SWISS BIOBANKING PLATFORM

ANNUAL REPORT 2021



SBP Network

SWISS BIOBANKING PLATFORM

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TABLE OF CONTENT

<u>INT</u>	RODUCTION3
<u>GO</u>	VERNANCE
<u>SB</u>	POSITIONING5
<u>SB</u>	PACHIEVEMENTS
1.	COMMUNICATION
2.	SBP LABELS
VIT	A LABEL
NO	RMA LABEL
OP	TIMA LABEL
3.	QUALITY
4.	VISIBILITY
SBF	P NETWORK EXPLORATION TOOL (SBP NEXT)
5.	INTEROPERABILITY
6.	NON-HUMAN BIOBANKING
Вю	LOGY ROADMAP FOR RESEARCH INFRASTRUCTURES 2025-2028 BY THE SWISS BIOLOGY COMMUNITY
7.	BBMRI COLLABORATIONS25
<u>Stf</u>	ATEGY 2022
AIN	/IS AND MILESTONES 2021-2024

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 and exploitation phase. The initial funding periods were ruled under two SNSF-SBP agreements 2015-2018 with a budget of CHF 3.2 Mio, and 2019-2020 with a budget of CHF 1.6 Mio.

The agreement elaborated and agreed for the period 2021-2024 has an increased budget of 4 Mio for four years with measures and milestones focused on the following goals :

- 1. SBP promotes a quality strategy for biobanks that serves both quality management issues and sample quality.
- 2. SBP develops guidelines to facilitate access to biobanking samples by establishing a Swiss biospecimen catalogue at the sample level. SBP provides advice in IT systems for quality and networked biobanks.
- SBP drives the quality management of biobanking activities.
 SBP consolidates the collaboration with the European networks of biobanks.
- 5. SBP provides a concept for its sustainable funding.

Based on the previous SBP achievements, this agreement aims at consolidating SBP's position with additional tools and services. It has also the objective of extending and adapting them to the non-human biobanking activities.

This report covers the activity period 2021 as delineated in the agreement 2021-2024 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's bylaws (https://swissbiobanking.ch/sbp-boards/). Since September 2019, the new SBP governance structure is in place for the years 2019 to 2022 (three year period).

GENERAL	GOVERNING			
ASSEMBLY	BOARD			
ORDINARY	ORDINARY + EXPERT			
MEMBERS	MEMBERS + MEMBERS			

At present, the General Assembly and the Governing Board are constituted of ordinary and expert members. 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 for three years.

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

Pr Antoine Geissbühler, Geneva University Hospital, assumes the presidency and Pr Aurel Perren, Bern University, the vice-presidency for a three year period (September 2019 to September 2022).





ORDINARY MEMBERS Basel

Bern Prof. Matthias Gugger FROM JANUARY 2021 Prof. Thomas Geiser Director Education and Research, Inselspital Bern

Geneva

TRD

Prof. Antoine Geissbühler, President Vice-dean for humanitarian and international affairs, UNIGE

Lausanne

Prof. Jean-Daniel Tissot Dean FBM, UNIL

FROM AUGUST 2021 Prof. Mauro Oddo Vice-medical Director, Research, Education and Innovation, CHUV

Zürich

Prof. Gabriela Senti Director Research and Education, USZ

EXPERT MEMBERS

Liquid biobanking Prof. Carlo Largiadèr Head of Liquid Biobank Bern, Inselspital

Tissue biobanking

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

Non-human biobanking Prof. Tosso Leeb Head Institute of Genetics, Vetsuisse Faculty, Bern

In 2021, Pr Matthias Gugger and Pr Jean-Daniel Tissot, two ordinary members, retired; we would like to thank them for their engagement and support all along these years since the creation of SBP. They were replaced in Bern by the new education and research Director of Inselspital Bern, Pr Thomas Geiger, and in Lausanne by the new vice-medical research, education and innovation Director of the CHUV, Pr Mauro Oddo. The representative from the University Hospital of Basel is not appointed yet and the process is ongoing.

SBP EXECUTIVE OFFICE (from November 2020)

SBP executive office has consolidated its expertise on specific biobanking domains with specialized collaborators. Globally, SBP executive office is thus in the position to offer specialized and competent advice and services as well as to professionally advise biobanks and researchers on scientific, quality, governance, access and interoperability issues,



SBP POSITIONING

(measure 5.1)

As the reference research infrastructure supporting human and non-human biobanks, SBP is a service provider for the research community and for biobanks that form the SBP valuable network.



To consolidate its position and offer dedicated services to clinicians, researchers and biobanks, SBP is collaborating with theSwiss and European organisations listed below.

A. Swiss National Science Foundation (SNSF)

SNSF is the founder and funder of SBP as well as the funder of the SBP-supported Biolink projects. In 2021, the co-organisation of the workshop on connecting researchers and biobanks, was a great success and showed the importance of these joint initiatives and collaboration (see chapter 1 – Marketing and communication).

B. Swiss Personalized Health Network (SPHN) and Swiss Clinical Trial Organisation (SCTO)

The executive directors of SPHN and SCTO are participating as guests to the SBP governing boards, and SBP executive director is invited in their respective steering boards. In parallel, five meetings took place this year at a frequency of once every two months between SPHN, SCTO, SNSF and SBP to promote collaborations where it is necessary, to avoid overlaps and to organize synergies at operational level.

Together with the presidents of these two research infrastructures and SNSF, SBP President has participated to the White Paper Clinical Research published by SAMS on May 3 2021. Next year, SBP executive Director will be part of the new Coordination Platform Clinical Research.

C. Swissethics

Swissethics endorses SBP harmonized documentations, has shown great interest in the SBP labels and considers SBP as the infrastructure monitoring and enforcing good biobanking standards (see chapter 2 – SBP Labels).

D. Federal Organization of Public Health (FOPH/BAG)

SBP collaborates actively with the Federal Office of Public Health (FOPH) in the development of the Swiss Health Study (SHeS) Pilot project, organizing the biobanking activities following SBP recommendations and improving the quality of the processes by the new service on quality assessment (see chapter 3 - Quality).

E. BBMRI and ESBB

As the Swiss node in the BBMRI network, SBP attends online 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 (see chapter 8 – BBMRI collaboration).

SBP ACHIEVEMENTS

SBP provides tools, documentations and services to the research community to be implemented in the daily practice. Convinced that having only a classical approach to harmonize biobanking activities with international and national standards is necessary but not sufficient, SBP has developed innovative tools to help biobanks implement the documentations and edited guidelines.



Integrating these two approaches, SBP reinforces its position based on a strategy relying on three pillars enabling biobanks to gain in quality, visibility, and interoperability.



