



Children are entitled to appropriate,
researched and safe medicines.

NordicPedMed

NORDIC investigators network for PEDIatric MEDicines

3rd Nordic Conference on Pediatric Medicines
09October2019, Helsinki

Pirkko Lepola

Executive Secretary of FINPEDMED

General Secretary of NORDICPEDMED

Helsinki University Hospital, Department of Children and Adolescents,

Digital and Innovation Services

Helsinki, Finland

www.finpedmed.fi

www.finpedmed.com

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Background – Nordic similarities

- Similar high living and educational standards
- Well-functioning public health-care systems
- Nationwide registries & e-patient data
- Personal ID for all citizens
- Positive public opinions for clinical research
- Patient's high compliance in trials
- Tradition of high-level expertise
- High technology and easy communication

Background - 1. Article – 2013

ACTA PÆDIATRICA
NURTURING THE CHILD

Acta Pædiatrica ISSN 0803-5253

REVIEW ARTICLE

Limited impact of EU Paediatric Regulation on Finnish clinical trials highlights need for Nordic collaborationMatti Korppi (matti.korppi@uta.fi)¹, Pirkko Lepola², Kim Vettenranta³, Seppo Pakkala⁴, Kalle Hoppu^{3,5,6}

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Keywords

Clinical trial, EU regulation, Paediatric medicines, Research network

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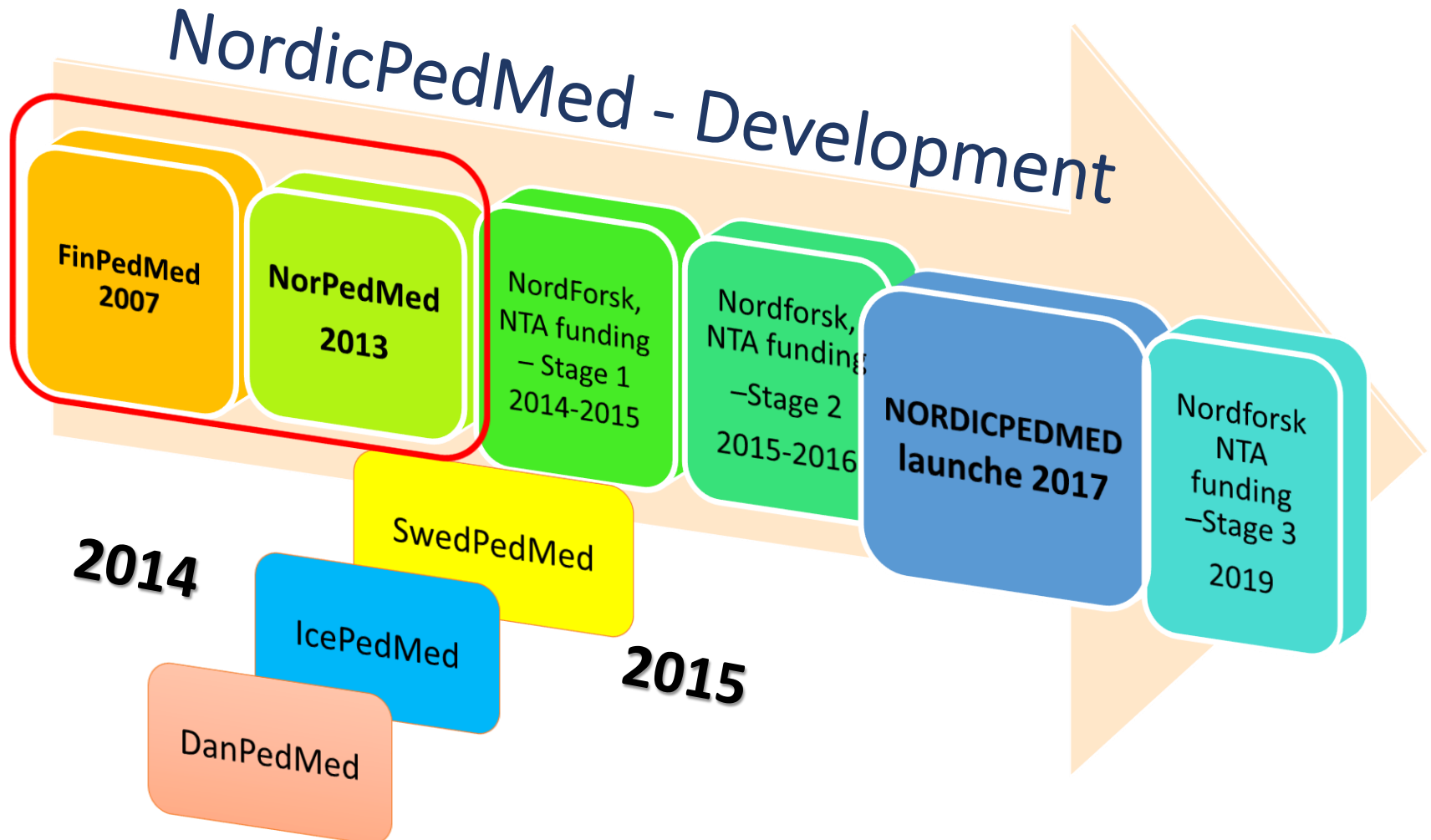
DOI:10.1111/apa.12372

