EUROPEAN MEDICINES AGENCY
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Enpr-EMA awareness webinar

European Network of Paediatric Research
at the European Medicines Agency

1 December 2016

In this webinar…

Introduction of Enpr-EMA and role of EMA in Enpr-EMA: Irmgard Eichler, Co-chair

Role of networks and what they can offer to industry: Mark Turner, Chair

Q&A session

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

Introduction

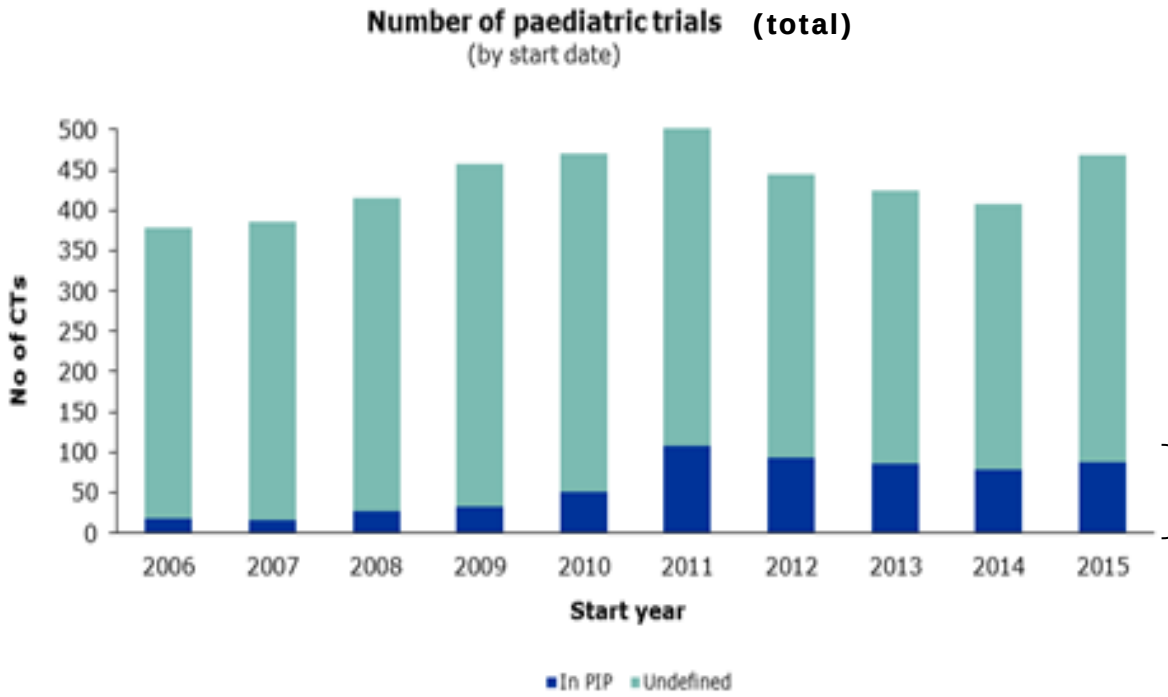
Irmgard Eichler, MD, Paediatric Medicines Office, EMA, Enpr-EMA Co-chair

