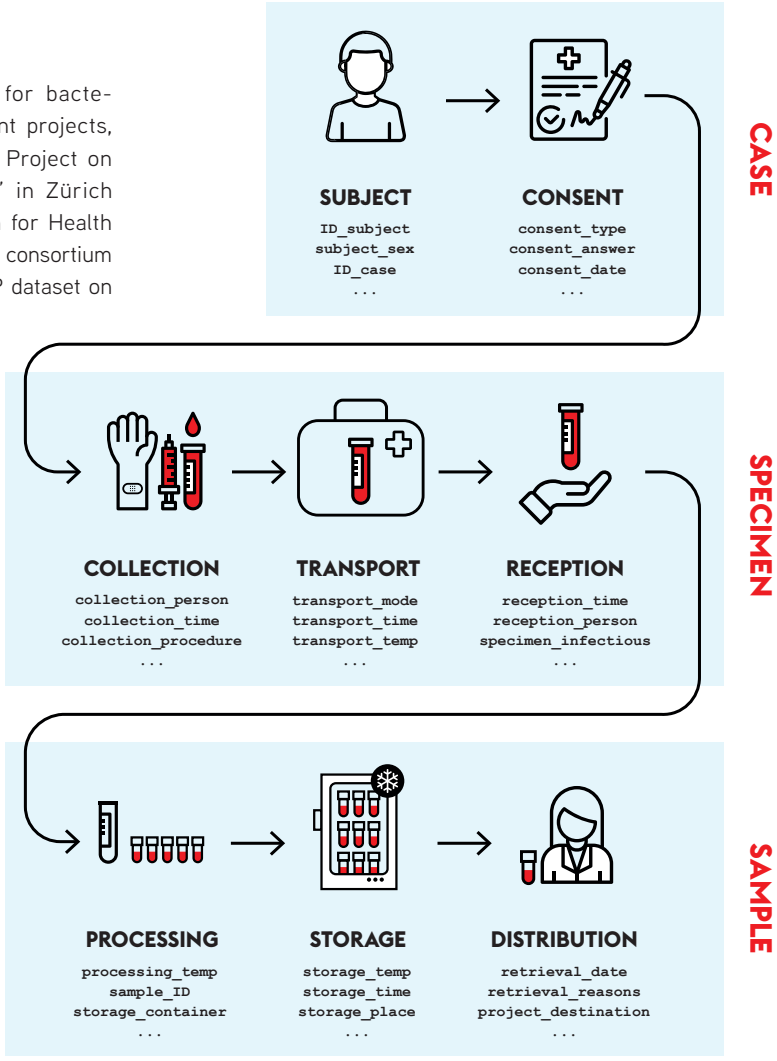
The chart provides the list of available procedures and templates required to fulfill governance, process and quality requirements:

	PROCEDURES (13 SOPS)	TEMPLATES (15 FORMS)
GOVERNANCE COMPLIANT	› Obtaining consent › Safety and complaint	
PROCESS COMPLIANT	› Data Protection › Data and sample traceability › Equipment Management › Personnel management › Biological Material Management › Validation of methods	› Participant ID log › Sample tracking form › Equipment calibration record › Equipment maintenance record › Expiring Consumables / Equipment Inventory › Personnel File › Sample Acceptance Criteria › Shipping Log › Quality Control results › Validation method record › Method List
QMS COMPLIANT	› Non-conformity management › Documentation management › Internal audit › Improvement Management › Quality Policy	› Non-Conformity Report › Non-Conformity Log › Management Review Report

2. DATASETS

SBP Working groups delivered five different datasets, representing the minimal data to be documented for each sample to define its quality. These data are focused on the preanalytical data that need to be integrated into a BIMS for any biobank to ensure traceability and documentation.

