



The Network of Paediatric Networks at the EMEA
Draft Implementing Strategy
(for public consultation until 20th August 2007)

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I INTRODUCTION

This document intends to fulfil the Agency’s obligation to develop a European paediatric network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population. This obligation was created by Article 44 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended, hereafter the Paediatric Regulation.

II BACKGROUND

1. Legal basis

The legal basis for the development of a European network is set out in the Paediatric Regulation in Recital 3 and Article 44.

Recital 3:

“Clinical trials in the paediatric population may require specific expertise, specific methodology and, in some cases, specific facilities and should be carried out by appropriately trained investigators. A network linking together existing national and European initiatives and study centres in order to build up the necessary competences at a European level, would help facilitating co-operation and avoiding duplication of studies. This network should contribute to the work of strengthening the foundations of the European Research Area in the context of Community Framework Programmes for Research, Technological Development and Demonstration Activities, benefit the paediatric population and provide a source of information and expertise for industry.”

Article 44:

“1. The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.

2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products, to build up the necessary scientific and administrative competences at European level, and to avoid duplication of studies and testing in children.

3. Within one year of the entry into force of this Regulation, the Management Board of the Agency shall, on a proposal from the Executive Director and following consultation with the Commission, the Member States and interested parties, adopt an implementing strategy for the launching and operation of the European network. This network must, where appropriate, be compatible with the work of strengthening the foundations of the European Research Area in the context of the Community Framework Programmes for Research, Technological Development and Demonstration Activities.”

Additionally, Article 6 includes a task for the Paediatric Committee:

The tasks of the Paediatric Committee shall include the following:

(f) to support and advise the Agency on establishing the European network referred to in Article 44.

2. Definition of a network

A network is a virtual structure defined by a formal agreement between individuals, organisations or structures sharing and collaborating towards the same objectives, goals and quality standards.

3. Basis for the current proposal

Following an initiative from a group of academics aware of the future Regulation, the Agency hosted in 2005 and 2006 a number of meetings with representatives of existing or developing paediatric networks. The Agency strived to invite representatives of all existing networks to attend these meetings. Members participated on a voluntary basis and did not receive any compensation from the Agency. The discussions resulted in the identification of additional networks, and a proposal for a mandate and more detailed objectives for the future European Network. The proposed implementing strategy is largely based on the outcome of these discussions.

4. Existing paediatric networks

In parallel to the meetings held at the EMEA in 2004 and 2005, an informal inventory has identified that many different paediatric networks exist in the Community, or are under construction. They can be identified as:

- national networks, generally benefiting from public funding (at present 7 national networks have been identified),
- European networks publicly funded, such as TEDDY (Task Force in Europe for Drug Development of the Young) which is funded through the 6th Framework Programme,
- paediatric ‘sub-speciality’ networks at European level and beyond, which group centres working in the same therapeutic area (e.g. HIV infection, rheumatology),
- age-related networks (e.g. neonatal networks),
- activity or structure-related networks (e.g. community-practitioners networks, hospital-based dedicated clinical-research centres linked by a common structure, pharmacovigilance networks)
- networks including paediatric centres but not dedicated solely to paediatric research.

5. Stakeholders of the future network

In addition to the members of the European network, the stakeholders or interested parties include:

- Patients, parents and families, and patients’ organisations
- Paediatric and other relevant learned societies
- Academia
- National Competent Authorities (for authorisation of trials or medicines authorisation)
- Ethics Committees (and Investigational Review Boards)
- Pharmaceutical industry
- Medical devices industry
- Clinical Research Organisations
- Hospital pharmacists
- Laboratories and imaging centres

6. Proposed consultation process

The legislation provides for consultation on the implementing strategy with the Commission, the Member States and interested parties. In order to meet the requirements and timelines of the Paediatric Regulation, the following consultation process is ongoing:

1. Consultation of existing networks (since 2005)
2. Consultation of Member States and the public, in particular patients via patients’ organisations, and industry via trade organisations (1st July – 20th August 2007)
3. Consultation of the Paediatric Committee at the EMEA (1st – 2nd meeting)
4. Consultation of the Commission (September 2007)
5. Submission to the Management Board (4th October 2007)

According to the Paediatric Regulation, the Management Board should approve the implementing strategy for the launching and operation of the network before 26 January 2008. The draft implementing strategy will be presented at the October Management Board meeting with final discussion and adoption during the December 2007 meeting (i.e. the last meeting before the legal deadline).

III PROPOSED IMPLEMENTING STRATEGY

The implementing strategy presented here determines objectives (including long-term), organisation and structure, action programme, priorities, resource allocation, and monitoring of the outcomes and performance of the network. Its strategic goals are the milestones the network aims to achieve, according to the strategy, and are translated into specific performance targets.

1. Objectives

1.1 High level objectives

One of the high level objectives of the Regulation is to foster high quality ethical research on medicinal products to be used in children. Research is aimed at demonstrating the quality, safety and efficacy of

medicinal products and their formulations. This should be achieved through efficient inter-network and stakeholder collaboration. The benefits of a European network of paediatric research include, but are not limited to building up and strengthening complementary scientific, technical and/or administrative competences in the performance of paediatric clinical trials through effective collaboration. They also include avoiding duplication of work and efforts, making the use of facilities more efficient and profitable, developing common methods of working with special attention to quality assurance.

Additional benefits are the facilitation of recruitment of patients, and avoiding unnecessary studies in children.

Finally the EU network aims at strengthening the foundations of the European Research Area by promoting European Commission framework programme applications.

The network is not intended to perform trials, or to decide on areas of paediatric research, which is under the responsibilities of the Member States, of the Commission through the Community programmes, or of each individual network. The network will not fund studies or research. The EMEA will ensure collaboration through a secretariat.

