open research data

National Strategy Council

ORD Task Force Health and Life Science Data
Final report

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Mandator
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Executive Summary

Context and goals

In response to the State Secretariat for Education, Research, and Innovation's (SERI) mandate, the Swiss National Open Research Data (ORD) Strategy was initiated in July 2021 by the four national education, research, and innovation (ERI) actors in Switzerland. The Strategy aims to guide the development of the research data ecosystem, with the StraCo leading the effort through its Blueprint Process. The Blueprint Process identifies disciplinary clusters within the ORD ecosystem that require concrete action, with the health and life sciences (HLS) cluster prioritized due to its highly fragmented nature and urgent need for coordination. The Task Force Health and Life Sciences (TF) was appointed to conduct a comprehensive analysis, building on previous efforts but distinguishing itself through a unique methodology.

Methodology

Using earlier findings as valuable reference points, this report provides a unique cluster-wide view, going beyond individual initiatives to investigate the use of available infrastructures and services across the entire data lifecycle and across data types and disciplines. The cluster was examined through various perspectives such as governance, funding, ORD-oriented infrastructures and services, findability, accessibility, interoperability, reuse, national coordination, and international cooperation. The TF's methodology involves stakeholder engagement through feedback on initiatives' factsheets, interviews with selected major players, and a Stakeholders' event. This inclusive approach ensures a nuanced and thorough examination of the HLS cluster.

Key findings

The analysis draws the picture of a fragmented landscape characterized by deficiencies in data sharing and reuse. These include the absence of standardized access regulations, obstructive legal obligations, and tensions surrounding the concept of data "openness". There is a strong impetus to act, as the continued absence of strategic coordination would have severe impacts on research communities and society in Switzerland. There appears to be a positive shift in stakeholders' readiness for collaboration.

To guide the StraCo in formulation strategic options to address these issues, The TF recommends focusing coordination efforts on the objective of data reuse. It also highlights three priority areas for the StraCo to act: clarifying national coordination, challenging the legal framework and leveraging funding. With these in mind, the TF identified more specific opportunities for coordination in the cluster.

Next steps:

Embedded within the National ORD strategy, this report establishes the groundwork for shaping strategic options that enhance coordination and efficiency within the HLS cluster as part of the StraCo's blueprint. Collaborating with the TF, the StraCo's Coordination Group has been tasked with translating these insights into actionable propositions for the cluster. These propositions will be assessed and refined by the StraCo in consultation with stakeholders in the course of 2024.

1. Introduction

1.1 The National ORD Strategy

In July 2021, the four national education, research, and innovation (ERI) actors in Switzerland (the ETH Domain, the Swiss Academies of Arts and Sciences, the Swiss National Science Foundation, and swissuniversities) published the Swiss National Open Research Data (ORD) Strategy[1], initiated by a mandate of the State Secretariat for Education, Research and Innovation (SERI).
The recommendations and principles of the Strategy were concretised through an Action Plan[2] published in January 2022. The Action Plan defined Action Areas and formalised the four ERI actors' partnership in establishing the National ORD Strategy Council (StraCo) as a new governance model. The StraCo is responsible for:

1. the strategic coordination of the ORD actions of ERI actors
2. the consolidation of the ORD Landscape, as part of the Action Plan's Action Area B and D[3]
3. the development and updating the ORD Action Plan
4. representing the national ORD vision and the interests of ERI actors.

In this framework, the StraCo has developed the Blueprint Process as a tool for the strategic coordination of the ORD landscape, of which this landscape analysis report is an integral part.

1.2 The Blueprint Process

The starting point of the Blueprint process is the identification by the StraCo of disciplinary clusters within the ORD ecosystem where concrete action is needed[4]. Task Forces are then assembled with the mandate of conducting an analysis of each cluster. Using the information from the cluster analysis, the StraCo develops strategic options to be integrated into its Blueprint. These options include directions for the development and coordination of the cluster (for instance development of new areas, extensions, closure, or merger of infrastructures). The Blueprint is meant as a guidance instrument, providing a framework for long-term planning to which funding decisions can refer, but it is not a decision-making instrument.

StraCo defines a cluster as a data- or discipline-specific area where:

- there is a highly dynamic ORD development
- multiple actors are operating (national and international)
- strategic coordination is needed and/or desired
- infrastructures of "foremost national relevance" are likely to exist.

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[1] Swiss National ORD Strategy (July 2021) (https://www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/Swiss_National_ORD_Strategy_en.pdf).
[2] Swiss National ORD Action Plan (January 2022) (https://www.swissuniversities.ch/fileadmin/swissuniversities/Dokumente/Hochschulpolitik/ORD/ActionPlanV1.0_December_2021_def.pdf).
[3] Ibid.
[4] In this context, a focus on ORD encompasses any activity involving research data that must be taken into consideration to reach the four objectives of the Swiss National ORD Strategy.

The three initial domain clusters to be investigated and strategically apprehended in the first phase of the ORD landscape consolidation work are:

- Health and life science Cluster 1)
- Social sciences and the humanities (Cluster 2)
- Data science (Cluster 3)

StraCo intends to establish a Task Force for each of these clusters, with the mandate of conducting a cluster-focused analysis which would allow the StraCo to explore strategic options and formulate the Blueprint for further coordination and consolidation of the cluster and the ecosystem. Cluster analyses are intended to be updated and extended on a regular basis to ensure they present an accurate representation of the field and incorporate new developments.

1.3 The Health and Life Sciences Data Cluster

The StraCo has decided to prioritize the health and life sciences (HLS) cluster because:

1. The HLS Cluster in Switzerland is highly fragmented, with an urgent need for coordination

In the last decade, various initiatives have emerged to enhance clinical studies and translational medicine, addressing the rising demands of personalized medicine, bioinformatics, and health/biomedical research data management. The HLS cluster saw a multiplication of data frameworks, set up to tackle different health-related issues or to fulfill specific policy objectives. In addition, the coordination of healthcare, such as the planning of hospital services or the licensing of outpatient service providers, happens at the cantonal level and, as such, many stakeholders have a high degree of self-administration and their own competencies. This has led to a fragmented landscape characterized by isolated systems, unnecessary duplication of efforts, and infrastructures that can be inadequate for their intended purpose.

The fragmentation is a hindrance to the digitalization of the Swiss healthcare system in general, and to the harmonization of data that can be used and re-used for research purposes, in particular. Currently, there is no coherent way to search for data across the existing initiatives, nor is a standardized access regulation for health data apparent. This lack of harmonization is further compounded by the obligations associated with data protection and by making the use of health data patient consent dependent. An obligation for declaration of consent by individual data providers is an additional obstacle. Further complications are added by the fragmented ethical approval system.

2. An efficient HLS cluster is crucial for impactful, future-driven research

In current and future health and life science research, the integration of diverse data types holds immense potential for scientific discovery and leadership. This shift has been evident in recent years, particularly with the integration of data in personalized medicine and bioinformatics, which has significantly shaped the data landscape in Switzerland. However, this trend goes beyond personalised medicine and bioinformatics. As an example, precision medicine combines genetic analysis with other molecular and cell biology techniques and imaging procedures to generate and analyze large amounts of data.

The versatile usage and combination of health data is further driven by the growing availability and diversity of data types:

- Healthcare data (electronic health records, scans/images, intensive care unit streams, medical registries)
- Laboratory data (genomics, transcriptomics, proteomics, microbiome, biomarker, metabolites, immune stats)
- Research data (clinical research, Randomized Clinical Trials, public health registries, longitudinal cohorts, omics)
- Lifestyle data (wearables, ambient sensors, patient reporting, environmental sensing)
- Administrative data (claims data, socio-economic information, federal statistics, health surveys)

The need for efficient data infrastructures and services in HLS research is becoming increasingly apparent, especially in light of recent advancements in AI and data science tools for scientific applications. These new techniques hold considerable promises not only for research communities but also for society at large. The potential for synergies is high for translational medicine, as seamless sharing and integration of diverse data sources would enable researchers to draw meaningful insights and accelerate the translation of scientific discoveries into tangible medical advancements and improved patient outcomes. It is crucial to strengthen the coherence of data infrastructures and services within the HLS Cluster, if Switzerland is to maintain its scientific excellence and ensure that citizens benefit from scientific progress in the HLS domain. Considering the critical intersection of research, technology, and public health within HLS, this prioritization underscores the StraCo's commitment to fostering breakthroughs and ensuring a healthier future for society. The cost of fragmentation and misalignment is too heavy to ignore, risking the erosion of Switzerland's scientific edge and missing out on valuable opportunities.

1.4 National Efforts and Current State of Discussion

The HLS cluster's fragmentation and difficulties to use health data for research has been acknowledged by both the Swiss healthcare sector and researchers, who notably underline the constraints posed by the current legal framework.

Several initiatives are underway to address issues with an aim to enable the reusability of data, for both healt research and for better understanding and improving healthcare policy, costs and performance. At least three seminal reports provide analyses of the landscape of clinical- and health research data infrastructures in Switzerland, each of them identifying shortcomings and suggesting solutions.

1. The Swiss Academy of Medical Sciences (SAMW) "White Paper: Clinical Research"[5] (2021) describes the achievements and challenges of major national initiatives, including those related to health data. It identifies the decentralized and fragmented Swiss clinical research landscape as a major obstacle for running efficient multicenter trials, observational studies and the production of interoperable data for research. The complexity of regulatory and data-related processes is identified as another major issue. The paper served to establish a coordination platform for clinical research (CPCR) by SERI,

[5] Swiss Academy of Medical Sciences (SAMS) (2021): White Paper: Clinical Research. In: Swiss Academies Communications 16 (4) (https://www.samw.ch/en/Projects/Overview-of-projects/White-Paper-Clinical-Research.html)

where the most important players in the field of clinical research in Switzerland are committed to the better coordination of all aspects of the competitiveness of clinical research in Switzerland.

2. "The SPHN Data Coordination Center (SPHN-DCC): Consolidating the SPHN infrastructures beyond 2024"[6] (2023) provides an overview of the SPHN-DCC's work at the end of two funding periods (2017-2023), along with the future development of the SPHN-DCC, as a "nationally coordinated infrastructure network, ensuring access to high-quality health data for research in Switzerland", focusing on secondary use of data, coordinated at a national level, in view of the examples from other countries. While the paper has successfully argued for the partial continuation and funding for 2025 by SERI, the long-term decision is yet to be made. To further develop data reuse in healthcare and in biomedical research, and to increase international competitiveness, the paper promotes the establishment of the National Center for Health and Research (NCHR). The paper also advocates for embedding SPHN-DCC and SPHN's regulatory, infrastructural, and procedural framework into the evolving national ORD strategies to increase synergies and avoid duplications.

3. The Swiss Science Council's so called Humbel report (2022)[7] explicitly addresses the optimisation of the re-use of health data to improve healthcare. This report forms the basis for Digisanté, a program of the Swiss Federal Council that aims to advance the digitalisation of healthcare in Switzerland.

These three publications, though tackling improved clinical research and better coordinated data systems from different angles, and highlighting diverse challenges, consistently point to common issues. The main hurdles include the absence of nationally coordinated, interoperable data systems with common standards, and lack of legal, ethical, and regulatory frameworks enabling access and re-use of sensitive data. Efficient use of health data for research requires successfully addressing these issues - as outlined in the following recommendations from the abovementioned reports:

- Facilitation of data interoperability and sharing through collection of data according to FAIR principles using a nationwide secure IT environment, in accordance with legal and regulatory requirements.
- Harmonization of ethics approval processes at a national level
- Creation of legal framework(s) that allow the re-use of health data through digital solutions for consenting (i.e., e-consent) and the use of unique patient and citizen identifier allowing to link clinical and research data of individual patients
- Establishment of interoperability of infrastructures, data, and metadata flows between and within institutions based on international standards; necessity to capture data in a structured and standardized manner with similar data standards for healthcare and research
- Creation of a national data coordinator for research health data
- Obligation for all publicly funded (clinical) research to adhere to standards and guidelines defined by the central coordination body for research health data
- Financial support

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[6] Swiss Personalized Health Network (SPHN) (2023): The SPHN Data Coordination Center (SPHN-DCC): Consolidating the SPHN infrastructures beyond 2024. In: Swiss Academies Communications 18 (4). DOI: 10.5281/zenodo.7919469

[7] Swiss Federal Council (2022): Mieux utiliser les données médicales pour assurer l'efficience et la qualité des soins (Humbel report, 4 May 2022), report following up on Humbel postulate 15.4225 of 18 December 2015 (https://www.admin.ch/gov/fr/accueil/documentation/communiques.msg-id-88631.html).

These reports and above-mentioned coordination efforts provide valuable points of reference for the ORD Task Force HLS, with the latter work placing the issues of fragmentation and coordination in the context of the implementation of the national ORD strategy. The three initiatives (CPCR, SPHN-DCC, Digisanté) that were established (or further supported in the case of SPHN-DCC) following the respective reports, are part of the current analysis.

While the work of the TF builds upon earlier findings, it distinguishes itself from previous efforts through its methodology and purpose.

The TF's methodology (see chapter 2) provides a cluster-wide view, which goes beyond individual initiatives and investigates how different research communities use available infrastructures and services across the entire data lifecycle. The landscape analysis dissects the multifaceted processes and relationships among actors in the cluster, enabling an in-depth exploration of the complex interactions, structures, and functions of data infrastructures and services within the cluster. To our knowledge, this is also the first comprehensive, cross-disciplinary report that examines both human (clinical) and non-human biology data infrastructures, using the same analytical tools. This approach allows the visualization of critical interfaces and facilitates the fruitful sharing of perspectives among stakeholders and researchers. Beyond the fragmentation of the landscape, the analysis also reveals varied extent of ORD practices and coordination among the research communities, providing valuable insights into the gaps between the perceived or understood FAIR practice by initiatives and the actual implementation in practice.

Through its embedment in the National ORD Strategy, this report also has a distinct function. It serves to provide material for pragmatic, cluster-wide decision-making by the Strategy Council, which is an unprecedented effort from the four national ERI actors (the ETH Domain, the Swiss Academies of Arts and Sciences, the Swiss National Science Foundation, and swissuniversities) to come together, share their perspectives and insights, and align to build coherence and efficiency throughout the research data ecosystem in Switzerland. The HLS cluster is thus treated as part of a wider ORD landscape. In sum, this landscape analysis, performed with an emphasis on national coordination opportunities, provides important insights and momentum for the StraCo and the stakeholders involved in the cluster to advance discussions addressing the technical, legislative, coordination, and support needs for health data towards strategic solutions and impactful outcomes.

1.5 Cluster analysis

The analysis of the cluster aims to offer a factual view on:

- an initial list of initiatives selected by StraCo and carefully supplemented by the Task Force active in the cluster (including the services and infrastructures they provide to researchers along the data lifecycle and with regard to ORD).
- the overall cluster dynamic, to understand more substantially how users navigate the services and infrastructures offered, how services and infrastructures interact with one another, how the existing facilities meet their needs, and to identify potential gaps and overlaps as well as bottlenecks for the coordination and development of the cluster.

Cluster analysis should offer a targeted partial representation of the ORD ecosystem that is neutral and inclusive. It should be recognised by the researchers and actors active in the cluster and facilitate engagement with them.

The cluster analysis methodology, described in the next chapter (2), was designed to take into account research data infrastructures (RDI) specificities: taking data and disciplinary clusters as a unit for analysis rather than individual RI, considering infrastructures and services across the whole ORD value chain (see Fig. 1), and focusing on interconnection between RDI, as an inherent part of the services they offer.

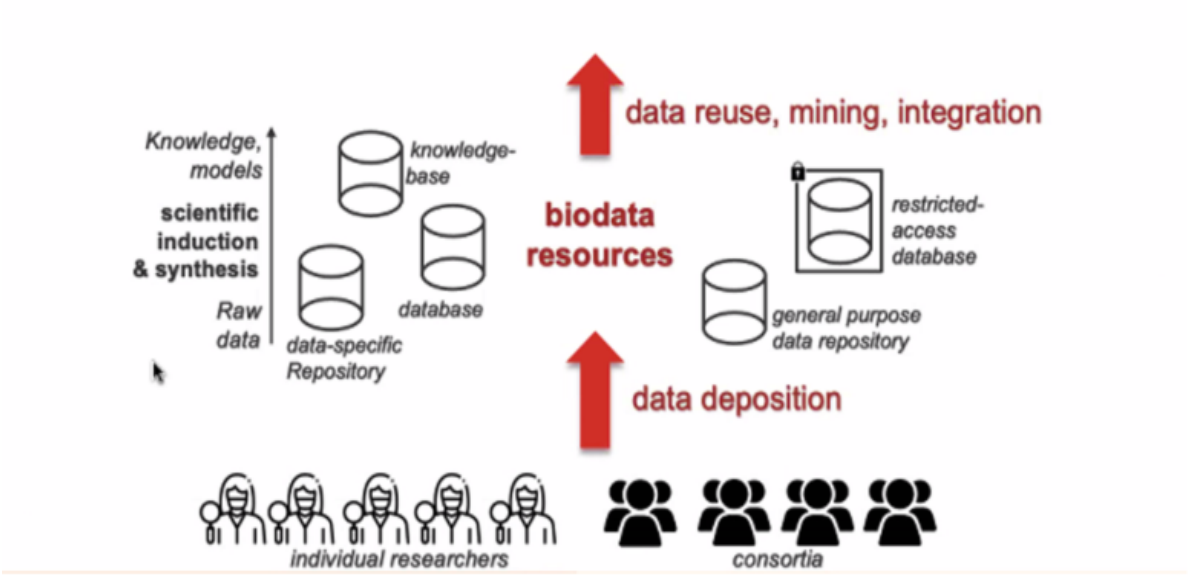


Fig. 1: Value creation in a disciplinary ORD cluster. This diagram was presented to the Task Force in the interview with C. Dessimoz from the Swiss Institute of Bioinformatics, with explicit approval for reuse.

1.6 Set up and composition of the Task Force Health and Life Sciences

The Task Force Health and Life Sciences (hereafter "the Task Force") has been mandated by the StraCo to conduct an analysis of the ORD ecosystem in the first prioritised cluster. The Task Force started its work in Autumn 2022 with 2 coordinators and 4 expert members. In April 2023, it was extended to 7 experts and a Chair[8] was appointed. An external scientific advisor was brought in to support the coordination team from October 2023.

Experts are researchers, technical experts, or administrators with expert knowledge in the cluster. Their role is to contribute to the development of the cluster analysis, by sharing knowledge, helping to collect and analyze data, contributing to drafting the report, conducting interviews, etc. Their objective is to ensure that cluster analysis is complete, credible, and relevant. Experts do not represent an initiative or an institution. By accepting their role, they commit to working in full independence and in view of the common interest of improving the research capacities in health and life sciences and in line with the principles of ORD.

The role of the Chair is to represent the Task Force to external stakeholders, with the aim that the work of the Task Force is legible and as open as possible, and that its analysis is accepted by stakeholders as a credible, common perspective of the cluster.

1.7 Initiatives as the starting point

The entry point in the investigation of the cluster for the Task Force is initiatives. They are defined as any organisation or network, providing research data infrastructures or services to researchers or academic institutions. The term initiative was versatile enough to accommodate the diversity of governance and financial structures of the service and service providers examined by the TF.

The StraCo first identified 8 initiatives to investigate, based on their national relevance and prominent position in the cluster. The TF complemented this list with 10 additional initiatives, as explained below. For instance, the TF decided to select two cohort studies (SHCS and STCS) as examples of SNSF longitudinal studies. Regarding the initial list, it quickly became clear that SSPH+ could not be understood as an initiative to provide data infrastructure or services to researchers. Nevertheless, the initiative has been included in the analysis because it has the potential to play a role in training medical staff in FAIR and open data in the future. When it comes to SDSC, its contribution to the cluster is evaluated from its specific activities in the health and life sciences vertical. The TF has also distinguished its current form ("SDSC") from its future design post 2025 ("SDSC+").

Original list in the mandate as specified by StraCo:

1. Swiss Personalized Health Network (SPHN-DCC)
2. Personalized Health and Related Technologies (PHRT)
3. Swiss Data Science Center (SDSC)
4. Swiss Institute of Bioinformatics (SIB)
5. Swiss Biobanking Platform (SBP)
6. Swiss Transplant Cohort Study (STCS)
7. Swiss HIV Cohort Study (SHCS)
8. Swiss School of Public Health (SSPH+)

Added initiatives:

9. Swiss Clinical Trial Organisation (SCTO). As the central national platform for patient-oriented clinical research, SCTO coordinates the cooperation between the clinical research centres (clinical trial units, CTU), building up a national, distributed clinical research infrastructure.
10. Swiss Group for Clinical Cancer Research (SAKK). The SAKK is the primary contact organisation for government authorities, professional associations, and pharmaceutical companies on clinical cancer research and acts as the Swiss service and competency center for multicenter trials in oncology.
11. University hospitals, research-driven hospitals, focus on Clinical Data Warehouses (CDW). In principle, any hospital or medical institution that obtains informed consent from their patients for their data to be used for research purposes is relevant to the cluster. The TF decided to consider the five university hospitals and focus on their CDW, developed in collaboration with SPHN and through which they manage routine clinical and health research data, as core infrastructures in the cluster.
12. Swiss Digital Pathology Initiative (SDPI). Along with the SBDe, SDPI was added as health and life sciences projects that are currently on the Roadmap for research infrastructures 2023?. Both projects explicitly include FAIR Data strategies for their communities and were seen as critical to taking the cluster to the next level of federated data for the sector in the coming years.

13. SwissBioData ecosystem (SBDe). See above.
14. Swiss Clinical Quality Management in Rheumatic Diseases (SCQM). Two industry- or pharma-funded disease-specific registries were added to the list in order to have the possibility to compare the two publicly funded disease-specific cohorts.
15. National Registry of Acute Myocardial Infarction in Switzerland (AMIS Plus). See above.
16. Swiss Federated Genomics Network (SFGN). Initiated by SPHN and PHRT, currently driven by the Genome Center, stands on its own feet and will be treated as an independent initiative. It is what Genomics England is to the UK and France Genomics to France.
17. National Coordination Platform Clinical Research (CPCR). Recent and emerging coordination initiatives were incorporated into the analysis due to their potential structuring effects on the cluster.
18. FOPH/FSO Initiative for digital transformation of health system and interoperable health data (Digisanté). See above.

