

The role of the Paediatric Committee and short history of previous activities

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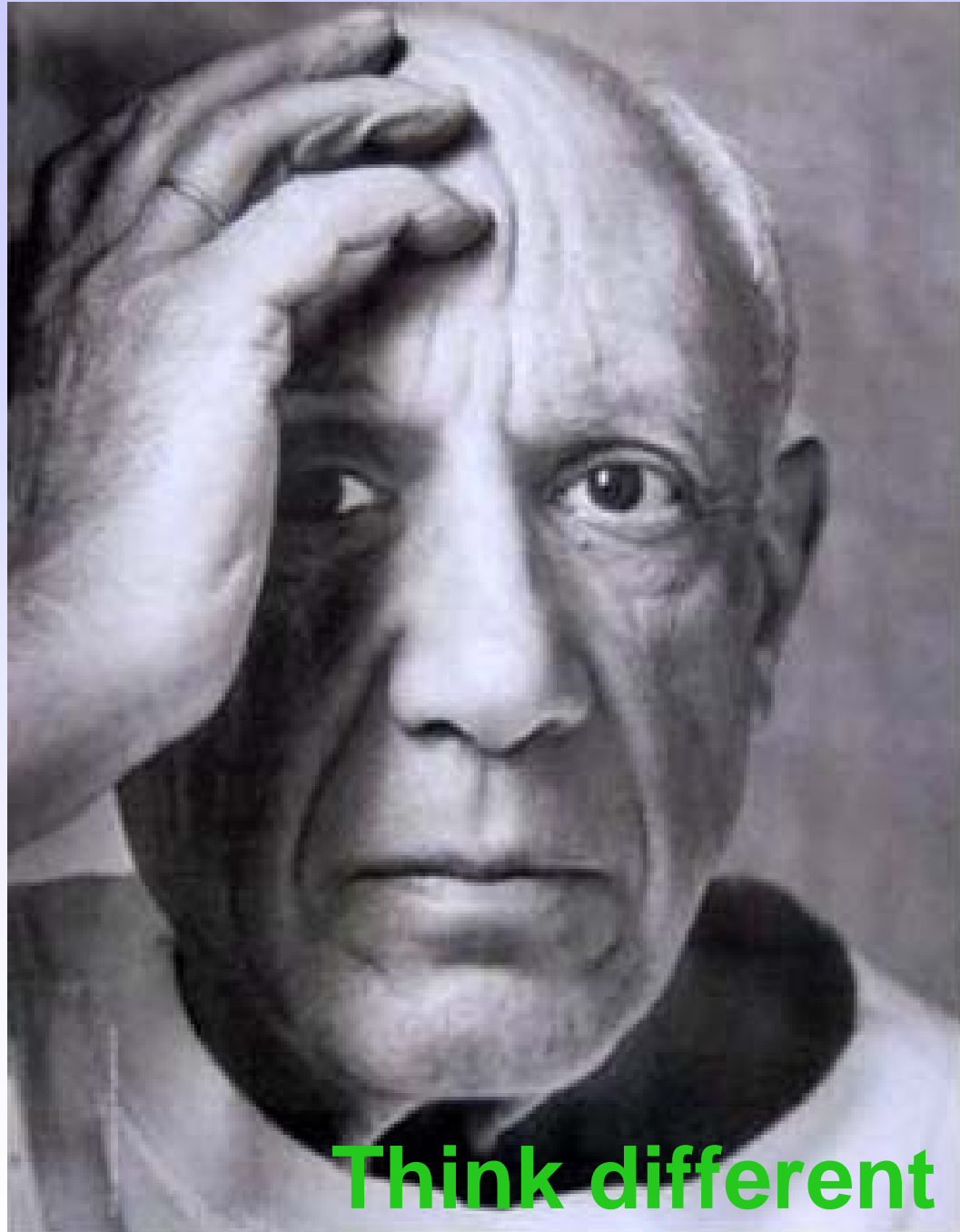
Children's Hospital Bambino Gesù