- The Liquid and the Tissue Working groups: list of data for human liquid and tissue samples based on the existing CEN/TS specifications or SPREC, the international references for specific samples.These datasets are already integrated in the Swiss Health Study pilot project and the Patholink project.
  https://swissbiobanking.ch/tissue-and-liquid-data-sets/
- The Veterinary Working group : list of data for veterinary liquid and tissue samples based on the human liquid and tissue datasets; this dataset is planned to be integrated in the Vetsuisse Biolink project 2019 (31BL30_189698).
  https://swissbiobanking.ch/dataset-veterinary
- The Microbiology Working group: list of data for bacteria samples. It has been implemented in different projects, the BioLink (31BL30_172630) and SPHN Driver Project on Sepsis in Basel, the Biolink project "Infectlink" in Zürich (31BL30_185302). The Netherlands Organisation for Health Research and Development and the recently started consortium VALUE-Dx are interested to further implement SBP dataset on bacteria with a possible collaboration with BBMRI.
  https://swissbiobanking.ch/dataset-bacteria/



BIOBANK SQAN *(measures 3.1 and 3.4)*

CONCEPT

To support biobanks in the development of their governance and quality strategies, SBP developed an interactive tool to help biobanks get compliant with the minimal requirements in terms of governance, process and quality management issues, integrating the different documentations listed above.

This tool is an online solution developed in collaboration with Vital-IT, called the Biobank Solution for Quality Assessment and Normalization – "the Biobank SQAN".

The Biobank SQAN integrates the critical factors a biobank should face to evaluate and monitor its practice. It is an innovative concept to educate biobanks and harmonize their practice with a compliance process.

BIOBANK SQAN
Biobank Solution
for Quality Assessment
and Normalization

This compliance process is based on a five-step approach for biobanks to reach the minimal levels of requirements, preparing biobanks to the new accreditation norm ISO 20387: 2018, and at the end to become visible in a Swiss directory.

The five steps are described below:

- Step 1: The questionnaire is made of ~250 questions covering multiple fields of biobanking.
- Step 2: Based on biobank answers, a score for different categories is calculated.
- Step 3: The reviewing step introduces the principles of compliance review by SBP, based on the ISO 19011:2018 methodology. During step 3, the analysis of the existing documentation is done and integrated into the report. For any missing documentation, SBP proposes its procedures and templates to the biobank.
- Step 4: The compliance process ends with the status whether the biobank fulfills the requirements. If yes, the biobanks receives a label, as a testimony of its compliance.
- Step 5: The compliant biobank is visible in the SBP Directory first, and in the BBRMI Directory.

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

1. Ethical and legal issues for the VITA label
2. Operational issues for the NORMA label
3. Quality issues for the OPTIMA label.

BIOBANK QUALITY LABEL BY SWISS BIOBANKING PLATFORM
VITA GOVERNANCE

BIOBANK QUALITY LABEL BY SWISS BIOBANKING PLATFORM
NORMA GOVERNANCE PROCESS

BIOBANK QUALITY LABEL BY SWISS BIOBANKING PLATFORM
OPTIMA GOVERNANCE PROCESS QMS

RESULTS

From April 2018 to April 2019, a pilot phase with volunteer biobanks allowed SBP to test the Biobank SQAN and to improve it with the biobanks' feedback. From May 2019 until October 2019, we improved the communication on the tool and stress that SQAN is a tool to improve quality of biobanking on an individual basis and not a certification tool, which is endorsed by the Governing Board.

The so-called "labelling process" was renamed into "compliance process", and the label is only here to indicate the compliance level, which the biobank has reached.

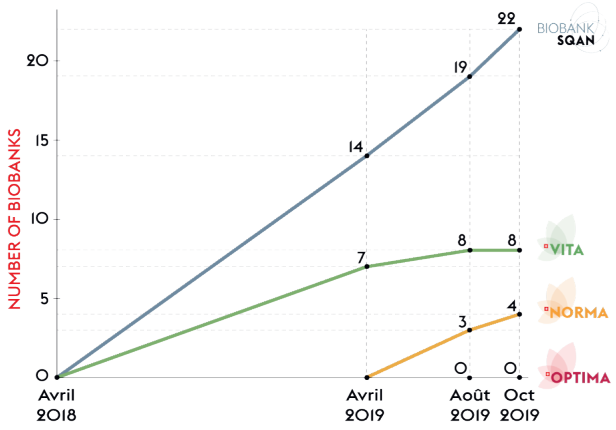
From September 2019, the not-yet-registered SBP clients were invited to use the Biobank SQAN, so that they could profit from harmonized documentations such as a biobank regulation template, datasets for tissue, liquid, veterinary and bacteria samples, and finally to a Material Transfer Agreement template researchers can use to access these biobanks.

