Enpr-EMA newsletter 2018

Dear friends and colleagues,

Before the year 2018 draws to a close we want to briefly inform you about the activities of Enpr-EMA throughout the year 2018.

4 new networks applied for membership of Enpr-EMA, all of them currently category 3 networks:

- PEDSTART - French national paediatric research network
- PIBD – Pediatric Inflammatory Bowel Disease network
- INCIPIT – Italian Network for Clinical Trial
- Paediatric European Huntington's Disease Network

Activities of Enpr-EMA working groups in 2018

WG "Dialogue and interaction with Ethics Committees":

Following the successful publication of the table of the requirements regarding consent of children in the various member states, on the Enpr-EMA website, as well as in the scientific journal Archives of Disease in Childhood (http://adc.bmj.com/content/101/11/1017) in previous years, the group has been working on a guidance document for all Enpr-EMA stakeholders on consent / assent information to be published on the Enpr-EMA website. Many relevant stakeholders' views were sought, including input from the European Network of Young People Advisory Groups. The comments received are currently being reviewed and incorporated into the document which is planned to be finalised early next year.

WG on public-private partnership:

Following the finalisation of their work on a consultation model how industry can best engage with Enpr-EMA networks and benefit from such consultations the related guidance document and diagram was published on the Enpr-EMA website inviting companies to use the various services offered by paediatric research networks.

WG on Young Persons Advisory Groups (YPAGs):

The group, which represents the voice of young patients involved in clinical trials, has contributed to the Enpr-EMA working group on trial preparedness and to the consent/ assent guidance document.

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Currently, the group is working on a new EU curriculum to train young patients/persons. The group will also closely work together with the new Enpr-EMA parent/patients WG.

WG on Good Clinical Practice (GCP) training

The publication of the results of the group's survey investigating the roles and training of paediatric research nurses across Europe in BMJ Paediatric Open in 2017 raised relevant points for discussion, such as different roles and funding of research nurses across countries.

About 40 European paediatric research nurse networks and groups have expressed interest in working together with Enpr-EMA, considering it as a central resource where to find and share information. To this end, information on paediatric research nurse networks and groups was published on the Enpr-EMA website: Table of European Paediatric Research Nurse Networks and Groups.

Facilitation of connection between the various groups and networks will be the next action point.

WG on clinical trial preparedness

The group has prepared a draft of guidance document setting out a framework for trial preparedness to increase the ability to complete high quality clinical trials in a timely manner. This work included among other things the review of regulatory guidance and literature and a survey and interviews with stakeholders (industry, CROs, patients/parents, health care professionals, regulators). The guidance document is planned to be published on the Enpr-EMA website for public consultation by early 2019.

Two new working groups were set up in 2018:

WG on parent/patient involvement

This working group aims at providing Enpr-EMA with a patient perspective for topics such as data collection, multi-stakeholder collaboration, and innovative clinical development models. As a first step a small core group including patient representatives in EMA Committees experienced in regulatory activities and medicine development in the paediatric population has been established. This core group is currently in discussions with various stakeholders to establish a second layer of 15 experts from Academia, health care professionals, CROs, Industry etc.

WG on international collaboration

At the Enpr-EMA annual meeting in London, it was suggested to set up a working group on international collaboration, with the purpose to identify, understand, and possibly address cross-jurisdiction challenges hampering increased international collaboration.

The membership of the WG was discussed at the Paediatric cluster. As a first step, the WG will be made up of representatives from the Regulatory Authorities (NCAs), and national networks from the following five Regions: USA, Europe, Canada, Australia, and Japan.

The regional NCAs i.e. FDA, EMA, PMDA, Health Canada and TGA, proposed the following paediatric clinical trial networks:

- USA: Institute For Advanced Clinical Trials For Children I-ACT and Duke Clinical Research Institute
- Europe: Enpr-EMA
- Japan: Center for Pharmacovigilance and Networking, National Center for Child Health and Development (Office of Japanese Children Trials Network)

- Canada: Maternal Infant Child & Youth Research Network (MICYRN)
- Australia: Paediatric Trials Network Australia (PTNA)

A first teleconference meeting will be held in December to define the scope of the group and agree on priorities and the initial action items

We thank all working group members for their enthusiasm and efforts.

Additional Enpr-EMA activities in 2018

- The 2018 Annual workshop of the European Network of Paediatric Research at the European Medicines Agency marked the 10th anniversary of the network. In the ten years Enpr-EMA has grown substantially with new specialty networks in therapeutic areas where none existed 10 years ago. Enpr-EMA has expanded beyond Europe through networks from the US, Canada and Japan. The workshop was followed by the networks and the Coordinating Group meetings on the next day (16-17/05/2017). The meeting reports are published on the Enpr-EMA website.
- Enpr-EMA welcomed Luca Sangiorgi as representative of the European Reference Networks as observer to the Coordinating group to ensure close communication and collaboration with this group of centres of excellence in the field of rare diseases.
- First contact with the Clinical Trials Facilitation Group (CTFG) as well as with the European network for health technology assessment (EunetHTA), has been established with the aim to increase communication and collaboration with these bodies in view of a holistic approach to paediatric medicines research.
- In March 2018 several Enpr-EMA members attended the EMA-EC multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation.
- Relevant Enpr-EMA work has been included in the EMA/EC paediatric action plan, which aims to boost the development of medicines for children. Various Enpr-EMA initiatives are expected to feed into the delivery of actions points, such as the increase of global interactions between regulators and networks, the preparedness guide, information on assent/consent forms, and training of research nurses to name but a few. Progress updates on the action plan are expected to add visibility to these initiatives.
- The "Severe Paediatric Asthma Collaborative in Europe (SPACE)" published a protocol for a European registry in *Breathe* 2018; 14: 2–8. http://breathe.ersjournals.com/content/14/2/93
- In May 2018 Conect4Children (c4c), a new public-private partnership to improve clinical trial infrastructure to facilitate the development of new drugs for children in Europe was launched. Several Enpr-EMA members are partners or affiliated partners of this important IMI2- project.
- Throughout 2018 the Paediatric Committee (PDCO) continued to invite representatives of Enpr-EMA networks (or other collaborative partners) to attend a plenary meeting, either in person or via telephone conference. This represents an opportunity for the PDCO to learn about the networks' activities, and vice versa, and about how collaboration between the networks and the committee could be improved. In practical terms, agreements could be made e.g. on how the PDCO could best solicit network input on general scientific questions (as opposed to individual expert opinion) during PIP procedures. The following networks were invited: European network of young people advisory groups (eYPAGnet); Newcastle CCLG Pharmacology Group.

Next year will bring several changes:

- Due to the EMA's Business Continuity Planning in relation to its relocation to Amsterdam it will not be possible to organise the usual annual open workshop. However, a face to face meeting of the coordinating group and the networks is planned for Q4 2019 with a tentative date of 14th of October 2019. Enpr-EMA members will be informed of a definitive date as soon as possible.
- A new chair of Enpr-EMA will be elected at the face to face meeting.
- As of January 2019 Gunter Egger will take over co-chairmanship of Enpr-EMA from Irmgard Eichler.

We want to thank you all for your continuous support and activities towards Enpr-EMA.

We wish you and your families a

Merry Christmas, happy holidays and all the best for the New Year

May the year 2019 turn our plans into reality and all our efforts into further achievements to the benefit of children.

Mark Turner (Chair) **Irmgard Eichler** (Co-chair)