

TEDDY General Assembly, Rome, 14th January 2018

A new phase for paediatric clinical research : a play role for TEDDY ?

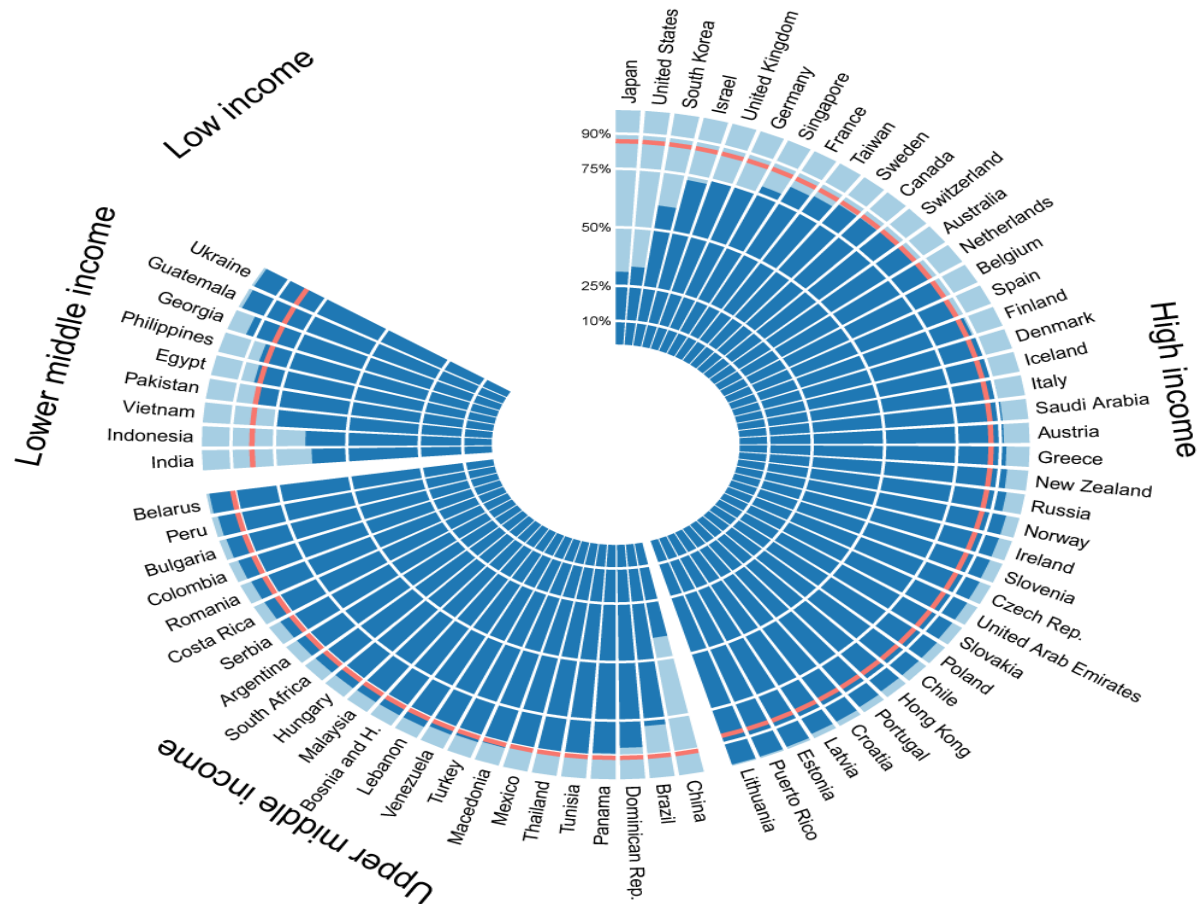
The PedCRIN project : promoting high quality clinical research in children through strengthened international collaboration

