

What do c4c academic proof of viability studies bring to our Paediatric Clinical Research National Network?

Pr Régis Hankard

French Paediatric Clinical Research National Network (Inserm-PEDSTART)



Overview

- How is Paediatric Clinical Research organized in France?
- Our c4c experience
- Our role in the c4c academic proof of viability studies

PEDSTART is the National Paediatric Clinical Research Network in France



Inserm is the French National Agency for Medical Research

F-CRIN is the Inserm National Infrastructure for Clinical Research (Adults and Children)

- 11 Thematicized Clinical Research networks in which **PEDSTART** is for Paediatrics
- 4 « central services » and Coordination


INTERACT WITH OTHER F-CRIN COMPONENTS



The PEDSTART NETWORK



conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

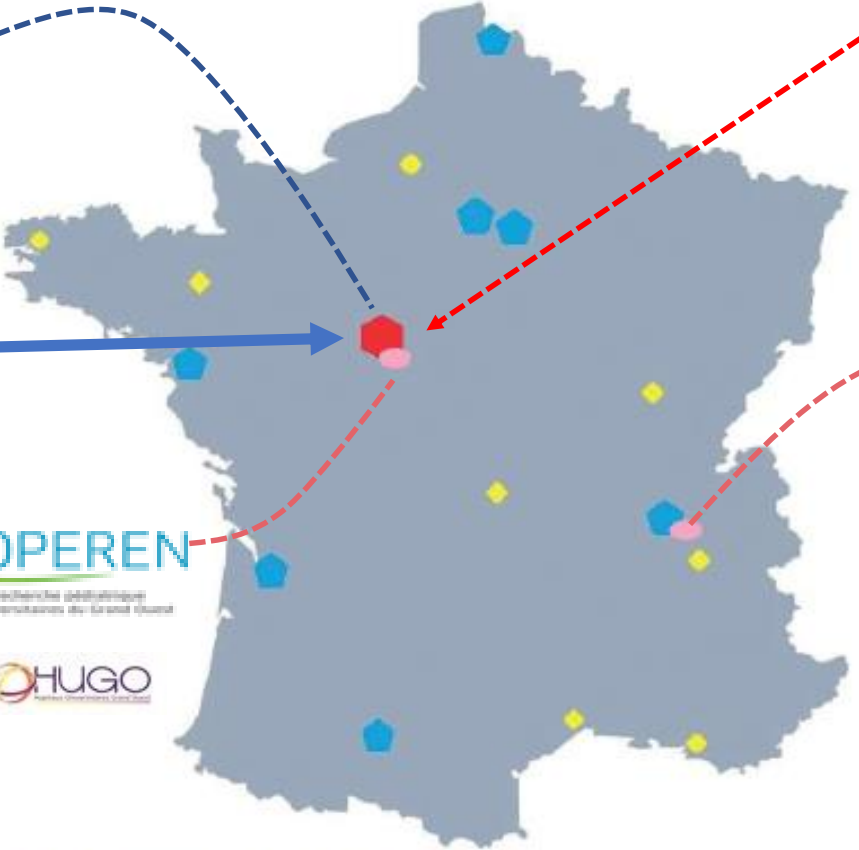


This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389. The Joint Undertaking receives support from the **European Union's Horizon 2020** research and innovation programme and **EFPIA**.

