



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Update on Enpr-EMA activities, achievements and challenges

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An agency of the European Union





## Summary of progress

- Last couple of years: small tasks to show we can work together
- Next couple of years: develop business case for more extensive work together
- Bridge between industry, regulators, networks and sites
- Contribute to bridge between EMA and FDA
- Engagement of children, young people and families





# Topics

- Internal
  - Working groups
  - Collaboration with PDCO
  - Other work
- External: <http://www.systemsmedicine.net/posts/enprema>



## Enpr-EMA

- a network of research networks, investigators and centres with recognised expertise in performing clinical studies in children.
- aims to foster high-quality ethical research on quality, safety and efficacy of medicines to be used in children
  - networking and stakeholder collaboration with members
  - within and outside the European Union (EU)
- works through meetings and working groups





## Membership

To ensure certain quality standards, Enpr-EMA introduced a set of minimum recognition criteria which have to be fulfilled in order to become so called category 1 member of Enpr-EMA and to be eligible as coordinating group member. The recognition criteria were developed by the networks themselves by consensus formation techniques (Arch Dis Child 2012;97:185-188 ) and focus on:

- Research experience and ability
- Efficiency requirements
- Scientific competencies and capacity to provide expert advice
- Quality management
- Training and educational capacity to build competences
- Involvement of patients, parents or their organisations





## Aims of Enpr-EMA

Fostering high quality ethical research on the safety and effectiveness of medicines for children.

Efficient inter-network and stakeholder collaboration in order to build up necessary competences at EU level and to avoid unnecessary duplication of studies.

Informing parents, carers, children and young people about clinical trials and encouraging their participation.

Raising awareness among health care professionals of the need for clinical trials in all ages of children and supporting their involvement in such studies.

Assisting and entering into discussion with ethics committees on issues relevant to research and clinical trials in children.





## Contact points

Fully searchable database:

[enprema.ema.europa.eu/enprema/](http://enprema.ema.europa.eu/enprema/)

Single point of contact for all European networks:

[enprema@ema.europa.eu](mailto:enprema@ema.europa.eu)



## Working groups (WG):

- How to establish communication between Enpr-EMA, networks and industry
- Sharing good practices within Enpr-EMA and with industry
- Dialogue and interaction with Ethics Committees
- Neonatology (with PDCO)
- Strategies for funding and maintaining a paediatric clinical trial network
- Joint ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) and Enpr-EMA WG on Pharmacovigilance





## Collaboration with the Paediatric Committee (PDCO) at the EMA

- Standard Paediatric Investigation Plans (PIPs) for rhabdomyosarcoma and Acute Myeloid Leukaemia
- Participation at EMA-expert meetings (Cystic Fibrosis; Type 2 Diabetes Mellitus)
- Contribution to PDCO advice to the European Commission (EC) on communication of arrangements available for conducting paediatric research



## Other work

- Collaboration with the EMA Small and Medium-sized Enterprise (SME) office
- Support for the development of new specialty networks: Gastroenterology, Cardiology, Diabetes/ Endocrinology
- Involvement of children – young person's groups:
  - Survey among Enpr-EMA members on young people and family involvement
  - Publication of available strategies for young people advisory groups



# External work

The screenshot shows the Systems Medicine.net website. At the top right, there are links for About, Contact, Sitemap, Legal Notice, and Disclaimer. The main header features the Systems Medicine.net logo, social media icons for Home, Facebook, Twitter, Google+, LinkedIn, and RSS, and a search bar. Below the header is a navigation menu with links for HOME, EVENTS, PROJECTS, POSITIONS, RESOURCES, and PUBLICATIONS. The main content area features a 'Project Spotlight: The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)' with a date of April 30, 2015, and a 'CONTRIBUTE' button. A 'Featured Articles' section highlights an article from May 22, 2015, titled '10 Questions to Prof Werner Müller'.

<http://www.systemsmedicine.net/posts/enprema>





## External work

- Global Paediatric Clinical Trials Network
  - Meeting convened by American Academy of Pediatrics, November 2014
- European Network
  - Discussions with EFPIA
  - Meetings in Brussels February and May 2015
- European Research Infrastructure



# Challenges

- Marketing the work of networks and Enpr-EMA
- Educating colleagues and the public about clinical trials
- Time and energy



# Thank you for your attention

## Further information

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