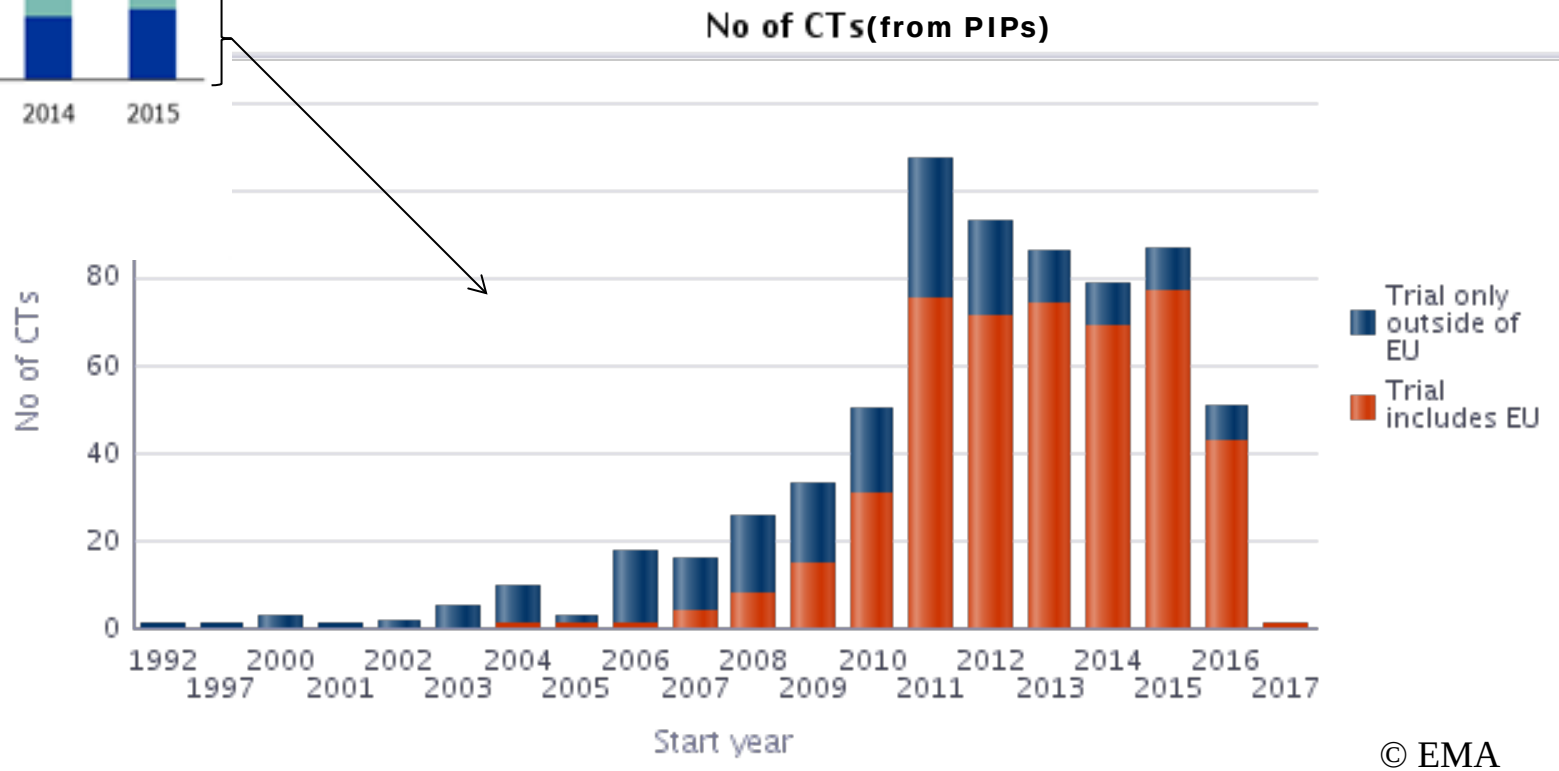
Introduction and background

Legal basis

European Paediatric Regulation - Art 44:

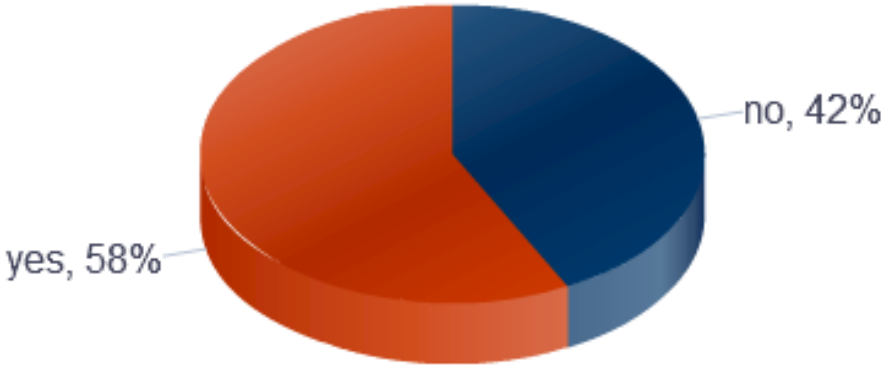
"The EMA shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population."





