27 October 2015
EMA/701987/2015
Human Medicines Research & Development Support Division

Minutes of the Enpr-EMA Coordinating Group (CG) teleconference meeting

21 October 2015, 13.00 to 15.00 UK time

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler

Enpr-EMA secretariat: Roberto De Lisa, Isabel Perez

Coordinating Group Members: David Coghill, Pamela Dicks, Jose Drabwell, Kalle Hoppu, Anne Junker, Behrouz Kassai, Pirkko Lepola, Christoph Male, Ettore Napoleone, Nicola Ruperto, Mike Sharland, Angeliki Siapkara, Gareth Veal, and Saskia de Wildt

Industry observer: William Treem and John Watson

Apologies: Stephen Greene, Andrea Biondi, Carlo Giaquinto and Wolfgang Goepel

Item	Summary of discussion	Action
1	The minutes of the last CG teleconference as well as the draft agenda for this CG teleconference were adopted.	N/A
2	• Cardiology (Task Force of AEPC) network: No update of the task force received. • EUCADET (European Children and Adolescent Diabetes and Endocrinology Trials network): The steering group of this network recently met to discuss: – Results of a survey documenting the research interests, clinical trials experience of diabetes/endocrine paediatric specialists across Europe. – 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 to be rolled out in 2016.	Enpr-EMA Co-chair

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	– Need to establish working groups within EUCADET to address critical areas for further development over the next year, such as groups in collaboration with ESPE to identify future needs/opportunities in the fields of bone disorders, disorders of sexual development and lipodystrophy and a diabetes working group which will collect data on prevalence of T2D and enthusiasm/impediments to recruitment of subjects with T2DM (continuing problems relating to suboptimal recruitment worldwide to PIPs for T2D). Working group will also explore possibility of network support for repositioned T2D drugs for adjuvant therapy in type 1 diabetes outside of the proposed INNODIA structure.	
3	Updated work plans and new deliverables for year 2016: <u>WG on Public-Private Partnership:</u> • Develop a model to put on the EMA website showing how industry can engage with Enpr-EMA/networks and how this could benefit them. – Draft by end of 2015 to present at January TC – Finalised by end February 2016 to launch at May Enpr-EMA Workshop • Draft an advertisement that could be used to publicise this model – End March 2016 • To launch at May Enpr-EMA workshop <u>WG on Ethics:</u> The group is interested to explore how to support guidance for paediatric specific issues that must be considered during the assessment of trials involving children and young persons in the implementation of the new Clinical Trial Regulation with the view that these efforts will create a more favourable environment to speed up high quality paediatric research. Through the review of the latest clinical trial Regulation the group has come up with a few preliminary ideas of ways to contribute to a favourable environment for paediatric research. One example of this would be the definition of risk level for each trial that occurs as an initial step to trial assessment. The assessment and definition of risk level can be different for children compared to adults. Without paediatric specific considerations for risk assessment, the appropriate evaluation of the clinical trial can be difficult. Guidance on this topic may be helpful in implementing this part of the Regulation for paediatric research. Planned activities: 1. Take a role in the ongoing discussions around the implementation of the Regulation at both the EU and member state level. 2. To build on the previous work done by focusing on issues around informed consent in contributions to the implementation of the Regulation. 3. Support Enpr-EMA to act as the paediatric voice in the implementation of the Regulation.	Enpr-EMA Co-chair, WG-chairs

