

November 2015

Implementation of the “Swiss Personalized Health Network” (SPHN) Initiative

*Report
of the mandated Core Project Group (CPG)*

consisting of the following members:

*Peter J. Meier-Abt (SAMS/chair), Ron Appel (SIB), Urs Frey (SNSF),
Detlef Günther (ETHZ), Vincent Mooser (CHUV), Nicole Probst-Hensch (UniBas),
Michael Röthlisberger (SAMS), Daniel Vonder Mühl (ETHZ)*

submitted to SERI, approved by the Steering Committee on January 7, 2016

1. Background

„Personalized Medicine” (also called „Precision Medicine“) is in rapid development worldwide as emphasized again by the recent initiation of a “Precision Medicine Initiative (PMI)” in the USA [1] and/or the Summary on Personalized Medicine of the European Academies Science Advisory Council (EASAC) [2]. In Switzerland, a national research initiative „Systems Medicine – Personalized Health” (called here „Swiss Personalized Health Network (SPHN) Initiative“) has been proposed to the State Secretariat for Education, Research and Innovation (SERI) in 2014 [3]. This initiative aims at creating a national „Swiss Personalized Health Network (SPHN)” that integrates all relevant Swiss research institutions and organizations (e.g. University Hospitals and Universities, Swiss Institute of Bioinformatics (SIB), Swiss National Science Foundation (SNSF), Federal Office of Public Health (FOPH)) as well as ongoing related projects (e.g. Swiss Biobanking Platform (SBP), Human Biomonitoring / Cohort Project (HBCP)) in order to cooperate by joining forces nationwide, to include all available competences and to coordinate the required infrastructures all over Switzerland. Subsequently, a further report provided evidence that nationwide interoperability of clinical and –omics data is achievable in Switzerland provided that the “participating hospitals adhere to common standards, terminologies and procedures, and that they make the necessary informatics developments in order for a minimal subset of –omics and clinical patient data to be automatically exported and integrated into a national research database” [4]. Based on these and other complementary information the SERI decided to implement the SPHN Initiative during the period 2017-2020.

On June 15, 2015, the SERI formed a small core project group (Peter J. Meier-Abt SAMS/chair, Ron Appel SIB, Urs Frey SNSF, Detlef Günther ETHZ) that has been extended by the representatives of the projects SBP (Vincent Mooser) and HBCP (Nicole Probst-Hensch). The core project group is supported by Daniel Vonder Mühl (ETHZ), and Michael Röthlisberger (SAMS). The mandate of the core project group is to develop an organizational structure for the implementation of the SPHN Initiative including the denomination of the SPHN members, the definition of the data organization (e.g. standards and interoperability of clinical data systems), the formation of a superordinate steering committee and the installation of relevant entities (scientific, technical, ethical, legal working groups / boards). The organizational structure of the SPHN Initiative must be defined until December 2015, so it can be implemented in spring 2016, being consistent with the publication of the SERI message dispatch 2017-2020 that has to be approved by the Parliament in fall 2016.

2. Aims and Objectives

This report complements the two previous reports [3], [4] and responds specifically to the SERI mandate of June 2015 (see above). It provides concrete suggestions for the practical implementation of the SPHN Initiative including 1) governance, structure and organization, 2) data collection, organization, standardization and harmonization, 3) stakeholders („members“) to be involved, 4) ethical, legal and social implications (ELSI), and 5) financial and other aspects. These issues were further discussed with representatives of relevant institutions and organizations in a workshop on August 31, 2015 (see Annex 1). Five working groups (*WG1 to WG5*) discussed the various issues and provided short consensus reports, which together with the previous papers [3], [4] constitute the basis for this implementation report. Each of the following sections recapitulates the major question(s) to be answered, especially in relation to the SERI mandate or related requirements, summarizes the opinion of the respective *WGs* and provides final implementation conclusions.

3. SPHN: Governance, Structure and Organization

SERI Mandate: „The project core group defines until end of 2015 an appropriate structural organisation for the SPHN Initiative (e.g. superordinate steering committee, scientific/technical and legal/ethical advisory boards; management; members of the structural organisation and their subunits). The implementation of the structural organisation should be possible in spring 2016. The overall supervision of the preparatory work for the implementation of the SPHN Initiative is in the responsibility of the SAMS.“

“The SPHN Initiative should be started with two clusters. Once the feasibility of adequate data collection, management, and storage within the two clusters’ network has been established, other potential stakeholders can join SPHI”.