Rome, Italy

1st EMEA Workshop on European Paediatric Network

EMEA, London 16 February 2009





Think different



Agenda

- **The role of PDCO**
- **PEG**
- **EU Paediatric Network**

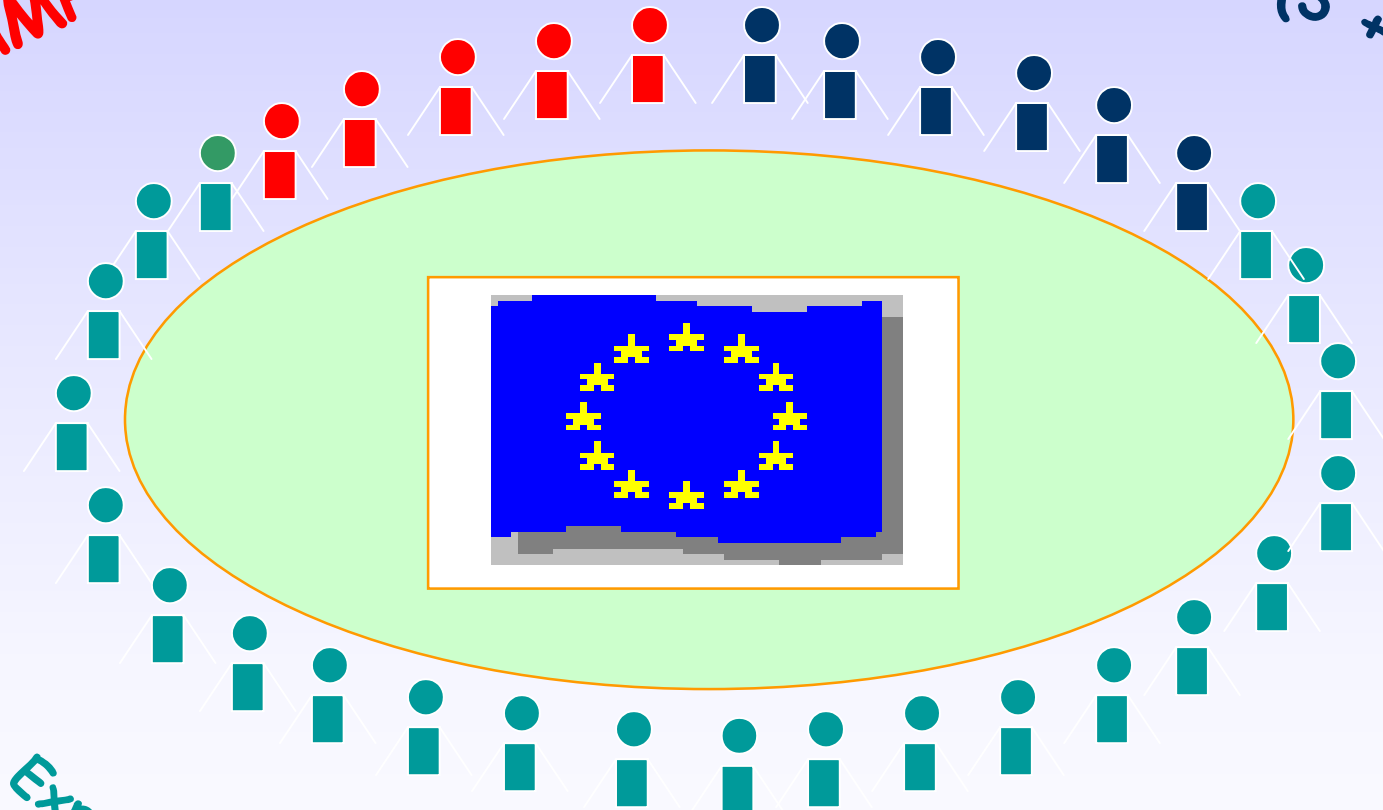
Outline

- **The role of PDCO**
- **PEG**
- **EU Paediatric Network**

Paediatric Committee - PDCO

CHMP members (5)

Patient/family and health professionals (3 + 3)



Experts from National Competent Authorities (22) + 2 EEA



Main roles of PDCO

- Opinions on **PIPs** and **Deferrals, Waivers**
- Opinion on compliance with PIP
- Opinion on Quality, Safety and Efficacy on request from CHMP (marketing authorisations, scientific advice)
- Other task:
 - **Survey** format and content and **Paediatric Needs**
 - **Network(s)** ←
 - Eudra CT

