Swiss Personalized Health Network: Funding Principles (01.03.2017)

The Federal Council proposed funds for a *Swiss Personalized Health Network (SPHN)* initiative to foster infrastructures and research in Personalized Medicine/Health in Switzerland in its *Message on Education, Research and Innovation for 2017-2020*, which was approved by the Swiss Parliament. This paper defines the funding principles and, thus, provides the basis for the concrete and binding funding regulations within the SPHN initiative.

Summary

The final goal of the SPHN initiative is to make Switzerland a leading country in Personalized Medicine/Health. During the first phase, SPHN will fund the additional effort/capacity (e.g. personnel & hard-/software) necessary to make clinical phenotype data interoperable and usable for research and to link them with other types of human data (e.g. –*omics* data, imaging data, lab data etc.). It will support the development of Clinical Data Warehouses (CDW) and of local/regional interdisciplinary (translational) platforms required to connect basic molecular, biological and clinical sciences. SPHN is a national initiative and, therefore, nationwide data interoperability and data sharing are indispensable conditions for funding, which will be based on the "matching funds" principle. In order to build a national database, the Initiative will support the four strategic main streams that were identified for the period 2017-2020 following a project matrix approach. The matrix will be based on the technical roadmap developed by the Data Expert Group (DEG) and consists of horizontal and vertical initiatives that will allow to develop and test the required infrastructure. The overall strategy was discussed with representatives of the ETH-Domain to align SPHN and the ETH-Domain Strategic Focus Area (SFA) in Personalised Health and Related Technologies. Proposals will be evaluated by the International Advisory Board (IAB).

1 What is the Swiss Personalized Health Network (SPHN)?

To make use of the potential in the great amounts of biological and clinical health data for research and innovation, researchers at the Swiss Federal Institutes of Technology (ETHs), Universities and University Hospitals proposed a research initiative in the area of Personalised Health. This initiative has been taken up by the State Secretariat for Education, Research and Innovation (SERI), which commissioned the Swiss Academy of Medical Sciences (SAMS) to create a concept for the development, structure and implementation of a SPHN. The resulting SPHN initiative aims for a nationwide harmonisation of molecular and clinical data semantics and of health information technology systems in order to achieve data interoperability among all relevant stakeholders such as University Hospitals, Universities, Swiss Federal Institutes of Technology (ETHZ, EPFL), research funding institutions (e.g. SNSF), other research performing hospitals, political authorities (e.g. FOPH) and relevant biomedical organizations (e.g. Swiss Biobanking Platform).

As specified in the adopted implementation report of November 2015, initial funding shall focus on the development of essential infrastructures. Subsequently, funding of research projects will become more and more important.

An International Advisory Board of SPHN will peer-review specific funding proposals and regularly review the initiative as a whole.

More information about SPHN is available at: **www.sphn.ch.** This SPHN homepage provides also regular information about ongoing activities and progress in the development of the initiative.

2 Federal Funds available for the SPHN initiative

For the period 2017-2020 a total amount of CHF 68 mio of federal funds shall be reserved for the SPHN initiative; funding for the Strategic Focus Areas of the ETH-Board is separate (see Table 1). Thereby, CHF 18.0 mio are reserved for the so-called BioMedIT project that focuses on providing a secure IT environment (IT hardware and support staff shared between research institutions and University Hospitals) where sensitive data, not only personalized health data, can be handled. The remaining CHF 50.0 mio shall be under the final responsibility of the National Steering Board (NSB) of SPHN for the implementation and development of IT and data infrastructures required to achieve common data standards and nationwide data interoperability, and for so-called “driver projects” that are research based but help aligning and improving the various infrastructure platforms.

3 Funding Principles within SPHN

The final goals of the SPHN initiative is to make Switzerland a leading country in Personalized Medicine/Health. For this purpose, it is necessary to share Personalized Health relevant technologies and data and to make them interoperable between all relevant research hospitals, Universities and ETH institutions of Switzerland. As a consequence, three main conditions apply for all projects to be funded by the SPHN initiative:

1) all projects have to demonstrate a clear and practical step forward towards nationwide data interoperability including –*omics* data, clinical phenotypes and life style data as supervised by the Data Expert Group (DEG);
2) all projects must convincingly demonstrate adherence to the data sharing principles between all SPHN partners as defined by the ELSIag and the DEG (e.g. no sharing – no money); the ELSIag will elaborate legally and ethically appropriate solutions for data access, privacy and trust;
3) the matching funds principle applies to all financial contributions, i.e. the participating institutions must provide their own contributions (in cash and/or in kind) to at least match the funds provided by SPHN.

