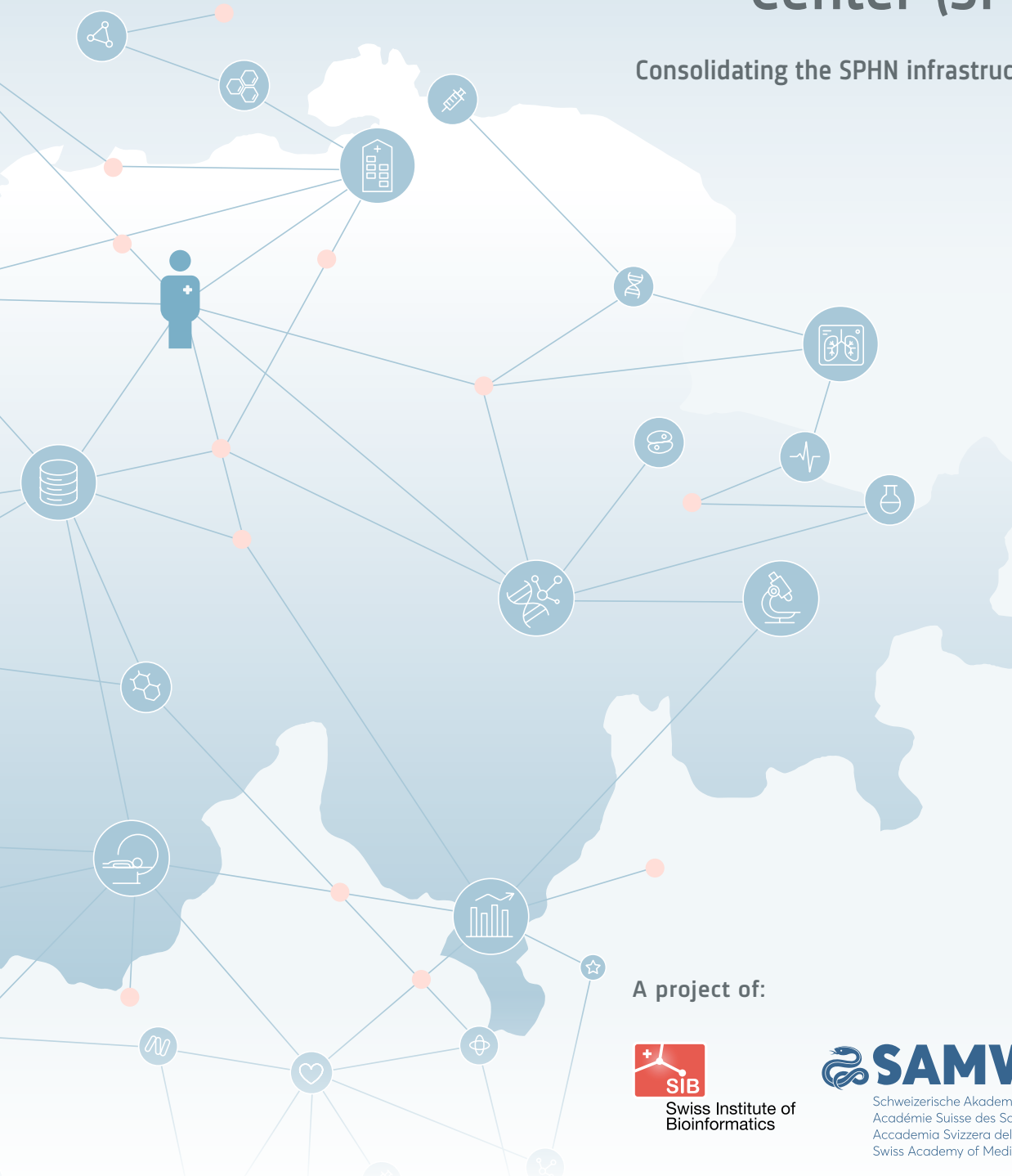swiss academies
of arts and sciences

The SPHN Data Coordination Center (SPHN-DCC)

Consolidating the SPHN infrastructures beyond 2024

A project of:

SIB
Swiss Institute of
Bioinformatics

SAMW ASSM
Schweizerische Akademie der Medizinischen Wissenschaften
Académie Suisse des Sciences Médicales
Accademia Svizzera delle Scienze Mediche
Swiss Academy of Medical Sciences

Information on the preparation of the publication

This Swiss Academies Communications is based on a report submitted to the State Secretariat for Research and Innovation (SERI) in December 2022. With a view to a sustainable provision and use of infrastructures and services beyond the two SPHN funding phases (2017–2020 and 2021–2024), the "Zusatzprotokoll zur Leistungsvereinbarung 2021–2024" between the Swiss Academy of Medical Sciences (SAMS) and SERI includes the mandate to set out options for a stable continuation of the data infrastructures after 2024. The process for assessing the activity portfolio and potential future host institutions as well as financing and governance options for the future SPHN Data Coordination Center (SPHN-DCC) was coordinated with SERI in a stepwise approach as follows:

First, a wide-range stakeholder survey was carried out by an external company (advocacy AG, see Annex Table 3 for the interviewed stakeholders) to assess the stakeholder's expectations, needs, and requirements for the future SPHN-DCC. From this feedback, it became clear that the future SPHN-DCC must have a multi-stakeholder, network-type structure. The SPHN National Steering Board (NSB) mandated a dedicated working group to subsequently elaborate SWOT (strengths, weaknesses, opportunities, and threats) analyses for possible organizational structures and affiliations for multi-stakeholder solutions. Based on the outline analysis from advocacy AG and the SWOT analyses, the working group developed a first draft report, including a shortlist of three scenarios fulfilling the requirements of the future SPHN-DCC at the technical and organizational level. Following discussions in early 2022 within the NSB and SERI, further specifications regarding the finances, the portfolio, the commitment of the partnering institutions and clarifications of interfaces with ongoing national initiatives in the domain of health data were deemed necessary. Over the summer 2022, several bilateral meetings were organized to further clarify the roles and responsibilities of the future SPHN-DCC and its partners. A written consultation of all NSB member institutions was carried out in October 2022, and the results were consolidated during the NSB meeting on 17 November 2022.

The present publication 'The SPHN Data Coordination Center (SPHN-DCC): Consolidating the SPHN infrastructures beyond 2024' is largely based on the final report that underwent consultation by the SPHN partner institutions and was submitted to SERI at the end of 2022. Relevant parts of the manuscript were reviewed by the concerned stakeholders in March 2023 and the final version was approved by the SPHN National Steering Board and the SAMS Executive Board in May 2023.

The SPHN Data Coordination Center (SPHN-DCC)

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SDGs: The international sustainability goals of the UNO
With this publication, the Swiss Academy of Medical
Sciences contributes to SDG 3: «Ensure healthy lives and
promote well-being for all at all ages.»

> sustainabledevelopment.un.org
> eda.admin.ch/agenda2030
> English > The 2030 Agenda > 17 Sustainable Development Goals

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Preface

The Swiss Personalized Health Network (SPHN) initiative was launched in 2016 by the Swiss Government to establish a national data infrastructure for clinical and omics data for research. It works closely together with the complementary initiative 'Personalized Health and Related Technologies (PHRT)', mandated by the ETH-Domain. Using a federated approach that builds upon existing large-scale data sources and infrastructures, SPHN aims to set up a nationally coordinated network to efficiently manage, exchange, and process consented health data in accordance with ethical and legal requirements. The Confederation provides support for this initiative for eight years, split into two funding periods 2017–2020 (CHF 68 Mio) and 2021–2024 (CHF 67 Mio), with the intention to afterwards consolidate the developed infrastructures in a permanent, sustainable, and scalable setting.

A first report on the achievements of SPHN between 2016–2019 was published as an Academies Report in 2021 [1]. The present publication is based on a second report submitted to SERI at the end of 2022, describing different options for a stable continuation of the SPHN data infrastructures after the initiative has finished. The publication summarizes the expectations and needs from the Swiss health research community on the activities of the SPHN-DCC and, more specifically, the technical, organizational, and financial requirements for a sustainable SPHN-DCC as part of the Swiss research infrastructure landscape promoting data-driven medicine and personalized health at national and international scale. Special emphasis is given to the many interfaces of the SPHN-DCC with its partners in research, the healthcare system, and administration.

Over the past years, it has become evident that there is a great need for support and coordination at a national level in the areas of data findability, data accessibility, data interoperability and data analysis, and the provision of secure IT platforms enabling collaborative research with sensitive health data. These infrastructures will not only facilitate multi-center data-driven precision medicine but will be a key element in the landscape of all aspects of health-related research, adhering to the highest standards of data security and the Swiss legal framework (HRA).

Many stakeholders and partners of SPHN have expressed their firm support and commitment towards the consolidation of the established SPHN infrastructures in the long term. The stakeholders emphasized that the SPHN-DCC must ultimately serve the needs of a broad community including patients and citizens, and address both the data providers and the data users. Strategic, financial, and operational independence is thus key for the success of the SPHN-DCC, which will lead to shared benefit for all partners. Its role must further be viewed in the larger context of the evolving research landscape in Switzerland towards "Open Research Data" (ORD) and a health data space. The clarification of roles and responsibilities and the interfaces between the SPHN-DCC and its partners (hospitals, universities, PHRT, SCTO, SBP, SNSF, SAKK, SIB, SDSC, FOPH, FOS, patient representatives, etc.) and other complementary initiatives is an ongoing process of utmost importance. Going further, stakeholders from research, care and the public health sector have expressed a strong positive opinion towards developing an empowered structure for Switzerland in the long term, in the form of a "National Center for Health and Research" (NCHR). Such a structure could have a significant impact for the field of health-related research and subsequently improve healthcare and public health in Switzerland. A NCHR will not only increase the coordination between the stakeholders and improve the efficacy and quality of research but will make Switzerland more attractive for international research collaborations, including collaborations with industry partners.

Given the fundamental work of SPHN, PHRT, and the SPHN-DCC in recent years, and the high sense of urgency within the stakeholder landscape, we continue our commitment to help shape the national health research landscape of the future.

Prof. Dr. Urs Frey
Chairperson of the SPHN National Steering Board

Dr. Katrin Crameri
Director Personalized Health Informatics Group SIB

Dr. Thomas Geiger
Managing Director SPHN

Executive Summary – English

The Swiss Personalized Health Network (SPHN), a research infrastructure initiative commissioned by the Swiss government in 2017, takes a coordinated approach in building the infrastructures and processes necessary for the use and exchange of large-scale health data for research purposes. Such data are a prerequisite, particularly for data-driven health research and precision medicine approaches that ultimately aim to improve prevention, treatment and health of patients. With the involvement of university hospitals, universities, technology platforms, and other data-producing institutions, uniform standards are applied in order to make the various data comparable, linkable ("interoperable"), and usable in a secure and regulatory conforming environment, according to the Swiss laws.

The SPHN Data Coordination Center (SPHN-DCC) is at the heart of this initiative, acting as data intermediary between data providers and data users. It is responsible for the technical implementation of key SPHN milestones, including several infrastructure components such as the FAIR data framework and semantic strategy, the Federated Query System (FQS), (meta-) data catalogs and data exploration systems, data repositories, and the secure BioMed-IT network. Machine learning and AI algorithms as well as multi-omics analytical technologies can safely operate on this network, connecting latest technologies from universities and the ETH-Domain with real-world health data and thereby supporting innovation and clinical decision support tools in the healthcare sector. The numerous central services provided at a national level by the SPHN-DCC include support for harmonized implementation of health data standards, data management support, an ELSI framework and support facilitating data governance and access, and support for cross-institutional national and international collaboration.

Funding provided by the State Secretariat for Education, Research and Innovation (SERI) for the SPHN initiative is due to expire after the second finance period (2021–2024), at which point the initiative will wind down. With a view to a sustainable provision and use of infrastructures and services beyond the two SPHN funding phases, SERI mandated SPHN to set out the options for a stable continuation of the infrastructures after 2024 (in the realm of a future SPHN-DCC).

In a first step, SPHN mandated an external company (advocacy AG) to carry out a systematic wide-range stakeholder survey to assess expectations, needs and requirements of the future SPHN-DCC activity portfolio and governance structure.

The main results from the outline analysis are summarized as follows:

– The interviewed stakeholders unanimously agree on the importance of the SPHN-DCC for Switzerland as biomedical research location. The secondary use of health data for research purposes is dependent on various central support services and infrastructure elements in the areas of data findability, data accessibility and data interoperability, and with regard to the provision of a secure IT platform, for data analysis. These services must be sustainably guaranteed at a national level and should also organize and enable data access, controlled by data providers, not only for academic research but also for the private research sector and public institutions.
– Given that the SPHN-DCC must serve the needs of a broad community, including patients and citizens, and address both the data providers and data users, all stakeholders strongly recommend that its governance is multi-stakeholder and independent from

any individual institution or particular interests at the strategic, financial, and operational level.

– Most of the involved persons as well as the SPHN International Advisory Board share the vision that some sort of national institution should be installed – in the long run – in order to bundle up existing institutions and to foster health data research and secondary health data use in general. Most of the interviewees are aware, however, that the establishment of such a national institution cannot be carried out within the framework of the current four-year funding period. In the meantime, the SPHN-DCC should consolidate and expand the existing network, also providing its services on a national level to researchers and data providers beyond the scope of the SPHN initiative.

The development of the SPHN-DCC is taking place on the background of a convergence of processes in health research and health care. As in many other countries, there is a widely formulated wish in Switzerland to further develop data reuse, especially in health and in research. Multiple political initiatives at national and cantonal level are calling for a strategy and action to improve reuse of health data. Firstly, FOPH is pursuing a health data space suitable for research, improving data management in the health system, and is currently revising the Electronic Patient Record Act and the Human Research Ordinance. Secondly, a Swiss national strategy for Open Research Data (ORD) formulates principles to ensure research data are as open as possible. Thirdly, with their large portfolio of technologies, the ETH-Domain and the universities have a great interest in health data research and could support innovation in healthcare.

It is becoming increasingly recognized that the learnings and groundwork concepts and frameworks of SPHN and the networking efforts, infrastructures, and services of the SPHN-DCC can make a valuable contribution to the establishment of a coherent health data strategy in Switzerland. The SPHN-DCC actively collaborates with numerous partners in health research, to build a common understanding of the requirements and to coordinate and align on strategies and processes with the goal to build seamless interfaces between the different infrastructure components and services. It is of ut-

most importance that research and healthcare go 'hand in hand' and the SPHN-DCC has become a frequent advisor to federal and cantonal authorities and programs for health research data management and interoperability.

Based on the stakeholders' expectations and in the context of national and international developments, a broadly supported vision for the further development of the SPHN-DCC with respect to its activity portfolio, governance and financing was elaborated:

– **Activity portfolio:** The SPHN-DCC first and foremost needs to consolidate its role as the national competence and coordination center in Switzerland for FAIR data in the domain of health research, enabling exchange and use of such data across the country. Its mission is to ensure standardized processes focusing on interoperability of health data (legal, technical, syntactic, semantic), enabling, monitoring and enforcing their implementation, acting in a proactive dissemination role (e.g., communication, teaching, training), and providing infrastructures and services facilitating findability, accessibility, and reuse of health data for research and other societally important domains. It is assumed that, in the scope of the developing health data and research landscape, the services requested from the future SPHN-DCC will expand significantly over time. The portfolio and the organizational and financial setup therefore need to be scalable with a high degree of flexibility to accommodate additional data providers, data users and services, as needed.

– **Governance:** Four dimensions of the SPHN-DCC governance should be considered: 1. A strategic layer for the coordination with other Swiss health research partners, for setting the perimeter of the SPHN-DCC's activity portfolio and interfaces with the partners. The national "Coordination Platform Clinical Research" (CPCR), proposed in the White Paper Clinical Research and currently being established under the management of the Swiss Academy of Medical Sciences (SAMS) would be an obvious body to serve in this role. 2. A governance level with an SPHN-DCC Steering Board responsible for the oversight, finances, and general principles of data

governance and access policies. The steering board should include patient representatives and all contributing stakeholders, hosted by a trusted entity independent of particular interests. 3. A technical and organizational level involving the central IT network support, BioMedIT, interoperability, standards, the FQS, tools, interfaces and services. 4. A fourth layer for the data provision, processing, and analysis, which generally takes place in decentralized infrastructures and under local/project-specific data governance. Data governance generally needs to be managed non-centrally, i.e., by data providers (hospitals, universities, ETH-Domain) and the SPHN-DCC facilitates processes for data requests and data access and provides high-quality standards and guidelines.

— **Finances:** In general, SPHN stakeholders agree that a core financing for the future SPHN-DCC is important and most partners commit to continuing their already existing, relevant, in-kind contributions. The total annual costs of the future SPHN-DCC are estimated to amount to approximately CHF 13 Mio for 2025. They need to be financed by the Confederation and matching funds by the institutional partners and are split into central costs at the SPHN-DCC itself for operations, services, maintenance and further development of central infrastructures, and into noncentral costs on the side of the data providers (e.g., to implement and maintain data standardization etc.). Additional noncentral costs will incur at the three BioMedIT nodes. Potential sources of income are 1. core funding from SERI («Sockelfinanzierung»), 2. core funding from university hospitals/data providers and higher education institutions/data users, and 3. user fees.

The multi-stage consultation process and numerous bilateral discussions with SPHN stakeholders and partners have shown that the SPHN-DCC not only plays an indispensable role in SPHN, but is also of great importance for the future secondary use of health data in Switzerland beyond 2024. The concept of the SPHN-DCC should therefore be viewed in the context of an emerging and evolving health data landscape. Overall, the partners have expressed their broad-based commitment to the SPHN-DCC

and university hospitals and universities have signaled their general willingness to contribute to the operations of those infrastructures, especially through 'in-kind matching funds'.

Finally, different stakeholders from research, care, and public health expressed the widely formulated wish to facilitate and further develop data re-use and data-driven health research by establishing, in the long-term, a comprehensive structure at a national level. This was also strongly recommended by the SPHN International Advisory Board. Such a structure could bundle up existing institutions and foster biomedical research, clinical research, health data research, and secondary health data use in general. To increase international competitiveness, health research and care need to grow closer in a stepwise evolution towards a greater vision for an independent "National Center for Health and Research" (NCHR). This larger vision should be pursued in parallel to the recommendations for the developing SPHN-DCC, and embedded in the emerging national and international data ecosystems.