ABSTRACT

The Finnish Investigators Network for Paediatric Medicines (FINPEDMED) was established in 2007, to meet the expected increase in paediatric clinical trials following the new EU Paediatric Regulation. Between 2007 and 2012, FINPEDMED received 91 trial requests, 18 trials were started, and in 24 cases, Finnish investigators were not selected by sponsors.

Conclusion: This experience from Finland highlights the need for Nordic collaboration to increase expertise, recruitment base and attractiveness for sponsors.

Background – Project funding from Norforsk



Background – Aim

Pediatric population in Nordic area 5,3 mil.



The network's **objectives** are to help meet the therapeutic needs of children by facilitating medicine development, increasing knowledge and communicating information on appropriate use of medicines and other therapies for the pediatric population.

The **NORDICPEDMED** is a **joint development project within Nordic countries; Denmark, Finland, Iceland, Norway, and Sweden**. Established in 2015, and finalized in 2017. Connection to the European Network of Paediatric Research at the European Medicines Agency, Enpr-EMA, through national networks. Collaborative initiatives: Conect4Children,c4c, the Paediatric Clinical Research Infrastructure Network, PedCRIN).

Status - 2. Article – 2019

ACTA PÆDIATRICA
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ACTA PAEDIATRICA PERSPECTIVES

Tardy development of safe medicines for children: a Nordic network offers new platform to reduce this inequity

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Status of NordicPedMed National Networks



FINPEDMED[®]

Finnish Investigators Network for Pediatric Medicines
Det nationella nätverket för forskning av barnläkemedel
Kansallinen lastenlääkkeiden tutkimusverkosto

