What Ever Happened to the IMI2 Proposal?

Still Alive and Kicking and Heading for a Submission of a Call Topic Text to the EU Commission in late August

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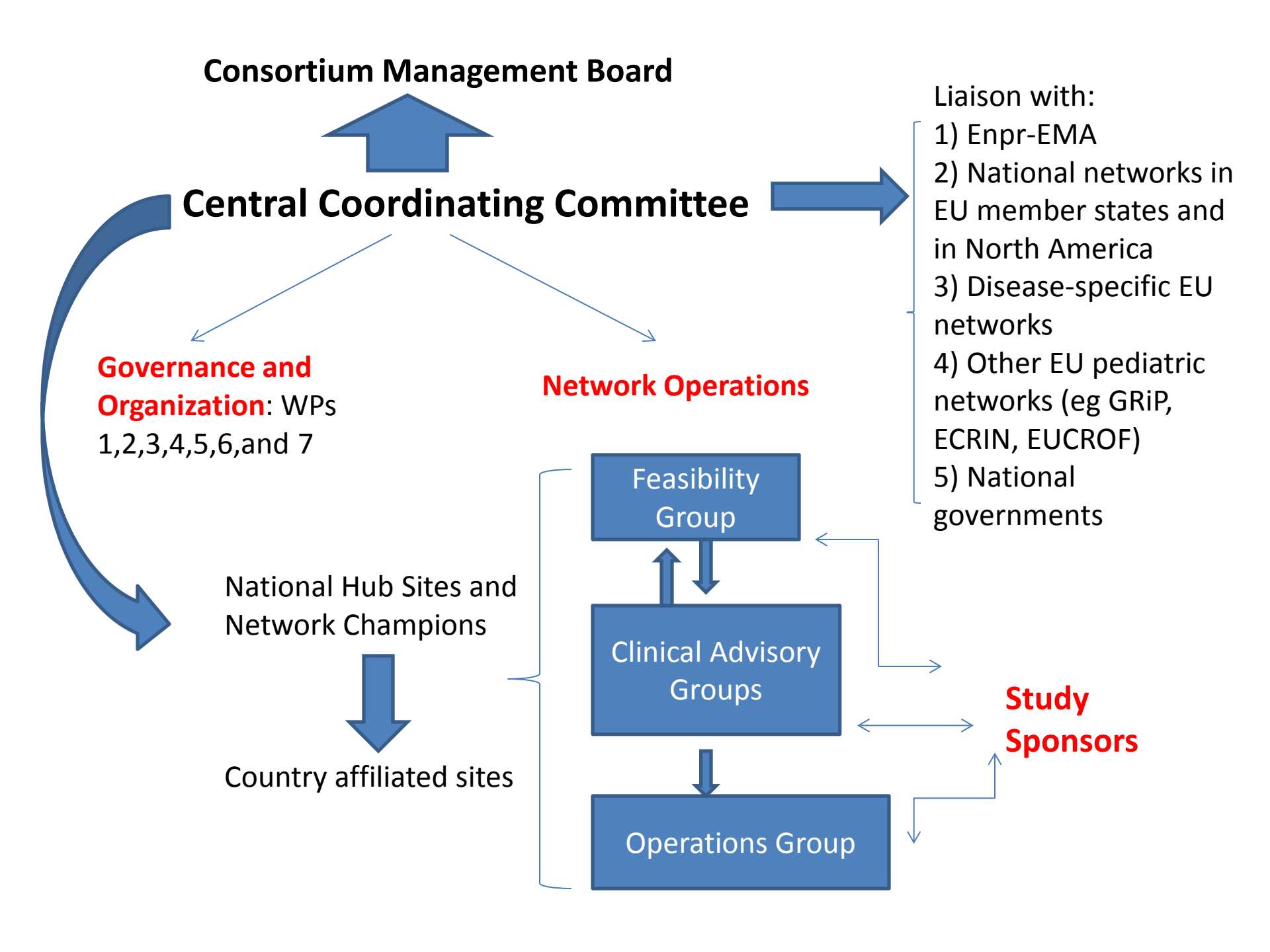
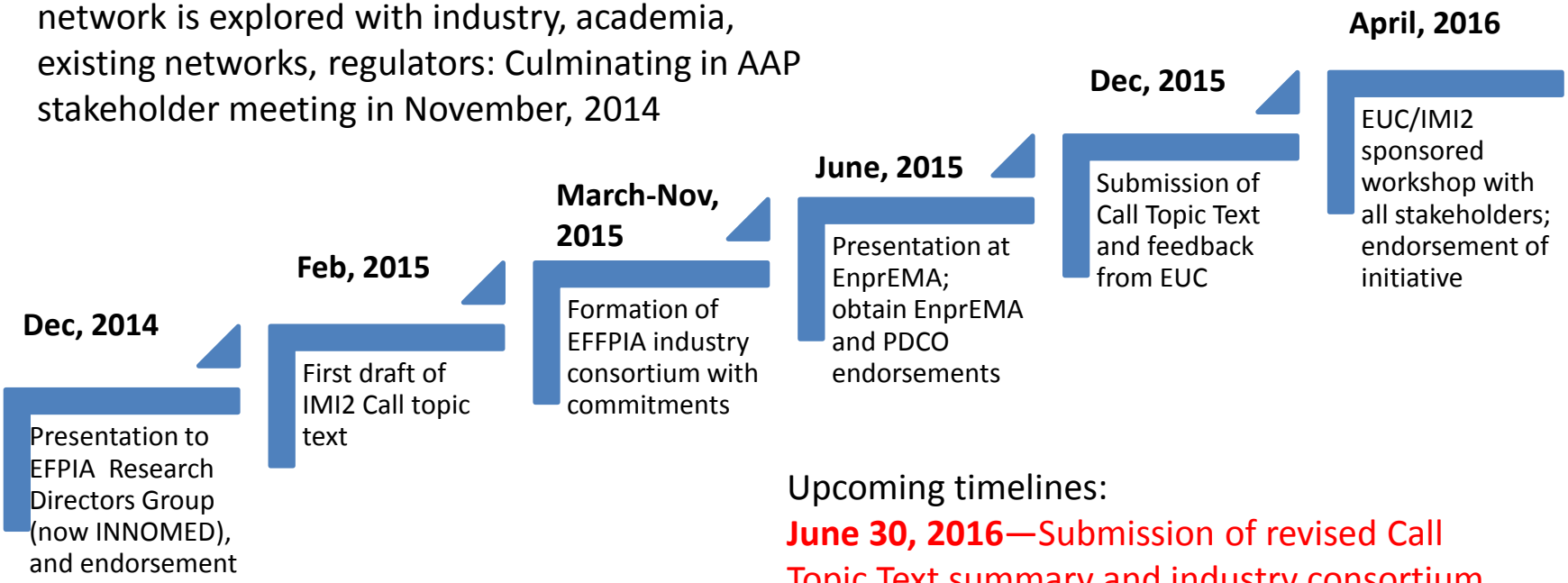
What's the Solution?: Building a Sustainable Pediatric Clinical Trials Network