QUALITY

To improve or get compliant with the minimal requirements in terms of governance, process and quality management, SBP supports biobanks with the interactive tool Biobank SQAN (SBP SQAN). Through SBP Biobank SQAN, harmonized documentations (e.g. policies, SOPs, templates), in accordance with the European and international requirements, are provided and implemented if necessary.

Three different labels were setup to certify the compliance with governance (VITA), process (NORMA) and quality (OPTIMA) requirements. These labels are focused on human biobanks first but could be easily adapted to non-human biobanks.

VISIBILITY

Once certified, the biobanks are registered in the Network Exploration Tool (NExT) combining both a directory to offer visibility to biobanks and a request portal for researchers to access high-quality samples. The NExT is also the link with the BBMRI directory and is the first step in the construction of a future national one-stop shop model for researchers.

INTEROPERABILITY

To facilitate sample sharing and reach a high quality sample level, biobanks should document their practice based on common datasets integrating international practice. Implementation of these datasets through the development of a dedicated Biobank Information Management System will help biobanks switching the excel sheets with a direction connection on the NExT.

1. COMMUNICATION

Although SBP is clearly positioned in the Swiss research landscape, it is not yet well-known enough. The word of mouth and peer-to-peer referrals (University hospitals, Research Ethics Commissions) do not lead to satisfactory results. In 2021, a first focus was therefore set on establishing SBPs notoriety with reinforcement of its communication through more frequent newsletters, and a more active place in the social network, mainly on LinkedIn.

The target groups SBP is trying to reach, are first the biobanks and biobank infrastructures which collaboration needs to be strengthened, and the biobank's users, mainly the researchers. It is more difficult to raise the latter's attention since biobanking is not yet considered as a priority in the research activities.

Conforming to the communication strategy, a conversion phase will finally be activated in order to generate registrations on the platform. Collecting the data about the website visitors will allow SBP to set up campaigns that encourage them to perform the predefined action.

SBP communication is reinforced and emphasized through different means :

- > Newsletters
- > Marketing campaigns on social media
- > Website
- > Workshops

NEWSLETTERS

The newsletters inform on SBP's deliverables and activities. These are sent to the SBP network, and relayed in the BBMRI network as well. It has become a more friendly monthly publication with a timeline announcing the next subject titles.

- O September How biobanks are making samples visible through the NExT ?
- O August Optima Label: Optimization of quality assurance measures for the overall quality system
- 9 July/2 Norma Label: Standardization of the multiple biobanking processes and equipment management
- **1** July/1 VITA Label: Compliance with law and ethical standards
- June Whats' "SQAN" ?
- May Access to NExT: Discover the new exploration instrument !
- 5 April/2 The main takeaways from the SBP-SNSF Workshop
- April/1 Official launch of NExT at the Workshop co-organised with the SNSF
- March NexT "community" feature: The biobank's opinion
- 2 February NexT; Testimonials from biobanks
- January What's "NExT" ?

According to the purpose of creating more engagement, the newsletter has changed look, periodicity and is now provided in 4 languages, the recipients being able to choose their preferred language.

NEWSLETTERS

From September 2020 to September 2021



MARKETING CAMPAIGNS

In terms of social media, Twitter still highlights and relays the important information to the BBMRI partners and researchers, but Linkedin has proved to be the most suitable social media for the business-to-business approach of SBP. Once a month, in the event of a Newsletter, SBP publishes a post on Linkedin to gain notoriety within the research scene with a 30% increase of followers during the year.



This growing audience could be attributed not only to the frequency and the sponsorship of the posts, but also with the new concept of relaying information on any biobanking related activity through a "Did you know" native post, which seem to reach new partners and raise attention to a broader audience, consolidating SBP's position.

WEBSITE

SBP website (https://swissbiobanking.ch/) is still 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.).

The structure and look of the website have evolved with the new positioning of SBP this year and will be consolidated in 2022. The content and constitution of the web pages aim to become more dynamic and intuitive for the visitors, in line with the communication strategy. Visibility of the tools and close link with other communication channels are the priorities. Strategic personalized messages will then be delivered together with emotion arousing images to achieve the top-of-mind awareness.

WORKSHOP ON APRIL 20, 2021



This year SBP and SNSF invited the research community to a virtual Workshop on "Connecting researchers and biobanks: the BioLink experience. What's "NExT"?". The workshop was a great success with many interactions between the 137 registered participants (<u>https://biobankingconference.ch/</u>)

The objectives were to :

- share the experience of the SNSF BioLink projects for the interoperability of biobanks, each BioLink having a time slot to present its work
- showcase the new SBP tool, the Network Exploration Tool (NExT) to help the biobanks and the research community to share biological material.

The format of the workshop was structured in three parts: the first presenting SNSF and SBP strategies, the second giving the floor to each BioLink project of the three funding phases to present its results, challenges and vision for the future BioLink application, and the third discussing in four concurrent sessions chaired by SBP key players the challenges for Swiss biobanking and research :

- > Prof. Adrian Egli University Hospital Basel
- > PD Dr. med. Alexander Leichtle Inselspital
- > Prof. Marc Ansari University Hospital Geneva
- > Dr. med. Michaël Weisskopf University Hospital Zürich
- > Prof. Carlo Largadièr Inselspital Bern, moderation.

Four main topics were discussed and highlighted by the majority:

> Sustainability of BioLink projects

An asset for the future BioLink grantees, would be to rely on the past Biolink calls experiences. They could benefit from business cases to further support the sustainability of their projects as well as learn from their encountered challenges, from the harmonization practice issues and the developments that had to be made to ensure success. The sustainability aspect is proposed to be integrated by SNSF in the next BioLink Call and requires the involvement and commitment of the strategic management at institutional level. Aligning each other's interests is also key to contribute to this sustainability issue and provide a valuable solution to serve a larger research community.

> Experience sharing

The importance of sharing experience to learn from each other and benefit from the gained knowledge of people working on similar projects or sharing common issues has been raised. We received a lot of feedback about the need of connection, enhanced communication across initiatives and learning more about success stories to support the scientific communities and foster exchange of practice.

> Integration of non-human partners into SBP network

The distinction between human and non-human samples is not always so easy to draw. Both types of samples share commonalities but are processed differently. The minimal requirements and applicable standards to apply must be clearly defined to ensure the quality of these important varieties of samples. The similarities and differences between human and non-human biobanks have to be considered to define the proper variables to be documented and design custom minimal datasets to be implemented. Integration of the non-human biobanks into SBP network is key to bridge with other research partners and/or national initiatives.

