NordicPedMed

NORDIC TRIAL ALLIANCE (NTA) WP9

NORDIC INVESTIGATORS NETWORK FOR PEDIATRIC MEDICINES FEASIBILITY REPORT (D09.1)

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Background

Due to the past history of drug discovery and registration of new medicines, more than 50% of children all around the world receive medication used off-label or off-license. One consequence is common lack of knowledge and experience of paediatric clinical trials among the paediatricians and other health care professionals as well as authorities and the pharmaceutical industry. The European Union (EU) Paediatric Regulation No 1901/2006, a public health measure to improve the health of children in Europe, entered into force in January 2007. The regulation requires the pharmaceutical industry to develop all relevant new pharmaceutical products also for children, or an agreed waiver if the product is considered unnecessary or unsafe for children. The success of the Paediatric Regulation will require more clinical trials (CTs) than previously, and consequently capacity building to make the necessary investigators, patients and trial sites available. The paediatric CT`s to fulfil the obligations of the EU Paediatric Regulation are sponsored by the pharmaceutical industry.

Following the Regulation, the European network of paediatric research at EMA (Enpr-EMA) was launched in 2011. Enpr-EMA is a network of research networks, investigators and centres with recognised expertise in performing clinical studies in children. So far, Enpr-EMA has recognised 34 networks and eighteen of these have been accepted as full members, including five (5) national paediatric networks (Finland, Italy, Scotland, the UK and the Netherlands). The Finnish Investigators Network for Pediatric Medicines, FINPEDMED, established in 2007, was the first national paediatric network in northern Europe. It is currently the only Nordic full member of the European Network of Paediatric Research at EMA (Enpr-EMA). A Norwegian pediatric research network (NorPedMed), established in 2013, has been developed with some help from FINPEDMED. In the other Nordic countries, such national networks do not yet exist.

From the pharmaceutical industry´s point of view, the paediatric population of individual Nordic countries may be too small to be really interesting for Paediatric CT`s. A network of all the Nordic countries would have a larger paediatric population size, substantially increasing recruitment potential and making it more comparable to the paediatric population available to networks of large European countries. A Nordic network can have a stronger position within Enpr-EMA and in discussions with the pharmaceutical industry than national networks alone. Nordic countries share many unique competitive advantages, which can be utilized through collaboration in the area of CTs of paediatric medicines.

The Nordic Trial Alliance (NTA), a 3-year project funded by NordForsk, aims to enhance Nordic cooperation on clinical multi-centre trials. NTA intends to increase Nordic cooperation on clinical research and boost the attractiveness of the Nordic area by making it easier to carry out clinical research in the Nordic countries. Following the same aims, NordicPedMed, was established as a 1-year NTA project, to be implemented between 1.1. - 31.12.2014 (or within 12 months of receiving the funding). 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.

NordicPedMed aims to develop new innovative approaches built on the strengths of our somewhat similar health care, standards and experience of paediatric clinical research. NordicPedMed wants to foster high-quality, ethical research on the safety and efficacy of medicines for use in children, and enable collaboration between networks and stakeholders. The core function is based on study coordination avoiding unnecessary trials in children, and building a scientific and administrative competence at a Nordic level to help recruitment of patients for clinical trials. Most importantly, NordicPedMed wants to benefit sick children in Nordic countries by offering opportunities for early access to new promising medicines in a safe and controlled way in clinical trials. This report is the first planned project deliverable, D09.1. The final report, D09.2, will be submitted by the end of June 2015 due to delayed start of the project in March 2014.

1. NTA WP 9 - Nordic investigators network for Pediatric Medicines

1.1 Project group

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Management:

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1.2 Project objectives

The main objectives of NordicPedMed:

- Increase paediatric research opportunities by:
  - Increase competitiveness of Nordic Area and develop stronger position within the European Network of Paediatric Research at European Medicines Agency (Enpr-EMA)
  - Raise the recruitment potential through a larger child population (5.2 million < 18 yrs. old)
  - Foster high-quality, ethical research, to study safety and efficacy of paediatric medicines
  - Enhance collaboration between the networks and various stakeholders
- Avoid unnecessary trials in children
- Create scientific and administrative competence at a Nordic level
- Benefit sick children in Nordic countries by offering opportunities for early access to new promising medicines in a safe and controlled way in clinical trials.

Project objectives of WP 9:

1. Evaluate the feasibility of Denmark, Sweden and Iceland joining the current FINPEDMED - NorPedMed collaboration (the possible options include establishment of national networks in Denmark and Sweden, or individual centres or investigators joining the FINPEDMED - NorPedMed collaboration as an interim or permanent solution).