Workshop of August 31, 2015, WG5 and Round Table Discussion (see Annex 1)

A) General principles:

The assembly unanimously agreed on the following general principles:

- 1) The SPHN Initiative must be a national program which is accessible to every research institution in Switzerland, who is able and willing to contribute and participate. It is led by the SAMS on behalf of the SERI and has the legal form of a “Simple Partnership”.
- 2) The start of SPHN Initiative is based on two already preformed Personalized Medicine clusters „Lausanne-Geneva“ and „Zurich-Basel“. Bern has decided to join the Lac Léman cluster. Whether additional clusters will be built depends on the evolution of the SPHN initiative.
- 3) Already existing infrastructures and/or PH related projects/platforms/programs/organizations such as SCTO/CTUs, PedNet and SBP have to be involved as partners. The same is true for HBCP, provided it will be realized and financed during the period 2017-2020.
- 4) Patient data must come from hospital databases as well as from SNSF supported well-established cohorts (e.g. Swiss HIV, Swiss transplants and Swiss Hepatitis C cohorts) and rare disease registries.
- 5) In a second phase, there is a need for a large healthy population based reference cohort. Thereby, coordination and interoperability with the planned HBCP is of utmost importance.

- 6) The whole SPHN Initiative follows a „**quality driven approach**“ involving the definition of standards for biobanking (in concordance with the SBP), *-omics* and clinical patient data, bioinformatics and IT standards as well as common semantics and interoperability of data.
- 7) SPHN related research projects must be initiated from bottom up by the researchers and should be evaluated independently by the SNSF.
- 8) It is planned to run the SPHN Initiative over more than just one Federal ERI period of four years. In the first two years (**2017, 2018**), focus on funding of infrastructures lays the **ground** for a „quality driven approach“, the harmonization of standards and the interoperability of data with only a few pilot research projects. Afterwards (**from 2019 onwards, and in a possible second SPHN phase after 2020**), the emphasis is put more and more on the funding of research projects while the development of the required infrastructures is maintained (Fig. 1).

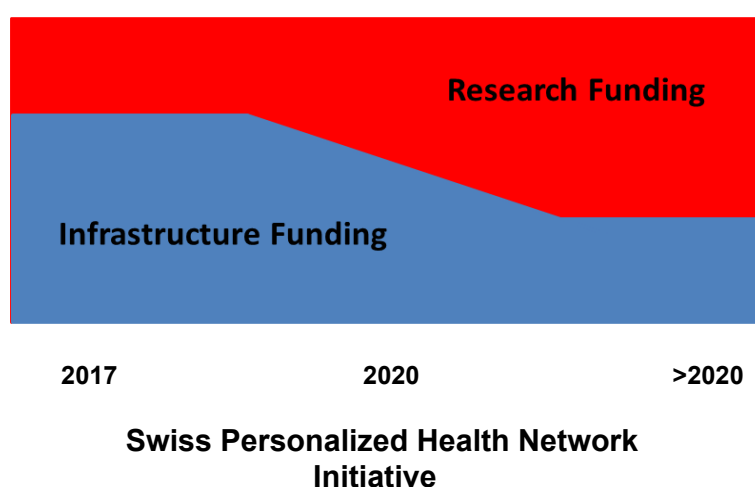


Figure 1: The sequential phases of the SPHN Initiative: focus moves from infrastructure towards research project funding.

B) Structure of the organization:

With respect to the **structural organization** of the SPHN Initiative, the following three levels have been agreed upon by the participants of the August workshop (see Fig. 2):

- At the **national level** are the political authorities (i.e. SERI), the SAMS, a National Steering Board (NSB), an Executive Board (EB) and a Management Office (MO). An International Advisory Board provides peer reviews and international perspectives. Research projects are evaluated independently by the SNSF.
- The **technical level** ensures data collection, quality standards, security and interoperability of databases as well as biobanking (SBP). The ELSI advisory group (ELSIag) ensures a coherent and integrated adherence to ethical standards and regulatory frameworks (law).
- And **at the institutional level** are the participating institutions and associated partners. They are the most important members of the SPHN Initiative, since ultimately all research projects will be defined thematically by a bottom-up process.

