Enpr-EMA newsletter 2019

Dear friends and colleagues,

Before the year 2019 draws to a close we would like to briefly look back at what we have accomplished this year at Enpr-EMA.

We have been able to progress our goals because of your support - whether through engagement in working groups or through other contributions. The working groups yielded several important outcomes (e.g. publication of draft framework on trial preparedness, bringing together regulators of several regions working on guidance related to clinical trial applications, an inaugural meeting of an Enpr-EMA research nurse group, guidance on informed consent / assent, just to name a few).

This year we had a face-to-face meeting of Enpr-EMA members and the Coordinating Group (CG), which took place on 14 October. At this meeting Pirkko Lepola of the Finnish Investigators Network for Paediatric Medicines (FinPedMed) was elected as the new chair of the CG. We would like to take the opportunity to thank Mark Turner, who retired as chair, for his work during two three-year mandates.

As we take a moment to take stock and reflect, we thank you all for your ongoing support and hard work, which is crucial for the success of Enpr-EMA and our efforts to enhance and accelerate the development of safe and efficacious medicines for children.

With recent developments of new paediatric research initiatives, the importance of Enpr-EMA's role as a platform for dialogue for a large group of research networks and other stakeholders has become particularly evident, in order to harness synergies and avoid duplication of efforts.

You will be able to find further details on achievements in 2019 and important topics for our work in 2020, in the Report of the 2019 annual face-to-face meeting, which is currently under review and will be shared and published on our website early in 2020. A short summary of the working groups' achievements in 2019 is also included in the Annex below.

We welcomed three new networks who joined Enpr-EMA this year:

- conect4children (c4c)
- Severe Paediatric Asthma Collaborative in Europe (SPACE)
- Stand4Kids (Supporting Paediatric Trials in Portugal)

Moreover, a new member of the CG was endorsed:

- European Network of Excellence for Paediatric Clinical Research (TEDDY)

We wish you a relaxing festive season and all happiness in the New Year, and we look forward to continuing our work together in 2020.

Best wishes,

Pirkko Lepola (Chair)

Gunter Egger (Co-chair)

Annex: Activities of Enpr-EMA working groups (WG) in 2019

Working group on public-private partnership

Following the publication of the guidance document for network consultation, 'network consultation recommendation', which was developed by the WG and published on the Enpr-EMA website and outlines the recommended model for consulting paediatric research networks, all agreed tasks of this group were completed and the group was closed.

Working group on ethics

A guidance document related to consent / assent information has been developed, including input and recommendations from the European Young People Advisory Groups network (eYAGnet). This document is expected to be published on the Enpr-EMA website soon, followed by a related article in a scientific journal.

Pirkko Lepola presented the work of the WG at the European Network of Research Ethics and Research Integrity (ENERI) Boot Camp in March 2019. Further ways of collaboration with the European Network of Research Ethics Committees (EUREC) are being explored.

Working group on young persons' advisory groups

Building on the work of this WG, the European Young Persons' Advisory Group Network (eYPAGnet) was established and became a Category 4 member of Enpr-EMA in 2018.

Recent activities include the implementation of standard operating procedures, the launch of a website (www.eypagnet.eu), and the establishment of an advisory board. Other activities included YPAG

involvement in c4c activities, contributions to the work of other Enpr-EMA WGs (on ethics, trial preparedness, and parents & patients), one book chapter in "Ethics of research involving minors" and several scientific publications.

As eYPAGnet had been successfully established and was operational as a member network of Enpr-EMA the group was closed.

Working group on parents and patients

A core group/steering committee was set up involving patient representatives and regulators from the EMA Committees and the Patient-Consumer Working Party (PCWP) with experience in regulatory activities and medicines development in the paediatric population. The group identified inefficient use of research data and lack of interoperability of data as major hurdles to efficient clinical research in children. As the group's first task it will explore ways to facilitate data sharing in paediatric clinical research, taking into account the FAIR Guiding Principles for scientific data management.

Working group on research staff

Previous work identified the need to enhance connection and communication between paediatric research nurses as well as the lack of dedicated associations for research nurses in some countries, as the lack of connection and communication creates major hurdles to exchanging best practices and building up expertise related to paediatric clinical trials. It was agreed that a research nurse group under the umbrella of Enpr-EMA could provide a useful central resource for sharing information between interested parties at a European level.

In February 2019 the inaugural teleconference of an Enpr-EMA research nurse group was held.

Working group on clinical trial preparedness

A preparedness guidance document was published on the Enpr-EMA website. A two-month public consultation on the draft framework was held until 15 November 2019.

It is planned to publish an updated version of the framework, taking into account feedback received during the public consultation, on the Enpr-EMA website, followed by the submission of a manuscript for publication in a scientific journal.

Working group on international collaboration

Representatives from regulatory authorities and national networks from the following five regions are part of this WG: USA, Europe, Canada, Australia and Japan.

The WG is working on an overview and guidance document related to the clinical trial authorisation processes in the different regions in order to assist investigators and industry involved in conducting multiregional studies.