Minutes - Enpr-EMA Coordinating Group meeting with chairs of the Working Groups

Tuesday 12 January 2016

Chairpersons: Mark Turner / Irmgard Eichler

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1	**Adoption of agenda** Apologies were noted and the agenda was adopted without changes.
2	**Update on status of emerging networks:** • Cardiology (Task Force of AEPC): No update was sent to Enpr-EMA secretariat • **Endocrinology / Diabetes (EUCADET)** The group received an update on INNODIA (Innovative approach towards understanding and arresting T1DM), an approved EC IMI2 consortium which will support a pan-European clinical study group/clinical trials network: launch January 2016. The group was informed that a self-assessment will be soon received from EUCADET to be registered as Enpr-EMA network.
3	**Feedback on updated work plans and work progress from each Enpr-EMA WG** • **WG on GCP Training** The key tasks, timeframes and outputs for establishing a training program for research nurses involved in conducting clinical trials, have been laid down. The WG put together a questionnaire to compile information on what training models for research nurses are already available. The questionnaire will be circulated to all Enpr-EMA members for comments. Members were of the view that existing learned societies and other relevant groups should also be involved. It was proposed to approach EFGCP (European Forum for Good Clinical Practice) regarding potential connections with the EU learning Platform EMTRAIN. • **WG 4 on Dialogue and Interaction with Ethics Committees** After finalization and successful publication of the toolkit on informed consent and assent on the Enpr-EMA webpage, the group contacted the Deputy Head of Unit D6, Directorate General

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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	for Health and Consumers, European Commission – who, after internal consultation, agreed to offer the WG4 involvement in the currently ongoing revision of the document *Ethical considerations for clinical trials on medicinal products conducted with the paediatric population*. The working group now contributes to the planned revision by collaborating with a small group of PDCO members and members of the Paediatric Medicines Office at the EMA. Other activities included commenting on the proposed changes to the US Common Rule - Implications for Pediatric Research (Federal Policy for the Protection of Human Subjects). The consolidated comments from the working group were submitted on behalf of Enpr-EMA stressing the value of taking an international perspective when revising the Common Rule and commenting on the standards of Informed Consent. • **WG How to establish communication between Enpr-EMA networks and industry & Sharing Good Practice within Enpr-EMA and with Industry Partners** This group's role is facilitating exchange of information between industry and Enpr-EMA network members. The first task was analysing communication between networks and industry. A manuscript summarizing the results of a survey among industry and networks, together with recommendations for better interactions has recently been published in the journal "Applied Clinical Trials". The next activity will be the development of a model for industry on how to engage and get in contact with Enpr-EMA for future publications on the Enpr-EMA website. A draft manuscript 'Network consultation process and guideline' will be circulated to Enpr-EMA members for comments once ready. It was emphasised that interaction at 'pipeline development' stage would be useful for the therapeutic area of oncology. It was proposed to ask for a discussion slot at this year's EFGCP/DIA/EMA meeting on Better medicines for children to present the group's activities to a wider audience. • **WG on Young people advisory groups** The WG is trying to get an overview on Young Person Advisory Groups (YPAGs) already established within the Enpr-EMA network members and to develop a database of existing YPAG's. This database could be used to develop operational links between the advisory groups and act as a resource tool for EMA and industry. The WG plans to also approach additional groups/organisations that may have youth groups, such as disease specific support groups, patient groups, to identify additional Young Person Advisory Groups. To this end, two surveys targeting Enpr-EMA and Non-Enpr-EMA members' have been finalized. The survey to Enpr-EMA members will be sent out in January. EMA will ask patient organisations represented within EMA's patient and consumer working party to complete the non-Enpr-EMA members' questionnaire. The response time will be left open to allow continuous input of information from patient groups.