> Sample and data sharing

Another important aspect raised was the urgent need to ease thepractice of sharing samples and data to foster collaborations. Heaviness of the regulatory and exchange procedures is a clear burden to researchers wishing to access and use biological resources in their projects. Having an exchange platform such as NExT to support sample and data sharing is of high value to connect biobanks and researchers. This interactive tool could become the first step towards harmonization of a "common" sharing practice. The minimal regulatory / sharing requirements should be defined within the NExT community to facilitate and encourage collaborations through the platform.

Due to the success of this latest event and to the strong demand. SBP plans to organize each year an event; a national workshop and an international symposium on specific biobanking topics alternately. The aim of such events is to share updated information and knowledge on the biobanking field with the scientific community and to foster the use of SBP tools and guidance to allow collaborations.

2. SBP LABELS

THE BIOBANK SQAN

To support biobanks in the development of their governance and quality strategies, SBP developed an interactive tool in collaboration with VITAL-IT (SIB), called the Biobank Solution for Quality Assessment and Normalization – "the Biobank SQAN" helping biobanks get compliant with the minimal requirements in terms of governance, processes and quality management issues. The key features and objectives of the SQAN are summarized in the figure below :



The Biobank SQAN compliance process is based on a five-step approach for biobanks by providing specific support and documentations and integrating the main principles of the new accreditation norm ISO 20387: 2018.



ANNUAL REVIEW

Once the label issued, an annual review is planned to ensure accuracy of the information provided to the biobank users and to reflect up-to-date practice of the biobank, as well as to measure Key Performance Indicators on the biobank.

THE LABELS

The outcome of the Biobank SQAN is the possible delivery of three different labels certifying the compliance with different types of requirements as described below. The label the biobank will obtain depends on the level of requirements the biobank will be complying with :



Once the biobank fulfills at least the VITA label, it becomes visible at a national level through the SBP directory, and if interested, at a European level in the BBMRI directory, with the support of SBP managing the data capture and followup within this European network. SBP labels are not only addressed to biobanks which collect and provide samples for research purposes, but also to biobank infrastructures which provide services to biobanks such as storage facilities, sample processing, transport, etc. The only difference is that biobanks should comply with the VITA requirements at first, and the biobank infrastructures should directly comply with the NORMA requirements in their quality-of-service providers.

SBP NETWORK

The labelled biobanks are then part of SBP network which is growing over the time with new biobanks and biobank infrastructures well spread within the country.

The majority has registered spontaneously after having heard from already labelled biobanks, or through the Research Ethics Commission of Canton de Vaud or Basel requiring that biobanks have at least the VITA, meaning that there is a large potential of growth once SBP will proactively canvass new biobanks.





NUMBER OF LABELS BIOBANKS

NUMBER OF LABELS

Biobanks

In 2021, the network of biobanks reaches 43 VITA, 10 NORMA and 3 OPTIMA labelled biobanks. The highest increase for this year is the VITA awarding with 21 newly VITA labelled biobanks, while 19 are already in the evaluation process. There is also a marked interest of biobanks in reaching the NORMA label with 3 new biobanks and 9 additional waiting to be certified. The OPTIMA label is, as planned, the less envisioned level, but still promising with 1 additional biobank certified and 3 already in the pipeline. In terms of organization and time, these two last labels require onsite visits and thus could not be compared to the VITA label efficiency. However, the biobanks that commit to reach NORMA and OPTIMA requirements are dedicated and trustful partners in the network with whom SBP could count on for its future developments.



Biobank infrastructures

In terms of biobank infrastructures, the number of labelled infrastructure has increased with 3 new NORMA and 1 new OPTIMA, while 12 are in the process of labelling. These infrastructures are very important for biobanking since they facilitate an efficient biobank development and allow economies of scale for institutions hosting biobanks.

INFRASTRUCTURES 2 OPTIMA 5 NORMA 12 REGISTERED

As depicted in the figure below, the landscape of partners is gaining in diversity, even though no active prospection has yet been done. SBP was first focused on University Hospitals' biobanks and, upon request, supported other institutions (universities and other hospitals) and even private or semi-private institutions.

BIOBANK NETWORK BY TYPE OF INSTITUTION								
19 8	REGISTE	RED	33 LAI	BELLED		UNIVERSITY HOSPITAL		
2 5					UNIV	ERSITY / EPF		
6	6		MEDIC	AL OR LAI	OTHE	R HOSPITAL / ORY CENTER		
5	3					PRIVATE INSTITUTION		

These new collaborations forced SBP to adopt different approaches with these new partners. For universities and other hospitals, biobanks are less supported in terms of funding and strategy, allowing SBP to provide an efficient approach from the beginning. For private partners, a partnership agreement has been setup and agreed by SNSF to regulate this collaboration and to make it pay at a cost price.

a. SBP strategy to universities and cantonal hospitals

SBP strategy proposed to universities relies on the creation of a local infrastructure providing a centralized storage or processing services to biobanks within its Institution. The infrastructure will undergo SBP SQAN evaluation to achieve the Normal label at minimum guaranteeing the quality of its operational processes as per the applicable standards (e.g. ISO 20387). The local infrastructure will host sample collections or biobanks whose Governance will then be assessed independently through the Vita label. Using this strategy, biobanks will benefit from a local Infrastructure whose services will have been evaluated and qualified according to SBP requirements. This shifting paradigm towards the professionalization of biobanking activities paves the way to increase harmonization of practices not only in University Hospitals but also in other research organisations.

b. Partnership agreement with private or semi-private institutions

Private or semi-private entities are willing to benefit from SBP consulting services and/or to register into SBP's Biobank SQAN process. Being a non-profit association initiated by the Swiss National Science Foundation (SNSF) and financed by public funds, SBP accepts the collaboration under the strict terms and conditions defined below:

The Biobank and/or Infrastructure is willing to enter into the Collaboration and commits to :

- ✓ collaborate with the academic sector
- ✓ be integrated in the SBP NExT as a new partner of the national network
- ✓ register into the Biobank SQAN and achieve at least the Norma label.

Hence, and provided that all the following conditions are fulfilled, SBP accepts the Collaboration.

- 1. Collaboration with the academic sector :
 - a. The principles of research freedom, research independence and freedom to publish are upheld (Art. 13)
 - b. No pecuniary benefit from the collaborative work will be derived (Art. 13)
 - c. Researchers publish the research results in accordance with their obligation to open access by the SNSF and make them available to other researchers without hindrance can (Art. 47).
- 2. Registration into SBP's Biobank SQAN
- 3. Biobank SQAN's annual review
- 4. Communication on SBP used services and issued labels
- 5. SBP Support documents usage

The Biobank agrees to pay SBP CHF 1500 for a VITA label, CHF 3500 for a NORMA and CHF 5000 for an OPTIMA, allowing SBP consulting services to be covered in terms of staffing and expertise.

