

Working group mandate:

Harmonized Swiss Cohort and Registry Strategy: principles and standards for IT-solutions & FAIR data

Background

Cohorts and registers in Switzerland function as independent entities; each investigator runs its own independent “organization” on diverse IT-infrastructures. While there are guidelines for individual cohorts or registers¹, synergies between cohorts have not yet been sufficiently exploited, resulting in a large heterogeneity of tailor-made parallel systems. Not only does this make efficient data management more difficult but also impedes the interoperability of cohort data, making re-use for different purposes often problematic or not possible at all.

Proposed mandate:

The Working Group shall develop a “**Harmonized Swiss Cohort and Registry Strategy**”. The concept should build upon existing guidelines, be compatible with the SPHN environment, principles, and efforts and integrated into the overall Swiss landscape. It should focus on the needs of cohorts and the use of cohort data for research, identify areas where harmonization is beneficial in order to achieve technical and semantic interoperability. Adopting the FAIR principles (Findable, Accessible, Interoperable, and Reusable), common guidelines, streamlined processes and toolboxes should provide usable resources not only for new cohorts but also for existing ones. The Cohort and Registry Data (CRD) Working Group works in close collaboration with the Data Life Cycle Management (DLCM) Working Group.

Deliverables:

- Mapping of current cohort landscape in Switzerland;
- Definition of roles and responsibilities of funders, PIs, infrastructure providers, data providers, (e.g. DCC/BioMedIT network, cohorts, hospitals, SCTO/CTU-network) over the life-cycle of different types of cohorts and registries (e.g. existing versus new; SNF funded);
- A work plan (scope and focus, feasibility, timeline, work packages, milestones, resource requirements);
- Regarding **findability** of data:
 - Define a harmonized meta data set for cohorts (align with international initiatives);
 - Define a plan for federated data discovery and query for cohort data (scalable) and integrate/align with the efforts for a meta-data catalogue on a national level;
- Regarding **accessibility** of data:
 - Describe existing governance processes;
 - Develop a strategy for implementation of a central data request portal in accordance with the existing governance processes;
- Regarding **interoperability** of data and related processes:
 - Identify processes, which should be harmonized to ensure interoperability (e.g. bio-banking procedures; consent procedures; etc.);

¹ Such as the Register Recommendations of ANQ, FMH, H+, SAMS and unimeduisse (<https://www.anq.ch/de/anq/publikationen/registerempfehlungen/>)

- Develop a strategy on uniform principles and standards for IT-solutions, encompassing recommendations for clinical data management systems (CDMS) and a toolbox to supplement the CDMS (e.g. electronic consent management, enrolment log, patient identity management, etc.);
 - Define the interface with the Hospital IT environment (technical and processes);
 - Define a concept for national interoperability of the cohort and register data (considering international standards and SPHN clinical standards);
- Regarding **reuse** of data:
- Provide a concept for a secure system for the long-term storage of the data;
 - Provide a concept for a sustainable long-term plan for cohorts and registry (landscape, roles, responsibilities).

Proposed work plan:

A series of meetings is arranged with the Working Group. The meeting schedule is according to the availability of the members. During the meetings, the draft strategy is discussed and further developed. The meeting documentation should be sent at least 1 week prior to the meeting.

Financial needs for the working group:

Reimbursement of travel expenses for Swiss participants
 Reimbursement of travel expenses for international experts
 Refreshments

Total

CHF 20'000.-

Proposed composition of the working group

Members from existing cohorts and registries:

- Adrian Spoerri (Swiss National Cohort, ISPM Bern)
- Murielle Bochud (Cancer Registry, CHUV)
- Huldrych Günthard (HIV cohort, USZ)
- Luca Crivelli (Health economics, SUPSI)
- Carlo Largiadè (Liquid Biobank Insel)
- Nicole Probst-Hensch (SwissTPH)
- Valérie Pittet (Swiss IBD cohort study)
- Michael Koller (Swiss Transplant Cohort Study)

Members from infrastructure and data providers:

- Thierry Sengstag (sciCORE)
- Michael Weisskopf (USZ)

Legal representation (on demand)

- Marc Fillietaz (Legal department SIB)

Members from funders/government/organisations:

- Stephanie Wyss (SNSF)
- Martine Bourqui-Pittet (FOPH)
- Patrick Wright (SCTO, Coordinator Data Management)

Chairperson: Murielle Bochud

Coordination: PHI Group