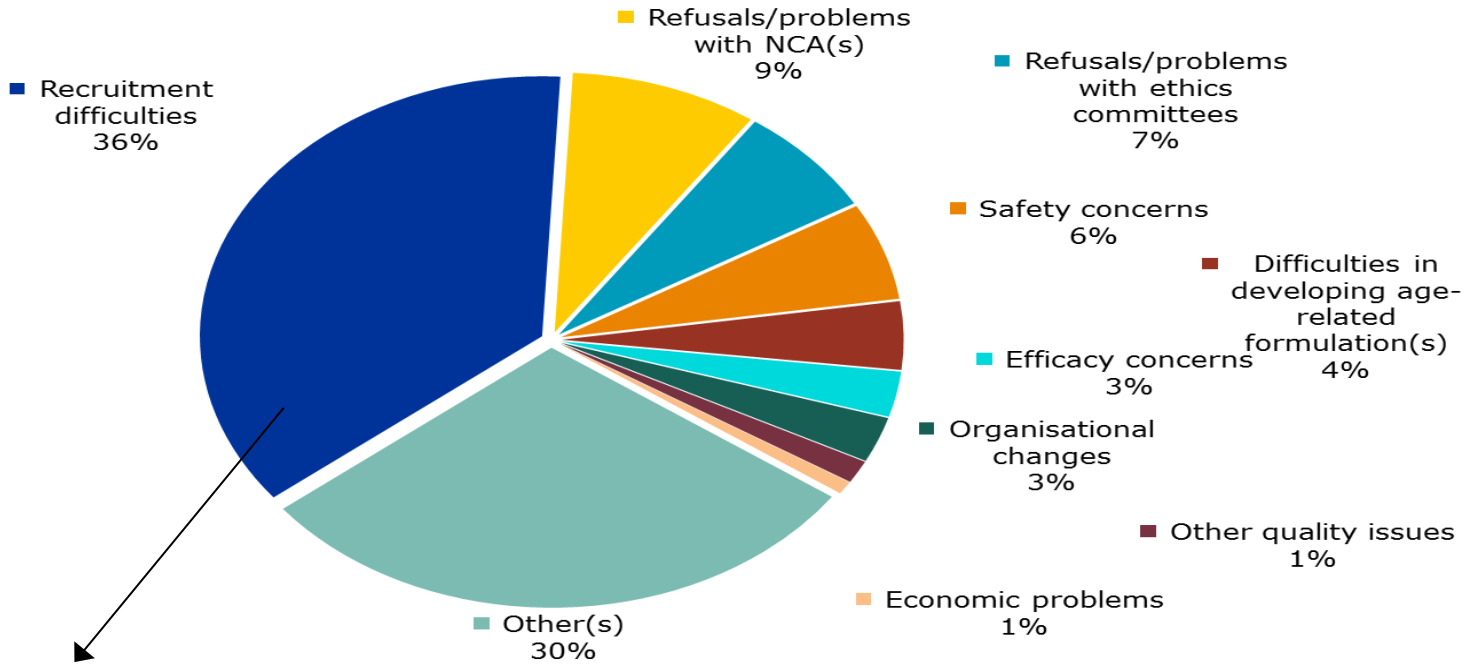
10-year Report to EC on the Paediatric Regulation
http://ec.europa.eu/health/files/paediatrics/2016_pc_report_2017/ema_10_year_report_for_consultation.pdf

PIP progressing as planned?



Only applies to products already authorised in adults

Problems with PIP progress



Recruitment difficulties (36.1%)

10-year Report to EC on the Paediatric Regulation
http://ec.europa.eu/health/files/paediatrics/2016_pc_report_2017/ema_10_year_report_for_consultation.pdf

Why is recruitment so difficult ?

- Across pediatric populations it is difficult to:
  - Find qualified sites
  - Identify experienced pediatric investigators
  - Access the necessary patient populations for studies

Adapted after Dr Samuel Dr Maldonado

Introduction and background

Enpr-EMA - umbrella network of existing networks

- provides access to networks/sites with expertise in performing clinical trials in the paediatric population
- enables collaboration/learning of individual networks from each other
- versus different role of the clinical trial networks which actually conduct and perform the clinical trials

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

Membership

- To ensure certain quality standards, Enpr-EMA introduced set of minimum **recognition criteria** which have to be fulfilled
  - to become category 1 member of Enpr-EMA
  - to be eligible as coordinating group member
- Recognition criteria were developed by networks themselves by consensus formation techniques 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
- Self-assessment to be updated every second year

Arch Dis Child 2012;97:185-188

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
DCRI	ITCC			PRINTO	EBMT	ECFS-CTN
NIHR-MCRN	Newclastle-CLLG	EUCADET	PEDDCReN			
ScotCRN	IBFMSG		EPLTN	JSWG of PRES		
FinPedMed						
MCRN-NL	CLG- of EORTC					
MICYRN						
CICPed						
RIPPS						
OKids						
NorPedMed						
MCRN-Hungary						
IPCRN						
Futurenest CR						
SwissPedNet						
Red SAMID						
NCCHD-Japan						

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.

