conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

The c4c project: a comprehensive overview

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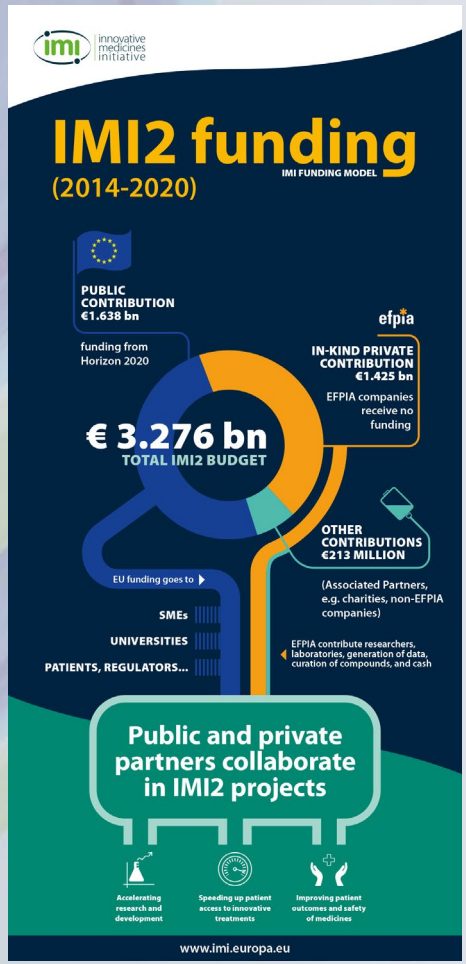
Vision

Better medicines for babies, children and young people through a pan-European clinical trial network

A pan-EU Paediatric Clinical Trial Network

A project under the EU Innovative Medicines Initiative (IMI)



- Ensure **efficacy, safety & quality** of health products
- **Reduce time** to clinical proof of concept
- Improve the current **drug development process**
- Develop **new therapies** for diseases with **high unmet need** & **limited market incentives**
- Allow **engagement** in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research

Private-public partnership between Academia and Pharma

Version 1.0

6 years to deliver

Type of study	Industry/non-industry
Intervention	Drug, biologics, devices
Geography	Europe
Phase of study	Ph 1- 4; registry studies, non-interventional
Endpoints	PK/PD, efficacy, safety
Responsibilities	The **c4c** network will provide some **central services for trials**, for example, trial feasibility, pharmacovigilance activities and commissioning of trial supplies. Other operations to be supplied by the sponsor

Mission

c4c will use a coordinated approach to deliver high quality "regulatory grade" clinical trials in:

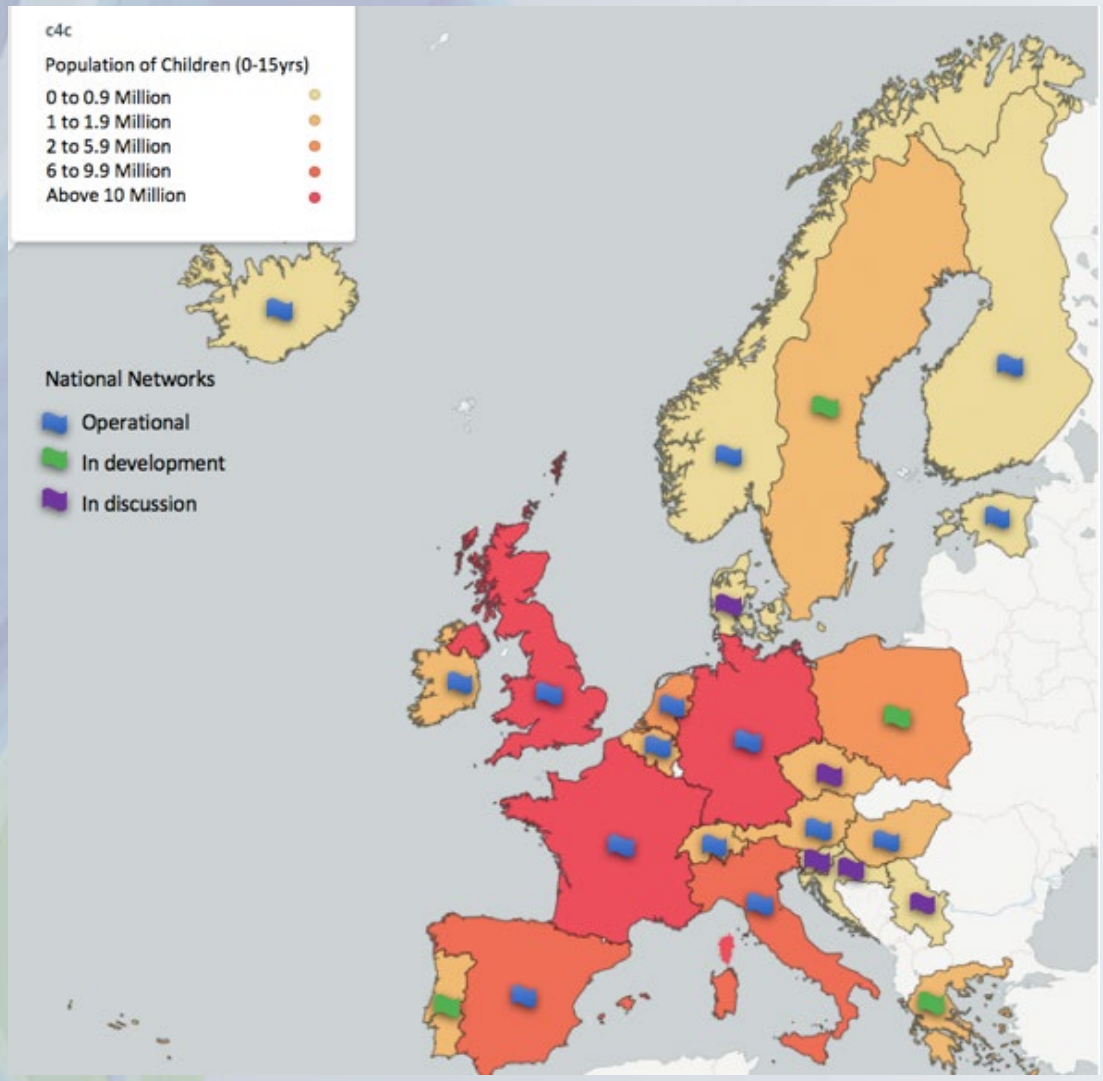
- Multiple countries
- Multiple sites
- All paediatric age groups

