SWISS PEDNET
Swiss Research Network of Clinical Pediatric Hubs

Rules about the procedures within each hub and between individual hub

Preamble

According to the decision of the SwissPedNet General Assembly made on November 20, 2015 a working group with representatives from Basel, Bern Lausanne and Geneva elaborated this document to define and harmonize the characteristics of a SwissPedNet pediatric clinical research hub.

The SwissPedNet pediatric clinical research hubs respect the overall rules of SwissPedNet and the SCTO. Activities of the pediatric clinical research hubs, SwissPedRegistry and SwissPedPha shall concur with the law and the national strategies related to biobanking, registries and the personalized health initiative.

Description "pediatric clinical research hub"

A SwissPedNet pediatric clinical research hub is a service platform for clinical research in children and with children. The pediatric clinical research hub has a head, dedicated staff and resources necessary for the conduct of clinical studies in pediatrics.

The core business is the conduct of clinical trials (patient recruitment, study visits, blood draws, data management, safety reporting, etc.) in compliance with the Human Research Act and its ordinances.

The pediatric clinical research hub is part of the children's hospital or clinic and bound by e.g. cooperation agreement with a Clinical Trial Unit (CTU) from the SCTO CTU network. Services available from the CTUs that are not pediatric-specific will be obtained from the CTUs. There shall be no parallel infrastructures in the pediatric clinical research hubs. The CTU supports investigators in the planning of their research project regarding study design, statistics, data capture, data analysis, monitoring, finances / grants, submission to ethics committees and Swissmedic, etc. Staff from the pediatric clinical research hubs links the researchers with the CTU.

All staff is trained according to GCP, and all trial activities strictly follow the national laws and regulations and comply with the current version of GCP.

The pediatric clinical research hub does not take over the sponsor role, the investigator keeps control and responsibility for his/her research project all the time.

Collaboration within the SwissPedNet members

Within SwissPedNet the pediatric clinical research hub is closely connected to SwissPedRegistry, the pediatric registry center at the Institute for Social and Preventive Medicine (ISPM) at the University of Bern and SwissPedPha, the Swiss pediatric pharmacology center at the University hospital Basel.

SwissPedRegistry and SwissPedPha have a Service Level Agreement with SwissPedNet, which is accessible for all hubs.

Contact details for SwissPedRegistry and SwissPedPha are available in the pediatric clinical research hubs and at the SwissPedNet coordination office.

Rules about the procedures within each hub and in between the individual hubs

Each pediatric clinical research hub elaborates rules for procedures according to this document, adapted to local requirements but not contradicting it.

1. Procedure for new projects to be conducted in the pediatric clinical research hub

The clinical hub provides a contact form for all investigators and sponsors with minimum requirements to be completed to contact the clinical hub to use their infrastructure and receive support.

The following information is needed to decide about a new research project conducted in the pediatric clinical research hub:

- Academic or industry sponsor
- Details about the research project
    - Title, objective of the study
    - date of initiation and duration
    - mono-/multicenter study
    - national/international
    - number of enrolled patients needed
- Request for support needed from the pediatric clinical research hub, e.g.
    - coordination of different involved parties and/or sites
    - data management, creation of CRFs or questionnaires
    - adaptation/creation of patient information and informed consent forms
    - patient recruitment
    - management of IMP(s) and/or randomization
    - submission to EC/Swissmedic
    - elaboration of contracts, study budget
    - etc.

An appointment with the study nurses and/or secretary of the pediatric clinical research hub will help to clarify the needs of the investigator and re-assess the investigator's estimates.

A scientific board assesses the new research projects and decides whether or not the involvement of the pediatric clinical research hub is feasible and meaningful.

Consider including a representative of the CTU to be part of the board.

2. Contact in each hub and collaboration between all hubs

Each hub has a contact point for requests for collaboration. A phone number and e-mail address is provided on the website of each hub or children's hospital.

The SwissPedNet coordinator at the SCTO executive office supports coordination and communication tasks between all hubs.

3. Financial flow within the pediatric hub

Chargeable services rely on the fees as defined by the SNSF or corresponding CTU.

Aim: same fees in all 9 hubs. However, each hub has the possibility to have own rules in addition.

There are different fees for researchers from the institution and academia and for commercial sponsors.

4. Verification to adherence to the specified quality

The SwissPedNet Board will ensure compliance with these rules. They may apply audits within each hub.

Business plan

The business plan is an essential planning tool for the individual pediatric clinical research hub. It shows how the pediatric clinical research hub and its services will be implemented, what resources are needed and what results may be expected.

Each pediatric clinical research hub has a business plan elaborated with settings and goals for the time going operational with federal funds (as of 2017), after 1 year and 5 years.

Document history

Version 1.0, new document, approved at the 4th General Assembly on November 18, 2016