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	During the discussion the need for automated alerts was identified to inform Enpr-EMA secretariat whenever a paediatric trial has been authorized through the central EU portal; Enpr-EMA could then disseminate to all relevant Enpr-EMA members. Enpr-EMA secretariat will explore feasibility of introducing such alerts. WG on interactions network-industry-regulators when issues with conducting PIP: The group is developing a SOP to allow Enpr-EMA the set-up of appropriate meeting discussion with all stakeholders (industry, academic networks, regulators) when difficulties arise in performing trials in a specific therapeutic area (although specific product related matter do not fall under the remit of this WG discussion) or critical topics of any other related nature are reported. Working Group on Young Persons Advisory Groups (YPAGs) • To design a survey on Google Groups to scope what YPAGs are running in the member networks of Enpr-EMA, to identify the structure of the groups, their contact details, the services they provide, some examples of projects they have been involved in, their funding etc. The European, Canadian and US groups will be included. – The second draft of the survey has been distributed for comment. • To design a second survey targeted at non Enpr-EMA disease specific and patient support groups. – The second draft has been distributed for comment. • To distribute to Enpr-EMA networks. – End November • To collate lists of support groups, patient groups etc. – end of November – Enpr-EMA members will be asked to assist in providing contact details. • To collate the information and ask Enpr-EMA to host it on the Enpr-EMA website – Update provided at Jan TC • To determine if the groups would like a platform where they could access and share resources such as training materials. – End February • To review platforms such as Google Groups where that could be hosted. End March 2016. • To review all data collected and determine if it should be published. To be discussed at June Workshop, alongside completed surveys. WG on GCP Training: An information gathering exercise for requirements across Europe for the qualification of 'research nurses' as well as a model of best practice related to the role of this profession in the conduction of clinical trials is being carried out. A questionnaire-type survey is to be designed and an initial draft is planned to be presented by early December to Enpr-EMA for review, as well as agreement of appropriate target audience. Discussion will be scheduled for the January 2016 coordinating group meeting.	

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	In the following discussion the current lack of research nurses in the psychiatry or mental health field was flagged.	
5	John Watson introduced himself as the new EUCOPE (European Confederation of Pharmaceutical Entrepreneurs) representative to the Enpr-EMA coordinating group. He was welcomed and was also invited to advocate among SMEs the established Enpr-EMA collaboration with the EMA Small and Medium Enterprise (SME) office.	Industry observer
6	The group reflected a more structured approach to the topic approval process for dedicated Enpr-EMA ad-hoc meetings. It was clarified that budget has been allocated for 3 meeting each with 10 attendees, pending final approval. The group agreed that proposals for topics should be presented at the January CG meeting. A call for topics will be circulated soon with a submission deadline by mid-January 2016. Contextually the group was informed that a proposal had already been put forward for a meeting to discuss how the many concurrently ongoing clinical trials in the field of RSV infections could best be coordinated.	CG members Enpr-EMA secretariat
7	A revised networks' financial disclosure form was presented and adopted by the CG-group. Every network is encouraged to publish on the network's own individual webpages the completed and up-to-date network disclosure/funding source. They will not be published on the Enpr-EMA webpages. However, a list of networks that have disclosed the financial information will be made available to promote this good practice for transparency.	Enpr-EMA co-chair
8	Update on international initiatives: • EU Paediatric Clinical Trial Network: William Treem presented the principles and objectives of the IMI2 project proposal to build a sustainable Pediatric Clinical Trial Network. Once created the network will strictly interact with Enpr-EMA. The Consortium Management Board is made up of network champions from each of the industry consortium companies and each of the applicant consortium organizations; and acts as a governing board that will receive periodic reports from the Central Coordinating Committee (CCC) and Work Package leaders, and vote on issues that arise. Governance and organisation will be established during the first months of activity. And the CCC will maintain close liaisons with Enpr-EMA, already existing national networks in EU member states, disease-specific pan-EU networks, and other EU paediatric advisory networks. A preliminary response from EU Commission expected by mid-November. An update will be provided at the January 2016 CG-meeting.	Industry observer
	• Global Paediatric Clinical Trial Network: Mark Turner presented a brief update on the current status of the US initiative to develop a "Global" (mainly North American) Paediatric Clinical trial network and explained the relationship between the IMI2 project and the US initiative: both initiatives are running in parallel and are complimentary; they are	Enpr-EMA chair