The partnership agreement has been validated by SNSF in April 2021 and is provided to interested biobanks from now on. Already, four agreements have been signed with a revenue of CHF 7500 for this year with the following partners :

- Davos Biosciences AG
- Bioledger at EPFL
- Swiss Center for Musculoskeletal Biobanking (SCMB) at Balgrist Hospital (ZH)
- SwiSCI Biobank infrastructure at Nottwil Paraplegic Center.

VITA LABEL

The VITA label is the first step in the certification process allowing the biobank to get visible into the SBP NExT as well as in the BBMRI directory.

The objective of this label is to evaluate the biobank key documents in terms of governance as described in the table below.

Compliance with legal and ethical standards





> Complaints

From January 2019, 43 biobanks are compliant with the VITA label and, out of them, 9 had an annual review. Year 2021 follows the exponential increase of 2020 having doubled the activity and with already 19 biobanks in the waiting list. The canton Vaud is clearly the more represented region in the network of biobanks with the Research Ethics Committee (REC) addressing biobanks to SBP directly. Basel and Ticino RECs have also decided to adopt this strategy, while Swissethics is interested in the concept of labels.



During the evaluation process, biobanks are using one or the other harmonized documentation provided by SBP; as an example, 29 out of 43 biobanks already use the SBP harmonized biobank regulation.



In terms of issues raised, SBP points out some recurrent improvements to be done around :

- Governance documentation (missing biobank regulation or MTA if sharing occurs)
- Consent process documentation (missing SOP to train personnel)
- Communication to participants, in particular regarding complaint management (no procedure or strategy to handle possible complaints)

NORMA LABEL

The NORMA label focuses on the evaluation of the processes and resources necessary to run a biobank.

The review is based on the requirements and the key documents described below :



Standardization of the multiple

management

biobanking processes from consent

including personnel and equipment

NORMA

presentation to sample shipment,

During the evaluation process, biobanks show areas of improvements and support documentation in terms of :

- LIMS with audit trail to guarantee sample and data traceability
- Aspects that can impact quality directly (lack of method validation and Quality control strategy)
- Documentation issues.

In addition, more than half of the biobanks use the SBP harmonized SOPs provided during the SBP-delivered consulting.

From January 2019, the SBP network has 15 biobanks compliant with the NORMA label, and out of them 6 had an annual review. In the year 2021, 3 biobanks and 3 biobank infrastructures obtained the NORMA label with 3 biobanks having expressed their willingness to reach the OPTIMA label. Concerning the biobank infrastructures, they get the NORMA label first with already 12 in the pipeline.



OPTIMA LABEL

The Optima Label allows the Biobank to establish a QMS with a proper documentation management and the implementation of Quality Indicators to monitor and optimize its operational processes. Optimization of the overall biobanking management system with focus on the implementation of quality assurance measures



This ultimate step helps implementing a strategy that will support the biobank's long term activities. These developments are in alignment with the requirements set by international standards, such as ISO 9001 and 20387.



> Business model and cost recovery

(sustainability)

From January 2020, 5 biobanks are compliant with the OPTIMA label, 3 biobanks and 2 biobank infrastructures, which 3 had an annual review. Year 2021 follows the exponential increase of 2020 with 1 newly labelled biobank and 1 infrastructure.

SBP contributes concretely to the optimization of the following biobanking aspects in order to enhance biobanks' quality with this label on the following topics :

- Documentation management
- Continual improvement including internal audits and management of non-conformities
- Risk management



3. QUALITY

(measure 1.1)

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 is developing and updating its guidance giving an exhaustive idea of what needs to be built, maintained and documented for a state-of-the-art biobank.

SBP's guidance provides different types of documents (policies, procedures, templates and datasets) covering crucial aspects that biobanks should follow in terms of governance, quality and interoperability. It is aimed to support biobanks operational activities, from their establishment, through the improvement of their operational and quality management and ultimately towards the implementation of a proper documentation system.

At the top of the pyramid is placed the quality manual, as the cornerstone of the biobank strategy integrating where and when the documentation should be organized. Highlighted in the figure below are the new deliverables produced during this year and presented in this report.



Quality manual

The Quality Manual template is the reference deliverable guiding the biobank in the definition of its quality strategy. The template is easily adaptable to each biobank's practice making it a practical document supporting biobanks or biobank infrastructures to set up and document their quality management system (QMS).

It is planned to be released in November 2021 once SBP governing board validation. aims at working towards standardized operational processes, quality improvement of samples and data management.

Describing all elements of a quality management system allows to have an efficient overview of the biobank operational procedures and helps identifying and addressing potential gaps.

A quality manual can be established both by biobanks and biobank infrastructures, as its content will be defined by the type of conducted activities. This document is intended to be used internally as a reference document for the biobank personnel and externally for auditors, customers, and external collaborators.

Documentation of the quality management system is a requisite for the ISO 20387-General requirements for biobanking and for the obtention of a SBP OPTIMA Label, as the latter preparing biobanks to the ISO accreditation.

Even though, the quality manual is required for the OPTIMA Label, it should be used as a guide to build up the requirements that a biobank should follow for the VITA and NORMA Labels as indicated in the figure below.

/°) 88	Chapter 2 ORGANIZATIONAL REQUIREMENTS	2.1. 2.2. 2.3.	GovernanceVIRoles and responsibilitiesVICommunicationVI
	Chapter 3 QUALITY REQUIREMENTS	3.1. 3.2. 3.3. 3.4. 3.5.	Quality policy and objectivesImage: Constraint of the sector
°□- €: 	Chapter 4 RESOURCES	4.1. 4.2. 4.3. 4.4. 4.5. 4.6.	SustainabilityImage: Constraint of the second s
0-0 Co-0	Chapter 5 PROCESSES	5.1. 5.2. 5.3. 5.4. 5.5. 5.6. 5.7.	Quality control of sample and dataImage: ConsentImage: Co

Figure 1: Structural content of the Quality manual, highlighting the hierarchy of organizational requirements applying to all chapters, the quality requirements applying to resources and processes and finally the resources required to operate the processes.

Together with the SBP Quality Manual, a new SBP procedure (SOPs) on risk management and a new often required template, the Service Level Agreement template have been developed.

SOP risk management

SBP SOPs are based on Good Biobanking Practices and should serve as reference guidance for biobanks to develop site-specific Work Instructions. This SOP provides insights into the biobank risk and opportunities management procedure, including:

- Identification of threats/hazards that may cause harm to people (biosafety) or issues that may impact quality objectives, data integrity, IT infrastructure security (data breach, data loss), governance/ethics/regulatory aspects or any related areas.
- > Determination of the likeliness that each hazard will occur and the severity of the possible consequences.
- > Decision on actions to be taken to stop hazards from occurring or to mitigate the risk.
- > Opportunities arising from the taken actions and continuous improvement.