www.ecriin.org

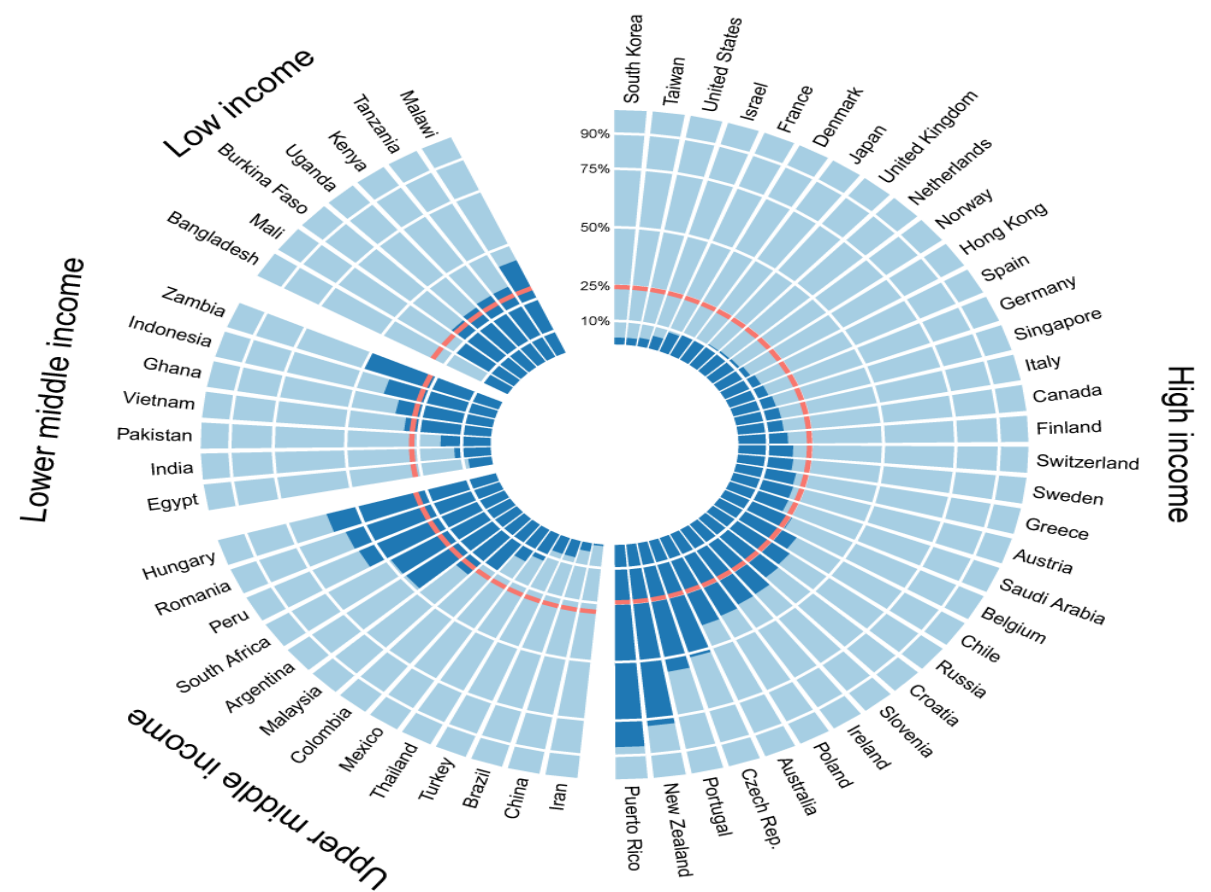
jacques.demotes@ecriin.org

International cooperation : industry-sponsored vs. academic trials

Industry-sponsored



Non-industry-sponsored



Attal et al. "Differential Globalization of Industry- and Non-Industry-Sponsored Clinical Trials" [PLoS One](https://doi.org/10.1371/journal.pone.0145122). 2015 Dec 14;10(12):e0145122.