HUS⁺

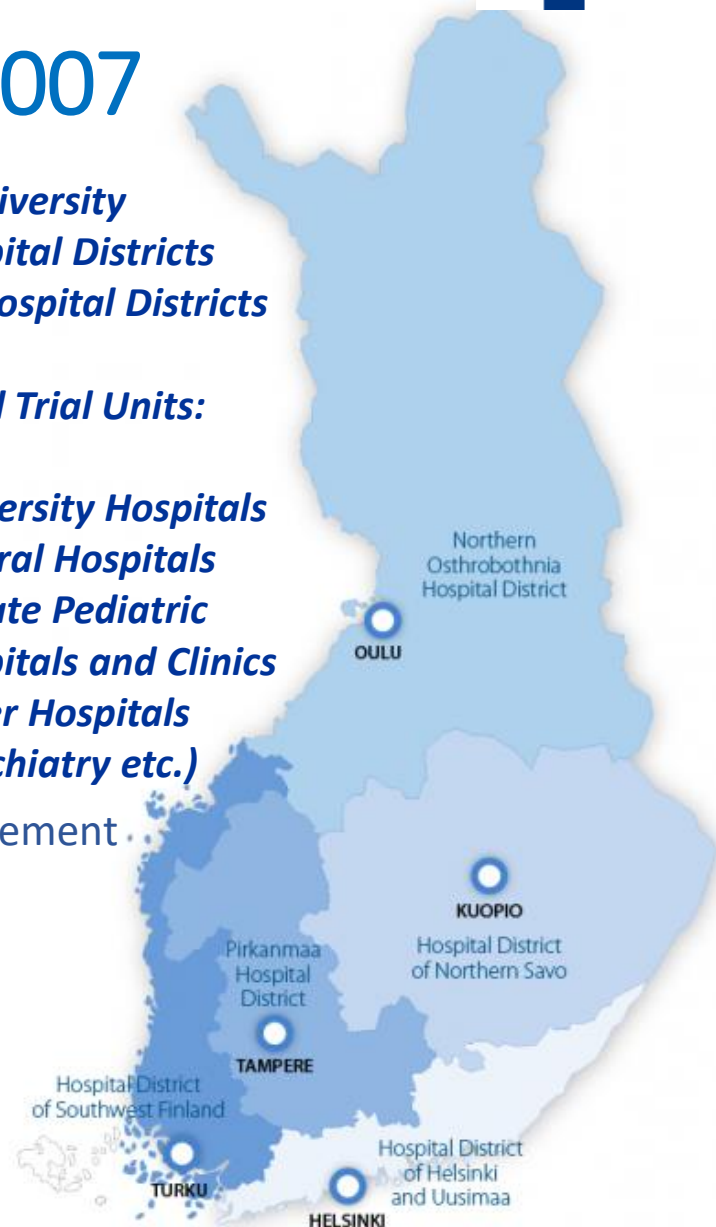


Finland - FinPedMed since 2007

by pediatric subspecialties:

1. Pediatric Hematology - Oncology
2. Pediatric Neurology
3. Pediatric Endocrinology
4. Pediatric Rheumatology
5. Pediatric Infectious Diseases
6. Neonatology / Neonatologia
7. Pediatric Gastroenterology
8. Pediatric Allergology
9. Pediatric Nephrology
10. Pediatric Cardiology
11. Pediatric Anesthesia - Intensive Care & Pain Management
12. Pediatric Surgery
13. Pediatric Clinical Pharmacology
14. Child and Adolescent Psychiatry
15. Rare Diseases

- **5 University Hospital Districts**
- **20 Hospital Districts**
- **Clinical Trial Units:**
 - **University Hospitals**
 - **Central Hospitals**
 - **Private Pediatric Hospitals and Clinics**
 - **Other Hospitals (psychiatry etc.)**



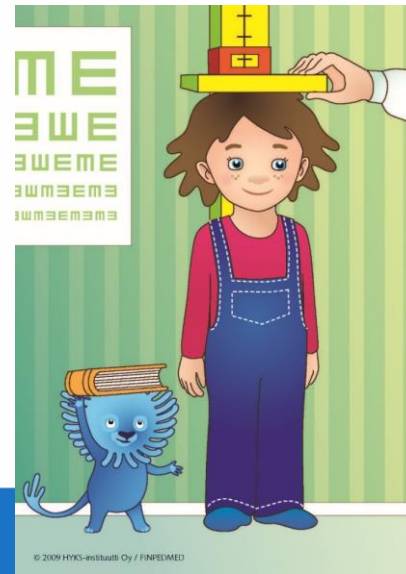


Status – 2019

- **Legal entity: Helsinki University Hospital (HUS), Department of Children and Adolescents, Digital and Innovation Services**
- **Steering Committee: All University Hospitals (5)**
- **Funding: All university Hospitals – Annual Fees**
- **National level clinical research infrastructure & services for all stakeholders**