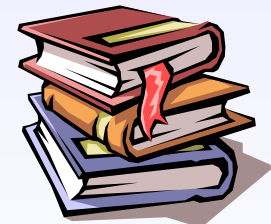
Paediatric Investigation Plans

- Details of timing and measures proposed (i.e studies, trials and pharmaceutical development) necessary to obtain a paediatric indication with an age appropriate formulation in all paediatric subsets affected by the condition

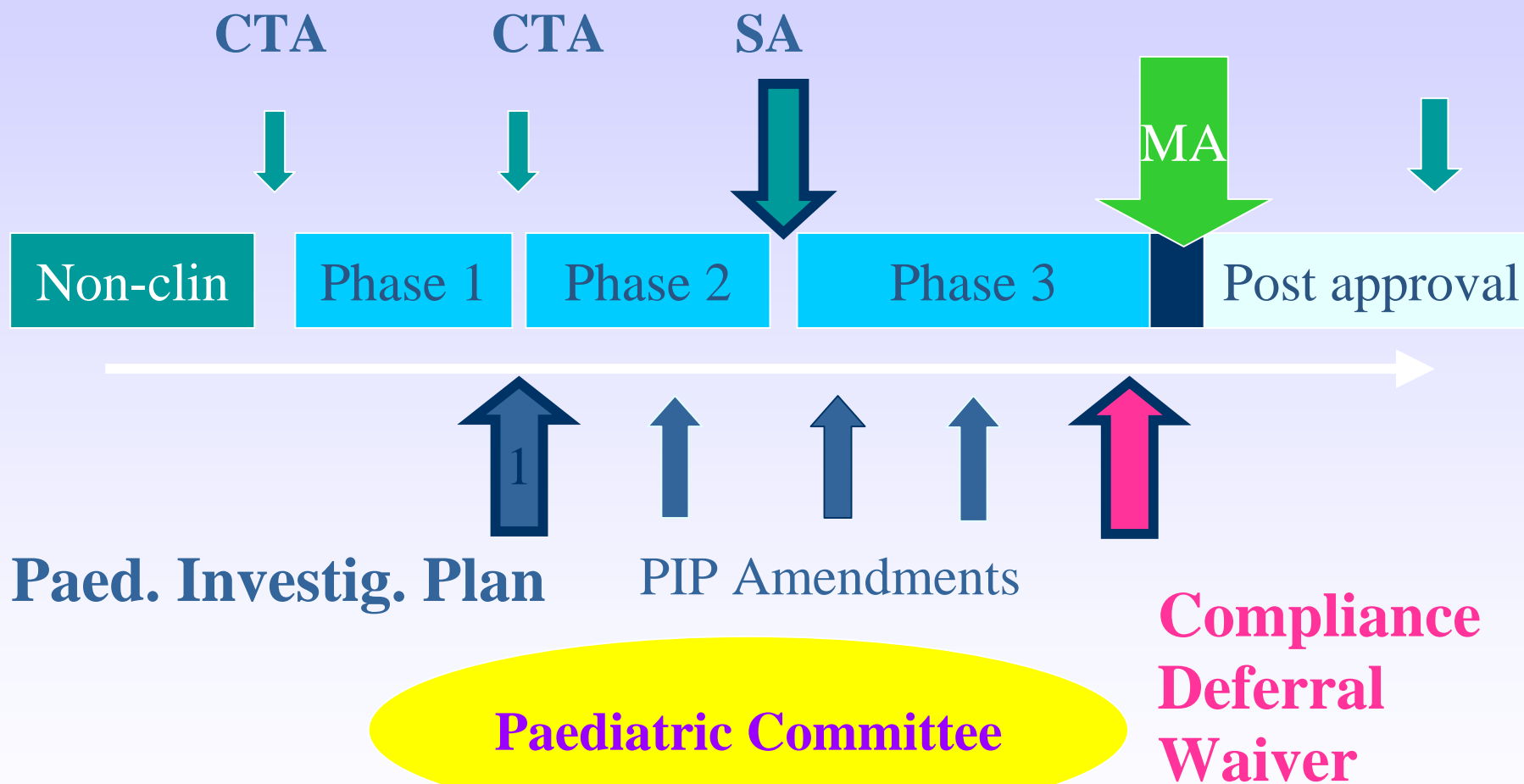
- Quality
- Safety
- Efficacy



**Marketing
Authorisation
criteria**

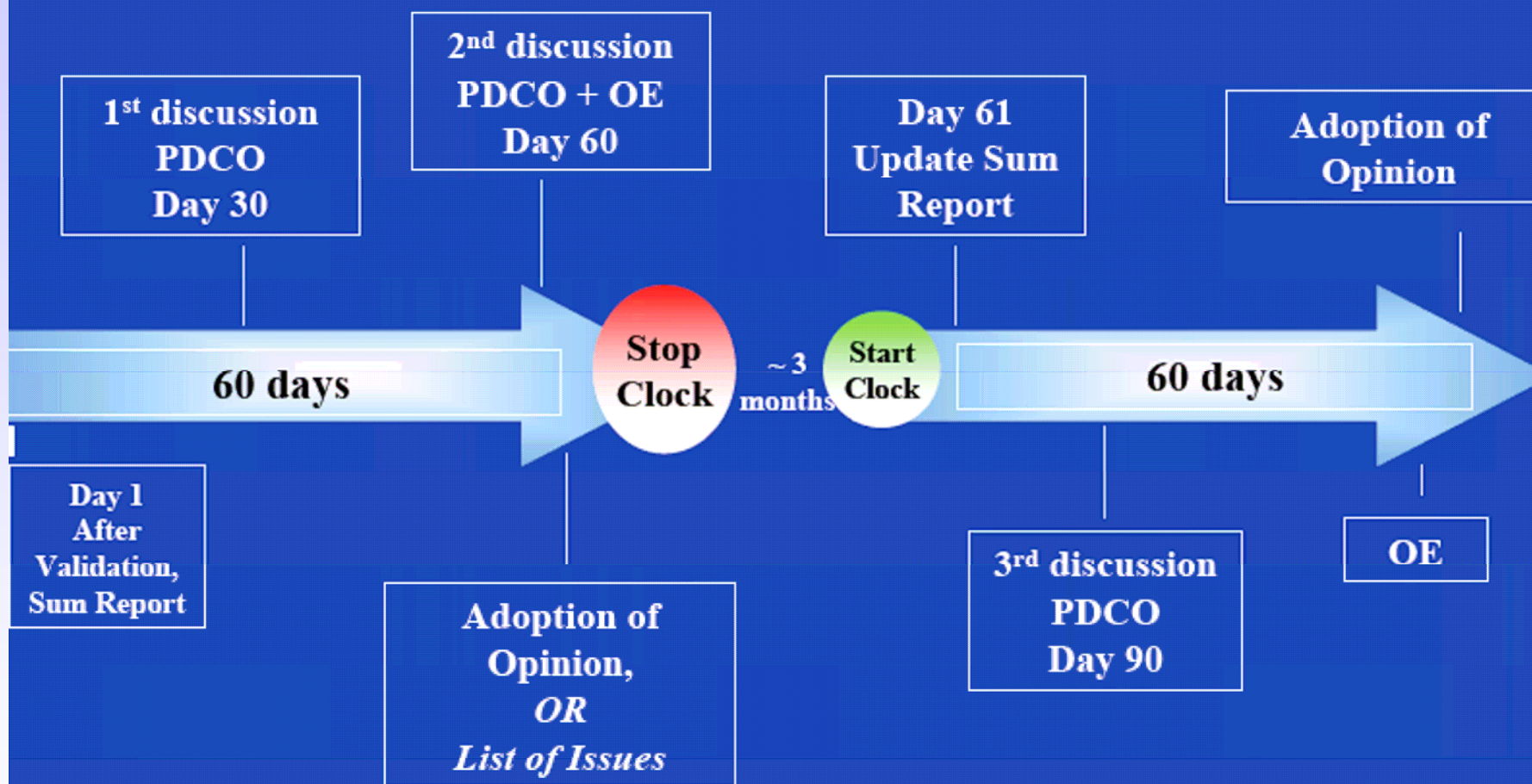


Timing of PIP application (new products)





