Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 22 June 2020; 15:00-16:45 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), Annagrazia Altavilla (TEDDY), Anette Solli Karlsen (PDCO), Carmelo Rizzari (I-BFM-SG), Cathy Turner (TREAT-NMD), Cecile Ollivier (EUCOPE), Christine Nguyen Demange (PIBD-Net), Collin Hovinga (iACT), Cristina Calvo (RITIP), Cristina Seren (RECLIP), Donato Bonifazi (TEDDY), Martine Dehlinger-Kremer (EUCROF), Eoin McGrath (EBMT), Etienne Sokal (PCIC), Franca Rusconi (SPACE), Gilles Vassal (ITCC), Heidi Glosli (NorPedMed), Heike Rabe (Neo-Circulation), Hidefumi Nakamura (NCCHD), Ines Cabrita (Stand4Kids), Ivan Foeldvari (JSWG of PRES), Luca Sangiorgi (ERNs), Marek Migdal (PDCO), Mark Turner (c4c), Nicolino Ruperto (PRINTO), Pamela Dicks (ScotCRN), Pascale Wenger (SwissPedNet), Pierre Rohrlich (EORTC CLG), Ricardo M Fernandes (Stand4Kids), Robert Simko (Hungarian network), Ruth Ladenstein (OKIDS), Sabine Scherer (PDCO), Saul Faust (NIHR CRN), Segolene Gaillard (RIPPS), Sigrun Hjelle (NorPedMed), Thierry Lacaze (MICYRN), Wolfgang Goepel (GNN), Regis Hankard (Pedstart), Thomas Halvorsen (NorPedMed)

EMA participants: Irmgard Eichler

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): Alessandra Nardone: PENTA Cecile Ollivier – EUCOPE Sabine Scherer – PDCO Anette Solli Karlsen – PDCO	The new members briefly introduced themselves and were warmly welcomed.

Agenda	Minutes
(observer)	
Brief Updates from the working groups (WG): • WG on ethics (Pirkko Lepola) • WG on parents and patients (Dimitrios Athanasiou) • WG on research staff (Vincent O'Mahony) • WG on clinical trial preparedness (Mark Turner & Sabine Scherer) • WG on international collaboration (Thierry Lacaze) • Clinical practice evidence in the labelling (Saskia De Wildt)	<u>WG on ethics:</u> EMA internal review of the summary and overview table of guidance regarding contents for the consent and assent documents in Europe has been finalised. This document references current ethics guidelines, the upcoming Clinical Trial Regulation, Data Protection Regulation, as well as input from the young person advisory groups. The summary table will be published on the Enpr-EMA website; a more detailed manuscript will be submitted for publication in a scientific journal. <u>WG on parents and patients:</u> Dimitrios was unable to attend. The WGwas planned to focus on data usage and sharing optimisation. Gunter informed the CG about the joint HMA/EMA Task Force on Big Data, which seeks and offers various opportunities for stakeholder input on data usage and sharing optimisation. It was recommended that the members of the WG on parents and patients should provide input related to paediatric aspects and to ensure that FAIR (findable, accessible, interoperable and reusable) principles are taken on board by the Task Force. Instead of continuing as a separate WG, members of this group will feed into the joint HMA/EMA Task Force on Big Data under Dimitrios' lead, who acts as a link to Enpr-EMA. It was agreed to close this WG. (Post meeting note: Dimitrios agreed with the agreed course of action.) <u>WG on research staff:</u> Due to Vincent's absence Gunter presented on his behalf: Due to COVID-19 pandemic and its impact on the day-to-day workload Vincent was unable to commit to the WG's activities, but hopes to continue later in the year, e.g. last quarter of this year. The Scottish network might be able to offer support. A few senior research nurses from the Scottish Paediatric network, including Susan Macfarlane who previously worked with Gareth Veal on the GCP Training work package, were currently shielded due to the pandemic and unable to be redeployed to support clinical work. This is an opportunity to increase support for the work of the WG. Pamela to directly liaise with Vincent to discuss how to proceed. <u>WG on clinical trial preparedness:</u> Mark together with Sabine agreed to act as new chairs of the WG. The final document, taking into account the feedback from the public consultation, was internally reviewed by EMA and will be recirculated among all WG members before publication on the Enpr-EMA website.