SPECIAL ACTIVITIES / AGE GROUPS

Unable to fill self-assessment report

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

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:

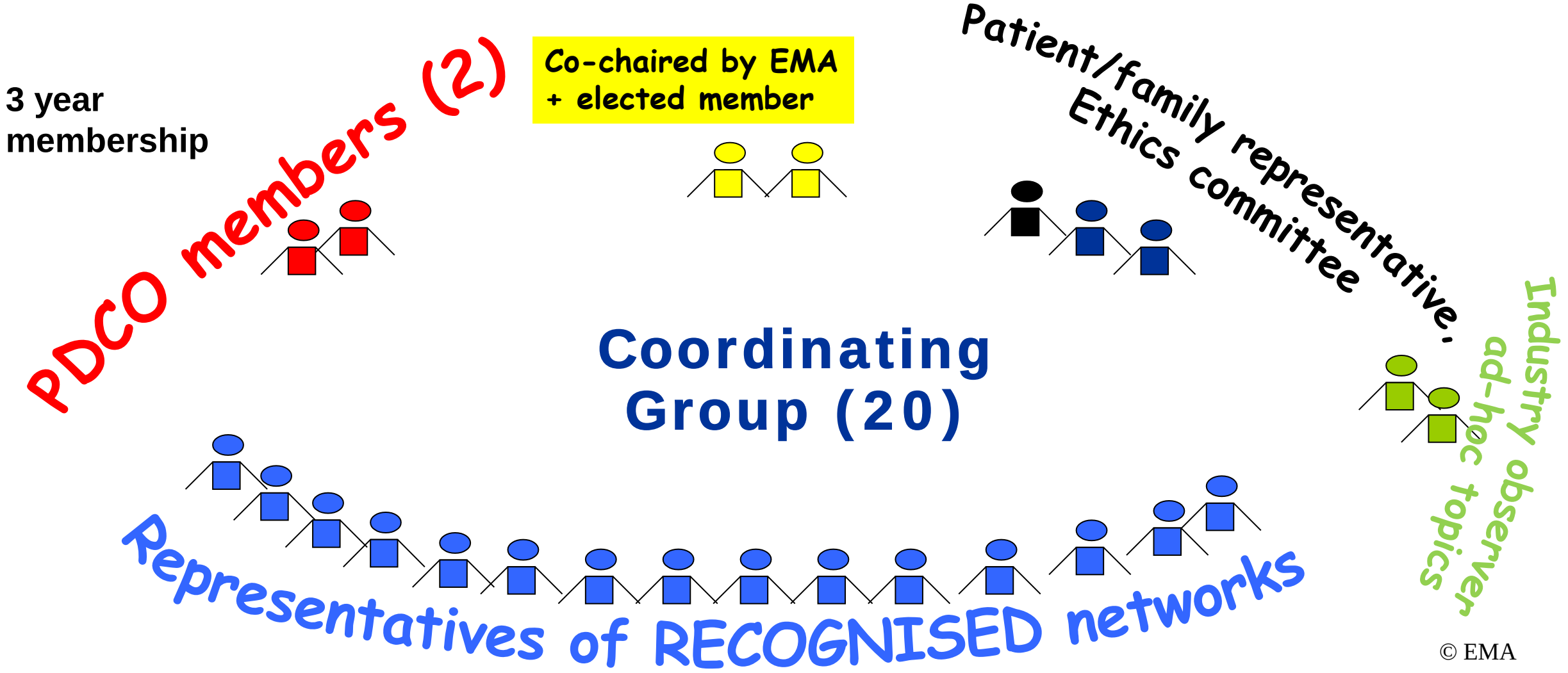
This database provides easy access to data about each individual Enpr-EMA network.
The information includes sources of expertise and research experience across Europe.
This is the central resource for researchers and study sponsors seeking to identify research networks for paediatric clinical trials 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)

Operational centre - Coordinating Group



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

What Enpr-EMA can offer to industry

- Access to expert advice
  - treatment options (standard of care)
  - paediatric needs
  - feasibility of paediatric clinical trials
- Pool of patients for inclusion - Speeding up recruitment
- Provide parent/patient input
  - feasibility, use of diaries, trial duration, …
- Neutral platform for multi-stakeholder meetings with investigators, networks, patient/parents, regulators
- Access to academic partners by collaboration with EMA's SME office

http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp&mid=WC0b01ac05801df74a#Enpr-EMA activities

