Enpr-EMA
European Network of Paediatric Research at the European Medicines Agency

Exploring commonalities between the networks
Introduction and background

- Enpr-EMA is a network of research networks, investigators and centres with recognised expertise in performing clinical trials in the paediatric population
- Members perform research with children (newborns to adolescents), in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance
Introduction and background

Legal basis

European Paediatric Regulation:

“The EMA shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.”
Mission statement

Enpr-EMA will facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population.
Mission statement

This will be achieved by:

• 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 encourage 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.
Main Stakeholders

➢ Pharmaceutical Industry

➢ CRO’s

➢ Patients, parents and patient organisations

➢ National Competent Authorities

➢ Ethics Committees
Recognition criteria

- Networks to be recognised by quality of paediatric research
- 6 recognition criteria and quality standards for self-assessment
  - 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
- Each criterion composed of several sub items
- Set of minimum criteria to be fulfilled
- Self-assessment to updated annually
Recognition criteria for self-assessment

Criteria for the recognition of an investigator*, site* or network as a member of the EnprEMA

* only when the investigator or the site is not part of a network

**Identification**

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<thead>
<tr>
<th>Name</th>
<th>Include legal address, define acronyms</th>
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<tbody>
<tr>
<td>Type</td>
<td>Indicate type of reporting party, e.g. national or speciality network. May include short mission statement</td>
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<td>Street</td>
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<td>Email for general enquiries</td>
<td>If available (see criterion 4)</td>
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<tr>
<td>Representative (main) contact</td>
<td>Include first and second name, email, telephone, address, as far as available</td>
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www.ema.europa.eu
## Breakdown of networks by type and category

<table>
<thead>
<tr>
<th>National</th>
<th>Oncology/Haematologic Malignancies</th>
<th>Diabetes/Endocrinology/metabolic disorders/Gynaecology</th>
<th>Gastroenterology/Hepatology</th>
<th>Allergology/Immunology/Rheumatology</th>
<th>Stem Cell/Organ Transplantation/Haematology/Haemostaseology</th>
<th>Respiratory diseases/Cystic Fibrosis</th>
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<tr>
<td>NIHR-MCRN</td>
<td>Newcastle-CLLG</td>
<td>AMIKI</td>
<td>ESPGHAN</td>
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### Category 1:
Networks fulfilling all minimum criteria for membership of Enpr-EMA.

### Category 2:
Networks potentially fulfilling all minimum criteria – but needing to clarify some issues before becoming a member of Enpr-EMA.

### Category 3:
Networks currently not yet fulfilling minimum criteria.

### SPECIAL ACTIVITIES / AGE GROUPS

<table>
<thead>
<tr>
<th>Cardiovascular diseases/Nephrology</th>
<th>Psychiatry/Neurology</th>
<th>Infectious diseases/Vaccinology</th>
<th>Intensive Care/Pain/Anaesthesiology/Surgery</th>
<th>European neonatal network</th>
<th>European paediatric pharmacists</th>
<th>special activities (Phv, long term follow up, community paediatricians)</th>
<th>Expertise in clinical trial methodology</th>
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<tbody>
<tr>
<td>EUNETHYDIS</td>
<td>PENTA-ID</td>
<td>Pediatric Critical Care</td>
<td>GNN</td>
<td>FIMP-MCRN</td>
<td>TEDDY</td>
<td>PRIOMEDCHILD</td>
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<td>ESDPPP</td>
<td>GRIP</td>
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Unable to fill self-assessment report
What Enpr-EMA can offer to industry

- Pool of patients for inclusion
- Speeding up recruitment
- Expert advice
  - treatment options (standard of care)
  - paediatric needs
  - feasibility of paediatric clinical trials
- Access to academic partners through collaboration with the EMA SME office
What Enpr-EMA does not do

- **fund** studies
- act as a **CRO** and **manage** studies
- **decide** on research priorities which remain the responsibility of
  - the Member States
  - the Commission through the Community programmes
  - each individual network
Potential Cooperation Enpr-EMA - ENCePP

Scientific:
- Encourage Enpr-EMA members with expertise in PhE and PhV to become partner of ENCePP
- To contribute to paediatric aspects for methodological standards

Organisational:
- To circulate paediatric related industry queries to Enpr-EMA
- How to increase visibility to industry
- How to acknowledge and raise visibility of active members
- How to motivate members to actively contribute
Where to find information - contact details

- www.ema.europa.eu - Enpr-EMA
- enprema@ema.europa.eu
**Enpr-EMA overview**

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

**Members**

Enpr-EMA members perform research in children (from newborns to adolescents) in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance.

**Would you like to join Enpr-EMA?**

Networks, centres or investigators interested in becoming members of Enpr-EMA are invited to complete a self-assessment form (available on the European Medicines Agency’s website) and send it to: enprema@ema.europa.eu

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**Further information**

Visit [www.ema.europa.eu](http://www.ema.europa.eu) and click on this banner:

Or contact:

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**Facsimile:** +44 (0)20 7423 7040

**E-mail:** enprema@ema.europa.eu

**Website:** [www.ema.europa.eu](http://www.ema.europa.eu)
Thank you - Questions ??

Enpr-EMA

European Network of Paediatric Research at the European Medicines Agency
Back-up slides
Structure - Coordinating Group

Co-chaired by EMA + elected member

PDCO members (2)

Patient/family representative, Ethics committee (max 4)

EC (DG)

3 year membership

One representative per RECOGNISED network/group
Coordinating Group - Composition

- Max 20 members (for a maximum of 3 years): 2 PDCO + 18 Networks
- Aim to be as diverse as possible (various types of network, different therapeutic areas, special activities, age subsets)
- Only category 1 networks eligible
- Need for networks to group themselves to be jointly represented in CG, when number of category 1 networks exceed 18
Coordinating Group

Role of the Coordinating Group:

➢ to contribute to the short and long-term strategy of the network
➢ to address operational and scientific issues for the network
➢ to agree scientific quality standards
➢ to act as a forum for communication
Interaction with stakeholders

- Annual workshop – open to all stakeholders
- Virtual meetings
- Mail exchange
- Scientific/regulatory conferences
Key operational goals

• To link existing networks
• To provide expert advice and clinical access to industry
• To define consistent and transparent quality standards
• To harmonise clinical trial procedures
• To develop strategies for resolving major challenges
• To communicate with external stakeholders