1.8 The mandate

The StraCo's mandate to the Task Force lists questions to be answered for each initiative in order to investigate their position and interaction in the cluster. The Task Force has applied this list of questions unchanged to all initiatives in the list above.

1. What services and infrastructure do they effectively provide, and who are their beneficiaries/customers/users? What do they plan to develop?
2. What is their governance model? What coordination mechanisms with other Swiss and/or international initiatives, if any, are in place? What organisations are responsible for the initiative, and how are they funded?
3. Do they comply with the guiding principles and objectives for the ORD Strategy (sections 3 and 4 of the Strategy)?
4. To what extent do they currently meet the needs of the targeted research community? To what extent could they meet these needs in the future in view of the planned developments?
5. Are there research communities or research needs relevant to the cluster that are not served by existing initiatives?
6. What are the main international initiatives in the cluster?

2. The Task Force Methodology

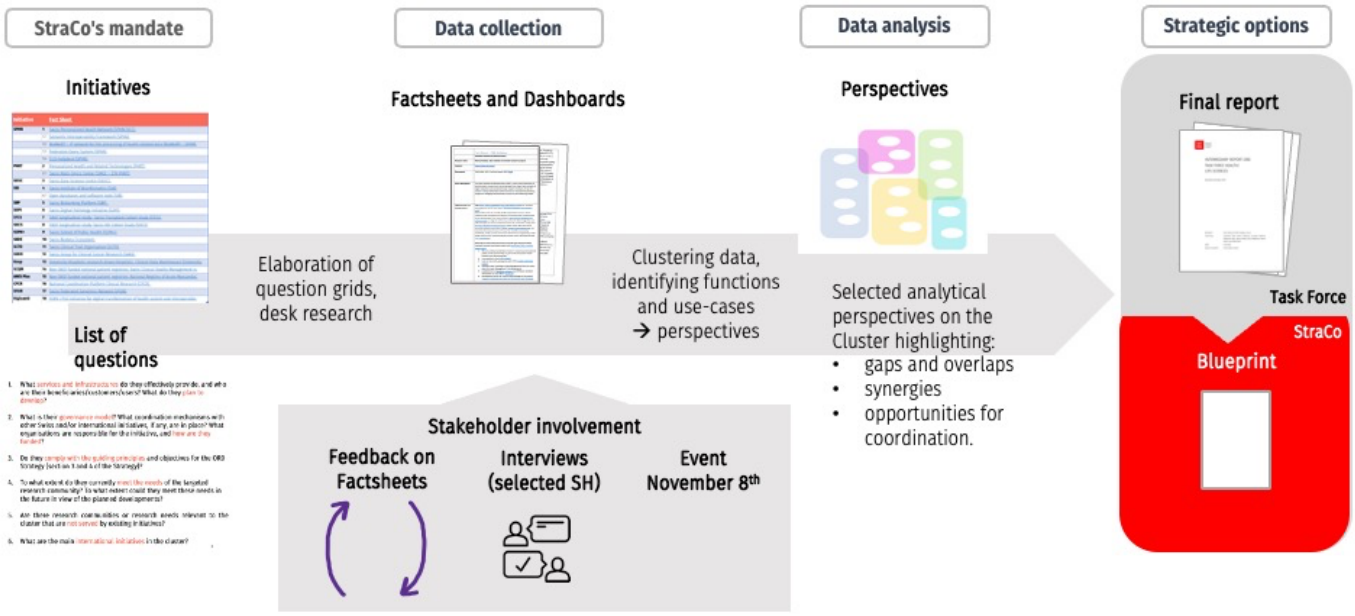


Fig. 2: The Task Force Methodology

The analysis starts with identifying key initiatives active in the cluster (section 1.7) and compiling information such as the infrastructures and services they provide as well as their governance and funding models. Data is compiled in Factsheets (section 2.1) that serve as factual references, and that are used to feed into initiative Dashboards (section 2.2). These Dashboards summarise the Factsheets in a succinct yet comprehensive overview avoiding conclusive content. Factsheets and Dashboards together with information received from stakeholders in eight interviews (section 2.4) are the basis for the Task Force's mapping exercise to understand the internal dynamics of the cluster and its relationships with the ORD ecosystem.

Due to its complexity, the Task Force chooses to visualise the interactions of initiatives, services, infrastructures, and actors through a set of perspectives (section 2.3). Perspectives offer an analytical lens on specific issues that are relevant to identify and highlight gaps, overlaps, and synergies between the ORD infrastructures and services provided by the initiatives and to understand where the opportunities for coordination are.

In the following sections, the different steps of the methodology are presented in sequential order.

2.1 Factsheets

The questions raised by the mandate (see Section 1.8) are meant to be answered mainly through secondary data such as the initiatives' websites, and their reports. For some initiatives, the information is supplemented by data from interviews conducted with representatives or experts (see section 2.4).

For each of the 18 initiatives investigated, the Task Force has compiled a document providing essential details and key facts about the initiative, called a factsheet. They serve as a reference guide for the Task Force throughout its analysis of the Cluster and contain the following information: type of research data handled, ORD services and infrastructures, access policy, beneficiaries/users, development plan, governance model, funding, alignment with the National ORD strategy, involvement of the targeted research communities, and coordination with national and international initiatives.

Some initiatives were too multi-modal to be analysed through a single Factsheet and were therefore split into separate Factsheets to capture their various aspects. It is the case of SPHN, with four separate factsheets (1. Semantic Interoperability Framework, 2. BioMedIT – IT network for the processing of health-related data, 3. Federated Query System, and 4. ELSI-helpdesk).

2.2 Dashboards

The information gathered from initiatives in Factsheets is showcased in the final report through Dashboards. Dashboards facilitate cluster analysis and comparison between initiatives by offering a condensed overview of initiatives' main characteristics. The Dashboards are organised along the questions asked in the mandate.

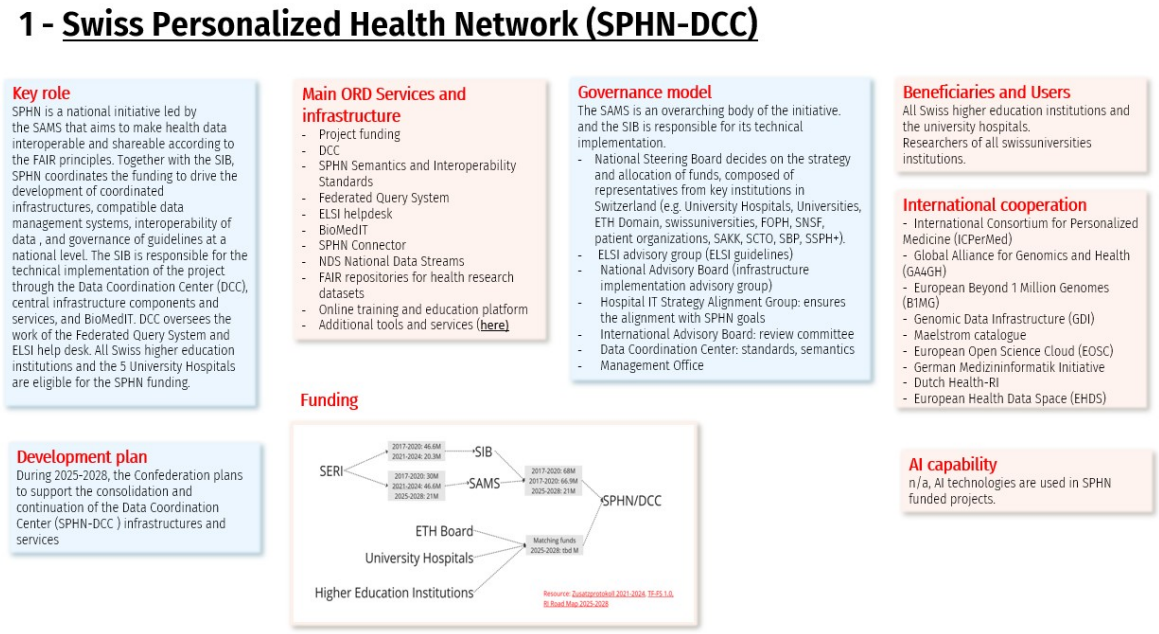


Fig. 3: Example of a dashboard.

2.3 The concept of Perspectives

After gathering individual data on the various initiatives operating in the cluster through Factsheets and Dashboards, the aim is to make sense of this information at the cluster level: what is the position of these initiatives, and what does the provision of ORD infrastructures and services within the cluster look like?

The Task Force used "Perspectives" as a methodological tool to delve into the cluster. A Perspective serves as a viewpoint, a 'lens' among others on the cluster. It allows a focused, in-depth understanding of what is happening in the cluster, answering the questions of 'who does what and for whom.' A distinction is made between two types of perspectives. "Structural perspectives" act as a framework for the analysis by providing an overview of the structural elements of the cluster: the initiatives' mandates (Fig. 5 and 6), funding (Fig. 7 and 8), and key ORD-oriented infrastructures and services (Table 2). "Thematic perspectives", illustrated through Unified Modelling Language (UML) diagrams (see below) provide an analytical view of the operationalisation of the FAIR research data principles in the cluster (one diagram per aspect), as well as coordination mechanisms and international relationships.

Structural Perspectives	
1	Initiatives' mandates
2	Available Funding
3	ORD-oriented services and infrastructures
Thematic Perspectives	
4	Findability
5	Accessibility
6	Interoperability
7	Re-Use
8	National Coordination
9	International cooperation

Table 1: List of perspectives (all perspectives are available and commented in section 4 of this report)

All perspectives were identified based on key questions from the mandate, present in the Factsheets and dashboards. Additional perspectives emerged from discussions with stakeholders, highlighting activities with a significant impact on the entire cluster. This fact emphasizes that the perspectives employed by the Task Force do not represent exhaustive, definitive overviews of the cluster, but rather are used as tools to guide discussions towards improved collective understating of the cluster.

It is important to note that, like any modelling exercise, despite efforts for completeness, perspectives inherently provide a schematic and somewhat simplified view of reality. Nonetheless, they remain a valuable analytical tool for the StraCo and the stakeholder community in a landscape analysis of clusters.

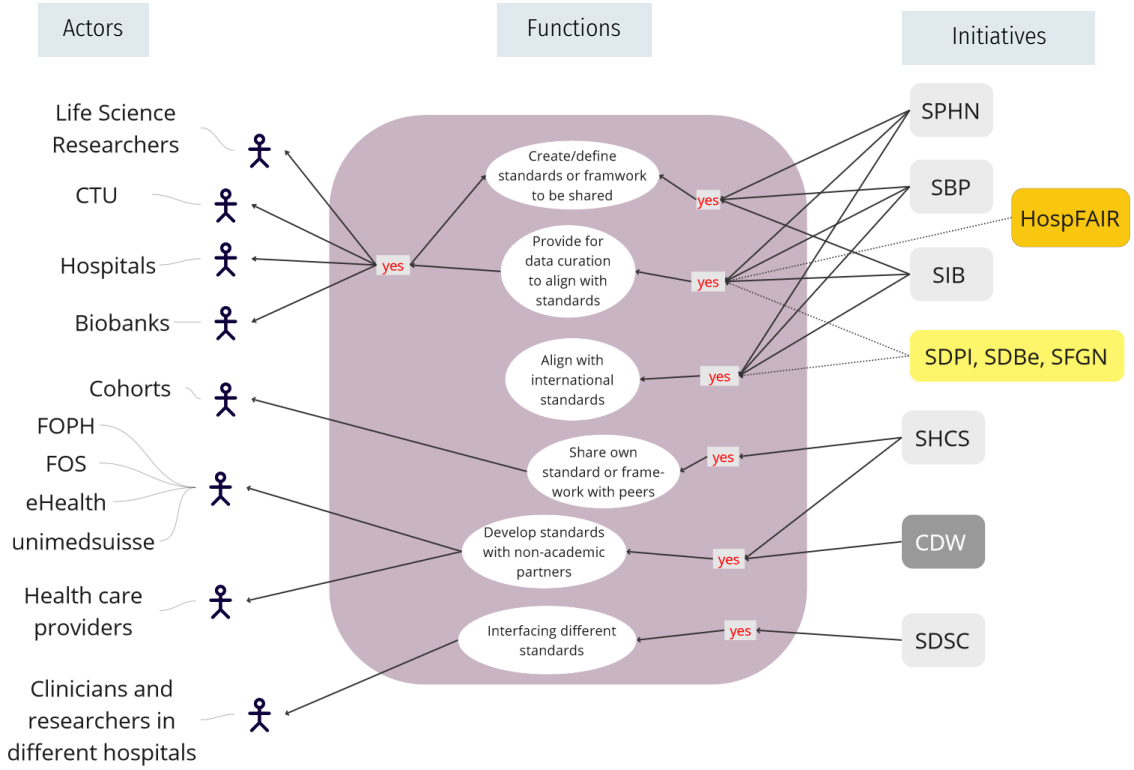


Fig. 4: Example of a 'perspective' (Interoperability). How to read: SPHN, SBP, SIB (initiatives in the right part of the diagram) create/define interoperability standards or framework (function in the middle part of the diagram) in collaboration with life science researchers, CTUs, Hospitals, and Biobanks (actors in the left part of the diagram).

2.4 Stakeholders' involvement in the process

Stakeholders are involved in the process through three different activities:

- Feedback on Factsheets. To ensure the quality and actuality of information, each Factsheet underwent review by the corresponding initiative representative and was then validated by the Task Force member who assumed responsibility for the individual factsheet[9].
- Interviews. To better understand the dynamics and relationships in the cluster, the Task Force has conducted eight interviews with representatives from initiatives and individual experts, either because they were major players in the cluster or because their roles required clarification. There have been two interview phases (see Annex 2).

[9] Consequently, Factsheets also serve as a tool to see how initiatives portray themselves. The Task Force acknowledges that Factsheets may be biased due to the involvement of initiatives, presenting them more favourably. This bias is especially noticeable when assessing how initiatives align with the ORD principles and objectives of the National Strategy. To counter this, the task force has monitored the original Factsheets (before initiatives' reviews) throughout the analysis.

- Stakeholder event. On November 8th, a workshop convened 35 stakeholders, aiming to introduce them to the Task Force's work and solicit feedback on both the methodology and proposed cluster perspectives. The stakeholders actively engaged with the Task Force, with the perspectives serving as a valuable tool to stimulate discussions and gather insights. Notably, there was a demonstrated willingness to sustain the conversation, a noteworthy observation for the Task Force regarding the cluster dynamics.

3. Perspectives on the cluster

3.1 Cluster Perspective: Initiatives by mandate

As a first incursion into the cluster, the Task Force initially sought to chart initiatives based on their governance structures (Fig. 5). While such depiction is helpful for visualising legal structures and responsibilities, it was considered limiting in uncovering opportunities for coordination.

The only notable aspect that such grouping along the legal structures of the initiatives might provide is that CDWs occupy a special position. They are categorised as research infrastructures, yet their governance does not align with established governance principles in research, unlike other research initiatives such as SDSC or PHRT, which are integrated into academic (publicly-funded) structures. This also implies that ERI stakeholders lack direct leverage to persuade hospitals on data governance. A coordinated strategy placing hospitals and subsequently other healthcare institutions at the beginning of the ORD value chain (see Fig. 1) as core producers and suppliers of health research data will have to be pursued through legal channels.

Since no obvious link can be made between the legal structure of an initiative and the organisation of its data services and infrastructures, the Task Force proposed an additional mandate-based view on the cluster, in which the individual initiatives are summarised according to their research data focus (Fig. 6):

- patient data-specific research data (clinical study units, research projects, data warehouses, biobanks)
- diagnostic or bioinformatic-specific research data (analytical, imaging, genomics platforms)
- diseases-specific data (consortia, cohorts, registries)
- coordination-oriented initiatives

This approach builds on precedent efforts in the field and notably on the SAMS' White Paper for Clinical Research in which the integration of clinical research units is outlined similarly[10]. Our categorisation aims at providing a structuring way of looking at the cluster. As such, the color coding used in Fig. 6 is carried over into the perspectives that follow.

[10] SAMS, Ibid., p.18

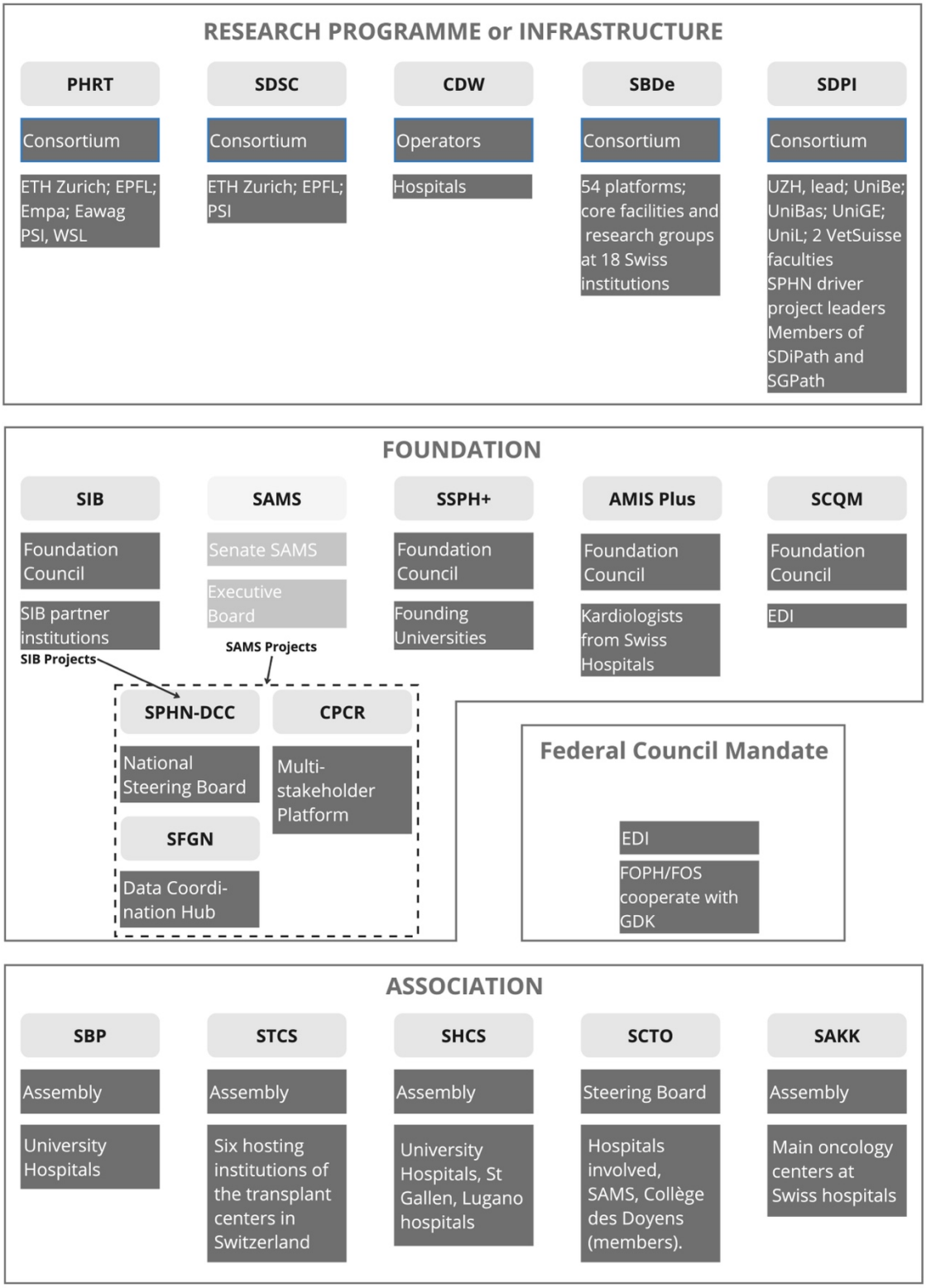


Fig 5. Legal structures and main beneficiaries of initiatives in the cluster, as per their mandates