Relevant to ERNs

by supporting:

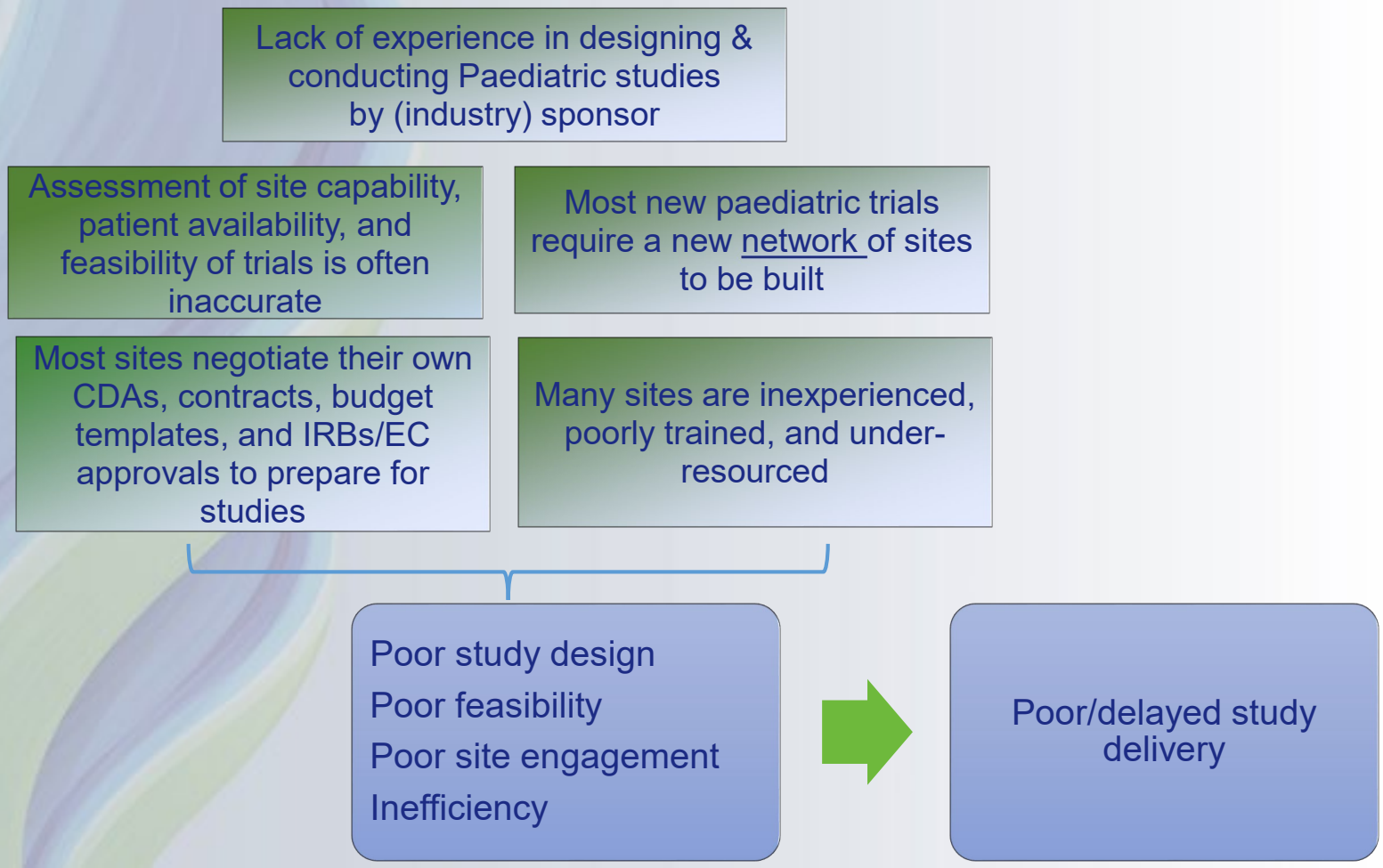
- **Trial implementation** using resources **shared** between studies
- **Trial design** through a combination of information about **natural history, feasibility, appropriate innovation, and expert opinion**
- **Education and awareness** within and beyond the network

