

PAEDIATRIC MEDICINES



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA/6

The first year of the European Network of Paediatric Research at the EMA (Enpr-EMA)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enpr-EMA was launched at the EMA on 11-12 March 2011 and one year on an update meeting will be held on 22-23 March 2012 at the European Medicines Agency in London. As part of this workshop, day one on the 22nd March is an open meeting to all stakeholders: patient/parent organisations, network representatives, pharmaceutical industry staff responsible for paediatric studies and regulators. Day two on the 23 March is closed to members of the Enpr-EMA network and the EMA.

Enpr-EMA (the European Network of Paediatric Research at the European Medicines Agency) is a network of research networks, investigators and centres with recognised expertise in performing clinical studies in children.

Enpr-EMA aims to foster high-quality ethical research on quality, safety and efficacy of medicines for use in children. It serves as platform for industry providing access to competent, high quality paediatric research networks and encourages inter-network trans European collaboration. Enpr-EMA represents a wide range of therapeutic areas from newborns to adolescents and relevant methodologies including pharmacokinetics and pharmacovigilance. Enpr-EMA's members are required to fulfil a list of criteria under six headings namely, Research experience and ability; Network organisation and processes; Scientific competencies and ability to provide expert advice; Quality management; Training and educational capacity to build competences; Public involvement.

At present 18 of the 34 networks fulfil all criteria. The details of all items under each of the six headings and returns from all registered networks are accessible on the Enpr-EMA web page – www.ema.europa.eu

Day one of the workshop is being organised with the assistance of TOPRA with the aim of strengthening communication between all stakeholders: patient/parent organisations, network representatives, pharmaceutical industry staff responsible for paediatric studies and regulators. It follows on from the first open day held on 11 March 2011.

Day two is devoted to discussions between networks, to reflect on the outcomes of day one, to select the Enpr-EMA members to the coordinating group, and to discuss and define priority tasks of the co-ordinating group for the year 2012-2013. This second day is only by invitation of the Enpr-EMA network and EMA.

This workshop provides an opportunity for representatives from regulatory authorities, industry, academia, clinical investigators and patient/parent organisations to be updated on the Enpr-EMA's efforts in fostering high quality paediatric drug research and to contribute to the further development of paediatric medicines research and clinical trials.

Chairpersons

Peter Helms, Chair of Enpr-EMA / Irmgard Eichler, EMA

Update on Enpr-EMA activities, achievements and challenges

- Emerging networks:
- New initiatives: Gastroenterology, Cardiology, Diabetes/Endocrinology
- Learn from successful networks: CF-CTN, PRINTO
- Responsibility/Role of learned societies to support development of CTNs (eg RES, EAACI etc)
- The interface: industry – CRO - Clinical trials networks
- Defining the roles
- Interaction PDCO networks
- Update on GCP directive
- Report on ethics meeting November 2011:
 - Analysis of barriers possible solutions
 - How can collaboration between Enpr-EMA and ethics committees be envisaged
- How to use Enpr-EMA different perspectives from various stakeholders
- The patient perspective
- Update what has been achieved since last year March 2011
- Networks' perspective: representatives from different Networks:
 - What networks can offer
- Industry proposals on how to interact and use Enpr-EMA representatives from industry - Big pharma, medium sized, SME
- Break-out session in small groups for discussion on:
 - Proposals on how to develop and foster new networks
 - Proposals on how industry can refer and use networks
 - Proposals on how patients can be involved in networks (trial design etc) and in trials
- Panel discussion with representatives from industry, Enpr-EMA, patient/parent organisations etc

For more information please visit:
www.topra.org/paediatrics2012
or contact TOPRA via email: meetings@topra.org

To book please visit www.topra.org/paediatrics2012bf

One-day Workshop

Date:

22 March 2012

Venue:

European Medicines
Agency, London, UK



Paediatric Medicines
6* hours

Lifelong learning

*For more information
please visit www.topra.org/lifelonglearning