Executive Summary – Deutsch

Die 2017 im Auftrag des Bundes lancierte Swiss Personalized Health Network (SPHN) Initiative koordiniert schweizweit den Aufbau von Infrastrukturen und Prozessen, um den Austausch und die Nutzung von Gesundheitsdaten im grossen Massstab für die Forschung zu ermöglichen. Solche Daten werden insbesondere in der datengestützten Gesundheitsforschung und in der Präzisionsmedizin benötigt, um die Prävention, Versorgung und letztendlich die Gesundheit von Patientinnen und Patienten zu verbessern. Unter Einbezug von Universitätsspitälern, Universitäten, Technologieplattformen und anderen datenproduzierenden Institutionen werden einheitliche Standards angewendet, um die verschiedenen Daten vergleichbar, verknüpfbar («interoperabel») und in einer sicheren, gesetzeskonformen Umgebung nutzbar zu machen.

Das SPHN Data Coordination Center (SPHN-DCC) steht im Mittelpunkt dieser Initiative und agiert als Vermittler zwischen den Lieferanten und Nutzern von Gesundheitsdaten. Es ist für die technische Umsetzung der wichtigsten SPHN-Meilensteine verantwortlich: Dazu gehören mehrere Infrastrukturkomponenten, wie die Strategie und der Rahmen für FAIRe Daten mit entsprechender Semantik, das Federated Query System (FQS), (Meta-)Datenkataloge und Datenexplorationsplattformen, Datenrepositorien sowie das sichere BioMedIT-Netzwerk. Algorithmen für maschinelles Lernen und künstliche Intelligenz sowie Technologien für Multi-Omics-Analysen können in BioMedIT sicher betrieben werden. Neueste Technologien des ETH-Bereichs und der Universitäten werden auf diese Weise mit «Real-World» Gesundheitsdaten verbunden und Innovationen und Tools zur Unterstützung klinischer Entscheidungen im Gesundheitssektor werden gefördert. Die zahlreichen zentralen Dienste, die das SPHN-DCC auf nationaler Ebene anbietet, umfassen die Hilfestellung bei der harmonisierten Implementierung von Gesundheitsdatenstandards und beim Datenmanagement, einen Rahmen in Bezug auf ethische, rechtliche und gesellschaftliche Implikationen (ELSI) und Unterstützung zu Fragen von Daten-Governance und -zugang. Des Weiteren spielt das SPHN-DCC eine zentrale Rolle bei der interinstitutionellen Zusammenarbeit sowohl auf nationaler als auch auf internationaler Ebene.

Die Mittel, die das Staatssekretariat für Bildung, Forschung und Innovation (SBFI) für die SPHN-Initiative bereitstellt, laufen nach der zweiten Finanzierungsperiode (2021–2024) aus und die Initiative wird abgeschlossen. Im Hinblick auf den nachhaltigen Betrieb und die Nutzung der SPHN-Infrastrukturen und -Dienste über die beiden Förderphasen hinaus, hat das SBFI SPHN das Mandat erteilt, Optionen für eine stabile Fortführung der Infrastrukturen nach 2024 (im Rahmen eines zukünftigen SPHN-DCC) darzulegen.

In einem ersten Schritt hat SPHN deshalb ein externes Unternehmen (advocacy AG) mit der Durchführung einer systematischen, breit angelegten Stakeholder-Befragung beauftragt, mit dem Ziel, die Erwartungen, Bedürfnisse und Anforderungen an das künftige Tätigkeitsportfolio und die Governance-Struktur des SPHN-DCC zu ermitteln.

Die wichtigsten Ergebnisse dieser Umfrage lassen sich wie folgt zusammenfassen:

– Die befragten Stakeholder sind sich einig, dass das SPHN-DCC für die Schweiz als biomedizinischer Forschungsstandort von grosser Bedeutung ist. Zentrale Dienstleistungen und Infrastrukturelemente in den Bereichen Datenauffindbarkeit, -zugänglichkeit und interoperabilität sowie – im Hinblick auf die Datenanalyse – die Bereitstellung einer sicheren IT-Umgebung, sind unerlässliche Voraussetzungen für die Sekundärnutzung von Gesundheitsdaten zu Forschungszwecken. Diese Dienste müssen auf nationaler Ebene nachhaltig gewährleistet werden. Ausserdem sollen sie den von den Datenproduzenten kontrollierten Zugang zu Daten nicht nur für die akademische Forschung, sondern auch für den privaten Forschungssektor und öffentliche Einrichtungen organisieren und ermöglichen.

– Das zukünftige SPHN-DCC muss den Bedürfnissen einer breiten Gemeinschaft gerecht werden. Dazu gehören die Datenlieferanten und Datennutzer und insbesondere auch die Patientinnen und Patienten und die Bevölkerung im Allgemeinen. Deshalb empfehlen alle Stakeholder eindringlich eine Governance-Struktur, die verschiedene Stakeholder abdeckt und die in strategischer, finanzieller und operativer Hinsicht von einzelnen Institutionen oder Partikularinteressen unabhängig ist.

– Die meisten Beteiligten und das International Advisory Board von SPHN teilen die Vision, dass auf lange Sicht eine nationale Institution entstehen sollte, die die heutigen Einrichtungen bündelt und die Forschung mit Gesundheitsdaten sowie deren Sekundärnutzung im Allgemeinen fördert. Den meisten Befragten ist jedoch bewusst, dass die Schaffung einer solchen nationalen Institution nicht im Rahmen der laufenden vierjährigen Finanzierungsperiode erfolgen kann. In der Zwischenzeit sollte das SPHN-DCC die bestehenden Dienste konsolidieren und ausbauen und diese auf nationaler Ebene auch Forschenden und Datenproduzenten über den SPHN-Rahmen hinaus anbieten.

Die Entwicklung des SPHN-DCC erfolgt vor dem Hintergrund konvergierender Prozesse in der Gesundheitsforschung und -versorgung. Wie in vielen anderen Ländern besteht auch in der Schweiz der weit verbreitete Wunsch, die Wiederverwendung von Daten weiter auszubauen – insbesondere im Gesundheitswesen und in der Forschung. Mehrere politische Initiativen auf nationaler und kantonaler Ebene fordern eine Strategie und Massnahmen, um die Wiederverwendung von Gesundheitsdaten zu verbessern. So setzt sich das BAG für einen forschungsgerechten Gesundheitsdatenraum ein, um das Datenmanagement im Gesundheitswesen zu verbessern, und revidiert derzeit das Gesetz über das elektronische Patientendossier und die Humanforschungsverordnung. Des Weiteren formuliert die nationale Schweizer Strategie für Open Research Data (ORD) Grundsätze, um eine grösstmögliche Offenheit von Forschungsdaten zu gewährleisten. Schliesslich haben der ETH-Bereich und die Universitäten mit ihrem breiten Technologieportfolio grosses Interesse an der Gesundheitsdatenforschung und könnten Innovationen im Gesundheitswesen unterstützen.

Es wird zunehmend anerkannt, dass die Erfahrungen, Grundkonzepte und Rahmenwerke von SPHN wie auch die Vernetzungsbemühungen, Infrastrukturen und Dienste des SPHN-DCC einen wertvollen Beitrag zum Aufbau einer kohärenten Gesundheitsdatenstrategie für die Schweiz leisten können. Das SPHN-DCC arbeitet aktiv mit zahlreichen Partnern in der Gesundheitsforschung zusammen, um ein gemeinsames Verständnis der Anforderungen zu entwickeln und Strategien und Prozesse zu koordinieren und untereinander abzustimmen. Das Ziel ist, nahtlose Schnittstellen zwischen den verschiedenen Infrastrukturkomponenten und -diensten zu schaffen. Forschung und Gesundheitswesen müssen unbedingt «Hand in Hand» gehen; so berät das SPHN-DCC bereits heute Behörden und Programme auf Bundes- und kantonaler Ebene bei Fragen zum Datenmanagement und der -interoperabilität in der Gesundheitsforschung.

Basierend auf den Erwartungen der Stakeholder und unter Berücksichtigung nationaler und internationaler Entwicklungen wurde eine breit gestützte Vision für die zukünftige Entwicklung des SPHN-DCC in Bezug auf sein Tätigkeitsportfolio, die Governance und die Finanzierung erarbeitet:

– **Tätigkeitsportfolio:** Das SPHN-DCC muss in erster Linie seine Rolle als das nationale Schweizer Kompetenz- und Koordinationszentrum für FAIRe Daten im Bereich der Gesundheitsforschung festigen und den Austausch und die Nutzung solcher Daten landesweit ermöglichen. Seine Aufgabe besteht darin, standardisierte Prozesse für die (rechtliche, technische, syntaktische und semantische) Interoperabilität von Gesundheitsdaten sicherzustellen und deren Implementierung zu begleiten und durchzusetzen. Weiter, eine proaktive Dissemination zu gewährleisten (z. B. durch Kommunikation, Aus- und Weiterbildung), sowie Infrastrukturen und Dienste bereitzustellen, die

die Auffindbarkeit, Zugänglichkeit und Wiederverwendung von Gesundheitsdaten für die Forschung und andere gesellschaftlich wichtige Bereiche erleichtern. Es ist anzunehmen, dass sich das Portfolio der künftigen SPHN-DCC-Dienste angesichts der Entwicklungen im Gesundheitsdaten- und Forschungsbereich im Laufe der Zeit erheblich erweitern wird. Dieses Portfolio muss daher, ebenso wie die organisatorische und finanzielle Struktur, skalierbar und hochgradig flexibel sein, sodass sie bei Bedarf zusätzliche Datenproduzenten, Datennutzer und Dienste integrieren kann.

— **Governance:** In der Governance des SPHN-DCC werden vier Dimensionen berücksichtigt: 1. Eine strategische Ebene für die Koordination mit den Schweizer Partnern im Bereich der Gesundheitsforschung, um den Rahmen des SPHN-DCC-Tätigkeitsportfolios und die Schnittstellen mit den Partnern zu definieren. Die im White Paper Clinical Research vorgeschlagene nationale Koordinationsplattform Klinische Forschung (engl. National «Coordination Platform Clinical Research»), die derzeit unter der Führung der Schweizerischen Akademie der Medizinischen Wissenschaften (SAMW) aufgebaut wird, würde sich als Gremium für diese Ebene anbieten. 2. Eine Governance-Ebene mit einem SPHN-DCC-Steuerungsgremium, das für die Aufsicht, die Finanzen und die allgemeinen Grundsätze der Daten-Governance und der Zugangsrichtlinien zuständig ist. Das Steuerungsgremium sollte Patientenvertretungen und alle beteiligten Stakeholder einschliessen und in einer vertrauenswürdigen, von Partikularinteressen unabhängigen Instanz verankert sein. 3. Eine technische und organisatorische Ebene, die den zentralen IT-Netzwerksupport, BioMedIT, Interoperabilität, Standards, das FQS, Tools, Schnitt-

stellen und Dienste umfasst. 4. Eine vierte Ebene für Datenbereitstellung, -verarbeitung und -analyse, was im Allgemeinen in dezentralen Infrastrukturen und unter lokaler/projektspezifischer Daten-Governance erfolgt. Die Daten-Governance muss im Allgemeinen dezentral erfolgen, also durch die Datenlieferanten (Spitäler, Universitäten, ETH-Bereich). Das SPHN-DCC erleichtert die Prozesse für Datenanfragen und Datenzugang und stellt hochwertige Standards und Richtlinien zur Verfügung.

— **Finanzen:** Im Allgemeinen sind sich die SPHN-Stakeholder einig, dass eine Sockelfinanzierung für das künftige SPHN-DCC wichtig ist, und die meisten Partner sind bereit, ihre bestehenden, relevanten Sachleistungen («in-kind contributions») fortzusetzen. Die jährlichen Gesamtkosten des künftigen SPHN-DCC werden für das Jahr 2025 auf rund 13 Mio. CHF geschätzt. Sie müssen vom Bund und von den institutionellen Partnern finanziert werden und setzen sich zusammen aus zentralen Kosten beim SPHN-DCC selbst für Betrieb, Dienste, Unterhalt und Weiterentwicklung der zentralen Infrastrukturen sowie aus dezentralen Kosten auf Seiten der Datenproduzenten (z. B. für die Implementierung und Fortführung der Datenstandardisierung). An den drei BioMedIT-Knoten werden zusätzliche dezentrale Kosten anfallen. Mögliche Einnahmequellen sind 1. die Sockelfinanzierung durch das SBFI, 2. die Sockelfinanzierung durch Universitätsspitäler/Datenproduzenten und Hochschulen/Datennutzer und 3. Nutzungsgebühren.

Der mehrstufige Konsultationsprozess und zahlreiche bilaterale Gespräche mit Stakeholdern und Partnern von SPHN haben gezeigt, dass das SPHN-DCC nicht nur eine unverzichtbare Rolle im Rahmen von SPHN spielt,

sondern auch für die künftige Sekundärnutzung von Gesundheitsdaten in der Schweiz über das Jahr 2024 hinaus von grosser Bedeutung ist. Das Konzept des SPHN-DCC sollte daher im Kontext einer entstehenden und sich weiterentwickelnden Gesundheitsdatenlandschaft betrachtet werden. Insgesamt findet das Konzept des künftigen SPHN-DCC breite Unterstützung bei seinen Partnern und die Universitätsspitäler und Universitäten haben ihre generelle Bereitschaft signalisiert, zum Betrieb dieser Infrastrukturen beizutragen, insbesondere durch die Bereitstellung von Sachleistungen.

Schliesslich äusserten verschiedene Stakeholder aus Forschung, Versorgungseinrichtungen und öffentlichem Gesundheitswesen den Wunsch, die Wiederverwendung von Daten und die datengestützte Gesundheitsforschung längerfristig durch die Schaffung einer umfassenden Struktur auf nationaler Ebene zu erleichtern und weiterzuentwickeln. Dies wurde auch vom International Advisory Board des SPHN nachdrücklich empfohlen. Eine solche Struktur könnte bestehende Einrichtungen bündeln und die biomedizinische Forschung, die klinische Forschung, die Gesundheitsdatenforschung und die Sekundärnutzung von Gesundheitsdaten im Allgemeinen

fördern. Um die internationale Wettbewerbsfähigkeit zu steigern, müssen Gesundheitsforschung und -versorgung schrittweise zusammenwachsen, hin zu einer grösseren Vision für ein unabhängiges «National Center for Health and Research» (NCHR). Diese umfassendere Vision sollte parallel zu den Empfehlungen für das sich entwickelnde SPHN-DCC verfolgt und in die entstehenden nationalen und internationalen Datenökosysteme eingebettet werden.

Executive Summary – Français

L'initiative Swiss Personalized Health Network (SPHN), lancée sur mandat de la Confédération suisse en 2017, coordonne au niveau national la mise en place des infrastructures et des processus nécessaires à l'utilisation et à l'échange de grands volumes de données de santé à des fins de recherche. Ces données sont nécessaires pour la recherche en santé basée sur les données et pour la médecine de précision, disciplines qui visent à améliorer la prévention, les soins et la santé des patient.e.s. Des normes unifiées doivent être appliquées, afin que les différentes données puissent être comparées, corrélées (interopérées) et utilisées dans un environnement sûr et conforme à la législation suisse.

Au cœur de cette initiative, le SPHN Data Coordination Center (SPHN-DCC) opère comme intermédiaire entre fournisseurs.euses et utilisateurs.trices de données de santé. Il est chargé de la mise en œuvre technique des principaux jalons du SPHN. Cela comprend plusieurs composantes d'infrastructure telles que la stratégie et le cadre pour obtenir des données FAIR avec la sémantique correspondante, le Federated Query System (FQS), les catalogues de (méta-)données et les systèmes d'exploration de données, les recueils de données et le réseau sécurisé BioMedIT. L'apprentissage automatique, les algorithmes d'IA et les technologies d'analyse multiomiques peuvent fonctionner en toute sécurité dans le réseau BioMedIT. Celui-ci crée le lien entre les données de santé issues de la vie réelle et les dernières technologies développées par les universités et par le domaine des EPF, favorisant ainsi l'innovation dans le secteur de la santé et le développement d'outils d'aide à la décision clinique. Le SPHN-DCC fournit de nombreux services centraux dans toute la Suisse, comme le soutien à la mise en œuvre harmonisée de normes relatives aux données de santé et à la gestion de celles-ci, un cadre quant à l'implication éthique, légale et sociale (ELSI) et une aide sur les questions de gouvernance et d'accès aux données. Le SPHN-DCC endosse également un rôle central dans l'encouragement de la collaboration interinstitutionnelle nationale et internationale.

L'initiative SPHN se terminera à la fin de la deuxième période du financement (2021–2024) accordé par le Secrétariat d'État à la formation, à la recherche et à l'innovation (SEFRI). Soucieux du maintien des infrastructures et des services mis en place pendant ces deux périodes, le SEFRI a toutefois chargé SPHN de définir les options permettant d'assurer leur pérennité au-delà de 2024 (dans le cadre d'un futur SPHN-DCC).

Dans un premier temps, le SPHN a demandé à une société externe (advocacy AG) de mener une enquête systématique d'envergure auprès des parties prenantes afin d'évaluer les attentes, les besoins et les exigences auxquels le futur portefeuille d'activités et la structure de gouvernance du SPHN-DCC devraient répondre.

Voici un résumé des principaux résultats de cette analyse:

– Les parties prenantes interrogées s'accordent unanimement sur l'importance du SPHN-DCC pour la recherche biomédicale en Suisse. L'utilisation secondaire des données de santé à des fins de recherche ne se conçoit pas sans des services centraux et des éléments d'infrastructure permettant la mise à disposition de ces données, leur accessibilité et leur interopérabilité, ni sans la disponibilité d'une plateforme informatique sécurisée pour leur analyse. Ces services doivent être durablement garantis au niveau national. Ils devraient également organiser et permettre l'accès aux données, sous le contrôle de ceux et de celles qui les produisent, non seulement pour la recherche universitaire, mais aussi pour le secteur privé de la recherche et pour les institutions publiques.
– Le futur SPHN-DCC doit répondre aux besoins d'une vaste communauté, incluant les patient.e.s et les citoyen.ne.s, et travailler autant avec les personnes et institutions qui fournissent les données qu'avec ceux et celles qui les utilisent. C'est pourquoi toutes les parties prenantes recommandent fortement que sa gouvernance soit indépendante de toute institution ou de tout intérêt particulier aux niveaux stratégique, financier et opérationnel.

– La plupart des personnes impliquées, ainsi que le SPHN International Advisory Board, étaient d'avis qu'il faudrait, à terme, mettre en place une sorte de structure nationale qui chapeaute les institutions existantes et encourage globalement la recherche sur les données de santé et l'utilisation secondaire de celles-ci. La majorité des personnes interrogées étaient toutefois conscientes que la mise en place d'une telle institution nationale ne pouvait se faire dans le cadre de la période actuelle de quatre ans. En attendant, le SPHN-DCC devrait consolider et étendre les services existants, en les fournissant également au niveau national aux chercheurs.euses et aux fournisseurs.euses de données au-delà du champ d'application de l'initiative SPHN.