Since 2007:

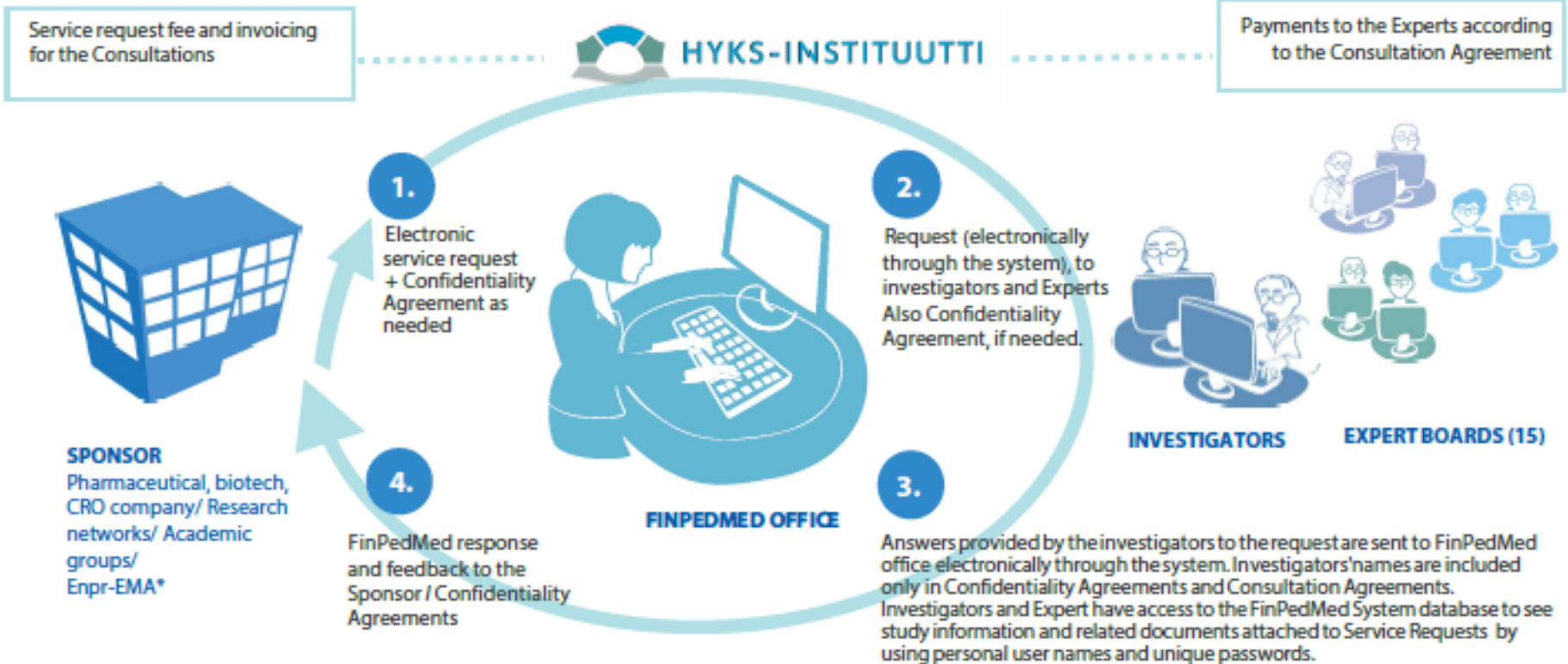
- **178 Registered Members**
- **182 New Trial Requests**
- **54 Consultations**





FINPEDMED e-Service Request

More information on terms of services
and service request fees
www.finpedmed.com



* En pr-EMA, The European Network of Paediatric Research at the European Medicines Agency



