EMA/61510/2016 Corr.1

Enpr-EMA newsletter 2016

Dear friends and colleagues,

We want to briefly inform you about the activities of Enpr-EMA throughout the year 2015 and plans for 2016.

Enpr-EMA expanded with the addition of 4 new networks that joined as Enpr-EMA registered

- Category 1:
  - Duke Clinical Research Institute (DCRI);
  - OKIDS (Austrian national multispecialty paediatric network).
- Category 2:
  - INFANT: Irish Centre for Fetal and Neonatal Translational Research Cork University Maternity Hospital Wilton, Cork Ireland.
- Category 3:
  - Paediatric Clinical Investigation Center Brussels (Multi-speciality, local and national, pediatric clinical investigation Center).

The French national multispecialty network RIPPS (Réseau d'Investigation Pédiatrique des Produits de Santé) was upgraded to category 1 network.

The following networks were deleted from the Enpr-EMA member table due to inactivity:

The European paediatric oncology off-patent medicines consortium (EPOC) funded under the seventh framework programme of the European Commission (FP7) is no longer an Enpr-EMA registered network (category 1) as the network has become inactive after funding stopped.

Since official launch of Enpr-EMA in 2011, 48 networks have submitted their self-assessment forms; however, only networks of category 1-3 that updated the forms regularly are visible in the Enpr-EMA Network Database.

At the end of 2015, Enpr-EMA had 39 registered networks:

- 20 category 1 networks;
- 3 category 2 networks;

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- 13 category 3 networks;
- 3 category 4 networks.

Activities of Enpr-EMA Working groups

WG "Dialogue and interaction with Ethics Committees":

Requirements for consent / assent vary greatly among Eu member states. This is one of the greatest challenges in achieving ethical approval across EU member states. The group developed a table that shows requirements regarding consent of children in the various member states, including legislative surroundings of the informed consent requirements for paediatric clinical trials. The table has been published on the Enpr-EMA website. (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199234.pdf)

Submission of comments on proposed changes to the U.S. Common Rule. The comments focused on two points relating to paediatric research:

- The value of taking an international perspective when revising the Common Rule;
- Informed consent.

WGs "How to establish communication between Enpr-EMA, networks and industry" and "Sharing good practices within Enpr-EMA and with industry" decided to merge.

The final report on the outcomes of the survey with, examples of good practice as well as a list of ideal services that networks can provide was accepted by Applied Clinical Trials journal: Pharmaceutical Industry and Pediatric Clinical Trial Networks in Europe – How Do They Communicate?

As next task the group will develop a model to put on the EMA website showing how industry can engage with Enpr-EMA networks and how this could benefit them. The working group will draft an advertisement that could be used to publicise this model and to launch it at the 2016 Enpr-EMA Workshop.

WG "Framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible".

The WG identified 2 key priority needs and summarised them in a draft report:

- Both industry and regulators need a "community of experts" for consultation on scientific expertise, feasibility and ethical considerations. Any such "community of experts" need to ensure complete clarity of potential conflicts of interest in a format that is unambiguous, easy to provide and to access. Academic networks themselves need explicit transparency regarding funding sources for their organisation and for any collaborative work or trials conducted under the name of that organisation.
- Multi-stakeholder meetings were identified as an efficient process to benefit patients/public as well as industry, networks and regulators when there are uncertainties about paediatric drug development. The meetings need a clear remit and terms of reference to find solutions. Industry consultation with Enpr-EMA networks should be enhanced when PIP feasibility issues occur.
- the group is preparing a standard operating procedure for Enpr-EMA hosted stakeholders meeting

WG "Neonatology":

Enpr-EMA members participated at the international meeting Applying Regulatory Science to Neonates: Launch of an International Neonatal Consortium (INC), co-organized by EMA and the Critical Path Institute. A manuscript on the INC was published: Global Collaboration to Develop New and Existing Drugs for Neonates. JAMA Pediatrics Published Online: August 10, 2015. doi:10.1001/jamapediatrics.2015.1640

Working groups for the following prioritised areas have been established: Bronchopulmonary dysplasia, neonatal seizure and brain injury. In addition, a draft manuscript "White Paper clin pharm neo paper: Considerations Regarding Safety, Dosing, and Pharmaceutical Quality for Studies that Evaluate Medicinal Products (including Biological Products) in Neonates" was prepared and will be finalised early 2016.

New Working groups

2 new working groups were set up in 2015:

WG on Young Persons Advisory Groups (YPAGs):

The group developed a survey to scope what YPAGs (within Enpr-EMA and non-Enpr-EMA patient groups) are currently established, which will be distributed early 2016.

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

This group plans an information gathering exercise for requirements across Europe for the qualification of 'research nurses' as well as a model of best practice related to the role of this profession in the conduction of clinical trials. A first draft of the research nurse training questionnaire was circulated among Enpr-EMA members to obtain further comments and will be presented to the coordinating group in January 2016.

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

Additional Enpr-EMA activities throughout 2015 included:

- Seventh open workshop between networks, industry and patients organisations, followed by networks and CG meetings. The meeting reports are published on the Enpr-EMA website.
- Presentation of Enpr-EMA at the TOPRA conference "Reviewing the Impact of Paediatric Legislation on Regulatory Strategy" (March 2015) as well as at the Euro DIA meeting (April 2015)
- Participation of young people advisory groups (YPAGs) from several Enpr-EMA network members at the first international summit of the International Children's' Advisory Network (ICAN) in the US (June 2015)
- Representatives from the YPAG of the Scottish clinical research network presented to the PDCO plenary as well as to EMA staff at the 20th EMA anniversary lunch event their work and proposals how YPAGs could be involved in the activities of the Agency and its committees. (October 2015)
- Participation of the Enpr-EMA chair at the panel discussion "Looking back at the 10 years of the paediatric legislation - the ways forward" at the EFGCP/DIA/EMA meeting (October 2015)

The next Enpr-EMA workshop will be on 2 June 2016 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.

Mark Turner

Chair

Irmgard Eichler

Co-chair