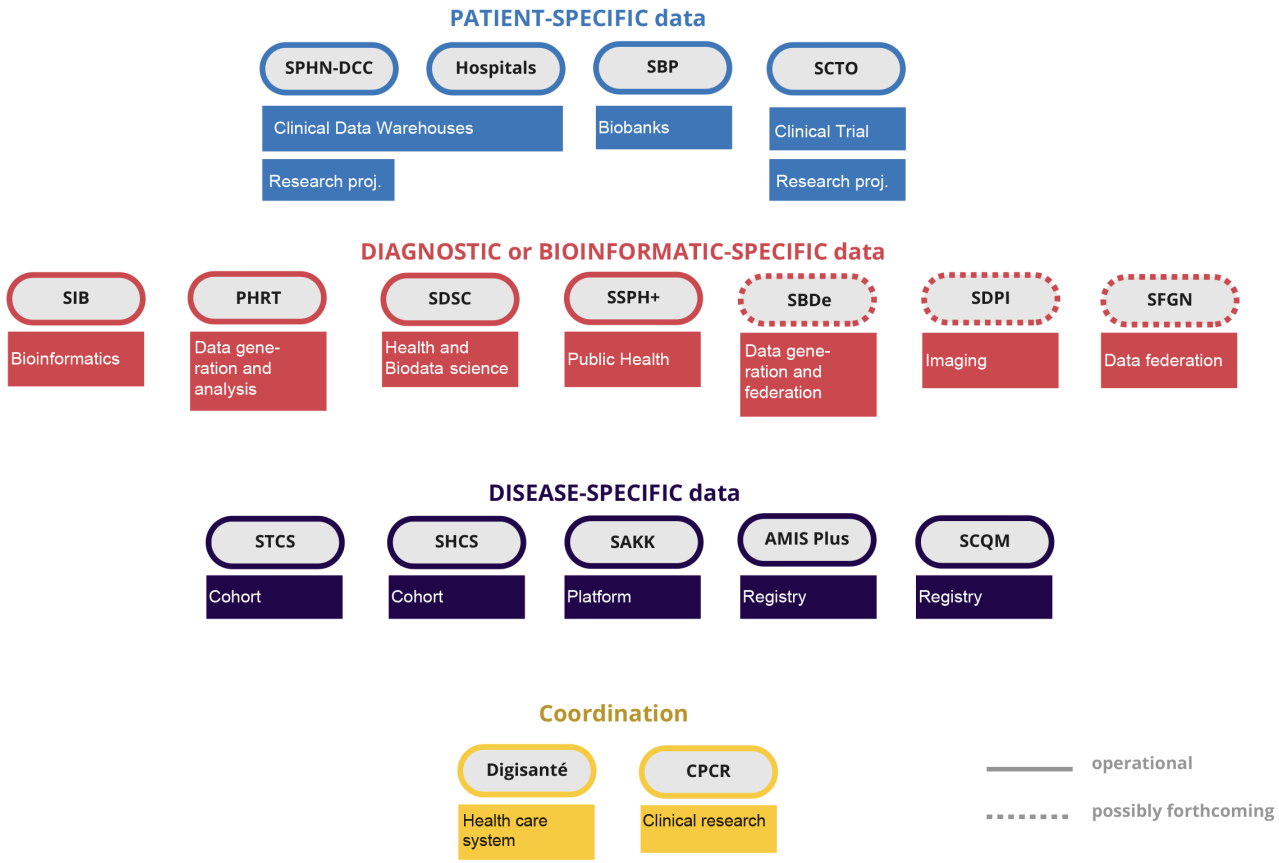
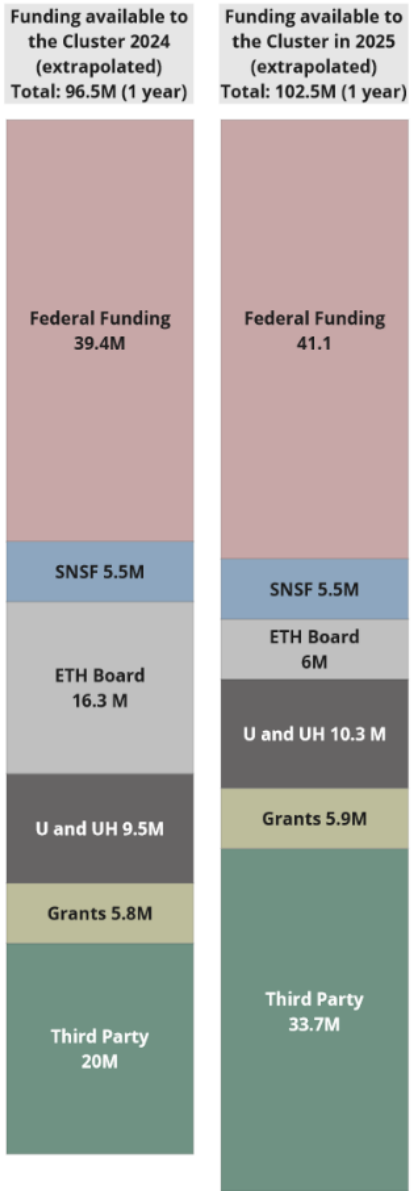


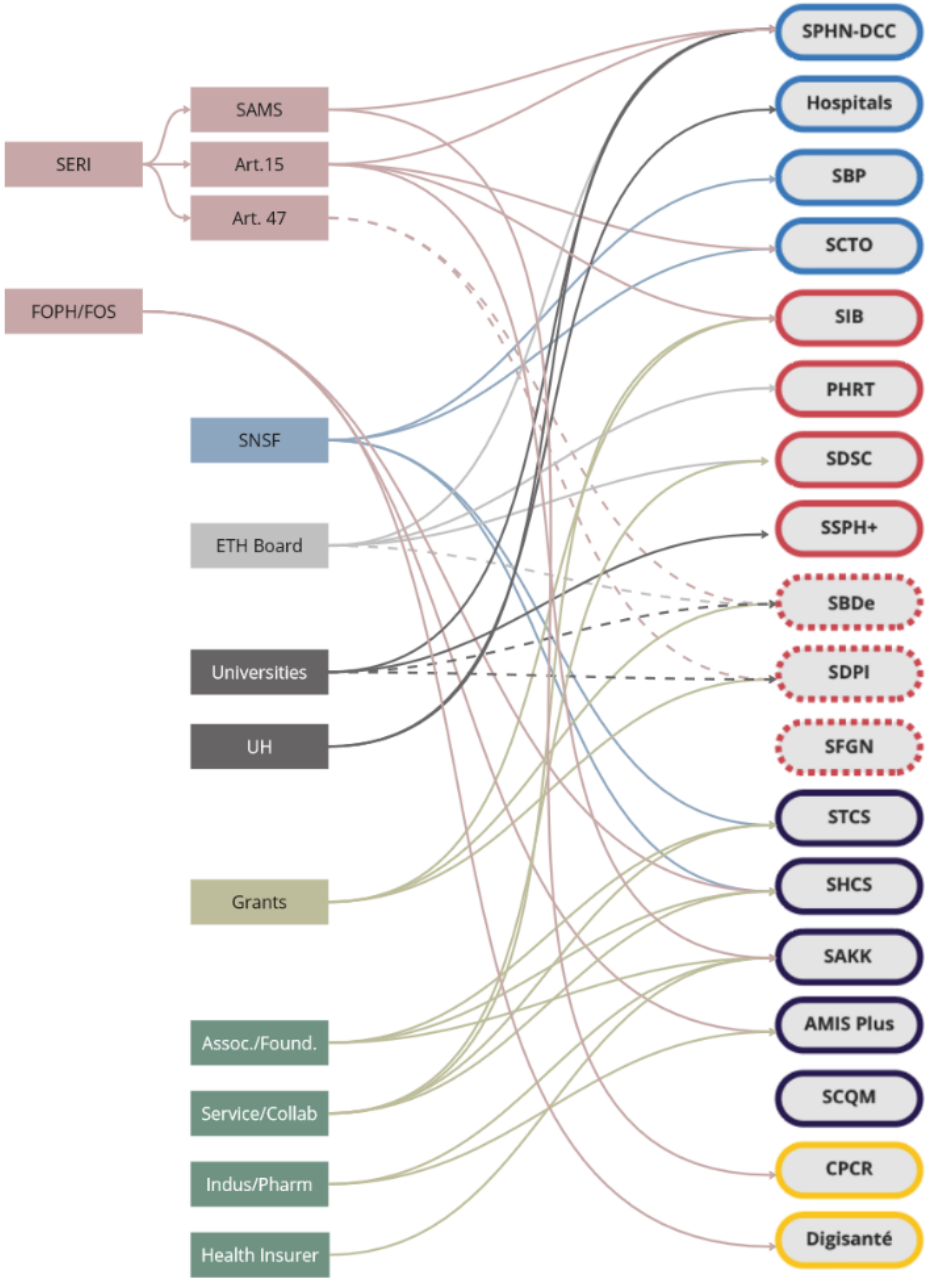
Fig. 6. Classification of the initiatives in the cluster based on their primary research data focus, as per their mandates.

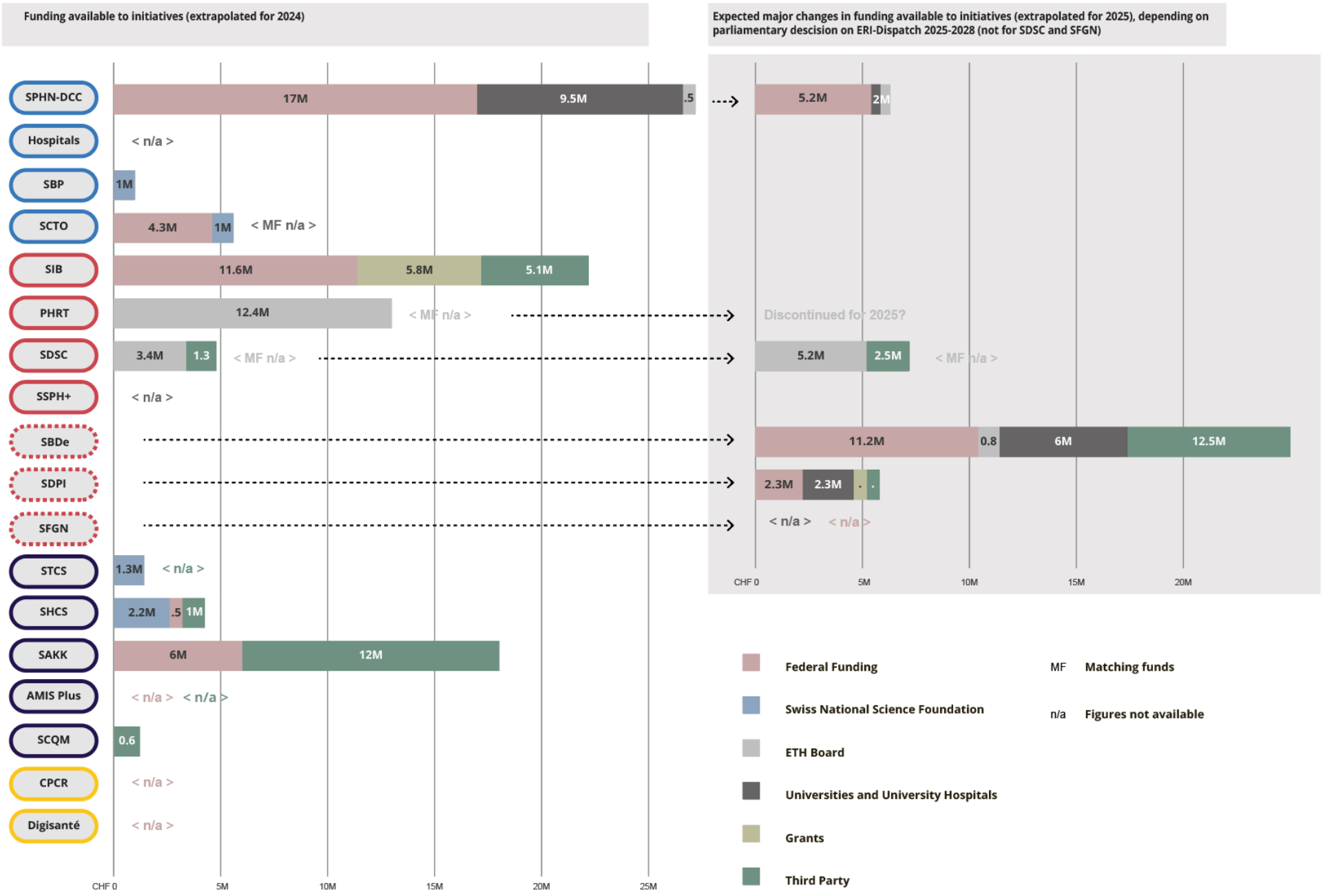
3.2 Structural Perspective: Funding available to the Cluster and the initiatives

The following figures map out the funding streams in the cluster, as a whole (Fig. 7) and from funders to individual initiatives (Fig. 8). The figures for 2024 have been extrapolated by the Task Force according to the information provided by the initiatives. The changes that can be assumed for the first year of the 2025-2028 funding period are also shown. The analysis of these complex funding streams allows for the formulation of a first set of opportunities for coordination.

On the next two pages:
Fig. 7: Funding available to the cluster (extrapolated for 2024 and 2025, for colour code of initiatives see Fig. 6)
Fig. 8: Funding available to initiatives (extrapolated for 2024 and 2025, for colour code of initiatives see Fig. 6)


Funding available to the Cluster 2024 (extrapolated) Total: 96.5M (1 year)
Federal Funding 39.4M
SNSF 5.5M
ETH Board 16.3 M
U and UH 9.5M
Grants 5.8M
Third Party 20M
Funding available to the Cluster in 2025 (extrapolated) Total: 102.5M (1 year)
Federal Funding 41.1
SNSF 5.5M
ETH Board 6M
U and UH 10.3 M
Grants 5.9M
Third Party 33.7M


SERI
SAMS
Art.15
Art. 47
FOPH/FOS
SNSF
ETH Board
Universities
UH
Grants
Assoc./Found.
Service/Collab
Indus/Pharm
Health Insurer
SPHN-DCC
Hospitals
SBP
SCTO
SIB
PHRT
SDSC
SSPH+
SBDe
SDPI
SFGN
STCS
SHCS
SAKK
AMIS Plus
SCQM
CPCR
Digisanté


Funding available to initiatives (extrapolated for 2024)
Expected major changes in funding available to initiatives (extrapolated for 2025), depending on parliamentary descision on ERI-Dispatch 2025-2028 (not for SDSC and SFGN)
SPHN-DCC
17M
9.5M
.5
5.2M
2M
Hospitals
< n/a >
SBP
1M
SCTO
4.3M
1M
< MF n/a >
SIB
11.6M
5.8M
5.1M
PHRT
12.4M
< MF n/a >
Discontinued for 2025?
SDSC
3.4M
1.3
< MF n/a >
5.2M
2.5M
< MF n/a >
SSPH+
< n/a >
SBDe
11.2M
0.8
6M
12.5M
SDPI
2.3M
2.3M
SFGN
< n/a >
< n/a >
STCS
1.3M
< n/a >
SHCS
2.2M
.5
1M
SAKK
6M
12M
AMIS Plus
< n/a >
< n/a >
SCQM
0.6
CPCR
< n/a >
Digisanté
< n/a >
CHF 0
5M
10M
15M
20M
25M
Federal Funding
Swiss National Science Foundation
ETH Board
Universities and University Hospitals
Grants
Third Party
MF Matching funds
n/a Figures not available

Description

The figure shows the funding movements across the cluster in 2024. An extrapolation of the funding information received from initiatives amounts to a total of 96.5M (millions of Swiss francs) in funds available in the cluster. This amount should be treated with caution, as some of the initiatives (such as SCTO) use their funding in the health/life science area not only for data purposes. Nearly 40% of the total are federal funds (39.4M), with SERI being the main contributor. FOPH/FOS contribute a small proportion to the cluster. The contribution from SNSF to STCS, SHCS, and SBP amounts to 5.5M, and that of the ETH Board to PHRT and SDSC of 16.3M. In addition to federal funds, 9.5M (mostly in- kind contribution to projects) are contributed by the Universities, 5.8M research funding, and 20M from third parties were channelled into the cluster. 2024 is the last year of the 2021-2024 funding period. Some developments are already foreseeable for the 2025-2028 period, as seen in the extension of Fig. 8. For example, a federal contribution of 21M is planned for SPHN-DCC for the entire period, which would amount to approximately 5M per year if evenly distributed over the four years (that would be 12M less federal funding than in 2024). The future of PHRT is uncertain, it might discontinued or be integrated into another initiative, while the SDSC will receive more funding from ETH Board). SDSC expects also that it will receive more third party funding. In addition to the expansion of the SDSC, it is noticeable that the SBDe will occupy a prominent place in the cluster funding in 2025. It is also included in the ERI Dispatch (budgeted total contribution: 30.5M per year).

Relations with industry and the private sector exceeded the scope of the Task Force's mandate and have not been a focus of the cluster analysis. The third-party funding in the figure (20M for 2024 and 33.7M for 2025) corresponds to what was declared by the initiatives as part of their budget. However, foundations and industrial stakeholders have recently undertaken initiatives securing substantial funding, reaching into the hundreds of millions. Third-party funding is therefore underrepresented in this account of funding in the cluster.

Analysis

The current organisation of funding strongly contributes to the fragmentation of the ORD service and infrastructure landscape. Present research infrastructures have been historically grown from different strategies of different stakeholders. The RI landscape of today is fragment, as shown by the current organisation of funding. The two maps together illustrate this fragmentation. The Federal Office of Public Health is funding SHCS but not STCS. SERI funds SIB, but not SBP, which in turn is funded by the SNSF. If multiple relevant projects are funded from multitude of funders, there is a risk that they have no or less motivation to be interoperable with the neighbouring projects. But what is behind this fragmentation? One reason is the time limit on project funding and the financing of infrastructures by public funders over funding periods (e.g. four-year). After the end of a project or a funding period, the funding is not necessarily renewed, or it is reduced after the initial development phase; the operators

of a research data infrastructure then look for other public sponsor or turn to private investors. Funders are following their own financial strategies, defined in multi-year plans. With each new plan, priorities may change and funding of specific research infrastructures may diminish or stop. However, fragmentation is not as linear as it looks here; it also occurs in a cycle. While the funding agencies only commit themselves to a data infrastructure for a short period of time thus denying themselves the opportunity to influence the development of an infrastructure in the longer term, it can also benefit scientific freedom and creativity, that are often seen incompatible with regulatory aspects that a long-term data governance strategy would entail (e.g. mandatory implementation of interoperability standards, no free choice of repository).

However fragmented the funding situation in the Cluster is, there are also regularities. For example , the two cohorts SHCS and STCS are at least partially funded by public funders and third parties. Coordination is possible here, as initiatives can be brought together by a funder to develop a problem-oriented solution aiming to achieve data sharing beyond the participating and other financing institutions. SNSF provides a good model for this type of data regulation request with SBP. SNSF has defined SBP as being a coordination platform for biobanking activities, with link to the international Research in the field (BBMRI). The development of SBP is set by an agreement with the SNSF, where the interests of both are defined in terms of goals and milestones to reach. The hand in hand collaboration allows flexibility and "political support" for SBP. It is in the best interest of SNSF to focus not only on commitments made in project applications but collaborating with initiatives by producing tangible outputs and holding them responsible for implementing ORD & FAIR principles.
The figures showing the funding available to initiatives and to the entire cluster clearly show the funding complexity of data infrastructures which represents a risk for the sustainability of infrastructures. The coordination of ORD initiatives requires time and effort, which implies that the initiatives have to perdure in the mid- to long-term. It is important that funders also join forces in common strategic goals for ensuring the sustainability of the infrastructures and the implementation of the ORD strategy.

<u>Opportunities for coordination</u>

1. Fund ORD related tools and activities to make services and infrastructures more competitive nationally and internationally (e.g. Genomic Center, FQS, etc.). Some dedicated funds (e.g. ETH Domain) would also benefit from coordinated approach to spending.
2. Provide specific rules for research data management that initiatives should abide by to receive funding from:

- SNSF (direct funding)
- SNSF (project funding)

- SERI funding through Art. 15
- ETH Board and Universities (matching funds)
- RI Roadmap: all funding for the start-up, maintenance, and expansion of Research Data Infrastructure (RDI) should be made contingent upon the continuous adherence to the agreed-upon ORD requirements of public funders.

3. Use the StraCo partnership of ERI Actors to collaborate on a common set of ORD requirements for initiatives, services and infrastructures
4. Work with a catalogue of requirements not only to be responded to in funding application. Use SBP labelling of biobanks as an example of a funder who is participating in implementing ORD requirements. Use follow-up financing of an initiative as a steering instrument

3.3 Structural Perspective: Key ORD and FAIR-oriented services and infrastructures

Table 2: ORD and FAIR-oriented services and infrastructures (see Fig. 6 for colour codes of initiatives; (x) = in planning)

Initiatives	Research Data competencies				Services along the ORD Value Chain								Additional services and capabilities supporting ORD and FAIR RDM						
	Health data (clinical)	*Health data (omics)*	*Biodata (non-human)*	*Samples*	Data generation	Data Standards production	Data curation	Health data hub, repos., database	Biodata hub, repos., database	Query & Catalogue	Safe Data Processing	Data analysis capacities	International collaboration	Project funding	Education/training	AI related technologies	Patient participation	Regulatory, legal guidance	National Coordination.
SPHN-DCC	x					x	x	(x)[a]		x	x	x	x	x	x	(x)[b]	x[c]	x	x
Hospitals	x				x		x	x											(x)[d]
SBP	x		x	x	(x)[e]	x	x	x		x			x		x				x
SCTO	x				(x)[f]								x		x		x	x	x
SIB			x			x	x		x	x		x	x		x	x			
PHRT	x	x			x			(x)[g]				x	x	x		(x)[h]			
SDSC	x	x	x				x				x[i]	x	x	x	x	x		x	(x)[k]
SSPH+															(x)[l]				
SBDe			x		(x)[m]	x	x		x			x	x			x			x
SDPI	x		x	(x)[n]		x	x	x				x	x			x			
SFGN		x				x	x	x		x			x						
STCS	x			x	x		x	x		x		x	x		x		x	x	
SHCS	x			x	x	x	x	x		x			x		x		x		
SAKK	x				x		x	x					x				x	x	x
AMIS Plus	x				x			x				x	x						
SCQM	x			x	x			x					x						
Digisanté						(x)													x
CPCR																			x

Notes for Table 2	
a.	SPHN/PHRT funded National Data Streams that establish FAIR platforms for mobilization and re-use of rich research datasets. SPHN plans to establish a Swiss federated EGA node for human genomic data and a national repository for phenotypic FAIR research data sets.
b.	PHRT/SPHN funded projects use AI technologies
c.	Patient organizations' representative (e.g. ProRaris) is a member of the SPHN national steering board
d	The heads of the CDWs participate in the SPHN HIT-STAG board (Hospital IT Strategy Alignment board) in charge of aligning SPHN IT decisions between the five university hospitals
e	SBP does not generate data. It collects and makes metadata related to samples of participating biobank network, available to researchers and biobanking community.
f	SCTO does not generate data. Data is generated by the CTUs or by the research projects that run clinical trials
g.	See note a
h.	See note b
i.	At the time of the publication of the report it was unclear whether the Swiss Data Custodian by the SCSC was already operational of still in planning
k.	As part of SDSC+, a community steering committee is envisaged to define the needs of the community and to also provide coordinating efforts
l.	At the time of the publication of the report it was unclear whether SSPH+ provides general biomedical or ORD focussed training.
m.	Data are generated by the participating platforms

Description

The third Structural Perspective provides an overview of what each initiative provides in terms of ORD and FAIR services and infrastructures for the research communities, based on the Factsheets compiled by the Task Force and complemented by the initiatives' representatives. This offer is sorted along three questions: 1) which data types does the initiative cover? 2) how does the range of services and infrastructures relate to the individual stages of the ORD value chain? 3) which additional FAIR and ORD services does the initiative offer outside of that ORD value chain? The initiatives are sorted according to their research data focus (see Structural Perspective 1, section 4.1). The table also includes three "forthcoming" initiatives (SPI, SBDe, SFGN), indicating their potential emergence post-2025. For all initiatives, the table distinguishes between currently offered services and those that are planned.