Iceland - IcePedMed since 2015

- IcePedmed concept known by Icelandic Health Director, hospital directors, paediatric society of Iceland, and health authorities
- IcePedMed is part of the **FinPedMed – 1 site** - without own national network organization



IcePaedMed

Icelandic Network for Pediatric Medicines Research



Children's Hospital Reykjavik

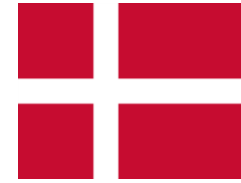


BARNASPÍTALI HRINGSINS

- www.barnaspitali.is
- s. 543 1000
- 101 Reykjavík
- Hringbraut

- 35 paediatricians in Children's Hospital – trained abroad + private doctors (approx. 50)
- Great interest to do trials and be involved in research infrastructure

Denmark - DanPedMed since 2015



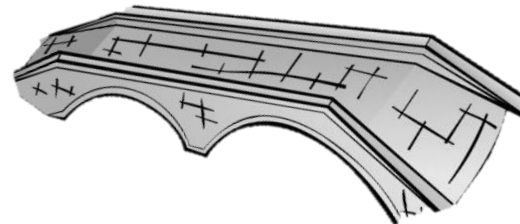
Trial Nation
Clinical Trials Denmark

What is **Trial Nation**?

- Trial Nation is a public-private partnership that aims to establish Denmark as a preferred country for clinical research – for the benefit of patients, the healthcare system and the life science companies
- Trial Nation is funded by the Ministry of Industry, Business and Financial Affairs, the Ministry of Health, several Danish life science companies and the five Danish Regions.
- Trial Nation is a **single entry point** to clinical trials in Denmark
 - All services are **free of charge** and available to both public and private stakeholders