EU Commission funding



➤ **2004 ECRIN-RKP**



➤ **2006 ECRIN-TWG**



➤ **2008 ECRIN-PPI**



➤ **2012 ECRIN-IA**



➤ **2017 PedCRIN**



(multi) national funding



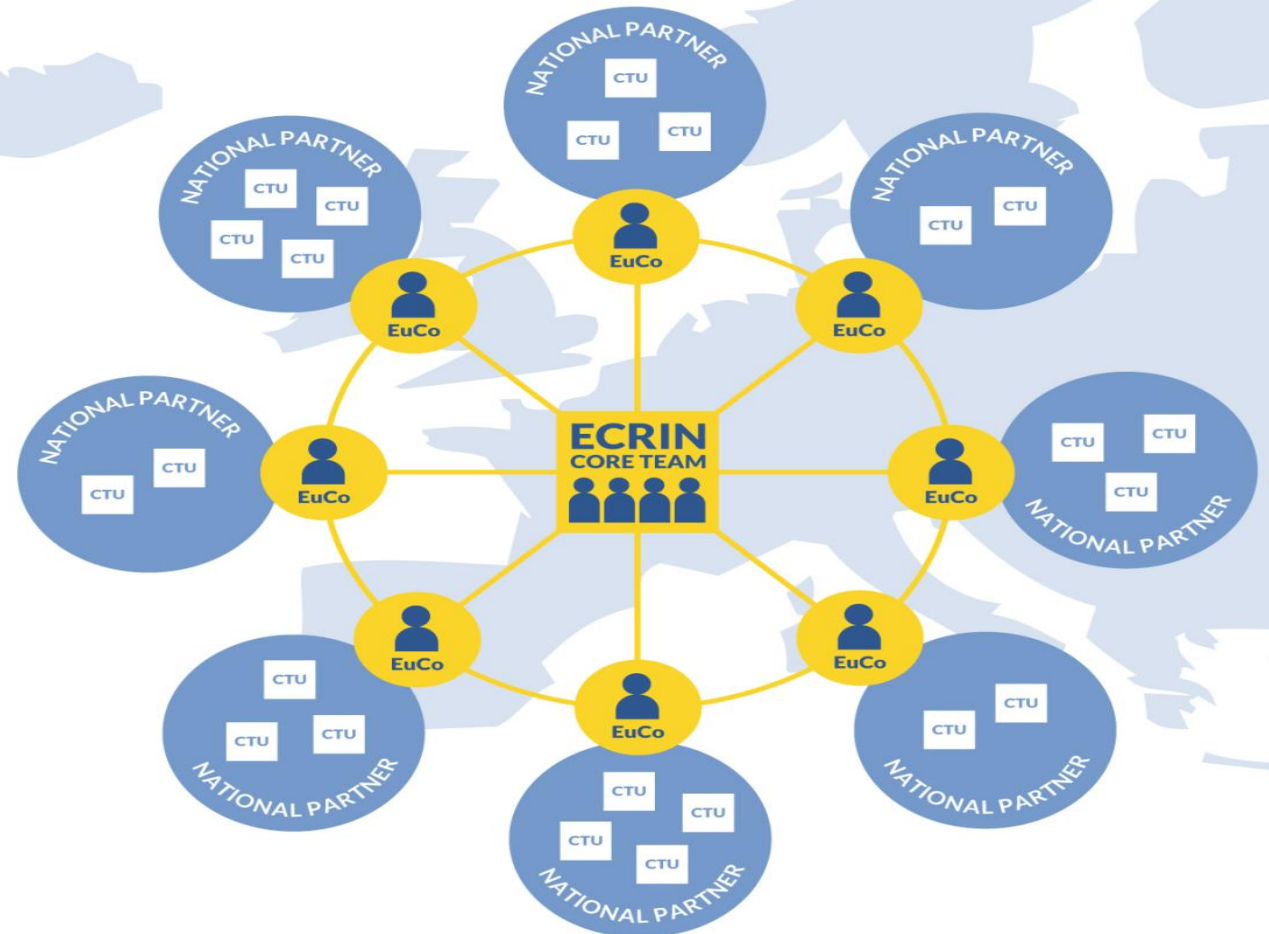
ECRIN-ERIC 2013



ECRIN and its national scientific partners

Core Team, European Correspondents, national hub, CTU networks

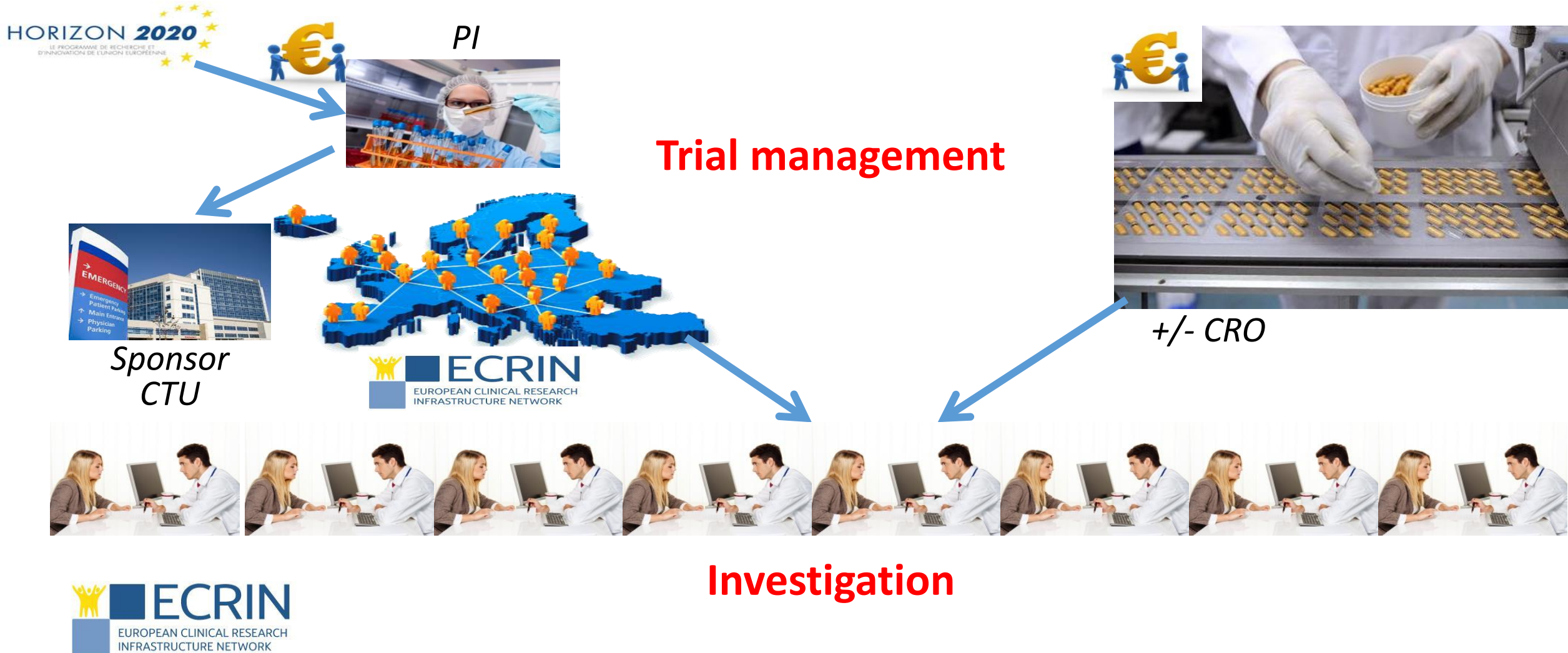
- Framework contracts with national scientific partners
 - ✓ provision of services
 - > “linked third party”
 - ✓ non-profit cost
 - ✓ hosting the European Correspondent



