Swiss Personalized Health Network:
Funding Principles

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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 Dispatch on Education, Research and Innovation for 2017-2020, which was approved by the Swiss Parliament. Support was renewed in the Dispatch on Education, Research and Innovation for 2021-2024, approved by the Swiss Parliament in December 2020. 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 and research. During the first phase, SPHN has funded 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, and lab data). It has supported 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 is based on the “matching funds” principle. To build a national database, SPHN will continue to support the four strategic main streams that were identified for the period 2017-2020 and reassessed for the period 2021-2024 following a project matrix approach. The matrix, initially based on the technical roadmap elaborated by the Data Expert Group (DEG) and further developed by the National Advisory Board (NAB) and NSB Ausschuss (NSB-A), 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 in Personalised Health and Related Technologies (PHRT). Proposals will be evaluated by the International Advisory Board (IAB) and experts with intricate knowledge of the Swiss health data research landscape.

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

To use the potential of 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 to achieve data interoperability among all relevant stakeholders such as university hospitals, universities, Swiss Federal Institutes of Technology (ETHZ, EPFL, PSI, Empa), 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.

The International Advisory Board (IAB) of SPHN will peer-review specific funding proposals, together with additional experts depending on the type of projects supported, 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 have been reserved for the SPHN initiative. In addition, CHF 66.9 mio were allocated by the Swiss Parliament for the follow-up period 2021-2024. Funding for the Strategic Focus Areas of the ETH-Board is separate (see Table 1). CHF 18.0 mio (2017-2020) and 18.6 mio (2021-2024) 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 (2017-2020) and 48.3 mio (2021-2024) shall be under the final responsibility of the National Steering Board (NSB) of SPHN used 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”, which are research-based but help aligning and improving the various infrastructure platforms.

3 Funding Principles within SPHN

The final goal of the SPHN initiative is to make Switzerland a leading country in Personalized Medicine/Health by investing in data interoperability, data standardization, research infrastructure, and the successful networking of data providers, data producers and research institutions. For this purpose, Personalized Health relevant technologies and data need to be shared and made interoperable between all relevant research hospitals, universities and ETH Domain institutions of Switzerland. As a consequence, three main conditions apply to all projects to be funded by the SPHN initiative:

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1) all projects have to demonstrate a clear and practical step forward towards nationwide data interoperability including –omics data, clinical routine data and other health-related data;
2) all projects must convincingly demonstrate adherence to the data sharing principles between all SPHN partners as defined by the ELSIag and the NAB (e.g. no sharing – no money); the ELSIag, the SPHN Data Coordination Center (DCC) and SIB's legal department have elaborated legally and ethically appropriate solutions for data access, privacy and trust;
3) the matching funds principle applies to all financial contributions for horizontal and vertical initiatives (see Table 1), 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.

Definition:

- The horizontal projects are devoted to build the progressive shareable data ecosystem. 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 focus on research or others goals, but that comply to the SPHN objectives.

The SPHN initiative has been extended to cover a total duration of eight years. Since until 2024 the infrastructures for an interoperable Swiss Personalized Health Network shall be established, funding of infrastructures, technology platforms and data standardization have priority. Research projects are not excluded, but must contribute to the establishment or further development of infrastructures and/or apply methods towards obtaining nationwide data interoperability and a data sharing network.

Funding priority is given to the SPHN partner institutions, i.e., the university hospitals, universities, ETH domain institutions, and universities of applied sciences. The SIB Swiss Institute of Bioinformatics is considered as integral part of the SPHN. Wider participation is also desired: i.e., research institutions and research consortia (e.g., Swiss cohort studies, SAKK), and/or cantonal hospitals (e.g., Aarau, St. Gallen, Luzern) and industry are encouraged to make joint applications together with at least one SPHN partner. Private sector entities applying in close association with one of the SPHN partner institutions must clearly regulate data access by distinct contracts. Private sector entities cannot be funded by SPHN and must cover their efforts with their own resources.

Once data interoperability and data sharing infrastructure have been established between university and other research hospitals (i.e., for clinical medicine), healthy citizens and public health institutions as well as cohorts and registries can be included into the initiative. It is encouraged that public health institutions partner with SPHN partner institutions and that they adhere early on to the semantics of SPHN to achieve interoperability in future research projects.

As data interoperability and sharing are key components of SPHN, access to pseudonymized and anonymized data shall be guaranteed for all SPHN partners and granted, without profit, at cost (remuneration of costs related to data recruitment) by partner institutions. These conditions must be abided by SPHN partner institutions in order to receive funding from SPHN. Institutions must adhere to the current valid version of the SPHN Ethical Framework for Responsible Data Processing and the SPHN Information Security Policy, and commit to data sharing principles.

