Quality Policy of the SwissPedNet

SwissPedNet, the Swiss Research Network of Clinical Pediatric Hubs, promotes, facilitates, coordinates and conducts clinical trials devoted to children ranging from newborn to adolescent age in all disciplines except oncology.

SwissPedNet is a not-for-profit organization. The network consists of ten clinical pediatric hubs, two specialty hubs (SwissPedRegistry and SwissPedPha) and a coordinating office. It is organized as a membership association and receives public funds.

Objectives of the SwissPedNet

It is our main priority to ensure patient and their parents' rights, patient safety and well-being, the integrity and reliability of clinical data, and the protection of data privacy in all our activites.

Clinical Pediatric Hubs of the SwissPedNet

The clinical pediatric hubs commit themselves to aligning their activities in accordance with the Quality Policy of the SwissPedNet applicable regulations as well as with GCP requirements and ethical standards for research in pediatrics.

Quality Management System

A process-oriented Quality Management System (QMS) will be implemented in all clinical pediatric hubs, which is based on the existing QMS of the existing Clinical Trial Units (CTU), but supplemented with pediatric specific documents.

The SwissPedNet guarantees adherence to the ethical principles of the Declaration of Helsinki, to GCP guidelines and to the ethical considerations for clinical trials in children. Studies are conducted according to SOPs and working instructions, they will be properly monitored and conducted according to a calculated budget. All sites participating in clinical studies passed a feasibility evaluation, the recruitment of patients follows written guidelines. Staff involved in study conduct is appropriately trained. Quality control and quality assurance procedures are in place for safe data collection.

As a rule, SwissPedNet clinical trials have a Data Monitoring Committee to address the exposure of the vulnerable population.

Reference documents

All activities of the SwissPedNet are in accordance with applicable national and international law, regulatory requirements, and ethical guidelines and regulations, in particular the following documents:

- CIOMS International Ethical Guidelines for Health-Related Research Involving Humans
- EMEA/CPMP/ICH E11(R1) guideline on clinical investigation of medicinal products in the pediatric population - Scientific guideline
- Regulation EC 1901/2006 on medicinal products for pediatric use and amending regulation (EEC) No 1768/92 (02006R1901-20190128)
- Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use (Rev 1, 2017)
- Human Research Act (HRA) and subsequent ordinances
- SAMW-Leitfaden, Forschung mit Menschen
- NEK/CNE Swiss National Advisory Commission on Biomedical Ethics, Opinion no. 16/2009, Research involving children

This Quality Policy is considered an annex to the Service Level Agreements with the SwissPedNet members and ensures that studies are conducted and data are generated, documented (recorded), and reported in compliance with ethical principles, the protocol and the applicable regulatory requirements and guidelines.