Analysis

It is through this perspective that the fragmentation within the cluster, mentioned in the introduction, becomes most apparent, with research infrastructure and services available in the cluster being heavily splintered. Notably, there is a certain degree of coordination in service and infrastructure provision among patient data-orientated initiatives (in blue), which is understandable as SPHN-DCC, SBP, and SCOT all offer National Coordination services (see last column of the table). Individually, there is coordination between biobanks, CTUs, and CDW. For the CTUs coordination exists (through SCTO), but data is not the main focus. Otherwise, the table shows that each initiative tailors its services and infrastructures to its own needs and serves its own specific community. There are elements of cooperation but no coordinated action. This is particularly evident in the disease data-oriented cohorts and registries (in purple). Each of these initiatives possesses distinct data registration, repository, and search/query tools, forming genuine data silos. It should be emphasised that this focus on the needs of members also has to do with the fact that observation and research on specific diseases also require specific data configurations (structures, annotation, metadata). The infrastructures and services of one initiative cannot be transferred to another one as is. Cross silo infrastructures and services would have to be specifically designed. This consideration extends to data protection as well. Consent forms are obtained specifically for patient data to be entered and used in the specific registry or cohort, which makes the exchange of data, services, and infrastructures even more difficult.

In this context, evaluating the strengths and weaknesses of existing infrastructures and services is not considered a viable tool to reduce the complexity and fragmentation in the cluster and to coordinate the offer of initiatives. Such an assessment of gaps and overlaps among initiatives would indeed overlook the data-specific qualities crucial to their respective thematic fields and communities. This approach would not be considered helpful by the initiatives and their sponsors, nor by the main actors and data owners, doctors and patients, involved.

The thematic perspectives that follow provide an in-depth view of the operationalisation of the FAIR research data principles in the cluster, as well as coordination mechanisms and international relationships. They are not merely a snapshot but also serve as a tool for actors to recognize their role in the “who does what, how, and for whom” within the cluster. Perspectives are a useful tool to see where the opportunities for coordination emerge, in the sense of areas of attention or concrete propositions for the StraCo to devise strategic options for the cluster in cooperation with stakeholders.

3.4 Thematic Perspective: Findability

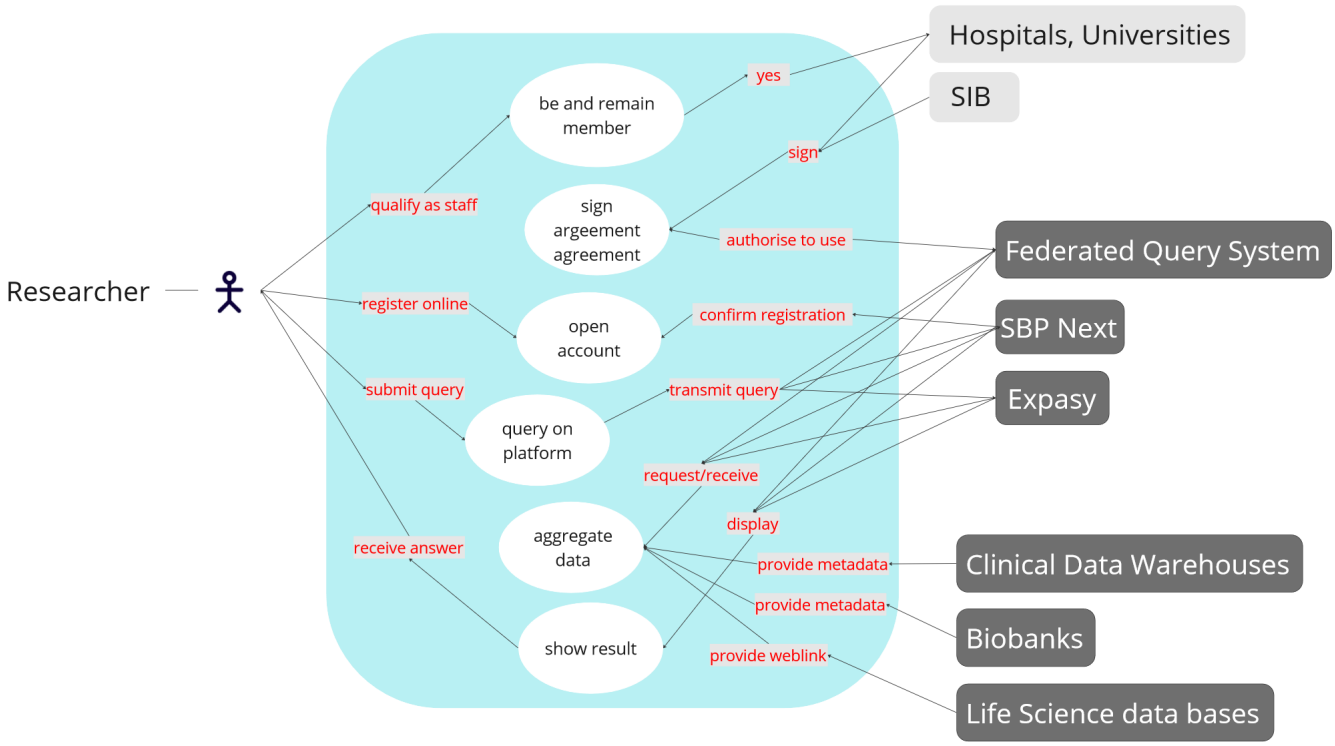


Fig. 9: Findability in the Cluster

Description

Within the cluster, three portals enable researchers to search for research data across multiple data resources, including CDW, Biobanks, and Life Science Databases, rather than one single data location: Expasy, the NExT catalogue and the Federated Query System. Researchers can submit queries to get information about what data is available, where this data is to be found, and for what purpose it can be used. Each portal is organised differently and specialized in a specific type of data.

Expasy (www.expasy.org), the Swiss Bioinformatics Research Portal is a website with a search function that is publicly accessible and contains 160 life science databases and software tools. Expasy redirects the user not to data but to the websites of the respective databases.

The sample catalogue called NExT (https://swissbiobanking.ch/next-biobanks/) is a biobank catalogue with a dual purpose of serving as a platform for biobanks to showcase themselves and enabling researchers to discover and access samples from these biobanks. The catalogue

is connected to the BBMRI-ERIC Directory at the European level (Biobanking and Biomolecular Resources Research Infrastructure), allowing to extend search and access to biobanks beyond Switzerland. Everybody (including the public) can open an account, which is required to obtain details from individual biobanks. Biobanks in the SBP NExT can choose to restrict data to specific user groups independently.

The Federated Query System (SPHN) (https://sphn.ch/fqs/) is an information retrieval system enabling researchers to query and search for fully anonymised clinical information across all five university hospitals while allowing the hospitals to retain full control over their data. The FQS does not directly make data available, it enables researchers to see where potential data for their study idea are located. FQS can be accessed through the BioMedIT portal by researchers from institutions that have an agreement with SIB. These are currently all Swiss University Hospitals, their associated cantonal universities, ETHZ, and EPFL, with additional institutions having the possibility to join later. The system enables researchers to verify the feasibility of their project and it allows the design and optimization of inclusion and exclusion criteria for study protocols without transferring any patient data.

Analysis

Improvements are needed in findability to increase transparency about what data are available and under which conditions, also for researchers who are not directly linked to a specific initiative. A starting point might be an information portal or website to provide guidance and links on how and where data is available and how researchers can go about finding research data.

The data-specific focus of the three search functions mentioned above is not seen as a disadvantage. Rather, the existing search tools should be improved by developing their access to data hubs and databases. SBP NExT plans on accessing the Clinical Data Warehouses to gain information on the availability and quality of samples in hospital biobanks. Integrating clinical data and samples is a promising endeavor for research. The Task Force considers the Federated Query System (FQS) to be a step in the right direction. While the system is federating across institutions, its functionality is governed by a central entity, in this case the SPHN-DCC. The University Hospitals made efforts to comply with the SPHN Semantic Interoperability Framework such that the information on their data is compatible with the FQS. This may have been inspired by the practices of the US National Institute of Health (NIH) and National Library of Medicine (NLM) which are running a top-down approach by maintaining these resources for the entire scientific community in the US and international collaborations. TI4Health is a follow-up to the FQS, which enables federated analytics, that is the analysis of data without having to move data out of the hospitals' CDW.

Findability does not limit itself to a technical dimension and has an important organizational component. It was stressed, that we need to distinguish queries that can be made only by

"members" of an initiative from queries that can be made by every outside researcher. Sometimes a simple registration, but no formal membership may be required. While some collaboration exists between these initiatives (e.g. SBP and DCC), a closely coordinated expansion of this area is recommended together with future initiatives involved in the development of additional or complementary data management processes (e.g., SDSC, SDPI, SBDe), to avoid potential redundancies and ensure the robust core competences in finding and accessing data at national level. A discussion and alignment with the planned Digisanté initiative will also be important to understand the coordination needs around research data.

Opportunities for coordination

1. Increase awareness and information sharing around the availability of data. A lot of users do not know what data is available and where to find it. The FQS is seen as a good medium for this. Having many different people looking at the same data will improve not only the understanding of the data, but its value too when it is shared. Effective, well performing FQS will attract the increased number of researchers to and can be used as a marketing instrument for FAIR data.

2. Support the development of the FQS. One of the avenues for improvement involves extending the FQS beyond University Hospitals and into cantonal hospitals and every health institution that produce consented patient data. Bottlenecks have already been identified, such as the curational effort to bring the information from the hospital source systems into an appropriate format, and the right people are on track, but the lack of funding is an obstacle for the FQS to address these issues.
3. Search and query tools cannot be seen as an independent tool. They are part of the research data management process, which ultimately caters to all four FAIR principles. For now, there is no single-entry portal that would present services and infrastructures available to researchers in the broader context of research data management.
4. Support linkages between query systems. The Swiss Federated Genomics Network (SFGN) is establishing a federated infrastructure to host genotypic and phenotypic data. Current efforts are aimed at building a federated European Genome-Phenome Archive (EGA, https://ega-archive.org/) node. This system will allow to search for genotypic and phenotypic data. In addition, a first effort to include some actual data in this federated EGA node is the Genome of Switzerland. Connecting the federated EGA node to the FQS would enable the findability of genotypes and clinical data in the hospitals. It remains to be seen how the mapping between these modalities can be realised, as there is still no agreement on a unique personal identifier across Switzerland.

3.5 Thematic Perspective: Accessibility

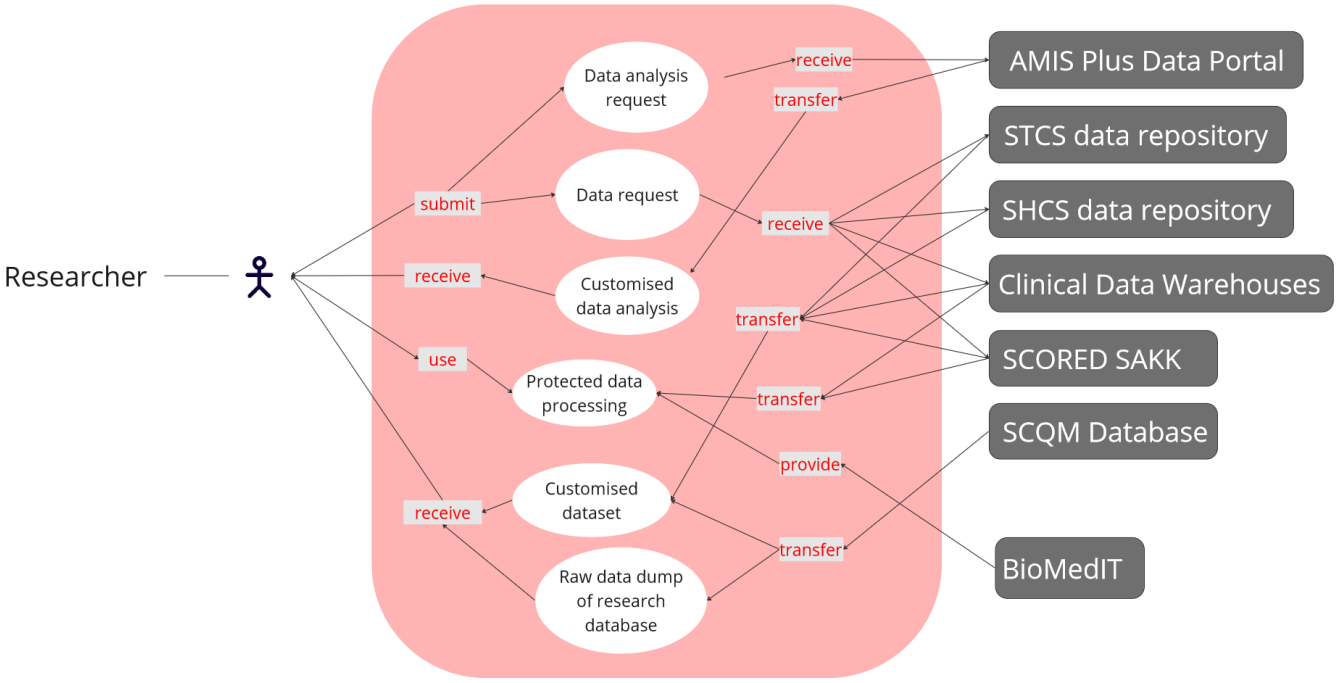


Fig. 10: Accessibility of clinical data in the cluster

Description

The distinction between health and life sciences data is most relevant, when it comes to accessibility. Because life sciences are mostly producing non-sensitive data, they are eligible for open access. Health data is by definition sensitive and open access is not justified or possible, without the full anonymization. However, FAIR principles can and should be fully implemented for health data. Legal and ethical requirements anyway prevent data producers, data repositories, or data streams in Switzerland from granting direct access to clinical/health data. However, access to research data also generally requires membership or being employed by an initiative, hospital, or institution. Exceptions here are the biobanking data provided by the SBP (metadata on samples, required to ensure findability) and the biodata by SIB (non-sensitive data in life science databases). Researchers who wish to access the sensitive data from the STCS and SHCS cohorts, from the SAKK repository, as well as from AMIS Plus and SCQM, must submit applications for data or data analyses. This also applies to the five University Hospitals' CDWs, the main providers of clinical data for research in Switzerland. Data is made available to researchers as customised data sets or raw data dump, but none

of the initiatives stream data for research purposes. SAKK and the CDWs use the secure platform provided by BioMedIT to transfer data for their analyses.

Analysis

Challenges in data flow efficiency: The current system for accessing and transferring clinical data in Switzerland faces inefficiencies due to various legal and procedural obstacles. This issue extends to both health and life sciences data. A critical hindrance is the limited liability of recipients of project funding, when not abiding by guidelines about accessibility. In addition, the lack of accessible metadata is making it difficult to even find data that researchers could potentially use for their research. Such constraints significantly impede not only accessibility, but all aspects of the FAIR principles.

Comparing Swiss practices with global standards: The Swiss model shows notable deficiencies when compared to international systems, such as those implemented by The Cancer Genome Atlas (TCGA) and the International Cancer Genome Consortium Accelerating Research in Genomic Oncology (ICGC-ARGO, https://platform.icgc-argo.org/). These organizations exemplify robust data access frameworks, complete with broadly available data access platforms, effective committees and annual renewal processes, ensuring data is centralized, and due diligence and liability are properly addressed. Most notably, the TCGA data is hosted by the National Institutes of Health (NIH) on their Genomics Data Commons data portal. However, this level of organization is currently lacking in Swiss data management.

Diversity in governance policies: A significant challenge in Switzerland is the wide variation in data governance policies across different hospitals and regions. This diversity complicates the pursuit of a unified, standardized approach to data management such as the coordinated access across Switzerland.

Secondary use of clinical data: An important aspect (not depicted in the diagram) is the opportunity for the secondary use of clinical data. This approach would shift focus from data curation in hospitals for specific projects to broader data curation by the research community. While challenging, this shift is increasingly becoming a reality and necessitates national-level funding and strategic understanding by entities like SERI and FOPH. It involves the understanding of the evolving needs for data access among both the community and institutions like the ETH Domain, that are engaged in biomedical research but lack direct access to hospital data. In addition, hospitals often lack a clear understanding of the data they have, since most of the data is unstructured and not immediately machine-readable.

Federated data analysis for sensitive data: Projects like the Federated Query System (FQS) of SPHN have shown that querying across multiple university hospitals is possible. A next step could be to have sensitive data (partially) analysed at the medical institutions and then the (partial) results are concatenated at the researcher's institution. By doing so, sensitive data could remain in the respective institutions and only aggregated results, that are not considered sensitive, are transmitted to the researcher. While this is not directly an open science practice, it follows the ORD principle of as open as possible and as restricted as necessary.

Furthermore, it does still require the data at the federating institutions to adhere to the FAIR principle, especially the interoperability aspect.

Initiative within SPHN National Data Streams (NDS): An experimental project within the SPHN, NDS demonstrates a collaborative effort where a consortium operates under a legal and ethical framework to use data from clinics for nested projects – in a secondary-use manner. Despite these efforts, hospitals maintain primary control over data access, underscoring the complex dynamics of data governance and sharing.

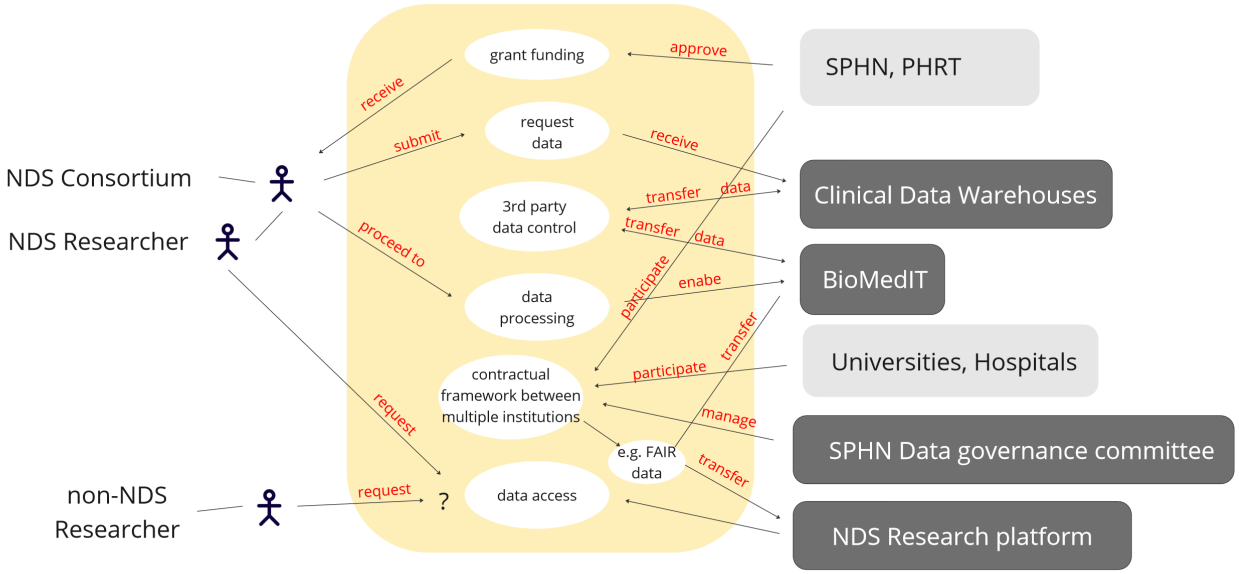


Fig. 11: Contractual Framework of NDS for secondary data use

Opportunities for Coordination

1. Advance the harmonization of legal and technical standards by developing a data management contract ontology. Such an ontology should build on existing international efforts yet maintain an appropriate flexibility to ingest Swiss specificities. One example of such approach is proposed by the SDSC in collaboration with CHUV and USZ to implement advanced hospital data policy management.
2. Utilize Reference Datasets for Interoperability Requests. Emphasize the use of API-enabled reference datasets. It might help to achieve interoperability organically through alignment with these reference sets, and it may be the way to ensure that accessibility is integrated during the development process.
3. Enable Flexible Data Access. Adopt the SBP model which empowers individual biobanks to control access to their data. This method places decision-making in the

hands of data owners, ensuring data protection and building confidence among biobank owners about making their samples visible.