Le développement du SPHN-DCC s'inscrit dans le contexte d'une convergence des processus liés à la recherche et aux prestations de soins en santé. Comme dans beaucoup d'autres pays, le souhait de développer davantage la réutilisation des données, en particulier dans le domaine de la santé et de la recherche, est très largement répandu en Suisse. De nombreuses initiatives politiques à l'échelon national et cantonal appellent à une stratégie et à des actions visant à améliorer la réutilisation des données de santé. Premièrement, l'Office fédéral de la santé publique (OFSP) s'emploie à créer un espace dédié aux données de santé adapté à la recherche, afin d'améliorer leur gestion à l'intérieur du système de santé, et révise actuellement la loi fédérale sur le dossier électronique du patient et l'ordonnance relative à la recherche sur l'être humain. Deuxièmement, la stratégie nationale Open Research Data (ORD) formule des principes facilitant autant que possible l'accès aux données de recherche. Troisièmement, du fait de leur large portefeuille de technologies, le domaine des EPF et les universités sont très intéressés par la recherche sur les données de santé et pourraient soutenir l'innovation en matière de soins de santé.

Il est de plus en plus reconnu que les expériences, les cadres et les concepts fondamentaux fournis par SPHN et les efforts de mise en réseau, les infrastructures et les services livrés par le SPHN-DCC sont susceptibles d'apporter une contribution précieuse à la mise en place d'une stratégie cohérente en matière de données de santé en Suisse. Le SPHN-DCC collabore activement avec de nombreux partenaires de la recherche en santé, afin d'arriver à une compréhension commune des besoins et de coordonner et d'harmoniser les stratégies et les processus. L'objectif est de créer des interfaces fluides entre les différents services et composantes de l'infrastructure. Il est absolument essentiel que la recherche et le système de santé travaillent main dans la main. C'est pourquoi le SPHN-DCC est de plus en plus amené à conseiller les autorités et les programmes fédéraux et cantonaux sur la gestion et l'interopérabilité des données de recherche en santé.

Sur la base des attentes des parties prenantes et compte tenu des développements nationaux et internationaux, une vision du développement futur du SPHN-DCC, largement soutenue, a été élaborée; elle comporte trois axes, à savoir son portefeuille d'activités, sa gouvernance et ses finances.

– **Portefeuille d'activités:** le SPHN-DCC doit avant tout consolider son rôle de centre national de compétence et de coordination de référence pour les données FAIR dans le domaine de la recherche en santé et permettre l'échange et l'utilisation de ces informations dans tout le pays. Il a pour mission de fournir des processus normalisés axés sur l'interopérabilité des données de santé (juridiques, techniques, syntaxiques, sémantiques) et d'accompagner et de garantir leur mise en œuvre. Il joue par ailleurs un rôle proactif dans la diffusion (communication, enseignement, formation) et fournit des infrastructures et des services facilitant l'accessibilité et la réutilisation des données de santé à des fins de recherche et dans d'autres applications importantes pour la société. Étant donnés les développements dans le domaine des données de santé et de la recherche, il

est fort probable que la palette de services que le futur SPHN-DCC devra offrir s'élargira considérablement au fil du temps. Le portefeuille ainsi que la structure organisationnelle et financière doivent donc être évolutifs et présenter une grande souplesse pour intégrer de nouveaux.elles fournisseurs.euses et utilisateurs. trices de données, ainsi que des services supplémentaires, selon les besoins.

— **Gouvernance:** quatre dimensions de la gouvernance du SPHN-DCC devraient être prises en considération: 1. Une dimension stratégique qui assure une coordination avec les autres partenaires suisses de la recherche en santé, afin de définir le périmètre du portefeuille d'activités du SPHN-DCC et les interfaces avec les partenaires. La Plateforme nationale de coordination de la recherche clinique (CPCR), proposée dans le «White Paper Clinical Research», actuellement en cours de mise en place sous la direction de l'Académie Suisse des Sciences Médicales (ASSM), serait un organe tout désigné pour jouer ce rôle. 2. Une dimension de gouvernance avec un SPHN-DCC Steering Board responsable de la supervision, des finances et des principes généraux en matière de gouvernance des données et de politique d'accès. Sous la houlette d'une entité de confiance indépendante des intérêts particuliers, ce comité directeur devrait inclure des représentant.e.s des patient.e.s et toutes les parties prenantes impliquées. 3. Une dimension technique et organisationnelle comprenant le réseau informatique central, BioMedIT, l'interopérabilité, les normes, le FQS, les outils, les interfaces et les services. 4. Une dernière dimension pour la mise à disposition, le traitement et l'analyse des données, se déployant généralement dans des infrastructures décentralisées et dans le cadre d'une gouvernance des données locale/spéci-

fique au projet. En règle générale, la gouvernance des données doit être gérée de manière non centralisée, c'est-à-dire par les institutions qui fournissent les données (hôpitaux, universités, domaine des EPF). Le SPHN-DCC facilite les processus de demande et d'accès aux données et fournit des normes et des lignes directrices de haute qualité.

— **Finances:** en général, les parties prenantes du SPHN s'accordent sur l'importance d'un financement de base du futur SPHN-DCC et la plupart des partenaires s'engagent à continuer de fournir leurs contributions en nature actuelles, si pertinentes (in-kind contributions). Le coût annuel total du futur SPHN-DCC est estimé à environ CHF 13 millions pour 2025. Il doit être financé par la Confédération et par les partenaires institutionnels. Le coût annuel comprend les coûts centraux du côté du SPHN-DCC lui-même pour le fonctionnement, les services, la maintenance et le développement ultérieur des infrastructures centrales et les coûts non centraux du côté des fournisseurs.euses de données (par exemple pour la mise en œuvre et le maintien de la standardisation des données). Des montants non centraux supplémentaires seront alloués aux trois nœuds BioMedIT. Les sources potentielles de revenus sont: 1. le financement de base du SEFRI («core funding»); 2. le financement de base par les institutions qui fournissent/utilisent les données (hôpitaux universitaires/établissements d'enseignement supérieur) et 3. les taxes d'utilisation.

Le processus de consultation en plusieurs étapes et les nombreuses discussions bilatérales avec les parties prenantes et les partenaires de SPHN ont montré que le SPHN-DCC joue actuellement non seulement un rôle indispensable dans SPHN lui-même, mais qu'il revêt

également une grande importance pour la future utilisation secondaire des données de santé en Suisse au-delà de 2024. Par conséquent, le concept de SPHN-DCC devrait être considéré dans le contexte d'un domaine de recherche émergent et évolutif. Dans l'ensemble, les partenaires sont très favorables au SPHN-DCC. Les hôpitaux universitaires et les universités ont manifesté leur volonté commune de participer financièrement au fonctionnement de ces infrastructures, spécialement par une contribution en nature.

Enfin, différentes parties prenantes de la recherche, des soins et de la santé publique ont largement exprimé le souhait de faciliter et de développer davantage la réutilisation des données et la recherche en santé basée sur les données par la création, à long terme, d'une structure globale nationale. Cette proposition a également été fortement recommandée par l'International Advisory Board du SPHN. Une telle structure pourrait regrouper les institutions existantes et favoriser la recherche biomédicale, la recherche clinique, la recherche sur les données de santé et l'utilisation secondaire des données de santé en général. Pour améliorer sa compétitivité internationale, la Suisse doit tendre vers une vision supérieure dans laquelle recherche et soins de santé se rapprochent progressivement pour aboutir à un National Center for Health and Research (NCHR) indépendant. Cette vision plus large devrait être poursuivie parallèlement aux recommandations relatives au développement du SPHN-DCC et intégrée dans les écosystèmes de données nationaux et internationaux qui émergent actuellement.

1   Introduction

1.1   Background

The Swiss Personalized Health Network (SPHN)[1] is a research infrastructure initiative mandated by the Swiss Federal Government, namely the State Secretariat for Education, Research and Innovation (SERI)[2], in collaboration with the Federal Office of Public Health (FOPH)[3]. SPHN seeks a coordinated approach to data organization for data-driven, personalized health research. In particular, the initiative has as its goal the creation and maintenance of a sustainable and nationally coordinated infrastructure network, ensuring access to high-quality health data for research in Switzerland. With the involvement of university hospitals, universities, technology platforms, and other data-producing organizations, uniform standards are to be applied in order to make the various data findable, accessible, interoperable[4] and reusable (FAIR[5] principles). Such data are a prerequisite particularly for data-driven health research and precision medicine improving the health of patients. FAIR health-related data are moreover also useful for other fields of health-related research such as clinical trial design, translational research, implementation research, health quality research and even basic science, by connecting clinical health data to its related biospecimen.

The goal of SPHN is to promote national networking among all relevant players and to connect the Swiss healthcare system, the research community, regulatory agencies, and ultimately also industrial partners involved in personalized health.

SPHN is implemented as a national collaborative endeavor between higher education institutions, (university) hospitals, and financing bodies, in close alignment with other Swiss research organizations and patient partners. SERI has assigned the overall coordination of the initiative to the Swiss Academy of Medical Sciences (SAMS), in close collaboration with the SIB Swiss Institute of Bioinformatics. The SPHN Data Coordination Center (SPHN-DCC)[6], currently operated under the responsibility of the SIB, is at the heart of this initiative, acting as data intermediary[7] between data providers and data users in the health research data space[8]. It is tasked with implementing key SPHN milestones including the FAIR data framework and semantic strategy and the SPHN Interoperability Strategy, as well as several infrastructure components including the secure support infrastructure – the BioMedIT network. The numerous central coordination services provided at a national level by the SPHN-DCC further include support for harmonized implementation of health data standards, data management support, an Ethics, Legal, and Societal Issues (ELSI) framework facilitating data governance and access, and support for cross-institutional national and international collaboration. The SPHN-DCC is headed by SIB's Personalized Health Informatics (PHI) Group[9].

1.2   Secondary use of health data for research

When health data are pulled together from multiple sources for research projects, there are various difficulties and challenges that can be addressed in either an ad hoc or a systematic manner. SPHN is committed to a systematic approach that will work in a way that is both scalable and sustainable with an eye toward future health data research projects. Typically, health data are stored in multiple databases and formats, making them difficult to locate, access, and therefore use for research purposes. In addition, the so-called secondary use of health data is usually hindered by local data codes, lack of data dictionaries, and lack of meta-

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1   www.sphn.ch All links to internet resources in this publication were retrieved in June 2023.

2   www.sbfi.admin.ch/sbfi/en/home.html

3   www.bag.admin.ch/bag/en/home.html

4   Data interoperability refers primarily to the way in which data is expressed, described, and formatted so that different data sets can be merged or aggregated in a meaningful way

5   The FAIR principles require that data are Findable, Accessible, Interoperable, and Reusable. Sensitive health data cannot be openly accessible to third parties, but taking regulatory requirements into account, the data should be FAIR–also with reproducibility and sustainability in mind. The main goal of the FAIR principles is the optimal preparation of research data for reuse by humans and machines.

6   www.sphn.ch/network/data-coordination-center/

7   Data intermediaries provide services for sharing data. They ensure the exchange of data between supply and demand. Data intermediaries can be organizations that operate infrastructure for the exchange of data (e.g., software, physical infrastructure), but also providers of subsidiary services such as identification or authentication. Source: Federal Chancellery.

8   A data space is defined as an organized structure with technical and physical components that connects data users and data providers with their data sources and regulates the access, processing, and further use of data. Source: https://www.admin.ch/gov/en/start/documentation/media-releases.msg-id-87780.html

9   www.sib.swiss/personalized-health-informatics

data and context descriptions. In addition, research with sensitive data, even if pseudonymized or even anonymized, implies a de-identification effort, in order to prevent a potential re-identification of individuals. Furthermore, research with sensitive data calls for specific IT system and procedural requirements, an awareness of privacy and information security on the part of the researchers, and knowledge of the relevant legal and ethical requirements. The complexity of multi-center research projects that include, for example, routine care data from different hospitals, is further increased by the requirement to conclude legal agreements that clearly define the roles and responsibilities of the various project partners and institutions.

1.3   Current areas of activity of the SPHN-DCC

The vision of the SPHN-DCC is to enable the exchange and use of FAIR health-related data on a national level. A sensitive data-focused IT platform – the BioMed-IT network – facilitates the transfer, storage, processing, and analysis of confidential research data while meeting stringent security requirements.

The current SPHN-DCC activity portfolio supports this vision by offering a broad range of infrastructures, tools, and services to enable data providers to turn clinical (routine) data into FAIR research data, and allow researchers to realize the potential of these data. The SPHN-DCC closely collaborates with different partners in Switzerland, e.g., the university hospitals (UH), technology platforms, eHealth Suisse, various expert working groups and task forces, the BioMedIT network partners, and the research community. Further, the SPHN-DCC facilitates the knowledge exchange with national and international communities and organizes training and events across the network, as well as providing helpdesk functions regarding semantic, technical, and legal/ethical matters that arise in the community. In addition, the SPHN-DCC takes a lead on education and training[10] across the network regarding the topics: "FAIR Health-Related Data for Research", "Responsible Use of Health-Related Data for Research", and "Information Security and Data Privacy". The following seven areas of activity are the focus of the SPHN-DCC's current work:

a) FAIR data in SPHN: The SPHN Interoperability Framework

The SPHN-DCC is mandated to promote the FAIRification of health data and, in this process, the consolidation and implementation of nationwide standards for data semantics and exchange mechanisms to achieve the interoperability goals of the SPHN initiative. In collaboration with its partners, the SPHN-DCC builds a framework based on a strong semantic layer, using controlled vocabulary and international references as well as graph-based representation of the data [2, 3]. The framework aims to add greater value to data and to ensure that information can be interpreted consistently by both machines and humans – across projects, systems, countries, and over time. Within the SPHN Interoperability Framework[11], several tools and services for both researchers (e.g., on the BioMedIT platform) and data-providing institutions have been developed. These will require maintenance and support beyond 2024 in order to sustain the FAIR health research data space established by SPHN. The SPHN-DCC collaborates closely with the relevant Swiss players in the field of health data, e.g., eHealth Suisse, the Federal Statistical Office (FSO), the FOPH, and data-providing and utilizing organizations such as the university hospitals. Various training modules covering topics around FAIR health-related data for research have been developed and are available as on-site courses or online training.

Infrastructure service provisioning for FAIR data, data interoperability, and data quality assurance, including:

– The national Dataset: A semantic definition of specific notions of data, called 'concepts', used for data exchange (including value sets, standards, and (meta)data elements to be provided). New Dataset releases are published on a regular basis, including additional and revised concepts.
– The national Data Schema: A technical and formal specification of the Dataset for the exchange of data in a standard format following the FAIR principles. New Schema releases are published on a regular basis.
– User guide and tools for projects to modify and extend the Data Schema according to their needs, in a compatible and consistent way.
– Terminology Service: The service of translating terminologies and the provisioning of a tool providing compatible, machine-readable versions of national and international vocabularies and classifications for use by data providers and data users (including FAIRification of external terminologies).

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10   www.sphn.ch/training/

11   www.sphn.ch/network/data-coordination-center/the-sphn-semantic-interoperability-framework/

– Training and consultancy on the use of different semantic standards, knowledge representation standards, technologies, and the use of the SPHN-DCC interoperability services.
– Quality control rules and tools: An initial set of quality check rules and statistical queries to validate data, and tools to easily generate quality control rules from any compliant Data Schema, as well as to execute quality checks.
– Consultancy, training and guidelines for data management plans and FAIRification of data.
– SPHN Connector: A tool to generate standardized data in a common format according to the Data Schema from database views or other input formats of data-providing hospitals.

Active collaboration with the following Swiss organizations: unimedsuisse[12]/UH (including clinical SME), eHealth Suisse[13], universities/ETHs, FOPH, FSO[14], Swiss cohorts and registries, Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung (SAKK)[15], Swiss Biobanking Platform (SBP)[16], Swiss Multi-Omics Center (SMOC)[17].

b) Support and coordination of implementing FAIR data locally

Data standardization efforts: The SPHN-DCC supports the Clinical Data Warehouse (CDW) teams and the UH divisions when it comes to a harmonized implementation of health data standards (at CDW and source level). In addition, it provides training on the different data standards, classifications and ontologies (e.g., LOINC, SNOMED CT, ATC) to promote their correct use and implementation throughout the country.

Active collaboration with the following Swiss organizations: unimedsuisse/UH, Medical Laboratories of Switzerland (FAMH)[18], eHealth Suisse, SAKK, Oncosuisse[19], SBP, SMOC, standardization organizations.

Scaling the availability of interoperable health data from various origins throughout the country: The SPHN-DCC supports and consults non-university hospitals in their aim of becoming real-world data providers for multi-site research projects. In the realm of the SPHN Cohort and Registry Task Force and the SPHN SACR Driver Project, the SPHN-DCC supports cohort studies and registries with regards to data interoperability and exchange in accordance with the SPHN Interoperability Framework.

Active collaboration with the following Swiss organizations: unimedsuisse/UH, universities, cantonal and specialized hospitals, SAKK, Oncosuisse, Swiss cohorts and registries, unisanté[20], Swiss Tropical and Public Health Institute (SwissTPH)[21], FOPH, FSO, etc.

Support of data management aspects and data repository services: The SPHN-DCC provides such services for (routine) clinical, and multimodal data (in close collaboration with the UH CDW/Data Lake teams), as well as for established datasets for reuse (e.g., from completed SPHN-funded projects). Provisioning (either directly or through BioMedIT) of data management tools (e.g., Open-Bis[22], labKey[23], slims[24], GraphDB[25], Renku[26]), coordination of the establishment of data and dataset repositories and catalogues (e.g., local EGA, FAIR data endpoints).

Active collaboration with the following Swiss organizations: unimedsuisse/UH, SIB, Swiss Data Science Center (SDSC)[27], BioMedIT node organizations (Unibas, UNIL, ETHZ), Health2030 Genome Center[28].