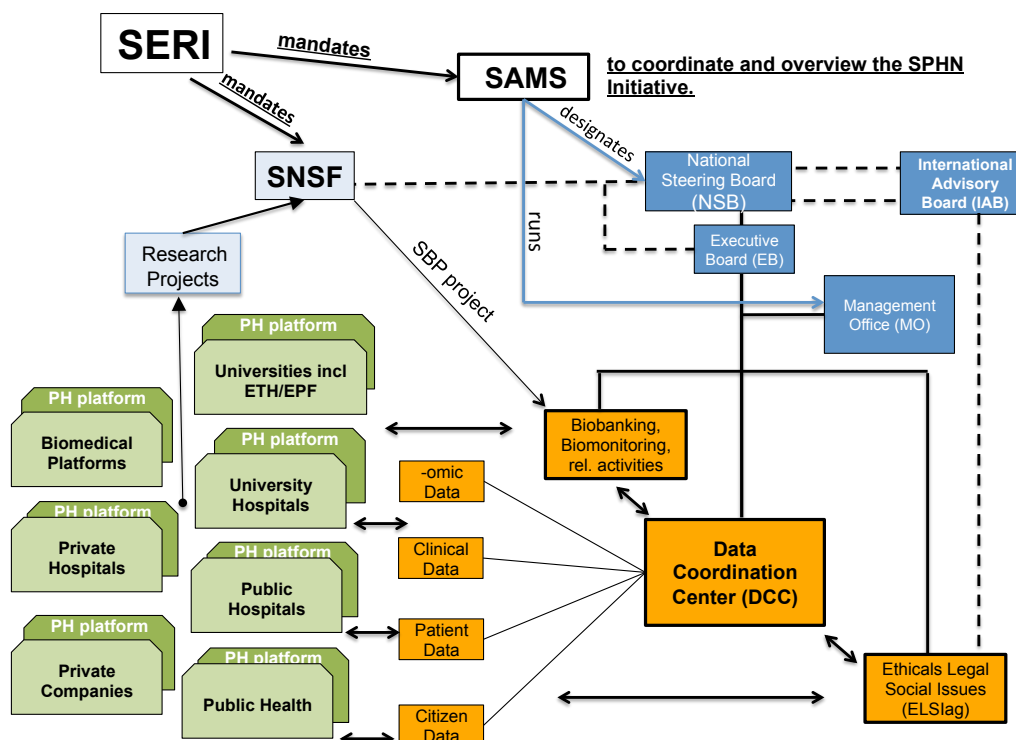


Figure 2: Proposed organizational structure for the SPHN Initiative on three levels: national (blue), technical (orange) and institutional (green)

C) Committees/bodies, responsibilities, tasks and composition:

National Level (blue color in Fig. 2):

- **National Steering Board (NSB):** The National Steering Board shall be the highest governing body of the SPHN Initiative. It has overall strategic responsibilities for the whole initiative including the coordination of data standards and interoperability, the integration of SBP and HBCP and the PH platforms at Universities and University Hospitals.

It maintains regular contacts to the superordinate political authorities (i.e. SERI, FOPH, Cantonal Public Health Ministers). It is coordinated by the SAMS in collaboration with partners (e.g. SNSF for SBP).

In particular, the NSB shall exercise the following duties and powers:

- Appoint and dismiss the Chairwoman/Chairman of the NSB and her/his alternate; as a rule the SAMS-President or vice-president shall act as the chairwoman/chairman;
- Appoint and dismiss the Chairwoman/Chairman and the members of the Executive Board;
- Annual report to the political authorities
- Approve the business plan prepared and submitted by the Executive Board and the yearly budget and the yearly management report including accounting;
- Determine the amount of the annual membership fee (if there is one);
- Approve the Managing Director upon proposal of the Executive Board;
- Approve the Bylaws (if any);

- (h) Supervise the activities of the other governing bodies;
- (i) Promote the SPHN's goals in industry;
- (j) Report yearly to the SPHN Partners' governing bodies if wished;
- (k) Modify the Partnership Agreement;
- (l) Define consequences of a Partner's withdrawal;
- (m) Represent the SPHN Initiative together with the EB to the outside;

In the NSB meeting, each member shall have one vote.