LIFE SCIENCE
INDUSTRY



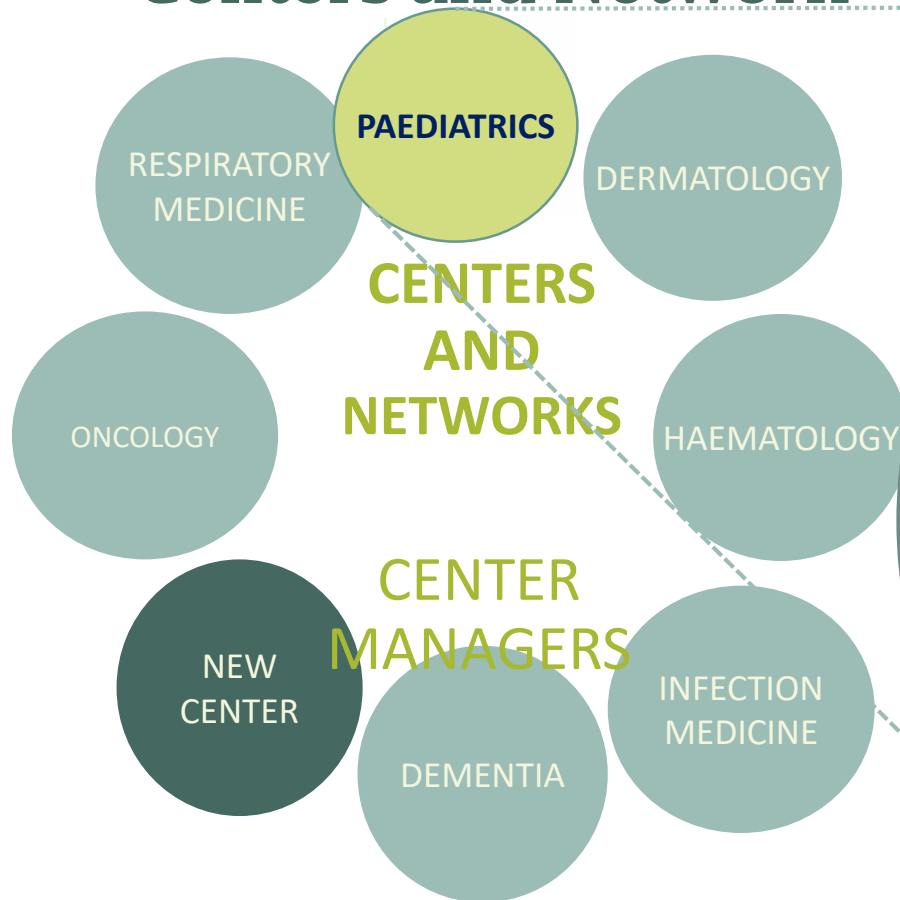
HOSPITAL

<https://trialnation.dk/>

DanPedMed - Status 2019



Centers and Network



DanPedMed

Network of 150 persons from Pediatric Departments

DanPedMed Steering committee:
Chairman: Lene Hartmann. Data and Development support, Region Zealand
Coordinator for DanPedMed: Pernille Skovby. Department of Pediatrics, Regional Hospital Unit West Jutland
Representatives in NordicPedMed: Rene Mathiasen. Pediatric and Adolescent Medicine, Pediatric oncology, University Hospital Rigshospitalet Copenhagen & Torben Laursen. Department of Clinical Pharmacology, Aarhus University Hospital
Representatives from Danish Society of Pediatrics: Pernille Mathiesen, Department of Pediatrics, Slagelse Sygehus; Klaus Bønnelykke, Copenhagen Prospective Studies on Asthma in Childhood (COPSAC) Herlev- og Gentofte; Søren Hagstrøm, Department of Pediatrics, Aalborg University Hospital and Department of Clinical Medicine, Aalborg University, Aalborg & Anne-Cathrine F.Viuff, Department of Pediatrics, Viborg Regional Hospital

The healthcare regions in Denmark have formed a legal network to ensure that the regions act as a united negotiation party in relation to the industry. The network is accessible via Trial Nation.



- Established in 2017
- Steering committee and reference group

www.SwedPedMed.se

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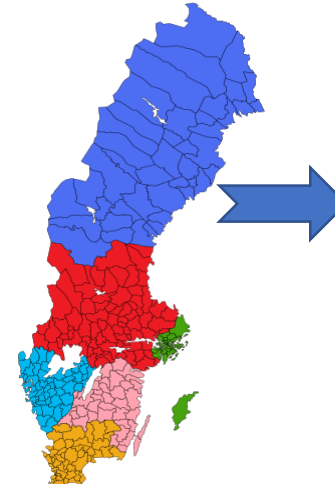
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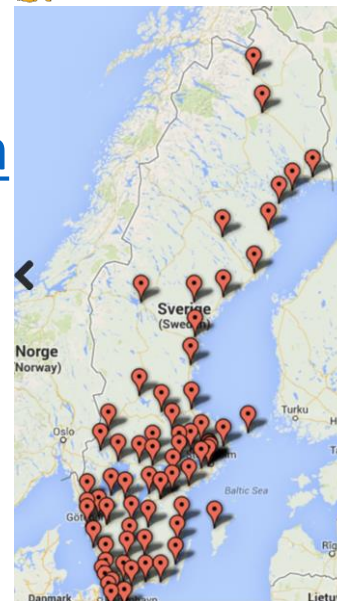


NETWORK:

- **Six health care regions**
Seven University hospitals

1. Umeå university
2. Uppsala university
3. Karolinska Institutet, Stockholm
4. Linköping university
5. Örebro University
6. Göteborg university
7. Lund university