A risk-based approach is the basis of decision-making in the biobank and is performed at all stages of the biobanking processes. In this document, the Failure Mode and Effect Analysis (FMEA) method was adapted to meet the ISO 20387 standard ("Biotechnology – Biobanking – General requirements for biobanking") requirements regarding risk management.

The objectives of this approach are the following :

- > Catalogue and prioritize all the possible threats to the biobank.
- > Analyze the significance and likeliness of the identified risks.
- > Identify actions to minimize the risks.
- > Use risk analysis to create opportunities and determine the need for risk control related to a specific hazard/ issue.
- > Raise awareness about hazards/issues (incl. ethics/regulatory issues) and risks to decision-makers.
- > Determine and document the financial added value of risk mitigation and better understand the return on investment.

SLA template

Biobanks often collaborate with service subcontractors who indirectly contribute to the successful implementation of their activities. These services typically include maintenance, cleaning, informatics (IT), human resources or purchase, or can be related to a specific biobanking process (e.g.: samples transport or storage). The biobank shall document its cooperation with these service subcontractors, in particular if the service provided can have a critical impact on the sample quality. In this case, the biobank shall implement measures to ensure that services are monitored and evaluated over time. The implemented measures shall be proportional to the degree of risk impacting the quality of the biobank related activities or samples (see Risk Management SOP by SBP).

This Service Level Agreement (SLA) template details in the format of a written contract the services provided and the expectations between the service provider and the biobank. Records of the service assessment shall be maintained and could be used as part of a regular review of the suppliers.

In a nutshell, this agreement specifies the parties' mutual obligations and communication aspects. The document describes the scope, the procedure for modification, the services controls and audits, the responsibilities, the duration and termination terms of the contract, and the expectations in term of guality for all services covered by the agreement.

SLAs are developed to satisfy a requirement from the ISO 20387 standard ("Biotechnology – Biobanking – General requirements for biobanking") regarding subcontractors. Fulfilling this requirement is mandatory to obtain the SBP Optima label when subcontractors are outside the host Institution and recommended as good practice if service providers belong to the same institution.

New service to come : Quality assessment

In terms of quality, SBP provides to the biobank community a new consulting service focused on continuous improvement. The idea is to position SBP not only at the certification step while checking the necessary requirements to run and setup a biobank, but also once the biobank processes are in place as an auditor to help improve the processes and reach higher sample quality. This new service will also help biobanks to evaluate decentralized biobanking processes to improve their activities, i.e., in the context of multicentric biobanks and in cohorts. It has initially been tested with the Swiss Health Study funded by the BAG and run in two centers, Lausanne and Bern.

Quality review of the Swiss Health Study, pilot phase

The Swiss Health Study (SHeS) pilot project assesses the health status of the Swiss population in relation to the impact of the environment, exposure to certain chemicals, lifestyle, infectious diseases (e.g. Covid-19) and certain predispositions. A pilot phase, running from 2019 to 2021, has been established to evaluate the methods and infrastructure needed for a national-scale study.

SBP supports the quality assessment of this pilot study by advising the two sites, Lausanne and Bern for a proper management of their samples and data. SBP oversaw the development of study documents and procedures (e.g. quality manual, quality control SOP, ...) to harmonize the practices across sites and manage biobanking activities under Good Biobanking Practices. Additionally, both participating sites have been evaluated and awarded with the NORMA label, which demonstrates the compliance of the SHeS operational procedures with SBP minimal requirements in terms of processes (mainly based on the ISO 20387 on Biobanking). SBP also performed analysis on the sample-related data to evaluate consistency across sites and on specific Quality Control check (e.g. time from sample collection to freezing). These analyses allowed recommendations to be made in order to improve the quality of the processes, data flow, standardization and documentation. SBP's recommendations and findings will be integrated into a scientific report for the Swiss federal council, for further funding evaluation to scale up the study at a national level.

Trainings

SBP contribution to SCTO Training through EasyGCS platform

SBP collaborated with SCTO to develop the "Biobanking" content of their new educational tool, the Easy Guide to Clinical Studies (Easy-GCS). Aiming to be a practical reference for all professionals involved in clinical studies, it provides targeted and concise information on specific subjects (e.g. Protocols, Ethics and Law, Data Handling, ...) within a defined study phase (from Concept to Completion). SBP documents and website will be linked as external resource and reference, providing enhanced visibility to the platform.

Certificate of Advanced Study (CAS) in biobanking

In collaboration with the University of Geneva, the Hset foundation and the Institut Pasteur, SBP is working on the development of a CAS concept that will help to educate the Swiss research community in the field as well as other countriespart of the Institut Pasteur network. The need of a training is clear, but the concept should really target the public through the development of modules; this concept is in the construction phase, and funding still needs to be found.

4. VISIBILITY

SBP Network Exploration Tool (SBP NExT)

(measures 2.1 and 2.3)

Promoting biobank's visibility and sample sharing being a central task, SBP has developed a centralized national ecatalogue, called SBP Network Exploration Tool (SBP NExT), combining the features of a directory (search at a the biobank level) with the ones of a catalogue (search at a sample level) using visualization aspects to facilitate the search.

The e-catalogue being integrated in 2021 (<u>https://swissbiobanking.ch/sbp-next/</u>), and the samples being accessible from 2022, the SBP NExT appears on SBP website as an initial version featuring only the SBP directory. The NExT has been officially released April 20 2021 at the workshop and advertised in a series of newsletters from January 2021.



This new tool has been developed and improved with the help of pilot biobanks who have challenged and tested the solution until end of 2020. They have still been very active in 2021 to help us improving the system and providing the first samples on the platform. A great diversity of pilots allow the NExT to fulfill multiple criteria and functions with a community of tissue biobanks taking part of the Patholink project, with a Vetsuisse biobank for non-human needs, with the Liquid Biobank Bern biobank infrastructure (LBB), and a Swiss cohort study, the Swiss Transplant Cohort Study (STCS).

FEATURES

NExT (for Network Exploration Tool) is the innovative and interactive instrument provided by SBP to the various biobanking stakeholders in Switzerland. It fosters visibility of biobanks and biobank infrastructures in the SBP network, enables search and exploration of biobanking entities as well as biological samples, and helps biobank administrators and researchers to find a mutual agreement facilitating the transfer of biological material.



To increase access and exchange of biological samples through its new platform NExT, SBP has developed a dataset for sharing. This newly designed dataset is based on existing defined datasets (i.e., SBP full datasets for liquid, tissue and bacterial samples), Minimum Information About Biobank data Sharing (MIABIS) guidelines completed with SPREC v3 (Standard PREanalytical Coding) information. The data fields were carefully chosen to define minimal data to be documented when sharing samples and were validated by SPHN as complementary to their datasets.