It is planned to extend the SPHN initiative over a total of at least 12 years. Since until 2020 the infrastructures for an interoperable Swiss Personalized Health Network shall be established, funding of infrastructures, technology platforms and data standardisation have priority during the first 4-year period. Research projects are not excluded, but must contribute to the infrastructures and/or apply methods towards obtaining nationwide data interoperability and a data sharing network.

Initially, funding priority is given to the SPHN partner institutions, i.e. the University Hospitals, Universities and ETHZ/EPFL. They are organized in two main clusters, the “Basel-Zurich” cluster and the “Bern-Geneva-Lausanne” cluster. The SIB Swiss Institute of Bioinformatics is an integral part of the SPHN. Wider participation is also desired, i.e. other Universities (e.g. USI, Fribourg), research institutions and/or hospitals (e.g. Aarau, St. Gallen, Luzern) and industry are encouraged to associate with one of these clusters and to make joint applications together with at least one SPHN partner. Private sector institutions apply for possible SPHN funding in close association with one of the institutions of a given cluster with data access being clearly regulated by distinct contracts. Alone they cannot be funded and must cover their efforts with their own resources.

Once data interoperability and data sharing infrastructure will have been established between University and other research hospitals (i.e. for clinical medicine), healthy citizens and Public Health institutions must be included into the initiative. It is encouraged that Public Health institutions partner with institutions of a given cluster and that they adhere early on to the semantics of SPHN in order to achieve interoperability in future research projects

As data interoperability and sharing are key components of SPHN, access to coded data and anonymised data for all SPHN partners shall be guaranteed and granted at no cost by partner institutions. These conditions must be abided by SPHN partner institutions in order to receive funding from SPHN. As an important data sharing principle, it is suggested to build a dynamic "progressive shareable data ecosystem" including a "dynamic, transparent and shared consent management system" (see Annex 1). The latter is already part of a NFP75 project, in which members of the SPHN ELSIag are also involved. The ELSIag will further develop data sharing principles and suggest a suitable data sharing governance, so a technical solution can be implemented by the DEG. Thus, an early agreement on the general concepts of data sharing will facilitate all other developments.

4 Funding Procedures 2017-2020

There are **three types of data** that must be distinguished and made accessible and usable within the SPHN network:

- **Clinical phenotype (patients) and life style (healthy citizens) data**, which have to be structured into research friendly semantics, categorized and stored in Clinical Data Warehouses / data management platforms, which must be coordinated/harmonized between the various University Hospitals or Public Health institutions in order to guarantee interinstitutional data interoperability. Life style data are obtained from heathy citizens that have agreed to share their "self-tracking" data for Public Health research.
- **Molecular -*omics* data** obtained either from direct "genetic" testing or from biochemical/pathological analyses of biological human samples ("probes"). To this category belong also biobank samples that are stored in situ for further molecular-biological analyses in the future.
- **"Other human data"** relevant for Personalized Health research such as for example imaging data (e.g. CT and MRI data), electrophysiological data (e.g. ECG, EEG), histopathological data (e.g. Histopathology of Biopsies) or longitudinal observational data (e.g. "quantified self").

Based on the above-mentioned data types there should be **four strategic main streams** for SPHN funding:

4.1) **Development of Clinical Data Warehouses (CDW)** with harmonized data semantics for clinical phenotypes and common principles of quality standards for clinical, - *omics* and other human research data (see above) establishing nationwide data interoperability.

A CDW is a collection of patient related data spread throughout its many systems into a consolidated, organized and accessible database for analysis, reporting and research purposes *(Rosen and Saitz, Boston Medical Center USA).* It contains 1) a database containing data from multiple sources, 2) data extracted

from databases of a medical centers' clinical software packages, 3) a database containing data related to each other with some unique identifier ("code"), and 4) a database that is only as good as the data entered (quality assurance). Within the SPHN, CDW remain local/regional data repositories. However, they are nationally coordinated and interconnected by the Data Coordination Center (DCC) and supervised by the DEG, which guarantee nationwide harmonized data semantics and data interoperability.

