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Federal Department of
Economic Affairs, Education and Research EAER

**State Secretariat for Education,
Research and Innovation SERI**
National research and innovation

Mandate

by the

Swiss Confederation

represented by the

**State Secretariat for Education,
Research and Innovation SERI**
Einsteinstrasse 2
3003 Berne

hereinafter referred to as the **mandating party**

to

Prof. Dr. Antoine Geissbühler
Prof. Dr. Primo Schär
Prof. Dr. Christian Wolfrum

hereinafter referred to as the **mandatees**

concerning

Object: Development of a strategy and implementation plan for the coordination of health data for research and other secondary usages after 2028

Duration:	18 months	Start:	February 1, 2025
		End:	July 31, 2026

Responsibilities:

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1 Initial situation

1.1 National initiative SPHN 2017-2024

With the “Swiss Personal Health Network” (SPHN, 2017-2024) initiative, the Confederation is pursuing the goal of establishing a Swiss network in “Personalized Medicine” in which all relevant research institutions in this field are involved. The operational focus of SPHN-DCC 2017-2024 is on the organization of clinical and related data (omics data) according to internationally established standards for the purpose of research. According to the additional protocol of the SPHN initiative 2021-2024, a possible opening up to include further health data can be examined after the initiative has been completed. As part of this mandate, it must be clarified which expansion is useful and feasible.

1.2 SPHN-DCC 2025-2028

The national SPHN initiative ended in 2024, but it has been planned to permanently establish the data coordination center SPHN-DCC once the initiative SPHN comes to a conclusion. As part of the consolidation of the Data Coordination Center (DCC), the SAMS was commissioned to present a report by the end of 2022 outlining the options for the consolidation of the Data Coordination Center (DCC) after 2024 and to carry out the necessary clarifications. Based on the SAMS’s clarifications in this regard, the ERI-Dispatch 2025-2028 plans to implement the DCC under the governance of the SAMS as an interim solution in the ERI-period 2025-2028. This will allow further clarifications to be made regarding the consolidation and positioning of the DCC after 2028, also taking into account other federal processes, such as the federal data strategy. SERI convened a round table chaired by the State Secretary on June 3, 2024 asking the invited stakeholders for feedback on the planned SPHN-DCC 2025-2028 (SPHN-DCC implementation concept) as well as possible paths to the SPHN-DCC after 2028 (goal of a permanent solution). The result of the round table was that 1) the SPHN-DCC 2025-2028 concept is supported by all stakeholders and 2) that three experts should be mandated ad personam to carry out the necessary clarifications on how the SPHN-DCC can be made permanent after 2028 resp. how data coordination can be ensured after 2028.

1.3 National Data Coordination Office in the realm of DigiSanté

As outlined in the Federal Council's report in response to the postulate 15.4225 Humbel “Better use of health data for high-quality and efficient healthcare” and the follow-up project “Data space for health-related research” in the realm of the DigiSanté programme, a National Data Coordination Office in the health sector (NDKS) is foreseen to be established. The NDKS is planned to be a service provider in the sense of a bundling of tasks in the foreseen Swiss Health Data Spaces to be established in DigiSanté, focusing on the secondary usage of health data. The NDKS assumes the role of data broker in data exchange as well as of a trust center with regards to data linkage (of different sources) and de-identification of data. As an organization within the competence of the federal government, the NDKS is planned to be equipped with the functional and technical units and legal foundations necessary to fulfil its tasks.
In the realm of the respective DigiSanté project, the responsible FOPH and FSO team is currently elaborating an NDKS concept encompassing solution requirements for infrastructure components regarding secondary data use based on the needs of the research community and in consideration of the requirements of the BK-DTI for trusted data spaces.

1.4 Steps towards a framework for multiple use of health data after 2028

On July 24, 2024, the State Secretary provided information on SERI's next steps with regard to the expert group tasked with developing a strategy and implementation plan for data coordination in the area of health data research after 2028, taking into account the broader development of the Swiss Data Space for health-related research and its planned infrastructure and service components, such as the NDKS. The experts will specify challenges to be discussed at a next round table.
Following this discussion, the aim will be to draw up an implementation plan. The State Secretary informed that SERI is mandating a core group of three experts in the field of data-driven research, namely Prof. Dr. Antoine Geissbühler, Prof. Dr. Primo Schär and Prof. Dr. Wolfrum, *ad personam* for this work. They will be tasked with setting up a larger working group to make the necessary clarifications on data coordination after 2028. SERI expects the relevant stakeholders and existing bodies (such as the National Steering Board of SPHN or the National Coordination Platform for Clinical Research CPCR and others) to be involved in an appropriate manner so that broad-based and sustainable results can be developed.