4. Promote Secondary Data Usage. Highlight the significant untapped potential in repurposing clinical data for broader research endeavours. Support medical institutions to better assess the value of their own data, by improving their data management and paving the way towards controlled accessibility by other institutions. This approach underscores the necessity for increased funding and understanding at the national level.
5. Showcase Success Stories. Accentuate the importance of highlighting successful instances of data access and utilization. These examples serve as powerful demonstrations of the benefits and feasibility of improved data sharing practices. A clear opportunity is some of the large consortium projects using machine learning/AI (e.g. SPHN NDS SwissPedHealth) requiring copious amounts of data for their pattern recognition.
6. Engage the Industry. Develop financial mechanisms to involve industry partners in supporting data accessibility. This collaboration can provide essential resources and expertise, enhancing the overall data access framework.
7. Consider simplifying processes stipulating conditions for mandatory data sharing

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3.6 Thematic Perspective: Interoperability

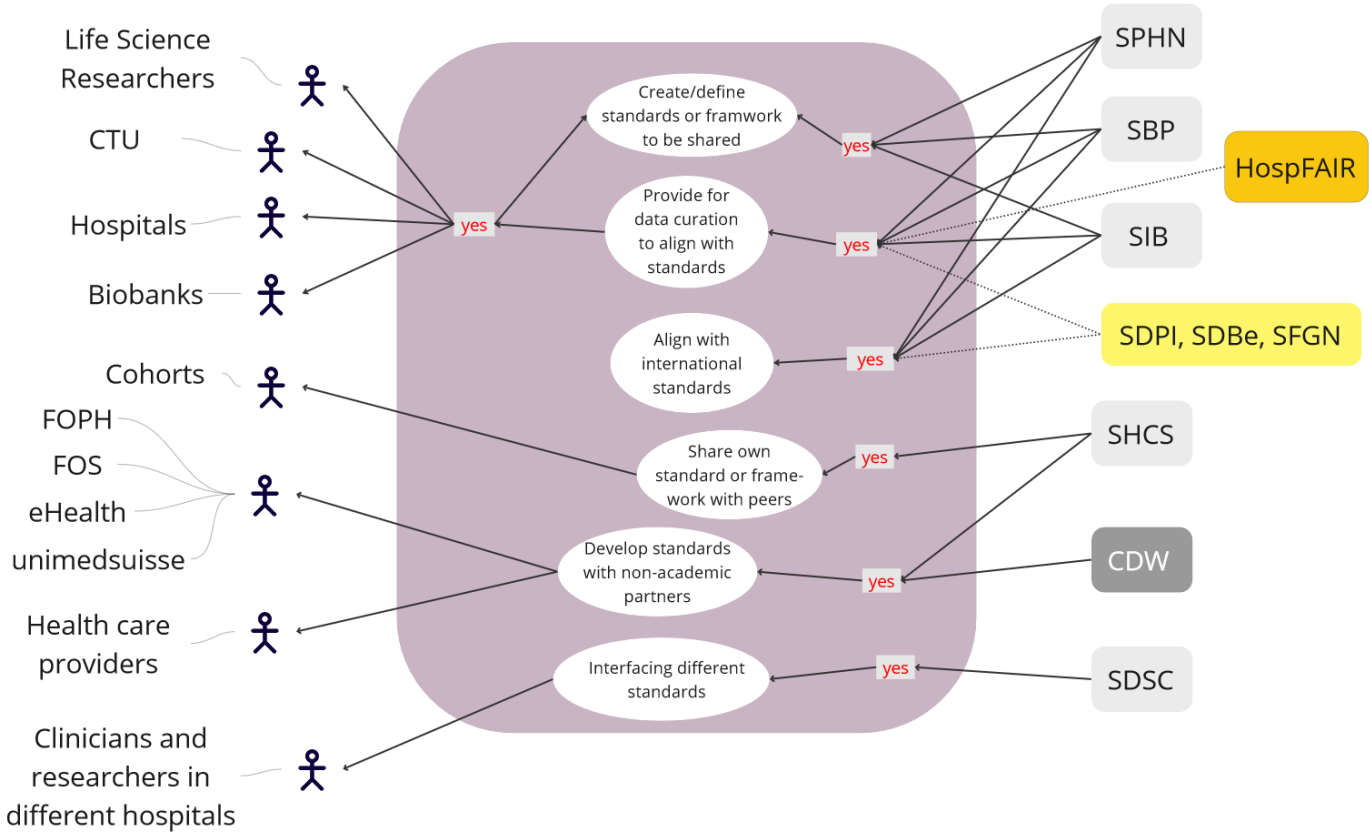


Fig. 12: Interoperability in the cluster

Description

Several initiatives provide data standards or so-called interoperability frameworks that researchers and data-generating platforms can use to standardise their data so that it can be seamlessly shared ultimately enabling machine-borne access and processing. SPHN, SBP, and SAKK have published reference datasets that they use for instructions on how to structure health data. The SPHN Semantic Interoperability Framework includes SPHN Concepts defining the "words" based on existing standards and ontologies, and the SPHN RDF Schema defining a "grammar" for use in a universal exchange language in healthcare. In that way, asking for a certain measurement works the same way all the time and is "understood" by anyone. SIB uses the UniProt database to train other databases (see the Re-Use, AI perspective). Data curation services are used to structure and annotate data based on provided references and in adherence to established standards. Such services for structuration and interoperability

purposes include SBP's evaluation of biobanks and awarding biobanks with specific quality labels. These labels are important as they combine, amongst other organisational things, interoperability standards for data sets (as designed by SPHN-DCC) and the other FA(I)R principles. Not only do these labels facilitate the proper setup of biobanks from a regulatory perspective, but they also support them in becoming more FAIRer. SIB provides training for data stewards on standardisation and interoperability. CDWs have data curation processes transforming data from hospital source systems into SPHN-compliant formats, including also the deidentification of the data. To that end, SPHN provides a tool stack to transform routine hospital data into FAIR research data. Under the guidance of SPHN, the CDWs are planning the HospFAIR programme, which aims to systematically streamline hospital processes so that the quality of data can be sustainably achieved. SHCS is also establishing its own data framework for patient registries with the intention that it can be adopted by other cohorts and customised to specific needs.
Moreover, an evident trend within the cluster is the alignment of local, sometimes orphan data standards with international standards and ontologies. The entire biobanking community in Switzerland benefits from this approach of harmonising its own standards with those of the international research community, as has been done by the SBP BBMRI-ERIC of the European research infrastructure for biobanking. This convergence is the key contributor to the interoperability achieved in biobanking data across Switzerland.
Some initiatives, with distinct objectives, pursue a strategy that goes beyond harmonising their data standards within the scientific community. They also aim to align these standards in a way that fosters data usage by external stakeholders. CDW align their standards with FOPH, FOS, and eHealth (the Swiss Competence and Coordination Centre of the Confederation and the Cantons for digital networking in the healthcare system). SHCS uses SPHN's IDEAL project to connect research institutions and healthcare organisations.
Finally, it is important to note that the integration of data types is carried out by creating interfaces between standards. It can be assumed that the incorporation of data, especially omics data, into broader clinical information systems happens with an emphasis on optimising data storage and use efficiency. In this context, SDSC speaks of intermodal data integration.

Analysis

A significant challenge lies in the fact that the data infrastructure within the cluster is primarily built on outdated (legacy) systems. This infrastructure has evolved incrementally, leading to a lack of interoperability. SAKK or SCQM are examples of initiatives that operate such frameworks. While data expertise exists across all initiatives, one of the main challenges lies in the fact that experts tend to operate in silos. Despite an expressed desire for interoperability and project plans such as HospFAIR that aim to move towards an interoperable setup, there are significant barriers such as the incompatibility between different software systems (for instance clinical information systems in different hospitals and often between different

clinics within a hospital) and the lack of willingness to align with standards that were not internally created.
Hospitals and any health institution in Switzerland typically choose their software based on criteria such as cost and suitability for staff, without necessarily prioritizing interoperability, especially towards research institutions other than themselves. Currently, there is lack of uniform standards or regulations for hospital software that would promote research data interoperability. It is also known that interoperability of medical research data is successfully achieved in those countries that have legislated the software market to comply with interoperability standards.
The diagram makes references to specific projects and initiatives that aim to improve interoperability, but many of these are still in the development phase. For example, the will among cohorts to share data standards is there, but there is no evidence of a successful transfer of a data framework from one cohort to another. Also, the hospitals are willing to integrate the SPHN Semantics Interoperability Framework into the CDWs, but the Clinical Trial Units (CTUs), which are also located at and regulated by hospitals, do not explicitly carry out trials and advise researchers to generate or curate data to be aligned with the SPHN Semantic Interoperability Framework or they promote even a different internal standard instead.
Creating standards and reference datasets in areas such as bio-banking and life science research to improve interoperability seems to be more streamlined. This has to do with the fact that metadata (for biobanking) and non-human biodata (for omics data) are not personalised in the same way as research data extracted from routine hospital data and must not be generated and curated in closed systems.

<u>Opportunities for coordination</u>

1. Clarify expectations surrounding terms like “open data” (or ORD) and “sharing data” in the context of health and life science research. This is a first step to ease tensions within some research communities regarding ORD and encourage them to go beyond data silos. There needs to be advocacy on ideas and concepts such as FAIR research data, traceability, liability, and accountability of data sharing.
2. Standards must be implemented. Data curation, along with adequate financing enabling it at the source of data production, should be at the heart of interoperability. Learn from and further develop data curation practices in the cluster, such as, for example, data stewardship (SIB), certifications of biobanks (SBP), design of data entry tools (SHCS), renku RDM platform (SDSC).
3. Confirm approval of and politically support the SPHN Semantic Interoperability Framework for health data (i.e. avoid a political battle to address a semantical problem) as an internationally aligned national standard for health data

4. Implement a national certification for data producing vendors, in particular those providing clinical data (e.g. clinical information systems in hospitals, computerized medical record in private practices). The certification would guarantee that these systems comply with nationally accepted standards for terminologies and data interchange formats[11]. This would shift addressing the data interoperability and reusability at the source, rather than having to normalize the data at a later stage, when data sharing occurs. Besides reducing the labor-intensive data curation work of manually translating routine clinical data into research data, it also results in substantial cost savings. Efforts in software regulation could be spearheaded through Digisanté or the CPCR. This could also pass by a parliamentary initiative and the drafting of a law detailing how the FAIR principles should be implemented in health care software. [12]is reviewing the development of the framework law on the reuse of data[13] commissioned by the Federal Council and to raise the issue of the regulation of hospital software with the parties involved.
5. Support local initiatives and practices to create interfaces between existing standards, in order to make them interoperable at national level.

[11] The Lucerne Cantonal Hospital, the Zurich Children's Hospital and the Insel Hospital have recently purchased healthcare software that implements interoperability standards so that data exchange is secured. See this polemical newspaper article on decision-making for hospital software in which interoperability arguments are weighted higher than, for example, the costs of new software: https://www.tagesanzeiger.ch/kinderspital-zuerich-kispi-kauft-trotz-finanznot-teure-software-839036084998

[13] Développer un écosystème intégré de données médicales pour la recherche et pour la société afin de faire progresser la numérisation du système de santé suisse (https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20220313).

3.7 Thematic Perspective: Re-use (focus on AI)

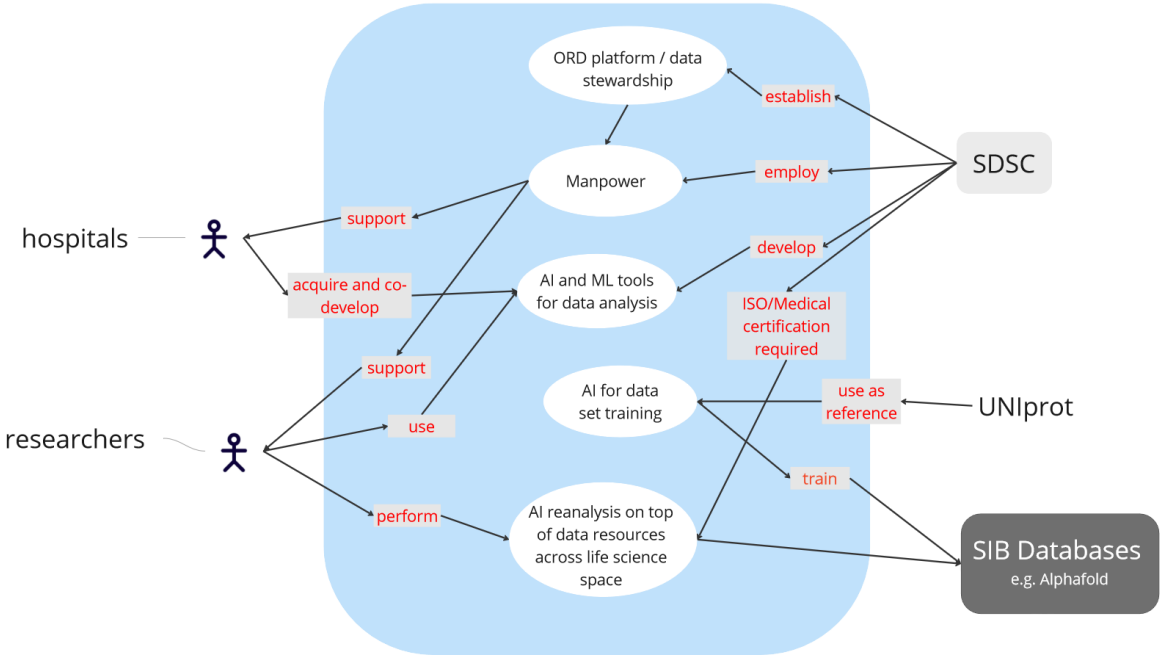


Fig. 13: Current use of AI in the Cluster

Description

Artificial intelligence (AI) comes into play three times within the cluster's data re-use process. First, SDSC supports researchers, the industry, and public institutions with tools (e.g. ORD platform and Data Stewardship), as well as providing manpower and AI tools for analyzing existing data. Second, SIB needs AI technology to train data sets (such as Alphafold) with data reference sets such as UniProt. Third, researchers use AI on top of life science datasets for the re-analysis of the data sets that may have been trained as described in the second step. Within SPHN projects, this happens on the BioMedIT infrastructure but is not limited to it. SDSC can support this process, as described in the first point, but may not be authorised to do so because no ISO/medic certificates are available.

Analysis

The use of AI for data analysis ignites a lot of hope and expectations among actors in the cluster. We are seeing research programs entirely focused on the utilization of AI technologies. Additionally, AI is integral to the core offering of the future development of SDSC (SDSC+), which aims to serve the health and life sciences community and biomedical research, to a lesser extent.

These future plans contrast sharply with the current utilization of AI technologies in the cluster. In particular, the diagram shows that AI in the initiatives' current work (especially SDSC and SIB) has less to do with data analysis (i.e. re-use) than with the preparation of data sets for possible re-use. AI technology is used by the SIB for data curation, not for data analysis. While some initiatives are planning to use AI for analysis they also indicate that they do not yet know how and in which capacity. It also needs to be acknowledged that most machine learning and AI efforts primarily occur at the local level. For example, the ETH AI Center possesses strong competencies and engages in biomedical research; however, it is, at best, a regional initiative rather than a national one. Despite this, these local areas of expertise are typically well-prepared on the computational/technical level to fulfil the FAIR spectrum of requirements.

In December 2023, the Swiss AI initiative was launched by EPFL and ETH Zurich in connection with the National Supercomputing Center (CSCS)[14]. The initiative is multidisciplinary by design, but one of its activities revolves around the development of a foundation model in the health domain. Due to its recent creation, the Swiss AI initiative was not part of this analysis, but it has the potential to provide resources for national capacity building on the use of Large Language Models (LLMs) in the cluster. Another interesting point to analyze would be the interaction and complementarity with SDSC as the AI tools provider in the cluster.

An extensive and collaborative integration of AI and data science tools within the HLS cluster holds great promise for advancing public health. This integration would empower translational medicine by accelerating the translation of scientific discoveries into practical medical advancements, offering substantial benefits for public health.

Opportunities for coordination

1. Revisit the initiatives with no clear understanding on how to integrate AI, to better understand what the needs and aims are.
2. Introduce a mechanism to coordinate AI and data science tools and services provided by and available to the life and data science research community.
   Identify ways to link to other national coordination efforts.

[14] More information on https://www.swiss-ai.org/.

3.8 Thematic Perspective: National Coordination

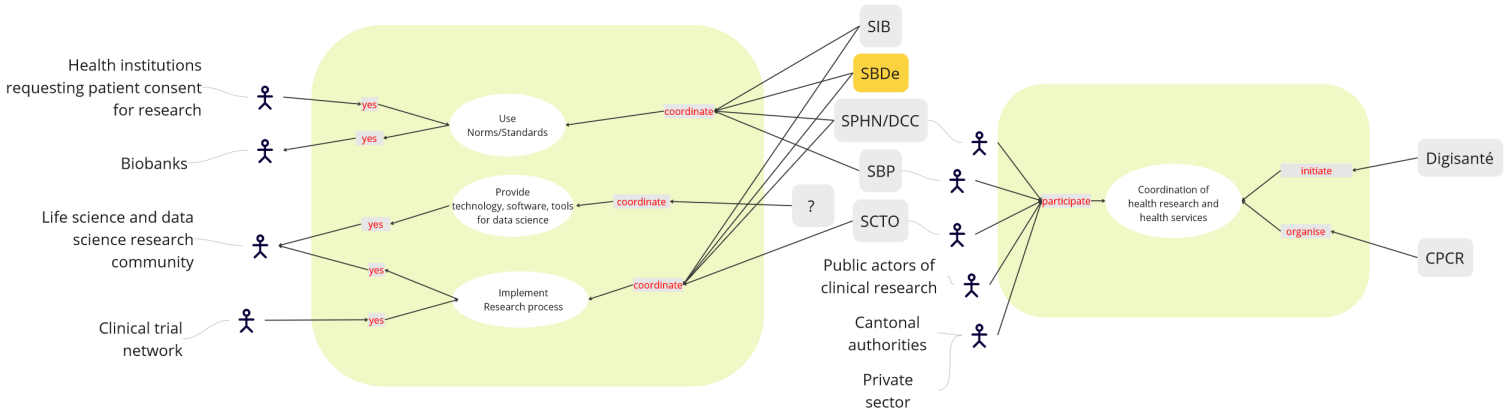


Fig 14: Coordination of norms, services and research process (left), coordination of actors (right) in the cluster

Description

To date, six initiatives play a coordinating role in the cluster at the national level. A seventh initiative, SBDe, is expected to supplement and possibly replace the current coordination of the life science community in Switzerland, which is currently done by SIB. As seen on the left side of Figure 12, the coordination in the cluster is focused on specific user goals or user groups. SPHN coordinates the health institutions in the development of research data standards and use. SBP coordinates the biobanks in Switzerland. SCTO coordinates the Clinical Trial Units. SIB and SBDe (planned) coordinate the activities of the life science research community. SBDe plans to coordinate the data generation and processing at the national level. For all these initiatives, coordination is a secondary function. This is not the case for CPCR and Digisanté where the coordination of different actors (amongst them cluster players) towards a clearly defined goal is the primary function. Digisanté and CPCR are looking at the coordination issue from a different, overarching perspective in which some of the cluster initiatives are involved (see the right side of Figure 12). The CPCR brings together all public stakeholders in clinical research active at the national level to strengthen institutional dialogue, utilise synergies, and prevent duplications. The Digisanté initiative aims to promote the digitalisation of the healthcare system in Switzerland, including the use and reuse of health data for research, with the involvement of cantonal authorities and the private sector under the leadership of the federal government.

Analysis

Several cluster initiatives provide coordination of the production of data norms and standards, either as their main function or in their supportive role. In addition, some initiatives coordinate the implementation of research processes and others focus on the strategic alignment of all or a specific group of cluster initiatives (e.g. CPCR, Digisanté).

The CPCR does not focus specifically on health data – its focus is on the improved institutional cooperation and strategic alignment of national actors of clinical research in general – but it is trying to bring more transparency on who is providing what services to whom in which local context, and to support an active cooperation between service providers. Given the overlap of these activities, a shared goal of strategic coordination of the Health and Life Sciences cluster emerges between the StraCo and CPCR, warranting a closer cooperation.

Biology Roadmap for the ERI-dispatch 2029-2032: it was supposed to be launched in the course of 2023 but has been interrupted, as were all activities in the Academies related to the RM, due to consultations. Respectively, the coordination has been a bit impaired due to this.

In addition, the cross-coordination between data producers (health institutions, biobanks, , CTUs), data services, tools and infrastructure providers, and research process coordination is insufficient. Institutional dialogue and cooperation on joint projects are taking place between institutions of the CPCR for instance, but the absence of an enforcing mechanism at the implementation sites is a major limitation.

It is also not clear to what extent the fragmented coordination approaches between the initiatives contribute to the lack of efficient data flow and integration in some cases, and insufficient ORD/FAIR process in others. Examples include the clinical data flow between the CTUs and the CDW, on one hand, and absence of ORD/FAIR enforcement mechanisms on another.

Finally, there is a gap in the cluster when it comes to the coordination of data science services, tools (mainly software), and infrastructures provided by specialist researchers (including those from SDSC and SIB, not shown in the diagram).

Opportunities for coordination

1. Initiate dialogue between the Chair of the CPCR and the StraCo to clarify the respective action areas, cooperate where possible and avoid duplications.
2. Introduce a binding mechanism for cross-coordination between data and service producers, and process implementors. Given the strategic cross-coordination role of the CPCR, consider linking it to the data coordination effort, including ORD.
3. Based on the better understanding of the clinical data flow between CTUs and Clinical Data Warehouses, and other cluster participants, consider supporting/reinforcing SPHN's effort to build a functional interface to facilitate interactions and optimize the data exchange.
4. Evaluate the maturity (extent) of the ORD/FAIR principles among the cluster, and suggest to Task Force to propose a coordinated approach to help achieve the ORD/FAIR goals, including an enforcement mechanism.