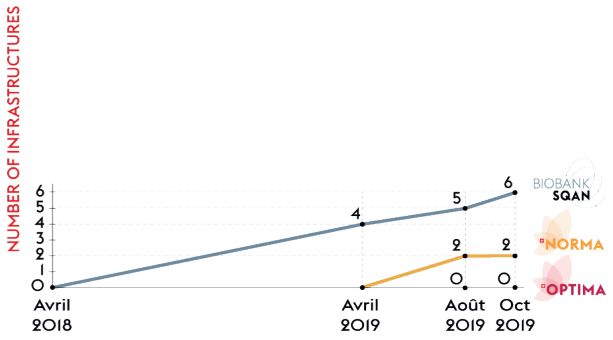
SBP distinguishes biobanks from biobank infrastructures, which are managed and promoted differently within the Biobank SQAN, and within the SBP Directory. The biobank infrastructure provide services to biobanks, in contrast to biobanks that collect their own samples. It is important for both to be visible, one to promote access to their samples and the other to promote the services available to any biobanks in an institution for economies of scales.

SBP has already registered 22 biobanks, 8 having reached the VITA requirements, and 4 the NORMA requirements as shown in the chart below.

SBP has also registered 6 biobank infrastructures, 2 fulfilling the NORMA requirements.

The Biobank SQAN has been setup for the Swiss biobanks. However, the interest from European countries to use it for their biobanks is increasing and this evolution needs to be analyzed.





BIOBANK SQAN IN SUMMARY

The Biobank SQAN is a five-step process allowing biobanking to get compliant with minimal requirements.

The Biobank SQAN helps biobanks improve their processes, and is thus essential in the support SBP is developing. The service provided by SBP collaborators is appreciated. Future developments and integration of more biobanks in the SBP network will help institutions have a better overview of their biobank practice and tailor their future services to the needs of biobanks and researchers in collaboration with SBP.

SBP DIRECTORY

The biobanks and biobank infrastructures compliant with at least the minimal governance requirements (Vita level) appear on the SBP Directory and, if agreed, in the BBMRI Directory.

The SBP Directory provides a list of aggregated information on biobanks and biobank infrastructures with the goal to increase their visibility at the Swiss level, as well as of contact information on biobankers, samples, infrastructures or biobanking services for biobankers or researchers who want to find samples in Switzerland.