1.2 Detailed goals of the network

The short term and long term goals of the network encompass:

Collaboration:

- Identify, co-ordinate and link together existing networks
- ensure efficient, timely communication and exchange of information between networks
- be a source of information and expertise for health professionals
- provide a forum for scientific discussion related to paediatric clinical trials with all stakeholders, where necessary

Building competences:

- define scientific and operational quality standards, and accreditation criteria for the purpose of the operation of the network and not yet covered through existing quality standards (e.g. GCP)
- develop and agree training and education curricula and provide training to network partners
- stimulate the development of new networks, centres and investigators
- organise and hold scientific meetings to discuss specific topics as identified by the Steering Committee
- stimulate research and educate on trial methodology

Avoiding unnecessary studies:

- avoid duplication of clinical trials in children by sharing information with European as well as international partners, in particular through the use of EudraCT,
- develop multidisciplinary research partnership

Stimulating high quality research

- raise awareness on the need for clinical trials for children and increasing understanding of the purpose of research
- advocate for ethical clinical research

Strengthening the foundation of the European Research Area:

- support the identification of research priorities into off-patent medicines
- develop off patent medicines for children
- stimulate research in areas of relevance such as trial methodology or assays

Facilitation of recruitment in clinical trials:

- enable rapid attainment of sample sizes large enough to allow valid conclusions; this is especially relevant and crucial for paediatric trials.

2. Proposed organisation and structure

2.1 Network level

A resource-saving structure for the operation of the network needs to be established at the EMEA. It is proposed to create a 'Steering Committee' which will contribute to the short and long-term strategy of

the network, discuss and solve operational and scientific issues for the network, report to the Paediatric Committee and act as a forum for communication.

The Steering Committee should consist of the following members and should not exceed 30 members in total:

- 1 representative per accredited network (networks may have to group themselves to be represented once the maximum number has been reached)
- 3 members of the Paediatric Committee
- 1 representative of the European Commission (namely DG Research)
- 2 EMEA representatives

- Additional members following a decision of the Steering Committee to bring additional expertise needed for its operation (e.g. patients' representatives, Ethics Committee representative)

Finally the Steering Committee should establish strong links with the Clinical Trial Facilitation Group (CTFG) to develop a common understanding and improvement of processes.

Membership of the Steering Committee is for 3 years only, to ensure sufficient renewal and involvement of various members.

Representatives of networks under construction or still in the accreditation process may attend as observers. Other participants may be invited to discuss specific issues on an ad-hoc basis, including representatives of stakeholders.

The Steering Committee is set up in 2 steps. During the construction phase of the Network, members work together on an informal basis. After agreement of quality standards and self-accreditation according to these criteria by the participating networks, the Steering Committee is formally established with members from accredited networks.

Meetings of the Steering Committee take place usually 3 times a year. In addition, it is planned that a workshop should be held on a yearly basis, open to all network participants.

2.2 EMEA level

Secretarial support to the activities of the network and the organisation of the meetings of the Steering Committee and workshops are provided by the EMEA. Support is focussed on the coordination of exchange of information between the network partners, providing information to external partners and stakeholders, and facilitating the work of the Steering Committee to ensure the objectives are met.

Members of the Paediatric Committee are involved in the Steering Committee to advise on scientific issues and on the future strategy of the network. The Steering Committee reports to the Paediatric Committee on a regular basis. The Paediatric Committee will act as the Scientific Committee of the network.

3. Proposed Action Programme

3.1 Timelines for launching and implementing

The network will be launched in 2008 once the strategy has been adopted by the Management Board. For 2008, the definition of quality standards and accreditation processes are the first priority. The Steering Committee will agree the other priorities for further implementation.

3.2 Deliverables according to the defined objectives

Collaboration:

Necessary communication facilities such as meetings, and workshops with stakeholders (patients, industry, CRO's),

Network website

Information source

Building competences

Definition of quality standards by the participating networks for expertise, infrastructure, transparency and quality assurance systems

Self certification (accreditation)

Training for network partners

Harmonisation of standards, procedures and processes

Training and education curriculum development

Avoiding unnecessary studies

Inter-network communication tools

EudraCT search capabilities

Joint research projects

Stimulate high quality research

Provision of information

Use of inter-network communication tools

Strengthening the foundation of the European Research Area

Identification of research priorities from networks

Provision of information on applications for EU framework programmes

Facilitation of recruitment

Information to patients' organisations on open recruitments into clinical trials

4. Resources

The main concern is to avoid creating a resource-intensive structure replicating existing bodies and generating potential overlap of activities and responsibilities. The network's human and financial resources should remain extremely limited.

The EMEA will act as a facilitator and a service provider in particular to ensure communication between networks and external partners. The EMEA will organise and host meetings. The EMEA will cover travel and accommodation expenses for the Steering Committee meetings and provide financial support for the open meetings with stakeholders (e.g. to patients' organisations).

5. Performance Monitoring / Progress Indicators

The successful implementation of the network strategy will be monitored using measurable outcomes. These should follow the timelines for the implementation of the agreed objectives.

Progress indicators may include:

- Number of meetings of the Steering Committee
- Number of workshop with stakeholders
- Reaching agreement on quality criteria
- Number of accredited networks in the first phase
- Number of new networks developed
- Number of new networks joining the EMEA network per year
- Number of training meetings
- Total number of trials performed through the network per year
- Number of industry studies conducted through the network
- Use of network for studies into off-patent medicinal products
- Age groups of children included in the trials
- Acceptance and use of EudraCT information by the network
- Identification of new measures to avoid duplication of trials

Further indicators may be developed with experience.

EMEA/295594/2007