- Use the IMI2 process to build a sustainable pan-EU multi-specialty capable pediatric clinical trials network
- 9 companies from EFPIA contributing in-kind expertise and studies: (**Janssen, Novartis, Bayer, GSK, Roche, Pfizer, Lilly, Sanofi/Genzyme, Servier)**
- 6-year project
- Multi-specialty capable, pediatric (neonates to adolescents) clinical trials network devoted to planning and executing studies for drug labeling and approval
- Work with existing national and disease-specific networks
- Central organization, plus national hubs and clinical sites throughout the 25 member states of the EU
- 3 initial "proof of network viability" studies from industry sponsors but open to non-industry sponsors as well
- Sustainable business model after initial 6 years of public/private funding
- Membership in EnprEMA


Consortium Management Board
Central Coordinating Committee
Liaison with:
1) Enpr-EMA
2) National networks in EU member states and in North America
3) Disease-specific EU networks
4) Other EU pediatric networks (eg GRiP, ECRIN, EUCROF)
5) National governments
Governance and Organization: WPs 1,2,3,4,5,6,and 7
Network Operations
National Hub Sites and Network Champions
Country affiliated sites
Feasibility Group
Clinical Advisory Groups
Operations Group
Study Sponsors

The Past and Future of the IMI2 Initiative to Form a Pediatric Clincial Trials Network

2013-2014: CHILD formed and idea of a sustainable multi-specialty capable pediatric clinical trials network is explored with industry, academia, existing networks, regulators: Culminating in AAP stakeholder meeting in November, 2014



Upcoming timelines:

June 30, 2016—Submission of revised Call Topic Text summary and industry consortium commitments to EFFPiA Innomed Group