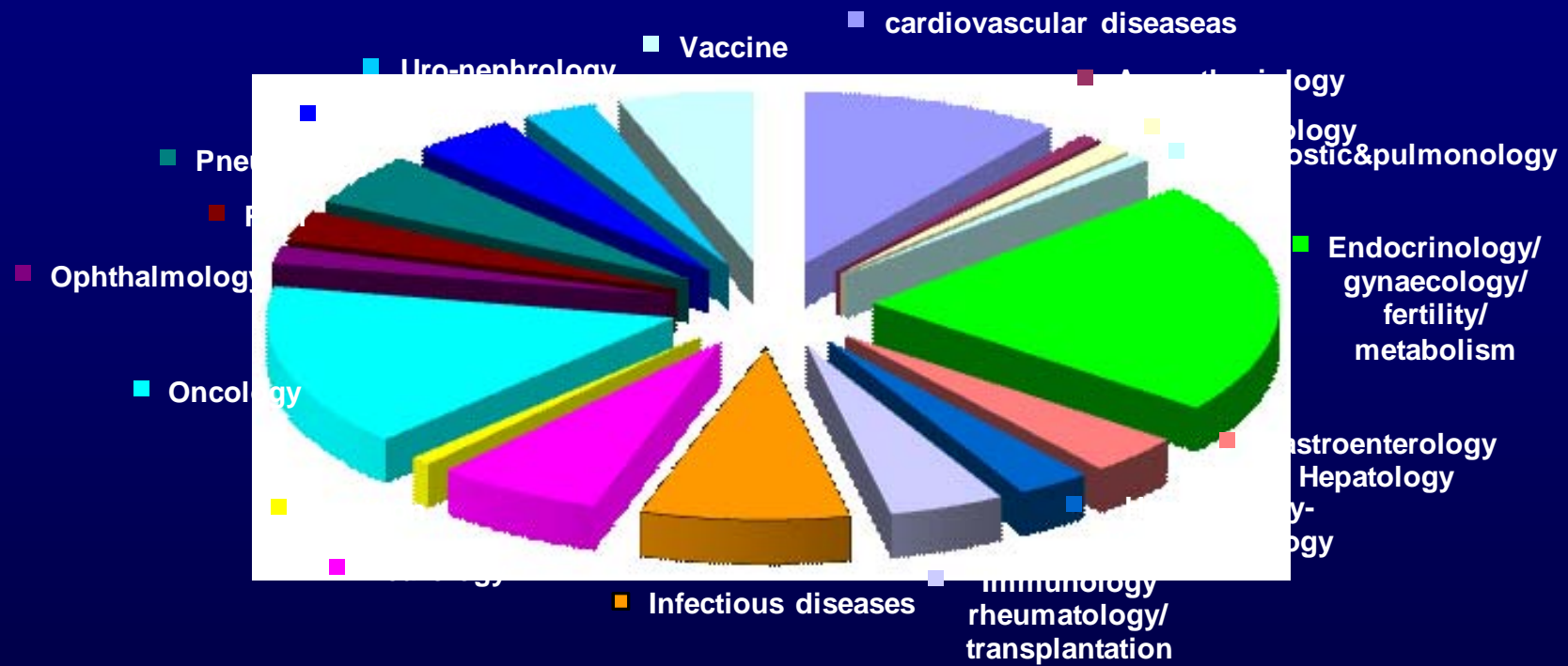
Overview PIP procedure



OE= oral explanation



PIP'S THERAPEUTIC FIELDS



Outline

- The role of PDCO
- PEG
- EU Paediatric Network

PEG – Paediatric Working Party (previous Paediatric Expert Group)

The PEG was established in order to coordinate the necessary actions and to advise the EMEA and CHMP on all questions relating to the development and use of medicinal products in children.

→Tasks:

- assessing, by therapeutic areas or conditions, a public health need or unmet medical need (paediatric use and available paediatric formulations) → **Update of Paediatric needs (in 2009) by PDCO; one updating in 2007 by PDCO**
- preparing, reviewing and updating guidelines to facilitate the development of paediatric products
- providing expert advice on paediatric issues to support the evaluation of centralised marketing authorisation applications and the preparation of scientific advice;
- providing advice on paediatric issues to the EMEA's scientific committees, the European Commission and other groups;
- liaising with interested parties, particularly children's and patients' organisations, **with a view to encouraging the creation of research networks for the development of medicines.**





Funding of paediatric research

- Community funding for studies into off-patent medicinal products
 - From Framework Programme(s)
 - FP7: in second call (dead line for bids: second half of 2007)
 - 30 million Euros for the 2 first years
 - Link with identified Needs and Priorities for research into off patent medicines (EMEA website)



