Mandate

SPHN Data Governance Working Group

February 2023, V1 (approved by the SPHN NSB)

Starting position

The contractual architecture for a collaborative use and exchange of health-related data for research depends on the project specifications and responsibilities of participating parties, and is part of the legal and regulatory framework.

In March 2019, a Data Transfer and Use Agreement (DTUA) Version 1.0 was published constituting a harmonized legal agreement template developed by the representatives of the Swiss university hospitals and national key actors of the Swiss research community.

This DTUA Version 1.0 did not yet include a Processing Agreement covering the processing role of the BioMedIT network to be used in SPHN-funded projects. This Processing Agreement part, as well as additional remaining aspects provided by some university hospitals such as

- Minimal security requirements
- Information and audits of security measures

were integrated in the agreement template represented as the DTUA Version 2.0 including a Data Transfer and Processing Agreement (DTPA).

The DTUA Version 2.0 was officially released in November 2020 (after two DTUAs based on Version 2.0 had been approved by the legal departments of all university hospitals, ETHZ and universities) and published on the SPHN webpage. Moreover, templates for a Consortium Agreement including a DTUA/DTPA were developed.

In the meantime, many DTUAs based on the version 2.0 (and a further adapted version 3.0) have been executed and some change requests have been expressed on a regular basis that should be addressed in a next version 4.0. According to the latest NDS call, reuse of data on a 2nd and 3rd level is a requirement, so that legal agreements set up for an NDS should allow the controlled reuse of data. In addition, regulations for using and transferring samples are integrated based on the MTA template of the Swiss Biobanking Platform (SBP).

To streamline the revision process, a “Master legal agreement template”, was created. This template, a CA/DTUA/DTPA/MTA, serves to discuss most important changes and added clauses. In particular, the following content is concerned:

- Use and transfer of biological material (MTA based on SBP template (Schedule 4 to CA))
- Controlled reuse of data (2nd and 3rd level use) in general allowed
- Additional responsibilities of Executive Board suggested to streamline reuse of data (approval of reuse by third parties)
- Reuse and preservation of data after termination of consortium to be regulated in a new agreement
- Restriction to download data from the BioMedIT Node
- Return of data upon termination (responsibility is with principals)
- Separate provision of financial terms of services

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Vision and Mission

To elaborate harmonized Switzerland-wide solutions for a contractual framework allowing a responsible use of health data, the current ad-hoc group of experts shall be established as an SPHN working group including representatives from Swiss hospitals and research institutions (and data subjects and industry). Different challenging topics of nationwide interest, for which so far no clear guidance exist, shall be discussed within this group, such as data governance and general value of health-related data and compensation for data providing institutions.

Alignment on the contractual framework and data sharing strategy for the reuse of data in multi-site research projects or non-research projects on a second and third level.

Composition and organization of the Working Group

The following representatives from legal departments, Data Protection Offices or Governance Boards of university hospitals, universities and further stakeholders are foreseen:

- Insel: Jana Rochlitz, Nesa Magdalena Marti
- HUG: Joëlle Becker
- CHUV: Pascale Meister
- USZ: Philip Gut, Elke Mittendorf
- USB: Thomas Gruberski
- UniBas: Danielle Kaufmann
- ETHZ: Tom Mitar, Aleksandra Goes, Alexa Mundy, Ayse Sezer
- EPFL Chiara Tanteri (DPO), Valentin Conrad and Adam Swetloff
- UNIL: Benjamin Amsler, Marie Pfammatter
- UniG: Andreas Schmalz
- UZH: Nora Lipp, Gil Scheitlin
- UniBe: Annina Keller
- Further stakeholders to be contacted on request:
    - Unitectra: Gabriela Burkart, Franziska Weise
    - swissethics
    - Interpharma
    - SAKK
    - Patient representatives, patient advocacy group
    - ELSIag (as subgroup, see below)
    - SCTO, SBP
    - FMH (data protection officer)

Ex officio: Julia Maurer (SPHN DCC, PHI Group, SIB Swiss Institute of Bioinformatics) , Frederic Erard, Mathilde Heusghem (LTTO, SIB Swiss Institute of Bioinformatics)

The DCC (SPHN Data Coordination Center) will be responsible for the WG and provide project management support (up to 0.2 FTE). The group chair needs to be defined upon agreement.

Tasks and deliverables of the Working Group

- Support the DCC in the development and maintenance of a harmonized legal agreement template to regulate general principles of collaboration and sharing of health data in multi-center research projects in compliance with Swiss law and, where indicated, further legal regulations, such as GDPR. In the realm of SPHN and PHRT, this concerns in particular the further development of the Consortium Agreement template including the Data Transfer and Use Agreement (DTUA) and Data Transfer and Processing Agreement (DTPA). In the long-term, the working group helps to further develop the contractual framework of multi-center research projects. The following issues are part of the development:
    - Provide an overview of internal data governance processes and requirements, which rule the sharing of health data with other parties. This should include internal approval processes and responsibilities including identified duly authorized representatives which are foreseen to sign the agreements per institution.
    - Evaluate acknowledgement of data providing institutions and involved parties (in particular compensation for non-inventive contributions, e.g., for curated data provided by hospitals)
    - Consultation of technical experts when needed
- Elaborate a harmonized nationwide data sharing guidance according to institutional data governance processes, which allow data usage internally and with third parties
- Review requests concerning legal agreements of research projects (SPHN, PHRT or other funded projects)
- Evaluate contractual setup for broader collaboration, e.g., data exploration, industry collaboration and patient involvement
- Evaluate conditions and responsibilities of data providers building a registry for sharing their data with third parties (part of the collaborative SCTO registry project)
- Evaluate the mechanisms by which research consortia platforms can make research data available to third parties, in particular the need to establish representation mechanisms
- Evaluate open data and open access requirements to expressly include them in guidelines and funding principles (creation of further public value through reuse of data)
- Investigate the requirements and practice for using health data for non-research practice (development of artificial intelligence based algorithms and decision making tools for patient treatment)

Timelines: The timeline for the WG to complete the mandated tasks is 2 years (1/2023-12/2024).

The ELSIag as optional consultancy group

The ELSI ag is providing additional consultancy and complementing the Data Governance WG by elaborating interdisciplinary topics concerning responsible health data sharing. ELSIag takes into account already released SPHN guidelines.

Current ELSIag members:

- Andrea Büchler (UZH)
- Susanne Driessen (swissethics)
- Matthias Baumgartner (UZH/Kispi)
- David Haerry (Eupati)
- Samia Hurst (UniGe)
- vacant (SAKK)
- Beat Rudin (Privatim)
- Effy Vayena (ETHZ, Chair)
- vacant (SAMS)

Further topics of interest are listed below and may overlap with tasks for the DG WG:

- Involvement of patients/society (PPI guidelines and monitoring, collaboration with SCTO)
- Investigate on criteria to evaluate true anonymization of data
- Open source regulations (ensuring due credits to data providing parties; Private Public Partnerships guidelines)
- Supporting risk based sensitivity level for health data usage (De-ID template implementation, SPHN Demonstrator project)