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4	**Industry chosen topic: Update on international initiatives** • **EUPCTN EU Paediatric Clinical Trial Network** The setup of EUPCTN, a EU Paediatric Clinical Trial Network to deliver paediatric studies under the framework of IMI2 was announced to the group. As next step a workshop with all stakeholders will be organised by IMI in April 2016. **GPCTN Global Paediatric Clinical Research Network** This project is planned to be realised in the next 2 years and will initially focus on North America, before broadening up to include other regions, including the simultaneously ongoing activities in Europe on establishing a EUPTCN (see above). The Critical Path institute C-Path is being tasked with establishing a pediatric trial consortium that will develop a proposal for a structure of the global paediatric network.
5	**EUCOPE (representative)** The topic was postponed
6	**Report on EFGCP initiative Children's Medicines Working Party of the EFGCP** An EFGCP workshop is planned in the framework of the next conference of the Better Medicines for Children to take place at the EMA premises on 10-11 October 2016 (the agenda is still under development). All participants of the Coordinating Group were called to participate in the meeting. Further information will be circulated when available.
7	**Neonatology initiatives** The International Neonatal Consortium is bringing together different parties involved (regulators, research, industry) in performing research in this population. A white paper on how to performed clinical pharmacology studies is being drafted and will be available for consultation in the second quarter of 2016. Four topic groups (neonatal seizures, bronchopulmonary dysplasia, and neonatal PK/clinical pharmacology and harmonization of data) have been established. Enpr-EMA networks representatives as well as PDCO members are participating in all topic groups. Guidelines are planned to be developed. Some wider consultations will be considered.
8	**Update on ESFRI** The Chair provided an update on how paediatric research can be heightened in the EU research agenda and on strategies for embedding paediatrics in the EU research infrastructure landscape. A bid for funding of paediatric infrastructure has been submitted to ESFRI with the participation of many Enpr-EMA members. The bid, unfortunately, was not supported. The conclusion was that paediatric research infrastructure should have high priority for EU funding, however, at present, the application was considered not sufficiently mature as closer collaboration with already existing infrastructures which currently do not include paediatrics, should be explored and included. A funding application could be prepared under Horizon 2020 for paediatric specific projects. Members agreed that is important to continue working with existing research infrastructures.
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9	**Next Enpr-EMA face to face meetings: 02-03 June 2015 afternoon** The date of the face to face meetings for 2016 was confirmed.
End of open meeting	
10	**Corporate response by Enpr-EMA WG on Ethics to proposed changes to the US Common - Implications for Paediatric Research** Refer to topic 3 Feedback from WG 4 on Dialogue and Interaction with Ethics Committees
11	**Topic approval process for dedicated Enpr-EMA ad-hoc meetings:** **Proposals received to call** The Chairs informed the group of the proposals received so far. 1. A proposal for 2 new working groups was received by PENTA: 1.1. antimicrobial study design: The CG agreed to create an additional working group on paediatric antimicrobials with the lead of PENTA-ID. This working group should include PDCO members to allow close collaboration in the currently ongoing drafting of a paediatric addendum to the EMA guideline on development of antibiotics. 1.2. RSV ReSViNET, an international network of academics working and researching in the field of RSV will convene a meeting at the beginning of March. It is proposed to await the outcome of this meeting before deciding whether a dedicated Enpr-EMA meeting/working group on RSV would make sense as duplication of work should be avoided. However, an Enpr-EMA meeting on RSV could be a good opportunity for piloting the SOP for Enpr-EMA stakeholder meetings under development by working group 6. 2. A proposal from FP-MCRN (Family Pediatricians -Medicines for Children Research Network) to discuss correct use of pharmaceuticals (antibiotics) in neonates and toddlers from 0 to 2 years. EMA will clarify exactly the scope of such request for further evaluation at the next Coordinating Group meeting. 3. The Paediatric Assembly of the European Respiratory Society reported on efforts to establish a clinical research collaboration in the field of severe paediatric asthma. In the case the initiative receives funding they requested to have a first kick-off meeting under the umbrella of Enpr-EMA. The CG will be informed of further development on these 3 proposals
12	**Report on Enpr-EMA workshop on Gastroenterology 8th December** EMA informed of the recently held workshop. The meeting was divided into two separate parts: the morning meeting was organized by the recently established paediatric network on rare gastrointestinal and PEDDCReN inform industry of the existence of PEDDCReN and to raise awareness on and discuss possibilities for establishing registries for rare gastrointestinal diseases in childhood. The afternoon session was organized by EMA together with some experts of the European

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	Cystic Fibrosis society and the European Cystic Fibrosis Society Clinical Trial Network (ECFS-CTN) to discuss gastrointestinal biomarkers as potential outcome measures for clinical trials with CFTR modulators. The Report on the European network of paediatric research-European Medicines Agency workshop on gastrointestinal (GI) outcome measures to evaluate CFTR modulators for the treatment of cystic fibrosis (CF) was published on the Enpr-EMA site.
13	**Adoption of the updated policy of transparency and mandate of Coordinating Group** The updated Policy on transparency and the handling of potential conflicts of interests of members of the European network of paediatric research at the European Medicines Agency(Enpr-EMA) Coordinating Group and working groups including information on the updated Enpr-EMA networks funding sources form, which was adopted in November, was presented to the Coordinating Group. The policy was adopted. A revised Mandate of the Coordinating Group of the European network of paediatric research at the European Medicines Agency(Enpr-EMA) was endorsed.
14	The Coordinating Group was informed that the following two networks submitted self-assessment forms, which are currently under evaluation by the Enpr-EMA secretariat: • EORTC Children Leukemia Group (EORTC CLG) • Medicines for Children Research Network (MCRN)-Hungary

List of Category 1 Enpr-EMA registered networks (20 networks):

Type of network and therapeutic area of the network	Name of category 1 network
National and multispecialty	NIHR-MCRN FinPedMed MCRN-NL MICYRN ScotCRN CICPed RIPPS OKIDS DCRI
Oncology (solid / haematologic malignancies)	Newcastle-CLLG ITCC IBFMSG
Allergology / Immunology/ Rheumatology	PRINTO
Stem Cell and Organ Transplantation / Haematology (non-malignant) / Haemostaseology	EBMT
Respiratory diseases / Cystic Fibrosis	ECFS-CTN
Psychiatry / Neurology	EUNETHYDIS
Infectious diseases / Vaccinology	PENTA-ID UKPVG
Neonatology	GNN
Special Activities (pharmacovigilance, long-term follow up, community paediatricians)	FIMP-MCRN