3.9 Thematic Perspective: International Cooperation

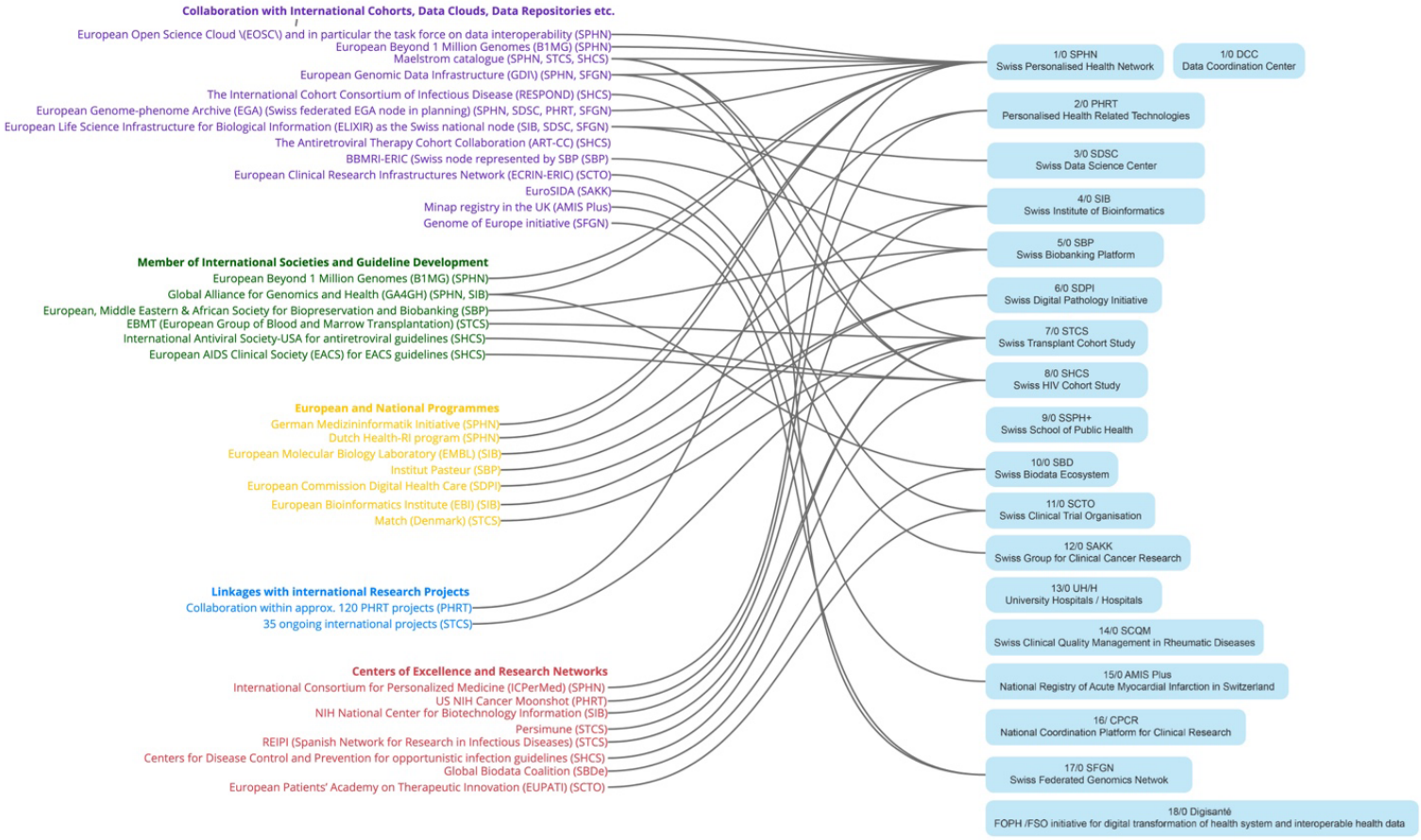


Fig. 15: International Cooperation in the Cluster

Description

Data publishing infrastructure needs are currently being addressed intensively on an international level, for example through the development of the European Open Science Cloud (EOSC). Ensuring that the quality of such services are appropriate for researchers needs requires common standards and (FAIR) principles.

The relationships of Swiss initiatives with international partners in the Health and Life Science cluster as shown in Figure 13 can be classified into five categories:

1) Collaboration with international cohorts, data clouds, data repositories, etc.
2) Membership in international societies and guideline development

3) European and national programmes
4) Linkages with international research projects
5) Centers of excellence and research networks

Analysis

Dependencies between Swiss initiatives and international partners can go in two directions: Swiss initiatives may depend on international relationships, but it may also be the case that international initiatives depend on Swiss contributions. Switzerland is a small country and large-scale research is often based on international collaboration. For example, multi-center clinical trials often enrol patients in different countries and common and FAIR data standards of clinical trial management systems are essential for an effective conduct and analysis. Developments in Switzerland can also be used outside of Switzerland, ideally in a coordinated manner. For example, the Swiss Institute of Bioinformatics is the largest national node within the ELIXIR consortium and provides part of ELIXIR's Core Data Resources.

To foster international relationships, national initiatives should organize their infrastructures in a way that international researchers find valuable and utilize for their research. The perceived value for the international scientific community is a crucial element for securing further funding and development of Swiss research data infrastructures. Compliance with international standards is typically a catalyst for the openness of research data. For instance, SBP invested efforts in internationalizing and raising the standards for sharing biological samples in Switzerland to a higher level. (see perspective Interoperability).

The importance of common data standards has also been emphasized in the context of international public-private collaborations. The European initiative IMI (Innovative Medicines Initiative) is the world's biggest public-private partnership (PPP) in the life sciences, jointly funded by the European Union and the European pharmaceutical industry. Many researchers contribute to IMI projects. IMI supports the FAIR principles, to ensure data harmonisation on an international level and across the public-private research landscape. Multicentre/multinational clinical trials are a good example where the involvement of the pharmaceutical industry is crucial to ensure the highest standards in data management.

Opportunities for coordination

1. Monitor the usage of Swiss infrastructure and databases on a regular national and international level to identify existing international connections and potential gaps. Appropriate usage from international researchers could also be used as a funding criterion.

2. Develop and implement the necessary legal framework to overcome obstacles in alignment of Swiss initiatives with international ORD partners. This applies in particular to clinical but also to genomic health research data. This point extends the proposed activities in Section 3.5 on national accessibility to the international domain.
3. Initiatives should include in their regular reporting details on their international cooperation. We recommend to use international reviewers of Swiss ORD initiatives

4. Discussion

- Overall insights on the cluster

The analysis of the ORD cluster, represented by 18 initiatives, reveals the complex and highly heterogeneous nature of Health and Life Science Research Data Infrastructures in Switzerland. The practice of ORD, and particularly the implementation of FAIR principles, varies significantly among initiatives, depending on their approach to data management. Additional complexity arises from differences in needs and expectations between health data producers (e.g. hospitals) and users (e.g. biomedical researchers, data scientists). In addition, there sometimes is a discrepancy between what is defined as a good ORD practice and what is perceived and deployed as such by the initiatives- making accurate assessments difficult.

Given that previous analyses pinpointed deficiencies in data interoperability and reusability, and since multiple initiatives have been developing processes for data management, the TF expected to come across gaps and functional overlaps within the cluster. However (and the need for additional, ongoing analysis notwithstanding), our analysis demonstrates that the key requirement lies in improving coordination and leveraging of synergies across various levels, including data governance and funding, to increase intra-cluster efficiency. Even more importantly, in order to effectively address the issues of data interoperability, reusability, findability, and access, essential adaptations are necessary at the legal, regulatory, and operational levels. Additionally, continued dialogue among the cluster stakeholders, supported by extended analyses of the cluster evolution, is crucial to further define ORD ground rules and actionable, enforceable FAIR mechanisms that can be reliably deployed at the sites of data production, exchange, and reuse.

Another aspect that surfaced in our analysis, especially through sustained exchanges with stakeholders, is an apparent positive shift in the readiness of actors within the cluster to actively coordinate and collaborate on recommendations to improve efficiency in the HLS landscape.

Nevertheless, the analysis also highlights how the conflicting requirements of data protection, and genetic and translational research (such as the re-identification of patients) introduced serious tension around the concept of data "openness". The StraCo needs to be aware of this while formulating strategic options for the future of the cluster: it is crucial to be specific about what can be expected in terms of ORD in the HLS cluster and be mindful of the specific obstacles stakeholders face when engaging in these processes (ethical and legal obstacles, competitiveness issues). The implementation of ORD requirements for biomedical research may encounter resistance, especially from patients and doctors, and it requires a careful consideration to ensure acceptance of proposed strategies.

- Suggesting re-use as the strategic focus

In this context, the TF recommends that the StraCo's concentrates its coordination effort in the HLS cluster on the goal of data reuse. This emphasis on data reuse aligns with ongoing discussions around clinical research (SAMS 2021), the government's efforts to digitise the healthcare system (Digisanté), and considerations about the continuation of the DCC after 2026 (SPHN 2023). By prioritising data reuse, the TF also sees an opportunity to structure coordination efforts around a more collaborative design of the cluster. In addition, an efficient reuse of health research data has repercussions beyond

benefiting biomedical research as it provides an effective tool for improving public health. A targeted effort on research data reuse would foster the sharing of multiple data types and thereby accelerate the translation of scientific findings into tangible medical applications for the benefit of society.

The task force suggests using the FAIR principles as coordination tools and prioritizing them in the right order to address the cluster needs: while findability and accessibility are typically prioritized in discussions about Open Research Data, interoperability is at the heart of many actions that are needed to achieve more openness if the effective reuse of research data is to materialize. The assumption is that infrastructures and services in the F&A direction will evolve as data becomes more interoperable.

- Three priority areas, supporting previous findings

The aim of this report is to provide the StraCo with the necessary insights to devise strategic directions for the coordination and optimisation of the HLS Cluster. Throughout our analysis, the TF has identified various 'opportunities for coordination'—pathways or pain points for the StraCo to formulate strategic options around. While some of these coordination opportunities differ from proposals outlined in previous reports (see section 1.4), the TF aligns with earlier findings in identifying priority areas for impactful action within the cluster:

1. National coordination

In order to achieve interoperability and reuse of health research data, semantic and technical standardisation is required within and across research and clinical domains, ideally with compatibility with international standards. High-level strategic coordination will likely be needed to ensure overall alignment and optimization.

We suggest considering the establishment of an overall coordination platform for normalization of health research data across the cluster, to include both clinical research and HLS data, along with an accreditation mechanism and the authority to define and promote FAIR rules. As an example, for clinical research data, such coordination could be provided by the CPCR, while the SPHN-DCC successor together with SBP and SBDe could cover the rest of the HLS data.

Considering the 7-year experience of developing interoperability framework for medical research data by the SPHN-DCC, and available funding for 2025, with an extension potential, the TF sees a significant opportunity for coordination of health data through SPHN-DCC. The TF sees equally strong opportunity for coordination of life science data through SBDe, given its vast network of 42 partners, encompassing the life sciences field.

While the current DCC has capabilities to implement its interoperability framework along with scaling up the normalization to other research data infrastructures, its core data set lacks the necessary attributes, e.g. the available dictionary, to be suitable for various data types and phenotypes. The involvement of the broadest possible share of the research community is crucial here.

Furthermore, the engagement of and ongoing connection with Digisanté, as well as with the Federal Statistical Office, including providing financial support to the DCC is of paramount importance- further justifying the application of the DCC's interoperability framework to areas of the healthcare system outside of research.

2. Legal framework

Given the constraints of data reuse, exerted by data ownership and privacy laws, it is important to create or adapt legal frameworks to allow the facilitated exchange and reuse of medical data, along with increased visibility and access.

There is a need to upgrade the consent process for sharing/reusing data by moving from a general consent paradigm to a dynamic consent paradigm where citizen can decide how to participate in research projects with their data at a higher granularity level than is possible now. This should increase trust and involvement of citizens. This can be done at the level of the law on the electronic patient record and with the introduction of a unique citizen patient identifier. Electronic patient record would thus evolve to become the source of data for biomedical research in addition to public health and healthcare purposes[15]. Without such evolution, Switzerland risks to miss opportunity to have access to useful data that may not be found in hospital information systems, and to further involve citizens in research and public health initiatives.

3. Adequate Funding

Investment is necessary to provide mid- to long-term support for data management, with emphasis on data sharing, until the regulatory solutions (e.g. certification of data software) become available. Such investments, ideally provided not only by SERI but also through e.g., Digisanté, might help reduce later efforts associated with data curation. The role of funding goes beyond fuelling current and future efforts towards in research data infrastructures and services: it should also act as a lever for coordination. By incorporating international connections and alignment with global standards into funding decisions, funders can contribute to unlocking barriers to data interoperability.

To further incentivize the data producing institutions for FAIRification of data, the prospective mechanisms of accreditation (or labelling) could be linked to the funding decisions (e.g. by SNSF for research) or to commercialization potential (e.g. healthcare information systems to be sold to hospitals and other care providers).

- Bridging knowledge gaps: further analyses needed

To better understand the evolving ORD needs and introduce effective additional measures for optimizing the HLS ORD landscape development, a thorough longitudinal analysis of the initiatives' output and impact is needed. Such 'postmortem' will also be important to reveal and avoid the bottlenecks and inefficiencies that may have occurred at the earlier stages of the cluster development.

Additionally and despite the specificities of our national system, enhancing the coherence and efficiency of Switzerland's HLS cluster would greatly benefit from comprehensive international

[15] *The models of citizen ID using a unique digital patient identifier and e-consent are discussed at several levels (see SAMS-SPHN report 2016–2019; Schwab, 2019; https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20214373; https://dkf.unibas.ch/en/competencies/patient-data-samples/econsent/ https://dkf.unibas.ch/fileadmin/user_upload/dkf/Forschungskonsent/Recommendations_GC_V1.0def_20200112.pdf) and should be considered further.

benchmarking. Analyzing success factors and failures in countries such as the UK, US, Denmark, or France will yield valuable insights for implementation.

5. Conclusion

This report investigates the challenges and opportunities in the HLS cluster in Switzerland in the framework of the National ORD Strategy, with the ambition of advancing the national agenda towards enhanced FAIR practices and an efficient, future-driven research data infrastructures ecosystem. By conducting an in-depth examination of the current disposition of available infrastructure and services, this landscape analysis aims to offer policymakers and stakeholders a well-rounded view on the cluster, which would serve as a basis to formulate strategic options for the StraCo's blueprint process.

The TF's methodology includes a thorough review of initiatives in the cluster, the data infrastructures and services available to research communities, and how these services and infrastructures interact at different levels, as shown through structural and thematic perspectives (initiatives' mandates, available funding, ORD-oriented services and infrastructures; findability, accessibility, interoperability, re-use, national coordination, international cooperation). This comprehensive assessment involved stakeholders at different stages in the process to ensure that the recommendations are both evidence-based and attuned to the specific needs and challenges of research communities across the HLS field.

Among the key findings and using previous analyses as reference points, the report identifies a notable fragmentation within the current data ecosystem, which hampers efforts to achieve a cohesive and efficient data management strategy. Issues such as inconsistent data standards, varying access policies, and a lack of interoperable platforms are underscored as critical barriers to data sharing and collaboration. Additionally, the report points out the need for more robust governance structures that can support the ethical and secure use of sensitive health data.

To address these challenges, the TF recommends concentrating coordination efforts on the HLS cluster's data reuse goal. With this strategic focus in mind, the TF suggests three priority areas where is it more promising for the StraCo to act: clarifying national coordination, challenging the legal framework and leveraging funding. With these in mind and for each analysed perspective, the TF identified opportunities for coordination:

- Funding: Coordinate funding initiatives to enhance the competitiveness of services and infrastructures at national and international levels, ensuring adherence to minimal requirements set by public funders.
- Findability: Improve awareness of available data through initiatives like the Federated Query System (FQS), enhancing its functionality and extending its reach to various healthcare institutions.
- Accessibility: Harmonize legal and technical standards, promote flexible data access models, and showcase successful data utilization to enhance accessibility while respecting data owners' autonomy.

- Interoperability: Overcome resistance to standardized practices, encourage realistic concepts like FAIR Research Data, and support initiatives for semantic interoperability and software regulation within health institutions.
- Reusability with focus on AI: Coordinate integration of AI into initiatives lacking clear implementation plans, and establish mechanisms for coordinating data science tools and services provided by research communities.
- National Coordination: Establish mechanisms for cross-coordination between data producers and implementors, support SPHN's efforts for functional interfaces, and evaluate and propose coordinated approaches to achieving ORD/FAIR principles.
- International Cooperation: Monitor and enhance international connections and usage of Swiss infrastructure and databases, aligning data management tools with global standards.

To better understand the evolving ORD needs and introduce effective additional measures for optimizing the HLS ORD landscape development, the TF further suggests the conduction of a longitudinal analysis of the initiatives' output and impact and comprehensive international benchmarking analyzing success factors and failures in other countries.

Embedded within the National ORD strategy, this report establishes the groundwork for shaping strategic options that enhance coordination and efficiency within the HLS cluster as part of the StraCo's blueprint. Collaborating with the TF, the StraCo's Coordination Group is tasked to translate these insights into actionable propositions for the cluster. These propositions will be assessed and refined by the StraCo in consultation with stakeholders. One of the report's significant contributions is its emphasis on the collective value that can be generated through better data management practices. It highlights how improving data FAIRness can not only facilitate scientific discovery and innovation but also strengthen Switzerland's position as a leader in health and life sciences research. The insights provided are intended to catalyze action among various stakeholders, including government bodies, research institutions, and funding agencies.

Annexes

Annex 1: List of opportunities for coordination

Funding

1. Fund ORD related tools and activities to make services and infrastructures more competitive nationally and internationally (e.g. Genomic Center, FQS, etc.). Some dedicated funds (e.g. ETH Domain) would also benefit from coordinated approach to spending.
2. Provide specific rules for research data management that initiatives should abide by to receive funding from:
   - SNSF (direct funding)
   - SNSF (project funding)
   - SERI funding through Art. 15
   - ETH Board and Universities (matching funds)
   - RI Roadmap: all funding for the start-up, maintenance, and expansion of Research Data Infrastructure (RDI) should be made contingent upon the continuous adherence to the agreed-upon ORD requirements of public funders.
3. Use the StraCo partnership of ERI Actors to collaborate on a common set of ORD requirements for initiatives, services and infrastructures
4. Work with a catalogue of requirements not only to be responded to in funding application. Use SBP labelling of biobanks as an example of a funder who is participating in implementing ORD requirements. Use follow-up financing of an initiative as a steering instrument

Findability

1. Increase awareness and information sharing around the availability of data. A lot of users do not know what data is available and where to find it. The FQS is seen as a good medium for this. Having many different people looking at the same data will improve not only the understanding of the data, but its value too when it is shared. Effective, well performing FQS will attract the increased number of researchers to and can be used as a marketing instrument for FAIR data.
2. Support the development of the FQS. One of the avenues for improvement involves extending the FQS beyond University Hospitals and into cantonal hospitals and every health institution that produce consented patient data. Bottlenecks have already been identified, such as the curational effort to bring the information from the hospital source systems into an appropriate format, and the right people are on track, but the lack of funding is an obstacle for the FQS to address these issues.
3. Search and query tools cannot be seen as an independent tool. They are part of the research data management process, which ultimately caters to all four FAIR principles. For now, there is no single-entry portal that would present services and infrastructures available to researchers in the broader context of research data management.
4. Support linkages between query systems. The Swiss Federated Genomics Network (SFGN) is establishing a federated infrastructure to host genotypic and phenotypic data. Current efforts are aimed at building a federated European Genome-Phenome Archive (EGA, https://ega-archive.org/) node. This system will allow to search for genotypic and phenotypic data. In addition, a first effort to include some actual data in this federated EGA node is the Genome

of Switzerland. Connecting the federated EGA node to the FQS would enable the findability of genotypes and clinical data in the hospitals. It remains to be seen how the mapping between these modalities can be realised, as there is still no agreement on a unique personal identifier across Switzerland.

Accessibility

1. Advance the harmonization of legal and technical standards by developing a data management contract ontology. Such an ontology should build on existing international efforts yet maintain an appropriate flexibility to ingest Swiss specificities. One example of such approach is proposed by the SDSC in collaboration with CHUV and USZ to implement advanced hospital data policy management.
2. Utilize Reference Datasets for Interoperability Requests. Emphasize the use of API-enabled reference datasets. It might help to achieve interoperability organically through alignment with these reference sets, and it may be the way to ensure that accessibility is integrated during the development process.
3. Enable Flexible Data Access. Adopt the SBP model which empowers individual biobanks to control access to their data. This method places decision-making in the hands of data owners, ensuring data protection and building confidence among biobank owners about making their samples visible.
4. Promote Secondary Data Usage. Highlight the significant untapped potential in repurposing clinical data for broader research endeavours. Support medical institutions to better assess the value of their own data, by improving their data management and paving the way towards controlled accessibility by other institutions. This approach underscores the necessity for increased funding and understanding at the national level.
5. Showcase Success Stories. Accentuate the importance of highlighting successful instances of data access and utilization. These examples serve as powerful demonstrations of the benefits and feasibility of improved data sharing practices. A clear opportunity is some of the large consortium projects using machine learning/AI (e.g. SPHN NDS SwissPedHealth) requiring copious amounts of data for their pattern recognition.
6. Engage the Industry. Develop financial mechanisms to involve industry partners in supporting data accessibility. This collaboration can provide essential resources and expertise, enhancing the overall data access framework.
7. Consider simplifying processes stipulating conditions for mandatory data sharing

Interoperability

1. work against the resistance to implement commonly agreed upon standards
2. discuss the appropriateness of using terms ‘open data’ (or Open Research Data) and ‘sharing data’ within health research and forward more realistic ideas and concepts such as FAIR Research Data, traceability, liability and accountability of data.
3. confirm approval and provide political support for the SPHN semantic interoperability framework for health data
4. explore the possibility of software regulation for health institutions, e.g. through stakeholder dialog within the Digisanté initiative or the Coordination Platform Clinical Research.
5. support local initiatives and practices to create interfaces between standards with an aim of establishing national best practices and standards

Reusability with focus on AI

1. Revisit the initiatives with no clear understanding on how to integrate AI, to better understand what the needs and aims are.
2. Introduce a mechanism to coordinate AI and data science tools and services provided by and available to the life and data science research community. Identify ways to link to other national coordination efforts.

National Coordination

1. Initiate dialogue between the Chair of the CPCR and the StraCo to clarify the respective action areas, cooperate where possible and avoid duplications.
2. Introduce a binding mechanism for cross-coordination between data and service producers, and process implementors. Given the strategic cross-coordination role of the CPCR, consider linking it to the data coordination effort, including ORD.
3. Based on the better understanding of the clinical data flow between CTUs and Clinical Data Warehouses, and other cluster participants, consider supporting/reinforcing SPHN's effort to build a functional interface to facilitate interactions and optimize the data exchange.
4. Evaluate the maturity (extent) of the ORD/FAIR principles among the cluster, and suggest to Task Force to propose a coordinated approach to help achieve the ORD/FAIR goals, including an enforcement mechanism.