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). This includes first-level research use of data (for a specific, approved, research project), second-level research use (further use in the context of a modified or new, approved, research project), and third-level

research use (controlled access by third parties). The ELSIag will further develop data sharing principles and suggest a suitable data sharing governance, so a technical solution can be implemented throughout the network. Thus, an early agreement on the general concepts of data sharing will facilitate all other developments.

4 Funding Procedures

Three types of data must be distinguished and made accessible and usable within the SPHN network:

- **Clinical phenotype (patients) and 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 to guarantee interinstitutional data interoperability.
- **Molecular -omics data** obtained either from direct "genetic" testing or frombiochemical/pathological analyses of biological human samples. 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 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, 2007). 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 DCC and supervised by the NAB and HIT-STAG, which guarantee nationwide harmonized data semantics and data interoperability.

Only the development of the research and not of the clinical care-related part of CDW can be funded by SPHN, although connections to healthcare data (e.g., electronic patient dossiers, EPD) are important and shall be aimed for. Funding should especially support "capacity building" (e.g., personnel, IT infrastructure) to ensure adequate governance of the CDW.

4.2 **Development of interdisciplinary (translational) platforms and adequate data infrastructures** connecting and linking –omics data, other human data, healthy-citizens 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" include projects that have a visible 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), while also supporting necessary research activities, and should be channeled 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 their connections to the CDWs and SPHN network.

4.3 **Nationwide accessibility and interoperability of encoded patient data and research health data**. The SPHN/BioMedIT initiative is a coherent ***national*** enterprise. Therefore, all local/regional activities/centers (see above) must be nationally coordinated and interconnected. Furthermore, repositories for FAIR (Findable, Accessible, Interoperable, Reusable) health research data must be established and maintained to enable and promote the re-use of health data that was assembled and curated for a specific research purpose. This is paramount to SPHN, so that data will be actively explored, integrated and analyzed by the research community in new contexts.

Mechanisms for controlled data access from such repositories or any regional health data platform 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 coordinates 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. The DCC will facilitate the nationwide accessibility of all encoded patient data. Although these second-level data will remain to be stored at local/regional data banks, anonymized 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 are directly supported by SPHN funds. Furthermore, the NAB and HIT-STAG will elaborate an infrastructure roadmap as a guideline for funding allocations.

4.4 **Ethical-Legal-Societal Issues (ELSI)**: Many new ethical legal and societal challenges are associated with personalized health research. These challenges have been – and will continue to be – addressed within all three strategic main streams outlined above. The ELSIag will further develop the SPHN Ethical Framework and concept of a progressive shareable data sharing system (see Annex 1) and, together with the DCC and SIB's legal department, elaborate legally and ethically appropriate solutions for data ownership(s), data exchange, privacy, and trust. These and related activities shall be supported by SPHN funds.

The overall progressive shareable data ecosystem of SPHN is being 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" and "National Data Streams" 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), all data must be generally accessible to all researchers. The NAB will elaborate concrete work packages for suitable vertical initiatives.

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

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

- **NAB**: The NAB 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, health research infrastructures, data lifecycle, genomics and multi-omics, interoperability of registry and cohort data with clinical data, biobanking related questions in collaboration with the Swiss Biobanking Platform (SBP), training and educational activities and "Driver" projects (including National Data Streams) 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 NAB, the HIT-STAG and BioMedIT/SIB.It coordinates and supports the local/regional platforms and CDW and will ensure nationwide data interoperability and data accessibility according to data provider specifications. The DCC collaborates with other relevant national partners such as eHealth Suisse, the Swiss Data Science Center (SDSC), 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 "earmarked" 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 20 FTEs distributed over the regional university data centers 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".
- **ELSIag**: See section 4.4 and Annex 1.
- **IAB**: The IAB will evaluate the applications and project proposals, together with additional experts, according to the Funding Regulations and the specifications of the Call documents. The IAB and additional experts will also contribute to the monitoring of projects;
- **NSB**: The NSB has the final decision which projects will be funded. In case of specific tasks, the NSB may mandate experts who will support and advise the SPHN community. As defined in the

Zusatzprotokoll zur Leistungsvereinbarung 2017-2020 and 2021-2024 of SERI with the SAMS regarding SPHN, the amounts that are available for SPHN are summarized in Table 1.

- **ETH Domain**: The ETH Domain has reserved separate funds in a specific Strategic Focus Area to support Personalized Health-Related Technology (PHRT) developments. The ETH-Domain and SPHN intend to jointly organize and fund vertically oriented "Driver" projects, including "National Data Streams". This way, the SPHN and ETH Domain initiatives will be well aligned.