>50 paediatric clinics



Sweden - SwedPedMed



Interaction and support in paediatric clinical trials



Specialist networks all paediatrics



Heads of paediatric departments



Medical universities

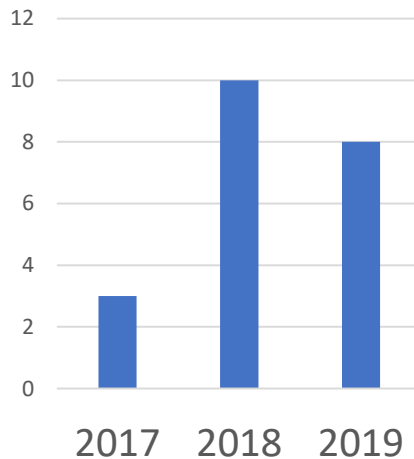


Clinical Studies Sweden

Network of clinical studies



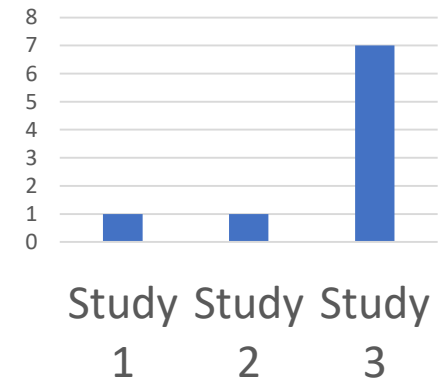
SwedPedMed feasibility request



Actions 2019:

- ✓ PedCrim
- ✓ Conect4children
- ✓ NordicPedMed
- ✓ Manuscript in Acta Paediatrica
- ✓ Short survey to heads of paediatric clinics
- ✓ Web-based survey to researchers
- ✓ Working on establishment of YPAG
- ✓ Feasibility requests
- ✓ Expert support PoV c4c studies

Number of sites for the c4c PoV academic studies



Norway - NorPedMed since 2013



- Works on a governmental mission (Dept. & Directory of Health)
- Budget unchanged since 2013, NOK 1 mill (EUR 100 000)
- Administratively a part of: “Medicines for Children Network, Norway”

https://www.legemidlertilbarn.no/fo_rskning/Sider/Medicines-for-Children-Research-Network-Norway.aspx

