



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Endorsement of new or updated applications for Enpr-EMA membership

May 2015

7th annual meeting of the Enpr-EMA CG, 29.05.15



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An agency of the European Union





NEW APPLICATIONS

OKIDS GmbH

➤ Outline:

Medicines for Children Research Organisation – Austria, established in 2012
National Network, multispecialty. Coordinating site: Vienna (AT)
Paediatric age ranges: 0-18 years

➤ Outstanding Minor Issue:

- Availability of the full OKIDS webpages in English (under construction and to be completed by June 2015) - currently only high level information on the Network is available online in English

➤ Proposed Category: Enpr-EMA category 1 (part of CG)

INFANT

➤ Outline:

Irish Centre for Fetal and Neonatal Translational Research – Ireland, established in 2003
National network. Maternal, Perinatal and Neonatal Conditions.

Coordinating site: Cork (AT)

Paediatric age ranges: 0-5 years

➤ Outstanding Issues:

- Clarification needed on existence of Steering Committee/Advisory Committee
- Availability of Network SOPs
- Request for Evidence on involvement of patient's/patents/patient's organisations (studies examples and description of input provided)
- Link with Enpr-EMA registered Irish Paediatric Clinical Research Network (IPCRN)/National Children's Research Centre (NCRC)

 **Proposed Category: Enpr-EMA category 3**



UPDATED APPLICATION

NEO-CIRC

➤ Outline:

Neonatology network: conditions affecting the preterm and term newborn, focussing on circulation and effects on long term neurological outcome.

Coordinating site: Brighton (UK)

Paediatric age ranges: 0-2 years

➤ Outstanding Issues:

- Clarification needed on existence of Steering Committee/Advisory Committee
- Clarification on internal database for disease, condition, treatment and outcome
- Availability of Network SOPs
- Request for evidence on involvement of patient's/patents/patient's organisations (studies examples and description of input provided)

➤ Proposed Category: **Remained Enpr-EMA category 3**