Distribution of roles in multinational trials : trial management vs. investigation

Investigator- or SME-initiated trial

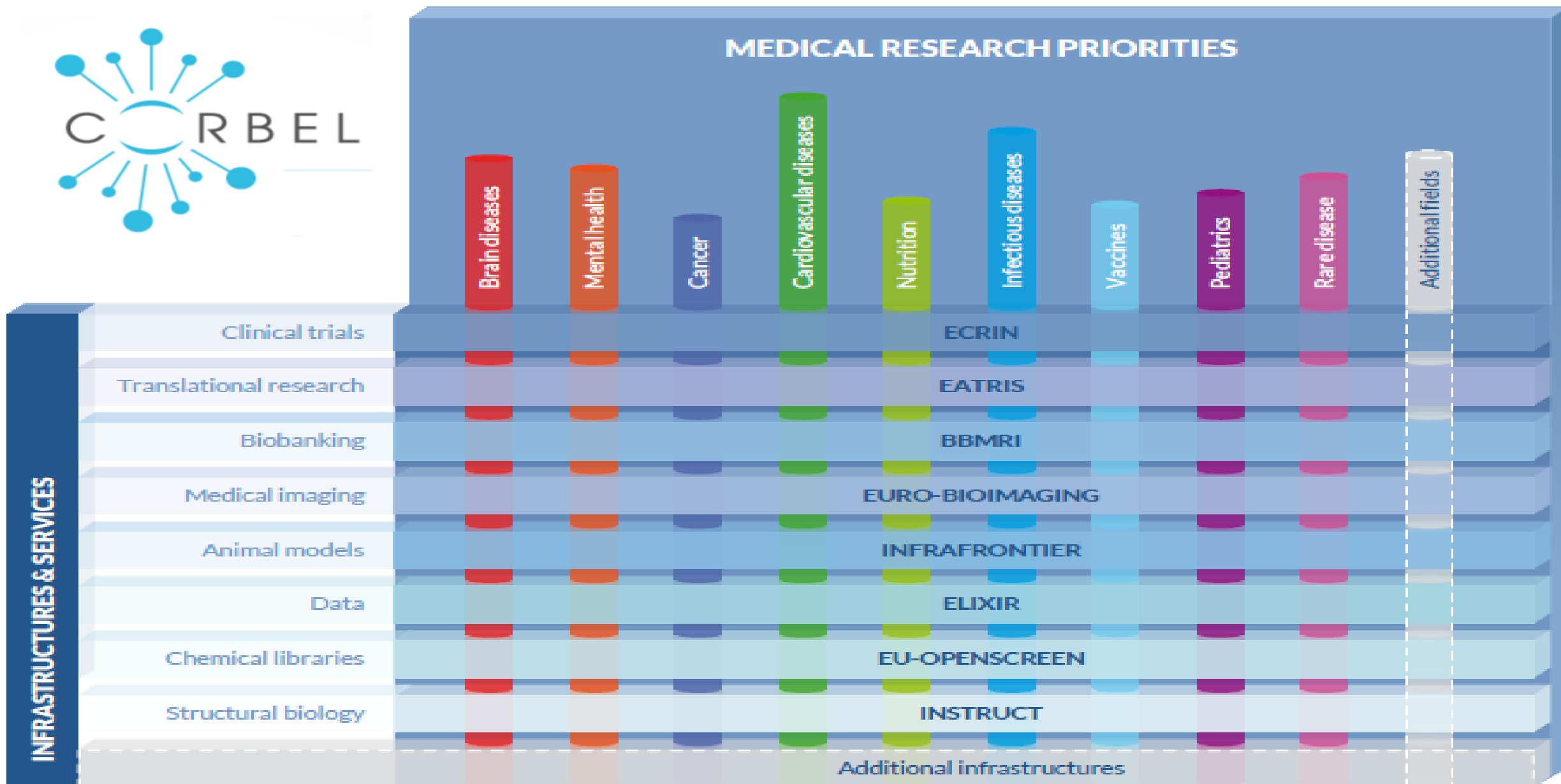
Industry-sponsored trial



Medical Infrastructures / Users Forum

HORIZON 2020