The NSB is composed of about 17 members which represent University Hospitals (3; 1 "Lausanne-Geneva-(Bern)" cluster; 1 "Zurich-Basel" cluster; 1 Verband für Universitäre Medizin), swissuniversities (3; including 1 representative of the Universities of Applied Sciences), ETH domain (2; 1 ETHZ and 1 EPFL), SNSF (1; SNSF representative), FOPH (1), SIB (1; director of the DCC), ELSI (1; president of ELSI advisory group), SAMS (2; president/vice-president plus 1 additional council member) and others (max. 3) , plus the Chairwoman/Chairman of the EB and the Managing Director without rights to vote. The represented institutions can propose the NSB members, and they are elected by the SAMS on behalf of the SERI.

- **Executive Board (EB):** The Executive Board shall be the operative body of the SPHN Initiative. The Executive Board shall be responsible for the scientific strategic planning and for the operative tasks of the initiative. The EB must cover the whole disciplinary range relevant to personalized medicine.

The Executive Board shall have the following duties:

- (a) Establish the business plan, the budgets, the annual account and the annual management report of the SPHN to be submitted to the NSB;
- (b) Registration of the research projects approved by the SNSF;
- (c) Create and appoint commissions or committees for specific purposes and appoint and dismiss the members of such bodies;
- (d) Create a Management Office and select a Managing Director to be proposed to the NSB;
- (e) Coordinate the collaboration in data collection and research in the field of personalized medicine;
- (f) Interact closely and ensure internal communications with the other committees/bodies within the SPHN;
- (g) Support interdisciplinary programs of Partners within the limits of financial resources available;
- (h) Present proposals and motions in all matters to be submitted to the NSB meetings;
- (i) Represent the SPHN Initiative together with the NSB to the outside.

Each member of the EB shall have one vote. The principle of "ad personam participation" shall apply, vote by proxy shall not be allowed.

The members of the EB shall be active scientists involved in basic, translational and/or clinical human research within their respective organizations/institutions. They shall have a strong international reputation in their research field and be able to dedicate time and their commitment to the SPHN Initiative. They are appointed by the NSB upon recommendation of SPHN partner institutions.

The EB shall be composed of about 11 members including active clinical scientists (2), Medical/Clinical Bioinformatics of University Hospitals (2; 1 "Lausanne-Geneva-(Bern)" cluster; 1 "Zurich-Basel" cluster), SBP (1), SIB (1), "technolomics" (2; 1 "Lausanne-Geneva-(Bern)" cluster; 1 "Zurich-Basel" cluster), CSCS (1, director),

Public Health/Epidemiology (1) and others (1), plus the Managing Director without a right to vote.

The EB shall constitute itself, with the exception of the Chairwoman/Chairman, who is appointed by the NSB Meeting.

(In case an issue is discussed in which an EB member has vested interests, she/he will have to withdraw from the discussion.)

- **Management Office (MO):** The MO shall be responsible for the daily operations of the SPHN Initiative under the supervision and instruction of the Chairwoman/Chairman of the NSB.

The MO shall be directed by a Managing Director.

The MO shall be integrated at the SAMS in Bern. The SAMS shall provide the necessary infrastructure for the Management Office.

The MO provides administrative support to all SPHN bodies (i.e. NSB, EB, IAB, ELSlag, etc) as well as to the whole SPHN Initiative as required by the actual needs.

Communication (internal as well as external) will be an important part of the SPHN Initiative. This will be organized and coordinated at the MO.

Salaries and running costs for the MO shall be financed through Federal Funds and, if possible, the Partners' yearly membership fees.