2 Objective and implementation of the mandate

The objective of the mandate is to develop a framework for data coordination in the area of health data research after 2028 that is financially viable and ensures long-term relevance for the various user groups. In order to find a solution for the coordination of data after 2028, it must be clarified in particular:

- What data (for secondary use) should / can realistically be coordinated after 2028 for purposes of research, health care and public health policy (multiple/secondary use)?
- How can the interoperability of these data be ensured in the long term?
- How would the coordination of this data be embedded in the existing ecosystem and how would it differentiate itself from or complement existing organizations in Switzerland (such as SCTO, SIB, SAKK, SBP etc.)? What would be the implications of the proposed structure for the existing ecosystem in terms of organization and coordination?
- Which governance / (legal) organizational form is suitable for the coordination of data after 2028 and how can it be technically anchored?
- What are the financial requirements (budget), which financing models are available (business model) and how could the financing be secured (willingness of responsible bodies to provide financing for *their* use, i.e. research, health care, public health policy and others)?
- Based on these clarifications: Is the SPHN-DCC the appropriate entity to address the functions and challenges elaborated in the previous bullet points? If yes: How could it be implemented after 2028. If no: What would be an alternative solution?

It is also necessary to examine how the implementation of data coordination in the realm of health data after 2028 can be coordinated with the federal government's sectoral policies. In particular, the activities in the DigiSanté programme of the FOPH and FSO and their implications for the organization and financing of a system for multiple/secondary data use after 2028 should be taken into account. In this regard, it is particularly important to clarify whether the proposed solution for data coordination can itself perform the tasks (or part of the tasks) of a National Data Coordination Office in the health sector (NDKS) after 2028, as outlined in the Federal Council's report in response to postulate 15.4225 Humbel. Therefore, it is necessary to clarify the extent to which the necessary framework for data sharing/re-use will already be covered in the context of DigiSanté in the future. If the finding is that data sharing for research purposes and for purposes of healthcare and public health policy should be organized as separate units after 2028, interfaces between the two must be defined.
The group of experts should use existing committees, in particular CPCR (which organizes many important actors in clinical and medical research via the coordination platform), to support its clarifications and recommendations. Projects of the federal administration, such as the electronic patient record or the Swiss Health Survey, are also to be examined in terms of their relevance to the proposed system for multiple/secondary data use in the health data space. To that end, the experts advise SERI on research policy issues related to the coordination of data in the health sector.

2.1 Development of a strategy report and an implementation plan

Plan for the implementation of the mandate (until first week of March 2025)
The three ad personam experts develop a plan that specifies how the mandate is to be implemented in practical terms (specification of the objectives and approach until the first week of March 2025 within the corner stones of this mandate) and identify opportunities and challenges related to this strategy. SERI will give the go/no go to the experts' proposal by the end of March 2025. Based on this decision, the experts will draft a strategic report (see below). The experts are to create a working group that includes the necessary expertise to address the questions mentioned below (**1.-6.**) in order to write the strategy report. Milestones should also be formulated and how they are to be achieved should be explained.

