



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enpr-EMA Annual Report 2020-2021

Pirkko Lepola, Chair, Enpr-EMA

28September2020

An agency of the European Union



Governance & Meeting activities



Meetings (Virtual)

02-March 21 (CG+Networks), 29-June 21 (CG+Networks), 28-September 21 (CG+Networks)



New CG Members & Networks

New members of CG: Kanecia Zimmerman, DCRI (Duke Clinical Research Institute, US) and Andrea Braun-Scherhag, EUCOPE (European Confederation of Pharmaceutical Entrepreneurs),
New Network; AEPC (Association for European paediatric and congenital cardiology) Task Force on Clinical (Drug) Trials; October 2020



New Membership Criteria & Updated Mandates

1. Membership Categories: Simplified from 4->to 3 categories – approved; February 2021
2. Recognition Criteria to Self-Assessment Form; *Will be updated - expected to be published 09/10-21*
3. Mandate of the Working Groups; March 2021
4. Mandate of the CG; October 2020



Information sharing:



Public Consultations



Regulatory News

Workshops



Initiatives

Training



1. Enpr-EMA information on COE/TEDDY initiative on children rights, i-CONSENT project; March 2021
2. Invitation to Participate in a WHO-funded International Survey of Ethics Committees; March 2021
3. Clinical Trials Regulation (EU) 536/2014 training info; April 2021
4. EU CTR & CTIS –related up-date information; August 2021
5. Public consultation: Blood, tissues and cells (BTC) for medical treatments & therapies – revised EU rules; January 2021
6. EU Commission WS: April 2021
7. EU Commission; Revision of Orphan Reg. and Paediatric Reg. updated rules - Individual contributions requested; May 2021
8. EFPIA & EFGCP Multi-Stakeholder WS on Paediatric Unmet Medical Needs; June 2021



Achievements & Challenges



Enpr-EMA Queries from Pharma Industry

1. September 2020: RD – Nephrology [(C3G), Primary IgA nephropathy (IgAN) and Primary membranous nephropathy (PMN)]
2. December 2020: Infectious Disease [Recurrent Clostridioides difficile Infection (rCDI)]
3. December 2020: RD – Endocrinology [Niemann Pick type C]
4. July 2021: RD – Allergology/Dermatology [Hereditary angioedema (HAE)]



Working Group's Deliverables & Publications

1. Preparedness of medicines' clinical trials in paediatrics: Recommendations published September 2020
2. + Article: Recommendations by the Enpr- EMA Working Group on preparedness of clinical trials about paediatric medicines process: ArchDisChild. March 2021
3. Assent / informed consent for paediatric clinical trials: Guidance document published February 2021



Enpr-EMA Presentations & Global collaboration

1. Pfizer Pediatric Day, 10 June 2021
2. MRCT virtual webinar, Advancing International Pediatric Research, 07 October 2021
3. EFGCP & DIA Better Medicines for Children virtual Conference, October 18-19, 2021
4. MICYRN Annual Meeting 29 November 2021
5. International collaboration between stakeholders for promoting paediatric drug development at the PMDA-ATC & U.S. FDA Pediatric Review Webinar, September 2021



WG International

2 Publications in writing process for CTA + EC, 1 Survey to Industry partners on planning stage



WG Research Nurses

On hold (strong COVID-19 impact)



WG Ethics

Publication submitted for review 07-2021.



WG Labelling

Focus under discussion.



Enpr-EMA member networks 2021