Essentially, the MO shall have the following duties:

- (a) Prepare the agenda for the meetings of the NSB and EB together with their respective Chairwoman/Chairman and record the minutes of the meetings;
 - (b) Support the implementation of the resolutions by the NSB and EB;
 - (c) Organize, direct and control the daily operations of the SPHN Initiative;
 - (d) Report, control and prepare the budget;
 - (e) Ensure timely and effective information flow between the MO, SNB and EB;
 - (f) Ensure the information flow between the various partner institutions, and in particular between the SNSF, the SERI, the FOPH and the office of the Cantonal Public Health Ministers.
- **Additional committees/bodies:** The **SNSF** is responsible for independent evaluation of SPHN-related research projects. The details of the exact mandate need to be worked out by the SERI and SNSF'. – An **International Advisory Board (IAB)** provides international advise, expertise and peer-review of the initiative as a whole. During the course of the initiative, additional panels (e.g. for infrastructure) may be installed.

Technical Level (orange color in Fig. 2):

The technical level links the NSB and EB to the member institutions and contributing partners and consists mainly of three parts: Data Coordination Center (DCC), biobanking/biomonitoring and related activities and the advisory group for Ethical-Legal-Social Issues (ELSlag).

- The **Data Coordination Center (DCC)** is coordinated by the Swiss Institute of Bioinformatics (SIB) and involves a number of high quality PH platforms, such as the SBP, the HBCP, the SCTO/CTU and various national –omics networks. The aim is to elaborate and define common technical data standards, harmonize semantics, data storage formats, data security, database management and quality control. The DCC links

to university and hospital IT departments, biobanks, and the registries of existing and new cohorts. In essence, the DCC ensures the interoperability of the various clinical and *-omics* data.

- **Biobanking/biomonitoring and related activities** ensure adequate coordination of SBP, HBCP, registries of existing and new patient cohorts as well as relevant healthy citizen organizations.
- **ELSI advisory group (ELSlag):** The ELSI advisory group treats ethico-legal challenges that the SPHN Initiative will face related to Ethical, Legal and Social Implications. It guarantees adherence to the data protection rules according to the Human research Act (HRA). ELSI shall develop robust ethical policies anticipating well-known challenges such as that of appropriate informed consent and privacy (see Fig. 3). Also, it should develop mechanisms and processes that will be ready to handle issues that have not been anticipated and will require a swift resolution. The ELSI shall play a key role in the development of such mechanisms. It provides advice to the NSB and EB but also to the SPHN research projects.

Based on its important and multiform significance the composition of the ELSI must be diversified and should consist of about 9 members including representatives of the following fields/organizations: Bioethics (2), SAMS (1), swissethics (1), Life Sciences Law (1), Social Sciences (1), others (max. 3). – The ELSI should be directly represented at the National Steering Board (NSB).

Institutional Level (SPHN members, contributing partners; green color in Fig. 2):

- **Institutions** are members of the SPHN Initiative and as such linked to each other via the technical level (see above). Members are typically hospitals and research institutions (Universities, Federal Institutions) that generate data that provide the basis for the SPHN Initiative. To start with, they are organized into two performing clusters: (a) Lausanne-Geneva-Bern) and (b) Zurich-Basel. Legal aspects of interactions with non-university partners will need to be defined by the ELSI advisory group.
- **International competition and partners:** The SPHN Initiative should develop an international profile due to its quality driven approach. Thereby, the focus must be the quality rather than the quantity of available clinical and *-omics* data. As such, the SPHN Initiative will become an attractive partner for international collaborators. Interactions with international biobanks and projects should be possible and regulated by the ELSI advisory group.

4. Data Standards, Data Interoperability and Data Organization

SERI mandate:

Data Standards, Data Interoperability and Data Organization: „In a first step the standards for data production and data storage must be defined. Most important is the interoperability of the clinical information systems and a standardised procedure to make clinical data usable for research. It remains to be decided whether data storage shall occur in a centralised or de-centralised organisation. – The Swiss Institute of Bioinformatics should have a leading role and connect with the medical informatics specialists at the University Hospitals. The standards and procedures to be followed must be defined until end of 2015!“ – It should become clear whether and how the goals can be met!

-Omics Data and Platforms: Which platforms are already in place and could be used for the SPHI ?