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12   www.unimedsuisse.ch/de
13   www.e-health-suisse.ch/en/home.html
14   www.bfs.admin.ch/bfs/en/home.html
15   www.sakk.ch/en
16   www.swissbiobanking.ch
17   smoc.ethz.ch
18   www.famh.ch
19   www.prevention.ch/organisation/oncosuisse
20   www.unisante.ch/fr
21   www.swisstph.ch/en/
22   www.openbis.ch
23   www.labkey.com
24   www.agilent.com/en/product/software-informatics/lab-workflow-management-software/slims
25   www.ontotext.com/products/graphdb/
26   www.renkulab.io
27   www.datascience.ch
28   www.health2030.ch

c) Central infrastructure components

In addition to the infrastructure components related to the SPHN Interoperability Framework, the SPHN-DCC has the mandate to develop, implement, and manage further central infrastructure components of SPHN, mostly related to the discoverability of data, in collaboration with the UH and BioMedIT. These infrastructure components include, among others:

– The SPHN Federated Query System (FQS)[29], allowing feasibility queries across the five university hospitals (CHUV, HUG, Insel Group, USB, and USZ). This system enables researchers to assess whether and where patients or patient data potentially suitable for a specific research question exist and to verify the feasibility of their project by running simple queries against a subset of clinical data of all five university hospitals. Since the end of 2022, the FQS has been open to researchers from the universities and university hospitals Basel, Bern, Geneva, Lausanne, and Zurich, and the ETHZ and EPFL, with a planned expansion to all Swiss higher education institutions. The FQS currently contains over 140 Mio data elements from more than 0.5 Mio patients, who agreed to the further use of their data for research purposes by signing a general consent. The SPHN-DCC is responsible for the coordination of regular data loads adding new UH data to the system, the expansion of the system with new variables, identity and access management, the determination of the data specifications to ensure compliance with the FQS data model and interoperability between the data coming from different UH, as well as for the hosting and maintenance of the central query instance.
– The Swiss Personalized Health Network Cohort Consortium[30] of the Maelstrom Catalog, enabling Swiss cohort studies to integrate their metadata in an internationally renowned catalog, in order to allow discoverability and the further use of these cost-intensive data collections. Metadata of 12 Swiss population-based and disease-specific cohorts has been integrated into Maelstrom. At the end of 2022, full study descriptions were searchable covering >120'000 annotated variables of over 80'000 study participants. While the SPHN-DCC is responsible for the coordination with the cohorts and the collaboration with the Maelstrom Research workforce, there are no maintenance duties for this catalog on the SPHN-DCC side.

– Federated confidential data exploration and analysis (pilot phase): The SPHN-DCC is running pilot projects for federated data exploration and analysis. The SPHN-DCC manages the pilot projects and supports the UH and data providers with the implementation.

Active collaboration with the following organizations/companies: unimedsuisse/UH, universities/ETHs, Swiss cohorts, Tune Insight[31], Clinerion[32], Maelstrom.

– Metadata catalog(s) and FAIR national repositories: While the SPHN FQS provides researchers feasibility testing on a high level (since only core data variables are searchable), a yet-to-be-developed catalog system shall provide researchers with an overview of which data and datasets are available within SPHN for research purposes and reuse. In this regard, a local repository for secure archiving and sharing of all types of potentially identifiable genetic and phenotypic data resulting from biomedical research projects (in alignment with the European Genome-Phenome Archive, EGA) is planned to be established.
– In the realm of the recently initiated Swiss Federated Genomics Network (SFGN), in collaboration with the ETH PHRT Swiss multi-omics center (SMOC) and with Swiss cohort studies and registries, the SPHN-DCC will act as the national coordination and management platform for the activities around the SFGN. As a central hub for coordination and interoperability, a single point of contact for coordinating data access and linking genomic data with biospecimens and with other data types generated for the same individual, planned responsibilities of the SPHN-DCC include:
  · Governance of a 'Genomic data atlas' (a catalog of unique identifiers and metadata for digitized biological samples) and processing requests for data access, either by centralized data access control provided through the associated Data Access Committee (DAC) for genomic data stored at the central data repository, or relaying requests to the respective data controller for genomic data stored by the various spokes.
  · Connection with stakeholders outside of the SFGN (e.g., SBP, ELIXIR[33], 1+MG[34]) and coordination of data linking between different types (e.g., clinical, other omics, imaging).

29 www.sphn.ch/training/sphn-federated-query-system/
30 www.maelstrom-research.org/network/sphn-cc
31 www.tuneinsight.com
32 www.clinerion.com
33 www.elixir-europe.org
34 www.b1mg-project.eu

· Definition of data and technical standards to facilitate interoperability at national scale and seamless plug-in mechanisms to international federated data spaces for genomic research and medicine.

Active collaboration with: PHRT, Health2030 Genome Center, unimedsuisse/UH, universities/ETHs, the BioMedIT network partners (ETHZ, Unibas, UNIL), SWITCH[35].

d) BioMedIT network

Given the sensitive nature of health-related information, research using patient data calls for high levels of security and data protection in Information and Communication Technology (ICT) infrastructures, processes, and expertise, in order to fulfill stringent legal, regulatory, and ethical requirements. The key challenge here is to provide researchers with an integrated solution. The SPHN-DCC, together with university partners, has established the BioMedIT network[36], a national platform for research with sensitive data [4]. The BioMedIT network and its tools and services cover the entire project lifecycle, from standardized, end-to-end encrypted data transfer (e.g., from Swiss data-providing institutions) to a secure and shielded project space on a BioMedIT node, where (high-performance) computing services for data analyses are offered, and which researchers can access via cloud technology. Access to the data and all central services of the SPHN-DCC can be reached securely via the BioMedIT portal. While BioMedIT relies on three main local nodes (at ETHZ, Unibas, and UNIL/SIB), the SPHN-DCC is responsible for a variety of BioMedIT central services and tools, the service management, and the overall coordination of the network. At the end of 2022, 28 data providers had established secure data transfer connections to BioMedIT.

Active collaboration with the following Swiss organizations: SIB, unimedsuisse/UH, universities/ETHs, the BioMedIT network partners (ETHZ, Unibas, UNIL), SWITCH.

e) ELSI support

In support of the Ethical, Legal and Societal implication (ELSI) efforts for the initiative, the SPHN-DCC fosters a harmonized data governance strategy and a consistent legal and regulatory framework throughout the network. In collaboration with the SIB legal department, the SPHN-DCC has developed a set of legal templates for multi-site collaborative projects[37], covering consortial aspects and conditions for transfer and use of sensitive health data. The SPHN-DCC supports researchers with regard to contractual and other ELSI questions and needs, and develops guidelines to support data providers (e.g., on the topic of de-identification of data[38]) as well as researchers (e.g., by providing a support document for writing a Data Management Plan). In close collaboration with the ELSI Advisory Group of SPHN, which creates the overarching guidelines for SPHN, various training modules on "Responsible Use of Health-Related Data for Research" are currently being created.

– Development of streamlined solutions and instruments for compliance with ethical and legal requirements for data sharing (in multi-site, collaborative projects) and re-use of existing datasets according to data governance regulations of health-data-providing institutions; special focus on information security and technical, organizational and administrative measures to protect privacy (legal agreements, policies, guidelines, trainings).
– Establishment of an overarching contractual framework for real-world, health data sharing in Switzerland, including the support of transparent and efficient processes.
– Hands-on support of researchers via the ethical/legal SPHN-DCC helpdesk on how to access already existing data or share datasets.
– Provision of training for researchers, legal services, and governance boards of data providers, and infrastructure providers on the points listed above.

Active collaboration with: unimedsuisse/UH, SBP, SAKK, Oncosuisse, swissethics, unitectra[39], universities/ETHs, Data Protection Offices.

35   www.switch.ch

36   www.biomedit.ch

37   www.sphn.ch/services/dtua/

38   www.sphn.ch/network/data-coordination-center/de-identification/

39   www.unitectra.ch/de

f) Cross-institutional collaboration

The SPHN-DCC is the coordination and contact point for all SPHN-funded projects and infrastructures. It promotes and supports cross-institutional collaborations throughout the country, including interfaces with the ETH-Domain programs PHRT and SDSC. Additionally, it has the mandate to assess the progress of the SPHN-funded projects with a view to interoperability and data security. The SPHN-DCC interfaces between all SPHN stakeholders (including, but not limited to, data providers, data producers, and researchers) with regard to technical, interoperability, and health data governance issues. It further coordinates the work of SPHN and BioMedIT expert working groups and task forces, bringing together subject specialists from the various stakeholder and partner institutions across Switzerland. In collaboration with the SPHN Management Office and these specialist groups, the SPHN-DCC produces blueprints, guidelines, policies, and training in the fields of real-world data, FAIR research data, data security, and other related areas.

The SPHN-DCC plays a central coordination and support role for the SPHN/PHRT National Data Streams (NDS) with regards to data interoperability, adherence of the NDS to the FAIR principles, usage of the BioMedIT network services, and legal, ethical, and contractual questions and issues of NDS and their partnering institutions. The SPHN-DCC acts as the central point of contact for data (including concept drafting and definition), data standards, data specifications, and data-quality-related issues, and supports the institutions providing data to the NDS with regards to streamlining efforts, harmonization attempts, and efficient coordination, so that duplicated efforts and inefficiencies can be avoided. Furthermore, the SPHN-DCC works closely together with the NDS project managers and data managers to support the NDS in their daily challenges in dealing with health data from various different sources, to ensure knowledge transfer between the four NDS, and to further promote the development of a Swiss community with regard to health-data-driven medicine and Personalized Health research. Moreover, the SPHN-DCC undertakes coordination and communication tasks common to all NDS, such as alignment and exchange with international initiatives and organizations, exchange with national entities in the health data space, and representation of NDS' interests with federal offices and other stakeholders in the field.

Active collaboration with: NDS-involved institutions, PHRT, SMOC, unimedsuisse/UH, the BioMedIT network partners (ETHZ, Unibas, UNIL).

g) National and international contact point

The SPHN-DCC acts as a contact point for all activities mentioned above for national stakeholders (academic institutions, private organizations, pharma industry, etc.) and federal and cantonal authorities and offices.

SPHN is a member of the International Consortium for Personalized Medicine (ICPerMed)[40] and thus interoperability with international research consortia is supported by the alignment with European standards, data protection policies, and interoperability frameworks.

In this context, when requested, the SPHN-DCC may help to facilitate international and industry networks, providing that the project-related regulatory aspects are ensured.

Active collaboration with the following Swiss organizations: unimedsuisse/UH, universities/ETHs, the BioMedIT network partners (ETHZ, Unibas, UNIL), SIB, SWITCH; and with the following international organizations: ICPerMed, GA4GH[41], ELIXIR, and various Personalized Health and Medical Informatics Initiatives of other countries.

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40   www.icpermed.eu
41   www.ga4gh.org

2   National and international health and research data strategies, influencing factors and requirements

2.1   International examples

Outside Switzerland, many national and international initiatives are underway to build sector-specific data spaces (like in the European Union) and national data infrastructures for future economic development in the healthcare and biomedical research areas. In the context of the elaboration of this report, an external mandate was issued to review approaches and institutions operating in the field of health-related data in Finland, the UK, Denmark, Germany, the Netherlands, and Australia, summarized below[42].

When it comes to the secondary use of health and health-related data for research, the range of different data types, data sources, and associated data governance models is wide. International equivalents to a "Data Coordination Center" are therefore also "equipped" differently, depending on the data that is made available for reuse. In countries where a variety of national (clinical) registry data are made available through a single coordinating and steering unit (as is the case in Denmark), an explicit political mandate and a respective legal basis are necessary. When it comes to direct reuse of routine clinical data from healthcare for research, noncentral approaches are normally chosen and governance aspects in particular play an important role, as does consent management. Regarding the reuse of research datasets (like in Health Data Research UK)[43], the ideological and financial support of a network of (research) organizations and the motivation or appropriate incentives for researchers to share their datasets with third party researchers can be sufficient.

As expected, there is no single operational or organizational model for supporting the secondary use of health data, because individual institutions take into account the specific, local context. Nevertheless, some key requirements or features can be identified:

Table 1: Key requirements/features for the SPHN-DCC, based on international examples

Identified key requirements/features	Corresponding components/aspects in SPHN
Some European countries, such as Finland, have changed the legislation that active patient consent is not required for the further use of health data for research. This regulatory framework facilitates data accessibility and greatly enables the development of health data spaces and personalized healthcare.	In Switzerland, the values of data protection and individual consent are culturally important. Therefore, the SPHN initiative has based its efforts so far on the principle of consented data. However, it should be discussed at a political level whether the Finnish legal framework could be an option for Switzerland in the future. This would require a nationally harmonized data governance strategy and a consensus on when and why the general and public interest outweighs the individual interest, together with the gained benefit.
Existence of a sophisticated IT infrastructure in which data are collected as standardized as possible, available for reuse.	The BioMedIT network offers cutting-edge technology. Its federated structure with centralized services and tools already serves as an example to other countries.
More recent approaches seem to favor decentralized data management with a unified data analysis process: Data are gathered on request from decentralized sources and provided to the client in a protected IT environment for analysis.	SPHN follows such a decentralized approach, with data remaining with data-provider institutions, being only compiled from the various sources within the framework of specific and approved research projects. Also query and analysis systems are set up in a distributed fashion in SPHN.

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42   A detailed outline regarding the researched international institutions and approaches was commissioned by SPHN to advocacy AG and is available at the SPHN Management Office (info@sphn.ch) on request.

43   www.hdruk.ac.uk

Identified key requirements/features	Corresponding components/aspects in SPHN
Access to the data for reuse is under the stewardship of a specific organization. Permission for data reuse is in general granted by a central Data Access Committee (DAC) on request. E.g., Findata[44] or Digital NHS[45] grant access only to clients which are legitimized and whose purpose for the data use is in the scope of the organization.	In Switzerland, the data governance is with the data-providing institutions (e.g., hospitals) or the consortia responsible for a data collection (e.g., cohort study or registry), and the criteria for access and use are very diverse. The regulation of the reuse of datasets (derived from completed research projects) is at present under discussion in SPHN, aiming at providing national harmonized standards/guidelines, to be deployed by providers (i.e., UH) when implementing data governance strategy locally at each institution.
All of the examined institutions operate on a legal basis for data reuse or have an external oversight body. As an example: The mandate and the governance of Findata are defined in the Finnish Act on the Secondary Use of Social and Health Data which entered into force in May 2019.	The HRA[46] provides the basis for the further use of biological material and health-related personal data for research. Special laws, such as the Cancer Registry Act, allow the reuse of registry data for research purposes. However, there is currently no political mandate, assigned responsibility, or legal basis for an operative coordination unit managing data from different sources and data access.

While international examples give inspiration for SPHN and the further development of the SPHN-DCC, other countries' initiatives also sought advice from the SPHN-DCC for their programs, including:

– European Health Data Space[47]
– German Medical Informatics Initiative[48]
– Dutch Health RI[49]
– EU Healthy Cloud Project[50]

2.2   National developments

As in many other countries, the legal and political environment for health data reuse is evolving in Switzerland. Some recent examples:

– The Human Research Act ordinances are under revision and will probably enable e-ID and electronic signatures for e-consent in the future.
– The federal administration is revising and structuring its data management (NaDB)[51], which includes correcting inconsistency in the data flows of hospital medical statistics.
– The FOPH proposes improvements to the data management in the health system (Federal Council's report, 12.01.2022)[52].
– The FOPH and the FSO have a mandate to specify how the reuse and linkage of data for health-related research in the health data space should be enabled in the future, whereby a national data coordination office could act as a trust center (Federal Council's report, 04.05.2022)[53].
– The introduction of the electronic patient record (EPR)[54] has been facing many challenges. However, the Federal Council is determined to promote the dissemination and use of the EPR and has therefore decided to subject the Federal Act on the EPR (EPRA)[55] to a fundamental review. One measure already taken concerns the integration of the primary systems with the EPR (ultimately relevant to research due to processes of convergence of care and research). The use of structured data instead of documents will follow. The extent to which the EPR can help to improve the structured digitization of health data in general, and how reuse on the initiative of the EPR data owners can be enabled (e.g., by interfacing with a platform like MIDATA[56]) will be the subject of further discussions. The

44   www.findata.fi/en/about-findata/

45   www.digital.nhs.uk

46   www.bag.admin.ch/bag/en/home/gesetze-und-bewilligungen/gesetzgebung/gesetzgebung-mensch-gesundheit/gesetzgebung-forschung-am-menschen.html

47   www.health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

48   www.medizininformatik-initiative.de/en/start

49   www.health-ri.nl

50   www.healthycloud.eu

51   www.bfs.admin.ch/bfs/en/home/nadb/nadb.html

52   www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-86762.html and report to improve the data management in the health system (12.01.2022)

53   Report of the Federal Council in fulfilling the postulate 15.4225 Humbel (Improved use of health data for high-quality and efficient health care, in German): www.parlament.ch/centers/eparl/curia/2015/20154225/Bericht%20BR%20D.pdf

54   www.patientrecord.ch

55   www.efk.admin.ch/en/publications/training-and-social-affairs/health/introduction-of-the-electronic-patient-record-federal-office-of-public-health.html

56   www.midata.coop/en/home/

Federal Council further announced that EPR data shall be accessible for research if patients consent[57].

– On the political level, the question is posed how health data from various sources may be reused and linked for research purposes via a unique digital patient identifier[58].

– The cantons of Basel-Stadt and Basel-Landschaft have asked the federal government to accelerate the efforts towards the digital transformation of the healthcare system, to enable such an ecosystem[59].

It has become generally accepted that some major requirements need to be in place in order to position Switzerland on the starting block for health data reuse:

– The identification/identity mapping problem needs to be solved, e.g., with the use of a unique identifier that can be applied to link data that is also allowed for research purposes.

– Smart technical solutions are needed that are compliant with data protection regulations and also solve the complex challenge of consent management in a trustworthy and feasible manner.

– Data should be captured in a structured and standardized manner at or close to the point of care and described with sufficient metadata. Data standards must not differ between healthcare and research.

The above-mentioned initiatives to meet these requirements are under way but may take years to complete.

Swiss National Strategy for Open Research Data (ORD)

Based on a mandate from SERI[60], swissuniversities[61] elaborated (in collaboration with the ETH-Domain, Swiss National Science Foundation (SNSF)[62], and the Swiss Academies of Arts and Sciences[63]) a Swiss National Strategy for ORD[64] and action plan[65] for its implementation 2022–2028.

– FAIR principles are to be applied to publicly financed research data, and the ORD Strategy formulates principles specifying that research data should be as open as possible, respecting disciplinary diversity, interoperable, internationally networked, and enabled to be sustainably financed.

– Health data have special characteristics in terms of data security, access rules, and governance structures and ethics. In the SPHN framework, these complex characteristics have now been established and harmonized between Swiss stakeholders. It is important that this SPHN framework is taken into account also in the ORD context.

– Access to research data is handled in a variety of ways in different disciplines and institutions. ORD solutions shall be development- and support-based on ORD practices from the respective research communities.