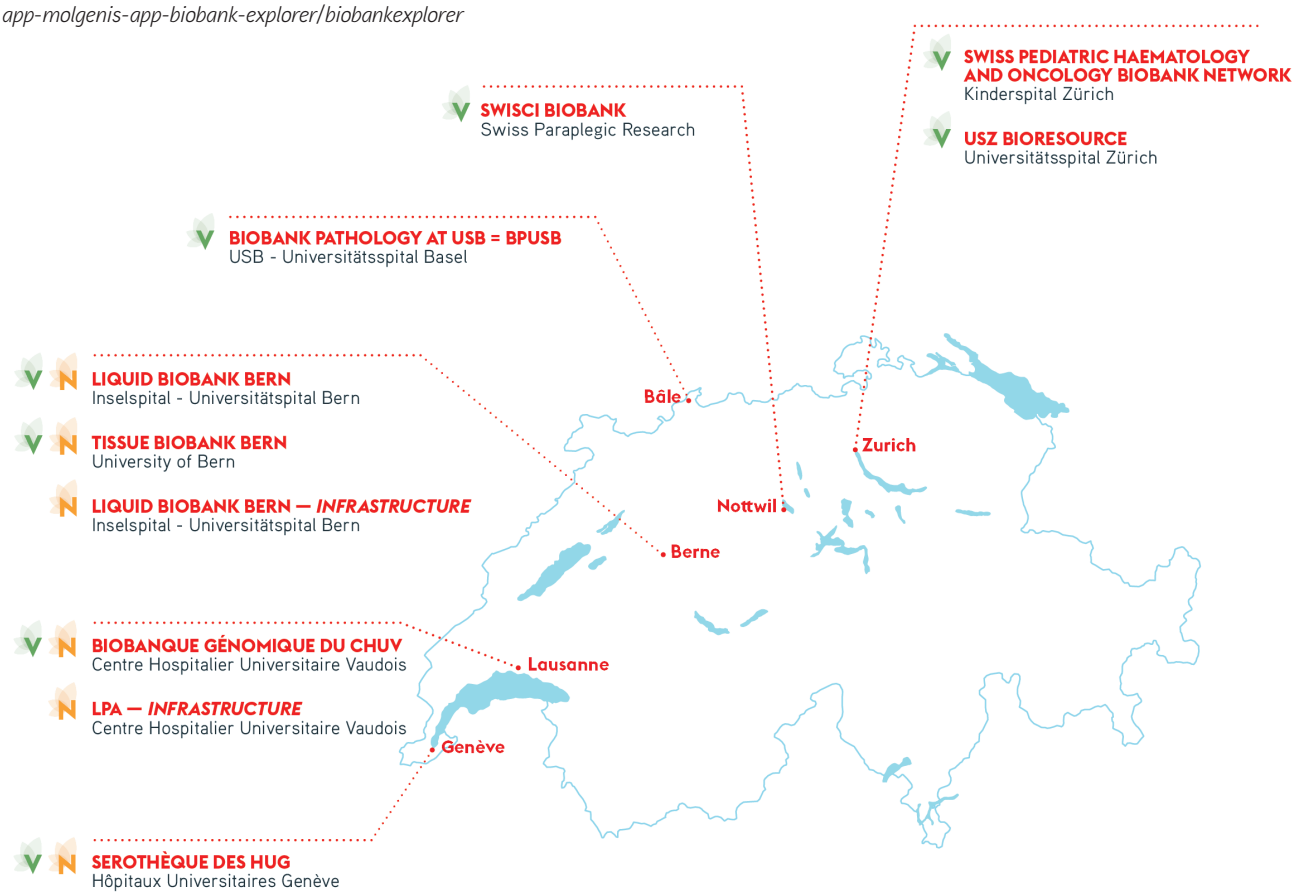
SBP developed an interactive map of Switzerland to localize more efficiently the partner biobanks. The level of compliance of the biobanks or infrastructures is also visible on the map.

Once on the SBP Directory, SBP makes the information available in the BBMRI Directory. Up to now, only one biobank, the Liquid Biobank Bern is visible at the European level. Others will follow after having agreed upon.

https://directory.bbmri-eric.eu/menu/main/app-molgenis-app-biobank-explorer/biobankexplorer

NEXT STEPS

> Integration of data infrastructures from SPHN in the Directory



PARTNER PROJECTS

In 2019, SBP worked actively with some pilot projects that could profit from the documentations and expertise developed by SBP. These projects allow SBP to test and improve its unique services and also identify the services that could be useful to provide and integrate in the SBP sustainability model.

SWISS HEALTH STUDY PILOT PROJECT (SHES-PP)

The major aim of the pilot study is to ensure the necessary framework for a nation-wide cohort associated with a biobank, in terms of infrastructure and procedures, participation, and organization. This involves identification of optimal data processes that meet national and international ethical and data protection standards. This also involves standardization of all processes including health examinations and the pre-analytical phase of biological material (sampling, transport, processing and storage) as well as the estimation of resources. In order to test the performance of the biobank, sample analytics will be included in the pilot phase: Selected biomarkers of effect and exposure will be analyzed in fresh or biobanked samples, respectively. Standardization of procedures at all steps is essential to ensure comparability of health examinations and SheS-pp results between different sampling sites and laboratories.

The Federal Office of Public Health (FOPH) is the main funder of the study and has commissioned SBP for the harmonization and coordination of the recruitment centers. SBP has subcontracted the study design and the operational work to research institutions, Unisanté and SwissTPH. The Liquid Biobank Bern has been selected for the preanalytical surveillance and central storage of the samples

More precisely, SBP provided the SHeS-pp with procedures and templates as well as expertise from the Liquid Working Group who evaluated the best pre-analytical conditions and wrote the specific Working Instructions for the project. SBP developed a complete workflow including quality documentation and management within a quality manual, a biobank regulation and a web-based BIMS system to be able to document and track sample related data..

