SWISS BIOBANKING PLATFORM

2015 ANNUAL REPORT

SBP Annual Report 2015

Sommaire

1. 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.

In 2013, after consultation of national and international experts in the field, the SNSF has launched a competitive call for concepts for constituting a national biobanking platform. The SBP concept was selected by an international panel of experts in biobanking activities and is presently in its construction phase under the supervision of the SBP Project Group, in close collaboration with the SNSF and the Swiss Academy of Medical Sciences (SAMS). In absence of a legally independent structure, the SAMS agreed to be temporarily partner of the project in providing advice and financial services to the SBP during the construction phase.

In its running phase 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 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.

2. 1st -year achievements

Funding of the SBP started on 1st November 2014 with a first installment of CHF 800’000 to recruit the project managers in charge of establishing and running the SBP according to the aims and milestones defined in the agreement between the SNSF, the SAMS and the SBP Project Group. The achievements described below refer to the deliverables and milestones of the agreement (enclosed, the reference to the aims number is put in bracket).

a. Agreement 2015-2018 (aim 1)

- The SNSF and the SBP project group have reached an agreement co-signed by the SNSF, the SAMS and the SBP Project Group on 29 June 2015This document includes a shared vision for the SBP, clarifies the roles of each party and clearly defined milestones and deliverables for the years 1 to 4 of the SBP.
- The parties are:

  _ SBP Project Group: Constituted of 4 members, is responsible for the construction and implementation of the SBP according to its aims and milestones, and oversees the financial aspects:

  - Prof. Vincent Mooser, principal investigator (PI), Head Laboratory Department and Director Clinical Research Support Platform at CHUV University Hospital Lausanne;
  - Prof. Tosso Leeb, co-PI, Head Institute of Genetics, Vetsuisse Faculty, University of Bern;
  - Prof. Aurel Perren, co-PI, Director Institute of Pathology, University Hospital Bern;
  - Prof. Nicole Probst-Hensch co-PI, Head Unit Chronic Disease Epidemiology, Swiss Tropical and Public Health Institute Basel;

  _ SAMS: Supports the implementation of the SBP and manages the budget until the SBP is fully established and runs independently;

  _ SNSF: Provides the funding and supervises the construction of the SBP according to the agreement.

b. Employment of the Executive Director (measure 1.2)

Upon a rigorous selection process with a nomination committee including senior representatives from SNSF, SAMS and the SBP project group, Christine Currat, PhD, has been nominated, among four short-listed candidates from Switzerland and Denmark, as Executive Director. She is taking office as of November 2015.

c. Employment of Central Project Managers (measure 1.2)

Four project managers covering specific biobanking fields have been recruited between November 2014 and September 2015:

- Rainer Warth, PhD, tissue and IT project manager based in Lausanne (100%);
- Christine Currat, PhD, liquid and ELSI project manager based in Lausanne (40%). She will be replaced by Laurence Chapatte, PhD (80%) as soon as Christine Currat will enter into office as Executive Director;
- Michaela Drögemüller, PhD, non-human project manager based in Bern (40%);
- Bettina Bringolf, MD PhD, population cohort project manager based in Basel (50%).

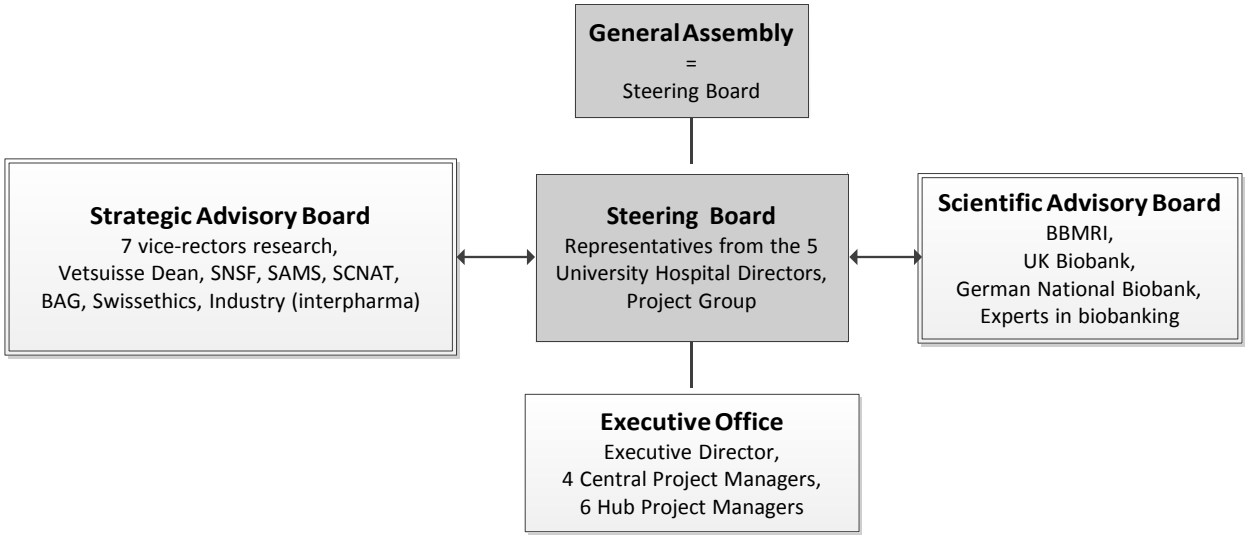
The project managers at the hubs, which are decentralized antenna-structures of the SBP at the University Hospitals, will be recruited in collaboration with the hub-directors and the SBP Executive Director by June 2016, in agreement with the planned time schedule.