Table 1a: Overview 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*, NAB, MO, IAB, symposia, 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 can be co-funded by SNSF and the ETH-Domain (see below).*
- **, the EB and DEG were replaced in 2019 by the NAB.*
- ***,* in the period 2017-2020, funds allocated to SIB for the DCC were treated as infrastructure implementation (horizontal) initiative; no matching funds rule was applied

Table 1b: Overview of SPHN funds (2021-2024)

SPHN funds 2021-2024		**CHF 66.9 mio**
BioMedIT (SIB) (federated secure IT infrastructure)		CHF 18.6 mio
Independent SPHN funds available		CHF 48.3 mio
Management, SPHN steering organs, symposia, workshops, reports	Management Office	CHF 5.0 mio
	Data Coordination Center (SIB)	CHF 7.0 mio
Horizontal and vertical initiatives	SAMS	24.6
	SIB	11.7

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 horizontal initiatives; collaboration agreements [Leistungsvereinbarungen]).
- Projects for **infrastructure development** based on work packages (bottom-up horizontal and vertical initiatives).
- **"Driver" projects, including National Data Streams,** (vertical initiatives): such Driver projects are based in a concrete research field (e.g., cancer research/oncology) or a specific topic (e.g., rare diseases, specific data types) with the purpose to drive the development of appropriate infrastructures and methodologies to ensure nationwide data interoperability within the respective discipline. National Data Streams are comprehensive Driver projects with a visible research component, assembling a growing set of interoperable clinical, multi-omics, and other data of a given topic and making it accessible for re-use based on an overarching legal and regulatory framework for first-, second- and third-level research use of data. National Data Streams must have a sustainability concept and a clear governance structure including a defined data sharing and data quality policy.

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

5.2 Submission

Submission of proposals for bottom-up initiatives shall be possible within the frame of an open or targeted SPHN call, in accordance with the Funding Regulations and the specifications of the call document.

5.3 Funding duration and conditions

Duration of funding, eligible costs, evaluation of progress, and conditions for release of tranches are defined in the Funding Regulations and in the respective call document. 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 achievement 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 all institutions requesting funding from SPHN 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 is acceptable.

5.3 Eligibility criteria

As a general rule, main applicants should be employed at SPHN partner institutions, which include Swiss higher education institutions (ETH-Domain, universities, universities of applied sciences), and university hospitals. Joint- application are encouraged:

- Regarding proposals for infrastructure implementation, the main applicant should be employed at a partner institution of SPHN.
- In the case of proposals for infrastructure development based on work packages approved by the NSB, consortia of institutions are eligible as main applicants.
- Regarding proposals for Driver projects, the main applicant should be employed at a partner institution of SPHN. The exact conditions are 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, Kantonsspitäler), established research consortia (e.g. cohort consortia), 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. Proposals that fail to comply with formal requirements will not be admitted to the next stage of the selection procedure and will be rejected if the defect cannot be easily and quickly corrected.

The following formal requirements must be met:

- Compliance with the submission deadline;
- Compliance with the SPHN mandate by SERI 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.
- Acknowledgement of compliance with the SPHN Ethical Framework for Responsible Data Processing and SPHN/BioMedIT Information Security Policy.

6.2 Selection procedure

6.2.1 Infrastructure implementation (see section 5.1)

Infrastructure implementation plans will be reviewed by a subgroup of the relevant SPHN governing bodies. The NSB decides on the composition of the subgroup and may appoint additional ad-hoc experts, if deemed necessary. The subgroup will verify that the technical requirements defined for the infrastructure implementation project are met. The subgroup will submit recommendations to the NSB. The NSB will decide on funds allocation upon proposal of the subgroup.

6.2.2 Infrastructure development projects & Driver projects (including National Data Streams) (see section 5.1)

All infrastructure development and Driver project (including National Data Streams) proposals will be reviewed by a committee with members of the IAB and additional experts. Preceding the review by the IAB, a subgroup of the relevant SPHN governing bodies, mandated by the NSB and supported by additional ad-hoc experts where necessary, will make a statement about the feasibility of each proposal with regard to the SPHN infrastructure. 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 in 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 management and data sharing plan;
VI. Potential for impact on health and clinical decision making;
VII. Financial planning in general and distribution of the funding (total costs, own contributions, federal grant applications, third party funding).
VIII. Quality of the project consortium (including governance) and project management plan
IX. Quality of the sustainability plan.
X. Other evaluation criteria specified in the call document.

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 approval and rejection of each proposal, including funds allocated to approved 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
ELSI	Ethical-Legal-Social-Issues
ELSIag	Ethical-Legal-Social-Issues advisory group
ETH	Swiss Federal Institutes of Technology
FOPH	Federal Office for Public Health
HIT-STAG	Hospital IT Strategy Alignment Group
IAB	International Advisory Board
IT	Information Technology
MO	Management Office
NAB	National Advisory Board
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

The SPHN Glossary can be found on the SPHN website: https://sphn.ch/document/sphn-glossary/

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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.

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