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	designed to support the creation of a new global solution that will advance pediatric clinical development.	
9	Neonatology initiatives: Mark Turner provided an update on current activities of the International Consortium on Neonatology group and announced that a neonatal clinical pharmacology white paper is planned to be finalized by end of this year.	Enpr-EMA chair
10	Update on the ESFRI 2016 Road Map, following the September hearing meeting: *(ESFRI: European Strategy Forum for Research Infrastructure)* Mark Turner reported back to the CG about the hearing meeting attended by Kalle Hoppu, Adriana Ceci and Mark Turner. The goal of the of the bid to build a case for national governments to support paediatric research infrastructure resulting in an increasing number of sites and countries with the expertise and capacity to conduct high quality paediatric clinical trials.	Enpr-EMA chair
11	Future of the Paediatric Regulation: proposal for a corporate message from Enpr-EMA on the future and improvements on the Paediatric Regulation: Irmgard Eichler announced that the European Commission will prepare a 10-year report on the functioning of the Paediatrics Regulation that will be released for public consultation. This will be the most suitable opportunity for Enpr-EMA to provide consolidated comments.	Enpr-EMA Co-chair
12	Use and dissemination of the work of the Nuffield Council on Bioethics: Irmgard Eichler informed the group about the work of the Nuffield Council on Bioethics which is an independent body advising policy makers and stimulating debate in bioethics. A report on Children and clinical research: ethical issues has been published in May 2015 together with an animation video on ethical issues' from the perspective of Mia – a character who goes through some of the questions and issues that might be raised when a young person is invited to take part in clinical research. The script was developed following a workshop with 14 young people aged 10 to 18 who had previously been in contact with the Council, but were not 'experts' in clinical research. The organization is keen to disseminate the document but resources for translation are limited. Enpr-EMA members are encouraged and invited to use their communication channels for further dissemination.	Enpr-EMA Co-chair
13	March 2016 FDA workshop on Long-Term Pediatric Safety: The group was informed of a workshop: 'Successes and Challenges of Performing Long-Term Pediatric Safety Studies' that the FDA is organizing in April 13-14, 2016.	N/A
14	Endorsement of newly received or updated applications for Enpr-EMA membership: • CG endorsed DCRI (Duke Clinical Research Institute) as an Enpr-EMA category 1 network. • CG endorsed INFANT (Irish Centre for fetal and neonatal translational research, Cork University) as an Enpr-EMA category 2 network.	N/A

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15	Representation of category 1 networks within CG: Irmgard Eichler explained that since the limit for participation as members in the Coordinating Group has been reached and there is a need to find a strategy to enable participation of all category 1 networks to the CG. Members concurred that one solution could be to assign observer status to international organisations reserving the status of members with voting rights for European networks. Such approach was endorsed. It is suggested to limit the number of international observers to 5 with good geographical representation.	Enpr-EMA Co-chair
16	Next Enpr-EMA CG and WG teleconferences to be scheduled in January 2016: A doodle poll will be sent to CG members to identify best convenient date and time. Irmgard Eichler announced that starting with 2017 the annual open workshop will be scheduled one day prior to a PDCO-meeting to facilitate mutual interaction.	Enpr-EMA secretariat
17	A.O.B • Dates for 2016 annual workshop and network member meeting: – Annual open Enpr-EMA workshop will be held on Thursday, 2 June 2016; – Annual face-to-face Enpr-EMA meeting on Friday morning, 3 June 2016; – Annual face-to-face Coordinating Group meeting on Friday afternoon, 3 June 2016. • Collaboration with: – The European Forum for Good Clinical Practice (EFGCP) has revived its paediatric working group; it is suggested to invite it for next year annual workshop. – Irmgard Eichler informed the Coordinating Group about a project of EURORDIS to organise a youth empowerment school (YES), targeting young patients above 18 years, and suggested to the Enpr-EMA WG on YPAGs to seek collaboration.	N/A