LE PROGRAMME DE RECHERCHE ET D'INNOVATION DE L'UNION EUROPÉENNE

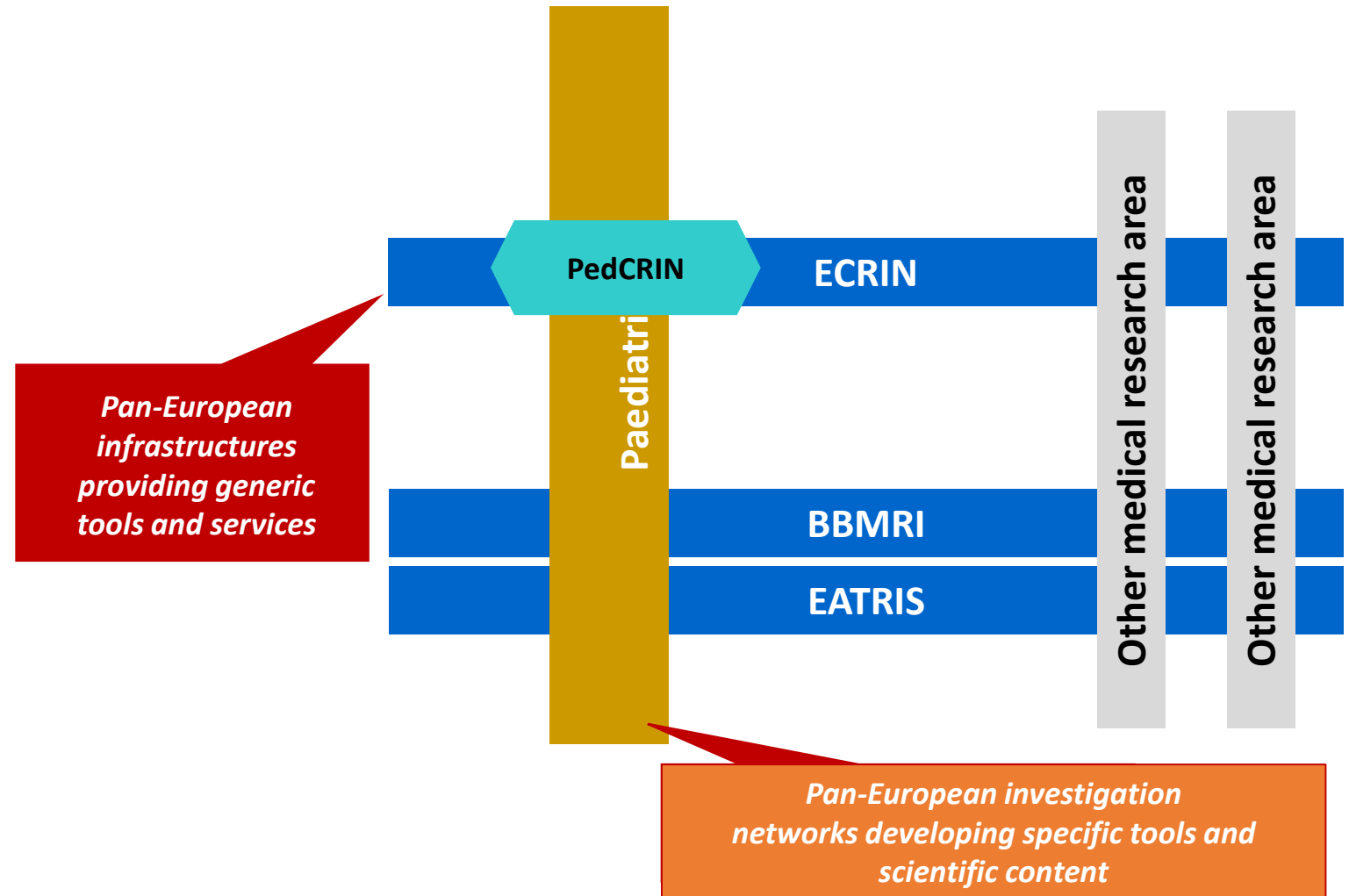


PedCRIN consortium and objectives



- ECRIN and linked third parties: trial management capacity
- EPCTRI partners: investigation capacity
- BBMRI and EATRIS as partners