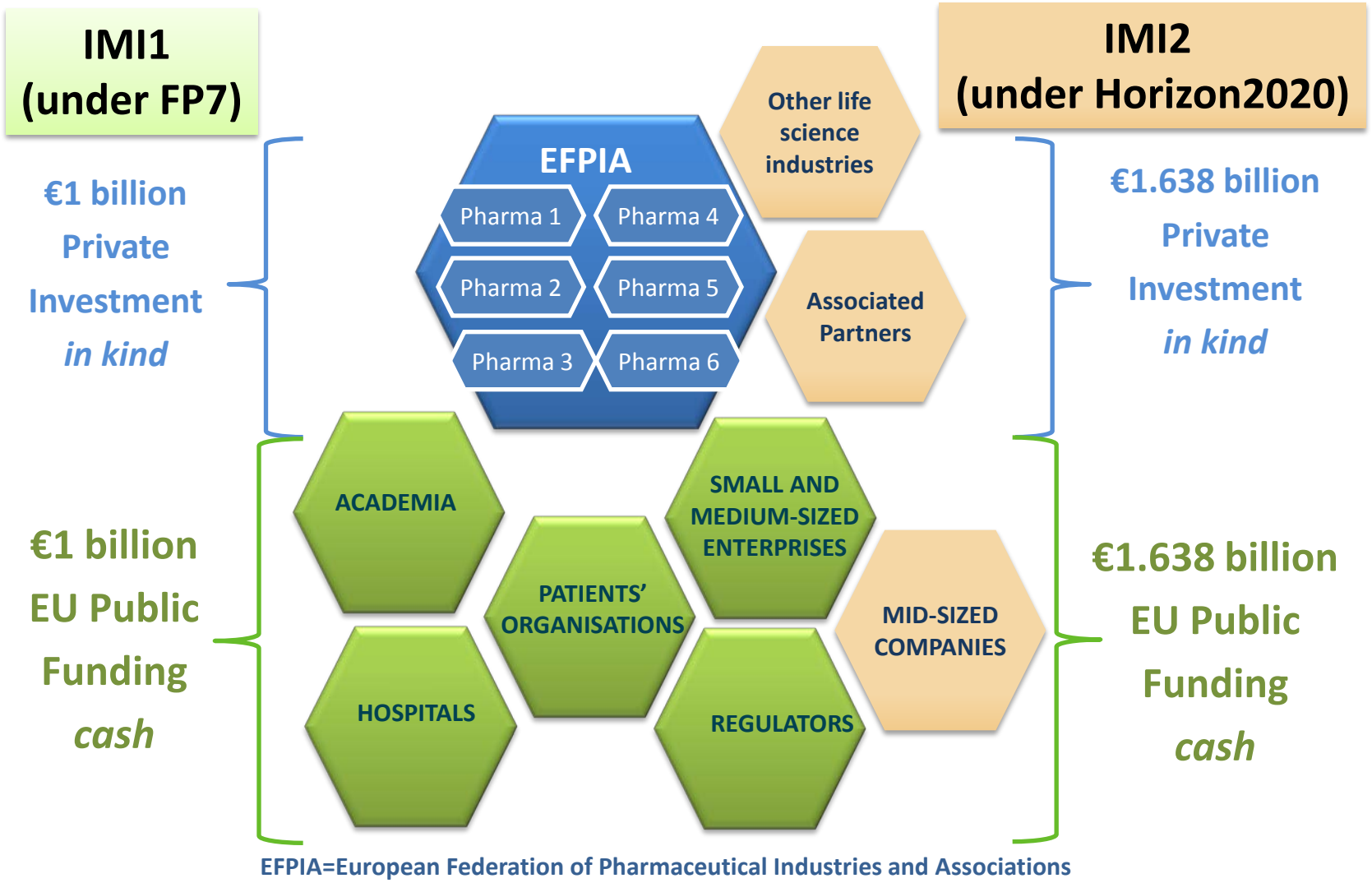
August 30, 2016—Submission of final Call topic text to EUC/IMI2

October 16, 2016—publication of Call topic text

Published Minutes from Workshop

- The EUPCTN initiative was welcomed as a solution to overcome formidable planning and operational challenges inherent in conducting paediatric clinical trials; and as a means to make Europe a competitive region for delivering high quality trials.
- Recommended that such a network:
  - Be open and serve both public and private interests
  - Integrate with current good models of national and disease-specific networks
  - Include components which help to create new innovative ways of designing / conducting pediatric clinical trials
  - Provide education, uniform training, and enhance national and site-specific capacity building
  - Immediately start work on a business model for sustainability beyond the period of IMI2 support including collaboration with national health systems
  - Ensure interoperability with other ex-EU networks to foster the ability to conduct global clinical trials

The Innovative Medicines Initiative (IMI)*



EFPIA=European Federation of Pharmaceutical Industries and Associations

Expressed Support for the IMI2 Project for a pan-EU Pediatric Clinical Trials Network Infrastructure

Companies

Janssen (leader,) Novartis, Lilly, GSK, Bayer, Pfizer, Roche, Sanofi/Genzyme, Servier, ? AZ

