EMA/385512/2019
Amsterdam, 4 July 2019

Minutes - Enpr-EMA Coordinating Group meeting

Date: 4 July 2019; 13-14.30 CET; via Adobe Connect

Attendees: Pamela Dicks, Tessa van der Geest, Wolfgang Goepel, Thierry Lacaze, Ruth Ladenstein, Tim Lee, Pirkko Lepola, Marek Migdal, Andrew Pearson, Christina Peters, Angeliki Siapkara, Cristina Seren, Mark Turner, Gareth Veal, Saskia de Wildt

Present (EMA): Gunter Egger, Irmgard Eichler, Isabel Perez

Apologies: Jose Drabwell, Gilles Vassal

Chairpersons: Mark Turner / Gunter Egger

Agenda	Minutes
Adoption of agenda	The agenda was adopted without changes.
Enpr-EMA's place in a changing environment: Strengths of the network Priority areas of activity	Members were asked for suggestions/wishes on Enpr-EMA's role in fostering paediatric research, driving research agendas, identifying needs and gaps. The following proposals were made: Challenging questions related to advanced therapy medicinal products (ATMPs) e.g. cell/tissue therapy: how the new cell therapy will change the currently available treatment armamentarium (e.g. in oncology: is it possible to substitute chemotherapy?); who is the owner of the patient's cells (the patients, universities, industry?) – a question which might be even more important for the paediatric population than for adults, as children might be in need for their cells/tissue in the future. Agreed action point: Christina Peters to prepare short problem statement as basis for potential discussion at face-to-face (F2F) meeting in October to define Enpr-EMA's role (e.g. raise awareness, organise multi-stakeholder meeting (e.g. industry regulators, academia, patients) with the objective to prepare European guidance)

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	In the cystic fibrosis field: increasingly children in Europe are recruited to trials that will support approval in the US but which will not support approval in the EU. Trials that will support approval in the EU follow later. This is followed by early authorisation in US and only later in Europe; thus European patients have delayed access to studies and new drugs despite having contributed to the trials that support early authorisation in the US. Question: is this problem specific to cystic fibrosis or similar experience in other therapeutic areas? Agreed action point: Tim Lee to prepare short problem statement with a few key questions which will be sent to all Enpr-EMA specialty networks, relevant European Reference Networks (ERNs) and potentially also learned societies/ paediatric specialty associations and the European Academy of Paediatrics (EAP) in preparation for a potential discussion at next F2F meeting Promoting Cohesion in the conduct of clinical studies among all EU member states as there are big differences in knowledge, standard of care, available resources, etc. among member states. Agreed action point: Ruth Ladenstein to prepare short problem statement, including experience/role of ERNs, in preparation for a potential discussion at F2F meeting on Enpr-EMA's role complementary to the ERNs activities. How to use existing data for updates of labelling information Agreed action point: Saskia to prepare problem statement as basis for a potential discussion at next F2F meeting
Update on F2F meeting in 4Q 2019	The F2F meeting with all networks, WG chairs and the Coordinating Group (CG) will be held on 14 October 2019, 11.00 - 16.00 at the EMA premises in Amsterdam, Sloterdijk.
Topics for F2F meeting	See proposals above; as the meeting will be shorter than usual in order to allow travelling to the meeting and back on the same day, a selection out of the above proposals might be needed to ensure most efficient use of available time and tangible outcomes.
Preparation for election of new Chair at F2F meeting	So far one expression of interest was received. All members of the CG were again invited to consider submitting their candidacy. Expression of interest should be submitted to the Enpr-EMA Secretariat not later than 30 September 2019 together with a brief statement in support of their candidature, which will be circulated to all members prior to the F2F meeting when the election will take place.

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	Mark Turner shared some thoughts about his time as chair of Enpr-EMA during the past 6 years. He expressed how much he appreciated the opportunity to come into closer contact with the Paediatric Committee (PDCO), getting to know in more detail the regulatory pathways, being invited to multi-stakeholder meetings organised by EMA with the opportunity to discuss paediatric issues, represent Enpr-EMA at various scientific meetings and having an active role in shaping paediatric research conditions.
Endorsement of new or updated applications for Enpr-EMA membership: Spanish Paediatric Clinical Trials Network (RECLIP) to represent RITIP and SAMID In prep: Irish Network for Children's Clinical Research to represent INFANT and NCRC	The update regarding representation of the Spanish networks within the CG was acknowledged.
AOB (potential topics) *Update on Conect4Children (C4C)* *Self-assessment form containing data protection published – For information* *Next CG teleconference*	Update on C4C: 18 national hubs have been established, 4 academic studies have been selected to prove viability of C4C; dialogue with other paediatric research initiatives has started in order to explore synergies and avoid duplication. *Next CG meeting will be at the F2F meeting; the next teleconference is planned for early 2020.* *A big thank you to Isabel Perez for all her hard work and support to the Enpr-EMA Secretariat in the past years and best wishes for her new position.*
End of meeting	