SWISS PEDNET
Swiss Research Network of Clinical Pediatric Hubs

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.

SwissPedNet is a not-for-profit organization. The network consists of eight clinical pediatric hubs and a coordinating office. It is organized as a membership association.

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.

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.

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, all SwissPedNet clinical trials will 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 Biomedical Research, Chapter 14. Research Involving Children
- EMEA/CPMP/ICH E11 Note for guidance on clinical investigation of medicinal products in the paediatric population
- Regulation EC 1901/2006 on medicinal products for paediatric use and amending regulation (EEC) No 1768/92
- Ethical considerations for clinical trials on medicinal products conducted with the paediatric population. Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC.
- Humanforschungsgesetz (HFG) / Loi relative à la recherche sur l'être humain (LRH) (Art. 21, 22, 23)
- SAMW-Leitfaden, Forschung mit Menschen, Kap. 10.1 Kinder und Jugendliche unter 18 Jahren
- NEK/CNE Swiss National Advisory Commission on Biomedical Ethics, Opinion no. 16/2009, Research involving children

By complying with this Quality Policy, we make our contribution that studies are conducted and data are generated, documented (recorded), and reported in compliance with ethical principles, the protocol, the applicable regulatory requirements and guidelines.

Clinical Pediatric Hub	Representative	Signature & Date
Children's hospital Aarau	Prof Henrik Köhler	23.3.13
University children's hospital Basel	Prof Urs Frey	2.5.13
University children's hospital Bern	Prof Christa Flück	5.4.13
University children's hospital Geneva	Prof Claire-Anne Siegrist-Juillard	11.4.13
University children's hospital Lausanne	Prof Andrea Superti-Furga	17.4.13
Children's hospital Luzern	PD Dr Johannes Rischewski	22.4.13
Children's hospital of Eastern Switzerland St. Gallen	PD Dr Jürg Barben	24.4.13
University children's hospital Zurich	Prof David Nadal	25.04.13