

European Paediatric Network

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Objectives of the European network

Why are you here?

What is it all about ?

Paediatric Regulation

Objectives:

Improve the health of children

- Increase high quality, ethical research into medicines for children
- Increase availability of authorised medicines for children
- Increase information on medicines

Achieve the above

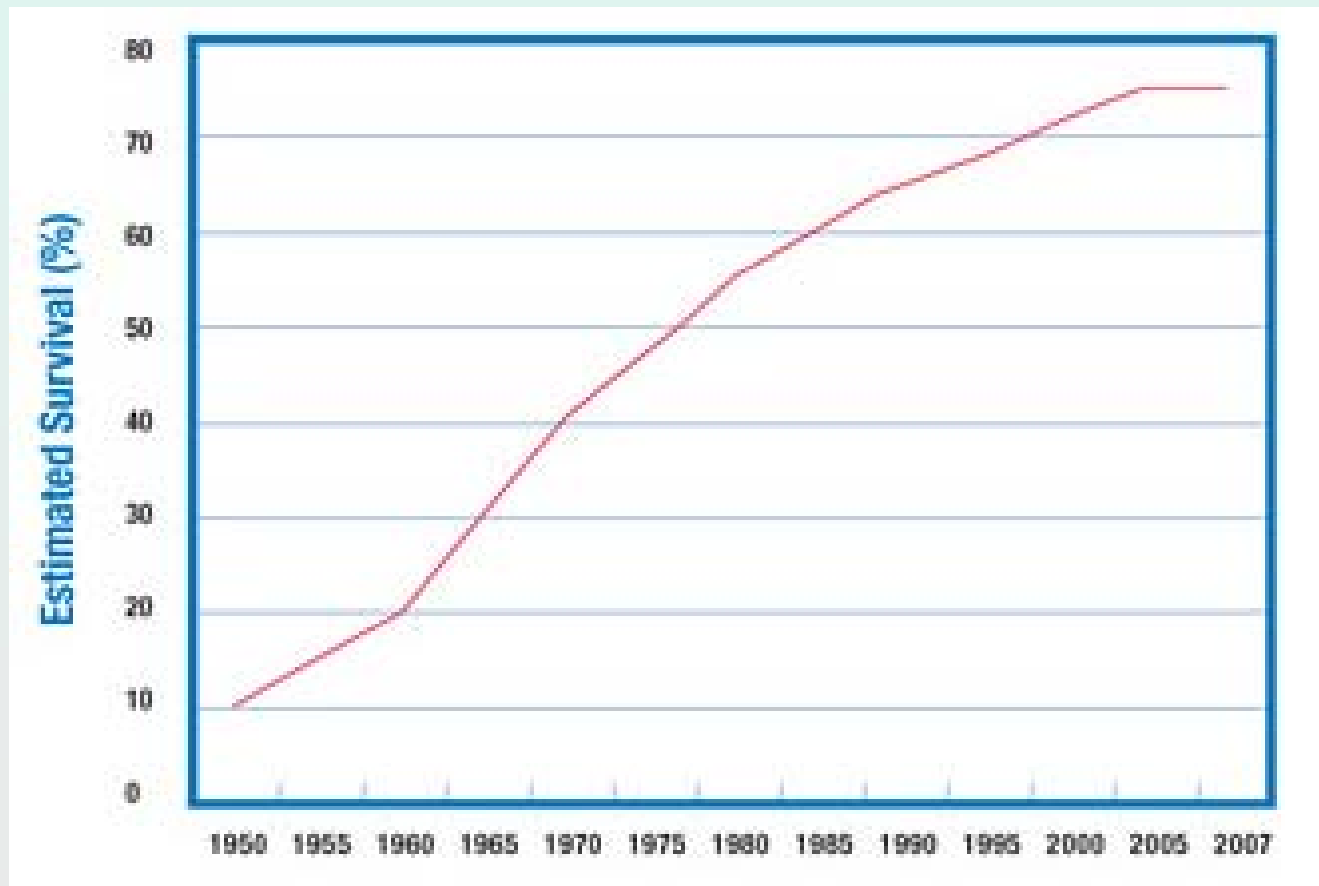
- Without unnecessary studies in children
- Without delaying authorisation for adults

Entry into force 26 January 2007

**Increase high quality, ethical research
into medicines for children**

WHY?