The c4c consortium members



- 10 EFPIA companies
- 18 pediatric national networks
- 2 large patient advocacy groups
- 8 EU Multinational sub-specialty Networks
- 200 large children's hospitals

Challenges when conducting paediatric trials



Relevant to ERNs

Project Concept

1. Use resources and funding of the IMI project to setup the network and its processes
    1. National
    2. International
2. Demonstrate the value of the network approach with selected
    1. Studies
    2. Sites
3. Generalise from the demonstration projects to the broader network

Avoiding duplication

Project Concept

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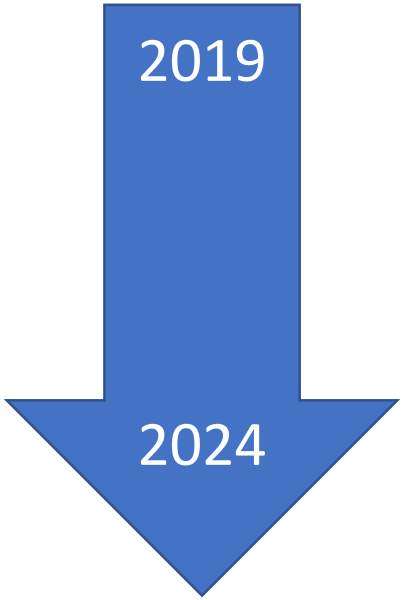
From
- **Specific**
- **Selected**

To
- **Generalised**
- **Sustainable**



Planning, set-up & conduct of a Paediatric Development Program

A multifaceted challenge…

Defining the medical need	Right indication and population	Preparing and agreeing a Paediatric Development Plan	Small patient populations – competing developments
Use/acceptance of innovative study designs	Insufficient trial infrastructure	Divergent view of Ethic Committees	Contradictory local regulations
Diverse standard of care across Europe	Impact on daily lives of patients and families	Dose, route of administration, application device	Acceptance of Paediatric research in society

