20 July 2015
EMA/366838/2015

Minutes of the seventh annual Enpr-EMA Members face to face meeting

29 May 2015, 09:00 – 12:30 UK time

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler (EMA)

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez

PDCO: Christoph Male

PCWP: Jose Drabwell

Enpr-EMA CG and Networks: Christina Peters, Tim Lee, Edina Stunya, Kalle Hoppu, Fernando Cabanas, Joana Claverol, Salma Malik, Eugene Dempsey, Mary Costello, Ettore Napoleone, Ivan Foedvari, Ruth Ladenstein, Edwin Spaans, Heike Rabe, Jonathan Grigg, Anne Junker, Alessandro Zuddas, Wolfgang Göpel, Adriana Ceci, Pamela Dicks, Pirkko Lepola, Gareth Veal, and Pascale Wenger

Industry Observer representing EFPIA: William Treem

Invited Participant: Florence Bosco

Apologies:

Angelika Siapkara, Nicola Rupperto, Evelyne Jacqz-Aigrain, David Dunger, Sylvie di Filippo, Saskia de Wildt, David Coghill, Nicholas Croft, Jenny Preston, Gilles Vassal, Carlo Giaquinto and Geneviève Michaux

	Item	Summary of discussion	Action
1	Outcomes pf the annual workshop and network's wish list for next year working plan	Summary of individual members' feedback: • The key focuses of the Enpr-EMA workshop from the networks' perspectives are on sharing networks experiences, structure, organisation, globalisation, study feasibility, building support and expertise. It is important to have a synergy for opportunities and scientific publications are strongly encouraged on this; it will also contribute to increase the visibility of Enpr-EMA to	Networks, EMA & Industry

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

	Item	Summary of discussion	Action
		external stakeholders. • Encountered issues by the networks should be brought to the attention of the PDCO within the legal and regulatory framework. • It is important to have more communication among networks between the Enpr-EMA meetings. • The break-out sessions of the Enpr-EMA meetings should focus more on concrete tasks. • It is important to have more industry representatives within the established Enpr-EMA WGs. Any industry representatives wishing to join any of the WGs, should email their intent to enprema@ema.europa.eu. • Industry needs to formalise their collaboration with the existing networks. There is also a need for more visibility of the achievements of Enpr-EMA to the eyes of industry: it is suggested to send a short (max 1 page) summary of last year's activities to EFPIA and EUCOPE. • There is a need for a sustainable educational training on paediatric clinical trials of the research staff within the network (and the EC representatives). The established GCP training WG should now be expanded to become a broader WG on educational training. New members have been nominated from the following networks: TEDDY, RIPPS, Newcastle –CLLG, IPCRN, ScotCRN. Discussion between new members of this broader WG is requested to happen so that a WG chair could be appointed asap. The chair of the current WG on GCP training does not wish to be chair of this newly broader WG. It is requested that the new chair, once appointed, provides the WG objectives and action points including deliverables and timelines, to enprema@ema.europa.eu, prior to next Enpr-EMA TC with the CG (October 2015).	
2	Welcome to new networks: • OKIDS GmbH • INFANT	The 2 newly registered Enpr-EMA networks were introduced to the other members of Enpr-EMA. It was clarified that INFANT has already built links with IPCRN (as members of the 2 Irish networks sit on a common Steering Committee), but these links need to be further formalised and enhanced.	N/A
3	Update on status of emerging networks: • Cardiology (Task Force of AEPC) • Endocrinology/ Diabetes (EUCADET)	• No new update since last TC of the Enpr-EMA CG group (21/01/15). • EUCADET had their first formal steering group meeting at the MRC in London in February 2015 and the launch of their website: www.eucadet.org. An application to the IMI-2 call translational approaches to disease modifying therapy of type 1 diabetes: an	N/A

	Item	Summary of discussion	Action
		innovative approach towards understanding and arresting type I diabetes (INNODIA) is under consideration: it will include funding to establish a clinical trials network for children with type I diabetes across Europe.	
4	Joint Enpr-EMA/ENCePP working group on paediatric pharmacovigilance: Interface between ENCePP and Enpr-EMA	• Keen networks wishing to conduct paediatric (Post-Authorisation Safety Studies (PASSs) are kindly requested to join ENCePP: www.encepp.eu • ENCePP centres with paediatric interest to share good practices in conducting PASS with keen Enpr-EMA networks once they have registered with ENCePP. • Presentation - Interface Enpr-EMA and ENCePP (Kevin Blake)	Networks
5	Overview of EMA registry strategy	• It was suggested that existing networks (e.g. ECAPN, ECFS-CTN) are included in the pilot phase (with 5 case studies of this EMA registry strategy). ECAPN and ECFS-CTN to liaise with EMA registry strategy staff to be included in the pilot phase. • It was suggested to that EMA staff overseeing the registry strategy makes contact with the Critical Path Institute, via the Enpr-EMA chair. • Presentation - European Union collaborative framework for patient registries (Jacoline Bouvy)	ECAPN & EMA
6	10 Year Report to the European Commission on the public health effects of the Paediatric Regulation: request for data collection from the Enpr-EMA networks	• A robust contribution to the 10 year report by network is essential to support the continued support of the Regulation. Clinical Research Networks may wish to work with colleagues in learned societies, professional groups etc. to show the benefits of the Regulation. • Questionnaire on input from the networks on the treatment/care guidelines will be amended to make reference to FP7 projects. It was confirmed that this questionnaire is related to medicines approved for children only. Non-approved medicines are outside the scope of this questionnaire. • Questionnaires on number of contacts each network has had with Industry re PIP trials only, input from the networks on the treatment/care guidelines, as well as additional free question on the conduct of paediatric clinical trials by the networks will be sent along with minutes of face to face members meeting, 29/05/15. • Networks are requested to complete questionnaires, with data collected from the period 2007-2015 for inclusion in the draft 10 year qualitative report to the EC on the	EMA EMA Networks

