NordicPedMed
Nordic Investigators Network for Pediatric Medicines
–NTA-project (WP9)–

26 January 2016, NTA SHM, Oslo

Pirkko Lepola
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c/o University of Tampere, Tampere Center for Child Health Research
Children are entitled to appropriate, researched and safe medicines.
About the Medicines for Children Network, Norway

Medicines for Children Network, Norway (the Network) was established in 2009, following processing of the Parliamentary Medicinal Report, published in 2005. The government was instructed by the Parliament to facilitate better nationwide competence relevant to all aspects of pediatric medicinal treatment on all levels, by establishing an interdisciplinary network encompassing relevant professions and institutions.

Medicines for Children Network, Norway presently consists of doctors, nurses and pharmacists, working together to ensure that medicinal treatment of children is being focused and given priority within the pharmaceutical industry, relevant national regulatory authorities and administrators, in pharmacies and amongst healthcare workers on all levels.

The Norwegian Directorate of Health has conferred the Network the following agenda:

- Patient safety issues
- Relevant competence should be:
  - Distributed
  - Enhanced
  - Developed and researched

The overall aim of the Network is to ensure that pediatric medicinal treatment is appropriate and safe, and as far as possible based on solid evidence, using products that are properly licensed by the authorities. All involved parties should have – or have free and immediate access to – relevant and authorized information, ensuring appropriate and safe professional conduct, and ditto interactions between involved professionals and professions.

All hospital trusts in Norway are represented in the Network. At all pediatric departments in the country, there is an interdisciplinary group with responsibility for medicinal issues

1st meeting in Tampere, Finland, 05Dec2012 with Norwegian network
NRI Conference Workshop 08May2013 Nordic Paediatric Research

Ideas for the workshop

• What is needed for Nordic collaboration ?
• How the collaboration could be done in practice ?
• What you can offer or do ?
• Is this a good “niche” for Nordic countries ?
The paediatric research working group included finally 15 attendees:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almlöf, Maria</td>
<td>Scientific Officer</td>
<td>Norwegian Medicines Agency</td>
</tr>
<tr>
<td>Bakken Rønning, Gøril</td>
<td>Studiesykepleier</td>
<td>St. Olavs Hospital</td>
</tr>
<tr>
<td>Bengtström, Mia</td>
<td>Senior Advisor</td>
<td>Pharma Industry Finland</td>
</tr>
<tr>
<td>Bäcklund, Nina</td>
<td>Study Nurse</td>
<td>St. Olavs Hospital</td>
</tr>
<tr>
<td>Einen, Margrete</td>
<td>Executive Secretary (Hospital Pharmacist)</td>
<td>Norwegian Medicines for Children Research Network (Haukeland University Hospital)</td>
</tr>
<tr>
<td>Gundersen, Astrid</td>
<td>Bioingeniør</td>
<td>St. Olavs Hospital</td>
</tr>
<tr>
<td>Halvorsen, Thomas</td>
<td>MD</td>
<td>Norwegian Medicines for Children Research Network (Haukeland University Hospital)</td>
</tr>
<tr>
<td>Håpoldøy, Renathe</td>
<td>Study Nurse</td>
<td>Haukeland University Hospital</td>
</tr>
<tr>
<td>Irgens, Henrik</td>
<td>MD</td>
<td>Haukeland University Hospital</td>
</tr>
<tr>
<td>Korhonen, Minna</td>
<td>Head Clinical Operations Nordic Countries</td>
<td>Boehringer Ingelheim</td>
</tr>
<tr>
<td>Lepola, Pirkko</td>
<td>Executive Secretary</td>
<td>FINPEDMED (CRI HUCH Ltd.)</td>
</tr>
<tr>
<td>Lonning, Lise</td>
<td>Study Coordinator</td>
<td>Haukeland University Hospital</td>
</tr>
<tr>
<td>Tøndel, Camilla</td>
<td>MD</td>
<td>Haukeland University Hospital</td>
</tr>
<tr>
<td>Wessel Lund, Hanne</td>
<td>Clinical Research Manager</td>
<td>MSD (Norway)</td>
</tr>
<tr>
<td>Lafoile, Pierre</td>
<td>MD, Prof.</td>
<td>Karolinska Institutet</td>
</tr>
</tbody>
</table>
Limited impact of EU Paediatric Regulation on Finnish clinical trials highlights need for Nordic collaboration

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Keywords: Clinical trial, EU regulation, Paediatric medicines, Research network

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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.

• WP9 Proposal approved by NTA 20.12.2013, Proposing countries: Finland, Norway, Sweden
• Contract signed in February 2014

Nordic Trial Alliance

The purpose of the Nordic Trial Alliance (NTA) is to make it easier to carry out clinical research in the Nordic countries.

The overall aim of NTA is to enhance Nordic cooperation on clinical multi-centre trials.

Increased Nordic cooperation on clinical research will lead to a rise in the number of joint clinical trials and thus boost the attractiveness of the Nordic countries as partners in research. Such activities will also promote knowledge transfer as well as increased efficiency and research output.