As a firm principle, only the development of the research and not of the clinical care related part of CDW can be funded by SPHN, although it is realized that some connections to health care data (e.g. electronic patient dossiers) must be possible. Funding should especially support "capacity building" (e.g. personnel, IT infrastructure) to ensure adequate governance of the CDW. In order to ensure coherence and continuous exchange between clinical, *-omics* and other human data, SPHN funding should go through Universities to University Hospitals.

4.2) **Development of interdisciplinary (translational) platforms and adequate data infrastructures** connecting and linking *–omics* data, other human data (see above) and clinical phenotype data as well as ensuring adequate data standards for high quality personalized health related research. Such "data connecting proposals" could include projects that have a scientific component, but at the same time drive infrastructure development/implementation and tackle identified technological and/or methodological bottlenecks (e.g. scale-up issues, algorithm development). As with CDW SPHN funding should be focused on "capacity building" (e.g. personnel, IT infrastructure) and channelled through Universities to University Hospitals.

Since the envisaged interdisciplinary (translational) platforms connect basic *–omics* data with clinical phenotype data stored within the CDW, overall financing should be complemented, besides the obligatory matching funds principle, by ETH- Domain funds. BioMedIT will provide secure storage systems, secure clusters and support personnel required for the data analysis. In addition, the DCC will coordinate the technical activities nationwide (e.g. common security concept, technical interoperability, software distribution). The ETH-Domain should support the required interdisciplinary (translational) platforms by financing the more basic research oriented infrastructures and sciences and their connections to the CDW houses.

4.3) **Nationwide accessibility and interoperability of encoded patient data.** The SPHN/BioMedIT initiative is a coherent **national** enterprise. Therefore, all local/regional activities/centers (see above) must be nationally coordinated and interconnected. For example, clinical phenotype data semantics should be defined by a national semantic group. Also, mechanisms for automated data access from any regional CDW must be implemented to allow researchers to have unobstructed nationwide access to the research data provided approval by the responsible ethics' commission has been granted. The DCC will coordinate the SPHN activities required to achieve nationwide data interoperability between

hospitals and other major health data producers to enable secondary use of data for PH-related research. And the DCC will ensure the nationwide accessibility of all encoded patient data. Although these second level data will remain to be stored at local/regional data banks, truly anonymised third level data could be stored at the DCC and made available to the whole scientific research community. The DCC is also closely linked to BioMedIT and managed by the SIB Swiss Institute of Bioinformatics. Its SPHN related activities should be directly supported by SPHN funds. Furthermore, the DEG will elaborate an infrastructure roadmap as a guideline for funding allocations.

4.4) **Ethical-Legal-Societal issues (ELSI):** There are many new ethical legal and societal challenges associated with personalized health research. These challenges should be addressed within all three strategic main streams outlined above. The ELSIag will further develop the concept of a progressive shareable data sharing system (see Annex 1) and elaborate legally and ethically appropriate solutions for data ownership(s), privacy and trust. These and related activities shall be supported by SPHN funds.

The overall **database of SPHN** needs to be built following a project matrix (see Annex 1) including:

a) **horizontal initiatives (projects)** that are "devoted to build a **progressive shareable interoperable data system** and the dynamic, transparent and shared consent management (incl. hardware, software, standards, semantics etc.), as well as the core support of technical platforms. Within the SPHN initiative typical horizontal projects include the above mentioned strategic main streams 4.1, 4.3 and 4.4.

b) **vertical initiatives (projects)** that include the development of infrastructures and research based "driver" projects developing and testing new technologies, methods and infrastructures for personalized health related research. – Within the SPHN initiative typical vertical projects are included in the strategic main stream 4.2 such as scientific "driver projects" that will drive the horizontal projects and will also help to establish and test technological and/or methodological infrastructures. Although vertical projects can be related to a specific discipline (e.g. oncology, pathology etc.), all data must be generally accessible to all researchers. The EB will elaborate concrete work packages for suitable vertical initiatives.

Vertical and horizontal initiatives (projects) must be developed in a coherent matrix to ensure overall a national interoperable data framework. SPHN will fund the **additional effort/capacity** (e.g. hard-/software & personnel) in the strategic main streams that is necessary to achieve nationwide data interoperability in personalized health.

