EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enpr-EMA

European Network of Paediatric Research at the European Medicines Agency

Update on recent activities

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Breakdown of networks by type and category

National	Oncology / Haematologic Malignancies	Diabetes / Endocrinology / metabolic disorders / Gynaecology	Gastroenterology / Hepatology	Allergology / Immunology / Rheumatology	Stem Cell / Organ Transplantation / Haematology / Haemostaseology	Respiratory diseases / Cystic Fibrosis
NIHR-MCRN	Newclastle-CLLG		PEDDCReN	PRINTO	EBMT	ECFS-CTN
ScotCRN	IBFMSG		EPLTN	JSWG of PRES		
FinPedMed	ITCC					
MCRN-NL	CLG- of EORTC					
MICYRN-Canada						
CICPed						
RIPPS						
OKIDS						
DCRI-US						
REDSAMID						
Futurenest CR						
SwissPedNet						
PCIC						
IPCRN						
NCCHD - Japan						
MCRN-Hungary						

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.
Category 4: Networks not performing clinical trials; e.g. methodology, infrastructure, etc.

Unable to fill self-assessment report

SPECIAL ACTIVITIES / AGE GROUPS

Cardiovascular diseases / Nephrology	Psychiatry / Neurology	Infectious diseases / Vaccinology	Intensive Care / Pain / Anaesthesiology / Surgery	European neonatal network	European paediatric pharmacists	special activities (Phv, longterm follow-up, community paediatricians, pharmacology)	Expertise in clinical trial methodology
	EUNETHYDIS	PENTA-ID	ESPNIC RN	GNN		FIMP-MCRN	TEDDY
	ECAPN	UKPVG		INFANT		ESDPPP	GRIP
				Neo-circulation			ECRIN

Fully searchable Enpr-EMA database

Search | Contact

http://enprema.ema.europa.eu/enprema/

EnprEMA NETWORK

Welcome to the EnprEMA Network Database

This database includes research networks and centres with recognised expertise in performing clinical studies in children. It is part of the European network of paediatric research at the European Medicines Agency (Enpr-EMA).

About the database:

This database provides easy access to data about each individual Enpr-EMA network.
The information includes sources of expertise and research experience across Europe.
This is the central resource for researchers and study sponsors seeking to identify research networks for paediatric clinical trials in Europe. Centres can be identified through networks.
The available data reflect the information received by the EMA every two years in the networks' self-assessment forms, including:

- Network identification and contact details
- Network description (including size of the network)
- Research experience and ability
- Scientific competencies and capacity to provide expert advice
- Quality management
- Training and educational capacity to build competences
- Public involvement

The database is fully searchable and allows the identification of Enpr-EMA registered networks in several ways (please see search page):

1. A global search (this will search on the entire information provided in the network self-assessment forms)
2. A detailed search (this will search on specific and relevant parts of the network self-assessment forms)

Ad hoc Working Groups:

- How to establish communication between Enpr-EMA, networks and industry
- Sharing good practices within Enpr-EMA and with industry
- WG: Ethical issues related to paediatric clinical trials
- Neonatology
- WG: Young Persons Advisory Groups

Ad hoc Working Groups:

How to establish communication between Enpr-EMA, networks and industry

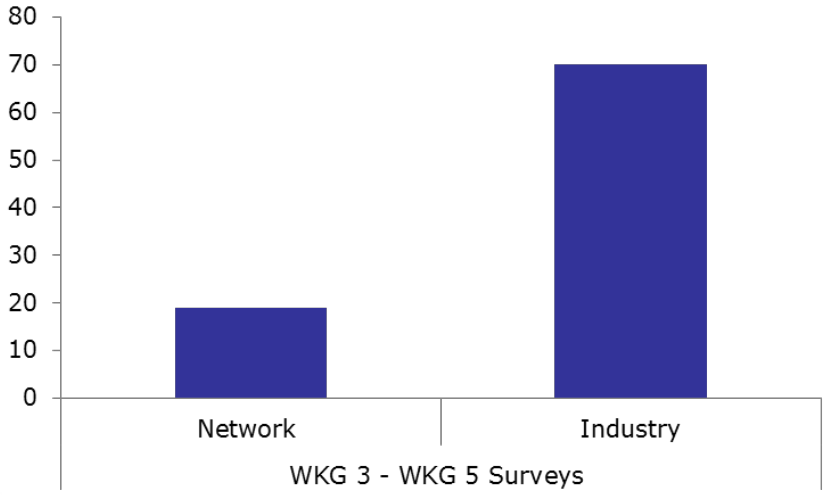
Sharing good practices within Enpr-EMA - with industry:

- Survey to collect good practice examples from both network members and Industry colleagues

Responses received: Total 89

Network responses: 19

Industry responses: 70



Survey among networks and industry

- Survey to collect good practice examples from both network members and Industry colleagues
- Based on results proposals to disseminate examples of good practice to Enpr-EMA members and industry
  - Specifications for “ideal paediatric clinical trial network” to provide best possible coverage and services for industry
  - Summary of results as recommendations for industry and networks
- Publication of results:

http://www.appliedclinicaltrialsonline.com/print/306311?page=full

WG: **Dialogue and interaction with Ethics Committees**

Table of EU EC details for informed consent for paediatric trials including legislative surroundings of informed consent requirements for pediatric clinical trials, listed by country

Informed Consent for Paediatric Clinical Trials in Europe 2015

Pirkko Lepola, Allison Needham, Jo Mendum, Peter Sallabank, David Neubauer, Saskia de Wildt

	Consent / assent from child		Consent from parent(s) / guardian(s)	General informed consent information	
Country	**Legal age of consent**	**Mandatory / suggested age ranges defined for assent (or consent if assent not used)**	**Number of required signatories**	**Official language requirements**	**IC template(s) / guidelines / information sources**
Austria	Not	8-13 years	Both parents	German	http://www.medunigraz.at/ethikkommission/Forum/index.htm

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199234.pdf

WG: Young Persons Advisory Groups (YPAGs)

- Several Enpr-EMA networks have established YPGS
- To review currently established YPGS within EnprEMA members
- To develop a database of YPAG's as resource for EMA and Pharma
- To develop operational links between groups, so that
  - their projects can be cascaded amongst the groups in a timely manner
  - that they can work collectively on providing their expertise, attitudes and advice.
- Canadian and US groups involved via the iCAN umbrella
- Based on experience from established YPAG in Europe, international children's advisory network iCAN launched in the US 2015; second summit: June 2016 in Barcelona

Ad hoc Working Groups:

Neonatology (PDCO)

- Member of and actively involved in International Neonatal Consortium (INC): a global collaboration formed to forge a predictable regulatory path for evaluating the safety and effectiveness of therapies for neonates.
- Chair of Enpr-EMA: co-director of INC

  http://c-path.org/programs/inc/

WG **clinical trial designs for paed antibiotic trials**

- about to be established
- Industry representatives invited to express interest in becoming a member

Emerging networks

- Enpr-EMA organised meeting on emerging networks to fill identified GAPS (Nov 2011)
- Paed Gastroenterology:
  - ✓ PEDDCReN Paediatric European Digestive Diseases Clinical research Network http://www.peddcren.qmul.ac.uk/
  - ✓ European Paediatric Liver Transplantation Network EPLTN
- Paed endocrinology/diabetes: EUCADET: European Children and Adolescent Diabetes and Endocrine Trials network http://eucadet.org/
- Asthma: ERS Clinical Research Collaboration (CRC) for “Enhancing participation of asthmatic children in therapeutic trials of new biologics and receptor blockers” – kick-off meeting 27th May 2016 at EMA

Collaboration with micro, small and medium-sized enterprises (SMEs)

Enpr-EMA and the Agency's SME office are acting as liaison between SMEs and academic investigators in paediatric-medicine research, both of which experience difficulty finding partners that complement their research interests

What can Enpr-EMA offer to industry

- Neutral platform for dialogue academia, industry, regulators
- Provide expert advice
  - feasibility, paed needs, standard of care, …
- Provide parent/patient input
  - feasibility, use of diaries, trial duration, …
- Contact point for industry to facilitate conduct of clinical trials
- Identify centres with capability to conduct trials (global trials)
  - Pool of patients for inclusion

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SAVE THE DATE

8th annual Enpr-EMA Workshop

2 June 2016