The sharing dataset has one part related to the sample itself and one part related to the protocol applied during collection or processing having a direct impact on sample quality; this gives the NExT a particularity of searching samples focusing on the preanalytical data being essential to provide researchers adapted samples for the technique used.



A MONITORING, EXPLORATION AND COMMUNICATION PLATFORM FOR BIOBANKS AND RESEARCHERS

As described in the scheme, the NExT is on one hand a monitoring platform for biobanks to upload samples, to choose the visibility for the research community at large or for a selected community and upload access policies at a later stage. For the researcher, it is an exploration platform to search biobanks and samples integrating preanalytical data as well as a communication platform once a selected sample list is of interest of a biobank.

SUPECTORL The following scenario illustrates a typical use case as currently supported by NExT:

Alice is the manager of a biobank focused on samples for cancer research. Her biobank has recently obtained the Vita label from SBP, making it findable on NExT, the national biobank directory and e-catalogue.

By logging into her NExT administration console, she was able to upload in a single file the data of all samples stored in the biobank, making these samples immediately findable on NExT as well. To filter future demand, she restricts visibility of her samples to members of cancer research communities.

Bob is an academic researcher working on the feasibility of an upcoming study. Through the NExT search interface, he selects various criteria of interest to get a sense of the availability of samples. His credentials enable him to see samples restricted to cancer research communities.

Among the various biobanks appearing on his screen, samples from Alice's biobank seem to be the best match for his query. Bob has some additional questions on the desired samples and would like a human confirmation of their availability. Without leaving NExT, Bob selects the samples of interest and sends an inquiry to Alice, providing some context regarding the intended research.

A notification alerts Alice of the new inquiry. Back on NExT, she can provide Bob with the precisions he needed and confirms availability of the desired samples. Bob is now able to append his feasibility analysis with exhaustive information regarding sample availability and specific biobank access policy.

When the time comes, the same inquiry interface will allow him to complete the order process simply and in clear mutual agreement.

NExT is currently functional and ready to welcome the data of all biobanks in the network. SBP is now starting to advertising NExT towards biobanks, encouraging upload of sample data. Once a viable mass of sample data is available, SBP will start advertising NExT towards researchers, making it the primary exchange platform for biological material in Switzerland.

5. INTEROPERABILITY

(measure 2.2)

A first step towards the biobank's interoperability has already been reached with the publication of datasets for tissue and liquid samples derived from human and animals, as well as for bacteria in 2019. This was a consequent work where national experts within Switzerland agreed on a list of data that need to be documented for each sample, with the feature of being mandatory or optional.

Out of these datasets, a selected number of data has been chosen to come up with the sharing SBP minimal dataset used in the NExT presented in the chapter 4 - Visibility.



A second step towards biobank interoperability is the implementation of the datasets in the biobanking practice as well as the documentation at every step of the biobanking process. To that end, based on the fact that the majority of biobanks operates on excel sheets and do not have a professional information management system, SBP has the objective to provide a biobank information management system (BIMS) integrating SBP datasets and being adaptive to a large number of biobanks.

DEVELOPMENT OF A READY TO USE BIOBANK INFORMATION MANAGEMENT SYSTEM (BIMS)

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

Thanks to its significative network of biobanks, SBP is well positioned for this development, understanding the various needs of biobanks of all sizes and scopes in Switzerland.

Such systems are referred to as Biobank Information Management Systems (BIMS), and to our opinion, the currently available BIMS offer a suboptimal solution to this complex problem. We identified the following shortcomings as the being most central:

- 1. Each available BIMS is designed to support a very limited set of biobanking settings and use cases, while heavily constraining the various workflows of the biobank, potentially hampering efficiency.
- 2. The process of determining the BIMS that most closely match the needs of a given biobank is highly laborintensive, as is the implementation of such a solution, resulting in potentially prohibitive costs.
- 3. Despite the complexity and cost of these solutions, unavailability or lack of technical and customer support are regular points of contention among biobanks.
- 4. Available BIMS offer poor support for large scale sharing and collaboration, e.g., integration in federated search solutions.

Therefore, SBP aims to build a new BIMS that would address these shortcomings for the use of Swiss biobanks.

The SBP BIMS should reach these four objectives to be successful and competitive in the market :

- 1. **Adaptive** SBP BIMS aims to be flexible enough to adapt to almost any biobanking use-case and to support any study-specific needs, in both human and non-human applications.
- 2. Affordable That flexibility would reduce both specification and implementation costs.
- 3. **Supported -** SBP BIMS use would rely on an available and local technical support.
- 4. **Interoperable** SBP BIMS would foster collaboration, sharing, reuse, and be readily compatible with the national e-catalogue SBP NExT.

CONCEPT

The core feature of our project is a dynamic study design tool that enables a precise and meaningful representation of any given study protocol in the BIMS data flow. This representation work would be done either in house by dedicated trained personnel, or as a service by SBP.



By solving these four issues, SBP plans to improve the Swiss biobanking landscape by:

- Increasing efficiency in regular biobanking processes,
- Making BIMS accessible to smaller structures,
- Increasing quality through data exhaustivity and interoperability.

Once the concept finalized, specifications will be sent through a Request For Proposal (RFP) process with identified potential partners that have been asked to provide a budget for the development of the SBP BIMS. Funding applications will be made to develop the BIMS in the coming years.

6. NON-HUMAN BIOBANKING

(measures 3.1 and 3.2)

Biology Roadmap for Research Infrastructures 2025-2028 by the Swiss Biology Community

SBP participated in the development of the SCNAT Biology Roadmap in 2019-2020 as well as in its review in November 2020. Published in March 2021, the Roadmap represents the need for national research infrastructures of the Swiss scientific community in the field of biology and is a formal element of the process to elaborate the Swiss Research Infrastructures Roadmap 2023.

This bottom-up contribution to the identification and selection of important national and international research infrastructures has been coordinated by the Swiss Academy of Sciences (SCNAT) on a mandate by the State Secretariat for Education, Research and Innovation (SERI). Researchers are invited to submit their applications for future research infrastructures.

SBP participates in the two following applications :

SwissBioCollections : Towards a nationwide research infrastructure for biological collections in Switzerland: broadening horizons after SwissCollNet and the Swiss Biobanking Platform

In June 2021, SBP has applied together with the SwissCollNet Initiative (SCNI), the national program dedicated to promoting physical and digital access to natural history collections to the "Biology Roadmap for Research Infrastructures 2025-2028" call launched by the SEFRI under swissuniversities supervision.

