Strategic Focus Area
Personalized Health and Related Technologies

Swiss Personalized Health Network

Swiss Personalized Health Network (SPHN) and ETH Strategic Focus Area "Personalized Health and Related Technologies" (PHRT)

Joint call for proposals - National Data Streams

Specifications for full proposals

17 November 2021

Update 6 December 2021: section 2.4.1 has been added

Purpose

These specifications provide **additional** information for those applicants invited to submit a full proposal for the joint SPHN and PHRT Call for National Data Stream (NDS). All requirements described in the Call document[1] (01 June 2021) also apply.

Templates for NDS full proposals will be made available on https://sphn.ch/services/funding/nds/ in the coming days.

Timeline

November 2021	Selected applicants are invited to submit a full proposal
27 February 2022 (23h59 CET)	Submission deadline for full proposals for NDS
03 May 2022 (in Zurich)	Interview of applicants by the evaluation panel
End of May 2022	Final selection of NDS by the SPHN NSB and PHRT EC
01 June 2022	Earliest starting date for NDS grants
31 May 2025	End date of NDS grants

Full proposal preparation

All IT services need to be discussed with the hospital IT and BioMedIT in advance and budgeted accordingly. **NDS applicants must contact CDWs and BioMedIT nodes early on**, otherwise services cannot be guaranteed.

[1] Available on https://sphn.ch/services/funding/nds/

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PHRT | Personalized Health and Related Technologies
CLP | Clausiusstrasse 45
CH-8092 Zürich
phrt-office@ethz.ch | www.sfa-phrt.ch

If your project includes support by PHRT, it is important to **liaise as soon as possible with the PHRT Office (phrt-office@ethz.ch) to discuss the PHRT part of the budget**, as there are strict rules governing the attribution of PHRT funding out of the ETH domain institutions which your budget must adhere to. PHRT funds mainly research parts of ETH Domain scientists that are involved in an NDS. In addition, it is possible to ask for clinical services funding outside of ETH Domain institutions.

As described in the Call document[2], approved ethics protocols will be needed at the start of the NDS. To speed up the process, **applicants may submit their study protocols to the relevant ethics committees (EC) before the final selection of proposals is made.** SPHN and PHRT will cover the costs from the EC (max. CHF 3'000) regardless whether the NDS will eventually be funded or not.

Requirements for full proposals

1. Required information on consortium composition (application template Part A)

1.1 BioMedIT staff

Staff of BioMedIT nodes shall principally not participate in the role of co- or associate applicants, but support NDS as service providers. Services that surpass basic support can be offered to NDS consortia at cost and must be clearly specified in the support letter/feasibility statement.

1.2 Project and data management requirements

Please provide the contact details of the project and data manager, if already known, in Part A of the application template.

A project manager position (1 FTE is recommended) shall be budgeted for. In analogy to a scientific officer at an NCCR, this person shall coordinate all project management aspects in regard to data, infrastructure, science, ethics and legal. This person is to be recruited at the start of the NDS funding at the latest, and will act as the main contact point for SPHN and PHRT Offices and DCC.

In addition, a data manager (1 FTE is recommended) is to be recruited at the start of NDS funding at the latest. The data manager is in charge of the smooth cooperation with the data provider teams, and responsible for data management, data standards, RDF Schema design, data linkage and data quality control from the start of the NDS, the management of data and data deliveries during the NDS, and FAIR data deposition, all in line with the SPHN Interoperability Framework and FAIR principles (see 5.2 for more information). This person will work closely with the SPHN Data Coordination Center (DCC).

[2] Available on https://sphn.ch/services/funding/nds/

2. Additional project requirements (application template Part B)

2.1 Executive summary (B.1)

A short description of the NDS proposal's relative position in the international landscape/international comparison shall be given.

2.2 Description of the consortium (B.2)

The experience of the specific consortium members and institutions in collaborating together shall be described.

2.3 PPI elements (B.3)

NDS shall provide a long-term, data-rich research platform for the next generation of researchers and clinicians. In this context, SPHN and PHRT regard it essential to embrace PPI similar to how it is practiced in other countries and since 2021 also in SNSF's Investigator Initiated Clinical Trials (IICT) program.

PPI encourages fruitful, sustainable, and enduring partnerships between scientists and patients/patient organizations, co-leading the way for systematic patient-centered research. NDS applicants shall orient their PPI activities on the respective fact sheets of the Swiss Clinical Trial Organization (SCTO)[3] and "PPI resources for NDS applicants" document on the NDS website[4].

NDS full proposals need to describe:

- How patients will be engaged and involved in the NDS to identify patient needs, highlight new research directions, design and develop research proposals, implement research, and contribute to interpretation, findings, and benefit for patients.
- How activities and findings of the NDS will be communicated and disseminated, also to lay people.
- 1-page lay summary.

PPI will be an evaluation criterion for NDS full proposals.

