European Network of Paediatric Research at the European Medicines Agency

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New perspectives regarding Enpr-EMA

Discussion on simplification of membership criteria

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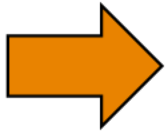
Aim for today

- **To collect ideas for simplification of self-assessment form**
  - in order to reduce application burden on members
  - but still keeping the necessary information
- **Starting with reviewing minimum requirements of the membership criteria**



We will draft a proposal for new form to be discussed with Coordinating Group

(We may need to rethink governance structure in future.)

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EU Paediatric Regulation Art. 44 – the legal basis

- MAIN AIM: To improve the health of children

Article 44:
"1. The Agency 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.
2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid duplication of studies and testing in children.

Proposed new Regulation (Art. 95):

- Addition of patient representatives, academics, medicine developers
- Additional focus on priorities and areas of unmet need

Members of Enpr-EMA

- Members **perform research with children (newborns to adolescents), in multiple therapeutic areas**
  - **National networks**;
  - **paediatric 'specialty' networks**;
  - **age-related networks**,
  - **multinational European networks**
- **Other stakeholders:** Learned societies; patient organisations; young peoples' advisory groups; PDCO members; healthcare professional organisations, industry associations, and beyond EU (currently: UK, US, Canada, Japan, Australia)

Recognition criteria for member networks since 2010

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Points to consider:

Relevant standard information collected?

Subject: Invitation to Paediatric Network Workshop

The times (always London time) and dates you are invited to attend are:

Date: 16/02/2009 From: 09:00 To: 17:00 Location: Room 2A
Place: EMEA, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

32 networks self-assessments;
-> 2010 Final Structure & Membership
Arch Dis Child March 2012 Vol 97 No 3

- **6 recognition criteria and quality standards for self-assessment**
  1. Research experience and ability
  2. Efficiency requirements
  3. Scientific competencies and capacity to provide expert advice
  4. Quality management
  5. Training and educational capacity to build competences
  6. Involvement of patients, parents or their organisations
- - Each criterion composed of several sub-items

Set of minimum criteria to be fulfilled

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

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Current Enpr-EMA membership

- Networks, specialised in paediatrics, and **interested in becoming members of Enpr-EMA are invited to complete a self-assessment form and provide info on funding sources**.
- **Form of 15 pages and ~80 questions**
- **6 criteria for minimum requirements**
- **3 categories** of member networks
- Guidance (5 pages) to complete the self-assessment form and glossary
- **Membership** (self-assessment form) should be **renewed every 2 years**

Is the membership application and renewal process feasible / ideal?

Purpose of Enpr-EMA membership criteria

1. **Externally:**
    1. Showcase network in public **Enpr-EMA database**
    2. Support stakeholders in search of suitable networks for collaboration
    3. Accreditation of network ?

2. **Internally:**
    1. **Tool for categorisation** (Cat 1, Cat 2, Cat 3)
    2. Eligibility for Coordinating Group membership

Revision of the membership categories in 2021

Points to consider:

Difference between 3 categories?

Benefits to being category 1 member?

- **Category 1:** networks **fulfilling** all minimum requirements
- **Category 2:** networks **not currently fulfilling** all minimum requirements
- **Category 3:** networks that do not run paediatric clinical trials but **have other expertise** in clinical trial methodology or support clinical research infrastructure.

Governance structure

- **Category 1** networks are part of the **Coordinating Group**, sharing responsibility for the network's long- and short-term strategy" (currently not all)

Points to consider:

Almost 50% of member networks are Category 1

Criteria from 2010 still relevant today?

Other ways to build governance?

"Umbrella networks" can lead to double/triple memberships of some networks

Enpr-EMA Database – useful for sponsors and networks?

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Points to consider:

Value of the database?

Informative for users?

Information relevant for stakeholders?

Categories useful?

1 - Research experience and ability

Identification | Description | Research Experience | Network | Competencies | Quality Management | Training and Education | Public Involvement

	Description
Name	**FINPEDMED - Finnish Investigators Network for Pediatric Medicines**
Number of completed trials	160
Number of ongoing trials	15
Total number of participants actually recruited each year	0
Proportion of eligible participants actually recruited each year	Child population is approx. 1.2 Million
Describe way of screening and participant recruitment	Screening and recruitment is done primarily through the direct patient contacts from hospitals / paediatric clinics.
Total number of collaborating centres	18
Academic investigator initiated studies	
Number of ongoing and completed clinical trials. Absolute number	5
Number of ongoing and completed clinical trials. Proportion of all studies	Approx. 30 % (average percentage counted from clinical trials including academic, industy and vaccine trials notified to Finnish Medicines Agency between 2006 and 2022)

Membership criteria I to VI

Criterion I:	Research experience and ability
Criterion II:	Network organisation and processes
Criterion III:	Scientific competences and capacity to provide expert advice
Criterion IV:	Quality management
Criterion V:	Training & educational capacity to build competences
Criterion VI:	Public involvement

Point to consider:
What evidence to be provided/checked?

Membership criterion I

Criterion

Criterion I:
Research experience and ability

13 main questions (18 including sub-questions)

Minimum requirements

- One ongoing *or* one completed paediatric trial

Membership criterion II

Criterion

Criterion II:
Network organisation and processes

10 main questions (20 including sub-questions)

Minimum requirements

- Identified contact person for external enquiries
- Either an internal steering committee *or*
- an external advisory/steering committee.
- Internal database(s) for disease, condition, treatment and/or outcome
- Provision to ascertain data protection and data security

Membership criterion III

Criterion

Criterion III:
Scientific competencies and capacity to provide expert advice

7 main questions (14 including sub-questions)

Minimum requirements

- Access to expert groups
- Capacity to answer external scientific questions

Membership criterion IV

Criterion

Criterion IV:
Quality management

7 main questions (14 including sub-questions)

Minimum requirements

- Documented adherence to clinical trial legislation and Good Clinical Practice (GCP) guideline (latest implemented versions)
- Documented adherence to the ethical considerations for clinical trials in children
- Capacity to monitor studies (academic trials, industry sponsored trials)
- Quality control and quality assurance, traceability and data safety

Membership criterion V

Criterion

Criterion V:
Training and educational capacity to build competences

6 main questions (13 including sub-questions)

Minimum requirements

- Evidence of collaboration with regulatory authorities
- Training courses either given by the network over the last 2 years *or* received by the network over the last 2 years

Membership criterion VI

Criterion

Criterion VI: Public involvement

3 Main questions (6 including sub-questions)

Minimum requirements

At least one of these three items:

- Involvement of patients, parents or their organisations in protocol design
- Involvement of patients, parents or their organisations in creating the protocol information packages
- Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children

Thank you!