



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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Report on first workshop on a European Paediatric Research network, 16 February 2009 **EMEA**

The EU paediatric regulation calls for the fostering of high-quality, ethical research on medicinal products to be used in children. To achieve this objective, the EMEA is responsible for developing a European paediatric network of existing national and European networks and centres with specific expertise in research and clinical trials relating to paediatric medicines.

On 16 February 2009 the EMEA convened a one-day workshop to discuss and initiate the development of this European paediatric network. Following a call for expression of interest, 38 networks and/or clinical trial centres have been identified. These networks were represented by 61 participants. In addition, the European Commission, the Clinical Trials Facilitation Group and the European network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) were represented. The meeting was co-chaired by the Vice-Chair of the Paediatric Committee (PDCO) and EMEA.

In the first morning session, participants were reminded of the European Paediatric Regulation and the objectives of this EMEA European network, and the role of the Paediatric Committee (PDCO). The link with the paediatric investigation plans, the extent of clinical trials proposed and the wide range of therapeutic areas addressed so far by the PDCO were highlighted, as it is expected that the network will be involved in performing the trials requested by the Paediatric Investigation Plans.

In the second morning sessions the proposed organisation and structure of the future European paediatric network were presented as laid out in the Implementation strategy, adopted by the EMEA Management Board following a large consultation process. This was followed by presentations of three existing but different networks: the “Medicines for Children Research Network” in the UK (MCRN-UK) (one of the national networks), the “PENTA foundation” for the treatment and care of children with HIV (one of the specialists’ networks) and the “Task-force in Europe for Drug Development for the Young” (TEDDY), a network funded by the Framework Programme, which does not perform any trial. Representatives from these three networks reported on their experience and made suggestions for quality standards and recognition criteria to be fulfilled by networks which intend to become a member of the future EMEA “network of networks”.

After the scene-setting presentations of the morning sessions two break-out sessions were held in the afternoon to brainstorm and discuss the possible structure and operational model for the European network as well as communication strategies (group 1), and quality standards and recognition criteria (group 2).

Group 1 discussed the composition of the future “Coordinating Group” as proposed by the implementation strategy. The participants of this break-out session concluded that the coordinating group should aim at being as diverse as possible, representing various types of networks: networks focusing on specific therapeutic areas, networks covering specific needs/age subsets (e.g. neonatal /adolescent networks) or specific activities (e.g. pharmacovigilance), and organisational networks (e.g. national networks linking together either several clinical trial centres or community paediatricians) to cover all areas of paediatric research. It was discussed that clinical trial centres are usually more interested in phase I-III studies whereas a network able to mobilise community paediatricians would be more appropriate for the conduct of long-term follow-up, phase IV studies.

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In addition, it was discussed that the composition of this steering group should also accommodate for regional differences throughout Europe with regards to how the medical care of children is organised. As the Coordinating Group is limited to 20 people, networks will have to federate and agree on common delegates.

There was consensus that

- the acquired experience of a national or international network and its representatives should be a main criterion,
- cross-fertilisation with other specialties/networks would be useful and should be encouraged.

With regards to communication, the need and importance for external communication with all stakeholders (industry and patients' organisations) was stressed. Relating to internal communication some participants reported from their experience that in addition to time-saving communication ways, such as e-mails, telephone and/or videoconferences, at least one or two meetings per year, inviting all members, proved to be helpful and were highly appreciated to overcome potential misunderstandings due to language barriers and different cultures across Europe.

It was suggested that networks might consider inviting other networks to their regular meetings to improve cross-fertilisation between individual networks. The representative from the European Academy of Paediatrics, offered to host meetings for all networks.

Most networks indicated the willingness to participate in a "paediatric network implementation working group". (Working Group 1).

Group 2 was tasked to define "recognition criteria". Proposals for recognition criteria included:

- Capacity to involve patients from both the design point of view and the recruitment
- Expertise in the therapeutic area
- Capacity to manage trials and to perform according to GCP
- Capacity to build up competence and involve further centres
- Capacity to innovate in trials (e.g. methodology, use of microassays)
- Established quality assurance of the network
- Potential conflicts of interest

Some participants commented that recognition criteria should not rely only on already *conducted* trials or past performance, so as not to exclude new networks, in the process of being established.

After a vivid discussion it was concluded that at present it is too early to agree on "recognition criteria". It was considered necessary to first precise the goals of the European network and the topics on which networks want to work together.

It was felt, that the European network should provide added value that is to be able to share competences and experience. Again, this requires specifying what competences are necessary. It was agreed that as a first step all networks should summarise the competences they have to inform others with a view to establishing necessary partnerships. The inventory of competences will be made public by the EMEA.

In break-out session 2 some participants were not in the position to nominate volunteers for the "recognition criteria working group" (working group 2) as they first have to consult within their network.

The second part of the afternoon session was dedicated to reporting back on the outcome of the two break-out sessions.

Additional comments were made from the audience relating to recognition criteria

- to include the willingness of networks to cooperate with other networks
- to avoid excluding smaller networks with the capacity to improve further.

The following further actions have been agreed:

- all networks are invited to check the information, to summarise their competences and send it to the EMEA
- to propose representatives for the two working groups.

Once established

- working group 1 will continue elaborating on the structure and operational model for the European network as well as communication strategies.
- working group 2 will continue working on the definition of quality standards and recognition criteria.

In approximately 6 months it is expected that both working groups should present their deliverables.

- Concerning the recognition criteria, once agreement is reached, these should be published on the EMEA web-page to enable individual networks to publish their self-assessment.

In summary, the workshop was well attended and very interactive. Participants were highly motivated and interested in further collaboration. The workshop was well received by the participants, expressing the wish for a follow-up meeting in about 6 months.

Please note:

All presentations will be sent electronically to all workshop participants together with a list of participants and the networks. Presentations will be placed on the EMEA website (unless the author objects).

Participants are asked to check their contact details and to add 2 or 3 main competences of their network, for further publication.