BIOLINK PROJECTS

(measures 3.1 and 3.4)

- **Sepsis and Infectlink** (31BL30_172630 and 31BL30_185302)
  The Sepsis (K.Rentsch in Basel) and Infectlink (A. Zinkernagel in Zürich) Biolink projects have integrated the bacteria datasets SBP has developed.

- **Patholink** (31BL30_1727189)
  The Patholink (H. Moch in Zürich) project involves the Swiss pathology institutes of the five University Hospitals to harmonize their reporting practices and provide access to their samples. The biobanks have registered in the Biobank SQAN to harmonize their practices, and will follow the SBP datasets produced for tissue samples. Access to the samples will be developed through the future SBP e-catalogue in collaboration with SPHN.

OTHER PROJECTS

- **ECOS project: « Espace de convergence des savoirs sur la santé personnalisée »**
  Led by Le ColLaboratoire in UNIL together with the Precision Medicine Unit in CHUV and SBP, the project compared the visions of three groups of stakeholders (i.e. researchers, primary care physicians and citizens) on questions related to personalized health. Among the deliverables, SBP is collaborating on the development of a vignette presenting a biobank case study. The vignette is presented with a set of cards game to explore and debate the various issues raised by genomic research and medicine.

- **RoTaBio - Round table discussions for research infrastructures in life sciences**
  The State Secretariate for Education, Research and Innovation (SERI) mandated the Swiss Academies of Arts and Sciences to prepare roadmaps for research infrastructures for various scientific fields. These roadmaps will serve as a basis for decision-making on the allocation of federal funding for costly research facilities over the period 2025-2028. Prof. T. Leeb, SBP Governing Board expert for the non-human biobanking and Dr. M. Creus from the University of Basel whose research focuses on antibiotic-resistance have presented at the second RoTabio meeting, organized by SCNAT, the relevance of biobanks in the context of national infrastructures and international programs.