In addition to the tasks already mentioned above, the various SPHN governing bodies have the following responsibilities relevant for funding decisions:

- **DEG**: The DEG has identified several key areas where concrete work is required. They compiled a task list that includes areas such as Clinical Research Data Warehouses (CDW), semantic interoperability and data quality, infrastructure and information security, bioinformatics and data analytics, biobanking related questions in collaboration with the Swiss Biobanking Platform (SBP), training and educational activities and so called "driver" projects that are research based but require nationwide data interoperability. Issues related to data sharing are addressed in partnership with the ELSIag.

- **DCC:** The DCC works in close collaboration with the DEG EB and BioMedIT/SIB. It coordinates and supports the local/regional platforms and CDW and will ensure nationwide data interoperability and data accessibility. The DCC collaborates with other relevant national partners such as the Swiss Data Science Center (SDSC), the Swiss National Supercomputing Centre (CSCS) and the Swiss Biobanking Platform (SBP) and international partners such as ELIXIR, the global alliance for genomics and health (GA4GH) and the European Genome Phenome Archive (EGA) to ensure national data interoperability, state of the art data analysis capabilities, and compatibility with international standards and efforts for SPHN.

- **BioMedIT/SIB:** Although BioMedIT/SIB is an independent project and has been allocated "ear-marked" funds (see Table 1), it is an integral part of SPHN and contributes to complementary funding and capacity building of Personalized Health relevant interdisciplinary (translational) platforms (see section 4.2) as well as to part of the staffing of the DCC. BioMedIT can provide support for up to 15 FTEs distributed over the regional University data centres as well as resources for the initial set up of secure storage, technical interoperability and software distribution systems. It helps to ensure that the whole SPHN initiative remains a national enterprise and does not disintegrate into local/regional "silos".

- **EB:** The EB will prepare a business plan constituting of work packages with associated costs. BioMedIT should be included into the business plan. All suggestions have to guarantee the main principles of the SPHN initiative such as data interoperability and data sharing. Also, the EB will prepare suggestions for funding activities to the NSB.

- **ELSIag:** see section 4.4 and Annex 1.

- **IAB:** The IAB will evaluate the applications and project proposals according to defined rules, which are described in a separate IAB mandate.

- **NSB:** The NSB has the final decision about what will be funded. In case of specific tasks, the NSB may mandate experts who will support and advise the SPHN community. As a preliminary, but not binding approximation the available SPHN funds shall be allocated as summarized in Table 1.

Table 1: Overview and possible allocation of SPHN funds (2017-2020)

SPHN funds 2017-2020	**CHF 68.0 mio**
BioMedIT (federated secure IT infrastructure)	CHF 18.0 mio
Independent SPHN funds available	**CHF 50.0 mio**
SPHN management (NSB, EB, DEG, MO, IAB, symposia, workshops a.o.)	CHF 4.0 mio
Horizontal & vertical initiatives	**CHF 46.0 mio**

Remarks:

- *IT infrastructure is also supported by BioMedIT.*
- *ELS issues are part of all strategic main streams and, thus, their funding must be allocated to the emerging specific questions.*
- *The vertical initiatives shall be co-funded by SNSF and the ETH-Domain (see below).*

SNSF: The Swiss National Science Foundation will fund independently Personalized Health related **research projects.** There will be a coordinated communication between SNSF, SAMS, and SPHN regarding the funding priorities and funding procedures.

ETH-Domain: The ETH-Domain has reserved separate funds to support Personalized Health related technology developments. The ETH-Domain and SPHN could jointly organize and fund vertically oriented “driver” projects. By this way, the SPHN and ETH-Domain initiatives could be well aligned.

5 Calls for Proposals

5.1 Types of projects

SPHN will support projects that fulfil the goals and Funding Principles outlined in Chapters 3 and 4 and fall into one of the following categories:

- Projects for **infrastructure implementation** (top-down DEG horizontal initiatives; collaboration agreements [Leistungsvereinbarung]).
- Projects for **infrastructure development** based on work packages (bottom-up horizontal and vertical initiatives).
- **"Driver" projects** (vertical initiatives). Such "driver" projects are based in a concrete research field (e.g. cancer research/oncology) and drive the development of appropriate infrastructures to ensure nationwide data interoperability within the perspective discipline. Milestones are infrastructure-based, not research-based.

Funding of **ELSI activities** shall be included in each proposal.

5.2 Submission

The calls for proposals shall be published in the first half of 2017 and 2018 and possibly 2019, respectively. Submission deadlines will be end of June or July. Proposals will be evaluated (see chapter 6) during summer time. Start of funding is foreseen in October of each year.

