SWISS BIOBANKING PLATFORM

ANNUAL REPORT 2017

SWISS BIOBANKING PLATFORM
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TABLE DES MATIÈRES

I) INTRODUCTION

The Swiss Biobanking Platform (SBP) is a newly created 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 increasing requests from researchers in biomedical sciences in terms of quality control, access, transparency and the interconnectedness of biobanks and their basic data for research purposes.

The SBP aims at centralising 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 treatment), information and counselling on legal and ethical aspects of biobanking, as well as information on repositories abroad. Moreover, the SBP links Swiss biobanks or networks of biobanks with the European Biobanking and Biomolecular Research Infrastructure (BBMRI-ERIC) as national node. It ensures the harmonisation of biobanking practices with international and EU standards, provides information on biobanks networks abroad and the related activities.

In 2013, the SNSF launched a competitive call for concepts for constituting a national biobanking platform. The SBP concept was selected by an international panel of experts in biobanking activities and is presently in its construction phase. A budget of CHF 3.2 Mio for 4 years was foreseen for the implementation and running phase of the SBP, distributed as annual installments of CHF 800’000.

The SBP construction phase started in 2014 under the supervision of the SBP Project Group, in close collaboration with the Swiss National Science Foundation (SNSF) and the Swiss Academy of Medical Sciences (SAMS), as defined in the implementation agreement and milestones signed by the three parties. Since 2016 the SBP is a legal independent association founded by the five Swiss University Hospitals together with the SBP Project Group.

II) ACHIEVEMENTS 2017

In 2017, the SBP has developed recommendations for biobanking activities based on quality, governance of biobanks, interoperability and public engagement. A close link with BBMRI and European networks has been strengthened and SBP brings its expertise in the BBMRI-ERIC working groups “Quality” and ”Common services ELSI” (Ethical Legal Societal Issues) and is recruiting biobanks for BBMRI proof of concept. SBP is on track to deliver products and tools according to the milestones in appendix of this annual report. In particular, SBP is supporting biobanks’ development with a specific toolbox to allow biobanks reaching quality standards. SBP is proposing independent audits on quality and governance issues as a service for biobanks and institutions, in an effort to facilitate biobanks’ interoperability and harmonisation.

A. SBP ASSOCIATION

The Governing Board (GB) of the SBP constituted by the 5 medical directors of the Swiss University Hospitals met in February and June 2016 and the SBP Strategic Advisory Board SAB) in December 2016. Following the resignation of Prof. Arnaud Perrier (HUG) due to a heavy workload in his institution, the GB elected Prof. Antoine Geissbühler as the new representative from “Hôpital Universitaire Genevois” (HUG).
A Governance Advisory Board (GAB) has been created regrouping representatives of instances involved in ELSI issues to advise the GB on biobanking governance issues. This board has already met once in September 2017, and is task will be to evaluate and develop harmonized biobanking guidelines. Its members are listed in the table below.

INSTITUTION	ISSUE	REPRESENTATIVE	FUNCTION
BAG/OFSP	Legal and public health	Dr. Andrea Raps	Direktionsbereich Öffentliche Gesundheit
CNE/NEK	Ethical	Dr. phil. Simone Romagnoli	Collaborateur scientifique
CHUV	Politics	Dr. Karim Boubaker	Médecin cantonal VD
UFFICIO DEL MEDICO CANTONALE	Politics and ethical	Mario Lazzaro	Médecin cantonal adjoint TI et vice-président Commission d’éthique de la recherche TI
INSELSPITAL	Hospitals	Danielle Krebs, PhD	Bereichsleiterin and University hospitals representative
SPO PATIENSCHUTZ	Societal and patients	Prof. Dr. Franziska Sprecher	Assistenzprofessur für öffentliches Recht and patients’organization representative
UNIVERSITÄTSSPITAL ZÜRICH	Ethical	PD Dr. med. Tanja Krones	Leitende Ärztin Klinische Ethik/ Geschäftsführerin
BASEL INSTITUTE FOR BIOMEDICAL ETHICS	Ethical	Prof. Bernice Elger	Head
INSTITUT DU DROIT DE LA SANTÉ – UNIVERSITÉ DE NEUCHÂTEL	Legal and public health	Prof. Dominique Sprumont	Professeur ordinaire

SBP REORGANIZATION (MEASURES 1.2 AND 2.1)

To support its implementation, the SBP established hub coordinators as external bodies of the SBP located in the university hospitals. They had to make the inventory of local biobanks,to promote SBP activities and implement SBP products. In that context, each University Hospital as well as St-Gallen Kantonsspital hired a hub coordinator either through SBP association or through a collaboration agreement between SBP and the hospital.

After 12 months of activity, the objectives given to the hubs have not been met or only partially and all parties agreed to terminate the collaboration. Moreover, in some hospitals, hub collaborators had difficulties to position themselves as part of SBP, which hindered the work of the newly created platform. Other hospitals see the benefit of an external counceling on biobankig activities and provided hub coordinators with well recognized independent positions. In such hospitals, collaborations are still ongoing. This emphasized the need of SBP to function as a national and independent entity providing support for biobanking activities without being part of the hospitals.

Accordingly, in its session of June 2017, the SBP Governing Board decided to decommission the hubs by 1st September 2017 and to centralize the work of SBP on the national level at the SBP Central Office.

Following this reorganization SBP tasks have been refocused on harmonization for human and non-human biobanks, governance, quality, IT and links with BBMRI.