– Additional objectives of the ORD Strategy include: consolidation and strategic development of infrastructures and services, on the basis of a coordinated governance while safeguarding the autonomy of institutions; skill development and the sharing of best practices between researchers; and the development of systemic, supportive framework conditions for institutions and research communities.

– Based on the objectives set forth in the ORD Strategy, four action areas are defined in the ORD Action Plan:

1. The promotion of ORD practices by researchers
2. The consolidation of financially sustainable infrastructures and services
3. Raising awareness of FAIR principles and ORD best practices
4. Implementing and enforcing (international) standards and legal and ethical aspects surrounding ORD practices

57   www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-88245.html

58   www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20214373

59   Standesinitiative 22.313, Standesinitiative 22.318

60   www.sbfi.admin.ch/dam/sbfi/de/dokumente/2020/04/open-research-data.pdf.download.pdf/vereinbarung-open-research-data-sign_d.pdf

61   www.swissuniversities.ch/en/

62   www.snf.ch/en

63   www.akademien-schweiz.ch/en

64   www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/Swiss_National_ORD_Strategy_en.pdf

65   www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/ActionPlanV1.0_December_2021_def.pdf

- The ORD Action Plan, supervised by a broad-based ORD Strategy Council, is funded over two ERI periods. The latest version of the Action Plan contains the planned federal funding for implementing those measures scheduled from 2022–2024. The partner institutions use funds they have already budgeted for ORD, of which some are federal project contributions from the Open Science I program. The Action Plan will be updated for the 2025–2028 period, based on the partner organizations' multi-year plans. A mapping of existing ORD infrastructures and services in the area of health and life sciences is ongoing and shall be completed in 2023.

It is critical that the established SPHN-DCC and the SPHN regulatory, infrastructural and procedural framework is embedded in the now newly developing national ORD and health data strategies, allowing seamless interfaces between the respective infrastructure and governance components and avoiding any duplication of efforts.

Two strategic focus areas of the ETH-Domain

The ETH Council defined and supported two strategic focus areas for 2017–2024 with relevance for biomedical research: Personalized Health and Related Technologies (PHRT) and the Swiss Data Science Center (SDSC).

PHRT
- The ETH-Domain funded PHRT as the complementary program to SPHN. PHRT and SPHN have been collaborating regularly and in various forms during both finance periods. ETHZ and EPFL are represented in the NSB and the chairperson of the PHRT Executive Committee participated in all strategy meetings.
- The key joint legacy of SPHN and PHRT are the National Data Streams (NDS) and related PHRT Swiss Multi-Omics Center (SMOC)[66] and hubs. The genomic arm of the SMOC, established at the Health 2030 Genome Center, operates as the expert genomics hub for the planned SPHN-PHRT Swiss Federated Genomics Network.
- The first four NDS projects were jointly approved by SPHN and PHRT in May 2022. These interdisciplinary and inter-institutional platforms generate specific interoperable health data in a structured manner for NDS-embedded research projects, feedback loops to clinic (e.g., molecular tumor boards) and re-use in future research.

- The SPHN-DCC coordinates the infrastructure and services for the NDS health data according to the FAIR principles.
- A first multi-omic dataset was generated by SMOC within a PHRT-initiated pioneer project with the University Children's Hospital Zurich [5]. These data are interoperable and demonstrate a generic applicability amongst the community. Moreover, this successful project demonstrated that, by combining the information obtained from different -omic technologies, it was possible to understand much better the pathogeny of disorders, and in this specific case, of an inherited metabolic disorder.

SDSC(+)
- Under SDSC+, SDSC will be expanded and opened to all actors in the RI landscape. This national platform for artificial intelligence, machine learning and data sciences will strengthen the high level of competence in a competitive and fast-moving sector.
- The goal of SDSC+ is to provide state-of-the-art full data-life-cycle capabilities to make a real change in science.
- On top of the core services, four verticals are envisaged, including one for biomedical data science. Each vertical has its community steering committee and has a representative in the SDSC+ steering committee. SDSC+ offers orchestration of existing services (not institutional integration).
- The SPHN-PHRT NDS project LUCID[67] uses SDSC services; the subject of this project is the improvement of quality of hospital healthcare.
- The ETH Board plans to build SDSC+ as a permanent ETH-Domain infrastructure that will provide services for universities, university hospitals, public institutions, industry, and civil society, i.e., the whole of Switzerland. The proposal is aligned with SERI and the National ORD Strategy.
- From an SPHN perspective, there is a need to develop technical solutions which allow optimal use of AI and machine learning tools at the interface between SDSC+ and SPHN-DCC, ensuring strict adherence to SPHN-related regulatory, data protection, and interoperability standards (see Table 2).

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66   smoc.ethz.ch
67   LUCID, Low Value of Care in Hospitalized Patients, www.sphn.ch/network/projects/project-page_nds_lucid/

Main Funder (Swiss National Science Foundation)

SNSF's main focus is the active contribution to the development of best practice in research funding and evaluation in collaboration with international partners (e.g., Science Europe) and the relevant communities (e.g., Research on Research Institute). As highlighted by the Swiss Science Council, SNSF's evaluation processes contribute to the adaption of Swiss quality standards and research culture to international norms. SNSF has an extensive, worldwide network of reviewers and state-of-the art tools to support the evaluation processes.

Through project funding, the SNSF funds phase I and phase IIa clinical trials. In addition, it funds (with its specific program: IICT) randomized phase IIb and phase III trials. The IICT program is targeted at researchers who wish to conduct an investigator-initiated clinical trial. Support will be given to trials that are of value to patients and address important unmet medical and societal needs but are not of industry focus. The SNSF was one of the first who introduced the public and patient perspective in the evaluation of clinical trials. Moreover, with National Research Programs (NRP) the SNSF has a major impact on certain topics and can push the use of certain data infrastructures and services that have a recognized standard. With these different instruments the SNSF also plays a key role in promoting the National ORD Strategy in the short-, mid- and long-term.

The SNSF has been active in the financing of data Infrastructure and Services (DIS) for a long time in the different domains and, specifically to the health/life sciences, in the Swiss HIV Cohort Studies (SHCS) and the Swiss transplant Cohort Studies (STCS). In 2017 the SNSF introduced the Data Management Plan (DMP) with data sharing for all researchers as a part of international best practice in evaluation. In order to implement the ORD policy, the SNSF introduced the DMP in most of its funding schemes. The aim of the DMP is to encourage researchers to reflect on research data management and data sharing from the start of their project. Furthermore, the Scientific Exchanges funding scheme supports the events that focus on Open Research Data, where research communities can discuss and define best practices for their disciplines.

SNSF directly finances the SBP (responsible for setting national standards in the field of sample collection and storage) and the Swiss Clinical Trial Organisation (SCTO)[68] and the seven Clinical Trial Units (CTUs) of the different Swiss hospital indirectly through the financing of projects (request of support from the CTUs for IICT submitted to the SNSF is highly recommended). SNSF made several efforts in trying to consolidate the fragmented landscape in the life science domain. Both SBP and SCTO are and were not only financed by the SNSF, but the SNSF was one of the initiators of these initiatives, having in this case a pioneering role.

Public health

Public health institutions conduct research with a strong focus on maintaining the wellbeing and health of the whole Swiss population, and with emphasis on evaluating access, quality, and efficiency of the healthcare system. In order to ensure interoperability of information from cohorts/healthy citizen data and biobanks with other clinical and clinical research data, it is critical that the same data standards, classifications and ontologies are applied also to public health data. That way, the potential of data can be leveraged not only for pathogenesis, but also for better care, prevention, and early detection of diseases (salutogenesis), and, ideally, public health decision making.

Towards a national health data strategy

It is becoming increasingly recognized that the learnings and groundwork concepts and frameworks of SPHN and the networking efforts, infrastructures, and services of the SPHN-DCC can make a valuable contribution to the establishment of a coherent health data strategy in Switzerland. The SPHN-DCC actively collaborates with numerous partners in health research, to build a common understanding of the requirements and to coordinate and align on strategies and processes with the goal to build seamless interfaces between the different infrastructure components and services (see below). It is of utmost importance that research and healthcare go "hand in hand" – the SPHN-DCC has become a frequent advisor to federal and cantonal authorities and programs for health research data management and interoperability.

3   Stakeholder expectations and ideas regarding the SPHN-DCC

Key stakeholders[69], including representatives of FOPH, eHealth Suisse, FSO, GDK-CDS, SAKK, SCTO, SBP, SNSF, Swiss Science Council (SSC), swissuniversities and Swiss higher education institutions, unimedsuisse, Health2030, and The LOOP Zurich, were interviewed in summer 2021 with regard to their expectations for the future purpose, tasks, clients, organization, and governance of the SPHN-DCC. Most of the involved persons shared the vision that – in the long run – a "National Center for Health and Research" (see chapter 8) should be established in order to bundle up existing institutions and foster data-based health research and secondary health data use in general, to promote personalized medicine and health in Switzerland. It is obvious, however, that the establishment of such a national institution cannot be carried out within the framework of one four-year financing period. Therefore, a two-step approach was proposed: in the coming financing period, 2025 – 2028: the SPHN-DCC organization should be further developed beyond its current mandate to expand the existing services on a national level to researchers and data providers beyond the current scope of SPHN. In this aspect, it would resemble other national research organizations such as SCTO, SBP, and SAKK. In parallel, convergent efforts must be engaged, aiming at the development of a new and overarching "National Center for Health and Research" in which the SPHN-DCC will be integrated and play a critical role in managing health data from 2029 onward.

Currently, the SPHN-DCC already provides an operational interface between data providers (university and cantonal hospitals, technology platforms) and data users (e.g., researchers, data scientists, digital service providers). It is therefore necessary that the concept of the future is supported both by data providers and data users.

3.1   Proposed tasks and services of the SPHN-DCC

The following SPHN-DCC tasks for the coming years were proposed:

- Be an essential pillar for health data management of academic health research in Switzerland.
- Further develop standardization processes with a view to interoperability (legal, technical, syntactic, semantic), with the involvement of the relevant organizations. Foster/enforce their implementation.
- Provide communication, teaching, and training resources.
- Provide a metadata base which allows data users to locate data assets and a federated query system for feasibility inquiries.
- Provide a safe and secure infrastructure for health data analysis (centralized and/or decentralized).
- Provide a trusted IT infrastructure for health data (e.g., BioMedIT tenants).
- Enable access processes for specific use cases by implementing a defined governance.
- Ensure international interoperability by exchanging information with similar institutions in other countries, by observing international developments and by recommending/implementing international standards.
- Assist in anticipating developments regarding the health data space.
- Make a first contribution towards a "National Center for Health and Research" in Switzerland, specifically addressing the health data aspects.

3.2   Clients of the SPHN-DCC

Major clients who have access to the services of the SPHN-DCC should be researchers who have a relevant research question, irrespective of whether they stem from academic institutions (federal, cantonal, or private) or from industry. In addition, the services should also be provided to clients from public administration, e.g., for questions on healthcare planning or the benefit of new drugs. The role of industry clients is somewhat controversial and needs further discussion. One possibility is that the industry does not act as a member of the main steering board but rather a dedicated subcommittee or working group for public–industry engagement and partnerships. Some stakeholders see the service of the SPHN-DCC beyond 2024 as a "service public" which brings benefit not only to academic research but also to the Swiss economy. Others are more cautious and propose that industry should reciprocate its benefit from using the publicly financed service by making their own data assets accessible through the SPHN-DCC. If such a collaboration with the private sector is retained, a business plan needs to be developed and accompanied with appropriate guidelines.

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69   A list of all interviewed stakeholders and a corresponding list of abbreviations is provided in the Annex (Table 3).

The SPHN-DCC should be instrumental in developing the framework for broad inclusion of data providers (e.g., further hospitals, ambulatory networks, disease-specific registries, biobanks, research laboratories), as a national infrastructure must reach beyond the university hospitals and come close to most data providers. Fundamental to this aim is data interoperability: the SPHN-DCC should enable data providers to reach the interoperability goal and to make their data actively accessible. Since the SPHN-DCC does not act in a vacuum, this will require a national strategy that includes the definition of the standards, legal conditions, and financial incentives (e.g., adherence as a condition for research funding).

3.3   Requirements from the research perspective

Depending on the field of research, research representatives see different priorities regarding future health data provisioning, accessibility, and coordination activities. The following outline from interviews with researchers summarizes the different demands and requirements for data availability and data usage, and indicates the focus areas and activities that should be on the to-do list of the SPHN-DCC from the researchers' perspective:

a) Accessibility of large biomedical datasets

Data and access requirements	Use cases
— Highly curated and annotated, de-identified dataset, data need to be self-explanatory (i.e., lots of metadata provided), machine readable (highly structured, highly standardized, use of controlled vocabulary, FAIR) — National searchable lists (depending on the overall number also metadata repositories/ catalogs) are needed for researchers to find datasets and get sufficient information (to decide if a data request is desired) — Data accessibility should be streamlined: clear and harmonized governance of available data, fast access, provision of templates, etc — Synthetic datasets to protect privacy and confidentiality of authentic data would be a very useful addition, since they do not relate to a real person; these datasets could be made available without tight access restrictions and shared across borders — Broad access possibilities for researchers from academic and private institutions to federated analysis tools containing use-case dependent datasets: inclusion of (structured, standardized, schema-compliant) data into privacy-preserving data exploration tools (share without sharing)	— Data exploration, data mining — Hypothesis generation — Machine learning — Reproducibility — "All eyes on the data" — Benchmarking, international collaborations — Industry use cases

b) Data (and patients) availability within the clinical setting/routine care

Data and access requirements	Use cases
— Availability of as many different clinical data types from routine care as possible (ideally in the CDW) that can be used in combination with molecular data/-omics data — Possibilities for rapid finding of patients and datasets, facilitating cohort building and clinical studies — Focus on outcome data urgently needed (including harmonized clinical outcome measures, patient reported outcomes, etc.) — Focus on structured and standardized data, but unstructured data can also be used (depending on the use case) — For multi-site projects, interoperability is key — For bilateral projects with clinicians that "know" the data, quality aspects and data availability are of greater importance than interoperability aspects — Data accessibility should be streamlined: clear and transparent governance of available data, fast access — De-identification and data transfer services provided by data-providing institutions — Federated analysis of use-case-dependent datasets: inclusion of pre-defined datasets (structured, standardized, schema-compliant) into privacy-preserving data exploration tools (share without sharing) — Precision medicine approaches relying on multi-modal omics/imaging/clinical technologies from ETH/university laboratories have particularly complex requirements	— (Bilateral) collaboration between research physicians and researchers outside the clinical sector (bioinformatics, data scientists, engineers, etc.) — Multi-site collaborative projects in one disease area (equivalent to the SPHN NDS and Driver Projects) — Use-case-dependent exploration of subsets of clinical data

c) Tapping into disparate sources to assemble an individual research dataset

Data and access requirements	Use cases
— Interoperability is key (highly structured, highly standardized, use of controlled vocabulary, FAIR) — Patient linkage must be possible (unique patient/citizenID necessary) — Coding schemas and interoperability services shall be provided — De-identification services required (centrally or, preferentially, distributed at the data sources) — Longitudinal trajectories essential for personalized health research (not only cross-sectional views in UH)	— Cross-disciplinary research projects using clinical data, outcome data, -omics data, imaging data, cohort data, registry data, etc

d) Additional requirements from public health research perspectives

Data and access requirements	Use cases
— Health data exchange should be possible, not only for research purposes, but also for non-regulatory public health surveillance and monitoring as well as health impact assessment — Data types must cover health services research and implementation research fields — Health data exchange solutions should also be implemented within other health institutions, broadly defined (i.e., not only university hospitals) — Health insurance data should be made easily accessible and available for publicly funded research. Lobbying efforts would be welcome to set up a national regulatory framework to improve the FAIRification of health insurance data in Switzerland — Necessity for linking routine healthcare data to out-patient sector and to home-based care data ("spitex", "soins à domicile") in order to be able to follow trajectories for research projects — A nationwide infrastructure should also be made available to answer questions on the entire population, for instance to capture lifestyle exposure data (e.g., diet, smoking, physical activity, profession, socio-economic status, education, environmental exposure) throughout the life course	— Public Health research — Health services research — Prevention — Clinical research — Real-world evidence

3.4   Governance

The opinion was unanimously expressed by the interviewed stakeholders that the SPHN-DCC should operate "independently" in the future when the national initiative has wound down. This "independence" refers less to an organizational affiliation and more to strategic, financial, and operational independence from one specific stakeholder. This is important because the SPHN-DCC must serve a broad community including patients and citizens, and address both the data providers and the data users. Therefore, a close organizational affiliation to (only) one stakeholder was rejected by all interviewees.

Overall governance of the SPHN-DCC and the governance of data access may be regulated at different operational levels and follow subsidiary principles. A few principles have been highlighted as important:

– Overall organizational governance of the SPHN-DCC (steering board) and project-based data access governance (e.g., National Data Streams (NDS)) address different questions and issues. They should thus be organized differently (subsidiarity).
– Overall organizational governance involves patients and all the stakeholders and regulates general principles and policies of data sharing, interoperability standards, etc. Data sharing and access policies should follow the Swiss regulatory framework (data access requires a clear purpose) and involve the network of data providers (data access points).
– Project-based data access governance: NDS-based and project-based data sharing should follow these rules, but practically it should be organized by the research consortia in collaboration with the data access points of the data providers (hospitals, universities). It should be possible that any researcher from the above partner institutions can launch novel projects and data streams using the BioMedIT network.
– Reuse of data should be facilitated and encouraged by the funding agencies. Interactions and collaboration between NDS's and projects on the BioMedIT network should be encouraged and facilitated within the regulatory framework to strengthen the research community.

3.5   Financing and business model

As there is no business case which would allow full cost-covering operations, there needs to be a core financing ("Sockelfinanzierung") for the SPHN-DCC which should be secured in the long run. Most stakeholders agree that the services of the SPHN-DCC should in the future be granted to academic research groups at affordable cost, while industry clients should be charged at market rates. A financing scheme that includes core funding would make the SPHN-DCC more attractive for active use and will strengthen the research community's overall compliance with the regulatory framework, information security measures, and privacy standards. Too-high costs to researchers could lead to circumvention of interoperability or privacy and data security requirements (e.g., by running projects on insecure IT environments), which would work against the long-term goal of a federated repository of interoperable and linkable health data, as well as a responsible use of sensitive research data.

4   Activity portfolio of the SPHN-DCC beyond 2024

4.1   Vision and mission

In the coming years, the SPHN-DCC first and foremost needs to consolidate its role as the national coordination and competence center in Switzerland for FAIR data in the domain of health research, enabling exchange and use of FAIR health research data across the country.