2. Develop a proposal for establishment and operation of a Nordic Investigators Network for Pediatric Medicines.

1.3 Project timing

Project milestones and deliverables:

Milestones		**Planned**	**Held**
M.09.1	First meeting of the project group in Sweden	Month 2	2.4.2014
M.09.2	Meeting in Sweden with representatives of the stakeholders (paediatricians, other paediatric investigators, industry, National regulatory agency)	Month 6 (Aug 2014)	26.8.2014
M.09.3	Meeting in Denmark with representatives of the paediatricians and other paediatric investigators	Month 9 (Nov 2014)	8.12.2014
M09.4	Workshop in Denmark to develop a proposal for establishment and operation of a Nordic Investigators Network for Pediatric Medicines	Month 12 (Feb 2015)	27.1.2015
Deliverables		**Planned**	**Delivered**
D.09.1	Report on feasibility of establishing a Nordic Investigators Network for Pediatric Medicines	Month 10 (Dec 2014)	31.3.2015
D.09.2	Proposal for establishment and operation of a Nordic Investigators Network for Pediatric Medicines	Month 15-22 (June 2015)	*scheduled 30.6.2015*

Project meetings:

Date	**Method (Meeting=M, TeleConference=TC)**	**Minutes (date)**	**Project attendees (number / countries)**
1. 02.04.2014	M, Stockholm	04.04.2014	5 / 3
2. 24.04.2014	TC	24.06.2014	4 / 3
3. 24.06.2014	TC	24.06.2014	6 / 4
4. 26.08.2014	M, Stockholm	27.08.2014	8 / 4 + 28 stakeholder´s reps.
5. 30.09.2014	TC	06.10.2014	9 / 5
6. 27.01.2015	M, Copenhagen	23.02.2015	9 / 5 + 2 investigators
7. 13.04.2015	*TC- Scheduled*	*n.a.*	

2. Project activities

At the time of the start of the project, the Project group consisted of partners from Finland, Norway and Sweden. Within the first 3 months contacts could be established also to paediatricians/Paediatric Societies in Iceland and Denmark and the Project Group was expanded accordingly.

2.1 Current status of the national activities

Finnish Investigators Network for Pediatric Medicines (FinPedMed) Finland, 2007-

- Personnel: 1 Executive Secretary (0,8 FTE)
- Members: 157 investigators (experts), 5 University Hospitals and 13 Other units
- Clinical trial proposals 2007-> 31.3.2015: 140
- Consultations on pediatric drug development or clinical trials 2007->31.3.2015: 40
- Both academic and industry initiated studies

Medicines for Children Research Network, (NorPedMed) Norway, 2013-

- Personnel: 12 part-time employed; office staff, investigators, study nurses (3.7 FTE)
- Units at all pediatric departments; total 20
- Clinical trials proposed or conducted: Total 30
- Both academic and industry initiated studies

Swedish network – interim board established within the Swedish Pediatric Society, 2015

- Interested individuals list established (40 names on list)
- Interim board established, working currently as Swedish Pediatric Society´s sub-committee; *Intresseförening för Barn och Läkemedel.* Plans for independent SwedPedMed after permanent board and funding.
- 3x Board meeting held; nominees for Permanent Board which will be constituted in spring 2015.

Danish network – interim board established within the Danish Pediatric Society, 2015

- 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.
- First meeting January 2015.

Icelandic network (IcePedMed) –discussed with Children's Hospital Iceland, 2014

- Collaboration with the Children´s Hospital Iceland (only one in Iceland), University of Iceland and the Icelandic Paediatric Society
- Representatives; Professor of Paediatrics and faculty chairman at the Children´s Hospital, The Icelandic Paediatric Society (FIBL) and The University Hospital – Landspitali
- An interim board will be established in the spring 2015and interested participants enlisted.

2.2 Participation and project presentations in meetings

- NTA StakeHoldersMeetings and WP-meetings:
  - 01-2013
  - 10-2014
  - 01-2015

- Nordic Health Research and Innovation Networks (NRI) Conference:
  - 05-2014
  - *05-2015 (Scheduled)*

2.3 Upcoming conferences and meetings for project presentations

- NTA Stakeholders Meeting – (WP 7) Pharma meets Academia, 22.-23.4.2015, Helsinki. Program: http://nta.nordforsk.org/ and http://www.laaketietokeskus.fi/en/training/training-calendar/nordic-collaboration-in-clinical-research

- NRI (Nordic Research and Innovation network) Conference, 4. - 5.5.2015, Bergen. Program: http://nordicnetworks.org/