- Budget 3.3M€
- Duration 36/48 months



PedCRIN consortium

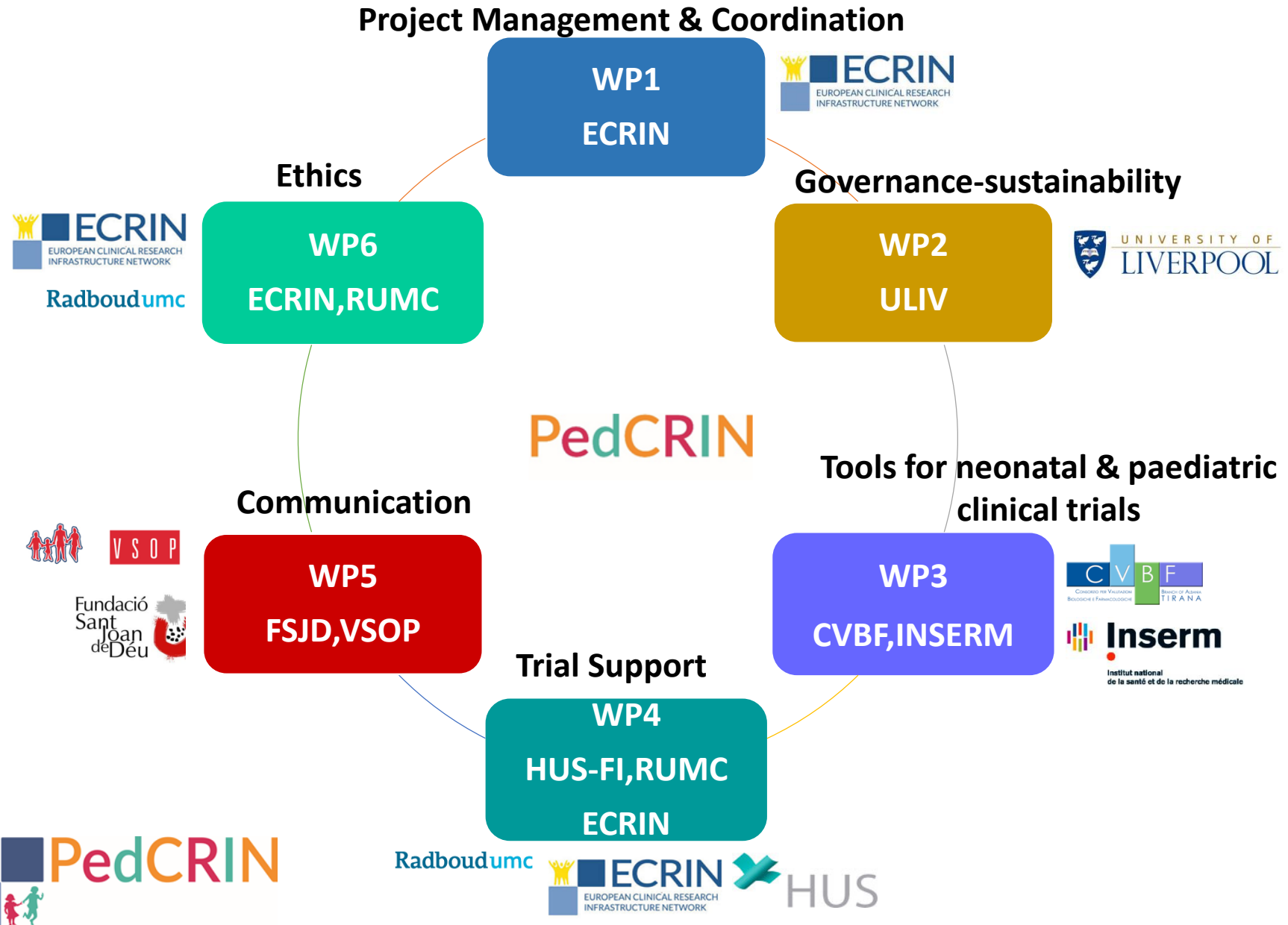
ECRIN & linked third parties

ECRIN
CH: SCTO
CZ : CZECRIN
DE : KKS
ES : SCReN
FR : F-CRIN
HU : HECRIN
IT : ISS
NO : NorCRIN
PT : PtCRIN
BBMRI
EATRIS

EPCTRI partners

AT : OKIDS
CH : SCTO
EE : UTartu
ES : FSJD
FI : HUS
FR : INSERM
GR : AUTH
IRL : NCRC
IT : CVBF
NL : RUMC, VSOP
NO : HUS
SW : KI
UK : ULIV