Agenda	Minutes
	The outcome of a survey among stakeholders, is planned to be submitted as separate publication in a scientific journal. WG on international collaboration: Results of the environmental scan on requirements for clinical trial applications in 5 different regions (Europe, US, Canada, Australia, Japan) were presented. The comprehensive overview summarised in a user-friendly table is planned to be published in a scientific journal to serve as guidance for sponsors of multiregional trials. At present, it is still under discussion whether to compile all the information in one scientific journal or split the CT approval requirements vs ethical requirements into 2 publications. The draft manuscript(s) will be drafted over the summer for submission to a scientific journal as an outcome of Enpr-EMA's WG on International Collaboration. In addition, the next task of this WG was briefly presented: to develop a survey focusing on sponsors expectations on sites' capacities / accreditations and to inquire how parents/patients are involved in designing CTs, and to identify barriers in that arena. WG on clinical practice evidence in the labelling: Due to Saskia's absence, Pirkko briefly informed the CG that Saskia has drafted a first structure of the white paper planned to be published; she is currently collecting some examples of medicines to build the case.
Feedback from networks on impact of pandemic on regular clinical trial activities, business continuity planning, and feedback on activities related to COVID-19 Discussion on • Impact of pandemic on operational issues of paediatric trials, lessons learnt – plans for the future • Enabling collaborative studies for COVID-19 (and otherwise), what is going on in the networks, how can Enpr-EMA help, what information should be	US activities: • I-Act surveyed networks regarding how many networks were functional despite pandemic, 2/3 of sites replied, about 70% still conducting clinical trials; second outreach is planned to the 22 sites who did not reply to find out whether they are not functional or busy with other activities, • I-Act plans to prepare guidance on how to restart trials and manage the current situation, how to prevent slow-down in similar situations in the future. It is planned to bring together registries gathering aggregated real-world data on COVID-19, to provide a platform to share data and to combine analyses. Canada: • In most paediatric academic centres, "non-essential" activities and non COVID-19 research related activities were shut down between mid-March and mid-June. Activities are not yet back to normal, but research staff is now allowed to screen, consent and collect data in acute and ambulatory care settings. Research Ethics Boards (REB) and Regulators

Agenda	Minutes
shared	focused their activities on COVID-19 related projects with short turnover. • Enpr-EMA network members expressed interest that the results should be shared with other networks. C4c – Europe: A business continuity survey was conducted among c4c networks - results are not yet available. The survey focussed on how a pandemic can affect the running of trials, it looks at disruptions and how to address them. Main problem identified: communication. C4c set up a system in real time which is ready to facilitate communication with ethics committees, sponsors, pharmacies and others. Harvard's MRCT (Multi-Regional Clinical Trials Center): • Initial output: common COVID-19 outcome core data set that could be easily analysed • Longer term: standardised system for use in future registries, expanding to other sources • Data would only be made available to those who contribute to the platform, at least until the individual contributors have published their data. Anyone (e.g. network, individual investigator, hospital) who has a registry and is interested to join, is encouraged to approach Mark who offers liaison with MRCT. WHO International Clinical Trials Registry Platform (https://www.who.int/ictrp/en/) • open access for everyone • synthesise data real time - meta analysis – but not actual raw data European reference Networks: • Many ERNs are running a questionnaire on impact of COVID-19 to patients with rare diseases. • Results will be shared once available. DG SANTE is organising within the 'COVID-19 Clinical Management Support System' (CMSS) a series of webinars which are open for everyone to support clinicians and other healthcare professionals at the frontline treating patients with COVID-19. During the discussion, issues/concerns related to on-line verification of raw data, issues with data protection, etc, were raised; seemingly everyone tries to find their own solution, a collective discussion and

Agenda	Minutes
	proposal would be appreciated.
Site accreditation by industry (survey by i-ACT)	As stated above (update on activities of WG on international collaboration) a survey is planned in order to understand any barriers in conducting CTs in different jurisdictions. The survey will focus on sponsors' expectations on sites' capacities / accreditations and enquire how parents/patients are involved in designing CTs, and to identify barriers in that arena. Initially, it is planned to approach only a small number of sponsors, to obtain clarity on wording/terminology and to potentially refine the survey before distributing it to a larger number of sponsors across the 5 regions. The selected companies would be of those global sponsors working also as stakeholders with Enpr-EMA. During the discussion it was suggested to include a question on whether industry's expectations differ depending on clinical trial types.
FDA request for information on establishing a rare disease clinical trial network	Gunter presented the topic: ○ FDA announced establishment of a rare disease clinical trial network and asked for comments/input from a wide range of stakeholders ○ It would be good to send an integrated Enpr-EMA feedback to FDA, apart from that every network is free to reply individually to FDA. ○ Deadline: 31 July 2020 • Donato presented some principles how this could be approached and expressed views of the TEDDY network. He highlighted the need of returning clinical trial data to study participants. He also mentioned the service for paediatric data interoperability that EPTRI is building in collaboration with ELIXIR. • Mark presented some principles to answer each of the questions listed by FDA. • Luca informed CG that ERNs have submitted a coordinated support action. • It was agreed to establish a drafting group to prepare a first document. • Pirkko proposed Mark to take the lead, and everyone interested should liaise with Mark • Donato, Luca (representing ERNs), Ruth, Pierre, Alessandro, Cecile, Hide, Segolene and Martine expressed interest in joining the drafting group.
Planning for workshop/meeting in autumn	• Date: 28 September 2020

Agenda	Minutes
• Logistical remarks • Topic suggestions	• Meeting will most likely be held virtually due to COVID-19.
CLOSED SESSION without industry observers	
Review of mandate of coordinating group	• Gunter presented proposals for minor updates e.g. on renewal of membership, on composition and representation within CG, to better reflect current situation. • The mandate will be circulated, and members should provide their comments by 31 July 2020. • Consolidated version to be presented to PDCO in September and then adopted at annual Enpr-EMA meeting later that month.
AOB • *Next CG teleconference*	After the annual meeting in September the next CG teleconference will be planned in Q1 2021. A Doodle poll will be sent to all members in due time.
End of meeting	