Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 29 June 2021; 15:00-16:30 CEST; By Webex

Chairpersons: Pirkko Lepola / Gunter Egger

Invitees: Coordinating Group members, Enpr-EMA member networks, working group chairs

Attendees : Alessandra Nardone (PENTA-ID), Alessandro Zuddas (ECAPN), Andrea Braun-Scherhag (EUCOPE), Anette Solli Karlsen (PDCO), Begonya Nafria Escalera (eYPAGnet), Bernhard Sandner (NETSTAP e.V.), Carmelo Rizzari (I-BFM-SG), Carmen Moreno (ECAPN), Christina Peters (EBMT), Cristina Calvo (RITIP), Daniel de Wolf (AEPC), Daniel Torrecilla (RECLIP), Donato Bonifazi (TEDDY), Geraldine Boylan (INFANT), Gilles Vassal (ITCC), Ivan Foeldvari (JSWG of PRES), Jose Drabwell (IPOPI), Kanecia Zimmermann (DCRI), Luca Sangiorgi (ERNs), Marek Migdal (PDCO), Mark Turner (c4c), Martine Dehlinger-Kremer (EUCROF), Paul Dimitri (NIHR CRN), Pierre Rohrlich (EORTC CLG), Rebecca Leary (TREAT-NMD), Regis Hankard (PEDSTART), Ricardo M Fernandes (Stand4Kids), Sabine Scherer (PDCO), Saskia de Wildt (Pedmed-NL), Segolene Gaillard (RIPPS), Sigrun Hjelle (NorPedMed), Tilmann Taube (EFPIA), Thierry Lacaze (MICYRN), Viviane Giannuzzi (TEDDY)

EMA participants: Liliya Dimitrova Todorova, Lifang Liu, Laura Fregonese

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OPEN SESSION (all networks and observers)	
Adoption of agenda	The agenda was adopted without changes.
Welcome to new observer members of coordinating group (CG): • Kanecia Zimmerman to replace Christoph Hornik for Duke Clinical Research Institute Welcome to new Enpr-EMA member	Kanecia Zimmerman introduced herself and was warmly welcomed as an observer to the CG. Daniel de Wolf introduced himself and briefly presented the AEPC Task Force on Clinical (Drug) Trials. AEPC was warmly welcomed as a new member network.

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networks: • AEPC Task Force on Clinical (Drug) Trials [Association for European paediatric and congenital cardiology]	
Update from WG on international collaboration • Clinical trial authorisation across jurisdictions - manuscript • Survey on requirements for paediatric trial sites	<u>Clinical trial authorisation across jurisdictions:</u> Thierry Lacaze provided an update on the status of the manuscript on requirements for clinical trial applications in 5 different regions (Europe, US, Canada, Australia, Japan), which is planned to be published in a scientific journal to serve as guidance for academic investigators and industry sponsors of multiregional trials. Moreover, it was stated that – following the UK's withdrawal from the European Union – the UK will join the group as a 6th region and provide their perspective. The initial survey results and the draft manuscript are currently being reviewed by the group members before discussion at the next meeting of the WG in July. <u>Survey on requirements for paediatric trial sites:</u> Members were updated about the intention of the WG to work on a publication with the aim to raise awareness regarding requirements for paediatric clinical trial sites. To this end, as a first step the WG intends to seek input from industry/sponsors on their experience and expectations of trial sites specifically for the conduct of trials in the paediatric population (e.g. site organisation, qualifications of principle investigator, training certifications for research staff, equipment). A draft survey has been prepared and it is intended to distribute it among industry via the trade associations (e.g. EFPIA, EUCOPE, EUCROF). Martine Dehlinger-Kremer (EUCROF) expressed her support for this initiative and offered to distribute the survey via EUCROF to Clinical Research Organisations in the EU, and beyond (via sister organisations in other regions).
Update from WG on research staff	No update was provided. Pamela Dicks, the chair of the WG, was unable to join the meeting.
Update from WG on clinical practice evidence in the labelling	Saskia de Wildt provided an update on the status of the draft manuscript, which advocates increased uptake of off-label evidence on the use of paediatric medicines into the product information. During the ensuing discussion it was suggested

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	that efforts to bring off-label evidence into the label should be targeted and focus on unmet medical needs and particularly on those products where the biggest benefit is expected (rather than systematically across the field of off-label use), criteria for this would still need to be defined. Product safety and liability issues were mentioned to be among the most challenging aspects of off-label use. Further, it was mentioned that the information in the label is important for insurance and reimbursement issues. It was suggested, that this WG should learn from experience of the Art.45 (of the Paediatric Regulation) data use. Saskia will be supported by Ivan for the preparation of the manuscript.
Academia collaboration matrix action plan Funding, training, and when	Lifang Liu presented tools available to support academia developers via the EMA's academia collaboration matrix action plan. Lifang clarified that for the public engagement of EMA "academia" is defined as "not for profit" and includes a wide range of stakeholders, including amongst others, experts, academic groups, research consortia and infrastructures, networks and learned societies. Enpr-EMA members are considered part of the academia stakeholders of EMA and may be approached in the future to provide input to specific questions of EMA's regulatory science research agenda, which is currently being drafted and expected to be published by the end of the year. Furthermore, it is planned to keep Enpr-EMA members informed about educational events of the matrix and training opportunities of relevance, as well as information on EU-funding opportunities and mechanisms. All training resources are free of charge, and mainly provided by web-based methods. Among other things, training webinars on the EU Clinical Trial Information System (CTIS) were highlighted. CTIS-Highlights (Issue 1) Further information can be found on the academia landing page of the EMA website.
Preparation of annual meeting (28 September 2021) • Revision of Paediatric Regulation (EC	Members were invited to comment on the draft proposal for topics to be presented/discussed at the Enpr-EMA meeting in September and to suggest others. Members agreed with the draft

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update) • Clinical Trial Regulation • COVID-19 developments • WG updates • Enpr-EMA membership	proposal of topics. It was stated that information on the revision of the Paediatric and Orphan Regulation should be included.
Update on paediatric developments regarding COVID-19 vaccines and therapeutics	Laura Fregonese provided an overview of the current situation of COVID-19 vaccine development for the paediatric population and the status of the related clinical trials.
CLOSED SESSION (without industry observers)	
N/A	*N/A*
AOB End of meeting	