	Item	Summary of discussion	Action
		public health effects of the Paediatric Regulation. Completed questionnaires by networks need to be sent back to enprema@ema.europa.eu by 16/11/15 latest • Presentation - 10 year report to the European Commission on the public health effects of the Paediatric Regulation: request for data collection from the Enpr-EMA networks (Benjamin Pelle & Irmgard Eichler)	
7	Published summaries of PDCO opinions on agreed PIPs and waivers	• Networks who are not yet familiar with these public summaries are asked to look at them and provide feedback to enprema@ema.europa.eu • 2 questions were raised to EMA. ➢ Would it be possible to search by company name on the database of published PIP decisions? ➢ Would it be possible to have again the publication of the full annexes of the PDCO monthly reports (which stopped being published since May 2014) EMA Feedback on these questions will be provided to networks, whenever possible. Presentation - Public summaries of PDCO opinions on agreed PIPs and waivers (Irmgard Eichler)	Networks EMA
8	Experience on transition from paediatrics to adults within the same long-term clinical study or study with a long-term follow up: feedback and sharing best practices between Networks	• Networks are asked to scope out what is already published in terms of guidelines/guidance on the issue and send to enprema@ema.europa.eu so that they can be shared with all networks. MICYRN to share P3G best practices for research involving children and adolescents. • A further discussion on this issue will be scheduled at the next TC with the Enpr-EMA CG which should then adopt common practices, based on available/published guidelines on the issue.	Networks & MICYRN CG
9	Update on SPIRIT C and CONSORT C	• The aim of SPIRIT and CONSORT C is to standardise the way information is added to clinical study protocols and clinical data is reported in clinical study reports. • Checklist document is near final. An explanatory document is ongoing and should be published soon. Once available, these will be circulated to all networks. • Presentation - SPIRIT (Standard Protocol Items for Randomized Trials) and CONSORT (Consolidated Standards of Reporting Trials) (Irmgard Eichler)	EMA
10	Networks financial disclosure to collect data on source of network funding	• The WG on “interactions network-industry-regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible”, found that lack of transparency about the activities and funding of networks is a serious impediment to discussion about generic issues, discussions of clinical trials in isolation or	Networks

Item	Summary of discussion	Action
	groups and discussions about drugs. • As an outcome of the work delivered by the WG on interactions network-industry-regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible, every network is encouraged to publish on network's own individual webpages the completed and up-to-date network disclosure/funding source. They will not be published on the Enpr-EMA webpages. • Ideally, each network would identify the source of all money received from industry and the proportion of the network's funding received from industry. For some networks it is too complex for the coordinating centre of each network to report all industry funding to members of the network. Several networks are not legal entities and their accounts are not prepared separately from parent bodies. Funding received by networks for specific trials is usually on a fee-for-service basis and is passed through to sites or is received directly by sites. Furthermore many networks benefit from significant in kind contributions from individuals and sites. Accordingly, it is impossible to calculate the total income for some networks while for other networks, the proportion of monetary income from industry would not reflect the true position of the industry income in the network's activities. • The networks agreed that whenever possible, networks should identify the source of all money received from industry, the amount received each year and the proportion of the network's funding represented by each industry project. However, the minimum required for a network to contribute to discussions organised through Enpr-EMA (discussion with PDCO, e.g. through PDCO ORGAM TCs, or meetings convened by Enpr-EMA, e.g. about conditions, PIPs or drug classes) will be: ➢ A list of all sources of income to the coordinating centre that are unrestricted or designated to support the generic, infrastructure of the network; ➢ The amount received by the coordinating centre of the network for projects that are unrestricted or designated to support the generic, infrastructure of the network on unregistered non-specific projects; ➢ A list of all companies that have paid the networks or its sites to conduct studies about medicines or to prepare for studies about medicines (including Sponsors and intermediary	EMA & Networks

	Item	Summary of discussion	Action
		companies). • A standardised disclosure form will be prepared by EMA. This form, once completed, will be published on the network's webpages before any discussions organised by Enpr-EMA. • Presentation - Financial discloser on source of network funding (Irmgard Eichler)	
11	Conclusions and next steps	*Summary of action points (i.e. next steps)*: • Network's disclosure to be completed by coordinating centres of each network and published on networks' own webpages • Data (2007-2015) to be collected for the 10 Y report to EC on 2 indicators • Source of information/guidance on transition from paediatrics to adults to be shared among networks • Broadening of the GCP WG onto an educational training WG, new members appointed, chair TBA • Prepare a short (max 1 page) summary of last year's activities to be sent to EFPIA and EUCOPE • Next face-to-face meeting: 02 or 03/06/2016 (TBC)	Networks