International cooperation

1. Monitor the usage of Swiss infrastructure and databases on a regular national and international level to identify existing international connections and potential gaps. Appropriate usage from international researchers could also be used as a funding criterion.
2. Develop and implement the necessary legal framework to overcome obstacles in alignment of Swiss initiatives with international ORD partners. This applies in particular to clinical but also to genomic health research data. This point extends the proposed activities in Section 3.5 on national accessibility to the international domain.
3. Initiatives should include in their regular reporting details on their international cooperation.

Annex 2: List of Factsheets per initiatives and categories available for each Factsheet

Initiative		Factsheet
SPHN	1	Swiss Personalized Health Network (SPHN-DCC)
	1.1	Semantic Interoperability Framework (SPHN)
	1.2	BioMedIT (SPHN)
	1.3	Federated Query System (SPHN)
	1.4	ELSI-helpdesk (SPHN)
PHRT	2	Personalized Health and Related Technologies (PHRT)
	2.1	Swiss Multi-Omics Center (SMOC – ETH PHRT)
SDSC	3	Swiss Data Science Centre (SDSC)
SIB	4	Swiss Institute of Bioinformatics (SIB)
	4.1	Open databases and software tools (SIB)
SBP	5	Swiss Biobanking Platform (SBP)
SDPI	6	Swiss Digital Pathology Initiative (SDPI)
STCS	7	Swiss Transplant Cohort Study (STCS)
SHCS	8	Swiss HIV Cohort Study (SHCS)
SSPH+	9	Swiss School of Public Health (SSPH+)
SBDE	10	Swiss Biodata Ecosystem (SBDe)
SCTO	11	Swiss Clinical Trial Organisation (SCTO)
SAKK	12	Swiss Group for Clinical Cancer Research (SAKK)
Hosp	13	University Hospitals, research driven Hospitals (factsheet on CDW)
	13.1	Clinical Data Warehouses (CDW)
SCQM	14	Swiss Clinical Quality Management in Rheumatic Diseases (SCQM)
AMIS Plus	15	National Registry of Acute Myocardial Infarction in Switzerland (AMIS Plus)
SFGN	16	Swiss Federated Genomics Network (SFGN)
CPCR	17	National Coordination Platform Clinical Research (CPCR)
Digisanté	18	FOPH /FSO initiative for digital transformation of health system and interoperable health data (Digisanté)

Annex 3: Additional information on interviews with stakeholders

First, between February 24th and March 14th, 2023, with a focus on initiatives identified by the Task Force as ideal entry points into the analysis of the cluster.

1. For the Swiss Personalized Health Network (SPHN-DCC), Prof. Dr. med. Urs Frey, Dr. Katrin Crameri, and Dr. Thomas Geiger.
   SPHN is the most politically and scientifically accepted nationwide network dealing and harmonising health data based on internationally defined interoperability standards and a strategy to work in an integrated way with the University Hospitals through the establishment of Clinical Data Warehouses (CDW).
2. For the Swiss Institute of Bioinformatics (SIB), Prof. Dr. Christophe Dessimoz.
   SIB has 25 years of experience with opening and sharing biodata (non-clinical) to the international Life Science community. Projects (co-)lead by SIB are not limited to biodata but can also deal with health-related data.
3. For the Swiss Biobanking Platform (SBP), Dr. Christine Currat.
   SBP is specialised in Biobank integration, visualisation, and certification in Switzerland. Amongst the initiatives on the StraCo list, SBP is the initiative that demonstrates the most substantial efforts to harmonise with other initiatives services and infrastructures (in particular with SPHN and the Hospitals).
4. As an independent expert on ORD from a university hospital perspective, Prof. Dr. med. Christian Lovis (University Hospital of Geneva, HUG).
   Hospitals are the key health data producers through their everyday operations. In the case of research-driven hospitals, they are decisive in terms of patient-research relationships and in the semantic description and structuring of FAIR data.

Secondly, from October 25th to November 3rd, 2023, the following initiatives were interviewed:

5. For the Clinical Data Warehouses (CDW), Patrick Hirschi and Michael Weisskopf (Universitätsspital Zürich), Dominique Furrer and Alexander Leichtle (Inselspital Bern), Marc Daverat (Hôpitaux Universitaires de Genève), and Solange Zoergiebel (Centre Hospitalier Universitaire Vaudois).
   As part of the SPHN initiative, each University Hospital was tasked with building a CDW, if not already in place, with the objective of serving as a data provider for research projects. CDW are spearheading the formulation of semantic interoperability standards together with SPHN-DCC.
6. For Personalized Health and Related Technologies (PHRT), Prof. Dr. Bernd Wollscheid
   While SPHN has a focus on establishing a network allowing to harmonise and share health data, especially between researchers and university hospitals, PHRT has a focus on research projects, utilising the aforementioned. Furthermore, lessons can be learned from PHRT on how funding programs can proceed to require abiding by the FAIR principles from their grantees.
7. For the SwissBioData Ecosystem (SBDe), PD Dr. Rémy Bruggman
   The University of Bern is the leading house of SBDe. It has been included in the RI Road Map 2023. It plans to organize data-generating and data-processing platforms Switzerland-wide, in line with ORD principles. Included are 54 platforms, core facilities, and research groups at 18 Swiss institutions (a list that will grow). The project will focus on biomedical and clinical/health related data / metadata, molecular sequences and various omics data. It will establish purpose-built software, data analysis workflows and federated resources.
8. For the Swiss Data Science Center (SDSC), Dr. Olivier Verscheure and Dr. Oksana Riba
   While SDSC today is actively, yet partially, involved in biodata projects and health data

projects, the Road Map project SDSC+ plans to offer in the future services (so-called verticals) tailored to the community's needs and requirements in specific fields. Within the "AI Health and Medicine" vertical, SDSC+ plans to customise its services for the health research community, to offer, for example, analysis for genomics and proteomics data, data clean-up, differential expression analysis, and biomarker selection. SDSC will develop and provide such key services and infrastructures, amongst others, in collaboration with SIB, PHRT, and SPHN. Initial efforts in this direction are already underway. For example, the SDSC established a data science collaboration with the University of Lausanne and CHUV in February 2023 and with HUG in November 2023.

Annex 4 (next pages): Dashboards for the 18 initiatives

1 - Swiss Personalized Health Network (SPHN-DCC)

Key role

SPHN is a national initiative led by the SAMS that aims to make health data interoperable and shareable according to the FAIR principles. Together with the SIB, SPHN coordinates the funding to drive the development of coordinated infrastructures, compatible data management systems, interoperability of data , and governance of guidelines at a national level. The SIB is responsible for the technical implementation of the project through the Data Coordination Center (DCC), central infrastructure components and services, and BioMedIT. DCC oversees the work of the Federated Query System and ELSI help desk. All Swiss higher education institutions and the 5 University Hospitals are eligible for the SPHN funding.

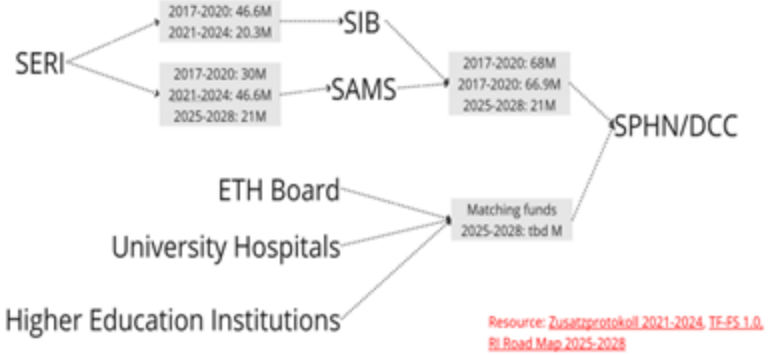
Development plan

During 2025-2028, the Confederation plans to support the consolidation and continuation of the Data Coordination Center (SPHN-DCC) infrastructures and services

Main ORD Services and infrastructure

- Project funding
- DCC
- SPHN Semantics and Interoperability Standards
- Federated Query System
- ELSI helpdesk
- BioMedIT
- SPHN Connector
- NDS National Data Streams
- FAIR repositories for health research datasets
- Online training and education platform
- Additional tools and services (here)

Funding



Governance model

The SAMS is an overarching body of the initiative. and the SIB is responsible for its technical implementation.

- National Steering Board decides on the strategy and allocation of funds, composed of representatives from key institutions in Switzerland (e.g. University Hospitals, Universities, ETH Domain, swissuniversities, FOPH, SNSF, patient organizations, SAKK, SCTO, SBP, SSPH+).
- ELSI advisory group (ELSI guidelines)
- National Advisory Board (infrastructure implementation advisory group)
- Hospital IT Strategy Alignment Group: ensures the alignment with SPHN goals
- International Advisory Board: review committee
- Data Coordination Center: standards, semantics
- Management Office

Beneficiaries and Users

All Swiss higher education institutions and the university hospitals.
Researchers of all swissuniversities institutions.

International cooperation

- International Consortium for Personalized Medicine (ICPerMed)
- Global Alliance for Genomics and Health (GA4GH)
- European Beyond 1 Million Genomes (B1MG)
- Genomic Data Infrastructure (GDI)
- Maelstrom catalogue
- European Open Science Cloud (EOSC)
- German Medizininformatik Initiative
- Dutch Health-RI
- European Health Data Space (EHDS)

AI capability

n/a, AI technologies are used in SPHN funded projects.

2 - Personalized Health and Related Technologies (PHRT)

Key role

PHRT is a strategic program of the ETH Domain supporting interdisciplinary research and education through dedicated grants with a focus on translational research and personalized medicine. Educational grants support doctoral and postdoctoral studies. Clinical studies are supported by the National Data Streams (NDS) and collect a large amount of clinical data. Technology platforms include the SMOC (Swiss Multi-Omics Center), which consists of Genomics, Proteomics , and Metabolomics platforms for data generation, analysis , and interpretation.

Development plan

The PHRT will conclude in 2025. The program will not continue in its present format; however, there will be the ETH Domain Joint Initiative program 'Human Health,' which will apply ORD and FAIR principles.

Main ORD Services and infrastructure

- Funding of interdisciplinary projects in education, and translational research
- National data streams (NDS) in collaboration with SPHN in oncology, pediatrics, infections, and quality of care
- Swiss Multi-Omics Center (SMOC) integrating three independent omics platforms: the Clinical Genomic Analysis Center (CGAC) , the Clinical Proteotype Analysis Center (CPAC) , and the Clinical Metabolomics Analysis Center (CMAC).
- Funding of two clinical trials in oncology using the ETH Domain technologies

AI capability

n/a

AI technologies are used in PHRT funded projects (tbc)

Governance model

1. PHRT Strategic Committee: the highest governing body, responsible for the overall strategy and composed of representatives (vice-presidents and directors) of each involved institution.
2. Executive Committee: responsible for the operational decisions within PHRT and composed of 12 professors from different disciplines employed at the involved institutions.

Funding

Beneficiaries and Users

ETH Domain researchers, and clinicians at collaborating hospitals.

International cooperation

- US NIH Cancer Moonshot initiative

3 – Swiss Data Science Centre (SDSC)

Key role

SDSC is a joint-venture between ETH Zurich, EPFL, and PSI. It supports the academic community, the industrial sector, and public institutions in their data science endeavor, putting to work AI and ML, and facilitating the multidisciplinary exchange of data and knowledge.

Development plan

SDSC is included in the Roadmap for Research Infrastructures 2023 and will serve the entire ERI landscape. SDSC will be significantly scaled up into a decentralized national e-infrastructure called SDSC(+), federating competences, and resources from around the country. It will offer simplified access to harmonized data and curated data-driven science, and a research collaboration and education platform to scientists and field experts, for academia, industry, and the public sector, nationwide.

Main ORD Services and infrastructure

- Production-Grade Data Ingestion
- Comprehensive Medical Data Integration (with a focus on omics)
- Dynamic Data Valorization & Enrichment
- Data Governance Policy Management
- End-to-End Data Science Project Delivery
- ORD Platforms for Enabling FAIR Practices
- Catalyzing Reproducible Research and Good Research Practices
- Education & Training in Data Science

AI capability

- Integration of advanced ML and AI solutions into certified and secure frameworks
- AI & ML model development
- Data science, machine learning and AI services for science, industry and public sector

Governance model

(proposed for SDSC (+))

Steering Committee
Executive Committee
Scientific Advisory Board
Scientific Review Committee
Each vertical to have a Committee for Specific Tasks

Governance at the vertical (domain specific pillart) level will enable a natural integration of communities by involving them in the steering of their vertical and being represented in the Steering and Scientific Review Committees.

Beneficiaries and Users

- Individual researchers and research groups from all Swiss Higher Education institutions
- Research facilities of national importance, university hospitals, administrations
- (Swiss) companies, public sector, and not-for-profit organizations

International cooperation

European Genome-phenome Archive (fEGA)

Funding

4 – Swiss Institute of Bioinformatics (SIB)

Key role

SIB is a non-profit federation of bioinformatics research and service groups from major Swiss schools of higher education and renowned Swiss research institutes. It has the mission to keep Switzerland at the forefront of innovation by fostering progress in biological and biomedical research and enhancing health. It provides a critical contribution to ORD through resources, excellence center and coordination.

Development plan

SIB's SwissBioData ecosystem (SBDe) is included on the Roadmap for Research Infrastructures 2023, with the aim to implement and operate a decentralized, nation-wide infrastructure, create a basis for data-oriented research in the life sciences (specifically excluding medicine and health), and strengthen Switzerland's ability to transform biological research data into knowledge and innovation.g

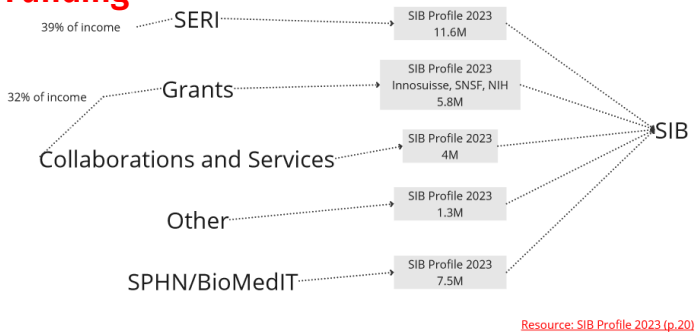
AI capability

- Providing data in machine-readable standard formats
- High-quality curation of data sets using AI technologies (database training)

Main ORD Services and infrastructure

- Provides a curated, openly accessible, and interoperable collection of databases and knowledgebases that adhere to FAIR principles and enable research data reuse.
- Centre of Excellence offering specialized training programs and tailored services to researchers and consortia to facilitate data sharing, interoperability, and reusability in the scientific community.
- Coordination at both national and international levels fostering collaboration, establishing data standards, and ensuring interoperability.

Funding



Governance model

- Board of directors: responsible for the operational business. It is supervised by the foundation council and advised by the scientific advisory board.
- Management and support teams
- Council of group leaders
- Individual Research Group

Every four years, the institute's external Scientific Advisory Board provides recommendations on the portfolio of SIB-supported resources (informed by peer reviews). Based on these recommendations, the Board of Directors decides the allocation of funding and the SIB management team then assists the groups in developing the resources in implementing their action plan.

Beneficiaries and Users

Researchers at Swiss universities and hospitals with a focus on bioinformatics and related disciplines.

International cooperation

- European Life Science Infrastructure for Biological Information (ELIXIR)
- European Bioinformatics Institute (EBI)
- The NIH National Center for Biotechnology Information (NCBI)
- European Reference Genome Atlas (ERGA)
- Biodiversity Genomics Europe consortium
- Pan African Bioinformatics Network for H3Africa (H3ABioNet)

5 – Swiss Biobanking Platform (SBP)

Key role

SBP is the national coordination platform for human and non-human biobanks. It ensures the quality, access, transparency , and interconnectedness of biobanks for research purposes and promotes ORD education and sustainability of biobanking.

Development plan

SBP plans to develop a ready-to-use Biobank Information Management System to facilitate traceability and interoperability of the data related to samples, as well as a CAS in biobanking with the University of Geneva and Institut Pasteur. SBP will interconnect the sample catalogue NExT to the SPHN Federated Query System. SBP is adapting its services to the non-human fields (veterinarian, microbiological, natural history museum collections).

Main ORD Services and infrastructure

- Quality of biobanks
- Visibility of biobanks
- Sample Catalogue (NExT)
- Interoperability of biobanks
- Education of biobanks
- Sustainability of biobanks

AI capability

Not planned.

Funding

Resource: TF-FS 5.0

Governance model

SBP is an independent association (founded in 2016).

- Governing Board: oversees Executive Office's work to conduct busines; composed of representatives of the five university hospitals and expert members from non-profit institutions recognized in specific biobanking fields.
- General Assembly: supreme governing body of SBP, decides on the propositions of the Governing Board.
- Advisory Board: will be constituted in 2024
- Executive office: operative business of SBP (incl. reporting to the SNSF)

Beneficiaries and Users

Biomedical research community using samples in their researc

International cooperation

- BBMRI-ERIC (SBP is the Swiss node and participates in the development of BBMRI-ERIC services)
- European, Middle Eastern & African Society for Biopreservaiton and Biobanking (ESSB).

* Approxiation of initiatives' self-assessment

6 – Swiss Digital Pathology Initiative (SDPI, forthcoming)

Key role

SDPI aims to develop a unified national DP infrastructure that brings together SPHN, Swiss university hospitals and subsequently cantonal and private institutions.
Once fully established, SDPI will facilitate access to well-curated clinicopathological data, which is crucial for the development of new methods for analysing clinical outcomes and treatment response.

Development plan

SDPI will establish a Swiss ecosystem for DP research and AI development for academic, hospital, and industry partners. A 'plug and play' paradigm between the partners and within the SDPI will kick-start the national infrastructure development and digitalization in healthcare diagnostics.

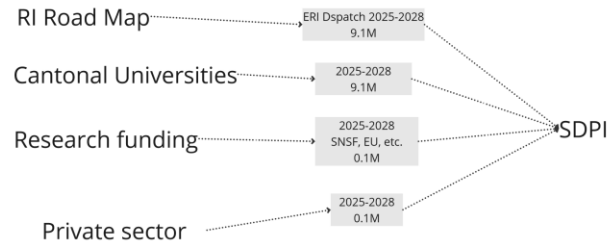
Main ORD Services and infrastructure

SDPI will promote digital diagnostic workflows on a national level by establishing five components: (a) data creation, (b) data storage, (c) data sharing, (d) data enhancement, and (e) data computing, all developed in line with FAIR principles.

AI capability

It will support current collaborations with AI experts working with DP data and the developme nt of more efficient computational workflows an d AI methods for biomedical image data.
The data-sharing infrastructure will be designed to support novel experimental setups, including federated machine learning. These
data and infrastructure will facilitate the longitudinal studies and subsequent improveme nt of computational models and algorithms.

Funding



Governance model

Governed through a consortium agreement, which is managed by the SDPI Executive Board: USZ/UZH, UniBe, UniGe. The SDPI Consortium represents all five Swiss Universities, 2 VetSuisse faculties, SPHN driver project leaders as well as key stakeholders in the DP development. Key stakeholders are organized in the Swiss Digital Pathology Consortium (SDiPath) and the Swiss Society of Pathology (SGPath).

Beneficiaries and Users

Swiss patients and clinicians, national and international research programs and scientists.

International cooperation

SDPI aims to collaborate with international researchers to support the large-scale integration of health data and pooling of resources for research purposes and clinical trials. Thus, SDPI aligns with both the national and international priorities -- of the European Commission on digitalization in healthcare and of the Swiss State Secretariat for Economic Affairs (SECO) for advancing research and innovation in the digitalization domain.

8 – Swiss HIV Cohort Study (SHCS)

Key role

SHCS is a systematic longitudinal study enrolling people with HIV in Switzerland. The major goal is to provide optimal patient care, reduce HIV transmission, and conduct research on HIV treatment, pathogenesis, co-infections, immunology and virus–host interactions. The core of the SHCS is the data repository and biobank. Standardized data collection includes epidemiological, demographic, behavioral, psychosocial, clinical, laboratory, and treatment information. The SHCS is supported by the SNSF to become a Data Infrastructure and Services (DIS), integrating ORD principles.

Development plan

-Transformation into SNF Data Information and services (DIS): more focus on FAIRification of data, especially in terms of interoperability with SPHN and SBP.
-Define legal structure, strengthening privacy concepts in development with ETH domain (personalized health and related technology, PHRT), integration of WGS and AI

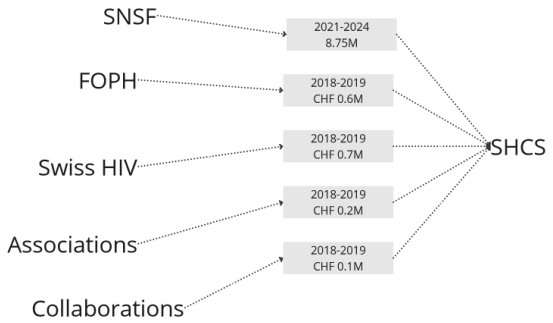
AI capability

n/a

Main ORD Services and infrastructure

- Data repository
- SHCS plasma and viable cell repository
- electronic data entry tool
- generic modular framework for IT infrastructure
- Facilitation of nested clinical studies and multi-cohort collaborations, and linkage to other studies
- Export of data for research
- collaborations with patient focus groups and the AIDS Hilfe Schweiz
- results of studies directly applied to patient care
- Services to physicians and clinics
- Services to public health authorities
- Promotion of education and outreach
- SHCS webpage

Funding



Governance model

The five university hospitals, the St Gallen cantonal hospital, and the regional hospital of Lugano are responsible for the initiative.

