

25 February 2015  
EMA/52510/2015

## Minutes of the Enpr-EMA Coordinating Group (CG) teleconference meeting

21 January 2015, 16:00 – 17:00 UK time

### Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez

Coordinating Group Members: Christina Peters, Wolfgang Goepel Anne Junker, Pirkko Lepola, Jose Drabwell, Kalle Hoppu

Industry observer: William Treem

Invited participant (emerging diabetes/endocrinology network): David Dunger

### Apologies:

Saskia de Wildt, Gareth Veal, Ettore Napoleone, Stephen Greene, Joachim Boos, David Coghill, Tim Lee, Andrea Biondi, Dirk Mentzer and Carlo Giaquinto

| Item | Summary of discussion                                                                                                                                                                                                                                                                                                                                | Action |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| 1    | Adoption of the minutes of last Coordinating Group teleconference on 24 October 2014<br><br>Adoption of agenda                                                                                                                                                                                                                                       | N/A    |
| 2    | Update on the Global Paediatric Clinical Trial Network <ul style="list-style-type: none"> <li>IMI 2 are considering whether to launch a tender for the European arm of a Global Paediatric Clinical Trial Network;</li> <li>Members of EFPIA will work on a proposed tender;</li> <li>The tender would be likely to be issued in Q3 2015;</li> </ul> | N/A    |

| Item | Summary of discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Action                   |
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|      | A proposal will build on existing structures, e.g. Enpr-EMA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                          |
| 3    | <p>Status update on new emerging networks:</p> <p>Cardiology</p> <ul style="list-style-type: none"> <li>No update. The task force of the AEPC will report at the next face to face meeting on 29/05/15</li> </ul> <p>Diabetes</p> <ul style="list-style-type: none"> <li>EUCADET (European Children and Adolescent Diabetes and Endocrinology Trials network): <ul style="list-style-type: none"> <li>Discussions with EFPIA led to some proposals being incorporated in an IMI-2 call on translational approaches to disease modifying therapy of T1DM. EUCADET was the highest ranking proposal and is now in negotiations with IMI2 and the Commission;</li> <li>Feb meeting to be held at MRC office with national representatives from endocrine/diabetes paediatric associations across Europe with the aim of establishing management of network structures; duration of the network will be for 7 years, with an obligation of conducting 1 to 2 clinical trials during that period;</li> <li>EUCADET is calling for established successful specialty networks to share their experiences in setting up/building up a specialty network. It was suggested that ECFS-CTN, PRINTO, PENTA could help. EMA will provide contact details from those networks to EUCADET.</li> </ul> </li> </ul> | Specialty Networks & EMA |
| 4    | <p>Topics to be discussed during the Enpr-EMA Workshop (28 May 2015): e.g.</p> <ul style="list-style-type: none"> <li>Updates on WGs</li> <li>Update on iKAN (Worldwide Involvement of Children in Clinical Research)</li> <li>Ways to fund involvement of children, young people and families in research</li> </ul> <p>The proposed topics for the annual workshop were agreed. The following additional topics were suggested and agreed:</p> <p>1) <u>Annual workshop</u></p> <ul style="list-style-type: none"> <li>Update on the Global Paediatric Clinical Trial Network (under the topic Business case and funding opportunities for clinical research networks ); A member from EFPIA or DG Research could be invited to report on IMI-2;</li> <li>Funding Young Persons Advisory Groups (YPAGs): operational model and resources needed; it was suggested to liaise with W.Chan (GRiP) and report on their best practices for creating aYPAG;</li> <li>Neonatology initiatives.</li> </ul> <p>2) Network meeting</p> <ul style="list-style-type: none"> <li>Transition of care from adolescents to adults clinics,</li> </ul>                                                                                                                                                            | EMA                      |