HUB



PEDSTART gathers Clinical Investigation Centers (CIC) belonging to both INSERM and Universities



- Centres d'investigation clinique pédiatriques c4c
- Centres d'investigation clinique pédiatriques non-c4c
- Coordination du réseau
- Réseaux de recherche : HUGOPEREN & RIPPS



CONTACTS

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- Membres fondateurs**
- Dr Mireille Castanet
 - Pr Michaël Fayon
 - Pr Frédéric Gottrand (co-coordonateur)
 - Pr Régis Hankard (coordinateur)
 - Pr Evelyne Jacqz-Aigrain
 - Pr Berhouz Kassaf-Koupal
 - Dr Claire Levy-Marchal
 - Pr Jean-Christophe Rozé
 - Pr Jean-Pierre Salles
 - Pr Jean-Marc Tréluyer





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

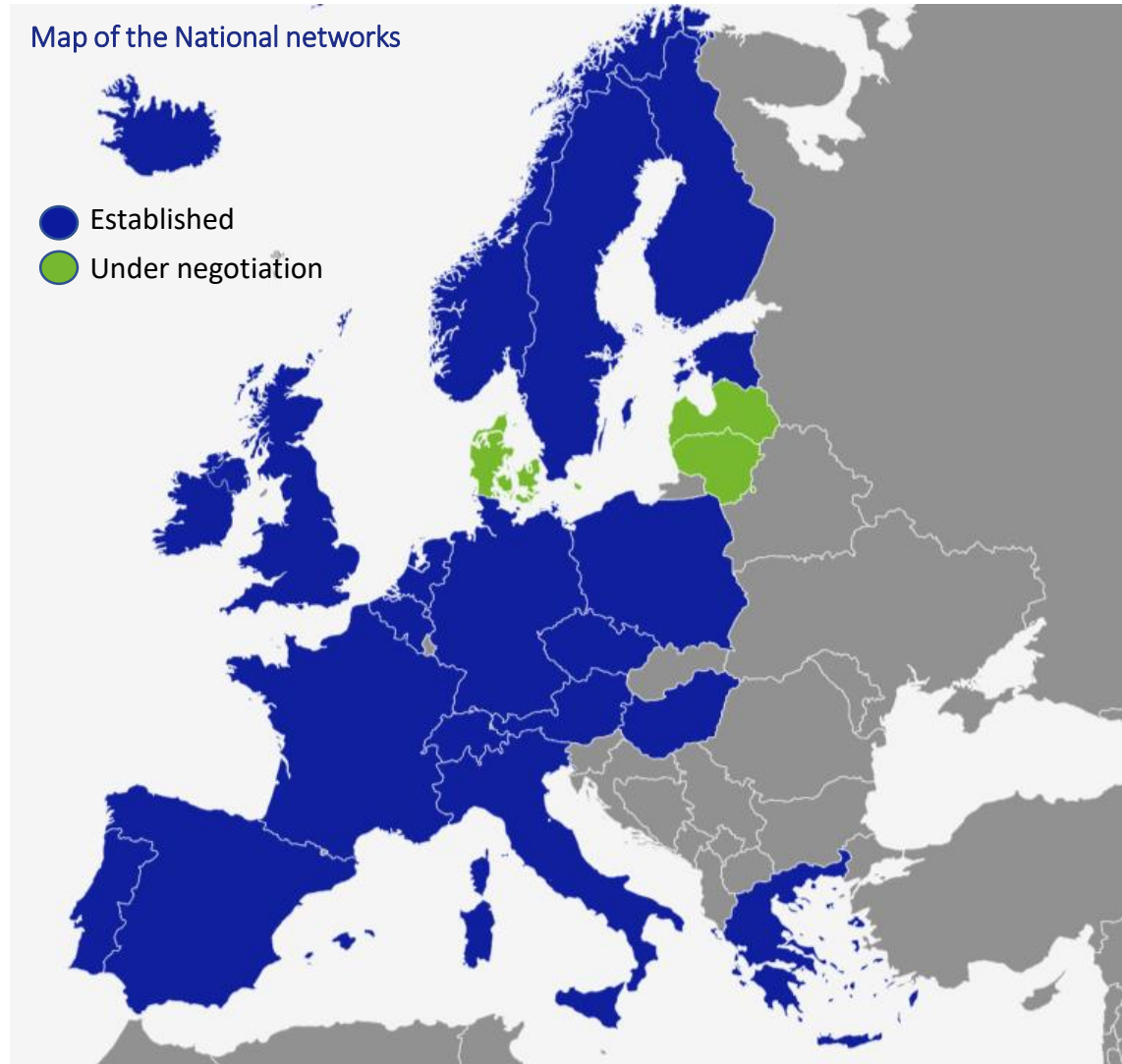
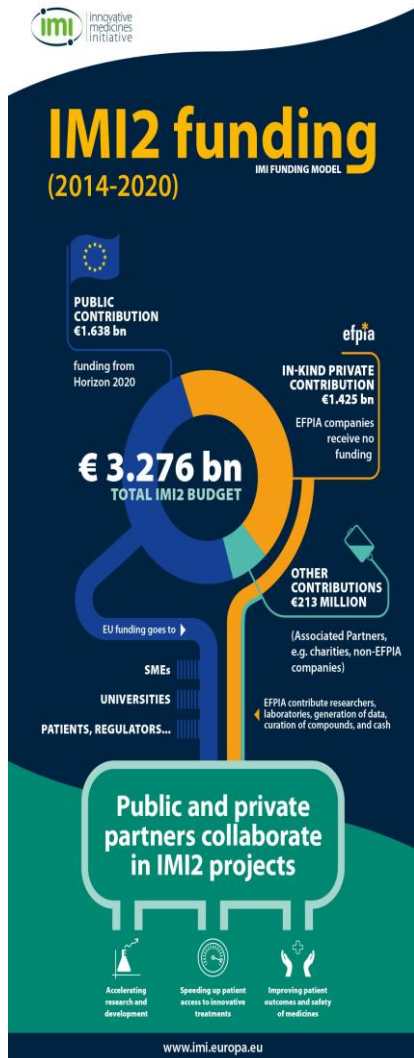
Proof Of Viability (POV) studies to test that the c4c processes run as intended