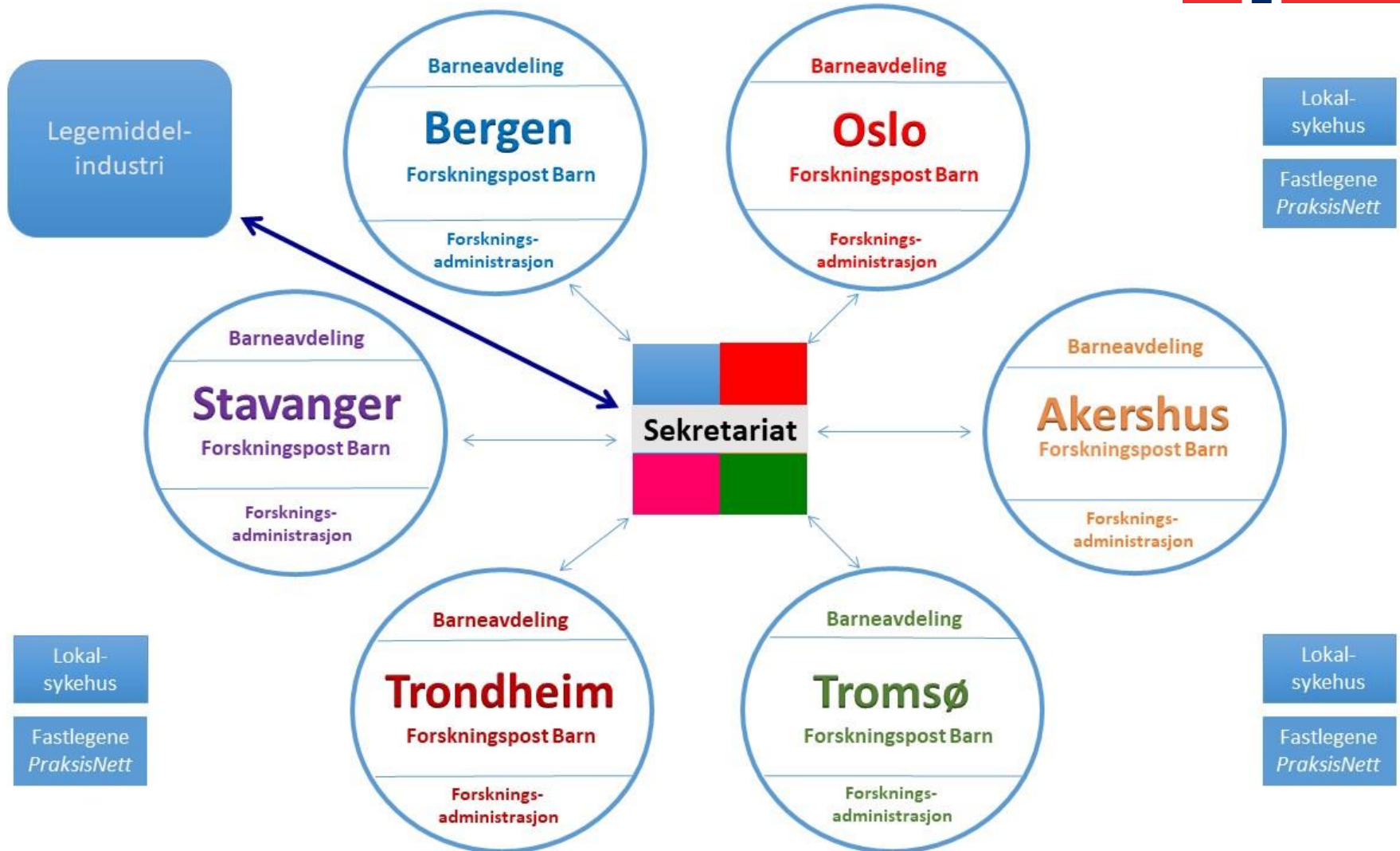


NorPedMed 2019



- Secretariat at Haukeland University Hospital, Bergen
- NorPedMed is not a legal entity
- Clinical Trial Unit (or ward) at five university hospitals
→ Ahus, Oslo, Stavanger, Haukeland, St.Olav, Tromsø
- Slightly different operating models
- Structures and activities are based on the participating CTUs
-i.e. not on individual membership for researchers/pediatricians
- NorPedMed has currently approx. 25 ongoing open studies
- **NorPedMed represented at all units (20% FTE)**

NorPedMed 2019



www.nordicpedmed.com

Contact details

NORDICPEDMED
Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

INVESTIGATORS
REGISTRY

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The **NORDICPEDMED** is a joint development project within Nordic countries; Denmark, Finland, Iceland, Norway, and Sweden. The first part completed already in 2015, but it was finalized during the 2016 to have the network governance. The development of a joint Nordic Investigators Registry will be finalized during the years 2017-2018. **The ultimate aim** of NordicPedMed is to develop a Nordic network of investigators, centres and national networks with recognized expertise in performing clinical studies on children and increase cooperation both on a Nordic and European level. NordicPedMed received funding from the Nordic Council of Ministers and NordForsk, through a 3-year [Nordic Trial Alliance \(NTA\) project](#).

The network's objectives are to help meet the therapeutic needs of children by facilitating development, increasing knowledge and communicating information on appropriate use of new medicines, medicines currently available, and other therapies for the pediatric population. Currently, NordicPedMed have strong European level connection via [FinPedMed](#) and [NordPedMed](#) memberships to the European research network, [Enpr-EMA \(European Network of Paediatric Research at the](#)

Contact details

NordicPedMed Board:

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FINPEDMED®

Finnish Investigators Network for Pediatric Medicines
Det nationella nätverket för forskning av barnläkemedel
Kansallinen lastenlääkkeiden tutkimusverkosto

Thank You!

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Finland

Sweden

Iceland



Norway

Denmark