Impact of clinical trials with children: paediatric cancer survival rates



Data from St. Jude Children's Research Hospital
http://www.stjude.org/Images/hosp-msc-survival_rates-0804

**Increase high quality, ethical research
into medicines for children**

HOW ?

European Paediatric Network

Legal basis



European Paediatric Regulation:

1. “The EMEA 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.”

European Paediatric Network

Legal basis



2. “The objectives of the European network shall be
- to coordinate studies relating to paediatric medicinal products
 - to build up competence at a European level
 - to avoid unnecessary duplication of studies and testing in the paediatric population.”

Key operational goals

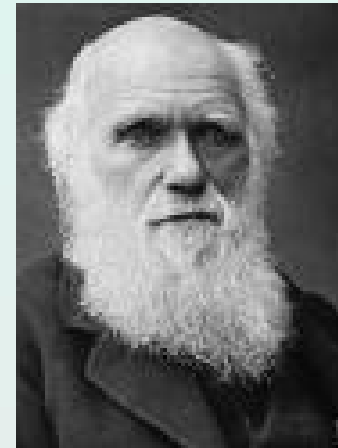
- To link together existing networks
- To provide infrastructure for industry to conduct studies in children
- To define consistent and transparent quality standards within the European network
- To harmonise clinical trial procedures
- To define strategies for resolving major challenges
- To communicate with external stakeholders

European Paediatric Network



What it is not

- an “exclusive club”
- survival of the fittest
- competition
- a funding body



BUT

- a platform for
 - collaboration
 - exchange of experience
 - optimising available resources

Role of EMEA

- to provide secretarial support to the activities of the network
- to organize and host meetings of the network
- to coordinate exchange of information between network partners
- to provide information to external partners and stakeholders
- The EMEA does not decide on recognition

What you can gain?

Potential benefits

- to present your network - at a European level
- to be visible as potential site(s) for industry-sponsored studies (requested by PDCO)
- to save resources by sharing work
- to share skills and expertise of other networks
- to shape and influence future development in paediatric research
- to access information and procedure of application for EC framework program

What are you expected to achieve today?

- To come to know each other
- To discuss and set up draft criteria of inclusion for networks to join the European network
- To discuss and agree on a draft operational model and draft structure of the network within the frame of the 'Implementation Strategy'
- To discuss efficient communication between networks

You are invited to form two working groups to elaborate:

- 1 next steps for implementation of the network
- 2 recognition criteria

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Discussion slides

Objectives European Network

- To link together existing networks
- To facilitate conduct of clinical trials in children
 - at European level
- To coordinate conduct of paediatric trials between national and European networks
- To provide information, expertise and access to infrastructure for industry to conduct high-quality studies in children

Objectives European Network

- To ensure effective coordination and communication between individual networks, investigators and paediatric clinical trial centres
- To set up criteria of inclusion for networks, investigators and paediatric clinical trial centres to join the European network
- To stimulate and facilitate the development and integration of new national networks and trial centres

Objectives European Network

- To define consistent and transparent quality standards within the European network
- To harmonise clinical trial procedures (SOP's, documents, data management, monitoring, training curricula, etc.) - at European level
- To define strategies for resolving major challenges of paediatric clinical trials (insurance, divergent Ethic Committee positions, lack of paediatric expertise, etc.)
 - at European level

Objectives European Network Proposal

- To prepare relevant Guidelines
- To be a forum for discussion on all aspects related to the conduct of paediatric clinical trials at a European level for National Networks, Patient Organisations, Ethics Committees and pharmaceutical industry
- To raise awareness on the need for clinical trials for children
- To increase understanding of purpose of research
- To collaborate with patient's organisation
- Collaboration with NIH / WHO

Objectives European Network Conclusion

- To improve the coordination and quality of paediatric research into medicinal products in Europe by
- coordinating ethical and high quality paediatric studies of medicinal products