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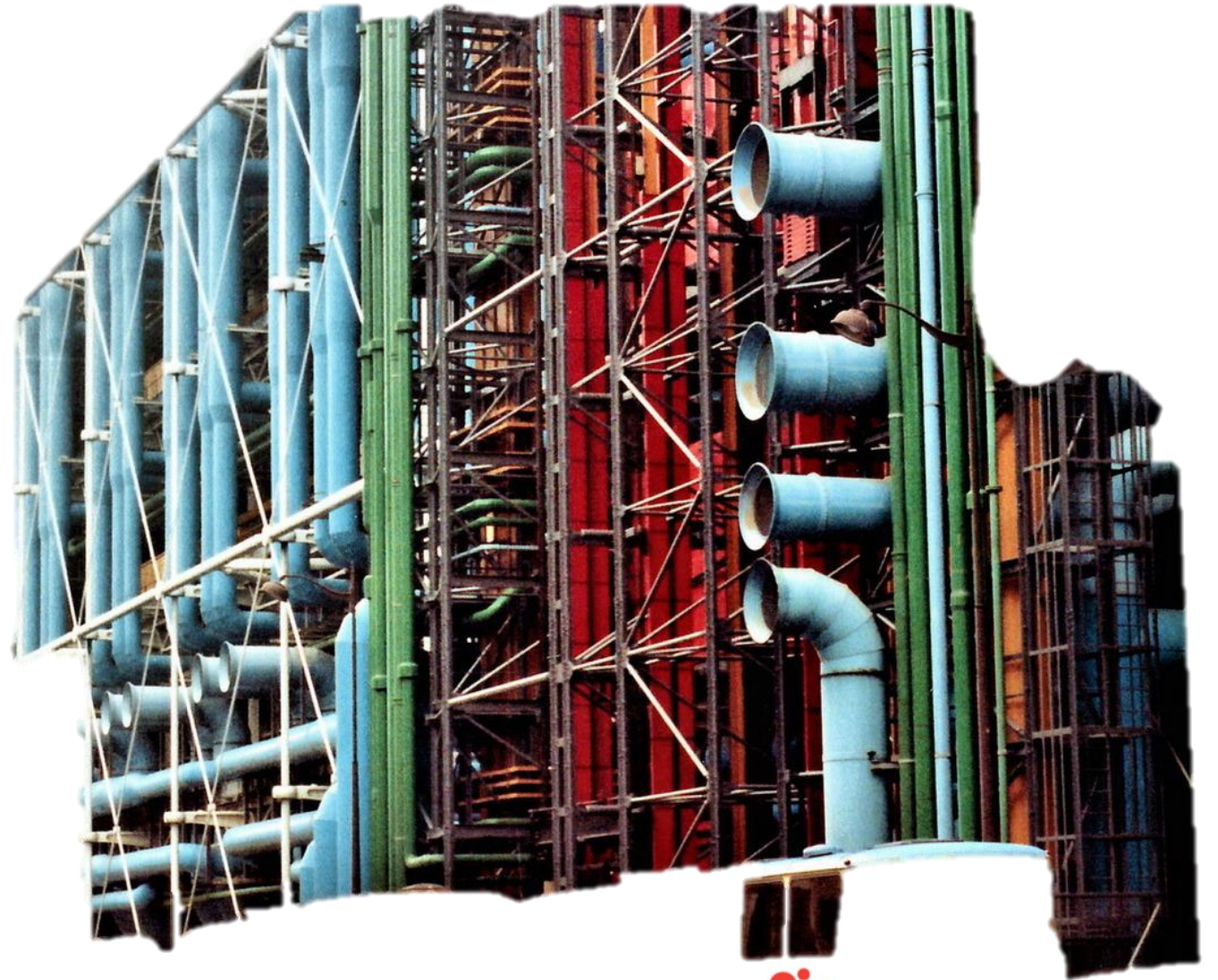
