Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 03 March 2022; 14:00-15:30 CEST; By Webex

Chairpersons: Pirkko Lepola / Gunter Egger

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

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OPEN SESSION (all networks and observers)	
Adoption of agenda	The agenda was adopted without changes.
Update from WG on international collaboration • Clinical trial authorisation across jurisdictions - manuscript • Survey on requirements for paediatric trial sites	Thierry Lacaze provided an update of the working group, its members and ongoing activities. The working group has focused on two main topics, clinical trial authorisation across jurisdictions and site requirements/preparedness. <u>Clinical trial authorisation across jurisdictions:</u> The project explores the process needed for obtaining authorisation for the conduct of clinical trials in 6 jurisdictions: Europe, UK, US, Canada, Australia and Japan. Two manuscripts are being prepared to cover firstly the clinical trial authorisation process in relation to regulatory authorities, and secondly the ethics review processes. The aim of the manuscripts is to detail the differences between the jurisdictions and to highlight if improvements are being implemented in the processes (e.g. risk based approaches in Canada). The objective is to publish both manuscripts to serve as guidance for academic investigators and industry sponsors of multiregional trials. <u>Survey on requirements for paediatric trial sites:</u> The aim of this project is to define the criteria (by identifying a common set of requirements) that that international Pharma Industry or CRO sponsors of paediatric clinical trials require for a

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	potential trial site to be considered as appropriate for conducting paediatric clinical trials. A global paediatric site standard survey was launched in October 2021, targeted at pharmaceutical companies and CROs across the 6 jurisdictions. However, the response rate, 13 completed surveys, was lower than expected, mainly due to the length of the survey and due to potential data protection and confidentiality issues. To overcome these issues and to obtain a higher response rate, the survey has been shortened and information on the handling of the data has been added. It will be launched again in March, and it will be followed up with personal interviews between April and June. It is planned to present the data obtained from the survey at the Enpr-EMA meeting/workshop in the autumn.
Update from WG on research staff	Pamela Dicks, the chair of the WG, explained that the WG has welcomed new members and was resuming its activities after having been on hold during the peak of the COVID-19 pandemic in 2020/21. Previous activity included survey to investigate the role of research nurses and to identify the potential training needs, with the aim to promote and develop the research nurse role within Europe. In line with this activity Building on the previously identified need for training opportunities and for better establishment of the role of research nurses across Europe a new work plan is to survey clinical research nurses/coordinators in order to explore career pathways and development opportunities as well as employment conditions and to identify training needs and possible issues regarding the role. These objectives have been translated into 3 actions: • A survey being launched for EU research nurses focused on education, role and prospects. • Implementation of peer support activities, with the establishment of a membership, forum and collaborative activities with other networks (e.g. c4c). • Improving training opportunities by developing training packages and developing links with other networks (e.g. c4c).
EU initiative: Accelerating Clinical Trials in the EU (ACT EU): for better clinical trials that address patients' needs	IJsbrand den Rooijen (EMA) presented a new EU initiative, which aims to promote and optimise the environment for clinical trials in Europe. The ACT EU initiative was launched in January 2022, with 4 defined objectives: to support the conduct of large and multinational trials; to facilitate coordinated scientific advice to support trial authorisation, marketing authorisation and the medicine lifecycle;

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	to ensure a unified European approach for trial processes and strategic matters at the international level; and to engage all stakeholders in order to deliver inclusive patient-oriented medicines development and delivery across populations. These objectives have been translated into 10 actions planned for 2022 and 2023. ACT EU along with the Clinical Trials Regulation and CTIS will entail bigger and better clinical trials, innovation in clinical trial methodology, generation of data to understand and address health needs and the opportunity to engage through the multi-stakeholder platform.
Problem statement: Inclusion of paediatric patients in trials across countries	Begonya Nafria presented the difficulties encountered regarding European cross-border access to paediatric clinical trials and how these problems have been impeding the fulfilment of patients' rights in terms of access to clinical trials as declared in the Convention of the Rights of the Child, Belmont Report and the Helsinki Declaration among others. The main difficulties relate to the difference in languages in the European setting, which causes translation requirements for study documents such as the Informed Consent and Assent Forms and issues with the availability of validated scales and patient facing materials used within the clinical trials. A working plan proposal is made to: • Launch a survey process to the paediatric clinical trial networks across Europe, to analyse the state of art to identify situations in which language and/or other factors have been used as exclusion criteria. • Multi-stakeholder discussion to assess solutions. • Drafting of multi-stakeholder guidance for cross-border access to clinical trials based on recommendations and best practices. • Creation of an Enpr-EMA working group to assess the patients' rights in regards of the cross-border access to clinical trials in Europe.
Organisational and planning: Upcoming Enpr-EMA meetings, logistics and priority topics.	Members were informed of the upcoming Enpr-EMA meetings: • Virtual meeting of the Coordinating Group and Networks on 30th June 2022. • Annual Meeting in September/October (tbd). Currently planned as a 1.5-day face-to-face meeting, including 0.5-day workshop on the topic of site preparedness.
CLOSED SESSION (without industry observers)	

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N/A	*N/A*
AOB End of meeting	