Its mission is to ensure standardized processes focusing on the interoperability of health research data (legal, technical, syntactic, semantic), enabling, monitoring and enforcing their implementation, acting in a proactive dissemination role (e.g., communication, teaching, training), and providing data infrastructures and services facilitating findability, accessibility, and reuse of health data for research and other societally important domains. The SPHN-DCC should not conduct research on its own and will not be a regulatory body, but act in an infrastructure/service-providing, coordinating, and enabling role for researchers and institutions (between the data suppliers as providers, the researchers as recipients, the consortium of data controllers, and the BioMedIT network as processor). Under the leadership of the SPHN-DCC, the BioMedIT network will continue to expand its services, offering researchers in Switzerland a flexible and secure platform for research with sensitive data. The SPHN-DCC furthermore will foster interoperability and alignment with similar international institutions in other countries and offer support for anticipating developments in the health data space. The SPHN-DCC essentially enables ORD for sensitive biomedical data, based on the FAIR principles through the following infrastructures and services:

Infrastructures
– Federated Query System for feasibility assessments and national health research (meta-)data catalogs
– Data exploration system or service
– Central infrastructure components for interoperable data provisioning (interoperability framework, terminology service)
– Secure delivery infrastructure for interoperable data from Swiss (university) hospitals to BioMedIT
– Data quality assurance tools for data providers and researchers
– FAIR data repositories (including planned Swiss federated EGA node for human genomic data)
– BioMedIT network for secure collaborative analysis of sensitive (health) research data
– Core infrastructure support for the four National Data Streams (NDS)

Services
– Generally, responsibility for and control over datasets remains with data providers and researchers/consortia (see below). However, services supporting subsidiary central governance structures (including coordination of a national Data Access Committee (DAC)) can be provided on request for the reuse of existing health research datasets if they are given into the responsibility of the SPHN-DCC through a legal basis with the data controllers and data providers.
– Coordination of efficient contractual frameworks (templates, framework agreement) and provision of support services (central ELSI helpdesk) in coordination with decentralized support structures, e.g., CTUs.
– Definition of nationwide standards for data semantics and exchange mechanisms for health research data in Switzerland, harmonized with other health domains (EPR, registries, etc.).
– Management and further development of national FAIR data repositories.
– Central service provisioning for the use of the BioMedIT trusted research environment.
– Promotion, support, and coordination (point of contact) of cross-institutional collaborations, international collaborations, and collaborations with the industry.
– Education and training in all fields relevant for health-data-driven research and real-world health data aspects (security, FAIR, ELSI, etc.).

It is assumed that, in the scope of the developing health data and research landscape, the services requested from the SPHN-DCC will expand significantly over time (see Annex Table 4 for a detailed description and prioritization of the SPHN-DCC activity portfolio after 2024). The portfolio and the organizational and financial setup of the SPHN-DCC therefore need to be scalable with a high degree of flexibility to accommodate additional data providers, data users and services, as needed. Scaling needs to carefully balance subsidiary principles with economy of scale, i.e., which components, processes and data are better organized on a local level and which components, processes, and data can be more efficiently organized on a national level. Close and synergistic collaboration with the national organizations in the field of human and biomedical research is consistently implemented so that existing redundancies are eliminated and unused potential synergies are efficiently exploited. Embedding the national data strategies and interfaces with other partners in the health research ecosystem is a mandatory prerequisite for the success of the SPHN-DCC.

4.2   Interfaces of the SPHN-DCC in the context of the Swiss research infrastructure landscape and health data space

Several research and funding organizations besides SPHN are currently actively shaping the evolving research landscape in Switzerland towards ORD. Beyond research, the FOPH, cantons, and the health industry are preparing to accelerate the digital transformation in the healthcare system and to build an integrated health data space. In addition, the Federal Council has entrusted the FSO with various tasks that aim in the same direction. In respect of the changing landscape, the SPHN-DCC has been closely aligning itself with the partners[70] and initiatives relevant for health research. The clarification of roles and responsibilities and the definition of interfaces is an ongoing process. Table 2 summarizes a selection of interfaces that will be particularly relevant for the coming years:

Table 2: Partners of the SPHN-DCC and mutual interfaces (selection). The role of the SPHN-DCC toward its partners is described in Annex Table 4

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
Healthcare providers, starting with university hospitals	— Part of the governing bodies of SPHN-DCC, participation in working groups developing the SPHN/DCC-framework and its implementation — Data providers as well as data users for clinical research and implementation — Each institution is responsible for the establishment of a unit for research data services operating a respective data warehouse or data lake (by now all UH have established such units) — In accordance with the SPHN initiative, the management of health research data by the participating data providers follows a clear strategy and is coordinated with defined processes and points-of-contact. The implementation of the SPHN-framework is supported by SPHN-DCC	Further development of UH infrastructures and services and scaling to other hospitals, ambulatory care and other healthcare providers with regard to: — Common ethical-legal standards and processes for data sharing and data governance — Interoperability framework — Efficient data provisioning — Deployment and maintenance of noncentral infrastructures	— Building and maintaining public trust in Swiss medical research data infrastructures — Cooperation with registries and cohorts, the Electronic Patient Record as well as federal and cantonal statistics and administrative data — Development of sustainable financing models for generating and storing data within the healthcare providers and the financial contributions of data users to the costs of data management — Inclusion of a wider range of healthcare providers
Higher Education Institutions	— Main users of the SPHN-DCC for research — Providers of research data — Partners in creating optimal conditions for data-driven and personalized health research in Switzerland	— Research services and infrastructures — Operation of BioMedIT nodes, currently at the high-performance computation (HPC) facilities of the University of Basel, ETH Zurich, and University of Lausanne (in cooperation with SIB) — Federated support structures (e.g., CTUs, core facilities)	— Implementation of ORD best practices and infrastructures for sensitive health data — Use of technologies from ETH-Domain institutions, universities and universities of applied sciences — Establishment of a network of analytical platforms

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70   More details about the mandates and roles of many of the SPHN partners described in Table 2, can be found in the White Paper: Clinical Research issued by SAMS [6].

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
ORD Strategy Council	— Establishes a common, strategy-level vision for the ORD landscape in Switzerland (i.e., ORD Blueprint), collectively supported by the Council's partners (Swiss HEIs/swissuniversities, ETH-Domain, SNSF, A+) — Within this landscape, supports the consolidation of initiatives, coordination of governance, and coordinated development of ORD infrastructure and services — Supports the interoperability of research data infrastructures and services while also underpinning the interfaces with other research areas	— Policy interface: blueprint of the ORD Strategy Council, in order to position the SPHN-DCC within the structure of the ORD landscape — SPHN-DCC engages with future coordination initiatives created by the Strategy Council	— Align the SPHN-DCC with the broader strategic framework of the Swiss ORD landscape, particularly within the cluster health/life sciences — Develop mutual interoperability of infrastructures, services, and governance in ORD landscape, e.g., for linking health data with other data and services — Define and implement common ORD best practices for: 1. Sensitive health data 2. Interoperability framework for research data
ETH-Domain	**PHRT** — Partnering with SPHN since 2017, complementing the clinical-medical expertise from universities and hospitals. Several joint project types have been implemented — Supporting state-of-the-art molecular analysis (multi-omics) and imaging platforms and other innovative biomedical technologies with respective support services for data integration and analysis — Providing expertise in data engineering, data integration, and data analysis	**PHRT** — The Swiss Multi-Omics Center (SMOC) offers a multitude of molecular profiling services, including clinical-grade sequencing with capacity for high-throughput analyses (SMOC-genomic), proteotyping analysis (SMOC-proteomic), and lipidomics/metabolomics analysis (SMOC-metabolomic) and integrating this different -omics information — SMOC is interoperable with the BioMedIT network and has established data transfer processes — Joint SPHN-PHRT National Data Streams (NDS) are large-scale, multicentric, and interdisciplinary research platforms serving as models and crystallization points for future research programs and clinical applications of personalized health — The SMOC genomic center will serve as the analytical hub of the joint SPHN-PHRT Swiss Federated Genomics Network (SFGN) for routinely sharing and reusing large-scale genomics data and launching a Swiss reference genomic database	

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
ETH-Domain	**SDSC(+)** — Providing state-of-the-art, full data life cycle capabilities in data management and data science and machine learning methodologies for select scientific disciplines, including biomedical/health — SDSC+ plans to provide, from 2025 on, a decentralized national research infrastructure that provides both a standardized offer through its core services in data management and data science (horizontals), and community-tailored services and know-how via its domain-specific pillars (verticals) — Core services comprise: 1. Secure data management (enhancing SWITCH Cloud offering) and data engineering and harmonization (in close collaboration with SPHN-DCC) 2. Data science, machine learning and AI services 3. Education and training services	**SDSC(+)** — Services for NDS, as currently done for the LUCID NDS — Biomedical data science 'vertically' to SDSC+ — Data and data science platforms, tools, and coordination services offered to academia, the public sector, and industry, fostering excellence in multidisciplinary data-driven research, accelerating best practices in ORD and Open Science, and promoting open innovation — Access to harmonized data and curated data-driven science in select application domains, with a fully-fledged research collaboration and education platform for scientists and field experts, thereby strengthening its position as a trusted partner for data and associated services, nationwide and beyond — Secure infrastructure for data processing and storage (BioMedIT or equivalent interface node(s))	— Innovating data management for regulatory compliance in biomedical research — Boosting the impact of the SPHN Interoperability Framework — Scaling and sustaining NDS data harmonization and management — Domain services on decentralized national research infrastructure (e.g., national interface node) — Best practices and standards for data-driven research

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
Department of Home Affairs (incl. FOPH and FSO)	The FOPH and FSO have been coordinating digital transformation processes in the healthcare sector at the federal level, among others: — The development and promotion of the EPR — eHealth Suisse coordinates, on behalf of the Confederation and the cantons, among other tasks, the exchange formats for the EPR — Measures for improving data management in the health system — The FOPH mandates different registries (e.g., National Institute for Cancer Epidemiology and Registration (NICER)) to systematically collect data on all respective patients in Switzerland — The Federal Quality Commission (EQK) is an independent extra-parliamentarian commission supporting the Federal Council to further develop quality assurance in healthcare. It aims to ensure that quality in the healthcare system is measured in a coordinated manner, quality concepts are developed, and quality measures are implemented — Establishing a data space for health-related research enabling the reuse and linkage of healthcare data for research and further purposes — Project 'SpiGes'[71] as an example for measures for improving data management in the health system — DigiSanté is the FDHA's program to promote digital transformation in healthcare. It is being developed by FOPH and FSO on behalf of the Federal Council by the end of 2023. DigiSanté is based on the concept of an ecosystem: various actors (service providers, insurers, cantons, supervisory authorities, research) produce, use, and process data from or for the benefit of healthcare. The data ecosystem comprises two dimensions, namely a content-related one (health policy) and a technical-infra-structural one (informatics, data and metadata, methods)	— SPHN-DCC participating in sounding boards and working groups for the revision of the Federal Act on the EPR and the use of EPR data for research — The SPHN-DCC has been in close contact with eHealth Suisse to ensure technical interoperability of EPD data and health research data — SPHN-DCC participating in the FOPH's National Expert Group for improving Data Management in the health sector. This multistakeholder expert group elaborates recommendations for the Federal Council on how data flows and data interoperability in the health sector can be improved — The requirements for registry data (standards, semantic and syntactic interoperability) should be aligned with the SPHN-DCC and an efficient framework for re-use of registry data in research established — SPHN has been exploring collaboration with the EQK with the goal to establish interoperability of health quality data and health research data enabling once-only data capture for both sectors — Explore synergies between SPHN-DCC, BioMedIT, FOPH, FSO and related actors with regard to ELSI, data linkage service, central metadata catalogues, national data coordination office, responsible use of data, regulated and secure further use of standardized data, secure infrastructure for data processing and storage — In the context of the DigiSanté program, the FSO is working on different tasks related to SPHN such as national data management (comprising interoperability and multiple use), the establishment of a Data Science Competence Centre (DSCC) as well as a Competence Network for Artificial intelligence (CNAI) and the secondary use of data for research. There are also contacts between SPHN and the FSO expert group on health statistics on these issues	**FOPH:** — SPHN-DCC with BioMedIT is recognized as a (inter-) national role model and provides the ideal basis for further development in the overall health data space — SPHN-DCC can play an important role in establishing structures and processes for data management and in shaping the health ecosystem — SPHN-DCC may engage as a key partner in the FOPH project "Data space for health-related research", and thus become part of the anticipated program for promotion of the digital transformation in the health system (DigiSanté) **FSO:** — The opportunities are that learning from each other can take place and information and best practices can be exchanged. In addition, the goal of providing data for medical research can be better achieved — Action points are not yet defined but they will concern the maintenance and further deepening of cooperation and interaction — Main point for the future will probably concern the program DigiSanté: 1. There is a connection between the SPHN Semantic Interoperability Framework and the IY14 platform through FSO. FSO semantics concern the harmonization of nomenclature, classification, and coding 2. Furthermore, a collaboration between SPHN-DCC, FSO and FOPH continues in the working group resulting from the report in answer to the Postulat 15.4225 Humbel 3. More collaboration will exist in the field of data science (DSCC) and within the framework in the National Expert Group for improving Data Management (according to Measure 5 of the Mandate of the Federal Council)

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71   www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitswesen/projekt-spiges.html

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
SIB (currently operating the SPHN-DCC and BioMedIT central services)	— The SIB Swiss Institute of Bioinformatics is the Swiss organization for biological and biomedical data science — Conceived BioMedIT and has had the overall responsibility for it in the period 2017–2024 — Provides the national and international life science community with a state-of-the-art bioinformatics infrastructure including resources, expertise, training, and services — Federates about 88 bioinformatics research and service groups, including core facilities, from the major academic institutions of Switzerland — Swiss node of ELIXIR, the European organization which brings together life science infrastructure from across Europe, including both clinical and non-clinical data	Activities of interest for personalized health development include: — expertise and support for the organization, analysis and interpretation of patient-related data (e.g., -omics data), offering custom-made solutions to answer complex biological questions — training in computational biology and data science across the spectrum of data analysis techniques, methods, and tools. Training programs in Personalized Molecular Oncology (SIB jointly with the University of Basel) and Data Stewardship (planned, SIB jointly with the University of Lausanne and six other institutions across Switzerland) — IT subcontracting services to BioMedIT node at University Lausanne and legal advice to SPHN-DCC — involvement in genomic surveillance activities for the FOPH, processing all Swiss SARS-CoV-2 (COVID19) sequencing data through the SPSP platform, and co-development of dedicated resources to track viruses (Nextstrain and V-pipe)	— Alignment of SPHN-DCC to Europe, e.g., via the 2024–2028 ELIXIR program. ELIXIR leads the Federated European Genome-phenome Archive (fEGA) and the European Genomic Data Infrastructure (GDI) projects, and the Federated Human Data Community — Through SIB, SPHN-DCC will continue to be closely linked to the Swiss bioinformatics research community (88 groups at 26 institutions) — Together with the University of Bern, SIB has applied to co-lead the 'SwissBioData ecosystem' Roadmap 2023 infrastructure project to support researchers from data generation, all the way to analysis, sharing, and reuse. Close alignment with SPHN-DCC will maximize interoperability of health and biological data, create synergies through transversal activities, and avoid duplications (e.g., sensitive non-health data could benefit from BioMedIT) — SIB's Centre of Excellence can support and/or complement SPHN-DCC activities, in particular for data and knowledge standards and management, training, and legal services — Collaborations with the industry: SIB has considerable experience in public–private partnerships (European Innovative Health Initiatives, InnoSuisse) and service contracts with the industry. Many of these collaborations focus on data management, standardization, FAIRification, federated computing, and training
Research support organization: SCTO	— Coordinating the national clinical research infrastructures of CTUs in 7 Swiss hospitals and the network for pediatric research (SwissPedNet); supporting all kinds of clinical research carried out under the Human Research Act, providing training and education as well as services required by Good Clinical Practice (GCP)	— Common ethical-legal standards and processes for data (and samples) sharing and governance — Local and central support structures — Interoperability framework — Secure infrastructure for data processing and storage (BioMedIT or equivalent interface node(s)) — Clinical research data and samples — Public health research — Longitudinal cohort studies with biobanks and integrated imaging data (population-based and disease-specific) — Disease registries	— Regulatory and GCP-related support (via CTUs and platforms) over project life cycle — Providing quality management systems as required by GCP and law — Implementation of General Consent (GC) at local level/hospitals — Data management services and systems for prospective (e.g., cohorts, registries), interventional and observational research — Run data centers for national and international multicenter projects — Negotiating data (and sample) provision based on templates provided by SPHN/SBP — Comprehensive training offer in clinical research for all levels of expertise and including all relevant topics

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
Research support organization: SBP	— As the national research infrastructure for biobanking activities, providing services to its network of biobanks and researchers for quality assurance certifying biobanks, with a comprehensive catalog of Swiss biobanks and biospecimens for researchers, for interoperability with datasets and a BIMS, as well as with an education program on biobanking	— Common ethical-legal standards and processes for data (and samples) sharing and governance — Local and central support structures — Interoperability framework — Secure infrastructure for data processing and storage (Bio-MedIT or equivalent interface node(s)) — Clinical research data and samples — Public health research — Longitudinal cohort studies with biobanks and integrated imaging data (population-based and disease-specific) — Disease registries	— Develop a one-stop-shop process for researchers integrating access to samples and data by promoting links to each available catalog, and common ethical-legal standards — Promote a better communication between research-support organizations through the development of a website dedicated to researchers where each support organization could promote their complementary services — Develop synergies between medical, public health, clinical, and biological research with a coordinated and integrative approach
Research support organization: SSPH+	— Supporting primary- and data-driven public health research (including surveys, cohorts, biobanks, health, and disease registries) for maintaining and promoting health and wellbeing, preventing disease, evaluating the public health utility of innovation and access as well as quality and cost-effectiveness of the healthcare system; promoting the health of populations in a socially equitable manner in an evidence-based science-to-policy approach at the level of society, governments, organizations, and communities — SSPH+ and its partner institutions have developed and are maintaining many population-based cohorts, biobanks, and disease registries.	— Common ethical-legal standards and processes for data (and samples) sharing and governance — Local and central support structures — Interoperability framework — Secure infrastructure for data processing and storage (Bio-MedIT or equivalent interface node(s)) — Clinical research data and samples — Public health research — Longitudinal cohort studies with biobanks and integrated imaging data (population-based and disease-specific) — Disease registries	— SSPH+ and its partner institutions are working collaboratively towards the implementation of a large Swiss Cohort and Biobank of at least 100'000 citizens of all ages [7, 8]. The healthy reference and health systems perspective to the secondary healthcare data-focus of SPHN will promote personalized and health research in many ways — Public health experts should be represented in a steering board for a future national health data center — Collaboration in data science and methods development, jointly designing, implementing, and maintaining surveys, registries and cohorts, training and education — Broaden the data focus by extending it to various aspects of wellbeing and health beyond data from medical care. Integration of health data from ambulatory care and from citizens more generally
Research support organization: SAKK	— Integrating Swiss university and non-university clinics into a national network for clinical oncology research. Swiss service and competency center for interventional, multicenter trials in oncology, designing and conducting interdisciplinary studies, central data base with clinical trial and real-world data	— Common ethical-legal standards and processes for data (and samples) sharing and governance — Local and central support structures — Interoperability framework — Secure infrastructure for data processing and storage (Bio-MedIT or equivalent interface node(s)) — Clinical research data and samples — Public health research — Longitudinal cohort studies with biobanks and integrated imaging data (population-based and disease-specific) — Disease registries	— Oncological patients are a "use case" for genomic and proteomic data, in oncology, data use is clinical reality to guide therapies. Direct transfer into patient's outcome and quality control possible — Pattern recognition of clinical data to define therapeutic pathways (including clinical data, molecular data and personal data) — Electronic Patient Reported Outcomes (ePROs) are a source of personal data, already part of clinical studies and clinical care