5.3 Funding duration & conditions

Contributions will be funded for a maximal duration of **three years**. The NSB will decide an overall award budget for each call.

In case of multi-year funding, milestones to be reached in each year must be defined. The prospective milestones will be defined by the DEG and EB and decided upon by the NSB. They will be communicated in the calls and must be adhered to by the applicants within their project proposals. The achievements of the defined milestones will be evaluated by the NSB on a yearly basis. The next portion of the totally approved funding will be released only if the planned milestones have been reached to a sufficient degree - i.e. continuous funding through the whole funding period depends on milestones achievement.

A letter specifying and confirming own contributions (in cash and/or in kind) by the main applicant's institution must be attached to the proposal. The own contributions must pertain to the scope and main goals of the SPHN initiative. They must support the aim of SPHN and the funding principle specified in this document, and not directly relate to clinical service and other health care issues. However, building interconnections between electronic patient records and Personalized Health research data infrastructures are acceptable.

5.4 Eligibility criteria

As a general rule, main applicants should be Swiss higher education institutions (ETH-Domain, Universities, Universities of Applied Sciences) and University Hospitals; joint-application are encouraged:

- In the case of proposals for infrastructure implementation, Universities, institutions of the ETH-Domain and University Hospitals should submit a joint-application whenever possible. In order to ensure adherence to the principle of free data sharing among the research community, direct funding to a University Hospital will be dependent on the availability of a written agreement document from the respective University.
- In the case of proposals for infrastructure development based on work packages defined by the DEG (e.g. Clinical Research Data Warehouses, semantic interoperability and data quality a.o.; see Chapter 4), consortia of institutions are eligible as main applicants. The proposal should be a joint-project between at least one University Hospital and one partner research institution.
- Regarding proposals for vertical “driver” projects, the main applicant should be a partner institution of SPHN. The exact conditions will be defined separately for each call.

Only SPHN partners and cooperating partners are eligible to receive SPHN funding.

It is up to the main applicant to compose a consortium for their proposal. In general, all SPHN partner institutions are invited to participate. They can associate with other Universities, hospitals, research institutions (e.g. USI, Kantonsspital St. Gallen, Paul Scherrer Institute) and/or professional societies and include them in the consortium.

Under certain circumstances (e.g. no Swiss research group can provide the respective know-how), it is possible to include research groups located in a foreign country. However, SPHN funds can only be provided to the Swiss research groups involved. Please contact the Management Office to discuss specific cases.

Note: *SPHN funds can only be used for Swiss academic partners. The private sector partners must cover their efforts with their own resources.*

6. Proposal evaluation

6.1 Proposal pre-screening

The selection of the proposals will be preceded by a formal check by the Management Office. Furthermore, the SAMS council will control the compliance of the proposals with the SERI-SAMS contract (Zusatzprotokoll zur Leistungsvereinbarung 2017-2020 zwischen der Schweiz. Eidgenossenschaft und der SAMW). Proposals which fail to comply with these formal requirements will not be admitted to the next stage of the selection procedure and will be rejected if the defect cannot be easily corrected.
The following formal requirements must be met:

- Compliance with the submission deadline;
- Compliance with the official SAMS mandate and the SPHN “Funding Regulations”;
- Use of the official forms and completeness of the proposal, written in English;
- Eligibility of the main applicant and co-applicant(s);
- Acknowledgement of the need for the provision of own contributions in the case the proposal is approved for funding. In a preliminary step, only the host institution must sign a letter;
- Acknowledgement of the data sharing principles.

6.2 Selection procedure

6.2.1 Infrastructure implementation (see section 5.1)

Infrastructure implementation plans will be reviewed by a subgroup of the DEG who will verify that the technical requirements defined in the DEG report are met. The DEG subgroup will submit recommendations to the NSB. The NSB will decide on funds allocation upon proposal of the DEG.

6.2.2 Infrastructure development projects based on work packages & “driver” projects (see section 5.1)

All infrastructure development and “driver” projects will be reviewed by the IAB who may appoint additional experts to assist them with the assessment. Proposals will be selected according to the following criteria:

I. Contribution to the implementation of a nationwide harmonisation of molecular and clinical data semantics and of health information technology systems in order to achieve nationwide data interoperability SPHN;
II. Integration of research data and clinical data in a common system;
III. Focus to develop the necessary IT and data infrastructures to achieve nationwide common data standards;
IV. Scientific quality, including added value of the project as a whole;
V. Quality of the data sharing plan;

VI. Financial planning in general and distribution of the funding (total costs, own contributions, federal grant applications, third party funding).

