Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 2 March 2021; 14:00-15:30 CEST; By Adobe Connect

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), Annagrazia Altavilla (TEDDY), Bernhard Sandner (NETSTAP e.V.), Christina Peters (EBMT), Cristina Calvo (RITIP), Cristina Seren (RECLIP), Donato Bonifazi (TEDDY), Ettore Napoleone (FP-MCRN), Fernando Cabañas (Red SAMID), Gilles Vassal (ITCC), Heike Rabe (Neo-Circulation), Ivan Foeldvari (JSWG of PRES), Luca Sangiorgi (ERNs), Lucia Ruggieri (TEDDY), Marek Migdal (PDCO), Mark Turner (c4c), Martine Dehlinger-Kremer (EUCROF), Nick Croft (PEDDCReN), Nicolino Ruperto (PRINTO), Pascale Wenger (SwissPedNet), Pierre Rohrlich (EORTC CLG), Rebecca Leary (TREAT-NMD), Regis Hankard (PEDSTART), Ricardo M Fernandes (Stand4Kids), Sabine Scherer (PDCO), Saskia de Wildt (Pedmed-NL), Saul Faust (NIHR CRN), Segolene Gaillard (RIPPS), Sigrun Hjelle (NorPedMed), Tessa van der Geest (Pedmed-NL), Thierry Lacaze (MICYRN), Thomas Halvorsen (NorPedMed), Tim Lee (ECFS-CTN), Viviane Giannuzzi (TEDDY), Wolfgang Goepel (GNN)

EMA participants: Irmgard Eichler, Laura Fregonese, Liliya Dimitrova Todorova

Agenda	Minutes
OPEN SESSION (all networks and observers)	
Adoption of agenda	The agenda was adopted without changes.
Welcome to new members of coordinating group (CG)	Andrea Braun-Scherhag, official representative of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), briefly introduced

	herself and was warmly welcomed as an observer to the CG.
Brief Updates from the working groups (WG): • WG on ethics • WG on research staff • WG on international collaboration • WG on clinical practice evidence in the labelling	WG on ethics: The working group has published recommendations regarding the contents of the various subject elements of consent / assent forms for each paediatric age group on the Enpr-EMA website: Informed consent / assent content recommendations for paediatric clinical trials in Europe The document, which takes into account input from young person advisory groups, provides an overview tool for informed consent and assent, publicly available to all stakeholders, in order to support the design and conduct of high-quality ethical paediatric clinical trials in Europe. The guidance document does not contain consent or assent templates, but merely guidance about the contents by listing various subject elements to be considered for every paediatric age group when designing consent / assent documentation. A more detailed manuscript will be submitted for publication in a scientific journal. As stated previously, this WG will now be closed until the need for further work on ethics arises. The chair of WG, Pirkko Lepola, thanked all WG members for their active contributions. WG on research staff: Pamela Dicks, who has taken over the lead, was unable to join the meeting due to last-minute changes to her schedule. Gunter Egger briefly informed everyone that this WG is reaching out to ensure alignment with the c4c nursing group to avoid duplication. Yet, due to the ongoing pandemic, the group's work has been seriously impacted and delayed. Everyone interested to join this WG - please contact Enpr-EMA secretariat (enprema@ema.europa.eu). WG on international collaboration: As presented previously, this WG has conducted and analysed results of an environmental scan on

	requirements for clinical trial applications in 5 different regions (Europe, US, Canada, Australia, Japan). The comprehensive overview, comparing regulatory and ethics clinical trial requirements, is planned to be published in a scientific journal to serve as guidance for academic investigators and industry sponsors of multiregional trials. However, there is a need for an update of the environmental scan due to several reasons: i) in some jurisdictions modernisation approaches are ongoing, looking at risk-based approaches related to the conduct of clinical trials, ii) some jurisdictions developed streamlined regulatory and ethics submission processes (i.e. submission of the regulatory as well as the ethics applications at the same time), iii) because of the pandemic, some processes have been adapted to expedite clinical trial authorisations. While these mitigation strategies were developed by regulators as interim measures to introduce flexibility in order to facilitate a broad range of COVID-19 related trials, some of them are now suggested to be continued and implemented permanently. Therefore, the WG now considers conducting another survey among its international members in order to update the initial results before publishing them, also with the intention to advocate implementation of the interim orders on a more permanent basis. <u>WG on clinical practice evidence in the labelling</u> The members were informed that the manuscript advocating increased uptake of off-label evidence on the use of paediatric medicines into the product information was well advanced and planned to be submitted for publication in a scientific journal soon.
Update from networks on mitigating impact of pandemic on clinical trial activities, business continuity planning Discussion on • whether new results from surveys on lessons learnt are available/published; how to consolidate the findings/recommendations and build	<u>conect4children (c4c):</u> c4c conducted a survey among all network members regarding mitigation measures put in place: e.g. allowing remote visits, allowing study visits at home, allowing sending medicines to the homes of study participants. Yet, not all mitigation measures are possible in all countries. Involving patient and parent groups for addressing some of the problems was found to be