- Enpr-EMA annual workshop 27.5.2015, London – open for all stakeholders. Program: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp&mid=WC0b01ac05801df74a

- ESDPPP Congress 23-26.6.2015, Belgrad, program for GRIP: http://www.esdppp.org/site/2015-congress-belgrade/

3. Result of Feasibility assessment (Project objective 1)

In the Workshop held in Copenhagen 27.1.2015, all partners unanimously agreed that a Nordic network should be established, and that establishment of a NordicPedMed is feasible. Two different options for the process to establish a Nordic Network were discussed:

1. National network development first in all countries, followed by development of the Nordic network

2. Nordic network to be established as soon as possible with development of new national networks in parallel

FinPedMed has built up knowledge, experience and has already developed applicable IT-structure that could be made available for use by all partners. As Denmark, Sweden and Iceland are just starting their national network development processes, which may take some time, it was concluded, that it would be a laborious and long process to select option 1. All the project group members endorsed option 2 to be the strategic and most feasible way to move forward.

3.1 Draft concept for a "NordicPedMed"

All interested investigators from each country could join the virtual "NordicPedMed" as individuals. The management of the Network members (investigators and experts) could be handeled by FinPedMed IT-structure, which includes an Investigators Registry.

FinPedMed could make the its IT-structure available and take care of the maintenance and up-keeping responsibilities of the system, provided that funding for the additional administrative work is found. FinPedMed and NorPedmed have already agreed to develop such an approach during the spring 2015.

In addition the (virtual) NordicPedMed can have common visibility (coverage) by a common web-page. This can be developed, once funding is secured. For practical operation a minimum requirement is for each country/national network to have 1 person (0.5 FTE or more ->) to serve as a direct contact (e-mail and phone) point to the national network.

A more detailed plan for establishment of a Nordic network ("NordicPedMed") will be presented as Deliverable D.09.2 by the end of June 2015.

A list of current national status and planned requirements:

	Funding status	Personnel (FTE)	Other info / notes:
Finland FinPedMed	Funding secured to the end of 2017. Funding covers 1 FTE and some IT costs.	2015: 0,6 FTE (0,4 FTE for GRIP) 2016-2017: 1 FTE	Web-address: www.finpedmed.com Needs additional funding for Nordic network development.
Norway NorPedMed	Funding secured	2015: 3,7 FTE for the 2 networks; mainly for the Medicines for Children Network, Norway – and partly for the NorPedMed 2016-2017: +20% FTE for several CT units	Web-address: http://legemidlertilbarn.no/forskning/Sider/What-is-NorPedMed.aspx
Sweden SwedPedMed	Funding applied	2015: 0 2016-2017: 0,5 FTE	Web-address: http://www.barnlakarforeningen.se/delforeningar/barn-och-lakemedel/
Denmark DanPedMed	Funding discussed / applied	2015: 0 2016-2017: 0,5 FTE	N.A.
Iceland IcePedMed	Funding ?	2015: 0 2016-2017: ?	N.A.

3.2 Summary

In Nordic countries, we have national and an ethical responsibility, as required by the EU Paediatric Regulation, to help meet the increased demand for paediatric clinical trials in Europe. This is an important work we can do for the benefit of northern European children. All paediatric patients need evidence based care with the help of medicines with available knowledge, safety and efficacy data, and new medicines becoming available after properly conducted trials. To enable this, we have to create a competitive network covering the Nordic area.

Paediatric drug trials performed within the Nordic countries can help to ensure that such trials are performed with the highest possible ethical standards, in accordance to national legislation and utilising health care systems that encompass all citizens, irrespective of personal financial situations or other potential limitations. Moreover, an all-encompassing health-care system makes it possible to use population based data, unbiased by factors that are bound to confound results from institution-based studies.

The characteristics of Nordic counties, general access to health-care enforced by law and a well-educated population ensures equality between participating patients, well-trained medical profession and availability of sponsors of studies, such as the pharmaceutical industry, are pivotal factors for future availability of high quality medicines for children all over the world, developed through properly conducted and ethically appropriate research. To achieve this aim, a competitive network for paediatric drug trials is needed in the Nordic countries.

During this NTA WP9 project it has become apparent that “NordicPedMed” is feasible and not very far from reality. All Nordic partners, including national Paediatric societies, are willing to build this network together. Next phase of the project will be defining the practical needs and resources, including minimum budget structure and calculations, for establishing the Nordic network for collaborative operations. The new national networks will continue their establishment, seeking expanding representativeness, drawing up plans for operation and for applying funding. Additionally, the new networks will consider applying for Enpr-EMA membership. The proposal of how this Nordic network could be established will be reported as planned, by the end of June 2015.