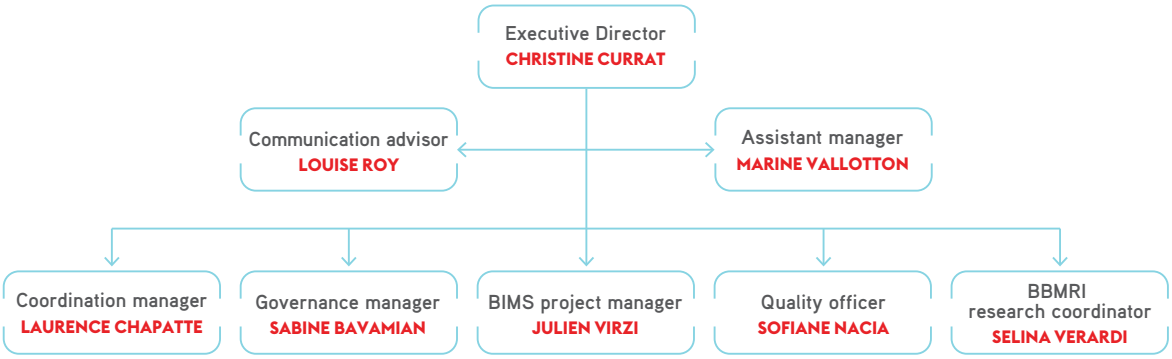


Figure 1:
SBP Central Office

NEW SBP ADVISORY FUNCTION

Since September 2017, SBP is part of the Swiss Personalised Health Network (SPHN) National Steering Board as permanent guest, represented by its executive director, Christine Currat. This allows strengthening collaboration and information exchange between the two Swiss initiatives and may lead to synergies and the avoidance of redundancy in the program of each initiative.

In the context of the National Consent for Research, the Swiss Academy of Medical Science mandated SBP to lead a working group in charge of evaluating the first version released in July 2017. To that end, SBP involved the newly created Governance Advisory Board and the Governing Board to formulate recommendations to the SAMS “Steuerungsgruppe.

SBP VISIBILITY

Since almost two years, SBP has been working at increasing its visibility in Switzerland and abroad by participating to BBMRI. Moreover collaborations are ongoing with:

- BAG in the context of the Human Biomonitoring Project,
- BBMRI in the participation to developing biobanking tools,
- CHUV for auditing the institution biobanks,
- A biobank in Geneva to developa specific Biobank Information Management System (BIMS) as a SBP pilot,
- The University Hospital of Bern to support the work on the datasets to be harmonized and documented,
- EPFL to train a SBP BIMS project manager to develop BIMS for biobanks at SBP.

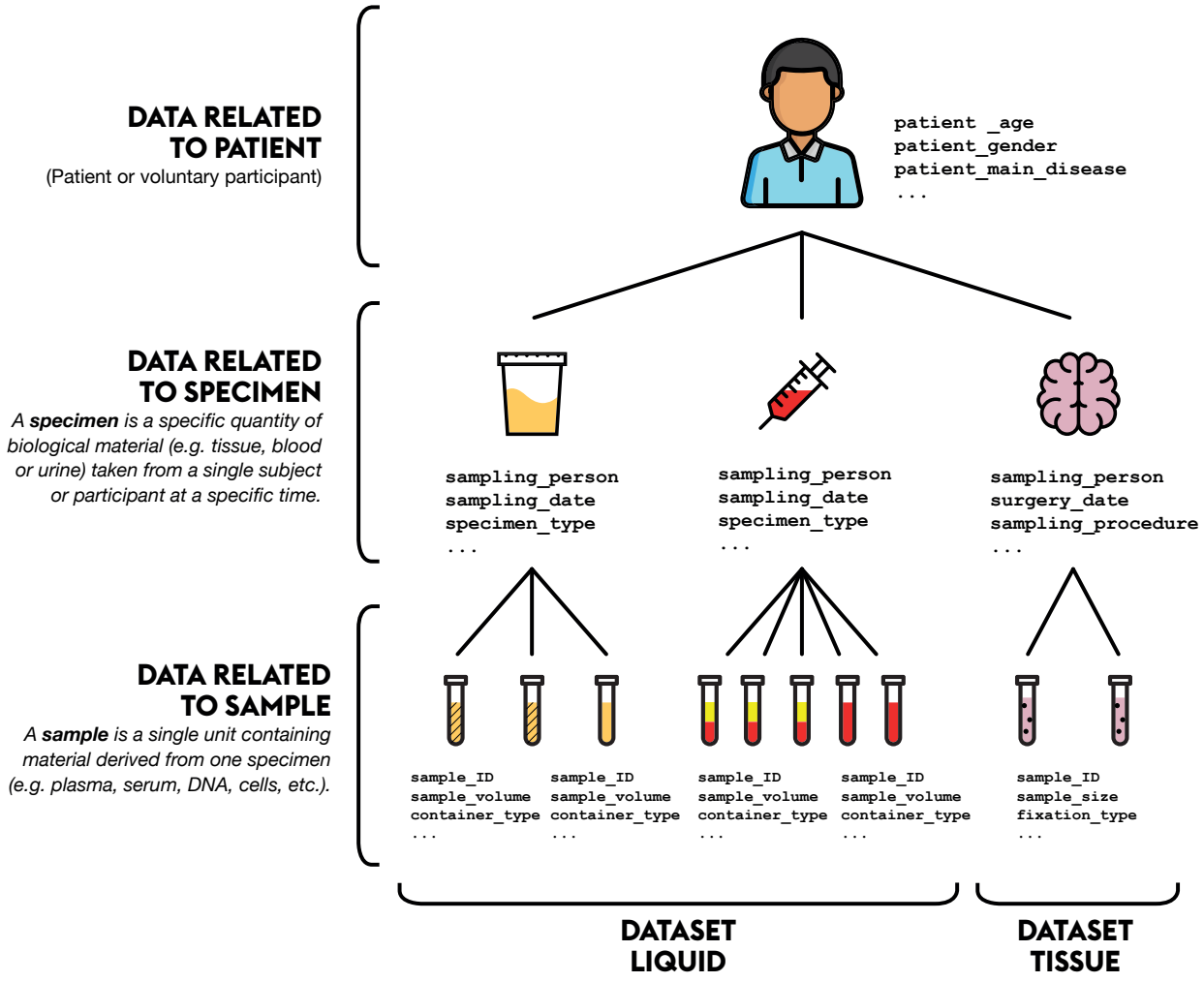
Next year, on 1st February 2018, SBP is organizing at EPFL its first symposium on biobanking, regrouping biobank experts from Switzerland and Europe. This symposium will be moderated by the science journalist Olivier Dessibourg, At that occasion, the new director of BBMRI will present the infrastructure to the Swiss biobanking community as well as the collaboration with SBP.