Workshop of August 31, 2015, WG1 and WG2 (see Annex 1)

The **interoperability** of both molecular and clinical patient data throughout Switzerland has been confirmed as the major challenge for the implementation of the three level data management hierarchy proposed in the report 2014 [3]. This issue should be addressed before the official start of the SPHN Initiative in 2017. Despite numerous impediments, there are already several positive developments towards reaching a common interoperable architecture for molecular and clinical data in Switzerland as demonstrated in some details in the report „Interoperability of clinical and omics data in Switzerland“ of February 2015 [4]. These mostly regional or local initiatives must now converge fast in order to achieve one nationwide harmonized database that is accessible by various biomedical research domains including fundamental, translational and clinical research, outcome research, health services research, and especially personalized medicine research. Such converging efforts can also support the development of powerful biomonitoring networks, such as for example for rare and/or emerging diseases. In order to meet these challenges and in accordance with the recommendations for the „Precision Medicine Initiative (PMI)“ in the USA [5], it is inevitable to establish one national **Data Coordination Center (DCC)** on the technical level of the SPHN Initiative (Fig. 2). The DCC operates under the direct supervision of the EB and the NSB, and is coordinated by the SIB. As a rule, the coordination shall consider and implement already existing and established national [6] and international standards and guidelines.

In order to fulfill the requirements of the SERI mandate (see above) the following action plan and schedule is proposed:

Until June 2016:

- Installation of a „**Data Expert Group (DEG)**“ group that defines standardized procedures for data production, data organization and data storage to reach nationwide interoperability of molecular and clinical patient data and to make them usable for personalized medicine research. The DEG should be led by an experienced SIB member, consists of about 14 members and includes the following representatives: SIB (3), Medical Information Scientists (5, one from each University Hospital), Clinical Researchers (3, from CTUs and/or SCTO), others (max. 3). – Special attention has to be given to an adequate representation of the two clusters „Lausanne-Geneva (Bern)“ and „Zurich-Basel“.
- The DEG will elaborate a technical roadmap for the implementation, responsibilities (tasks) and operation of the national **Data Coordination Center**. To clarify which data must be stored centrally and which shall remain locally is of particular importance.
- Organization and structure of the DCC will be defined.

Until end of 2016:

- Established mechanisms for defining data quality and data standards (incl. data semantics and formats) as well as for data sharing and data interoperability between the two clusters „Lausanne-Geneva-(Bern)“ and „Zurich-Basel“.
- Consult with hospital IT stakeholders and harmonize the technical requirements for implementing the interoperability at the five participating University Hospitals. Establish a close collaboration between the DCC and the local hospital IT infrastructure providers.
- Decision which data are stored only locally and which data need to be stored centrally (i.e. in the DCC).
- Data access policies approved and security levels based on the three levels data management hierarchy proposed in the report 2014 [3] implemented.

2017-2020:

- 2017: Implement the defined data structures and standards (see above) at the DCC and in parallel at the University Hospitals ensuring complete data interoperability between the participating institutions.
- Impose usage of the defined interoperable data structures and standards on all SNSF funded SPHN related research projects.
- Provide funding to the participating hospitals to enable them to implement the standardized data structures and semantics in their Clinical Patient Records.
- Establish the conditions to encode, store and use the data in accordance to the „Human Research Act (HRA)“ in close collaboration with the ELSIag (see section 8).
- Ensure training to personnel involved in PH related projects at the University Hospitals and associated research institutions.

5. Involved and Associated Institutions, Organizations and/or Projects**SERI and FOPH mandates:**

-Omics Data and Platforms: Which platforms are already in place and could be used for the SPHI ?

Involved and Associated Institutions, Organizations and/or Projects: „A Swiss Personalized Health Initiative should integrate as many related projects/organisations as possible“.