The newly proposed Swiss research infrastructure (RI) will support biomedical and biological biobanks as well as natural history collections under the name of SwissBioCollections. SwissBioCollections will strengthen and harmonize the biobanks distributed across the country and focus on specimen quality as well as data interoperability and accessibility. These developments and expertise, currently coordinated by SBP for the human medical and veterinary biobanks, will be broadened to incorporate other biological disciplines including evolutionary biology, ecology, agronomy and forestry.

Ultimately, biobanks and natural history collections, when integrated into a single research infrastructure would drive single point access, harmonization of processes, quality standards, and implementation of FAIR (Findable, Accessible, Interoperable and Reusable) data principles, enabling opportunities for cross-disciplinary, integrative research and creating synergies across a vast array of disciplines.

SwissBioCollection (Starting 2025)



The SwissBioCollections research infrastructure proposed is fully aligned with the SCNAT Biology roadmap covering entirely the first axis of this roadmap on collections and biobanks (SwissBioCollection), and has strong links with the three other axes, SwissBioData, SwissBioImaging, and SwissBioSites.

This proposal builds on current activities and develops synergies between already existing national distributed infrastructures supporting research for the 2021-2024 period (i.e the SwissCollNet initiative and the Swiss Biobanking Platform). It also demonstrates tight connections with European research infrastructures (DiSSCo and BBMRI-ERIC) and fits with the One Health concept, which combines, in a unique effort, multiple practices that work together at local, national and global levels to achieve optimal health for people, animals and the environment.

Different working groups were created where SBP is actively participating :

WG 1: Natural history collections

- WG 2: Museomics / imaging infrastructures
- WG 3: Biobanks
- WG 4: Living collections
- WG 5: Synergies and coordination

The WG 3 on biobanking is co-chaired by Sabine Bavamian and Pr Carlo Largiadèr from SBP, and the WG 5 is cochaired by Christine Currat, SBP and Nadir Alvarez, SwissCollNet.These working groups will help consolidate the vision for this project to be submitted to SNSF 31st December 2021.

MIMO : A microorganism-focused, modular multi-omics data and sample integration platform for data and sample sharing and analysis

MIMO integrates and relates to two core aspects of the Biology Roadmap while substantially contributing to a Swisswide shared national infrastructure in "SwissBioData" and "SwissBioCollection". The proposal expands on already existing platform and networks, such as the Swiss Pathogen Surveillance Platform (SPSP), linking to samples via the Swiss Biobanking Platform and adapting the Microbiota Vault initiative.

MIMO also relates to the general recommendation within the Biology Roadmap and aims to fulfill these core recommendations of the Biology Roadmap 2023-2028 with a dedicated focus on interconnected microbiological data and samples.

Different working groups were created where SBP will work on synergies and usage of systems already in place to support the MIMO research infrastructure proposal.

These working groups will help consolidate the vision for this project to be submitted to SNSF 31st December 2021.

SBP representation in a non-human related international project

The Netherlands Organisation for Health Research and Development, ZonMw is a public research funding organisation supporting health research and care innovation. One of the main aims of ZonMw is to improve the scientific and social impact of research output, including research data by creating data that are findable, accessible, interoperable and reusable (FAIR). This year, https://www.zonmw.nl/en/, has organised 4 workshops (May-June 2021) together with <u>GO</u> <u>FAIR, DTL and Health-RI</u> to educate the entire Infectious Diseases research community in working in a more FAIR manner.

SBP participated to these workshops and provided valuable input through SBP dataset for bacteria which has been reviewed and adapted to fit ID&AMR templates. SBP dataset for bacteria has been used as a highly relevant resource in the development of a set of machine-actionable metadata in the field of AMR/infectious diseases, which could be of great interest with a return on investment for the Swiss research community.

7. BBMRI COLLABORATIONS

(measure 4.1)

As part of the BBMRI European network of biobanks, SBP has greatly increased its activities within this organization on the following topics :

Strategy (SBP representative . Christine Currat)

Twice a month, SBP takes part to the management committees with the other node directors. On this topic, SBP has sent a report to the SERI and participated to a meeting with other ERIC Swiss representatives to see how valuable to be part of BBMRI-ERIC and ERIC networks.

SBP was appointed as a member of the Belgium advisory board, as well as an auditor of the Biobank Charité in Berlin. These nominations show that Switzerland, towards SBP, is now recognized as an important player in the field.

BBMRI Task Forces

To align the SBP strategy to the European one, SBP is actively participating in newly launched BBMRI Task Forces (TFs), with the opportunity to gain expertise and drive relevant developments to better serve and connect the Swiss biobanking community.

Task Force 1: Quality Assurance Markers (Aline Dousse, Biobank Officer) - SBP presentation on July 27th 2021

Task Force 2: Federated Search (Riad Gacem, IT coordination Officer)

Task Force 3: Biobank Data Quality & Certification (Joséphine Uldry, Quality Officer)

Task Force 4: Expedited Access Procedure for Samples & Data (Sabine Bavamian, Chief Scientific Officer)

Task Force 5: Data Pooling in BBMRI-ERIC (Riad Gacem, IT coordination Officer)

Task Force 6: Big Data Analysis (Khalil Klouche, Innovation Officer)

Task Force 7: National Node operations & NNs'/Biobanks' sustainability (Christine Currat, Executive Director)

Task Force 8: Success / Impact stories (Claudia Lagier, Marketing Officer)

Participation to the BBMRI's TFs has been promoted through the SBP network, inviting any interested biobanks to join and to address strategically important and scientifically exciting topics in this new format. The goals and milestones of each TF will be further specified once the TF has been formed.

Biobanks and biobank infrastructures in the BBMRI directory

Once they have fulfilled at least the VITA requirements, biobanks get the possibility to gain further visibility in the European network through BBMRI directory. In 2021, 14 new Swiss biobanks were consented to appear in the BBMRI directory. A total of 24 Swiss biobanks and 2 biobank infrastructures are now visible in the European network (<u>https://directory.bbmri-eric.eu/menu/main/app-molgenis-app-biobank-explorer/biobankexplorer#/network/bbmri-eric.networkID:CH_SBP</u>).



Since 2021, the BBMRI directory is linked to the BBMRI-ERIC Negotiator, a new communication platform to connect biobankers and researchers to request samples and/or data. SBP has also taken part to the new Federated Search project to allow researchers performing feasibility studies and access aggregated counts for samples data from all biobanks within its network.

Federated Search and Sample Negociator (SBP representative: Riad Gacem)

After the ADOPT project in 2018, SBP actively participates in the Federated Search project as a pilot together with Austria, Italy, Germany, Malta, Norway and UK. To that end, SBP identified a partner biobank, the Tissue Biobank Bern, interested in testing the system; a second phase in 2022 will be opened to other partner biobanks.

