

19 December 2013
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Enpr-EMA newsletter

December 2013

Dear colleagues,

Before the year 2013 draws to an end we want to briefly inform you about the activities of Enpr-EMA throughout the year.

New Chair of the Coordinating group

Following the completion of Peter Helms' term of office, Mark Turner, Associate Director for International Affairs, Medicines for Children Research Network (UK), was elected as new chair of the coordinating group.

Working groups

Following this year's annual workshop several ad hoc working groups (WG) were set up including network and industry representatives, and tasked with addressing the most important needs identified during the meeting. The purpose of the WGs is to develop pragmatic responses to some of the needs that can be implemented within six months. The focus is on stating what networks can do, or what networks need to do, rather than developing comprehensive guidance. There is already good practice in many of these areas so that EnprEMA needs to focus on disseminating good practice rather than developing new solutions. Each Working Group is responsible for defining its role, working practices and deliverables and to provide an update to the Coordinating Group in January 2014.

Working groups have been established to work on the following topics: 1) Priority setting; 2) Communication and sharing good practices within Enpr-EMA and with industry; 3) Dialogue and interaction with Ethics Committees; 4) Framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible; 5) Neonatology; 6) Paediatric pharmacovigilance, as joint Enpr-EMA and ENCePP working group; 7) Strategies for funding and maintaining a paediatric research network; 8) FP7 projects aiming to obtain Paediatric Use Marketing Authorisations.

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



Enpr-EMA resource database

As a response to criticism by industry and networks at this year's annual workshop that the information about networks currently published on the Enpr-EMA webpage is not user-friendly, a fully searchable database has been developed to provide easy access to the data of each individual Enpr-EMA network. The database offers information on the available sources of expertise and research experience across Europe, and serves as a central resource for both researchers and study sponsors seeking to identify appropriate networks and investigation sites for conducting paediatric clinical trials in Europe. The database will go live on the Enpr-EMA website in January 2014 and will replace the currently published self-assessment reports.

All Enpr-EMA members were requested to submit their most recently updated self-assessment reports which will be automatically downloaded into the database. If a network has not submitted their self-assessment report at the time the database go-live, they will not be recorded in the database, and consequently will not be visible for external users; they will be taken off the Enpr-EMA membership list. All network members who have not yet submitted their self-assessment report are kindly reminded to do so.

Consultation on EC guideline on the format and content of applications for paediatric investigation plans

The coordinating group submitted a corporate Enpr-EMA commentary to the European Commission during the public consultation on the commission guideline on the format and content of applications for paediatric investigation plans which is currently under revision.

(http://ec.europa.eu/health/files/paediatrics/2013-10_pip_guideline.pdf) It is proposed to add a recommendation to consult Enpr-EMA members, i.e. networks, in the development of a PIP.

Collaboration with EFPIA

An invitation was sent to EFPIA (European Federation of Pharmaceutical Industries and Associations) requesting a discussion meeting to better identify industry needs, and to explore opportunities for collaboration. A response by EFPIA is awaited in early 2014.

Collaboration with the EMA Healthcare Professional Working Party

(HCPWP) has been established. HCPWP member Adamos Hadjipanayis, representing the European Academy of Paediatrics, has been nominated as observer member for the Enpr-EMA coordinating group.

Update on the activities of emerging networks

Gastroenterology

Following the approval of a bid for funding, the Paediatric European Digestive Diseases Clinical Research Network (PEDDCReN) has been officially established. The steering committee (SC) of this network meets on a monthly basis through T-conference.

A European clinical trials skills and feasibility survey has been designed to identify potential centres and investigators with the ability and capacity to perform clinical trials in this therapeutic area. A proposal for a symposium was submitted to ESPGHAN for next year annual conference.

Cardiology

A task force for Drug and Therapeutics in Paediatric Cardiology within the Association for European Paediatric and Congenital Cardiology (EAPC) was established aiming at improving and promoting research on therapeutics (medicines, devices) to increase the availability of authorised products in the field of Paediatric Cardiology by creating a European Network of research centres and networks which have recognized expertise in performing studies in children with cardiac disease. A survey was sent to known paediatric cardiology centres across Europe inviting them to apply for membership and participation. 2 projects have started: creation of a Scimitar Syndrome register initiated by the Padova Group and contribution in the Cardiomyopathy register initiated by the European Society of Cardiology (ESC).

Endocrinology/Diabetes

An initiation meeting took place in February during the EMA workshop on type 2 diabetes mellitus, with participants from academia, PDCO, Pharma Industry & patient representatives. A request for funding to support the network has been submitted. A network website is under construction.

Young people involvement

- In 2012 Enpr-EMA members were asked to complete a survey on young people and family involvement in Enpr-EMA Networks. The outcome of the survey has been summarised and submitted for publication.
- At this year's annual network meeting practical tips and training on involvement strategies were provided by NIHR-MCRN and ScotCRN, the only 2 European paediatric research networks with established young persons' groups.

We welcome three new members:

- SwissPedNet (CH)
- RED SAMID (ES)
- Hospital Sant Joan de Deu (ES)

We want to take the opportunity to thank you all for your support and activities towards Enpr-EMA. We wish you and your families a merry Christmas, some relaxing holidays and all the best for a successful new year.



Mark Turner
Chair

Irmgard Eichler
Co-chair