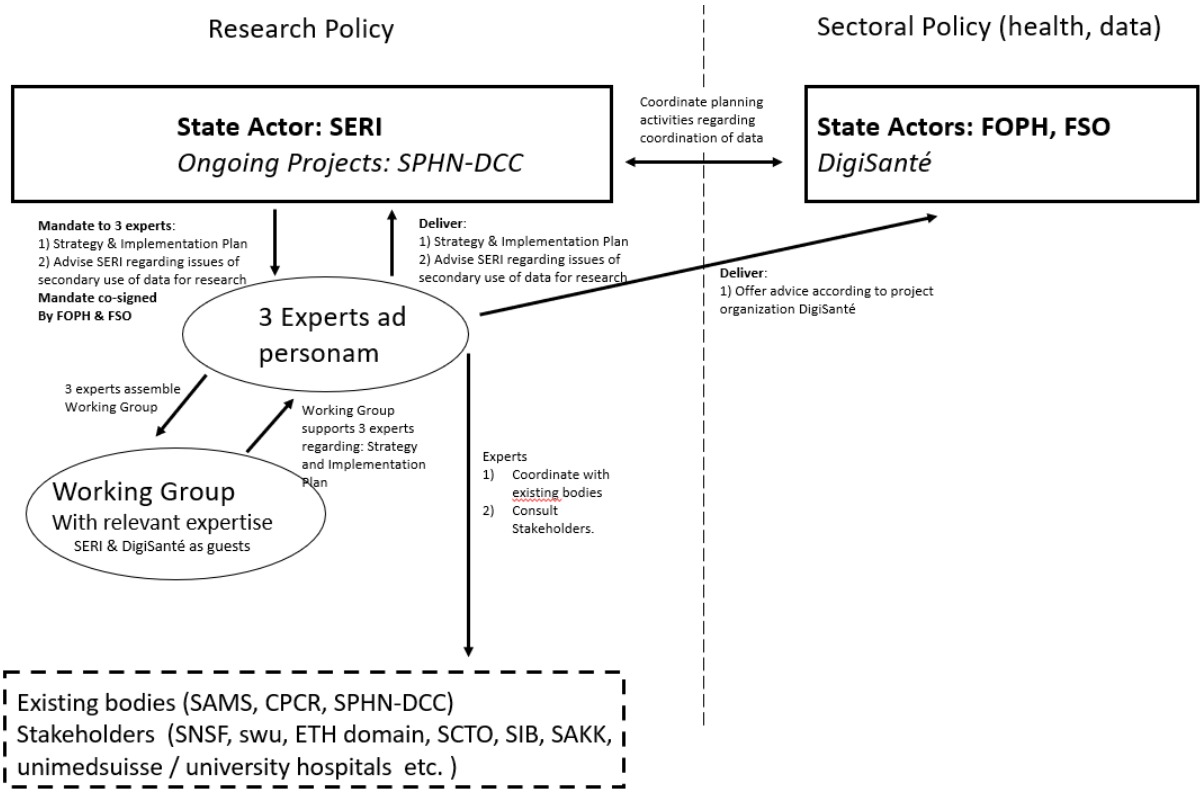
Strategy report (until mid-July 2025)
SERI commissions the three experts to write a strategy **report** in English by **mid-July 2025** (max. 20 pages), proposing solutions for the following issues:

1. **Governance, organizational form and embedding in the ecosystem:** What governance and organizational form should the proposed architecture for data coordination assume after 2028 and how should it be embedded in the existing ecosystem? Can the solution be built on the current SPHN-DCC or is there a need for a new entity? What are the interfaces to national (e.g. ORD, EPD) and international partners? What opportunities and risks are associated with the proposed architecture?
2. **Profile, tasks and competencies:** What basic tasks should the entity coordinating health data take on after 2028? What are the prerequisites and conditions allowing interoperability and data integration in the long term and how can they be realized? How does the proposed architecture relate to existing organizations in Switzerland? Does the proposed solution fit into the Swiss research funding system (if yes: why, if no: how can this be addressed)?
3. **Type of data:** Based on the data coordinated by SPHN-DCC in the period 2025-2028, it should be determined which additional data can realistically coordinated from 2028 on (in addition to technical questions, financing issues must also be addressed).
4. **Coordination with federal sectoral policies:** To what extent can the proposed architecture for data sharing address political objectives from federal sectoral policies (e.g. DigiSanté) with its content profile? How can these objectives from the sectoral policies be legally supported and financed by them? To what extent does DigiSanté cover the data coordination and related services necessary for research? How should the proposed architecture be coordinated with what is already provided under sectoral policies?
5. **Financing:** The financial requirements of the proposed architecture after 2028 onwards must be estimated. It also needs to be clarified: How can financing be secured (business model with appropriate detail of funding sources)? How could the financing be secured? According to the business plan, would the responsible bodies be willing or able to provide financing? Can a financing model be implemented without the financial support of SERI? If SERI is to provide finances for the multiple/secondary use of data in research, matching funds are required.
6. **International aspects:** How is the proposed architecture aligned with the European health data space and international standards to ensure that Swiss data and research can be interconnected internationally?

Implementation plan (until end of February 2026)
SERI will convene a **round table on the SPHN-DCC after 2028** in **October 2025** to consult stakeholders on this report. The three experts will be tasked with developing an **implementation plan** for the SPHN-DCC after 2028 in the form of a report based on this strategy report and the feedback from

the round table. In this implementation plan, further necessary concretizations are to be made. The report on the implementation plan must be available by **the end of February 2026**. Stakeholders will then be given the opportunity to comment on the final implementation plan by **the end of June 2026**. SERI will plan the implementation of the SPHN-DCC after 2028 onwards based on the implementation plan and the comments received.