d. Creation and location of the SBP Executive Office (measure 1.1)

The SBP Executive Office has been created on November 1st, 2014. By courtesy of the Lausanne University Hospital, it is officially located at the CHUV as an independent entity. To that end, an agreement has been signed between the CHUV making available the necessary office spaces for the SBP Executive Director, her collaborators as well as the Lausanne hub project manager for the next ten years. The agreement will be signed in November 2015 by the SNSF.

e. SBP Governance (measure 1.7)

For the project phase the SBP project group proposes a transitory governance structure until 2020 at the latest. It has to be approved by the SNSF:



The roles and responsibilities of the different boards are the following:

- The Steering Board (SB) defines the business objectives of the SBP according to the aims and milestones as agreed with the SNSF. The members of the SB are the directors or medical directors of the University Hospitals (or their delegates) are mainly representatives of human biobanking activities. This composition is temporary and will be completed by representatives of the non-human biobanking activities. .
- The General Assembly decides on the motions of the SB (voting and ratifying) and is responsible for accepting the annual reports. Its composition is identical to the Steering Board.
- The Strategic Advisory Board (SAB) guides the steering board on specific topics (e.g. IT, ELSI and Analytics) and is institutional-oriented with the vice-rectors research from each university and ETH and other key stakeholders (SNSF, SAMW, SCNAT, BAG, Swissethics, Interpharma).
- The Scientific Advisory Board guides the steering board on specific scientific topics and has national and international representatives with dedicated expertise in various aspects of biobanking.
- The Executive Office leads the business objectives implementation as planned by the steering board and runs the SBP.

The next steps related to governance are the designation and acceptance of each of the representatives in the boards, and then the finalization of the bylaws to create the SBP association.

f. Visual identity and web page (measure 1.4)

A visual identity has been created for the SBP, and will serve as a template for all SBP related documents as well as for the creation of a web site. This website will be designed for both professionals and public, and will be available by the end of 2015. The address is www.swissbiobanking.ch.

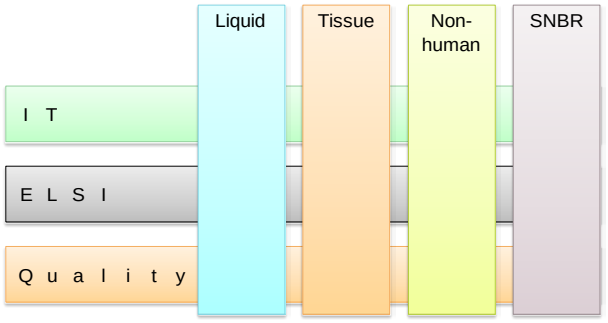
g. Contact with BBMRI (measures 7.1 and 7.2)

BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure) is the European umbrella organization for biobanking activities. At present, SNSF represents Switzerland in the various assemblies of BBMRI. Part of these representation activities will be transferred to Christine Currat, SBP Executive Director elected. She already made a first contact with both the general and the administrative directors of BBRMI-ERIC, Jan-Eric Litton and Markus Pasterk respectively, at London ESBB congress in October 2015 where she officially described SBP during a podium presentation. In addition, contacts with BBMRI representatives from Sweden and the Netherland nodes have been made. The SNSF will propose to the State Secretariat for Education, Research and Innovation (SERI) to delegate the SBP Executive Director as member of the Management Committee of BBMRI by the end of 2015.

3. Work in progress

a. Production of Standard Operating Procedures (SOPs - aims 4, 5 and 6)

SBP is built as a matrix organization representing all the necessary fields for SOP's production, as illustrated in the Figure below :



The four vertical pillars of the SBP are represented by liquid biospecimens, tissue biospecimens, non-human biospecimens and Swiss National Bioresource (SNBR) working groups. Each working group is led by one of the 4 PI, with the support from 4 central project managers. Milestones and composition of the 4 vertical working groups will be finalized by the end of 2015.

These working groups will be responsible for the production of Standard Operating Procedures (SOPs) for various biobanking activities as well as for demonstration of a pilot SNBR feasibility. The latter will be designed on the basis of study instruments of SAPALDIA and other national and international cohorts.

SOPs for non-human biobanks will be produced by the non-human working group in coordination with the other working groups.

b. General consent and ELSI (aim 5 and measure 6.4)

General consent allowing a broad use of biological samples for research purposes is a key asset for biobanks. This type of consent is aligned with the new federal law on Human Research Act (HRA) enacted in 2014. Such a general consent has already been implemented successfully at the Institutional Biobank of Lausanne (BIL) and the Inselspital in Bern, with a high participation rate.