Key operational goals

Platform for close interactions of all stakeholders necessary to facilitate the conduct of (large) studies in children

- To link together existing networks (EU and extra-EU)
- To share best practices
- To offer single point of contact for (European) networks

  enprema@ema.europa.eu
- To define strategies for resolving major challenges
- Enpr-EMA does NOT
  - fund / conduct clinical trials
  - act as a CRO and manage studies

The roles of Enpr-EMA include

- To identify problems and challenges for individual networks
- To act as an European voice to raise awareness on these challenges and difficulties on an European level
- To propose solutions – as some of the ad-hoc Enpr-EMA working groups have done

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 specified Practice 14 years	8-13 years EC may require younger assents	Both parents	German	http://www.medunigraz.at/ethikkommission/Forum/index.htm http://www.ethikkommissionen.at/ http://www.uibk.ac.at/strafrecht/scheil/scheil-einfuehrung-in-die-arzneimittelpruefung-bei-kindern-und-jugendlichen---kks--kids-ip.pdf

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

P Lepola, Arch Dis Child 2016

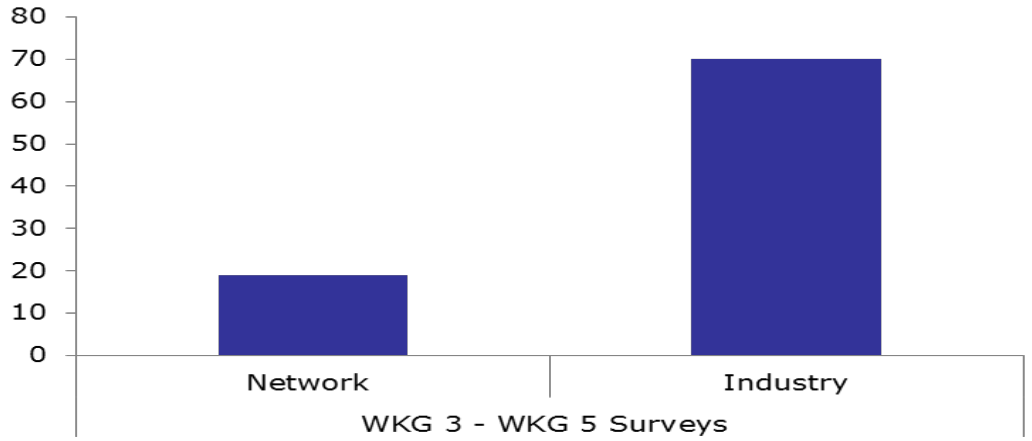
Pharmaceutical Industry and Paediatric Clinical Trial Networks in Europe – How Do They Communicate?

- Survey among industry and networks
- Results allowed to create specifications for “ideal pediatric clinical trial network” to provide best possible coverage and services for pharmaceutical industry:
- List of ideal network capabilities and services
- Survey results summarised as recommendations for industry and networks

Responses received: Total 89

Network responses: 19

Industry responses: 70



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

Benefits identified by industry

- Increased confidence with clinical development programme
- Better development of clinical trials
- Patient recruitment via highly skilled and motivated investigators
- Guide through perceived pitfalls with trial feasibilities
- Establishment of electronic database of physicians
- Benefit to patients “who could be treated outside her/his country through network collaboration”
- But difficult to find right network to collaborate with

→ **Enpr-EMA can help here**

WG: Young Persons Advisory Groups (YPAGs)

- Survey to review currently established YPGS within and beyond Enpr-EMA members
- Several Enpr-EMA networks have established YPGS