The evaluation will be made in due consideration of the personalized health approach and of the significance for SPHN. The IAB will submit funding recommendations to the NSB.

6.2.3 Funding decision

The NSB will decide on funds allocated to projects. If necessary, short-listed main applicants may be invited to present their proposal and discuss it with the NSB.

Table of abbreviations

CDW	Clinical Data Warehouse
DCC	Data Coordination Center
DEG	Data Expert Group
EB	Executive Board
ELSI	Ethical-Legal-Social-Issues
ELSIag	Ethical-Legal-Social-Issues advisory group
ETH	Swiss Federal Institutes of Technology
FOPH	Federal Office for Public Health
IAB	International Advisory Board
IT	Information Technology
MO	Management Office
NSB	National Steering Board
PH	Personalised Health
SAMS	Swiss Academy of Medical Sciences
SBP	Swiss Biobanking Platform
SERI	State Secretariat for Education, Research and Innovation
SIB	Swiss Institute of Bioinformatics
SNSF	Swiss National Science Foundation

Glossary

Anonymous data	Data which cannot (without disproportionate effort) be traced to a specific person.
Clinical data management system	A clinical data repository which contains both patient structured and unstructured data.
Driver projects	These vertical projects are based in a concrete research field (e.g. cancer research/oncology) and will push the development of clinical data management systems in all University Hospitals by testing data interoperability & data sharing principles within the whole network. Milestones are infrastructure based.
Encoded data	Data linked to a specific person via a code.
Horizontal initiatives (projects)	Projects that are “devoted to build a progressive shareable interoperable data system” and the dynamic, transparent and shared consent management as well as the core support of technical platforms.
Infrastructure	Resources, personnel, and softwares that are necessary for the installation of the required network. Computers are considered as consumable.
Infrastructure development projects	Projects that thrive to develop and test new technologies, methods and infrastructures for personalized health related research in connection with horizontal initiatives.
Vertical initiatives (projects)	Projects (e.g. “driver” projects, infrastructure development projects) developing and testing new technologies, methods and infrastructures for personalized health related research which will drive horizontal initiatives.

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ANNEX 1

SPHN – Elements to funding principles - The phenotype data pipeline

Prof. Christian LOVIS, 06.11.2016

Introduction

The massive data integration required to provide the complete phenotypic information to support *omics interpretation and to support new personalized preventive and therapeutics is facing major a major challenge:

> Building a paradigm bridging spatial scales, from individuals to populations, continuous in temporal scales, from molecules to lifestyle, inclusive of health data, care data, environmental and exposure data, lifestyle and behavioural data, regulatory and societal ecosystem data

To reach this goal, the only possible way is to build a progressive shareable data ecosystem, and not a shared data repository.
The shareable data ecosystem is a progressive convergence of multiple existing and to come data sources. By nature, it will not be possible to build a unique centralized data repository, thus it is of utmost importance to build a unified framework that support on-demand unified requests for data queries when needed and when all requirements, including legal requirements, are fulfilled.

> The progressive shareable data system must be independent from any regulatory framework, including consent. It must allow to bridge data when the regulatory constraints, including consent, requirements are fulfilled. It must then allow data query without technical or semantical barriers for further data processing

The same approach should prevail for consent management. It is important to move toward a new paradigm of consent, which covers the principles of being a) dynamic, meaning that it can be adapted at each moment; b) transparent, meaning that data providers and data users are mutually informed and c) shared, meaning that consent doesn't belong a researcher or a research group. The principles of dynamic, transparent and shared consent are distinct from the one of broad consent.

> To leverage data usage, a new paradigm of consent management is required: the dynamic, transparent and shared consent. These principles act rather on the process of management consent rather than the content of the consent.

The BEHALF NFP75 project by E. Vayena, C. Lovis, S. Hurst and M. Puhan that was just granted funding intends to address the challenge of providing a model of a dynamic, transparent and shared consent management system for Switzerland.

Funding principles

The funding principles should be a matrix of vertical and horizontal projects.

