Enpr-EMA newsletter 2017

Dear friends and colleagues,

Before the year 2017 draws to a close we want to briefly inform you about the activities of Enpr-EMA throughout the year 2017.

Enpr-EMA expanded with the addition of 8 new networks:

- Category 1:

  - Red de Investigación Traslacional en Infectología Pediátrica (RITIP) Translational Research Network in Paediatric Infectious Diseases

  - Spanish Paediatric Clinical Trials Network (RECLIP)

- Category 3:

  - Multinational Interdisciplinary Working Group for Juvenile Idiopathic Arthritis associated uveitis

  - ReSViNET (a specialty network focusing on RSV infections)

  - NETSTAP e.V. (network of paediatricans in Germany)

  - Central European Pediatric Oncology Early Trials Alliance, z.s. Milady Horákové 1953/5a 602 00, Brno, Czech Republic/CEPOETA

- Category 4:

  - European Young Persons Advisory Groups Network

  - TREAT-NMD (Specialty Network for neuromuscular diseases)

Since the official launch of Enpr-EMA in 2011, 58 networks have submitted their self-assessment forms; however, only networks of categories 1-4 that have updated the forms regularly are visible in the Enpr-EMA Network Database.

At the end of 2017, Enpr-EMA has 47 networks registered in the Enpr-EMA database:

- 24 category 1 networks;
- 3 category 2 networks;
- 17 category 3 networks;
- 3 category 4 networks.

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Activities of Enpr-EMA working groups

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), the group has been working on the 3rd task, i.e. a partly harmonised informed consent / assent templates. Next steps include: to compare different comments received and to identify conflicting elements in order to prepare a template that Enpr-EMA could place publicly for all stakeholders.

An additional ongoing task is the collaboration with the European network of research ethics committees (EUREC): on 13th November 2017 a face-to-face kick-off meeting with representatives of EUREC and the clinical trial facilitation group was hosted by EMA. The following action points were agreed:

1. Compilation of available "ethics" training programmes with paediatric specific aspects;
2. Compilation and reference to available guidance documents and draft template for ethical considerations in paediatric research;
3. Development of scope and framework for systematic involvement of young person's advisory groups (YPAGs) in ethics assessment about new CTs (consultation and informal opinion);
4. Development pf paediatric specific training modules for a EUREC training boot camp

WG on public-private partnership:

The group finalised their work on a model how industry can best engage with Enpr-EMA networks and how this could benefit them. The group has prepared a recommendation document and diagram to guide companies in taking advantage of scientific and logistic expertise available from paediatric research networks. The diagram (slide 17) was presented to PDCO in March 2017.

In order to prepare a pilot period and invite industry to use the networks' service, for which networks will charge a fee, the WG would like to send a survey to selected networks so that they can specify for which services they would be available. Networks are requested to send their feedback regarding the utility and content of this survey to the Enpr-EMA mailbox by the end of January 2018. After the pilot phase certain elements of the survey should also be included in the self-assessment forms and be made available via the Enpr-EMA database.

WG on Young Persons Advisory Groups (YPAGs):

Based on the outcome of a survey to identify currently established YPAGs, the four members of this working group founded the European network of young people advisory groups (eYPAGnet).

eYPAGnet has been accepted as a Category 4 member of Enpr-EMA. This new network will act as a single point of contact for all YPAGs in Europe.

Several members of this working group attended the iCAN (international children's advisory network) summit 2017 in Orlando, where they had the opportunity to meet, discuss and strengthen collaboration with members of Canadian and US youth groups.

As next step the group will focus on

- the elaboration of a new EU curriculum to train young patients/persons;
- to establish a single contact point;
- the development of a sustainability business model.

WG on the Educational Training of Research Staff involved in Paediatric Clinical Trials:

The group completed its first tasks by summarising the findings of the survey on requirements across Europe for the qualification of 'research nurses' in a manuscript "Investigating the roles and training of paediatric research nurses working across Europe: a questionnaire-based survey" which was recently published in BMJ Paediatrics Open. The link to the publication is also available on the Enpr-EMA webpage.

WG clinical trial designs for paediatric antibiotic trials

This working group was triggered by many challenges and difficulties encountered with the conduct of paediatric antibiotic trials. The group has been focussing on optimising trial design in paediatric infections and working on specific examples. The summary of a systematic review of safety signals in paediatric and adult antibiotic trials has been accepted in the scientific journal "Drugs".

Another broad manuscript about aspects and design of paediatric antibiotics trials is nearing finalisation. Once this is also published, the working group will have completed its tasks and will be closed.

New Working groups

One new working group was set up in 2017:

WG on clinical trial preparedness

This new working group, co-chaired by a PDCO member and the representative of a national multi-disciplinary network, had its 1st face to face meeting in October 2017 at the EMA. The following action points have been agreed:

1. Review the current regulatory guidance and academic publications in relation to the conduct of trials in the paediatric population to identify discussions on preparedness.
2. Summarise previous initiatives on paediatric clinical trials to identify existing valuable guidance on overcoming challenges.
3. Utilise deliverables from other Enpr-EMA WGs which have an impact on paediatric clinical trial conduct.
4. Development of a prompt guide/questionnaire to be used in interviews and brainstorming sessions on trial preparedness with stakeholder groups.
5. Development of preparedness-orientated guidance document including (a) narrative, (b) Q&A, (c) decision tree, (d) risk management strategy

We thank the members of all working groups for their enthusiasm and efforts.

Additional Enpr-EMA activities throughout 2017 included:

- 2017 annual workshop of the European network of paediatric research at the European Medicines Agency followed by the networks and the Coordinating Group meetings (16-1/05/2017). The meeting reports are published on the Enpr-EMA website.
- In March 2017 Enpr-EMA hosted the second meeting of the European Respiratory Society Severe Paediatric Asthma Collaborative in Europe (SPACE).
- Several Enpr-EMA members have contributed to the submission of an IMI2-aplication on the creation of a pan-European paediatric clinical trials network. The application passed successfully stage 1 and is now awaiting the outcome of the final evaluation.
- Throughout 2017 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: PRINTO (Paediatric Rheumatology International Trials Organisation) in January; representatives of the WG on public private partnership were invited to discuss "Interactions between CROs and networks (March); ECFS-CTN (European Cystic Fibrosis Society – Clinical Trials Network) in July; European Child and Adolescent Clinical Psychopharmacology Network (ECAPN) in August; German Neonatal Network (GNN) in November.
- A corporate response from Enpr-EMA was submitted to the European Commission during the public stakeholder consultation on the experience acquired with the Paediatric Regulation. (EnprEMA - European Network of Paediatric Research at the European Medicines Agency)
- FINPEDMED organised a Nordic Pediatric Conference with participation of industry representatives and PDCO members.

The next Enpr-EMA workshop will be on Thursday, 7 June 2018 at the EMA in London. On the next day there will be a meeting of the network members followed by a meeting of the Coordinating Group.

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

We wish you and your families **Merry Christmas, happy holidays and all the best for the New Year**. May the year 2018 turn our plans into reality and all our efforts into further achievements to the benefit of children.

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