B. SBP HARMONIZATION AND INTEROPERABILITY

SBP DATASETS (MEASURES 4.1 AND 4.2)

SBP working groups on liquid and tissue biobanking composed of experts from the university hospitals considered as essential for biobanking activities to define the biological factors expected to have an influence on biobanking sample quality. To produce common SOPs and based on International Good Biobanking Practices, on the specifications of the European Committee for Standardization (CEN) and the Standard PRE-analytical Code (SPREC) released by the International Society of Biological and Environmental Repositories (ISBER), the working groups agreed on 2 preanalytical datasets (Liquid & Tissue), to recommend to any Swiss biobank willing to harmonise and document their Biobanking practices,

The datasets are established to cover the different biobanking processes from sampling to retrieval and propose a common language describing pre-analytical attributes of samples. It also includes selected health related data required for searches of suitable samples. Finally, it covers fields related to quality of biobanking processes.



The datasets are focused on:

Sample quality
- Define the essential pre-analytical data that should be linked to samples
- Raise awareness on biobanking processes
- The detailed documentation of pre-analytical steps will allow biobanks to identify critical steps in their workflows, to monitor and improve their processes
- Improve quality of samples
- Once each step is documented, improvement can be measured

Harmonization & Interoperability
- Define the essential health related data that should be linked to samples
- Make samples from different biobanks comparable in their quality attributes
- Allow researchers to be able to judge the fitness-for-purpose of samples for their planned downstream applications.
- Promote exchange

Visibility
- Define the essential sample associated data that should be visible
- Make samples searchable on a common database
- Enhance visibility

At the European level BBMRI endorsed the datasets. A consultation process through biobanks has been initiated until 10 December 2017. The documents are available at http://swissbiobanking.ch/index.php/datasets-consultation/. This consultation will be extended until 10 January in Europe with the support of BBMRI.
More detailed information on the work done by the WG, their recommendations and the datasets can be found in the respective WG reports available on SBP website.

http://swissbiobanking.ch/wp-content/uploads/2017/10/SBP_WGLiquid_report.pdf
http://swissbiobanking.ch/wp-content/uploads/2017/10/SBP_WGTissue_report.pdf

A dataset specific for microbiology is planned for release beginning 2018, supporting the BioLink project 31BL30_172630 “Biobanking for state-of-the-art Sepsis research” to develop a Swiss-wide strategy for harmonisation.

IN SUMMARY

The datasets are a very important step to harmonization and is the first SBP deliverable that can be used by the Biobanking community. This work has been a long breathtaking work, but ends up into a compromise between the five University Hospital experts and the expertise brought by SBP through collaboration with BBMRI.

The next step would be to develop a “sample management plan” at SNSF on the same basis as the “data management plan”, giving incentives to the swiss biobank community to integrate these datasets in their practice.

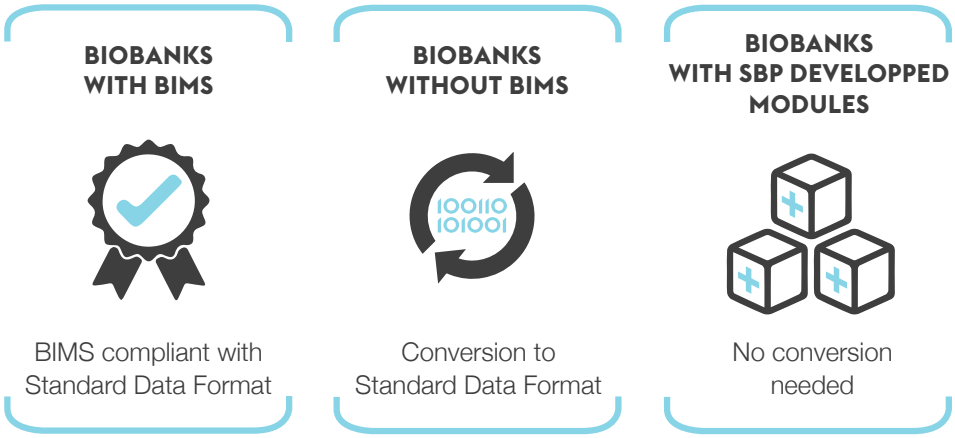
SBP BIOBANK INFORMATION MANAGEMENT SYSTEM (BIMS) STRATEGY (MEASURE 4.1)

To enable Swiss biobanks to interoperate and share sample, SBP is developing a Biobank Information Management Systems (BIMS) strategy to increase SBP datasets documentation and implementation by biobanks and their hosting institutions. The strategy is to provide a business model analyzing the benefits of having either a unique BIMS for Switzerland or even a common language to allow BIMS interoperability.

While management of biobanks with a professional BIMS is a prerequisite for setting up quality management system in biobanks, SBP is adopting solutions for:

A. Biobanks with or without BIMS needing a Standard Data Format: development of a common language and an exchange format focused on SBP published datasets in Q1 2018.

B. Biobanks interested in using the SBP BIMS modules integrating the Standard Data Format for SBP datasets and developed in collaboration with IT specialists at the EPFL life science department: a business model will be proposed to institutions and biobanks in Q1 2018.



Concerning the SBP BIMS specific development, SLIMS by the BIMS provider Genohm has been identified as a good candidate to work with based on user and interoperability issues, as well as local collaborations already ongoing at EPFL. This strategy will support some BioLink projects, only those who are interested in and whose timing is fitting the purpose.