on them	very beneficial as they helped to find creative solutions. In addition to pandemic-related problems, some structural problems at hospital site level were also identified. There were some delays in study initiations due to the pandemic, but now all c4c investigator-initiated proof-of-viability studies are up and running. <u>PEDSTART:</u> Regis Hankard reported on a survey among the national networks of the c4c consortium in Europe and two Canadian networks regarding the impact of the pandemic on paediatric research activities and mitigation measures put in place at site level (but not regulatory aspects). Responses to the survey identified a reduction in site activation visits and the number of hospital patient visits. The mitigation measures were very heterogenous. A manuscript has been prepared and is expected to be published soon. One proposal was to submit the manuscript to *Frontiers in Paediatrics*. Christina Peters offered to approach the editors. It was suggested to distinguish between two different implications of the pandemic: 1) regulatory processes requiring adaptation, e.g. obtaining informed consent, using electronic records, 2) the impact on recruiting processes (e.g. temporary recruitment stops, decreased incidence of respiratory syncytial and influenza virus). Finally, it was discussed whether it may be beneficial to combine this topic, i.e. the networks' perspective (what did/can investigators do) and the regulatory mitigation measures (what did/can regulators do) as learnings from the pandemic.
Information about paediatric COVID-19 - vaccine development and trial status	Laura Fregonese provided an overview of 5 paediatric investigation plans (PIPs) agreed to date for COVID-19 vaccines. At this point in time, age staggered studies in all age subsets (from birth) are required. Yet, it was mentioned that this might change once results are available of studies in vaccinated pregnant women. While immuno-compromised children would be

	one of the priority groups to enrol into studies, it would not be possible to start trials in this patient group without knowing the immune response in not immune-compromised children. Efficacy studies are not required in the paediatric population, only non-inferiority immunogenicity studies (response in neutralising antibodies) to compare immune responses in children to those in adults. To date, studies in adolescents with both the Moderna and the Biontech vaccine are completed, each enrolling approx. 3000 adolescents. Results of these studies are hoped to be submitted soon for regulatory assessment. Studies in adolescents with the Astra Zeneca and the Janssen vaccine have started in the UK. Laura also briefly touched upon the impact on increasing appearance of virus variants, and the impact on vaccinations strategy/ schedules. EMA and FDA have published guidance for studies regarding new virus variants.
AOB EU review – medicines for children & rare diseases Next meeting	<u>EU review of Paediatric Regulation:</u> The European Commission (EC) received more than 100 individual feedback submissions during the recent public consultation regarding the evaluation of the Paediatric Regulation and the Orphan Regulation. Currently study on the impact assessment is ongoing. Another open consultation is planned for 2Q 2021. <u>Council of Europe / TEDDY initiative on children rights in biomedical sector:</u> Further information about this initiative can be found at: children in decision making process. A survey on national provisions, guidelines and practices aimed at increasing children participation in decision making processes in the biomedical sector will be open until 31 March 2021 and is accessible here: Survey on children in decision making processes <u>i-CONSENT project:</u> The i-CONSENT project's final event "towards the future of informed consent in clinical research"

	will take place on 16 March 2021. Anyone interested in taking part can register at the following link: Towards the future of informed consent Next Enpr-EMA meetings: The next CG/network meeting is planned for late June and the main annual meeting towards the end of September. Invitations will be sent out in due course.
CLOSED SESSION (without industry observers)	
Enpr-EMA network membership criteria and proposal to simplify categorisation	A simplified categorisation of Enpr-EMA members was proposed and adopted: The current category 2 (networks potentially fulfilling all minimum requirements but in need of further clarifications) and the current category 3 (networks not currently fulfilling the minimum requirements) will be merged under the new category 2. The current category 4 will become category 3. The new categorisation is as follows: • Category 1: networks fulfilling all minimum requirements • Category 2: networks not currently fulfilling all minimum requirements • Category 3: networks that do not run paediatric clinical trials but have expertise in clinical trial methodology or support clinical research infrastructure The new categorisation will come into effect when the published self-assessment form for Enpr-EMA membership has been updated accordingly.
End of meeting	