Relevant to ERNs

Key Objectives

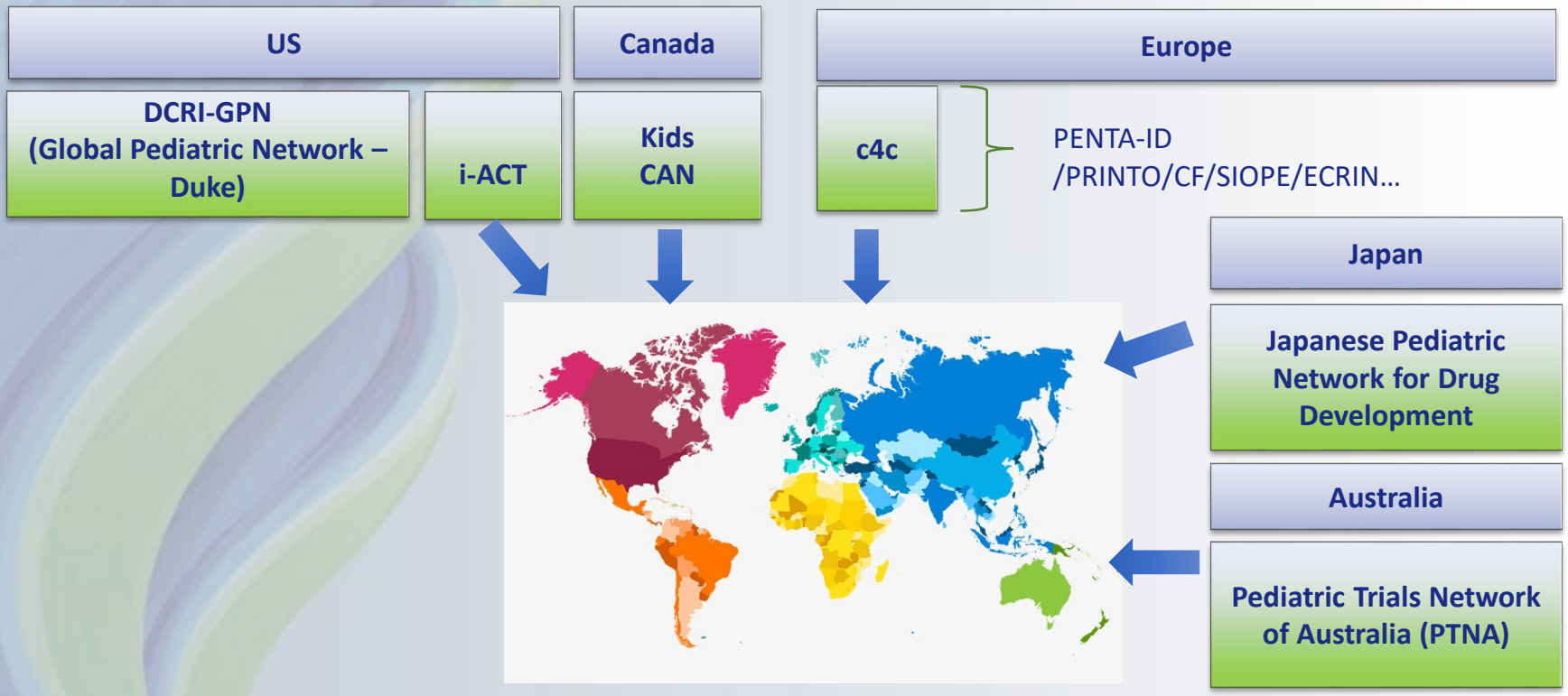
- More efficient trial implementation through the set-up of **national hubs** and qualified sites
- Input in clinical trial design and implementation from **pilot expert advisory groups** and other fora
- **Educational programme** for health professionals and **awareness raising campaigns** for the general public
- Identification of **Data standards** and performance metrics
- Business cases for **sustainability** beyond IMI funding

Key features

- **International network** with lean central coordination
- A single point of contact (**One-stop-shop**)
- Efficient **implementation** of trials
- Consistent procedures **across sites**
- Strategic and operational **feasibility assessment**
- Involvement of experts to develop **innovative trial designs and methodology**
- Multi-KEY **stakeholder collaboration**

Global Paediatric clinical trial networks

The **c4c** network will collaborate with other existing networks



Benefits for sponsors in placing a study with c4c

- High quality input in study design and preparation through rigorous strategic and **operational feasibility** assessment
- **Efficient implementation** by adopting consistent approaches, aligned quality standards and coordination of sites at national and international level
- A **single point of contact** for all sponsors, sites and investigators
- **Collaboration** with EU pediatric specialty networks

Benefits to the paediatric community

- **Harmonized, streamlined procedures** across the trial lifecycle
- Opportunities to **build economies of scale** at site and national level
- Reducing barriers to entry and so making paediatric research more attractive and **competitive**
- Access to a wide range of study sponsors through a **transparent**, evidence-based, network-wide vetting procedure
- Input from **relevant specialty networks** and methodologists on study design, implementation and assessment

Expected long term impact of c4c

- **Access to new experimental therapies** for children in well-designed clinical trials
- Better training for research personnel and **improved trial readiness** at all participating sites
- **Improved efficiency** in executing trials (faster, cheaper)
- **Improved data quality** for labelling of next generation medicines for children
- Enhanced role of **clinicians and patient/parent advocacy groups** in planning and designing studies
- **Broadening the access** of academic medical centers and clinical faculty across Europe to new experimental therapies

How c4c will be put to the test

- **Proof-of-viability trials**
  - Industry sponsored
  - Non-industry-sponsored
- selecting and comparing metrics about studies' start-up and conduct