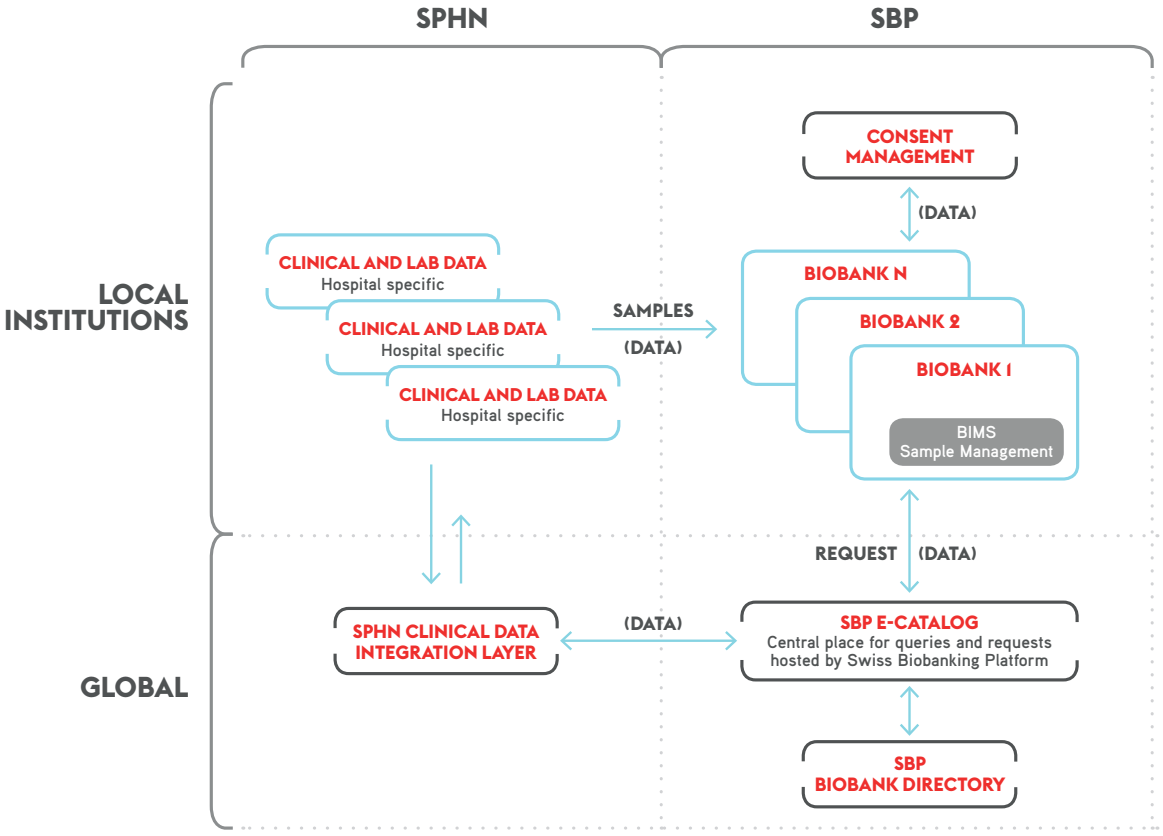
IN SUMMARY

A contract with EPFL has been concluded to develop a national strategy for the implementation of a BIMS. While EPFL is important for the technical development, it needs the expertise of SBP about the management of human material. In that context, a test server from SLIMS by Genohm has been installed at EPFL to develop a specific module integrating the SBP dataset Liquid and to support as pilot the development of the new Cansearch biobank in collaboration of Prof. C. Lovis and Prof. A. Geissbühler at HUG.

The next step would be to go for a public tender to identify strength of different BIMS providers and to support biobanks move to an interoperable solution in Switzerland.

SBP E-CATALOGUE (MEASURE 2.4)

Biospecimen data coming from BIMS and possibly other local or global data sources (e.g. SPHN) must be available for queries across biobanks either locally or globally. In the same way, it must be possible to request samples coming from the Swiss biobank network for research purposes. The SBP query tool available in the SBP e-catalogue aims at addressing this need.



The data and solutions for SBP e-catalogue will be identified and piloted through BioLink projects, 31BL30_172718 “Patholink”, regrouping tissue biobanks and 31BL30_172630 “Sepsis”, regrouping liquid and microbiology biobanks.
These collaborations will allow SBP to build up a first Swiss directory linked to the European directory (BBMRI), and to establish an e-catalogue for all biobanks willing to share their samples and data.

IN SUMMARY

SBP is collaborating with the SNSF BioLink projects, but also with BBMRI Common Service IT to develop a first web catalogue for Switzerland.

The next step is to collaborate with SPHN to adopt the same strategy on the creation of a biobank e-catalogue in view of having one reference source on biobanks in Switzerland.

C. SBP NON-HUMAN BIOBANKING STRATEGY (MEASURE 3.1)

VETERINARY

The Veterinary working group has developed a first consent template for animal owners allowing the reuse of animal material for research with a common and legal approach. This consent is still in revision by multiple stakeholders (clinicians and legal experts) and will be implemented in 2018.
In parallel, SBP was asked to audit one of the clinics having an interest in research and having some doubts on how to legally and operationally work, and to measure the quantity of work to be done to run a biobank.
Finally, synergies between the different SBP working groups Veterinary, Tissue and Liquid, have been established to share their expertise and experience.

IN SUMMARY

A first consent for animals' owner has been drafted and is in the process of acceptance at Vetsuisse. In parallel, the audit of a specific biobank at Vetsuisse is ongoing and will end up with recommendations in terms of consent and quality practice.

The next step is to create active synergies between the human and the veterinarian biobanks, showing how similar those fields could be, when samples are considered.

MICROBIOLOGY

The Microbiology working group has to define and identify quality standards that need to be harmonized for microbiology biobanks, one of the non-human biobanks type. It will propose a harmonized terminology and vocabulary to promote interoperability among those biobanks. Finally, the WG has already developed a dataset that should be linked to microbiological samples and will support the creation of a virtual network of strain collections in Switzerland.

IN SUMMARY

A first dataset has been defined within the microbiology experts in Swiss Universities and University Hospitals. A survey to evaluate microbiology biobanking practice is open and results will be analysed in January 2018.

The next step is to initiate the consultation of the microbiology dataset to favor the documentation and harmonization microbiological biobanking in Switzerland.

D. SBP QUALITY CONCEPT (MEASURE 4.1)

Quality is a major concern in the biobanking field and even if it is not yet mandatory as an accreditation or certification process, many biobanks today commit themselves to improve constantly their internal biobanking procedures to stay competitive in research.
SBP is part of Schweizerische Normen Vereinigung (SNV) expert group for the future ISO biobanking norm. This position of SBP is very important to give Swiss owners of biobanks the opportunity to comment and to tailor the future ISO norm, as BBMRI or other countries do. In this function, SBP asked Swiss biobanks owners to comment on the future ISO norm in summer and transmitted this information to SNV and BBMRI.
SBP will thus provide different tools to implement quality requirements and assess biobank performance with the development of quality management services and SBP labels.