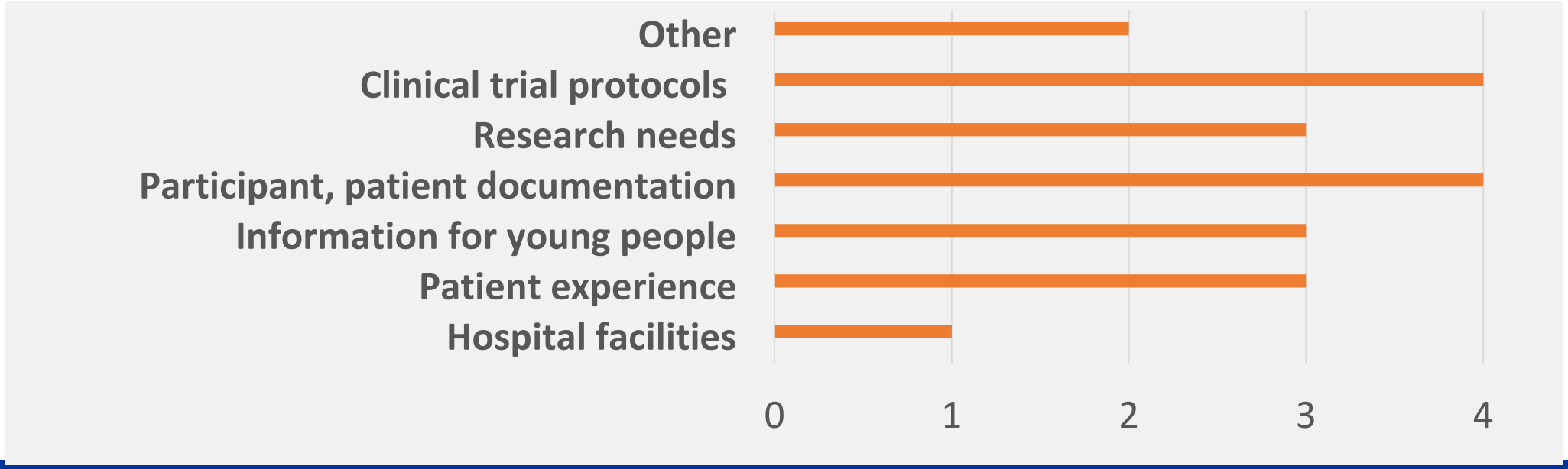
Survey among Enpr-EMA networks - results

6 responded YES to having a YPAG group

- GenerationR (R for Research)
- KidsCan
- ScotCRN YPG
- KIDS BARCELONA
- KIDS Fr
- Local: Neonatal Parent Forum International: European Forum for Care of the Newborn Infant (EFCNI)

- The majority of groups have 10-20 members
- Age range 11-20 years 1 group neonatal-adults
- All located in a Children's hospital

If they have an advisory role what do they advise on?



WG: Young Persons Advisory Groups (YPAGs)

- Review currently established YPGS within and beyond 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 childre network iCAN launched in the US 2015; second summit: June 2016 in Barc

iCAN International Children's Advisory Network

WG clinical trial designs for paediatric antibiotic trials

Kick-off meeting: 24th May 2016

Planned deliverables:

- Review current international regulatory guidance in paediatric CTs
- Review literature of conducted and planned paed antibiotic CTs
- Summarise key similarities / differences between children & adults
- Summarise key barriers in design and conduct of paediatric AB CTs
- Produce summary document of key components of design for paediatric AB CTs