A Swiss-wide general consent strategy needs to be put in place. To that end, a comparison analysis of general consent between Lausanne, Bern and Basel has been performed and discussions are ongoing between the SBP executive office, the SCTO, the Federal Office of Public Health (FOPH) and the SAMS.

It is anticipated that a working group "general consent harmonization" will be led by SAMS for the preparation of guidelines and by SBP for their implementations in each hub. In parallel, a roadmap with ELSI objectives will be designed and implemented in the next couple of years.

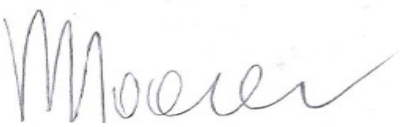
c. Survey and catalogue (aim 2)

A first survey instrument has been created and tested by several biobanks and cohorts, with the goal to come up, beginning 2016, with a final version, which will be used for the cataloguing of biobanking activities in Switzerland. In addition, work is ongoing to define which criteria will be used to select the biobanks to be registered by the SBP in its online catalogue.

d. Communication strategy and stakeholders' engagement (measure 1.5)

Development of a strong communication strategy with stakeholders' mapping is an efficient tool to maximize SBP success throughout the program development. An in-depth understanding of stakeholder's aspirations, constraints and resistances (see table below) shall help in designing an adapted and personalized communication. Nevertheless there will still be certain risks in the development of SBP, which shall be analyzed and reported throughout the process: the short timescale to come up with a consensus for harmonized processes, the large scope of SBP integrating human biobanks with non-human as well as barriers in terms of cantonal laws and IT systems compatibilities.

Stakeholders	Aspirations	Constraints	Resistances	Tactical moves
Swiss hospitals	Image, Recognition and Growth	Different strategies and processes	Culture and loss of responsibility	Obtain commitment with the help of hub project managers
Federal institutions	Image, Sustainability and research/health	Federal laws and concurrent organizations	Distrust and competition	Collaboration with clear mandates, objectives and support
Swiss biobanks	Support and research/health	Diversity and already installed processes	Increase in complexity, change	Integrate their needs, experience and constraints at the beginning
International biobanks	Quality and access	European laws and guidelines	Complexity and lack of compatibility	Lean on their knowledge and experience to position SBP at BBMRI
Patients/citizens	Research/health	Information and ethics	Ignorance and fear	Develop adapted information processes with their involvement



Christine Currat, PhD
Executive Director

Prof. Vincent Mooser
Principal Investigator

Lausanne, 29th October 2015

Enclosures
_ status 2015 “Deliverables and milestones” of the SBP Agreement

Swiss Biobanking Platform:

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
	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
	1.3 - the name "Swiss Biobanking Platform (SBP)" is protected (Switch) and the internet domain names for the SBP are registered.	07/2015	Achieved
	1.4 - the SBP web page is available	06/2016	In progress
	1.5 - a communication /expansion strategy is established and documented in a report	06/2016	In progress
	1.6 - the SBP elaborates its future structure which will be legally independent in consultation with the SNSF	12/2015	In progress
	1.7 - a proposition for the governance structure is submitted to the SNSF	09/2015	Achieved
	1.8 - contacts and collaborations with the national ethics commission and the Swiss ethics committees on research involving humans are established	12/2015	2nd year

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	In progress
	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	2nd year
	2.3 - inclusion criteria for biobanks into SBP and into the web-based catalogue are defined	06/2016	2nd year
	2.4 - the first online web-based version of a catalogue with information on access to samples and data is available	06/2016	2nd year
	2.5 - information on pseudoanonymisation of samples and data is provided	06/2016	2nd year
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	
	3.2 - the integration of non-human biobanks into the SBP catalogue has taken place	03/2018	
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	
	4.2 - SOPs for non-human biobanking activities are provided	03/2018	
	4.3 - standards for pseudoanonymisation of biospecimens and data are proposed along the HFG	03/2018	
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	2nd year
	5.2 - the SBP office and representatives are trained and competent	12/2016	2nd year

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	2nd year
	6.2 - the SBP quality concept is developed together with the hubs representatives (sampling, characterizing, information treatment, storage)	12/2016	2nd year
	6.3 - the quality concept is implemented in at least 3hubs to facilitate biobanking	12/2017	
	6.4 - consent procedures according to national and international standards are developed and proposed to the hubs. The hubs provide an implementation plan	06/2016	2nd year
	6.5 - in 1500 patients and 1500 persons from the general population the acceptance of biobanking research is evaluated (feasibility study)	06/2018	
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	In progress
	7.2 - the SBP provides updated information and fosters an efficient collaboration with BBMRI and other biobank consortia (human and non-human)	12/2015	In progress

8. The SBP provides a concept for its sustainable funding	8.1 - a business model is constructed 8.2 - measures for financing are worked out 8.3 - membership fees are defined	12/2016 06/2017 06/2017	2nd year
9. The SBP informs the SNSF and the SAMS on its advancement and operating according to the agreement.	9.1 - an annual business report is submitted to the SNSF	10/2015 10/2016 10/2017 10/2018	Achieved 2nd 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.