The SBP quality concept has the following objectives :

- Define a clear vision between biobanks and biobank infrastructures as well as other Biobanking related definitions into a glossary
- Propose a dynamic evaluation tool, called the SBP Toolbox, as a prerequisite for SBP premembership application but also as a tool to monitor biobank continuous improvement
- Deliver scoring in terms of governance and quality management system
- Provide audit services as an appropriate effective and reliable tool in support of quality management systems, providing information on which a biobank can act to improve its performance
- Deliver different SBP labels depending on the objectives of the biobanks.

SBP TOOLBOX (MEASURES 2.2 AND 2.4)

The SBP Toolbox is an innovative development with the primary goal to guide Swiss biobanks and biobank infrastructures on a governance and a quality management system based on state of art good biobanking practices (OECD, IARC, ISBER, NFS96-900).
This Toolbox will serve as a basis for a first SBP Directory, consisting in a list of biobanks in Switzerland being part of SBP, in connection with the BBMRI Directory, and will provide the first grading tool of biobanking activities. Around 250 questions will be asked, allowing different scorings on:

- Ethical and legal compliance with federal and international laws and with the Taipei declaration through 24 questions on these issues, and the necessary information for a biobank regulation template harmonized in Switzerland through 69 questions
- Quality compliance with international ISO norms through 94 questions.
    - **A.** Resource management will address questions around IT infrastructure, equipment monitoring, premise control and personnel training.
    - **B.** Process management will address questions from the consent presentation to the shipment of samples, including quality controls and validation of methods criteria.
    - **C.** Organization management will focus on Quality Management aspects with nonconformities management and continuous improvement.

The scoring end product is communicated to its customer with an audit plan and with a process to adhere to different SBP labels, bronze being a mandatory step for biobanks to apply for, silver and gold integrating the different ISO norms, ISO 20387 and ISO 9001 respectively.

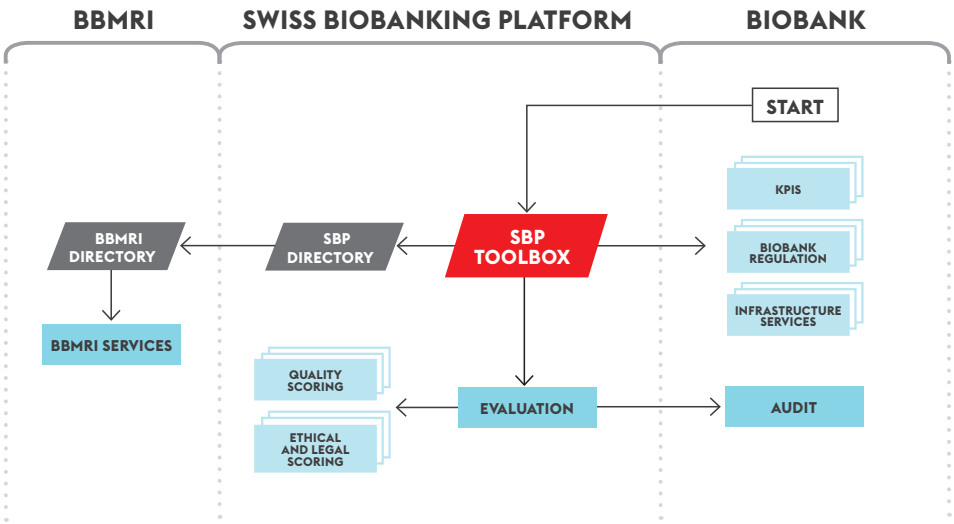
BRONZE LABEL
Ethical and legal
compliance

SILVER LABEL
Good biobanking practice
compliance

GOLD LABEL
Quality assurance
compliance

The SBP Toolbox has also been designed as a tool responding to different stakeholders' needs:

- For biobanks as an instrument to follow their activities with Key Performance Indicators (dashboards) and the possibility to integrate corrective measures following audit reports;
- For biobank infrastructures or other related infrastructures to promote their services to the biobank community;
- For SBP as a tool to measure its added value with Key Performance Indicators.



The Toolbox has been designed with VITAL-IT, a division of the Swiss Institute of Bioinformatics (SIB) and will be available after a one-year collaboration in January 2018. The official release of the SBP Toolbox is planned in Q2 2018.

IN SUMMARY

The Toolbox is an innovative concept to allow qualification of biobanks in Switzerland, and is complementary to the self-assessment tool developed by BBMRI. The response to 250 questions will allow to propose a scoring on biobank governance (24 questions) and quality (94 questions). The Toolbox will generate a harmonised biobank regulation for biobanks through 69 out of the 250 questions.

The SBP Toolbox is already included into an evaluation process of biobanks at CHUV; EPFL is also interested in that concept and will propose different biobanks to test the toolbox in January 2018.

This development also allows to deliver a Swiss Directory of biobanks listing only biobanks, having the minimal bronze label accepted in this directory. SBP will propose action plans to support biobanks reaching this bronze mandatory label, as well as other services for those willing to adhere to silver of gold labels. The Directory is thus the first step to the SBP catalogue, enabling biobanks to share their samples for research.

AUDIT STRATEGY

SBP audit service will be offered to Swiss biobanks willing to integrate SBP network and to reach the bronze label. As this step is a mandatory one, the audit service related to it will be offered to the biobank community. Labelled biobanks will pay an annual membership fee; this annual fee give access to services for bronze label's biobanks. For biobanks willing to reach the silver and the gold labels, the audit service will be chargeable, in addition to the basic annual membership fee.