- Executive board (EB)
- Scientific board (including patients community)
- Clinics and Laboratories Committee (CLC): decides on all clinical and laboratory parameters collected within the SHCS
- Swiss Mother and Child HIV Cohort Study (MoCHiV)
- EB, SB, CLC and the MoCHiV board form the Full Assembly (FA)
- Data Center: directly reports to the SHCS president
- SHCS plasma and viable cell repository: decentralized biobank hosted in 8 different laboratories.
- International Advisory Board: provides general advice, and includes two leading experts in the field

Beneficiaries and Users

International and national researchers and clinicians (highly pruductive scientific output) within or outside SHCS, health care providers and university institutions, other cohorts or registries, the government (FOPH, FSO)

International cooperation

National and international cohort studies (RESPOND, EuroSIDA, ART-CC, etc.)
Maelstroem catalogue
national and international collaboration projects
European AIDS Clinical Society

7 – Swiss Transplant Cohort Study (STCS)

Key role

STCS prospectively enrolls patients who receive a solid organ transplantation in any of the centres of Lausanne, Geneva, Basel, Zurich and St Gallen. Standardized data collection includes demographic, psychosocial, clinical, procedure-related, laboratory, treatment information, and long-term outcomes. STCS provides a data infrastructure, a data repository and a biobank around transplantation.

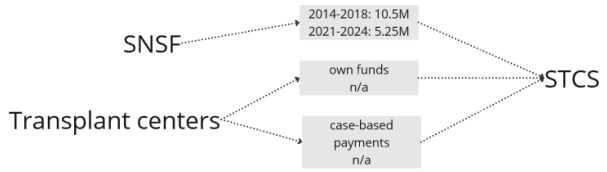
Development plan

STCS plans to become an SNSF Data Infrastructure and Services (DIS)- an independent legal structure and governance, with the integration of patient representatives. It involves the development of services towards FAIRification of the data, open access to metadata, regular integration of EHR routine clinical care data from hospitals with STCS data for research and clinical purposes, personalized biobanking sampling.

Main ORD Services and infrastructure

-Management of user requests
-Management of STCS' metadata
-Data management services
-Biostatistics or data science services
-Nested project planning and management
-Data repository and biobank
-Regulatory support
-Scientific IT services
-IDEAL: hospital-based software for patient identity management and record linkage
-Services for FAIRification, Open Data
-Training and tutorials for management, processing and analysis of STCS data

Funding



Governance model

Since 2022, the STCS is a legally independent association between the five University Hospitals and St. Gallen cantonal hospital- the six hosting institutions of the transplant centres in Switzerland.

- General Meeting of Members: highest governing body
- Steering Committee
- Management Board
- Scientific Committee
- Patient Advisory Board
- Strategic Advisory Board,
- Expert working groups

Full implementation of the new governance structure to be completed by end of 2024.

AI capability

Not planned yet.

Beneficiaries and Users

International and national researchers within or outside STCS, academic teaching hospitals, transplant centers and University institutions, other cohorts or registries, the national transplant physician community, the government (FOPH, FSO), the foundation Swisstransplant, patients with solid organ transplantations, candidates for solid organ transplantations, the public.

International cooperation

Persimune, Match (Denmark), REIPI (Spanish Network for Research in Infectious Diseases), EBMT (European Group of Blood and Marrow Transplantation, over 30 research collaborations.

9 – Swiss School of Public Health (SSPH+)

Key role

SSPH+ is based on the vision that public healt h is a scientific and professional field, shaped by a broad range of disciplines. It assembles the academic public health expertise available across 12 Swiss universities. Its Covid-19 platform facilitates the flow of expertise, questions, and answers between the science community and public leaders.

Main ORD Services and infrastructure

- Covid-19 related platform
- Other SSPH+ services not related to data

Governance model

SSPH+ is organised as a foundation consisting of founding universities. SSPH+ consists of the Directorate, the Foundation Board, more than 200 faculty members and leaders of educational programs (SSPH+ Fellows), as well as its researhers and PhD students.

Beneficiaries and Users

aduate students in public health related subjects. Corona Immunitas is a larger research project, which targets a wider audience including, among others, governmental institutions and the general public

AI capability

n/a

International cooperation

-

Development plan

SPPH+ submitted a large, national RI project for a “Swiss cohort and Biobank” for public health and population health in the context of the RI panning of SERI for the ERI period 2029-2032 (large cohort with 100 000 representatives of entire Swiss population). This project, which is not yet funded, would have direct relevance for the cluster. Reference: https://www.ssph-journal.org/articles/10.3389/phrs.2022.1605660/full

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Funding

11 – Swiss Clinical Trial Organisation (STCO)

Key role

A clinical Research Infrastructure acting as the central cooperation platform for patient-oriented clinical research in Switzerland. Ensures coordination and cooperation between the clinical research centres (clinical trial units (CTUs) to facilitate multicentre and multinational clinical research.
The CTU network provides support on research methods, data management, statistics, monitoring, project management, regulatory affairs, and patient and public involvement. The CTU network is also the main provider of education and continuous training in clinical research in Switzerland.

Development plan

Aim: Implementation of the measures for clinical research of the future ("White Paper: Clinical Research)
-Establish a performance monitoring system for the research infrastructure, adaptable for other RIs and usable for benchmarking
-Develop professional and practical solutions for current and emerging challenges in clinical research.
-Thematic platforms will continue alighning with overarching stratgy with focus on HRO, enabling access to clinical data warehouses, good management of research data, and harmonization.

Main ORD Services and infrastructure

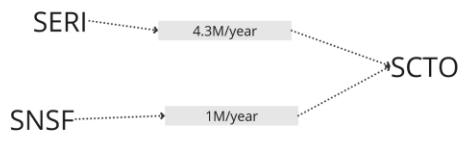
Clinical Trial Unit (CTU) Network is a well-established and nationally coordinated clinical research infrastructure that provides all the services and support needed to conduct high-quality clinical research projects

- CTUs participate in thematic SCTO Platforms in key areas of clinical research: Auditing, Data Management, Education, Monitoring, Project Management, Regulatory Affairs, Safety, Statistics and Methodology
- Support to national paediatric hubs
- Guidance documents, tools, position and strategy papers
- The SCTO and the CTUs often assume the role of data processors when handling clinical data through the services offered.
- - Yearly events for the clinical research community
- -CTUs actively support their home institutions to establish structures and processes to manage data access following the FAIR principles
- -The tools, publications, and resources elaborated by the SCTO Platforms are made freely accessible online to public.

Governance model

An association governed by a
- Steering Board with representatives of the directorates of all hospitals involved, the SAMS, and the Collège des Doyens.
- The SCTO Advisory Board
- Executive Board =The Board of CTU Directors
- Data governance is regulated locally at the hospital level

Funding



AI capability

n/a

Beneficiaries and Users

For the CTU network: academic clinical researchers, and sponsors of industrial clinical research projects

For the SCTO: institutional partners (see governance), authorities, international partners.

International cooperation

Hosts the national contact point for the European Clinical Research Infrastructures Network ECRIN-ERIC
European Patients' Academy on Therapeutic Innovation(EUPATI\)

10 – Swiss Biodata Ecosystem (SBDe, forthcoming)

Key role

The aim is to develop a decentralised national data infrastructure that organizes major research and data producers and providers. SBDe will enable efficient data sharing and reuse, according to the FAIR principles, commonly accepted quality and operational standards, and close collaboration between domain experts and data scientists. Included are 54 platforms, core facilities and research groups at 18 Swiss institutions. Through better coordination of the national and international data science systems, SBDe will help to avoid duplicating efforts and instead integrate existing initiatives and infrastructure. The participating members include experts in AI and big data analytics, who are embedded in the teams of life science experts – a model that ensures that the generated large-scale data is converted into knowledge via specifically developed and optimized data analysis methods.

Development plan

SBDe will be developed across four main pillars:

- Production
- Analysis
- Integration
- Cloud Services

Main ORD Services and infrastructure

- increasing the quality, standardization and efficiency in all workflows - from data production to platform federation
- providing state-of-the-art support to the Swiss research community to make their data, methods, software, and workflow FAIR
- establishing new resources that will reinforce Switzerland's international standing and competitiveness in data infrastructure for life sciences.
- training and education programs
- federating data production platforms, data reservoirs and computing resources
- unified portal relying on the national academic identity service SWITCH edu-ID.
- Production, analysis, integration, cloud services

Governance model

SBDe is governed by a consortium between the participating partner institutions. A consortium board manages the consortium. The Leading House (UNIBE) is mandated to represent the consortium and to receive funds from SERI and other sources on its behalf. It mandates the SIB to lead the Coordination Centre. The governance body will oversee: Project management; Legal, policies, incentives; ethics; dissemination and outreach.

AI capability

Plans to work with AI experts to support standardization, deployment and sharing of trained machine learning models.

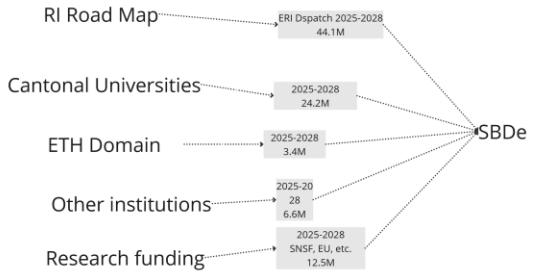
Beneficiaries and Users

A broad variety of Swiss experimental research groups that generate various data to address their specific research questions. Eventually, the scientific communities nationwide– experimental biologists, pathologists, clinicians or computational scientists, mathematical modeling and AI experts; academic and industrial scientists, and clinical researchers.

International cooperation

UniProt, IMI consortia, ELIXIR
Global Biodata Coalition
GA4GH

Funding



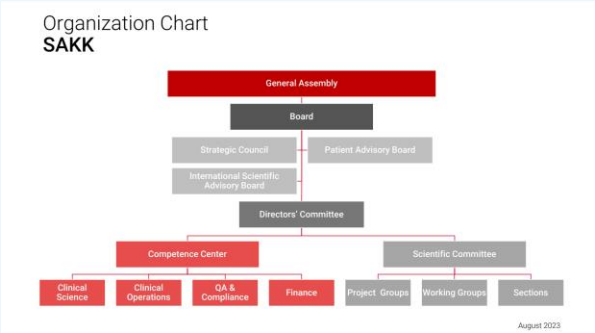
12 – Swiss Group for Clinical Cancer Research (SAKK)

Key role
A primary partner and competence center in clinical cancer research for authorities, associations and pharmaceutical companies in Switzerland. SAKK strives to further develop and improve existing cancer therapies. In clinical trials, SAKK investigates whether new treatments are effective, well-tolerated and safe.
SAKK is comprised of a national network of hospitals and collaborates with hospitals and study groups abroad.

Development plan
SAKK follows a detailed periodic strategy plan.

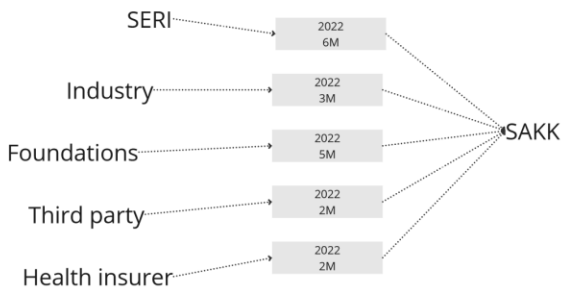
Main ORD Services and infrastructure
- Common semantic Core Data Set (CDS) aligned with the SPHN and NICER data
- Corresponding underlying infrastructure
- SCORED (Swiss Centralized Oncology Real world Evidence Data)
- Electronic Data Capture system secuTrial®.

AI capability
n/a

Governance model


Beneficiaries and Users
Clinicians and scientists from the Swiss research network and pharmaceutical partners in the contexts of research projects.

International cooperation
Hospitals and study groups abroad

Funding


13.1 – Clinical Data Warehouse

Key role

1. organizational units within a university hospital, or a research-oriented hospital committed to set-up the infrastructure and tools supporting researchers to get access to data in a compliant way and in line with their project requirement.
2. storing, organizing, and distributing data that is generated at hospitals as part of their routine work and/or in research projects.
3. work on the evolution of the IT landscape towards data driven products enabling researchers to use the data (analytics).

Main ORD Services and infrastructure

SPHN Federated Query System
SPHN Dataset
SPHN Connector
SPHN Semantic Interoperability Framework
HospFAIR

Governance model

The coordination and development of the CDWs at the university hospital in general is governed/advised by the Hospital IT Strategy Alignment Group (HIT-STAG). CDWs in other hospitals are not (yet) coordinated on a national level.

Beneficiaries and Users

Clinical researchers at the hospitals, collaborating researchers at universities. Potentially private and industrial research partners also.

AI capability

n/a

International cooperation

-

Development plan

HospFAIR aims to improve the quality of shared data and to systematize data standardization and extraction.

Enhance and streamline processes in the university hospitals to overcome bottlenecks for data interoperability and data delivery, through agile and iterative data production cycles.

Provide readily deliverable, high quality , efficiently available dat sets, due to the production pipeline that is systemically implemented at the CDW of the university hospitals.

Funding

* Approximation of initiatives' self-assessment

14 – Swiss Clinical Quality Management in Rheumatic Diseases (SCQM)

Key role

The aim is to enable new ways in the treatment of inflammatory rheumatic diseases through close cooperation between physicians, patients and researchers, and a national patient registry (launched in 1997). Registries:

- Rheumatoid arthritis
- Axial spondyloarthritis
- Psoriasis arthritis
- Giant cell arteritis and polymialgia rheumatica
- Unclassified and others

Development plan

The SCQM strategic and development plans are not publicly available.

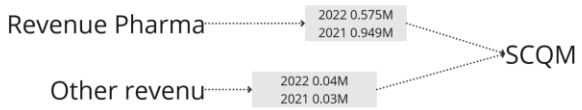
Main ORD Services and infrastructure

- SCQM Database
- SCQM Biobank (serum and DNA samples)
- SCQM imaging database
- Maelstrom Metadata catalogue
- Data Services in place
- SCQM is an EHDEN data partner (OMOP CDM

AI capability

n/a

Funding



Governance model

SCQM is run by the SCQM Foundation. Operational work is organized in an executive office which includes but is not limited to finance, curation of data, statistical data analysis, management of data & services.

Beneficiaries and Users

Rheumatologists in hospitals and private practices for quality management and research purposes

International cooperation

- EULAR, ASAS, CASPAR, FOREUM-collaboartions defining core data sets for certain diseases and collectiono f data for regitries.
- EuroSpA - collaboration on clinical data and on imaging projects leading to increasing alignment with similar registries in other countries.

15 – National Registry of Acute Myocardial Infarction in Switzerland (AMIS Plus)

Key role

Collects and analyzes data on patients with acute myocardial infarction in Switzerland in the pre-admission, hospital and follow-up phases since 1997. Currently over 75000 patients are enrolled. Emphasis is placed on the evaluation of risk factors, diagnostics, urgent therapy strategies and treatment. AMIS Plus data are important for quality assurance, assessing guidelines, improving compliance with guidelines in clinical practice, verifying whether results of randomized clinical trials are translatable into everyday clinical practice, investigating patient groups not extensively studied in large, randomized trials ,and improving therapeutic strategies.
Originally the data covered the hospitalization period. Since 2005, follow-up data collected 1 year after the event is included, if informed consent has been signed.

Development plan

There are currently plans to connect the database with BFS mortality statistics.

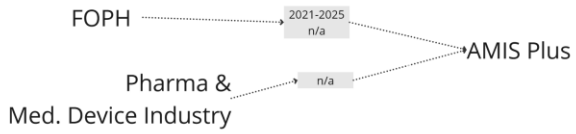
Main ORD Services and infrastructure

- AMIS-Plus datacenter
- Registry

AI capability

n/a

Funding



Governance model

AMIS Plus is a foundation since 2017. The organisation is headed by the Steering Committee. It has its own data center. 83 hospitals have participated in the AMIS project. Currently around 30 hospitals are active contributors, including all major university hospitals.

Beneficiaries and Users

The participating hospitals, including all major university hospitals. The hospitals have access to their own data and can ask for benchmarking with all other hospitals. Researchers from the participating hospitals can ask for specific research questions to be analyzed within the AMIS-Plus datacenter.

International cooperation

Minap registry in UK

16 – Swiss Federated Genomics Network (SFGN, forthcoming)

Key role

SFGN is a partnership of relevant actors in Switzerland and aims to support and harmonize the generation, processing, analysis, and sharing of genomic and other omics data in an ethical and lawful way for biomedical research in Switzerland.
The establishment of the SFGN will be driven by the Genome of Switzerland (GoS) national reference genomic dataset, to inform and test infrastructure development, demonstrate the feasibility of standardized genome data production and sharing at scale, and aid genomic medicine's implementation building knowledge and public trust required for genome-based health approaches. This dataset will further facilitate Switzerland's contribution to the "Genome of Europe" and other global genomic initiatives.

Development plan

-Establishment of the central data repository in the form of a federated EGA node (pre-implantation plan ready for BioMedIT board by March 2024; minimal viable product established by end of 2025)

-Publication of an initial reference WGS dataset from 1000 citizens by end 2024. Scaling to up to 13'000 WGS pending on additional resources.

Main ORD Services and infrastructure

- Genomic data repository
- Initial reference dataset
- Genome of Switzerland (GoS) national reference genomic dataset
- 'Genomic data atlas' (a catalog of unique identifiers and metadata for digitized biological samples)
- Standards to facilitate interoperability
- Seamless plug-in mechanism to international ecosystems of genomic research and medicine
- Field-specific hub for enabling state of the art and certified genomics resources and service capabilities for the community
- Central Data Repository bringing together genomic data legally eligible and consented for secondary use

Governance model

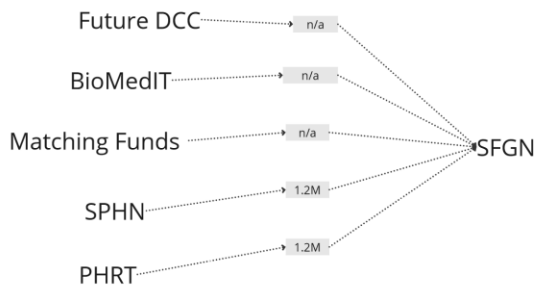
Data Governance

1. Data Coordination Hub: Governance of a 'Genomic data atlas' (a catalog of unique identifiers and metadata for digitized biological samples) and processing requests for data access.
2. Expert Genomics Hub: field-specific for enabling state of the art and certified genomics resources and service capabilities for the community.
3. Central Data Repository

Governance of the initiative

The coordination of SFGN is presently done by SPHN-DCC. No further decisions on governance have been taken yet. GoS will be run by a consortium including SPHN-DCC, Health 2030 Genome Center (hosted by the Fondation Campus Biotech Geneva), SBP, SIB, PHRT.

Funding



Beneficiaries and Users

Researchers in all biomedical disciplines, especially epidemiology and rare diseases (if setup in close collaboration with international initiatives, e.g., GA4GH), Medical geneticists at Swiss hospital

International cooperation

"Genome of Europe"
other global genomic initiatives

AI capability

n/a

17 – National Coordination Platform Clinical Research (CPCR)

Key role
- Strengthen the institutional dialogue between all key public players in clinical and health research active at the national level.
- Help define concerted priority areas for action
- Offer a national, single point of contact to stakeholders to better coordinate their activities.
- Contribute to the improvement of the framework conditions for clinical research in Switzerland.

Main ORD Services and infrastructure
-National, single point of contact
-Dynamic visual map of services

AI capability
n/a

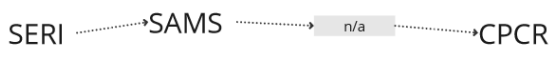
Governance model
The CPCR is a multi-stakeholder cooperation platform which reaches decisions by consensus. The CPCR Chairperson is designated by the SAMS Board. At the operational level, the CPCR is supported by the SAMS office.
Members: key academic organisations and stakeholder group. Permanent guests: SERI, FOPH. Ad-hoc guests: depending on the issues treated.

Beneficiaries and Users
Primarily member institutions. In addition, some outputs will be directly useful for the clinical and health research community (e.g., map of services of SAKK/SBP/SCTO/SPHN-DCC).

International cooperation
n/a, ensured by stakeholders

Development plan
-The CPCR mandate from SERI runs until the end of 2024. Its added-value, structure, organization, and necessary resources will be reexamined in view of the ERI period 2025–2028, so as to best serve the needs of clinical research stakeholders.

Funding



18 – FOPH /FSO initiative for digital transformation of health system and interoperable health data (Digisanté)

Key role

The Federal Department of Home Affairs' (EDI) program to promote digital transformation in the healthcare sector in Switzerland. Its objective is to establish the interoperability and secure exchange of data in the healthcare system for various purposes and users. The program plans to agree on standards and to prepare the legal and regulatory bases to allow data for treatment, billing, research and administration to be used and exchanged seamlessly. It also aims facilitate the secondary use of health data for planning, management and research within the legal framework. A stronger coordination between the participating federal administration bodies (e.g. Federal Council, FOPH, FSO) and all relevant stakeholders is focus of DigiSanté.

Development plan

- Preparation and initialization: until end 2024.
- Program running period: 2025-2034.

Main ORD Services and infrastructure

The aim is not the development of technical infrastructures and services, but the provision of necessary updates to the legal and regulatory bases through four strategic objectives and implementation packages.

-Prerequisite for digital transformation
Technical prerequisites to ensure seamless information exchange

- National infrastructure

Create the necessary infrastructure to enable secure and seamless data exchange.

- Digitizing government services

Improve quality and efficiency of data exchange between authorities and healthcare providers

- Secondary use for planning, management and research

Making data from the healthcare system seamlessly usable for planning and management by the authorities and stakeholders. Get academic and provate sector researchers a better access to health data.

Governance model

Federal Council gives a mandate to the Federal Department of Home Affairs (EDI), with FOPH and FOS as co-leading offices. They cooperate closely with the Conference of Cantonal Directors of Health (GDK) and involve all relevant stakeholders.

Funding

The Confederation plans to invest 392 Mio CHF over 10 years (2025-2034). Parliament will need to validate this credit.

AI capability

n/a

Research community addressed

Extremely broad: Patients, citizens, healthcare providers, authorities, administration, researchers, private sector.

International cooperation

All data standards will be set in alignement with international standards. The aim is to ensure an interoperability of all types of data from the healthcare system between all concerned stakeholders within Switzerland and with international partners (for research; for administrative data, focus on compatibility with systems from neighbouring countries).