Partner organization	Role in relationship to the SPHN-DCC	Interfaces with SPHN-DCC	Opportunities and action points for the future
SNSF	— Funding agency for researchers, research projects, national research programs (e.g., NRP 74, NRP 78, NRP 80), clinical research under the involvement of public and patient involvement, and research infrastructures (SBP, SCTO; STCS (Swiss transplant Cohort Study) and SHCS (Swiss HIV Cohort Study)) — Evaluating research initiatives and proposals — In 2017, the introduction of DMP under FAIR principles in Switzerland was already initiated for research projects searching for financial support by the SNSF	— Defining and enforcing standards for best practices in data-driven research (e.g., data management,ORD) — SNSF-funding for Data Infrastructures and Services (DIS) — Common best practice for evaluation procedures	— Be one of the initiators of best practices in ORD and also a pioneer in its use and application — Apply the SPHN standards and requirements in the IICT community that is looking for financing from the SNSF and therefore act as an accelerator in the diffusion of these standards and requirements
SWITCH	— Providing secure basic infrastructure, innovative solutions and targeted advice for digitalization issues that jointly concern the education, research, and innovation community in Switzerland — As part of its strategy, SWITCH aims to support Research Infrastructures (such as SPHN-DCC) in BFI 2025–2028	— SWITCH Cloud, the Enter-prise-grade and certified Cloud for the Swiss higher education sector, is uniquely qualified for the processing and hosting of sensitive data — Network, security, and identity management services	— SWITCH offers, on the SWITCH Cloud, IaaS services and is open to jointly develop PaaS services to support the processing and storage of sensitive data — Co-creation of Cloud services on top of the SWITCH Cloud for the health community of the Swiss higher education sector — Collaboration with BioMedIT — Connectome as well as any future data services (co-created with Swiss higher education institutions within the context of the national ORD program) — SWITCH is open to collaborate on all areas where it has core competencies such as cloud, network, security, identity management, procurement, and IT law

5   Governance of the SPHN-DCC

The SPHN-DCC must be a national service provider for all health research stakeholders in Switzerland. Furthermore it shall act as a national competence center facilitating and advising collaboration between academia, government, industry, and international counterparts. It shall not conduct nor define the frame of future research collaboration inside data provider or research institutions. Rather, the SPHN-DCC provides high-quality standards/guidelines that enable hospitals and research institutions to develop efficient data governance policies. The overall strategy of the SPHN-DCC must be closely aligned with and embedded in the national coordination efforts for clinical and health research. The development of the organization and the operating model must satisfy future needs. Such development will take place against the background of an international trend toward sector-specific data spaces and national infrastructures for data exchange (by data sharing or, of likely increasing importance, by sharing without physically sharing data, i.e., federated analyses approaches).

With regard to the use of the infrastructures coordinated by the SPHN-DCC and the implementation of the defined standards, it is primarily the responsibility of the higher education institutions, data providers, and the national funding institutions to declare the SPHN-DCC specifications as binding, and thus encourage or enforce the use of the SPHN-DCC framework.

5.1   Organizational governance of the SPHN-DCC

Four dimensions of the SPHN-DCC should be considered for its transformation and consolidation as a permanent research infrastructure (see Figure 1). First, a strategic level for the coordination with other Swiss health research partners for aligning the perimeter of the SPHN-DCC's activity portfolio and interfaces with the partners. The national "Coordination Platform Clinical Research" (CPCR), proposed in the White Paper Clinical Research [6] and established in 2021 under the management of the Swiss Academy of Medical Sciences

(SAMS) (based on a mandate from SERI), would be an obvious body to serve in this role. Second, a governance level with an SPHN-DCC Steering Board responsible for the oversight, finances, and general principles of data governance and access policies of the SPHN-DCC. It is essential to ensure independence from individual institutions and particular interests. The steering board should include patient representatives and contributing stakeholders from health-data-related fields in academia, healthcare and health services, government/federal and cantonal administration, funding institutions, and industry, in addition to the hosting institution for technical and organizational implementation. The third level is a purely technical and organizational level involving central IT network support, BioMedIT, interoperability, standards, FQS, tools, interfaces (e.g., to PHRT-SMOC platforms, SDSC, FOPH, FSO, etc.) and services (regulatory support, training, international collaboration, etc.). Data provision, processing, and analysis generally takes place in decentralized infrastructures and under local/project-specific data governance (fourth level).

Figure 1: Governance and embedding of the SPHN-DCC after 2024. Abbreviations: SERI: State Secretariat for Education, Research and Innovation; SAMS: Swiss Academy of Medical Sciences; SBP: Swiss Biobanking Platform; SCTO: Swiss Clinical Trial Organisation; SAKK: Swiss Group for Clinical Cancer Research; SSPH+: Swiss School of Public Health; CDW: Clinical Data Warehouse; FQS: Federated Query System
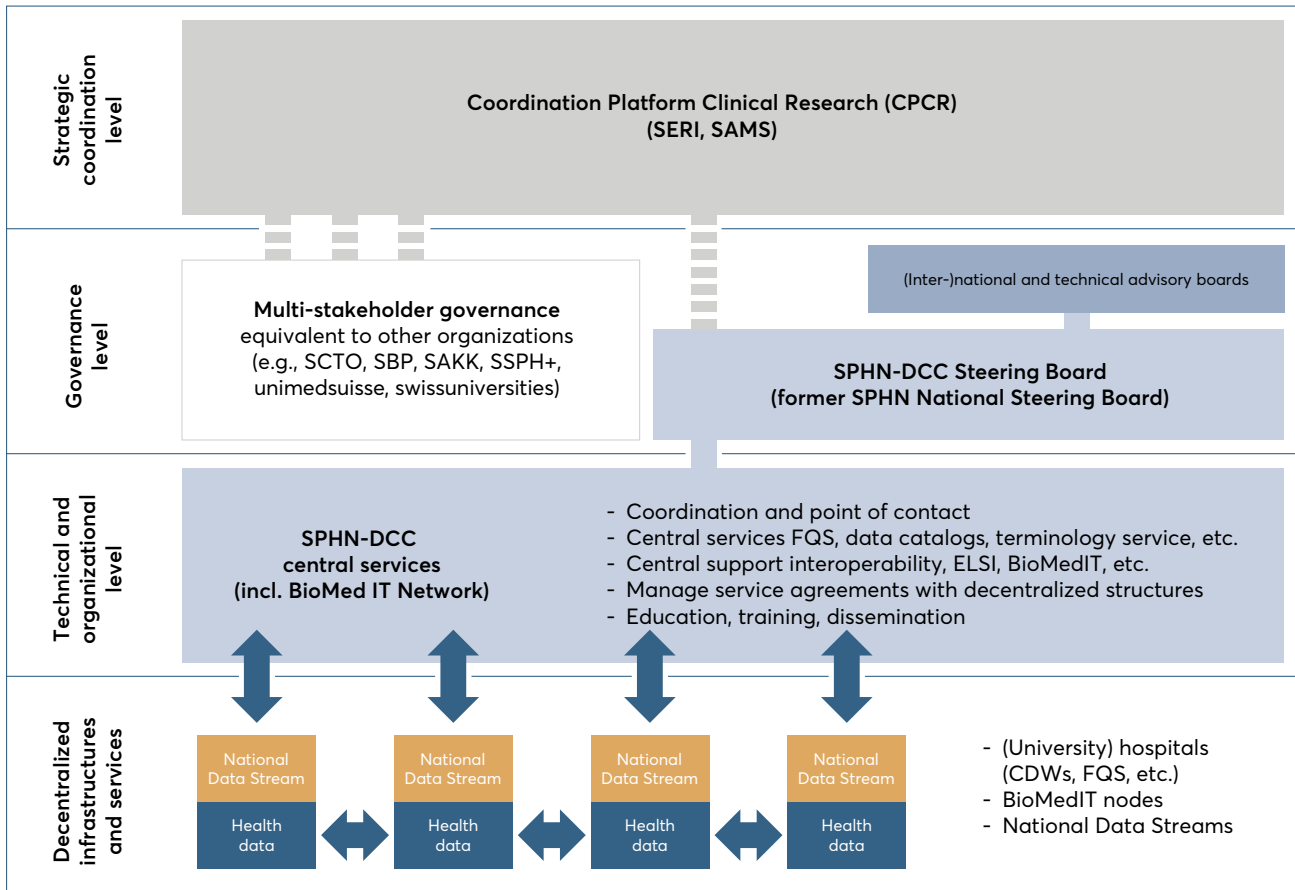
5.2   Governance over data and access to data

Data governance generally needs to be managed non-centrally, i.e., by data providers (hospitals, universities, ETH-Domain). The SPHN-DCC facilitates processes for data requests and data access and provides high-quality standards and guidelines. Data providers must be involved in relevant governance bodies and their decisions. Control over specific sets of data is typically organized on a project level (e.g., NDS, research consortia). Under certain circumstances (e.g., dissolution of a research consortium that collected and curated large amounts of data), on request from data controllers and with the approval of all data providers, custodianship over a research dataset in a FAIR data re-

pository can be transferred to the SPHN-DCC Steering Board, which subsequently becomes responsible for the data governance (e.g., ensured by a national Data Access Committee). Such a transfer of responsibility will require a clear mandate and adoption of a legal basis approved by the original data providers. Additionally, partial responsibility would be conceivable, in which the SPHN-DCC acts in the future as a processor of data on behalf of the controllers.

6   Financing of the SPHN-DCC after 2024

6.1   Financial needs

We estimate the total annual costs of a consolidated SPHN-DCC as amounting to approximately CHF 13 Mio for 2025. These should be financed by the Confederation (~CHF 6.5 Mio) and matching funds by the institutional partners (~ CHF 6.5 Mio in-kind/in-cash). This total sum splits, on the one hand, into central costs of the SPHN-DCC amounting to approximately CHF 5 Mio annually (start budget in 2025), comprising personnel and operations, compensation of governance board members and support structures, maintenance and further development of central infrastructures, and licensing and consultancy costs. On the other hand, there are noncentral costs on the side of the data providers (e.g., hospitals) to implement and maintain data standardization, data delivery pipelines, and data provision for research and NDS, plus the noncentral costs incurred at the three Bio-MedIT nodes for service staff and IT infrastructure. This amounts to approximately annually CHF 8 Mio starting in 2025. Financing these noncentral activities is absolutely critical for the availability of interoperable health data for research. While sustaining the core infrastructures of the SPHN-DCC and NDS is an indispensable requirement, powering state-of-the-art research using these platforms for large, consortial projects will require dedicated research funding. A funding instrument for developing new programs in biomedical research such as NDS is currently not available after the end of SPHN and PHRT, but urgently needed.

6.2   Sources of income

National (e.g., SCTO/CTU-networks) and international experience (e.g., large IT platform services like the IT Center for Science (CSC)[72] in Finland or the German network for bioinformatics infrastructure (de.NBI)[73] in Germany) show that costs for the development, maintenance, operation, and support of such infrastructure components for current and future projects can never realistically be fully offset through service fees to researchers, instead needing stable, long-term, top-down financing (i.e., in the form of core funding ("Sockelfinanzierung"). Particularly when it comes to data security, incentives

(also financial ones) must be set so that researchers prefer the use of secure infrastructures to non-secure (or even non-legal) alternatives. Furthermore, a stable basis of support for the central infrastructure will provide the security, independence — and therefore trust — needed by data providers to commit to and invest in establishing FAIR data sources.

The following sources of income can be envisioned:

a) Core funding from SERI: since the core mission of the SPHN-DCC is to nationally coordinate and provide data infrastructures and services for FAIR health data for research, the Confederation should ensure a critical portion of the required financing. This will guarantee the independence, sustainability, and trust needed for investments from other partners.

b) Core funding from university hospitals/data providers and higher education institutions: the most direct beneficiaries of the data infrastructures and services of the SPHN-DCC are the Swiss higher education institutions and university hospitals/data providers. Hence, these institutions should complement the federal contributions of the core financing, to be eye-level partners and to strengthen the federated nature and sustainability of the SPHN-DCC long-term. Hospitals as well as universities already significantly contribute in-kind and in-personnel costs to maintain these non-central infrastructures.

c) User fees: the basic services (but not the data curation costs of the data providers) and use of infrastructures of the SPHN-DCC should be free of cost for Swiss academic researchers, reflecting institutional contributions. Services and infrastructure needs going beyond the "base package" of the SPHN-DCC should be charged to the researcher as direct costs for the use of infrastructure for conducting a research project (and eligible to be defrayed from research grants). The exact business model for the future has to be refined after consultation with stakeholders. So far, a cooperative model has been proposed as a potential option: e.g., academic institutions not contributing to the core financing of the SPHN-DCC could obtain services for a higher fee. Industry partners (e.g., from pharma, med-tech, information technology) have great interest in using health-related data for research and to develop their businesses. As commercial entities, private part-
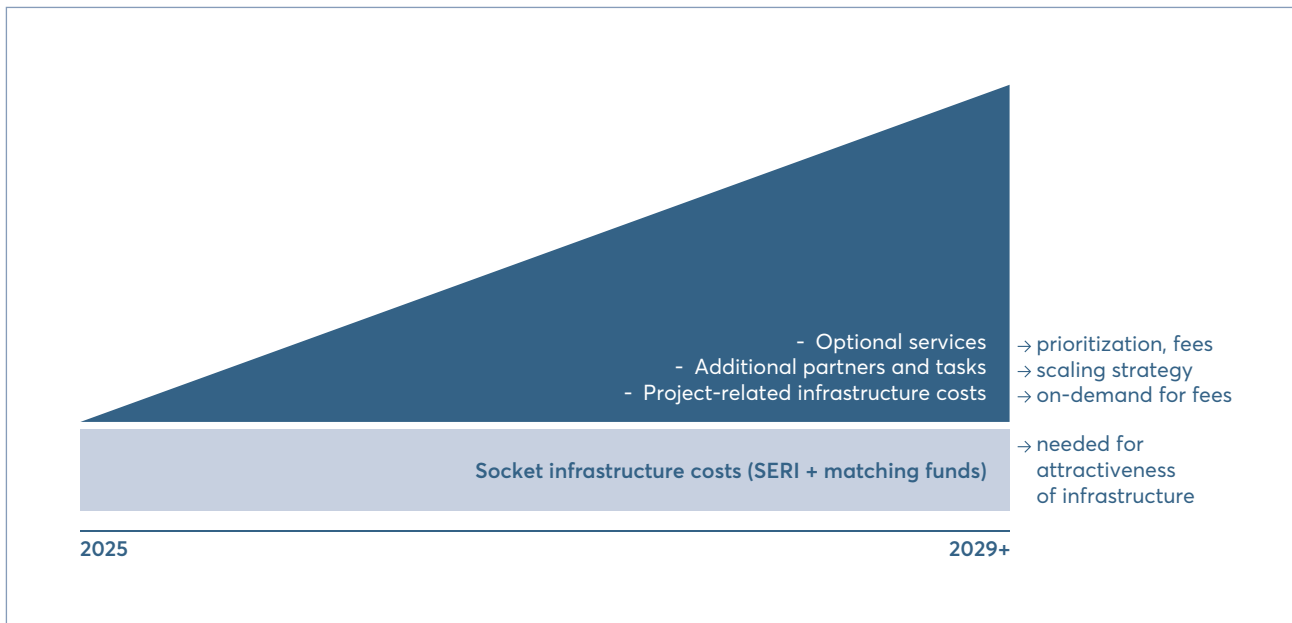
ners should pay market prices for services and use of infrastructures from the SPHN-DCC and all partners involved (e.g., hospitals, universities). Services could include coordination between industry partners and data providers, access to data catalogs, queries for data availability and feasibility, or contracted analysis of data with sharing of aggregate results.

6.3   Scaling concept

Both the activity portfolio of the SPHN-DCC as well as its 'clients' (data providers and data users) are likely to increase over time. For example, data services for federal and cantonal administration departments or for industry may be requested for reasons of public health, quality assurance, research, market authorization and

access, and other purposes. The sources for real-world health data should be expanded from university hospitals to other healthcare providers, and possibly citizen data (e.g., wearables). Therefore, a scaling concept is needed that enables the sustainable growth of the SPHN-DCC with respect to finances, but also governance and interfaces. While a stable core financing is needed to guarantee basic services with attractive conditions, optional services (see Annex Table 4) may be prioritized based on demand and offered for a fee. Additional partners could join the network if they provide own contributions (in-cash or in-kind) to offset the additional tasks and efforts. Finally, fees for project-related infrastructure costs could ensure that resources keep up with demand. A final business model needs to be elaborated jointly with the partners to ensure sustainability of the SPHN-DCC after 2024.