STRATEGY 2020

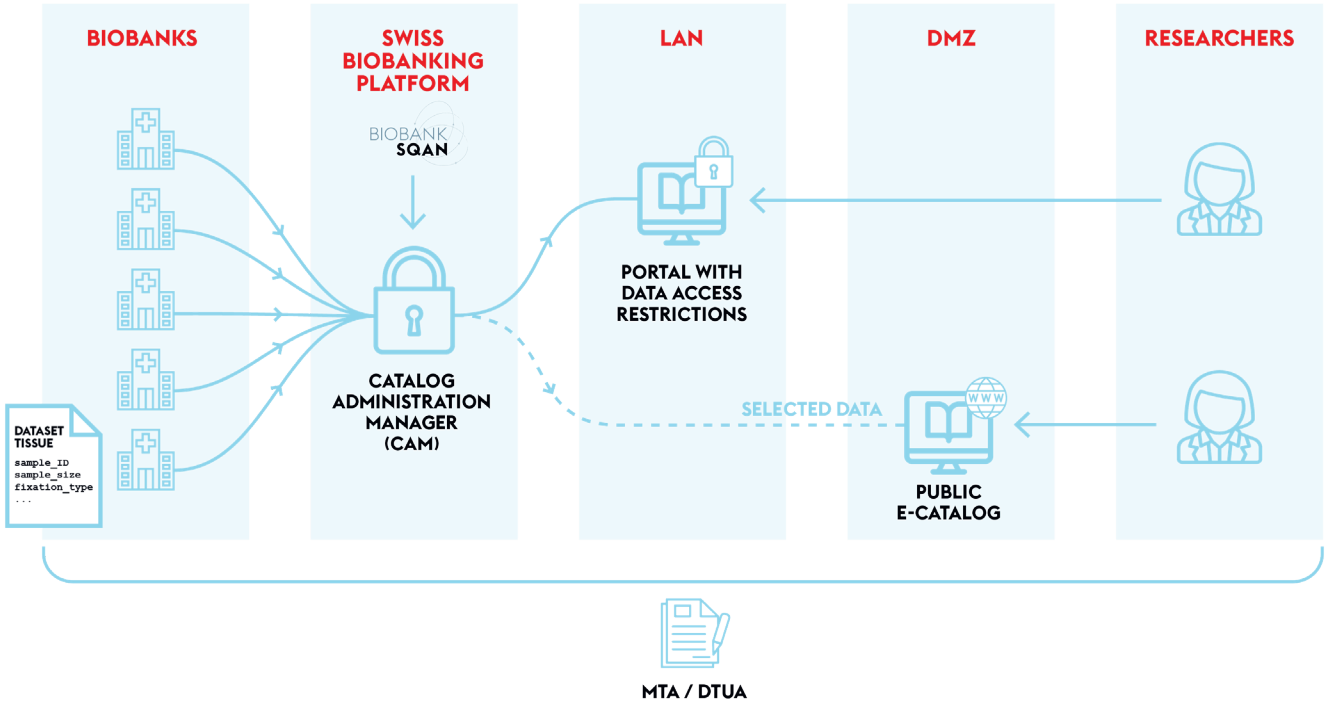
SBP E-CATALOGUE *(measure 2.1)*

One of the big challenges biobanks face is in the underuse of the samples banked. The biobanking community is trying to overcome this challenge by increasing visibility of the biobanks into catalogues. However, some problems arise such as legal and technological issues to facilitate exchanges between institutions or member states and the limited willingness to share samples.

With the implementation of the General Data Protection Regulation (GDPR) in Europe and the promotion of the free flow and use of personal data in scientific research, practical solutions are clearly needed. SBP is thus developing a concept for an electronic data infrastructure (e-catalogue) at the sample level with different access rights. This data infrastructure needs to be visible, efficient and useful to support access and interoperability of samples for research purposes. This SBP e-catalogue is containing more information at the sample level than the SBP directory

To promote scientific collaboration through the e-catalogue, the following requirements need to be met:

- Trust and commitment from users
- Multi modal solutions and flexibility (e.g. access rights)
- Efficiency measured with clear KPIs (e.g. timing between sample request and sample shipping, quality of samples)
- Integrative process with datasets, compliant biobanks and useful templates for the stakeholders (e.g. biobank regulation, MTA)



SBP CONCEPT FOR AN E-CATALOGUE

SBP is developing a concept for a highly secured public catalog with only selected data in a DMZ (demilitarized zone) and a local portal with data access restrictions in a LAN (local area network). These two query systems are linked to a Catalog Administration Manager (CAM), regrouping data from biobanks having implemented the harmonized SBP datasets and registered within the Biobank SQAN.

This infrastructure of well-annotated samples will be accessible to foster collaborative research and increase sample visibility. This will enable the researchers to query the data infrastructure to find the fit-for-purpose samples. The prerequisites to launch the SBP e-catalog data infrastructure are in place and key partners have been identified.

A close collaboration with SPHN, the DCC and BioMedIT are essential to link the SBP e-catalogue to the Clinical Datawarehouses that are under construction within the University Hospitals and the query system promoted by SPHN.

Besides, this important development, SBP is exploring the needs and interests to propose a BIMS strategy to ensure sample quality and traceability.

NEXT STEPS

> Collaboration with SPHN and BioMedIT in the construction of the SBP e-catalogue

Pr Antoine Geissbühler
President

DrSc Christine Currat
Executive Director

APPENDIX 1

TABLE OF DELIVERABLES AND MILESTONES

AIMS	MEASURES AND DELIVERABLES	TIME	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	IN PROGRESS
	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	YEAR 2
2. The SBP develops 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. The SBP establishes and manages a central web based catalogue of existing and *de novo* biobanks. The SBP provides information on access to the data and samples of the registered biobanks.	2.1 — SPB collaborates with SPHN to establish the Swiss biospecimen catalogue: SBP provides know-how on preanalytics and sample related issues.	10.2020	IN PROGRESS
	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	YEAR 2
	2.4 — A strategy for the future development of a SBP BIMS or a BIMS accreditation via SBP is developed.	10.2020	YEAR 2
	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	IN PROGRESS
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	IN PROGRESS
	3.2 — the SBP supports the SNSF in implementing a Sample Management Plan according to international quality standards.	10.2019	IN PROGRESS
	3.3 — the SBP develops a process for sample quality control.	10.2020	YEAR 2
	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	YEAR 2

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