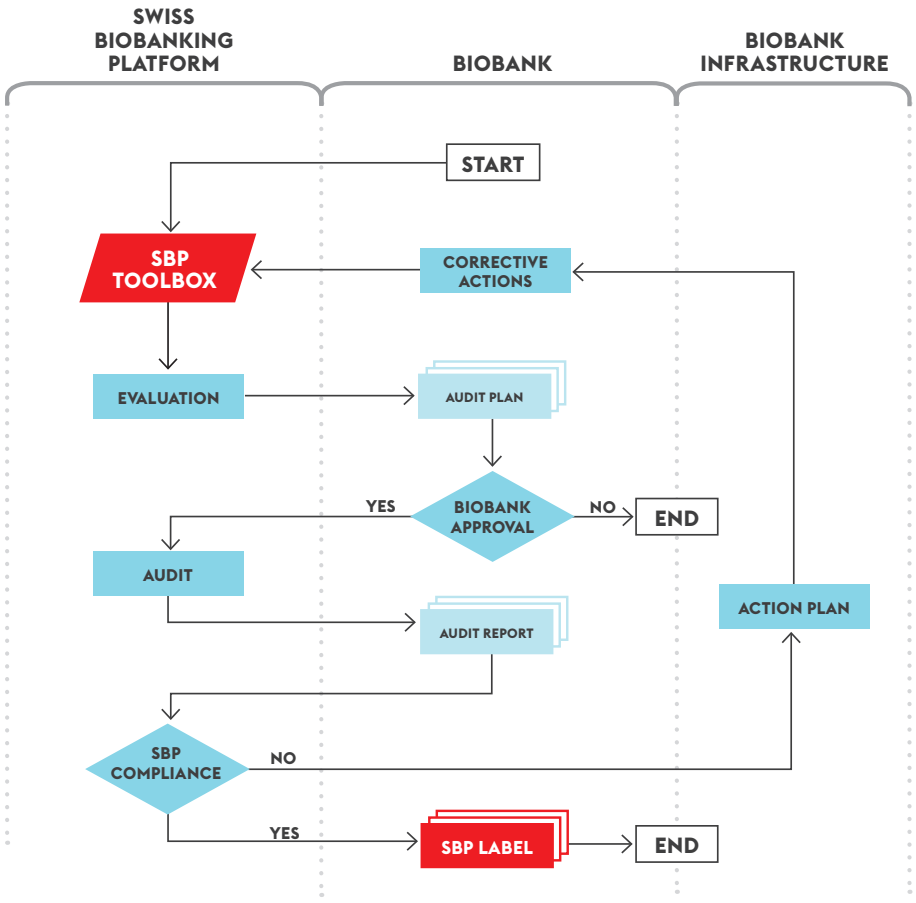
SBP is preparing documentation, templates and SOP's for each label, to support biobanks interested in the SBP certification or accreditation. What still remains to be decided is whether SBP should propose a service for accompanying biobanks during accreditation process, as a formal certification body.

To setup this audit service, SBP has audited three biobanks in 2017: a biobank associated with a clinical trial in St-Gallen, a biobank associated with a cohort in Lausanne and a Vetsuisse biobank. Four additional biobanks will be audited in 2018, to finalize the business model and allow SBP to launch the service.

The audit strategy is focused on the different aspects integrated in a future Good Biobanking Practice document covering governance, resource, process and organization management. A list of SOP's to support biobanks as well as specific templates will be provided through SBP together with the SBP audit service.

IN SUMMARY

A pilot phase with four audits in 2017, allowed SBP to tailor its future audit service. The audit of three additional biobanks in 2018 will consolidate the concept of the service. A workload of 4 to 6 days per audit is estimated, but this should be reduced once the SBP Toolbox could be used as the entry point, saving time in the process. This service is aligned with BBRMI audit strategy, and is complementary with the BBRMI self-assessment tool in compliance with the SBP gold label.



E. BIOBANK-GOVERNANCE STRATEGY (MEASURES 5.1 AND 5.2)

Adherence to the highest standards in Ethical, Legal and Societal Issues (ELSI) is essential to any biobanking activity and is one of the most important concerns SBP wishes to address. For biobanks in general, protecting participants against research risks is a key responsibility. To address this challenge, formal and strong governance frameworks have to be put in place to ensure that the particular ELSI issues of biobanking are appropriately addressed.
SBP Biobank-governance strategy shall allow:

- compliance with applicable ethical and legal standards for the use of health-related personal data and biological material;
- building public trust which is key for the success of biomedical and biological research
- a better understanding of the governance framework by all stakeholders;
- harmonization of biobanking practices.

BIOBANK-GOVERNANCE AT INSTITUTIONAL LEVEL

SBP is developing guidance aligned with the EU Recommendation CM/Rec (2016)6 and the Declaration of Taipei to give researchers a roadmap on how to ethically develop and run health databases and biobanks.

To that end, SBP guidance is designed around 3 pillars critical in the setup of a good biobank governance:

1. Biobank regulation which allows a biobank to describe its goals, functioning rules and organization;
2. Material Transfer Agreement (MTA) which governs the transfer and use of biological material and related data to a third party that wishes to use these biological resources for its own research purpose;
3. Broad consent to obtain voluntary and informed consent of research participants

SBP worked on the two first pillars and produced a Swiss biobank regulation template and a Swiss MTA template. These documents are in validation by SBP Governance Advisory Board (GAB) before going through a national consultation in January 2018, allowing the release of reliable documents whose implementation shall be facilitated and broadly accepted.
With SBP Toolbox, a governance evaluation has been developed to assess the biobank compliance level with the applicable legal and ethical standards. This evaluation will allow SBP to provide each biobank with the necessary supports for the establishment of a strong governance.

IN SUMMARY

Harmonization and delivery of a standardized biobank regulation is a key issue for SBP and is referred as a mandatory document that identifies the rules applied for a research project using samples out of a biobank. This development at SBP will be generated from the SBP Toolbox, and SBP registered biobanks will have a standardized regulation for Switzerland. Consultations for this template and the MTA template are planned in January 2018.

PUBLIC ENGAGEMENT STRATEGY

The working group "Public Engagement" has been created in September 2017 with different patient organizations and a society representatives, as the "Fédération romande des consommateurs" and "Interface Science et Société". During the meeting, the WG expressed its interest in being more involved in biobank governance aspects; SBP thus proposed to consult it for specific research questions or development of educational tools related to "Public Engagement" aspects (collaboration with Interface Science et Société, Leenaards project). The members of the WG "Public Engagement" are listed below.