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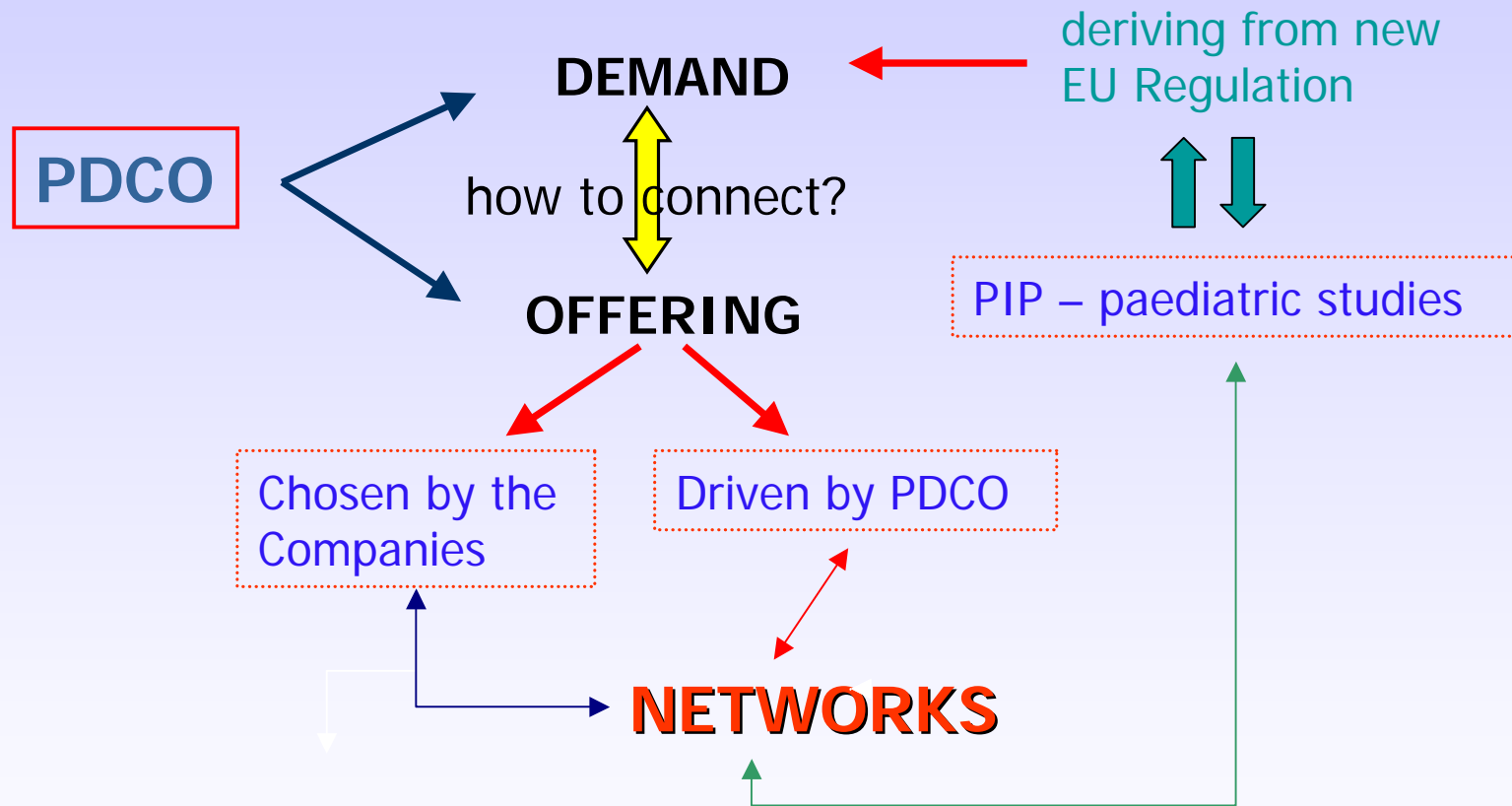
EMA Paediatric Research Network

Objectives:

- Collaboration
- Building competences
- Avoiding unnecessary studies
- Stimulating high quality research
- Strengthening the foundations of the European Research Area
- Facilitation of recruitment in clinical trials



Why PDCO is important for EU paediatric network?



Why PDCO is important for EU paediatric network?

PDCO as an “Coordinating Agency”
(organization and transparency)



BENEFITS

- reduction in timing for recruiting patients
- high quality of the planned studies (high standards of the Networks)
 - assess paediatric Needs and avoid the replication of the studies