PedCRIN Consortium



PedCRIN: Tools for neonatal & paediatric trials WP3

Survey

on infrastructure and service needs for paediatric and neonatal trials for

PedCRIN - Survey on infrastructure and service needs for paediatric and neonatal trials

Dear Colleague,

The H2020-funded project PedCRIN (Paediatric Clinical Research Infrastructure Network, GA 731046) has recently launched its activities to enrich the ECRIN tools and actions with paediatric specificities.

In order to optimize the forthcoming PedCRIN services and activities, we sought your collaboration in the identification of the needs and expectations of paediatric medical research communities.

For this purpose, we kindly ask you to complete the following brief questionnaire (5 minutes).

Please do not hesitate to contact us at the following e-mail address (helpdesk@teddynetwork.net (<mailto:helpdesk@teddynetwork.net>)) for any question about the survey and any further information.

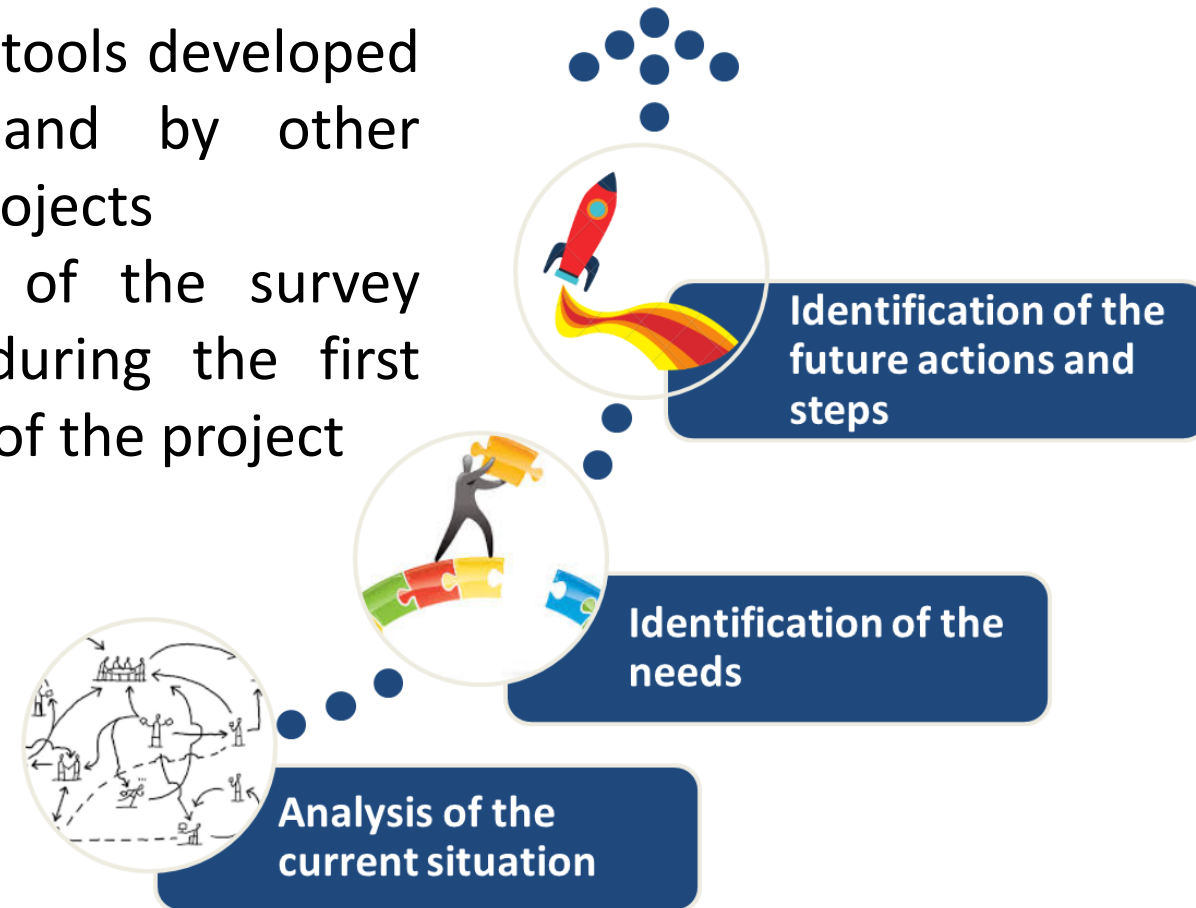
Thank you in advance for your collaboration!