The Nordic Trial Alliance is based on established national networks for clinical research, and will lay the foundation for increased collaboration between national and Nordic stakeholders.

The Nordic Trial Alliance (NTA) is a three-year pilot project funded by the Nordic Council of Ministers and NordForsk.

For Patients

Currently recruiting clinical studies
Clinical trials explained

The Nordic Trial Alliance (NTA) is a three-year pilot project running from 2013 to 2015, funded by the Nordic Council of Ministers and NordForsk.

News
Report from NORDIC investigators network for PEDIatric MEDicines May 19, 2015
Spotlight on Nordic Collaboration between Industry and Academia Apr 30, 2015
Final report on Transparency and Registration in Clinical Research in the Nordic countries published Apr 09, 2015
NTA Stakeholders Meeting 2015 held in Helsinki Feb 13, 2015
Project update for NTA Work Package 6 on Registration and Transparency Jan 08, 2015
More news…

Events
• Sep 09, 2015 - Sep 10, 2015 — Stockholm
  Nordic Life Science days 2015

Upcoming events…
• Based on experience of FinPedMed (2007)

• Project Management; FinPedMed / Clinical Research Institute Helsinki University Hospital Ltd. (CRI HUCH Ltd.)

• Period: 1 year (30.3.2014-30.6.2015)

• Funding: Nordforsk / NTA; 20% of 1 FTE
Management

**Finland:**
Pirkko Lepola, FINPEDMED (Clinical Research Institute Helsinki University Central Hospital Ltd)
Kalle Hoppu, MD PhD, FINPEDMED, Director Poison Information Centre, Helsinki University Central Hospital

**Partners**

**Norway:**
Thomas Halvorsen, MD, PhD, Director of the NorPedMed, Prof., University of Bergen, Haukeland University Hospital
Margrete Einen, MScPharm, Executive Secretary of NorPedMed and hospital pharmacist, Haukeland University Hospital

**Sweden:**
Anders Rane, MD PhD, Senior Professor, Karolinska Institutet, Karolinska University Hospital, Stockholm
Jenny Kindblom, MD PhD, As.Prof., Dept of clinical pharmacology, Sahlgrenska University Hospital, Gothenburg

**Denmark:**
Helle Holst, MD, PhD, Assoc Prof., Department of Clinical Pharmacology, Bispebjerg Hospital, Copenhagen
Mia Bjerager, MD, Overlæge Børneafdelingen Hillerød Hospital Nordsjællands Hospital, Hillerød

**Iceland:**
Ásgeir Haraldsson, Prof. of Paediatrics, Children's Hospital Iceland Landspitali - University Hospital, Reykjavík
Project Objectives - general

• Increase pediatric research opportunities by:
  • Increasing competitiveness of Nordic Area and develop stronger position within the Enpr-EMA
  • Raising the recruitment potential through a larger population
  • Fostering high-quality, ethical research & safety and efficacy of pediatric medicines
  • Enhance collaboration between the networks and various stakeholders

• Avoid unnecessary trials in children

• Create scientific and administrative competence

• Benefit sick children in Nordic countries
Barn och läkemedel

Möte på Arlanda - Sverige, Finland, Norge, Danmark

Arrangör: Barnläkarföreningen, svenska Läkemedelsverket. 140826

Deltagarkommentar från åhörarna: Man behöver en bättre infrastruktur och stöd för att få hjälp med kliniska prövningar. I synnerhet för att regelsystemet blir krångligare och krångligare.

Deltagarkommentar: Barnläkare är vana vid att hela tiden använda mediciner som inte finns testade för barn, vi ifrågasätter inte bristen på evidens.
Deltagarkommentarer angående ett nordiskt nätverk:

*Deltagarkommentar:* Det är oerhört skönt med en organisation som man kan hänvisa till när företag vill göra studier. Att man kan hänvisa till NOPHO.

*Deltagarkommentar:* Det är viktigt att det finns finansiering för ett nätverk. Organisationen NOPHO är en anledning till att barn med cancer har så pass hög överlevnad i Sverige. En fördel/problem är att NOPHO finansieras av barncancerfonden [alltså inte av statsmakterna].

*Pirkko Lepola* kommenterade detta och berättade att i FinPedMed är medlemmarna i nätverket från alla subspecialiteter så det finns läkare från NOPHO som också är med i FinPedMed, däremot verkar inte FinPedMed ha ett formaliserat samarbete med NOPHO.

*Deltagarkommentar:* Även bland barn med vanliga diagnoser (ex. astma), en ovanlig fenotyp, så finns det behov av kliniska prövningar, men här finns mkt litet pengar.


*Deltagarkommentar:* det är viktigt att vi fokuserar på bättre läkemedels-användning inte bara ”bättre läkemedel”. I detta ingår allt från vidareutveckling av läkare, och att introducera nya farmakologiska principer - t.ex. att kontrollera läkemedelsterapi med genetiska analyser etc. Viktigt att fokusera på ”Rational use of medicines”. Samtidigt är kanske ändå behovet av fortbildning och rationell läkemedelshantering är en fråga för läkemedelskommittéer.