INSTITUTION	REPRESENTATIVE
Schweizerische Patient Organisation (SPO)	Franziska Sprecher
Fédération Suisse des Patients (FSP)	Rebecca Ruiz
Esperare	Caroline Kant
Proraris et Blackswanfoudation	Olivier Menzel
Interface Sciences et Société	Alain Kaufmann
Patient Advocates for Cancer Research and Treatment (PACRT)	Karin Holm
Fédération Romande des Consommateurs	Joy Demeulmeester

The concept is that SBP stakeholders, like biobanks or hospitals, can consult the group by submitting a request to SBP with the topic(s) they would like to address. SBP will contact "Public Engagement" WG members to evaluate who could be interested in taking part of the submitted consultation. Its first task will be the evaluation of the national consent released this summer by SAMS.

IN SUMMARY

Public engagement strategy could be very interesting to position SBP as a privileged partner not only for biomedical research, but for society at large.

SBP actively participated in a survey on biobanks and « personalized » medicine developed by the Interface sciences-société (A. Kaufman et al., UNIL); the results should be available beginning 2018. SBP was also involved in a Leenards application called "ECOS project: Espace de convergence des savoirs sur la santé personnalisée" which passed the first selection round (A. Kaufman et al., UNIL).

NATIONAL CONSENT FOR RESEARCH

SBP has been mandated by the Swiss Academy of Medical Science (SAMS) to evaluate the v1 version of the national consent documents released in July 2017. The SBP Governance Advisory Board will fulfill this task. Specifically, SBP will consult for this important task:

- SBP WG on "Public Engagement" – patients/society point of view (research using biological material and health-related data will depend on the trust of this group towards institutions)
- SBP WG on Governance – Institutions' point of view (users of national consent, the success of its implementation directly relies on these stakeholders)
- BBMRI – largest biobanking organization in Europe – EU vision
- WMA – World Medical Association – International vision
- Préposé fédéral à la protection des données et à la transparence – National consent and compliance to data protection
- FOPH

A report will integrate those evaluations and will be submitted to the SBP Governing Board beginning 2018 with an action plan to propose to the "Steuerungsgruppe" at SAMS.

F. SBP PROOF OF CONCEPT (MEASURE 6.2)

HUMAN BIOMONITORING PILOT STUDY

The objectives of the pilot study have been defined between SBP and the Humand Biomonitoring Project (HBM) of the FOPH. The main focus is to measure the exposome of the Swiss population.

This pilot will test the feasibility of recruiting a large cohort of citizens (100000 participants). It will precisely:

- Optimize the recruitment strategy towards high representativity and participation rate
- Provide proof of the population acceptance, interest and willingness to actively participate in research consisting of mailed questionnaires, interviews, health examinations, biosampling and long-term participation
- Provide proof of the population acceptance to grant access to medical information and diagnostic biospecimens in the context of research projects
- Identify data and biospecimen needs of stakeholders from policy and research and actively involve the stakeholder network for building the national bioresource
- Obtain acceptance, exposome and phenome data including related biospecimens through innovative precision health methods from participants in the pilot study that satisfy immediate priority needs of relevant stakeholders
- Establish the governance for the Swiss Human Biomonitoring Cohort

The timeline of the project has been defined starting with a recruitment phase planning in August 2018. Diverse questionnaires including an acceptance questionnaire, an exposure questionnaire and an environment, lifestyle and social questionnaire are on the verge to be validated.
Moreover, the list of analytes have been prioritized.. Some analysis are already funded and will be done immediately after collection of the samples, while others are not yet funded and will be done later on samples stored in a biobank. Based on this list, SBP supported by experts in cinical chemistry will evaluate the best pre-analytical conditions and propose SOPs. A complete Biobank workflow will be tested including quality documentation and management designed only for this purpose. Moreover, SBP will provide a web-based BIMS system to be able to document and track sample related data.

G. BBMRI

SBP is a member of the BBMRI-ERIC network as the Swiss node and is an active partner on different issues:

COMMON SERVICE (CS) ELSI

SBP is integrated in 3 questions:

1. International Organisations' Policy Assessment and Monitoring;
2. Collecting good examples of what benefits may be achieved through biobanking.
3. «Using biobanks and associated data for the benefit of patients»

To anticipate the forthcoming General Data Protection Regulation (GDPR) (May 2018), SBP will develop a document on how to implement GDPR at national level, as the other European countries.

ISO AND QUALITY WORKING GROUPS

As part of these working groups, SBP is strategically one step ahead and could bring expertise in preparing for relevant future ISO stan¬dards before they are publicly available and allowing their development to be influenced according to Swiss stakeholders needs and expectations. In that context, SBP was the reference body for collecting comments on the future ISO for Switzerland in July 2017.

SBP is also very active in the developments of the BBMRI self-assessment tool, which is a complementary development to our SBP Toolbox. Moreover, SBP will advise and take a key role in the construction of an audit programme at BBMRI.

COMMON SERVICE IT

Once the SBP interoperability strategy and business model have been validated, an active collaboration with BBMRI Common Service IT will be put in place in 2018.

ADOPT PROJECT

SBP is taking part to the first BBMRI Pilot project on colon cancer by encouraging Swiss biobanks in this field to be part of the BBMRI biobanks network; SBP will receive an additional specific funding for this work; a first 40K CHF has already been received.

III) STRATEGY 2018

SBP will develop a business model up from 2019 integrating concepts and strategies presented in this annual report. The business model will be validated next year by the SBP Governing board. Mainly, SBP, as an independent association, will offer support and expertise in the different biobank domains – harmonisation, ELSI, quality, interoperability and BBMRI, with related services and tools, as defined in the SBP agreement.

Biobanks will be part of SBP association as associate members with an action on SBP development in the future. This membership will be regulated and an annual membership fee will be due that will support SBP development and sustainability.

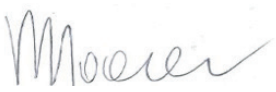
The entry point for any biobank interested in entering the SBP network is to receive the SBP bronze label. For biobanks not fulfilling these conditions, either they remain out of the network or they make the corrective actions proposed by a free SBP audit service.
For biobanks willing to reach the silver and the gold labels, the audit service should be fee-based, in addition to the basic annual membership fee.