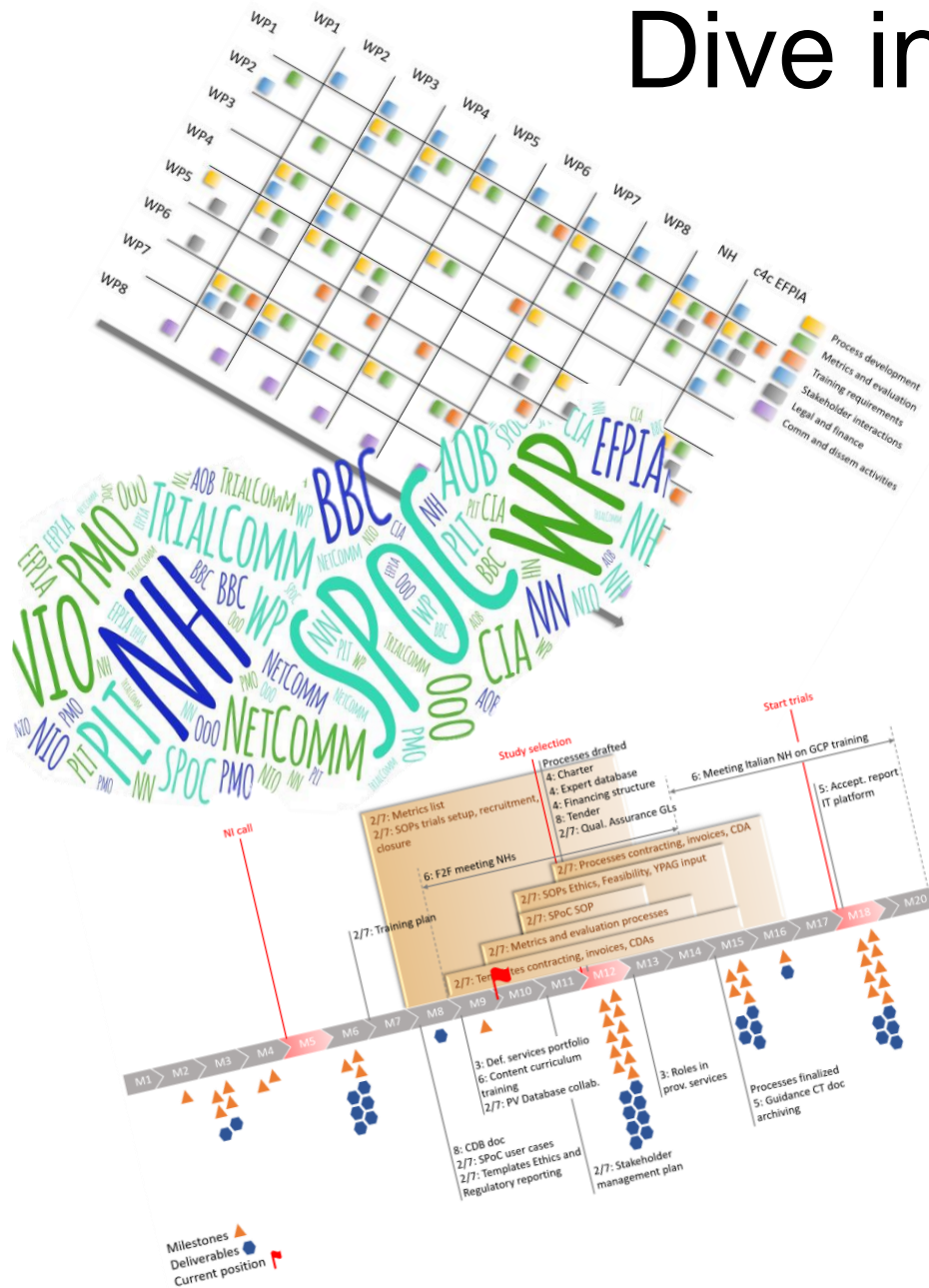
c4c network – IMI2 project 2018-2024