There are 18 questions in this survey

PedCRIN Gap Analysis

The PedCRIN gap analysis is based on the Analysis of

- The existing tools developed by ECRIN and by other paediatric projects
- The results of the survey conducted during the first five months of the project

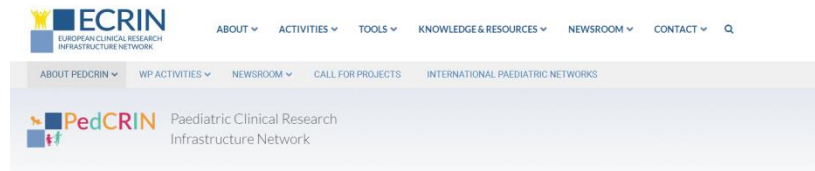


PedCRIN call for funding: WP4

| Project Title | Study Population Neonatal/Paediatric | Country |
|--|---|--|
| Project 1: A randomised trial of prophylactic oropharyngeal surfactant for preterm infants: the POPART trial | Neonatal | <i>Ireland</i> Denmark Sweden Norway Italy Portugal Czech Republic |
| Project 2: Does botulinum toxin make walking easier in children with Cerebral Palsy? | Paediatric | <i>Norway</i> France Poland |
| Project 3: Oxytocin Treatment in Neonates/Infants with Prader-Willi syndrome: effects of intranasal administrations of oxytocin in infants aged from 0 to 3 months vs. placebo on sucking and swallowing (phase III clinical trial) | Both | <i>France</i> Belgium Italy Netherlands Germany |

PedCRIN: Communication, dissemination, empowerment WP5

Website



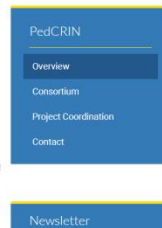
OVERVIEW

What's PedCRIN?

The Paediatric Clinical Research Infrastructure Network (PedCRIN) brings together the European Clinical Research Infrastructure Network (ECRIN) and the founding partners of the European Paediatric Clinical Trial Research Infrastructure (EPCTRI) to develop capacity for the management of multinational paediatric non-commercial clinical trials. PedCRIN is a four-year project funded by the European Union's Horizon 2020 programme, launched on the 1st January 2017 (grant agreement number 731046).

PedCRIN will effectively bridge paediatricians and other partners across Europe (and internationally) to combine resources and expertise to conduct and manage robust studies, while minimising risk and protecting the child participants.

Why PedCRIN?



<http://www.ecriin.org/projects/pedcrin>



facebook



twitter

FACT SHEET

PedCRIN factsheet

To explain the importance of having Paediatric Clinical Trials and a European Clinical Trial Network a PedCRIN factsheet is developed. The factsheet is available in different languages and is readable for everybody who is interested in paediatrics and paediatric clinical trials.

| | |
|---------|--|
| English | |
| Finnish | |
| Dutch | |
| Italian | |
| German | |
| Spanish | |

PedCRIN

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Paediatric Clinical Research Infrastructure Network (PedCRIN)

Towards better medicines for children: Enhancing research infrastructure to conduct and manage more robust paediatric clinical trials

Brochure



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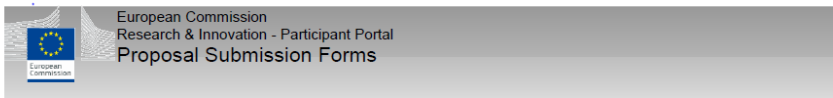
The aim of PedCRIN is to develop the necessary tools and capacity to enhance the quality, safety, efficacy and ethical standards of multinational, non-commercial paediatric clinical trials. PedCRIN will effectively bridge paediatricians and other partners across Europe (and internationally) to combine resources and expertise to conduct and manage robust studies, while minimising risk and protecting the child participants. Continue reading about the PedCRIN project, the work packages it contains and the project partners on the [website](#). If you would like to stay informed about PedCRIN follow its [Facebook](#) and [Twitter](#) profiles.



PedCRIN: Sustainability, strategy, governance, business plan WP2



Development of services to paediatric research



Horizon 2020

Call: H2020-INFRADEV-2016-2017

(Development and long-term sustainability of new pan-European research infrastructures)

Topic: INFRADEV-01-2017

Type of action: RIA
(Research and Innovation action)

Proposal number: 777554

Proposal acronym: ID-EPTRI

*European Paediatric Translational Research
Infrastructure (ID-EPTRI)*



**COllaborative Network for European Clinical Trials For
Children (conect4children, c4c)**

*Collaborative effort between industry and non-industry Partners
addressing the needs of all participants and stakeholders*

**European Joint Programme
on Rare Diseases:**