| Item | Summary of discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Action                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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|      | <ul style="list-style-type: none"> <li>• Collaboration with HCP organisations and need for GCP Training for network staff</li> <li>• Update on GRIP deliverables (and opportunities to incorporate new education, knowledge and products in research)</li> <li>• Business case and funding opportunities for clinical research networks</li> <li>• Update on Paediatric Regulation and its implementations (role of EMA, Ethics and implications for networks)</li> </ul> | <ul style="list-style-type: none"> <li>feedback from a patient's organisation and discussions;</li> <li>• Update on SPIRIT C and CONSORT C;</li> <li>• YPAGs as part of EU Patient's Organisations and initiatives with EMA/PDCO.</li> </ul>                                                                                                                                                                                                                       |
| 5    | <p>Endorsement of new or updated applications for Enpr-EMA membership</p> <ul style="list-style-type: none"> <li>• ECAPN</li> <li>• RIPPS</li> </ul>                                                                                                                                                                                                                                                                                                                      | <p>ECAPN will be registered as Category 3 network</p> <p>RIPPS will be upgraded as Category 1 network. Attendance of only 1 member representing French national networks at Enpr-EMA workshop and face-to-face meetings is however necessary. Agreement between RIPPS and CICPed and Enpr-EMA chairs for 1 member attending the meetings and 1 member being the alternate will be arranged.</p> <p>EMA</p> <p>Enpr-EMA chairs, RIPPS and CICPed</p>                |
| 6    | <p>SPIRIT C, CONSORT C</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p><u>SPIRIT</u> (Standard Protocol Items for Randomized Trials):</p> <ul style="list-style-type: none"> <li>• Introduced an evidence-based guidance that defines the key items to be addressed in trial protocols, with the aim of improving the quality of protocols and enables accurate interpretation of trial results;</li> <li>• Endorsed by large number of high-ranking peer-reviewed journals, research institutions, the Cochrane</li> </ul> <p>N/A</p> |

| Item | Summary of discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Action |
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|      | <p>Consumer Network and some pharma companies. Trials in children require additional and modified standards;</p> <ul style="list-style-type: none"> <li>• A paediatric specific extension of the checklist (SPIRIT-C) with additional and modified standards and guidance for the design and conduct of clinical trials in the paediatric population has been generated to cover the complexity of paediatric trials with the aim to improve the safety, use and impact of clinical research.</li> </ul> <p><u>CONSORT</u> (Consolidated Standards of Reporting Trials):</p> <ul style="list-style-type: none"> <li>• Standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting and aiding their critical appraisal and interpretation;</li> <li>• Will be extended (CONSORT-C) to highlight the key elements in the reporting of paediatric trials that differ from adult trials, to develop a checklist of essential items that authors should include when reporting the main results of paediatric clinical trials with the aim to improve quality of information reported from paediatric trial.</li> </ul> |        |
| 7    | <p>PDCO class waiver list review</p> <p>PDCO is conducting a review of the list of Class Waivers (CWs) for 46 diseases for which applicants are exempted to submit an application for a PIP or waiver. This review is aimed at revoking, revising or confirming the existing CWs. During the review process, input on the scientific justifications, would be very welcome, from the Enpr-EMA networks specialised in the following areas:</p> <ul style="list-style-type: none"> <li>• Neurology</li> <li>• Cardiovascular diseases</li> <li>• Metabolism</li> <li>• Oncology</li> </ul> <p>However, it is expected that the timeframe for the network to provide input/comment on the scientific justifications may be short. EMA will send further information shortly.</p>                                                                                                                                                                                                                                                                                                                                                                                              | EMA    |
| 8    | <p>Next Enpr-EMA CG meeting: face-to-face meeting at EMA on 29 May 2015</p> <p>The potential need for an additional meeting via T-conference to prepare the annual Enpr-EMA workshop was mentioned.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | N/A    |

| Item | Summary of discussion                                                                                                                                                                                                                                                                                                                                                                                 | Action |
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| 9    | <p>A.O.B</p> <p>Timeframe for publication of the minutes of Enpr-EMA CG meetings and teleconferences: the CG endorsed the proposal to expedite the publication of the CG meeting minutes to improve transparency and visibility: after each CG meeting/TC CG-members will have 2 weeks to comment on the draft minutes, which then will be adopted and immediately published on Enpr-EMA webpage.</p> | EMA    |