The horizontal projects are devoted to build the progressive shareable data ecosystem and the dynamic, transparent and shared consent management. This includes all required layers, such as hardware, software, standards, semantics, etc.

The vertical projects are devoted to achieve personalized medicine objectives, that can have a deep focus on research or others goals, but that comply to the SPHN objectives.

> Horizontal projects, devoted to build the national SPHN framework and vertical projects, focusing on specific personalized medicine objectives, must be supported in a matrix and collaborative vision to ensure convergence of the infrastructure.

The landscape is fundamentally distributed. To achieve the largest data shareable data ecosystem, the environment must be carefully prepared from the start. While the SPHN intends to start with a distributed network of regional clusters of university hospitals, there is already needs to include data from ambulatory care settings, such as other hospitals and ambulatory care settings (“spitalexterne Hilfe und Pflege” - SPITEX) and numerous other sources to provide the most complete image of care processes and determinants of health.

To maximize chances to reach the goals of a progressive shareable data ecosystem, it is crucial to ensure a good mix of bottom-up and top-down activities, and a strong coordination between vertical projects. This is the duty of the horizontal projects. The horizontal projects must provide:

- Educational activities about the importance of data interoperability, which means “data shareability”. To improve adoption, it is important to promote the concept of shareable rather than shared. A good understanding of the added-value for the care system is an important asset for the success of the project. Well defined semantics and standards will also support direct care, such as decision-support, knowledge coupling, and also support internal governance strategic processes such as key performance indicators.

- Standardizing activities, at choosing, sharing, building resources that will ensure data interoperability. This includes the construction of multilingual resources for Switzerland, the support of adoption for standard coding for care activities, such as LOINC for the laboratory, ICD-0 for oncological diagnosis, etc. This work must be done in close collaboration with existing structures such as BAG, e-health-suisse, ANQ, etc. to avoid duplicate encoding,
- Support and promotion for shared tools, such as natural language processing, data processing (such as I2B2, Redcap, Transmart, etc.), data encryption and anonymization (such as homomorphic encryption, etc.). This support must help increasing the global level of competences in the field of data analytics, which is near to inexistent in Switzerland.

The horizontal projects must include an implementation part that is the deliverable of the project. The vertical projects must comply to the implemented aspects of the horizontal projects. Horizontal and vertical projects must coordinate to provide a converging result.

Strategy

The success cannot be achieved if SPHN is working alone. The strategy must involve the major stakeholders in the field of research, care and health in Switzerland, namely:

- SNF and STCO: should adopt a set of rules constraining the funding of research projects that deal with clinical data acquisition (cohorts, trials, etc.), such as use of common coding, standards and terminologies. This is more important than using the same tool (such as SecuTrial), but heterogeneous representation systems.
- ANQ is playing an increasing role in constraint documentation of clinical activities and outcomes for care settings, generating important amount of coded information that should be usable in the SPHN.
- BAG and e-health-suisse are the cornerstone of the Swiss Shared Patient Record, with the federal law that should be enforced in Spring 2017. Under this umbrella, numerous key elements are being structured, such as discharge summaries (EPD IPAG) or care plan with all medications. In this field, some work has already been funded to ease the use of a common representation for laboratory analysis by FAMH (led by Fierz and Lovis).
- Swissmedic is the recipient of all reporting for drug effects and side effect, and is also an invaluable source of information.
- Others.

Conclusion

1) The strategy must be to build a progressive shareable data ecosystem able to promote convergence of any data source that might be useful for the global aim of personalized medicine in Switzerland.
2) This can only be achieved in building a transparent and distributed network of shareable data and consent.
3) This implies that each independent source must be able to adopt the prerequisites that will allow future potential sharing of the data for secondary usage. This implies that primary usage must be seen as a priority, and secondary usage as an added-value. This is known to bring a maximum data quality.
4) Vertical and horizontal projects must be developed in a coherent matrix. The horizontal projects must ensure a national interoperable framework.
5) To have the major stakeholders be involved and adopt a coherent strategy for data representation and thus ensuring data reusability for second purposes, the major goals of the global strategy cannot be limited to research, but must encompass a wide understanding of added-value of health and care data for all actors.
6) A solid cornerstone of standards, coding systems, and lexico-semantic resources should be developed and maintained, ideally in a shared structure between all secondary usages. This should be done within a national structure between care system (such as BAG) and research organizations.