Workshop of August 31, 2015, WG2 and WG3 (see Annex 1)

The Swiss Personalized Health Network Initiative is a research initiative in the medical – clinical - life science area with a strong focus on and outreach to the health sector. Therefore, the most important participating institutions in the SPHN Initiative are the five University Hospitals including the respective Universities and other public research institutions (Universities, ETH domain, Universities of applied sciences, others). The SPHN members are supposed to provide together coordinated interdisciplinary research platforms that closely interconnect molecular-genetic (e.g. *-omics*) technologies and research, medical and clinical bioinformatics, biobanking, patient oriented clinical and health-services research (so called „Personalized Health Platforms“, see Fig.2) [3], [4]. Such platforms have already been initiated within the „Lausanne-Geneva-(Bern)“ cluster (i.e. „Lemantic Center for Personalized Health“) and more recently also within the „Zurich-Basel“ cluster (collaboration between the „Competence Center for Personalized Medicine (CC-PM)“ Zurich and the „Personalized Health Platform“ Basel). Within the two clusters „**-omics Data and Platforms**“ provide a large spectrum of top-of-the-art technologies in various *-omics* fields including

genomics, proteomics, lipidomics and metabolomics (so called „**technomics**“). Furthermore, medical imaging techniques have been developed that are of considerable help in the association of *-omics* research with phenotypic monitoring. In order to capitalize from special local strengths it is suggested to form leading houses for certain „technomics“ such as for example genomics, proteomics and metabolomics as well as neuroimaging. Such „leading houses“ should coordinate the collaborations between local platforms and make sure that new developments in specific „technomics“ fields are implemented in local platforms as well as across the whole SPHN sites.

The SPHN Initiative does not start from scratch. There are numerous related projects, organizations, structures and activities with large experience and know-how. Integration, association of, or collaboration with such already ongoing relevant projects and organizations to the SPHN Initiative is obvious and important. These organizations and projects are to be linked with the SPHN Initiative:

- **Swiss Clinical Trial Organization (SCTO):** provides clinical research infrastructures through the network of Clinical Trial Units; provides processes and standards for the use of patient data and samples in accordance with ethical and legal requirements; facilitates and performs clinical trials across Switzerland; provides training programs to researchers and study personnel.
For pediatric patients the **SwissPedNet** (Swiss Research Network of Clinical Pediatric Hubs) must be incorporated. – SCTO and SwissPedNet shall be members of the Executive Board (EB).
- **Swiss Biobanking Platform (SBP):** has been mandated and funded by the SNSF since 2014; coordinates all biobanking activities in Switzerland; facilitates the storage and usage of human and non-human specimens; sets up and pilots the foundation for a Swiss National BioResource (SNBR) in Universities and large Hospitals. – SBP shall be a member of the Executive Board (EB).

Links to **other institutions/organizations or projects** such as the Swiss School of Public Health (SSPH+), swissethics, the Human Biomonitoring Cohort Project (HBCP), as well as to industry and health insurances have to be developed during the course of SPHN Initiative development.

6. Ethical, Legal and Social Issues

Requirements according to the SERI mandate: *All data within a Swiss Personalized Health Network must be collected and stored according to the ethical and legal requirements of the Federal Act on Research Involving Human Beings (Human Research Act, HRA). Consequently, a nationally harmonized “General Research Consent” should be installed that permits the collection of biological material and/or personal health data under the same conditions all around Switzerland. How can we meet these needs?*

Workshop of August 31, 2015, WG4 (see Annex 1)

There is broad acceptance that the SPHN Initiative needs an advisory group for ethical, legal and social issues (ELSlag; see Fig. 2). One of the most important initial tasks of the ELSlag is to implement a „*National Harmonized General Research Consent (GRC)*“ (Fig. 3). The ELSI advisory group has to ascertain that all activities within the SPHN conform to the legal regulations such as the Human Research Act (HRA) and the Data Protection Act. Furthermore, communication channels to the broader public have to be developed in order to ensure public trust to and public collaboration with the SPHN Initiative. Finally, the ELSI advisory group must advise the various SPHN committees and research projects. This covers the whole array of additional ethical considerations including obligations to

participants in terms of data sharing, return of results, benefit-sharing, conditions for collaboration with industrial partners, transparency of processes etc.

**Request for a Nationwide Harmonized General Consent Procedure
for Use of Biological Material and Health-Related Personal Data
for further Use for Research.**

For further use for research of biological material sampled or health-related personal data collected we need a nationwide harmonized interinstitutional General Consent procedure that can be taken at the first contact of each individual with the health system in Switzerland.

To Master New Challenges !

Informed consent




Figure 3: The SPHN ELSI advisory group will implement a „National Harmonized General Research Consent (GRC)“.