- 10 EFPIA companies
- 19 paediatric national networks
- 2 large patient advocacy groups

≈ 140 M€

Dive into a new dimension



c4c-Academic Proof Of Viability trials EU

	Countries	Sites	France Sites	N
TREOCAPA FR	17	63	12	748 + 30
MOI GB	9	12	2	30
KAWASAKI GB	15	56	5	262
CASPER-CF IT	11	33	4	135

Rare diseases : 2



Very tight timelines !

Prophylactic **t**reatment **O**f the du**C**tus **a**rteriosus in **p**reterm infants by **a**cetaminophen

Pr Jean Christophe Rozé, CHU Nantes

- **Anticipate**
- **Scientific and medical relevancy**
- **Collaborate at the national and European level**

5



Sept. 2017

January 2018



July 2018- c4c call

3

57

LOI- September 30th, 2018
Results :October 7th 2018

3

27

Full file-January 15th,2019

2

11

“Short List”

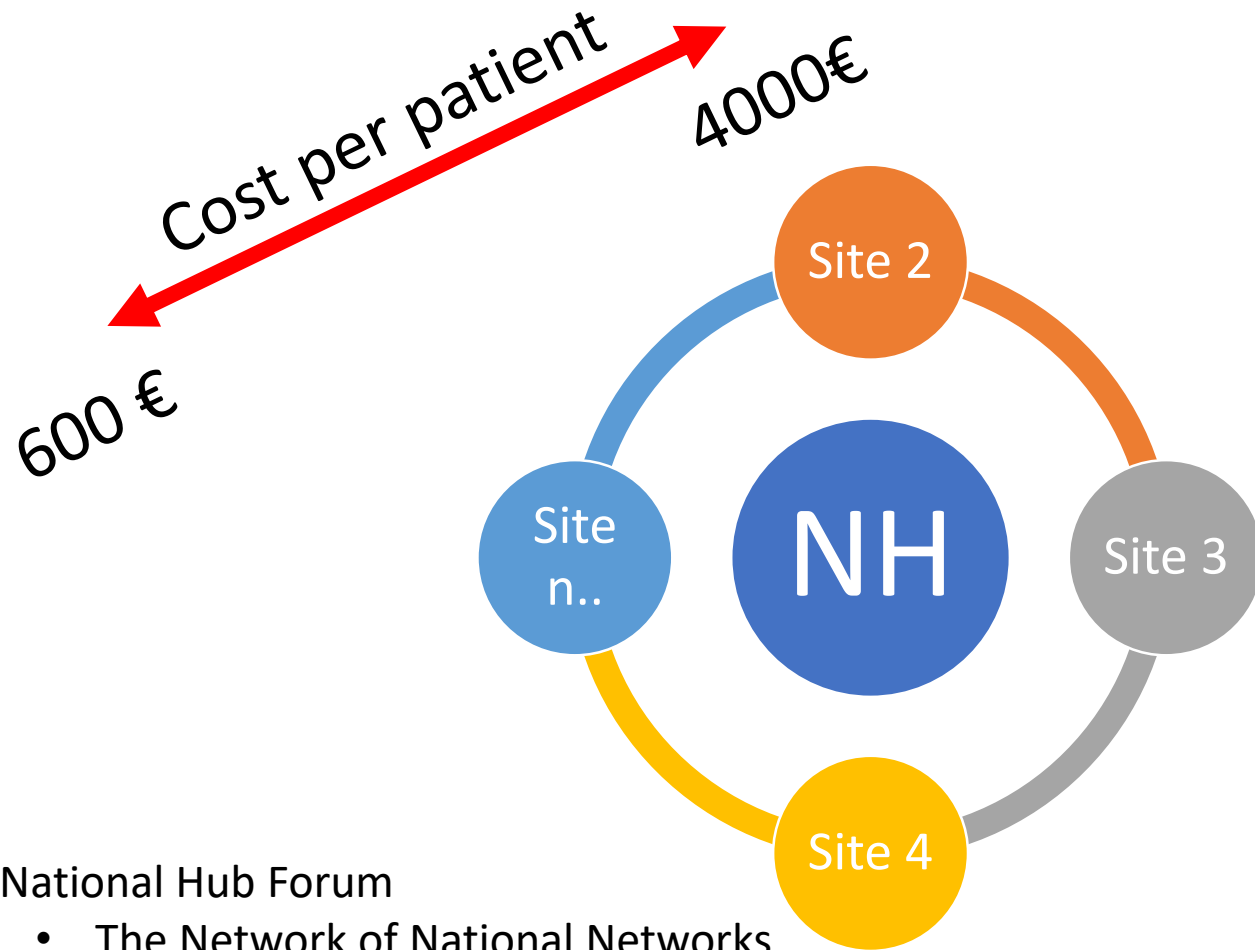
1

4

Results- April 4th, 2019



Different countries-different experiences and organisations



- National Hub Forum
 - The Network of National Networks

Already existing network or not

Confidentiality Disclosure Agreement

The text 'Already existing network or not' is written in a curved path above a group of black silhouettes representing people. Below the silhouettes, the text 'Confidentiality Disclosure Agreement' is written in a curved path.

Strengths and Weaknesses (French point of view)

- National organisation (Inserm)
- Support for study design
- Pharmacovigilance
- Speciality groups

- Resources
- Lack of harmonization
- Method

- To implement
 - Network quality system
 - Harmonized procedures at national and European level

Strengths

- Bring resources
- « Real-life »
- One contact per country
- Pace

Weaknesses

- Timeline
- Network vs Science

Threats

- Time to set-up
- Size of organization
- Brexit

Opportunities

- Organisation
- National Hub
- « The others »

- Identify our limits and work differently
- General interest over local interest
- National football team
- European football team?

