SwedPedMed – a Network for Pediatric Clinical Studies

Plan for Implementation Across Sweden

Background

SwedPedMed (Swedish Pediatric Medicines) emerged during the latter part of the 2010s as an independent, non-commercial network working to develop medicines for children in an ethical manner. In the initial startup of the network it was based at Karolinska University Hospital in Stockholm, later relocating to the Pediatric Clinical Research Center (PCRC) at Drottning Silvias Barnsjukhus, Sahlgrenska University Hospital in Gothenburg.

In May 2018, SwedPedMed became the National Hub for Sweden in the EU project Conect4Children (c4c). This project involved 20 countries and worked to develop procedures for pediatric clinical trials and to provide a single point of contact for sponsors seeking to initiate pediatric studies. The project concluded in April 2025 and was taken over by the c4c-Stichting foundation — a non-profit legal entity in which SwedPedMed is a member and acts as the National Hub for Sweden.

The network is also a member of, and collaborates with, international networks and organizations. These include the Nordic network NordicPedMed (Nordic Investigators Network for Pediatric Medicines), in which all Nordic countries participate through their respective organizations, and Innovative Treatment for Children and Adolescents with Cancer (ITCC). SwedPedMed is a Category-1 member within Enpr-EMA and part of its Coordinating Group (CG). The CG functions as a governing part and plays a key role in shaping the direction of Enpr-EMA. Jenny Kindblom, Professor of Clinical Pharmacology at the University of Gothenburg, serves as SwedPedMed's representative in Enpr-EMA.

Each year, approximately 100,000 children are born in Sweden, and about 1.8 million children aged 0–18 live in the country. The prevalence of diseases requiring healthcare and treatment is relatively low compared to adults. Pediatric healthcare spans the full disease spectrum, which results in a relatively small and heterogeneous patient population compared to adults, despite children being a large group in society. Few medicines are developed specifically for children, and knowledge about pediatric pharmacotherapy remains limited. A large share of prescriptions for children is based on medicines tested in adults, and data on long-term effects, side effects, and safety are lacking for pediatric populations. The need for clinical research and drug development for children is therefore considerable.

The pediatric clinical research units in Gothenburg and Stockholm have established relationships to support a joint network—nationally and internationally—with the aim of giving more children the opportunity to participate in clinical drug trials. Recently, two units from Skåne University Hospital joined the network. Continued expansion is needed to enable more studies to open in Sweden and to ensure that children across the entire country can be included in safe pediatric clinical trials.

Purpose and Goals

SwedPedMed works toward three main objectives:

1. Children living in Sweden shall have the right and opportunity to participate in clinical studies regardless of place of residence.
2. To make Sweden an attractive country for clinical trials.
3. To establish contact with SweTrial and highlight the specific conditions related to pediatric research.

Now and Going Forward

The Pediatric Clinical Research Center at Drottning Silvias Barnsjukhus, Sahlgrenska University Hospital in Gothenburg (PCRC), and the Clinical Trial Center at Astrid Lindgren Children's Hospital, Karolinska University Hospital in Stockholm (CKB), together with units at Skåne University Hospital, conduct clinical studies in pediatrics and actively participate in the SwedPedMed network.

Pediatric healthcare covers all of Sweden, but in several regions, pediatric clinics and university hospitals are located far from families' homes. To increase opportunities for children in these regions to participate in studies, we aim to establish working methods involving decentralized study elements supported by a main site at a larger hospital, possibly including satellite sites connected to other healthcare providers. The possibility of conducting certain study elements close to home reduces the burden on families participating in a study.The network can support the study process, encourage staff at other healthcare providers to perform clinical procedures or selected study-specific tasks.

This work aligns with the Swedish Medical Products Agency's national collaboration with the healthcare system to promote safe and appropriate medicine use in children and adolescents. SweTrial has also commissioned UCR in Uppsala to develop a knowledge base for decentralized studies.

Plan

1. *Establishing a structure for the network*
   a. Steering group – Regular meetings for network development.
   b. Meetings where different professional groups can share experiences, challenges, and successes.
   c. Larger annual meetings for all members of the network.
2. *Expanding the network through contact with key individuals at hospitals/regions.*
3. *Promoting delegated study activities and establishing satellite sites when appropriate.*
4. *Working toward establishing contact with SweTrial.*

Budget

The network will apply for funding from external sources to build a robust network.