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# Report of the 2018 annual face-to-face meeting of Enpr-EMA members and the Enpr-EMA Coordinating Group (CG)

8 June 2018

Chairpersons: Mark Turner / Irmgard Eichler

## Open session with industry observers

### *Welcome and introduction of new Enpr-EMA members:*

### NETSTAP

NETSTAP is a network of paediatricians for clinical studies in children in ambulant treatment with approximately 100 members across Germany.

Main aims:

- Improving environment for clinical studies in child and adolescence population (evidence based medicine).
- Promoting studies and study designs suitable for children.

Presentation - Welcome to NETSTAP

### TREAT-NMD

TREAT-NMD, a category 4 member of Enpr-EMA, is a global organization bringing together leading specialists, patient groups and industry representatives in the neuromuscular field that aims to ensure that the most promising new therapies reach patients as quickly as possible. It focuses on the development of tools needed by industry, clinicians and scientists to bring novel therapeutic approaches into clinical practice, and on establishing best-practice care for neuromuscular patients. The network has developed registries, standards of care and provides training, translated into different languages.

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## HunPedNet

The Hungarian Primary Care Paediatricians' Research Network (HunPedNet) was created with the aim of obtaining new medicines, formulas and vaccines for Hungarian children via facilitating clinical trials in children. Earlier the paediatric primary care clinical sites worked separately and only a few of the paediatric clinical trials were conducted in primary care offices.

The network consists of almost one hundred primary care paediatricians (the number is continuously growing) responsible for the care of 80,000 children.

Presentation - Welcome to HunPedNet

## Outcomes of the 10th annual workshop 2018

The action points discussed during the Enpr-EMA meeting day 1 were reviewed and accepted.

For further information see the section 'Action points' in minutes of Enpr-EMA annual workshop.

## Industry perspective & proposals for Enpr-EMA action plan 2018/2019

Companies should contact selected network(s) very early in drug development process, involve networks in the development of a PIP and throughout the development until MAA and beyond.

Proposal for Enpr-EMA action plan 2018/2019:

1. Establish international collaboration between regulators (EMA, FDA, Canada, PMDA) and networks (e.g. Enpr-EMA representing Europe):
    1.1. Initiative would be beneficial for global drug development and global trials.
2. Best practice for defining criteria of standard of care:
    2.1. Enpr-EMA has role of facilitator/integrator.
3. Parents/patient involvement:
    3.1. Parents/Patients organisations to be involved in Enpr-EMA to support development of parent/patient "friendly" protocols and thus improve recruitment and retention. Motivate parents to have a positive attitude towards paediatric research.

Presentation - Industry perspective and proposals for action plan 2018-2019

## Interaction with ERNs (European Reference Networks)

The questions and a summary of the results of the ERN-wide survey on status quo of ERNs and their clinical research activities related to paediatrics (part of the project '677024 / RD-ACTION') were presented.

Presentation - Status quo of ERNs and clinical research: results of the ERN-wide survey

## *Closed session for Enpr-EMA network members only*

## Interaction of Enpr-EMA with Conect4Children (c4c)

How to best work with c4c:

Not all Enpr-EMA members are also partners in the recently launched 6-year IMI2 project Conect4Children (**Co**llaborative **n**etwork for **E**uropean **c**linical **t**rials **for children**), a consortium consisting of 10 industry (members of EFPIA) and 33 academic partners from 20 European countries.

The need for strong interaction between Enpr-EMA and c4c was emphasised to ensure continued dialogue and sharing good practices with networks not being part of c4c, to avoid duplication of work, as well as to enhance capacity building of EU paediatric trials expertise across Europe. Enpr-EMA should act as a platform for connecting all networks. The consortium was invited to apply for Enpr-EMA membership as soon as possible to ensure much needed close collaboration.

The importance of ensuring that the work undertaken by Enpr-EMA feeds into c4c was emphasised.

PDCO representatives suggested inviting c4c representatives to a PDCO meeting to allow PDCO members a better understanding of c4c and its activities.

## Enpr-EMA membership criteria

It was discussed and agreed that all members of Enpr-EMA must be public-benefit organisations and this will need to be evidenced in order to be eligible to be part of Enpr-EMA.

## Enpr-EMA/PDCO interactions:

Since 2017 a timeslot during the PDCO plenary meeting is reserved for Enpr-EMA members (currently every other month) to present their network and the network's activities and to discuss how the PDCO could best solicit network input on general and scientific questions during the PIP assessment.

Both, PDCO representatives and networks mentioned the utility of the meetings and the need of further improving this channel for communication between Enpr-EMA networks and the PDCO as it is of high interest for all parties and is hoped as a means to address identified problems/challenges as early as possible.

Networks expressed the wish to improve and increase dialogue with PDCO to discuss paediatric needs, study design, standard of care as well as a need for training in regulatory science and procedures for members of the network.

Presentation – Enpr-EMA/PDCO interactions

## Communication of difficulties with paediatric studies to PDCO

Guidance to facilitate and improve the communication between the networks and PDCO, addressing both non-product specific discussion as well as product specific communication, is under development and will be published on the Enpr-EMA website.

PDCO members mentioned the need for a consolidated network expert opinion on general scientific questions (as opposed to individual expert opinion) within a 2-3 week timeframe because of the tight timelines of PIP procedures.

Presentation - Communication of difficulties with paediatric studies to PDCO

## PDCO perspectives & proposals

The PDCO explained the main challenges they face from the regulatory side in order to identify where further collaboration with the networks would help:

- Identifying and defining paediatric therapeutic needs.

- Prioritisation - positioning of a medicine among several ongoing/upcoming developments.
- Methodological issues, e.g. standard of care.
- Restrictions at national level negatively affecting the feasibility of performing clinical trials.
- Study designs, outcome parameters, novel approaches, scientific basis of extrapolation.
- Input on regulatory guidelines.

The PDCO proposed some action points to improve the interaction / collaboration with the networks:

- Increase network capacities: on networks' invitation regulators (e.g. PDCO members) could provide training sessions to improve understanding of licensing requirements.
- Streamline network feedback regarding PDCO requests for specific products within strict PIP timelines.
- Increase information and transparency on networks' conflict of interests.
- Identify therapeutic areas where Enpr-EMA networks are still missing.

Presentation – PDCO perspectives and proposals: Enpr-EMA coordinating group

## Enpr-EMA action plan for 2018/2019

The action points will be circulated for comments. See section 'Action points' in minutes of Enpr-EMA annual workshop.

The networks were notified about:

- the need for selection of new chair of Enpr-EMA at 2019 annual face-to-face meeting,
- the planned adding of data protection notice to the Enpr-EMA database.

## Conclusions agreed by the Coordinating Group (CG)

- Adoption of the minutes of the last Coordinating Group teleconference on March 2018.
- Endorsement of the proposed Enpr-EMA membership criterion regarding status of public-benefit status.
- Endorsement of new Enpr-EMA members of NESTAP, TREAT-NMD and HunPedNet.
- Endorsement of Luca Sangiorgi as observing member of the CG to represent ERNs.

## Next steps

A Doodle pool with possible dates for the next Enpr-EMA CG teleconference will be sent (to be scheduled in October 2018).