EFPIA

EU Government Ministries of Health

UK, Switzerland, Austria, Spain, Italy, Poland, Albania, Netherlands

National Networks

Ireland, Finland, Iceland, Estonia, Sweden, UK, Austria, Netherlands

Rheumatology, HIV/ID, Oncology

Barcelona, Warsaw Childrens

EU Multinational Sub-specialty Networks, large children's hospitals

Enpr-EMA (European Network of Paediatric Research at EMA), PDCO

Health Authority

European Genetic alliance
European Rare Diseases Alliance

Patient advocacy groups

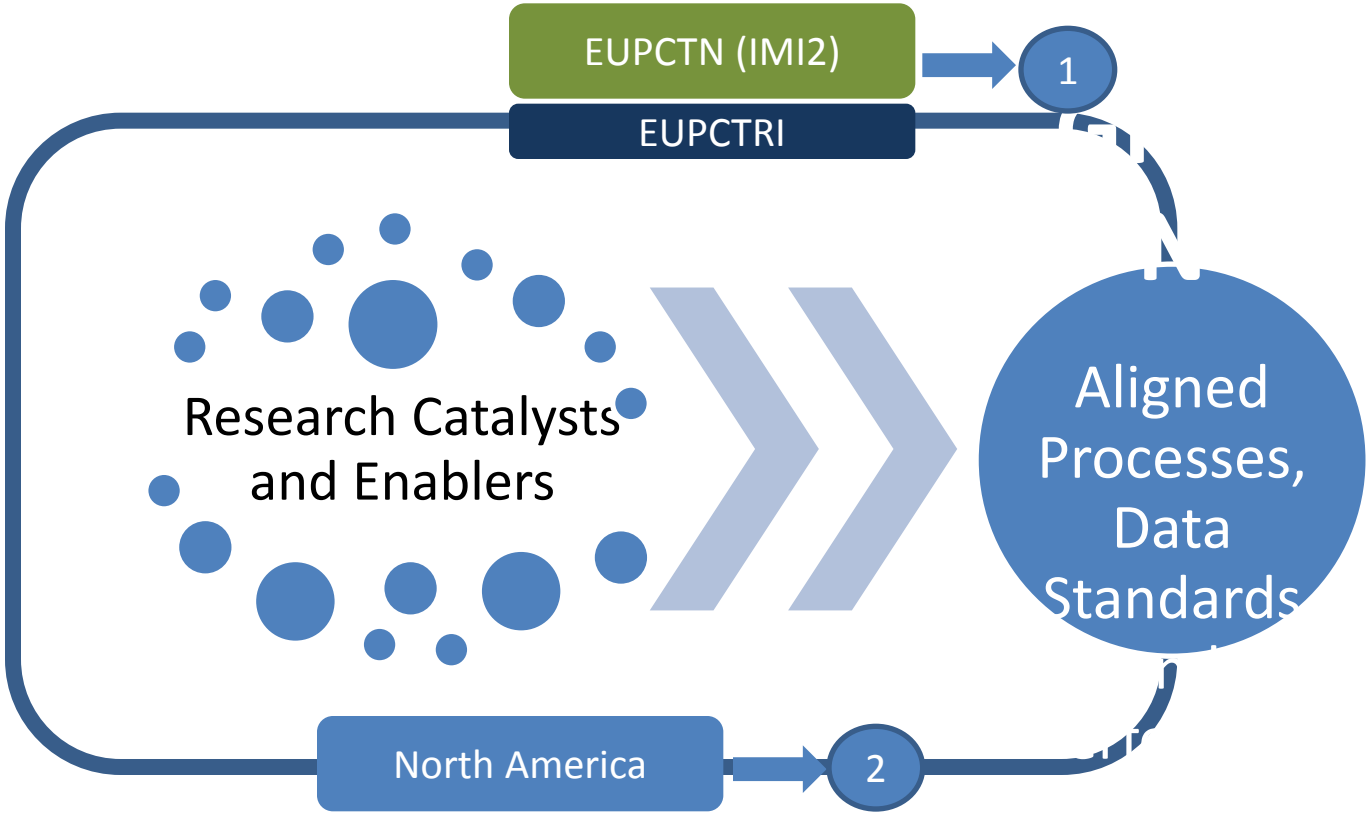
Letter by PDCO in support of Enpr-EMA involvement in planned IMI2 project to develop a sustainable Pan-EU Paediatric Clinical Trials Network (EUPCTN) for the Conduct of Interventional Paediatric Drug Trials

08/24/2015

The PDCO herewith expresses its support for this important initiative expected to improve the timely completion of paediatric studies agreed in Paediatric investigation plans (PIPs), and wishes to emphasise the importance of ensuring that the work undertaken to date by the European network of paediatric research at the EMA (Enpr-EMA) feeds into this initiative.

pan-European Paediatric Clinical Trials Network

Part of a broader initiative to address needs in Children globally



Research Catalysts and Enablers include (not complete):

- International Neonatal Consortium
- GRiP, TEDDY, ECRIN, **EnPr EMA**
- Specialty Networks