Timelines: draft first quarter 2017

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

How to find Enpr-EMA webpage

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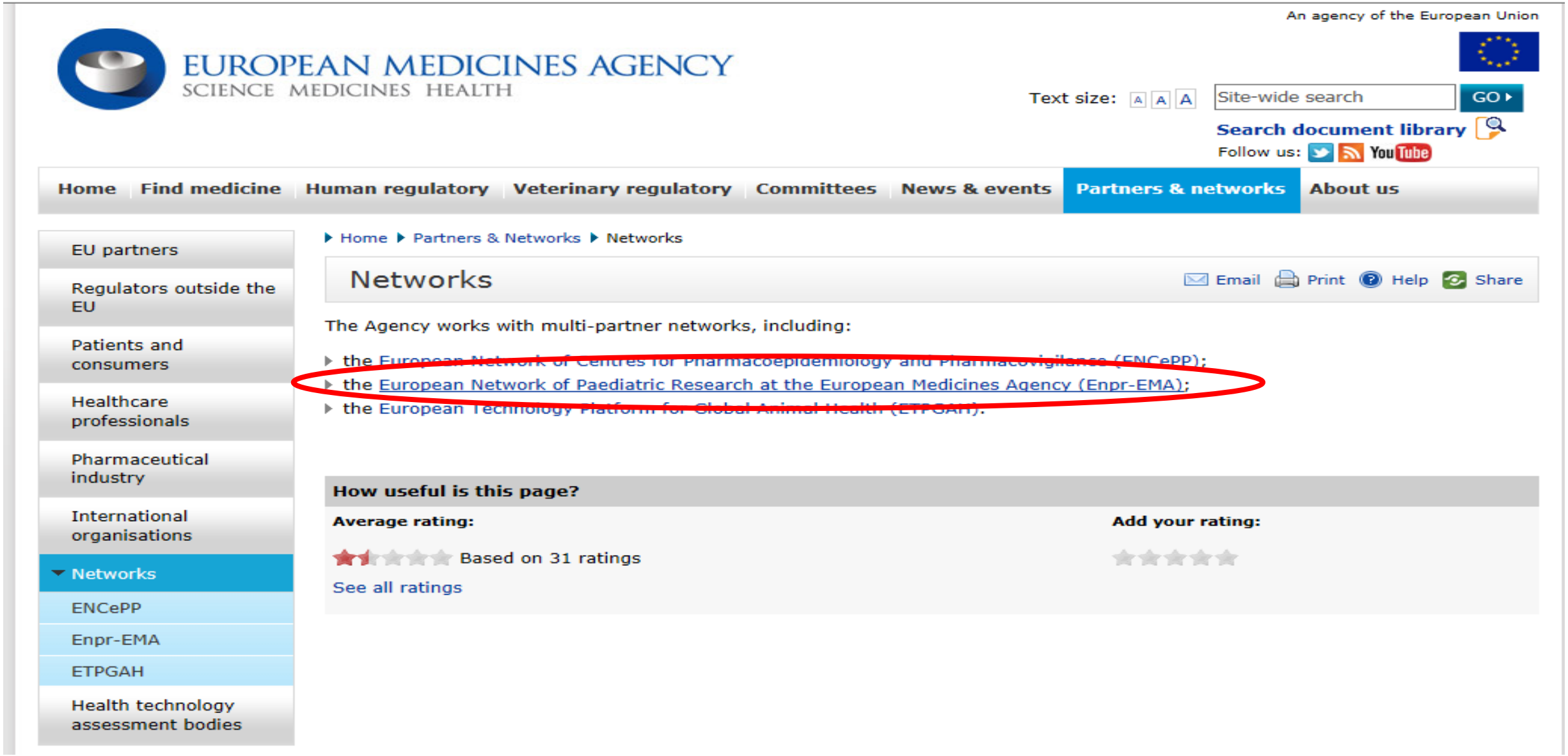

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European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)

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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 studies in children.

Enpr-EMA's main objective is to facilitate studies in order to increase availability of medicinal products authorised for use in the paediatric population, by:

- fostering high-quality, ethical research on the quality, safety and efficacy of medicines for use in children;
- helping with the recruitment of patients for clinical trials;
- enabling collaboration between networks and stakeholders;
- avoiding unnecessary duplication of studies;
- building up scientific and administrative competence at a European level;
- promoting European Commission framework programme applications.

Enpr-EMA works by allowing networking and collaboration with members from within and outside the European Union (EU), including academia and the pharmaceutical industry. The network does not perform clinical trials or fund studies or research or decide on areas for paediatric research, as this is the responsibility of Member States, the European Commission or each individual member organisation.

The European Medicines Agency (EMA) is responsible for providing secretarial support to the activities of the network ensuring exchange of information between the network partners, as well as providing information to external partners and stakeholders.

Related content

- Paediatric medicines: Overview
- Paediatric Committee
- Paediatric medicine development

External links

- Enpr-EMA Network Database

Publications

- Successful private-public funding of paediatric medicines research: lessons from the EU programme to fund research into off-patent medicines
- Pharmaceutical Industry and Pediatric Clinical Trial Networks in Europe – How Do They Communicate?
- Informed consent for paediatric clinical trials in Europe

Contact point:

- enprema@ema.europa.eu

In conclusion

- **Enpr-EMA** – a thriving forum for interactions between networks, Pharma, CROs, regulators and children and families
- Well established as pan-European voice to promote research into medicines for children
- Platform for sharing good practices among networks within Europe and with other parts of the world
- Single point of contact for European paediatric clinical research networks: enprema@ema.europa.eu
- Direct collaboration with industry initiated:
  - industry representatives member of various Enpr-EMA WGs
  - industry representative nominated by EFPIA and EUCOPE as observer in CG

Thank you for your attention

More information:

e-mail: enprema@ema.europa.eu website: www.ema.europa.eu

Enpr-EMA Database:ww.enprema.ema.europa.eu/enprema

Brochure

Standard set of slides to download