Representation of the responsibilities that are regulated or assumed under the mandate



2.2 Procedure for developing the strategy and implementation plan

- Plan for the implementation of the mandate by the experts until first week of March 2025.
- The three experts set up a working group to cover the competencies required to implement the mandate (i.e. develop a strategy and an implementation plan).
- The experts ensure that their work on the strategy report and implementation plan for the proposed solution for the coordination of health data after 2028 is coordinated with existing organizations, committees and projects by the federal administration and that there is no duplication of effort. These are in particular (but not exclusively)
    - Swiss Academy of Medical Sciences and the bodies under its responsibility: CPCR & SPHN-DCC
    - ORD Strategy Council
    - Project “Data Space for Health-Related Research” (DigiSanté)
- The experts ensure that stakeholders are involved in an appropriate manner in order to achieve broad-based results.
- The experts take into account relevant publications, such as the report “The SPHN Data Coordination Center (SPHN-DCC): Consolidating the SPHN infrastructures beyond 2024” (SAMS, 2023)
- SERI is responsible for the overall process, the experts are in regular contact with SERI and inform SERI promptly about relevant developments. SERI takes the lead in the exchange with the ERI stakeholders as well as with stakeholders from the Federal Administration such as the Federal Office of Public Health (FOPH) and the Federal Statistical Office (FSO).

2.3 Advise to SERI and DigiSanté (FOPH/FSO)

SERI and DigiSanté work together in order to achieve a solution for the multiple/secondary use of health data in the health data space for the purposes of 1) planification, 2) steering and 3) research. Research shall be distinguished in several types: a) academic research, b) industrial research and c) research by the federal administration ("Ressortforschung").[1]
The funding and policy of 1) planification, 2) steering and 3c) research of the federal administration in the domain of health (or other domains) lies in the responsibility of the respective federal offices.
On the level of the federal government, SERI is responsible for creating optimal conditions for academic research (funding and policy regarding basic and applied), whereas it has the lead in the coordination of the research by the federal administration ("Ressortforschung").
Industrial research is funded and implemented by private entities, whereas the Swiss Confederation aims at creating fertile environment for that type of research by its policy and funding of academic research.

Multiple/secondary data use in the health domain		Funding responsibility on the federal level (in case of federal funding)
1) Planification		DigiSanté (FOPH/FSO)
2) Steering		DigiSanté (FOPH/FSO)
3) Research		
	academic	SERI
	industrial	(Responsibility of private industry)
	by the federal administration ("Ressortforschung")	DigiSanté (FOPH/FSO), [other offices, if applicable]

Table 1: Types of Research and responsibilities on the federal level

- The experts advise SERI on research policy issues related to the coordination of data in the health sector (SPHN-DCC & DigiSanté, Health Cohort etc.). The experts support SERI in other relevant projects, such as the "Health Study" (cohort study, mandate Federal Council to FOPH with implication of other offices)
- The experts advise DigiSanté in accordance with the program organization in the expert panel (Fachgremium) of the project "Data Space for Health-Related Research: Framework for the Secondary Use of Data for Research and Evidence-Based Policy Making in the Health Sector" in Relation to Research Policy Issues for the Coordination of Data in the Health Sector. (See Fig. 1)
- Contact SERI-DigiSanté-Experts: According to the DigiSanté program organization, there are defined contacts at the level of the project "Data Space for Health-Related Research". SERI will be represented in an internal committee of the federal administration (FOPH, FSO and SERI) (Fachausschuss) and the mandated experts will be represented in the project's expert panel (Fachgremium), so that an optimal flow of information is ensured

2.4 No financial compensation

The mandated experts do not receive any financial compensation from SERI for fulfilling the mandate.

[1] Cf. Report on Postulate 15.4225 Humbel, p. 13ff. & DigiSanté Dispatch, p. 47.

2.5 Milestones

The following milestones are planned for the development of the concept

Date	Milestone
First week of March 2025	Concept by the experts for the implementation of the mandate: objectives and approach (within the parameters of this mandate).
End of March 2025	Go / No-Go SERI on the experts' concept on the implementation of the mandate (strategy report, implementation plan)
End of July 2025	Submission of interim strategy report in English
mid-September 2025	Submission of strategy report in English to SERI
Early October 2025	Dispatch of strategy report to participants of the round table by SERI
End of October 2025	Round table on the strategy report
End of November 2025	Dispatch of any written comments from the round table participants on the SPHN-DCC strategy report (incl. minutes of the round table)
End of January 2026	Implementation plan, based on strategy report and discussion at round table, sent to SERI
End of February 2026	Implementation plan sent by SERI to round table participants
End of June 2026	Written statement from round table participants on the implementation plan to SERI
From July 2026 on	Implementation plan as input for the planning of SERI and other involved institutions

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