SBP, through its NExT platform has the IT environment necessary to install the required (BC-LINK) tool hosted on the SIB server besides the NExT and the SQAN. SBP with the partner biobank, have mapped and converted their sample data to BBMRI-ERIC's dataset and ensured compliance with local regulations regarding the shared dataset.



By consenting to take part to the BBMRI-ERIC Federated Search, SBP biobanks will benefit from our support to automatically upload their sample data in the BBMRI Catalogue and become visible at the European level.

Quality (SBP representatives : Joséphine Uldry, Aline Dousse and Sabine Bavamian)

Beside its representation at the European Biobank Week (17-20 November 2020, poster presentation: "Towards a quality strategy for multicenter biobanks"), SBP has been actively engaged with the BBMRI QM to gain insight from BBMRI Quality experts regarding its quality strategy, support to Swiss biobanks, next deliverables and how to foster Swiss/European collaborations. In this regard, SBP presented its QM activities to BBMRI QM (June 14th 2021) and participated to the new format "the consultation hours" in the pillar Knowledge Hub. "Get insights from the outside" is the motto of these consultation hours on quality-related topics in the field of biobanking and biomedical research. The aims of these new meetings are to promote the National Nodes and their QM activities to make them more visible to the public and to all interested parties worldwide. The "BBMRI.QM Newsroom" took place in June 29 2021 and is planned 4 times a year following this structure:

- 1. BBMRI.QM update on current BBMRI QM developments
- 2. Presentation from 3 National Nodes
- 3. Guest presentation new viewpoints on QM
- 4. Exchange ideas, brainstorm and building new visions

On June 29th 2021, SBP has been supported by Prof. Carlo Largiadèr who presented as a guest speaker on the topic of the Digitalization of biobanking processes and its benefits for QM.

ELSI (SBP representative : Sabine Bavamian)

SBP took part to the BBMRI Helpdesk / Support Service meetings (September 30, 2020, May 31, 2021 and September 7, 2021). Discussions were focused on how to offer good ELSI support services and promote trust. The Group also shares knowledge and experience on ELSI hot topics (e.g. Access policies and industry, Data Protection Impact Assessment). The objective of the meeting in September 2021 was to stake on changes from the NNs regarding national biobanks and data sharing laws.

SBP also took part to the «Hospital-based biobanks for biomedical research» workshop (26th January 2021). This event featured Prof. Carlo Largiadèr (Head of Inselspital and SBP expert members for Liquid Biobanking) who presented on behalf of SBP the status of the implementation of the harmonized general consent in Switzerland from a hospital-based biobank perspective. This workshop aimed at mapping the current landscape for general consent to hospital-based biobanking in Europe and identifying main opportunities and bottlenecks. The outcome identified the main principles for general consent and outlined joint conclusions that may guide the development of future recommendations.

STRATEGY 2022

As presented in the Appendix, a list of objectives and deliverables are already planned for 2022 and a short update is listed in this section following the structure of the present report :

Governance

SBP's governance will be resumed with a new election round for the SBP ordinary and expert members, as well as the appointment of the SBP's president and vice-president.

An analysis of the bylaws could be appropriate to ensure that SBP's governance is still aligned with the development and the positioning SBP is aiming at in the near future. As an independent association, SBP's network could play a stronger role in the governance and the representation of key stakeholders that could be envisioned.

These proposals will be first elaborated with the SNSF and discussed with the governing board, to be then validated by the ordinary members at the next General Assembly in 2022.

Communication

A three-phase marketing strategy is going to be applied to win customers and therefore registrations on the platform. SBP's website will be renewed with a look and feel reflecting the evolving corporate dynamic and a more easy-to-find way to our tools and documentations.

A monthly newsletter will be mailed to update the SBP network on relevant activities with a more targeted information through the segmented database, in the chosen language.

Due to the success of the latest Workshop, SBP plans to organize an annual event, on a regular basis.

SBP Labels and quality

The labels have proved their efficiency to pave the way towards biobank harmonization and quality. The sequential approach to leverage the biobanks' quality needs to be evaluated and updated to the reality of the practice and the evolution of the biobanks' requirements.

The ISO norm on biobanking will be in the focus of 2022 to develop SBP services serving biobanks that are interested in this accreditation together with a specific focus on how trainings could help biobanks understand and implement quality standards.

Visibility

The challenge of 2022 will be to encourage biobanks uploading their samples' data and to have them regularly updated. On the other hand, SBP will be able to attract researchers with the NExT and to act on the access and usage of samples. The concept of a one-stop-shop to promote sample sharing will also be studied in collaboration with other Swiss research infrastructures while working on the guidelines and tools to facilitate national and cross-border exchange.

Interoperability and non-human

Two major projects will be elaborated in 2022. First a review and consolidation of the datasets published in 2019 with a special focus on the non-human biobanks' needs, and second with the funding and development of the SBP BIMS.

BBMRI

The collaboration with BBMRI is still of great importance and needs to be maintained. How to integrate or to make SBP's network benefit more from this collaboration could be seen as a task to reinforce the position of SBP as the Swiss node.

A.C.iuu

Pr Antoine Geissbühler President

CCA

DrSc Christine Currat Executive Director

AIMS AND MILESTONES 2021-2024

Aims	Measures and deliverables 2019-2020	Milestone	Deliverables	Statu s
1. SBP promotes a quality strategy for biobanks that serves	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	Ŋ
both quality management issues and sample quality.	1.2 — Enlarge the SBP national network of biobanks to other hospitals, universities, public	10.2021		\oslash
	or private research organizations.		Biobanks from Universities are part of the network	Ŋ
		10.2023	Interest of other research partners is encountered	
		10.2024	Interest of private industries is considered and evaluated	Ŋ
	1.3 — Develop and update guidance, know-how and consulting services in terms of quality on a	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	
		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	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	ß
establishing a Swiss biospecimen catalogue at the sample level. The SBP		10.2021	SBP BIMS concept is developed with a business plan	Ŋ
provides advice in IT systems for quality and networked		10.2023	SBP BIMS is developed and implemented in interested biobanks	
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	Ŋ
	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	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	Ŋ
activities.	3.2 — Identify an international non-human biobanking consortium or initiative to network Swiss biobanks as BBMRI for the human biobank		The consortium or initiative is identified and the collaboration is defined	Ŋ
	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		
	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	\oslash
	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		Interested services are provided and a price is calculated for each	
	4.3 — Organize regular national and international conferences to promote knowledge-	10.2021	a national conference is organized	\oslash
	sharing on different biobanking aspects aligned with european guidance	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		Q
	5.2 — Develop a concept to be integrated in the SERI list of research infrastructures of national importance	10.2023		Q
	5.3 — Develop a business plan with financing measures	10.2023		