7. Financial Issues

The SPHN Initiative shall be funded by separate Federal money according to the SERI dispatch 2017-2020. In order to guarantee goal oriented allocation of the funding, the funds should be under the final responsibility of the NSB. However, portions of the total finances will be „ear-marked“ (*kreditiert*) for special tasks such as „data coordination“ (SIB, hospital bioinformatics), „local PH platforms, ELSI, project management“ (SAMS). The NSB should be given the responsibility to allocate all the SPHN money to the various institutions according to predefined procedures. These SPHN funds allocation procedures will have to be defined by the NSB until end of 2016 (see below).

Two basic principles must be strictly adhered to in the funding allocation process:

- Funds are strictly reserved for research related **additional** efforts such as research appropriate data editing, data infrastructures and data management. No financing of data infrastructures or any (not research-related) other matters specifically used for clinical services (e.g. eHealth) is possible. However, methods to translate and/or transfer routine clinical data into research feasible configurations is fundable.
- For the infrastructural part (see Fig. 1) the “matching fund” principle is applied as requested by law for the whole SPHN initiative. Hence, institutions have to contribute at least 50% of the total additional costs by own means while up to 50% are covered by the SPHN initiative.

8. Schedule of Implementation Steps

Until June 2016:

- Installation of the National Steering Board (NSB)
- Installation of the Executive Board (EB)
- Setting up the Data Expert Group (DEG)

Until end of 2016:

- Initiation of the Data Coordination Center (DCC)
- Installation of the Management Office
- Installation of the International Expert Panel (Advisory Board?)
- Installation of the ELSI advisory group
- Creation of a „national harmonized general research consent“ procedure
- Definition of standardized data structures and semantics ensuring data interoperability on a nationwide basis
- Organization of adequate Personalized Health Platforms within the two initiation clusters „Lausanne-Geneva-(Bern)“ and „Zurich-Basel“. Clarification of the role of Bern.
- Integration and/or association of SCTO and SBP
- Definition of SPHN funds allocation procedures
- Establish link to HBCP, SSPH+ and/or swissethics

2017-2020:

- **2017:** Installation of the definite project organization; finalization of the setup of central and local infrastructures.
- **2018 plus:** start of bottom-up research project (call for proposals, review, funding);

9. Selected References

- [1] Collins FS and Varmus H: A New Initiative on Precision Medicine. - *N Engl J Med* 2015; 372:793-795
- [2]http://www.easac.eu/fileadmin/PDF_s/reports_statements/EASAC_Summary_on_Personalised_Medicine.pdf
- [3] Konzept Nationale Förderinitiative: „Systems Medicine – Personalized Health“. - *1st SERI commissioned Report by Working Group „Leyvraz-Lovis-Meier-Abt-Schulthess-Täuber-Vetterli“*, September 2014.
- [4] Interoperability of clinical and omics data in Switzerland - *2nd SERI commissioned Report by Working Group „Appel-Beckmann-Lovis-Schwede-Vonder Mühl-Xenarios“*, February 2015
- [5] Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH, September 17 2015
(<http://www.nih.gov/precisionmedicine/09172015-pmi-working-group-report.pdf>)
- [6] Medizinische Register: Empfehlungen zum Aufbau von Registern für Entscheidungsträger aus Verwaltung, Politik und Öffentlichkeit (Stakeholder) im Gesundheitswesen sowie Registerführende in der Schweiz. Verbindung der Schweizer Ärztinnen und Ärzte (FMH), Nationaler Verein für Qualitätsentwicklung in Spitälern und Kliniken (ANQ), Die Schweizer Spitäler (H+), Schweizerische Akademie der Medizinischen Wissenschaften (SAMW) und Verband Universitäre Medizin Schweiz. Vernehmlassung, Version 10 vom 23.9.2015.

November 17, 2015

For the Core Project Group

A handwritten signature in black ink, appearing to read 'P. Meier-Abt', written in a cursive style.

Prof. Dr. Peter J. Meier-Abt
President SAMS

A handwritten signature in black ink, appearing to read 'Daniel Vonder Mühl', written in a cursive style.

Dr. Daniel Vonder Mühl
Project leader