Membership fees shall be proposed to any interested biobank, but could also be seen as an institutional membership. A list of other services and tools has to be defined, and in this context, different models shall be built with different membership fees. Services as audits, consulting services in terms of governance and quality management systems, and trainings have to be calculated and costs validated by the Governing board in 2018.

For 2019 and 2020, SBP should keep running with a funding part of 800K CHF, and any additional development shall be financed through either membership fees or services. In future, the amount of self-financing will increase.

A business model is being prepared for the next years leading to the self-sustainability of SBP. Alternative funding sources are investigated and a system for membership fees and other financial contributions is being developed.

CHRISTINE CURRAT, PHD
Executive Director



PROF. VINCENT MOOSER
President

Lausanne, 4th December 2017

Enclosures_ status 2017 "Deliverables and milestones" of the SBP Agreement

TABLE OF DELIVERABLES AND MILESTONES (SBP LEISTUNGSKATALOG)[1]

AIMS	MEASURES AND DELIVERABLES	TIME	STATUS
1. The SBP is established under the terms and conditions of the Agreement signed by the SNSF and the SAMS and sets the premises for a professional organization with adequate structures	1.1-the SBP-project group assures the availability of the needed infrastructure for the SBP office (bureau, IT resources). During the transition phase 2015, the office will be located in Lausanne, as confirmed by an agreement signed by the CHUV.	06/2015	ACHIEVED Y1
	1.2 - the collaborators of the SBP Central Office are hired. The Executive Director (ED) runs the SBP and is located at the Central Office. The SNSF and SAMS take part in the ED recruitment.	06/2016	ACHIEVED Y2
	1.3 - the name "Swiss Biobanking Platform (SBP)" is protected (Switch) and the internet domain names for the SBP are registered.	07/2015	ACHIEVED Y1
	1.4 - the SBP web page is available	06/2016	ACHIEVED Y2
	1.5 - a communication /expansion strategy is established and documented in a report	06/2016	ACHIEVED Y2
	1.6 - the SBP elaborates its future structure which will be legally independent in consultation with the SNSF	12/2015	ACHIEVED Y2
	1.7 - a proposition for the governance structure is submitted to the SNSF	09/2015	ACHIEVED Y1
	1.8 - contacts and collaborations with the national ethics commission and the Swiss ethics committees on research involving humans are established	12/2015	ACHIEVED Y2
2. 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 - a process for cataloguing is established which will include a survey template, the list of persons to contact and the format of survey return in all hubs	10/2015	ACHIEVED Y2
	2.2 - each hub has filled the survey and has returned the information to the Central Office, in the format pre-established for the analysis	12/2015 – 06/2016	ACHIEVED Y3
	2.3 - inclusion criteria for biobanks into SBP and into the web-based catalogue are defined	06/2016	ACHIEVED Y2
	2.4 - the first online web-based version of a catalogue with information on access to samples and data is available	06/2016	IN PROGRESS
	2.5 - information on pseudoanonymisation of samples and data is provided	06/2016	IN PROGRESS
3. The SBP integrates non-human biobanks	3.1 - the report of the work group in charge of identifying the needs and activities of non-human biobanking, in collaboration with SNSF, presents a concept for the integration of non-human biobanks	06/2017	ACHIEVED Y3
	3.2 - the integration of non-human biobanks into the SBP catalogue has taken place	03/2018	4TH YEAR

AIMS	MEASURES AND DELIVERABLES	TIME	STATUS
4. The SBP coordinates biobanking activities and contributes to the harmonization and standardization of biobanking activities.	4.1 - the SBP has a quality concept with essential and state of the art international recognized SOPs for human biobanking activities (sampling, characterizing, information treatment, storing)	06/2017	ACHIEVED Y3
	4.2 - SOPs for non-human biobanking activities are provided	03/2018	4TH YEAR
	4.3 - standards for pseudoanonymisation of biospecimens and data arebproposed along the HFG	03/2018	4TH YEAR
5. SBP provides support for legal and ethical issues, nationally and internationally	5.1 - information on the Swiss law and praxis in the ELSI domain is available on the web page	12/2016	ACHIEVED Y3
	5.2 - the SBP office and representatives are trained and competent	12/2016	ACHIEVED Y3
6. SBP provides proof of concept for the credibility of the platform	6.1 - access and benefit sharing guidelines, questionnaires, and phenotyping SOPs are developed	06/2016	IN PROGRESS
	6.2 - the SBP quality concept is developed together with the hubs representatives (sampling, characterizing, information treatment, storage)	12/2016	ACHIEVED Y3
	6.3 - the quality concept is implemented in at least 3hubs to facilitate biobanking	12/2017	4TH YEAR
	6.4 - consent procedures according to national and international standards are developed and proposed to the hubs. The hubs provide an implementation plan	12/2016	ACHIEVED Y3
	6.5 - in 1500 patients and 1500 persons from the general population the acceptance of biobanking research is evaluated (feasibility study)	06/2018	4TH YEAR
7. SBP provides information on biobanking activities abroad and ensures the link to BBMRI	7.1 - the SBP Executive Director is member of the Management Committee of BBMRI	12/2015	ACHIEVED Y2
	7.2 - the SBP provides updated information and fosters an efficient collaboration with BBMRI and other biobank consortia (human and non-human)	12/2015	ACHIEVED Y2
8. The SBP provides a concept for its sustainable funding	8.1 - a business model is constructed	12/2016	IN PROGRESS
	8.2 - measures for financing are worked out	06/2017	IN PROGRESS
	8.3 - membership fees are defined	06/2017	IN PROGRESS
9. The SBP informs the SNSF and the SAMS on its advancement and operating according to the agreement	9.1 - an annual report is submitted to the SNSF	10/2015 10/2016 10/2017 10/2018	ACHIEVED Y1 ACHIEVED Y2 ACHIEVED Y3 4TH YEAR

[1] The milestones have been settled in collaboration with the SBP-project group. They can be modified according to the needs of the SBP, upon request formulated in each annual report.