2.4 Data requirements (B.5)

To evaluate the quality and feasibility of the NDS full proposal, the set of data to be used by the NDS must be specified up-front (incl. requested concepts/variables, origin of data, structured/unstructured, availability, standards). The NDS full proposal application template will contain a respective table/description (see chapter 4, required appendices).

In- and exclusion criteria for the patient cohort need to be clearly defined in the full proposal.

To ensure NDS can seamlessly integrate with other SPHN and PHRT infrastructures and to conform with FAIR principles for data according to the SPHN Interoperability Framework, the following requirements are mandatory:

- Data of the NDS must be transferred, stored, and made available for reuse in RDF (an SPHN and FAIR compliant knowledge graph) according to the latest SPHN RDF schema. Exceptions are multimedia and omics data; however, the metadata are also required in RDF. Requests for other exceptions

[3] https://www.scto.ch/en/publications/fact-sheets.html
[4] https://sphn.ch/services/funding/nds/

must be very well justified and the compliance with the FAIR principles needs to be guaranteed. Projects not complying with the SPHN Interoperability Strategy will not receive support from the DCC.

- All data variables must be semantically defined as a concept according to the latest SPHN dataset. If a variable is not yet defined in the SPHN dataset, the NDS is in charge of proposing a new concept and must work with the DCC and subject matter experts to include a harmonized semantic concept in an upcoming release.

For questions regarding data requirements, please contact the DCC (dcc@sphn.ch).

Requirements during the NDS funding period

Change requests regarding the requested data from the university hospital clinical data warehouses (CDWs) during the project must be limited to ensure efficient use of resources. Change requests to the NDS dataset shall be made in a structured way (6 months and 12 months after the start of the NDS) and must be budgeted adequately.

An NDS data specification in form of an NDS RDF Schema needs to be developed and sent to the data providers (e.g., university hospital clinical data warehouses) within the first 6 months of the start of the NDS. The NDS RDF Schema needs to comply with the SPHN RDF Schema and the SPHN guidelines for extension. Change requests to the NDS RDF Schema shall also be limited and formally submitted by the NDS data manager. The NDS data manager distributes and manages new versions of the NDS RDF Schema to all data providers via their specific central GitLab folder. The NDS is obliged to update to the latest SPHN RDF Schema release.

2.4.1 University hospital contact persons for data requests

To submit data requests and change requests pertaining to university hospital data, please use the following contact information:

USZ	ctc-rdsc@usz.ch
Inselspital	productline_LF@insel.ch (Dominique Furrer)
CHUV	solange.zoergiebel@chuv.ch
HUG	catherine.chenaud@hcuge.ch
USB	bram.stieltjes@usb.ch

2.5 Data governance (B5.4)

To permit the most efficient and ethical use of data, the consent should be as inclusive as possible, following the provisions of the General Consent template of Swissethics.

Support for drafting and reviewing legal agreements for data sharing in the framework of the SPHN and PHRT NDS program is available through the ELSI helpdesk.

SPHN has drafted a set of recommendations for organizational structures facilitating adherence to the regulatory framework for data sharing in SPHN-funded projects[5], in line with the provisions of the NDS Call for Proposals.

2.6 Implementation (B.7)

Clear work packages, milestones, and timelines for the entire project are needed and must be clearly communicated in the implementation plan of the application template.

Risk assessment and contingency plans are required.

3. Additional budget requirements (application template Part C)

Please make sure to include the following expenses in your budget:

- Data manager (1 FTE recommended)
- Project manager (1 FTE recommended)
- IT services and data (change) requests during the project

4. Required appendices (application template Part D)

For NDS full proposals, the following supporting documents are required:

- Commitment letters of all applicants' institutions receiving SPHN funds, specifying the contributions of the applicant and/or their institution (own contributions, SPHN-funded contributions, third-party contributions)
- Letter of support incl. feasibility statement from all data and service providers (incl. PHRT platforms/centers/hubs, clinical data warehouses, and BioMedIT nodes). This includes budgets for eligible costs (data curation, analysis costs, bioinformatics costs, etc.; see chapter 8 of the Call document)
- Detailed consortium agreement: governance, organizational structure, ethical, regulatory and legal framework including data sharing, intellectual property, and publication policy
- A data management plan
- A table/description of the data to be used in the NDS, incl.
    - List of SPHN concepts (v 2021.1) to be used
    - List of additional variables to be specified and included (provide suggestion for concept following the SPHN Dataset as template where available)
    - List of data standards, origin of data, structured/unstructured
    - Availability of data (per center), automated or manual extraction.

[5] https://sphn.ch/document/recommendations-for-organizational-structures-facilitating-adherence-to-the-regulatory-framework-for-data-sharing-in-sphn-funded-projects/

4.1 IT services

As mentioned above, a binding feasibility statement/letter of support from **each** service provider, specifying the services provided and resources required, must be submitted with the full proposal.

BioMedIT provides a base package for all projects without costs, covering basic compute resources (20 TB storage, 20 CPU cores, and 32 GB RAM), access technologies, data transfers, pre-installed software and standard support. Additional services have to be defined in a service agreement with the service provider.