



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2016
EMA/683953/2016
Human Medicines Research & Development Support Division

Minutes - Enpr-EMA Coordinating Group members meeting

Thursday 06 October 2016, EMA room 03-K and via Adobe Connect;
13.00 to 15.20 UK time

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader	Minutes
Open agenda			
13:00	Adoption of agenda	Mark Turner	The agenda was adopted without changes
13:05	Feedback on updated work plans and work progress from each Enpr-EMA WG	Irmgard Eichler / Mark Turner	Members of the working groups present during this meeting gave brief updates on the work done since the last face to face meeting in May.
13:40	Industry chosen topic: IMI 2 project	William Treem	Presentation Aim to build a pan-European paediatric clinical trials network. There was a multi-stakeholder workshop sponsored by the EC in April 2016.
13:50	Webinar on Enpr-EMA	John Watson	Presentation The objective of the webinar is to raise awareness for Enpr-EMA among SMEs and big pharma, 1 hour webinar scheduled for 24 November 2016. Gareth Veal and Kalle Hoppy to liaise with Mark Turner to prepare the joint presentation on what networks do and can offer. Post meeting note: The propose date is likely to be moved to December 2016 at the request of EUCOPE



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13:55	Update on - EMA guidance for organisation of multi-stakeholder meetings - networks' financial disclosure to collect data on source of networks' funding: Current status	Irmgard Eichler	It was discussed that networks whose financial disclosure is not made publicly available either on the network's website or by submitting the financial disclosure form to Enpr-EMA secretariat will not be able to participate at multi-stakeholder meetings. A reminder with this information to be sent to all networks.
14:05	Plan to establish Enpr-EMA WG on "Trial preparedness"	Mark Turner	Agreed to plan a multi-stakeholder meeting next year on this topic, building on outcome of the discussions at the EFGCP/DIA/EMA meeting in October; Potential deliverable "White paper"
14:08	Update on: - PDCO: how to work /communicate with networks - Update from networks to provide PDCO contact points - Update from networks re contact with learned societies	Mark Turner /Irmgard Eichler	FinPedMed, NIHR CRN-Children and RIPPS to present during the November 2016 PDCO plenary their work, what they can offer, how they differ from CROs. PRINTO (proposed date January 2017) will be invited to participate (via TC) to report on experience with obtaining data post-authorisation (PHARMACHILD study) PDCO to come up with list of questions they would like to have addressed by the networks during the October PDO meeting.
14:13	Update on PEDCRIN	Mark Turner	PEDCRIN will develop the paediatric capabilities of ECRIN, the European Clinical Research Infrastructure Network. PedCRIN has been awarded €3.3 million and will start work in January 2017.
14:20	How to prepare for the corporate response to public consultation of 10 year report on Paediatric Regulation	Gunter Egger/Mark Turner	Public consultation planned to start in November 2016 for a three-month period. Small task force to prepare first draft : call for volunteers; currently Mark Turner and Saskia de Wildt
14:25	Suggestions for 3 Enpr-EMA working group meetings 2017	Irmgard Eichler / Mark Turner	Trial preparedness, then one topic in one particular therapeutic area , e.g. RSV; other suggestions were antibiotics, oncology, rheumatology.

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14:35	Feedback on meeting with EUREC: how to train Ethics Committees on paediatric specific issues?	Pirkko Lepola	It was agreed to proactively approach EUREC and invite Dirk Lanzerath to a TC with participation of Mark Turner, Irmgard Eichler and Pirkko Lepola with any additional volunteers who are interested to discuss how collaboration could be further pursued; 2 areas proposed: • paediatric specific training for Ethics Committees members; • compilation of contact points/chairs of various national ethic committees among EU member states
14:45	Next Enpr-EMA CG and WG teleconferences to be scheduled in January 2017	Irmgard Eichler	Doodle poll to be sent for second half of January
Close agenda			
14:47	Propose topics for network specific slot in the annual f2f meeting without industry	Irmgard Eichler / Mark Turner	A dedicated slot to discuss among national networks to share best practices, funding models, organizational structures, etc... Kalle Hoppu volunteered to chair 1.5-(2) hour slot; proposed time: after open workshop on day 1.
14:52	Project: analysis of factors influencing successfully completed paediatric clinical studies.	Irmgard Eichler	A few additional aspects (e.g. change of sponsor/CRO) to be considered in the project planning were suggested.
14:57	Endorsement of newly received or updated applications for Enpr-EMA membership: • EAPRASnet (category 4) • NorPedMed (category 3)	Irmgard Eichler	Endorsement agreed; Need to clarify how NorPedMed as national Norwegian network is collaborating with the other Nordic countries listed in their self-assessment report
15:00	Revised self-assessment forms	Irmgard Eichler	Networks requested to submit their suggestions within 1 month in writing.
15:10	• Grouping of networks for joint representation within CG: RIPPS/ CICPed	Mark Turner / Irmgard Eichler	While broad participation is considered beneficial for sharing information, keeping a limited number of participants is more efficient for decision making.

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	Proposal: only have one annual f2f CG meeting and invite all networks as observers to the other 2 CG Teleconferences?		The proposal to split agenda into a section with topics for discussion and information to which all networks are invited and then one closed section for category 1 networks as per mandate of the CG. The proposal to be re-discussed among Co-chairs and finalized before adoption at next CG meeting in January. RIPPS currently representing French national networks will prepare minutes of this CG meeting to share with the other French national network CICPed.
15:15	Publishing updates on networks	Isabel Perez	Networks will be invited to submit their updates in a more harmonized structured format, limited to 1 page max which will then be published on the Enpr-EMA website annually.
15:20	End of meeting		

List of Category 1 Enpr-EMA registered networks (20 networks):

Type of network and therapeutic area of the network	Name of category 1 network
National and multispecialty	NIHR-MCRN FinPedMed MCRN-NL MICYRN ScotCRN CICPed RIPPS OKIDS DCRI
Oncology (solid / haematologic malignancies)	Newcastle-CLLG ITCC IBFMSG
Allergology / Immunology/ Rheumatology	PRINTO
Stem Cell and Organ Transplantation / Haematology (non-malignant) / Haemostaseology	EBMT
Respiratory diseases / Cystic Fibrosis	ECFS-CTN
Psychiatry / Neurology	EUNETHYDIS
Infectious diseases / Vaccinology	PENTA-ID UKPVG
Neonatology	GNN
Special Activities (pharmacovigilance, long-term follow up, community paediatricians)	FIMP-MCRN