*Deltagarkommentar:* Det är intressant att det svenska läkemedelsverket tar initiativ till detta möte. (LMV/ Viveca svarade att det inte finns medel att stödja ett nätverk, LMV har som sin uppgift att facilitera ett nätverk och kommer att tala väl om nätverket (för socialdepartementet)).
### Project milestones and deliverables

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Total: 8 meetings (F2F &amp; TC)</th>
<th>Planned</th>
<th>Held</th>
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<tbody>
<tr>
<td>M.09.1</td>
<td>First meeting of the project group in Sweden</td>
<td>Month 2</td>
<td>2.4.2014</td>
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<tr>
<td>M.09.2</td>
<td>Meeting in Sweden with representatives of the stakeholders (paediatricians, other paediatric investigators, industry, National regulatory agency)</td>
<td>Month 6 (Aug 2014)</td>
<td>26.8.2014</td>
</tr>
<tr>
<td>M.09.3</td>
<td>Meeting in Denmark with representatives of the paediatricians and other paediatric investigators</td>
<td>Month 9 (Nov 2014)</td>
<td>8.12.2014</td>
</tr>
<tr>
<td>M09.4</td>
<td>Workshop in Denmark to develop a proposal for establishment and operation of a Nordic Investigators Network for Pediatric Medicines</td>
<td>Month 12 (Feb 2015)</td>
<td>27.1.2015</td>
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<thead>
<tr>
<th>Deliverables</th>
<th>Planned</th>
<th>Delivered</th>
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<tr>
<td>D.09.1</td>
<td>Report on feasibility of establishing a Nordic Investigators Network for Pediatric Medicines</td>
<td>Month 10 (Dec 2014)</td>
</tr>
<tr>
<td>D.09.2</td>
<td>Proposal for establishment and operation of a Nordic Investigators Network for Pediatric Medicines</td>
<td>Month 15-22 (June 2015)</td>
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<tr>
<td>Country &amp; Network</td>
<td>Personnel (FTE) + activities</td>
<td>Other info / website</td>
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| Finland FinPedMed | • 2016-2017: Personnel: 1 full-time; 0,6 FTE (0,4 FTE for GRIP Project)  
• Members: 154 investigators (experts), 5 University Hospitals and 13 Other units  
• Clinical trial proposals 2007-> 20.1.2016: 143  
• Consultations/expert advise 2007->20.1.2016: 45  
• Both academic and industry initiated studies | Web-address: www.finpedmed.com |
| Norway NorPedMed  | • 2016-2017: Personnel: part-time employed in several positions (total of ~0,8 FTE)  
• Units at all pediatric departments; total 20  
• Clinical trials proposed or conducted: Total 30  
• Both academic and industry initiated studies  
• Will be using FINPEDMED developed network IT-solution  
• GRIP Roadshow training organised 2016 | Web-address: https://www.legemidlertilbarn.no/omoss/Sider/About-the-Network.aspx |
• Interested individuals list established  
• Interim board established, as Swedish Pediatric Society´s subcommittee; Intresseförening för Barn och Läkemedel  
• GRIP Roadshow training organised 2016 | Web-address: http://www.barnlakarforeningen.se/delforeningar/barn-och-lakemedel/ |
| Denmark ”DanPedMed” | • 2016-2017: ? FTE  
• Representatives from the different regions identified  
• Interim board established with members of the Danish Pediatric Society and The Department of Clinical Pharmacology Bispebjerg Hospital, Copenhagen  
• GRIP Roadshow training organised 2015  
• Funding secured from regions for 2016 | N.A. |
• Children´s Hospital Iceland (only centre in Iceland) | N.A. |
Future: design common IT structure for services

Readiness for Nordic database of investigators

e-system for services

1. Electronic service request + invoicing information + Confidentiality Agreement as needed
2. Request (electronically through the system), report and agreement templates and service fee form by e-mail. Also Confidentiality Agreement, if needed.
3. Answers provided by the investigators to the request are sent to FINPEDMED office electronically through the system. Investigators' names are included only in Confidentiality and consultation agreements and in web based study information accessed using personal passwords. Confidentiality agreement as requested by the sponsor.

SPONSOR
Pharmaceutical company/Research networks/Academic groups/Enpr-EMA*
Service requests received through Enpr-EMA free of charge

FINPEDMED OFFICE

NTA-WP9

INVESTIGATOR MEMBERS

EXPERT BOARDS (14)
NordicPedMed – larger, stronger and more effective

The NORDICPEDMED is a development project. The first part completed already in 2015, but it continues during the 2016 for the development of a joint Nordic Investigators Registry. 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 between investigators both on a Nordic and European level.

https://nora.agileus.fi/layout/nordicpedmed/
Thank You!
Pirkko Lepola
EXECUTIVE SECRETARY

FINNISH INVESTIGATORS NETWORK FOR PEDIATRIC MEDICINES – FINPEDMED

CLINICAL RESEARCH INSTITUTE Helsingi University Central Hospital

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