Figure 2: Scaling model for the SPHN-DCC activities and partners after 2024. Abbreviations: SERI: State Secretariat of Education, Research and Innovation

- Optional services   → prioritization, fees
- Additional partners and tasks   → scaling strategy
- Project-related infrastructure costs → on-demand for fees

Socket infrastructure costs (SERI + matching funds)   → needed for attractiveness of infrastructure

2025   2029+

7   Subsequent benefit for patients, healthcare and public health

The SPHN-DCC is the core infrastructure for a data-enabling environment of health-related research data in Switzerland. It facilitates research with and efficient secondary use of centralized and decentralized health data. These data can be real-world routine clinical data, biological data (such as omics data), or clinical research data, e.g., from registries or cohort studies. Platforms such as the National Data Streams can serve as crystallization points for future research consortia, connecting clinicians and researchers and promoting the shared benefits from the collaboration of these consortia. In the context of precision medicine, the SPHN-DCC will make it possible to work with sufficiently large datasets and create reference datasets. This will contribute to a more precise individual characterization of a patient with a particular disease. For example, in the context of rare diseases, it will allow genetic abnormalities associated with the disease to be rapidly distinguished from normal genetic variations in a population. It will help provide better prognosis, improve the quality of care, and determine the effectiveness of treatments and their side effects in a real-world setting. Based on existing real-world data, new research hypotheses can be identified for at-risk populations, which can then be tested in randomized clinical trials. The effectiveness of novel treatment strategies in actual medical settings can be better tested in implementation research. For many chronic diseases, early diagnosis and early treatment or prevention are at the heart of health research and care. Therefore, it is of high priority to establish interoperability (data formats, standards) between health data from hospitals and other medical facilities and public health population data. The latter will help develop biomarkers that detect disease onset before it occurs. While these clinical benefits have yet to be demonstrated on a larger scale, the SPHN-DCC and SPHN data framework are a prerequisite for facilitating medical research and innovation for our next generation of physicians and researchers. It is also of utmost importance that patient needs and ethical frameworks are systematically considered in all these developments, and that solidarity is sought with equivalent initiatives and institutions abroad to empower international coordination and collaboration.

8   Future vision

8.1   A National Center for Health and Research in Switzerland

In Switzerland, there is a widely formulated wish to further develop data reuse, especially in the healthcare and (health) research sector. Multiple political initiatives at national and cantonal level are calling for a strategy and action to improve reuse of health data. The White Paper Clinical Resesarch [6], elaborated by national experts from health research and published by the SAMS, recommends to reduce the complexity of regulatory and data-related processes and to create a national coordination platform, which was soon thereafter established at the end of 2021. Local personalized health infrastructure initiatives are ongoing in several places. Their connection and interoperability with the SPHN-DCC is of great importance.

Going further, to increase international competitiveness, a "National Center for Health and Research" (NCHR) should be envisioned for Switzerland in the long term (i.e., after 2028), notwithstanding further analysis and evaluation by main stakeholders (universities, university hospitals, ETH-Domain, etc.). This vision was inspired by the suggestions in the stakeholder interviews and also strongly recommended by the SPHN International Advisory Board. At present, this structure is not established, however it could encompass, at least in a federated structure, existing institutions (e.g., the SPHN-DCC, SCTO, SAKK, SBP, national cohorts and disease registries) and foster data-based health research and health data use in general. Like examples from other countries (e.g., the US' NIH, the UK's NIHR, or INSERM in France), such a national center should bridge health research, care, and policy. A close collaboration with partners (SDSC, SIB, SNSF, ETH, EPFL, universities, hospitals and particularly FOPH, FSO) should be envisaged. FOPH has supported this idea, pointing out the benefit for data-driven improvement of healthcare

(e.g., use-inspired research and quality of care). Access to technology platforms and interfaces to health, science, and societal data spaces should be elaborated and fostered in order to make optimal use of data quality and scientific excellence in Switzerland. The national center would need a clear coordination and performance mandate by the federal government and the cantons and – in the mid-term – a legal legitimacy. Furthermore, it would need sufficient financing and empowerment to fulfill its tasks and enforce data provision according to defined standards.

It is evident that the establishment of such a structure is dependent upon broad scientific and political support and coordination with the respective organizations in the different health data subsystems (research, care, health service, public health, pharma, etc.). The time seems to have come to start reflections and possible activities in this direction. The fundamental work of the SPHN-DCC in recent years, the high sense of urgency within the stakeholder landscape, the establishment of the CPCR, and the current support from politics and industry should be used to improve the health data landscape and health research with a visionary approach towards a national center and a supporting health data space at scale. This larger vision should be pursued in parallel to the measures proposed above for the SPHN-DCC and also integrate the health data strategy of FOPH and FSO. The CPCR appears to be the ideal platform to work towards such a national center, into which the SPHN-DCC should eventually be integrated.

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Epilogue

Since 2017, the Swiss Academy of Medical Sciences (SAMS) has proudly hosted the Swiss Personalized Health Network (SPHN) initiative. This program was initiated by the Swiss government to establish a national infrastructure for clinical and omics data.

Its achievements can already be seen as a great success. Starting almost from scratch, the actors in the field (mainly university hospitals) have been convinced to mutualize their consented health data in a nationally coordinated network allowing safe data management, exchange, and processing within a strict legal and ethical frame. However, this success needs to be consolidated beyond the term of the initiative by the end of 2024. The future of the proposed data coordination center (SPHN-DCC) is clearly outlined in the present report. It has been elaborated with the collaboration of the broad community of health research institutions in close conjunction with the ETH-Domain, and has been submitted to SERI.

In parallel to the SPHN initiative, SAMS issued in 2021 a white paper which analyzes the major driving forces that are transforming clinical research and identifies the weaknesses and redundancies of the current state of clinical research in our country. As a first consequence, a National Coordination Platform Clinical Research (CPCR) was set up, which brings together all institutions in the field, including SPHN, to streamline the actions of the individual actors under the auspices of SAMS. The future SPHN-DCC will certainly be an important part of the CPCR. If and how the CPCR itself could become the nucleus of a wide "National Center for Health and Research", is presently being scrutinized. Such an ambitious vision would offer new perspectives for strengthening clinical research and health data management in Switzerland over the coming decades.

Prof. Henri Bounameaux
SAMS President

10   Appendices

10.1   Stakeholder interviews advocacy AG

Table 3: Stakeholders and persons interviewed in July–August 2021 by advocacy AG

Stakeholder	Description	Name
eHealth Suisse	The competence and coordination office of the Confederation and the cantons for eHealth issues and the electronic patient dossier	Adrian Schmid
FOPH	Federal Office of Public Health	Victoria Sarraf
FOPH	Federal Office of Public Health	Sang-Il Kim
FOPH	Federal Office of Public Health	Brigitte Meier
FSO	Federal Statistical Office	Jacques Huguenin
FSO	Federal Statistical Office	Marco D'Angelo
GDK-CDS	Konferenz der kantonalen Gesundheitsdirektorinnen und –direktoren; Conférence des directrices et directeurs cantonaux de la santé	Kathrin Huber
SAKK	Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung	Roger von Moos
SAKK	Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung	Martin Reist
SBP	Swiss Biobanking Platform	Christine Currat
SCTO	Swiss Clinical Trial Organisation	Annette Magnin
SDSC	Swiss Data Science Center	Olivier Verscheure
SNSF	Swiss National Science Foundation	Irene Knüsel
SSC	Swiss Science Council	Marianne Bonvin
swissuniversities	Rectors' Conference of the Swiss Universities	Christian Leumann
swissuniversities	Rectors' Conference of the Swiss Universities	Falko Schlottig
unimedsuisse	The Association of Swiss University Medicine	Primo Schär
unimedsuisse	The Association of Swiss University Medicine	Oliver Peters
Health2030	Multicentric and multidisciplinary initiative aimed at exploring and exploiting the potential of new technologies in the fields of health and personalized medicine, bringing together the Universities and University Hospitals of Bern, Geneva, and Lausanne as well as the "Ecole polytechnique fédérale de Lausanne" (EPFL).	Jacques Fellay
Health2030	See above	Katrin Männik
The LOOP	The LOOP Zurich is a translational research center focused on precision medicine in Zurich, combining basic biomedical research and bioinformatics from the ETH Zurich and the University of Zurich with clinical research from four university hospitals.	Jens Selige
The LOOP	See above	Markus Rudin

10.2 Activity portfolio of the SPHN-DCC after 2024

The activity portfolio of the SPHN-DCC after 2024 includes not only – as required by the SERI mandate – the continuation and management of the data infrastructures currently financed through the SPHN initiative, but should also be oriented in such a way that data-driven research in Switzerland is enabled and promoted on a national level in a sustainable and scalable way. The SPHN-DCC will not conduct research on its own, but act in an infrastructure/service-providing, coordinating, and enabling role for researchers and institutions. The activity portfolio of the SPHN-DCC therefore includes the following tasks:

Table 4: Activity portfolio of the SPHN-DCC after 2024

Stakeholder	Description	Name
Priority: '×' = budget-relevant must-haves 'optional' = budget-relevant nice-to-haves 'service' = on-demand, fees may apply 'support' = resources from SPHN-DCC required, but lead is with other stakeholder 'driver' = active promotion without budget-relevant resources		
National competence center for FAIR health research data	**Findability:** — Operation of a federated query system or service — Operation of a national health research (meta-)data catalog (and other catalogs, e.g., Maelstrom, clinical metadata catalog). **Accessibility:** — Coordination of efficient contractual frameworks (templates, framework agreement) — Provision of support services (central ELSI helpdesk) in coordination with decentralized support structures, e.g., CTUs. — Operation of a data explorer system or service — Working towards being an enabler for requests of health research data, adhering to the governance of data controllers. **Interoperability:** — Definition of nationwide standards for data semantics and exchange mechanisms for health research data in Switzerland, harmonized with other health domains (EPR, registries, etc.). — Promotion and support of internationally recognized standards (in close collaboration with eHealth Suisse), terminologies in healthcare and FAIR research data. — Operation and maintenance of central infrastructure components for interoperable data provisioning (Interoperability Framework). **Reusability:** — Coordination and enabler for reuse possibilities of datasets (under own governance or/and under external governance): including SPHN Driver Projects, National Data Streams, etc. — Progressively incorporate 'all' health research data in the Interoperability Framework. — Monitoring national and international developments and proposing strategies. — Advisor to academia, government (policy), funders, industry, etc. — Point of contact for international stakeholders.	× optional × × optional driver × × × × × driver driver ×

Stakeholder	Description	Name
Priority: '**×**' = budget-relevant must-haves '**optional**' = budget-relevant nice-to-haves '**service**' = on-demand, fees may apply '**support**' = resources from SPHN-DCC required, but lead is with other stakeholder '**driver**' = active promotion without budget-relevant resources		
Data Governance	— Act as a coordinating service provider; support the implementation of harmonized standards and guidelines and promote scientific collaborations and multicenter projects at a national level. Generally, responsibility for and control over datasets remains with data providers and researchers/consortia.	support
	— However, services supporting subsidiary central governance structures (including coordination of a national Data Access Committee, DAC) can be provided on request for the reuse of existing health research datasets if they are given into the responsibility of the SPHN-DCC with approval of the data controllers and data providers through a legal basis.	service
	— Develop a framework agreement for data reuse among previous SPHN partner institutions; progressively expand partners, including cantonal and regional hospitals.	×
	— Act as a facilitator/coordinator for data access (work towards data request portals from catalogs).	optional
	— Support ELSI policy making for data-driven health research.	×
	— Develop, in collaboration with academic institutions, frameworks for collaboration with industry, payers, and other partners.	×
	— Contribute to discussions and debates on the societal issues related to the use of health data for research.	×

BioMedIT technical infrastructure	— Provision of a secure platform for research with sensitive data covering the entire project lifecycle:
	  1. Standardized end-to-end encrypted data transfer (for all potential data providers)
	  2. Secure and shielded project space for researchers
	  3. Provision of technologies, services, (HP) computing capacity
	  4. Access control and support
		×

	— Maintenance and further development of the established BioMedIT network infrastructures.	×
	— Management and further development of national FAIR data repositories.	support
	— Onboarding of further academic institutions (based on needs, e.g., cantonal hospitals, SAKK, cohorts, registries).	×
	— Provision of terminology service.	×
	— Hosting of federated core research data repositories for hospitals.	service
	— Management of an RDF data delivery pipeline (connector, loader, etc.).	×
Research/ health data space	— Hub for cross-institutional collaboration and intermediary/facilitator between different stakeholders.	support
	— Data support hub for all medical research disciplines (e.g., translational/clinical research, health services research, public health research).	×
	— Management, maintenance, and further development of SPHN central infrastructures (including SPHN IT Architecture in close collaboration with the University Hospitals).	×
	— Promotion, support, and coordination of cross-institutional collaborations throughout the country, international research collaborations, and collaborations with the industry.	support
	— Sustainable SPHN-DCC network that serves the SPHN-defined use cases and National Data Streams (NDS).	×
	— Switchboard for the collaboration with other data players in Switzerland (FSO, registries, FOPH, cohorts of national importance, etc.).	support
Innovative solutions	— Provision of processes and tools for quality management for data providers and researchers.	service
	— Administration of privacy-preserving technologies for data exploration and data analyses.	service
	— Administration of the interfaces necessary for the realization of genomic medicine and precision medicine relying on multi-modal omics technologies in Switzerland.	support
Monitoring and enforcement	— Consolidation and implementation of standards, in coordination and cooperation with other important players (e.g., eHealth Suisse, FOPH, FSO, FMH).	driver
International interfaces and collaborations	— Alignment and exchange with international standard organizations, infrastructures, research initiatives, and funding bodies (ELIXIR, GA4GH, 1+MG, etc.).	×
Education, training, and outreach	— Information and communication platform.	×
	— Education and training in all fields relevant for health-data-driven research and real-world health data aspects (security, FAIR, ELSI, etc.).	×
	— Provision of comprehensive documentation.	×
	— Provision of training materials for health research stakeholders (universities, hospitals, legal departments, etc.) and offer of central training on FAIR health research data, infrastructures, best practices, etc.	×
	— Providing active communication to the public and other stakeholders.	×

10.3 Short form definitions

1+MG	European 1+ Million Genomes Initiative
ATC	Anatomical Therapeutic Chemical
BBMRI-ERIC	European Research Infrastructure for Biobanking
CAS	Certificate of Advanced Studies
CDW	Clinical Data Warehouse
CHUV	Centre Hospitalier Universitaire Vaudois
CPCR	Coordination Platform Clinical Research
CSC	IT Center for Science Finland
CTUs	Clinical Trial Units
DAC	Data Access Committee
DaSCH	Swiss National Data and Service Center for the Humanities
de.NBI	German Network for Bioinformatics Infrastructure
DIS	Data Infrastructures and Services SNSF
DM	Data Management
EGA	European Genome-Phenome Archive
ELIXIR	European Life Science Infrastructure for Biological Information
ELSI	Ethical, Legal, and Societal Implications
ELSIag	ELSI Advisory Group SPHN
EMPA	Swiss Federal Laboratories for Materials Science and Technology
EPR	Electronic Patient Record (Dossier)
EPFL	École Polytechnique Fédérale de Lausanne
ETH	Eidgenössische Technische Hochschule
ETHZ	Eidgenössische Technische Hochschule Zürich
FAIR	Findable, Accessible, Interoperable, and Reusable
FORS	Swiss Centre of Expertise in the Social Sciences
FOPH	Federal Office of Public Health
FQS	Federated Query System SPHN
FSO	Federal Statistical Office
FTE	Full-Time Equivalent
GA4GH	Global Alliance for Genomics and Health
GBC	Global Biodata Coalition
GCP	Good Clinical Practice
GDK-CDS	Schweizerische Gesundheitsdirektorenkonferenz. Konferenz der kantonalen Gesundheitsdirektorinnen und –direktoren; Conférence des directrices et directeurs cantonaux de la santé
HIT-STAG	Hospital IT Strategy Alignment Group SPHN
HRA	Human Research Act
HUG	Hôpitaux Universitaires de Genève
IAB	International Advisory Board SPHN
ICT	Information and Communication Technology
ICPerMed	International Consortium for Personalized Medicine
INSERM	L'Institut National de la Santé et de la Recherche Médicale
LOINC	Logical Observation Identifiers Names and Code
LUCID	Low Value of Care in Hospitalized Patients (an SPHN-PHRT National Data Stream)
NAB	National Advisory Board SPHN
NaDB	National data management (Federal Statistical Office)
NDKS	Nationale Daten-Koordinationsstelle (FOPH)
NICER	National Institute for Cancer Epidemiology and Registration

NIH	National Institutes of Health
NIHR	National Institute for Health and Care Research
NKRS	Nationale Krebsregistrierungsstelle
NSB	National Steering Board SPHN
PHI	Personalized Health Informatics
PHRT	ETH-Domain strategic focus area Personalized Health and Related Technologies
PPI	Patient and Public Involvement
PSI	Paul Scherrer Institute
RDF	Resource Description Framework
RWD	Real World Data
SACR	Swiss Aging Citizen Reference (an SPHN Driver project)
SAHS	Swiss Academy of Humanities and Social Sciences
SAKK	Swiss Group for Clinical Cancer Research
SAMS	Swiss Academy of Medical Sciences
SATW	Swiss Academy of Engineering Sciences
SBP	Swiss Biobanking Platform
SSC	Swiss Science Council
SCNAT	Swiss Academy of Sciences
SCTO	Swiss Clinical Trial Organisation
SDSC	Swiss Data Science Center
SERI	State Secretariat of Education, Research and Innovation
SIB	Swiss Institute of Bioinformatics
SFGN	Swiss Federated Genomics Network SPHN
SMOC	Swiss Multi-Omics Center PHRT
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SNSF	Swiss National Science Foundation
SSPH+	Swiss School of Public Health
SWITCH	A foundation of the Swiss Confederation and 8 cantons for IT solutions in teaching and research
SWITCHaai	SWITCH Authentication and Authorization Infrastructure
UH	University Hospital/s
Unibas	University of Basel
UNIL	University of Lausanne
USB	University Hospital Basel
USZ	University Hospital Zurich
WSL	Swiss Federal Institute for Forest, Snow and Landscape Research

10.4   Authors

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– Prof. Beatrice Beck Schimmer (SPHN and UZH)
– Dr. Christine Durinx (SIB)
– Prof. Antoine Geissbühler (SPHN and HUG)
– Dr. Irène Knüsel (SNSF)
– Annette Magnin (SCTO)
– Prof. Torsten Schwede (SPHN and Unibas)
– Dr. Michael Weisskopf (USZ)
– Prof. Bernd Wollscheid (PHRT and ETH Zurich)

Writing Group
– Prof. Urs Frey (SPHN, Chairperson)
– Dr. Katrin Crameri (SIB PHI group)
– Dr. Thomas Geiger (SPHN Management Office)
– Dr. Liselotte Selter (SPHN Management Office)

advocacy AG
– Mathis Brauchbar
– Dr. Dominik Steiger
– Natasa Stevanovic

Original SERI report under consultation by:
– SAMS Executive Committee, swissuniversities, unimedsuisse, ORD Strategy Council, PHRT, FOPH, SIB, SCTO, SBP, SAKK, SSPH+, SNSF.

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