



## **Paediatric Clinical Research Infrastructure Network PedCRIN**

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## **PRESS RELEASE**

### **Towards better medicines for children: PedCRIN project builds research infrastructure**

PARIS (31 January 2017) – The European Clinical Research Infrastructure Network (ECRIN) has announced the launch of the Paediatric Clinical Research Infrastructure Network (PedCRIN).

The three-year project brings together ECRIN and the founding partners of the European Paediatric Clinical Trial Research Infrastructure (EPCT-RI) to develop capacity for the management of multinational paediatric clinical trials.

Children represent 20% of the European population and their health is a major societal challenge for Europe and the world, requiring the development of evidence-based paediatric medicines and treatment strategies. Yet, there is a current lack of data specific to neonates, infants and children; over 50% of the medicines used in these groups have not been tested on them specifically, but rather, on adults. This is problematic as neonates/infants/children and adults differ widely in many ways, from their physiology to their metabolic pathways

It is thus important to conduct paediatric trials to increase the knowledge base to develop appropriate, safe and effective health interventions for neonates, infants and children. However, there are various challenges to paediatric studies including dosage and form, recruitment, and many ethical concerns (informed consent, exposure to molecules while still developing, etc.). Therefore, the management of paediatric trials requires the highest level of ethical standards and scientific rigour.

Through PedCRIN, ECRIN aims to address the above challenges to paediatric trials. This will be achieved by bridging 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.

The three-year PedCRIN project involves five work packages, including project coordination and implementation; definition of the PedCRIN business strategy and governance structure; development of tools specific for paediatric and neonatal trials (trial methodology and (patient-centred) outcome measures, adverse event reporting, bio-sample management, ethical and regulatory database, monitoring, quality and certification); provision of operational support to selected pilot trials, which will be coordinated by ECRIN with the support of national paediatric coordinators hosted by paediatric networks (that currently exist or are being set-up); and communication targeting user communities (including industry partners) and policymakers, and aiming to empower patients and parents.

‘Through PedCRIN, we hope to develop the necessary tools and capacity to enhance the high quality and ethical standards of multinational paediatric clinical trials. These tools will be tested through the project, refined, and then shared by the European and international scientific community, ensuring that the project gains become sustainable’, said Jacques Demotes, Director General of ECRIN.



PedCRIN has received funding from the European Union’s Horizon 2020 programme (INFRADEV-3 call) under grant agreement number 731046.

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**About ECRIN:**

The European Clinical Research Infrastructure Network (ECRIN, [www.ecrin.org](http://www.ecrin.org)) is a sustainable, not-for-profit, distributed infrastructure with the legal status of a European Research Infrastructure Consortium (ERIC). ECRIN provides support for the development and implementation of multinational clinical research projects in Europe.

ECRIN currently has seven Member Countries (France, Germany, Spain, Italy, Portugal, Hungary and Norway) and two Observer Countries (Czech Republic and Switzerland). Additional countries are about to join.

ECRIN primarily provides support to sponsors in investigator-initiated trials for trial preparation, the validation of study protocols, and trial management. ECRIN's focus is on independent, multinational academic research as well as trials initiated by biotech and medical device small and medium enterprises (SMEs).

ECRIN's 'distributed infrastructure' includes a Core Team based in Paris, France (headquarters) and European Correspondents (EuCos) working in each Member and Observer Country. EuCos are part of ECRIN's national scientific partners, which are networks of academic clinical trial units or clinical research centres located at or affiliated to national universities and hospitals.

## **PedCRIN: Towards better medicines for children through infrastructure development**

### **What is 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 (EPCT-RI) to develop capacity for the management of multinational paediatric clinical trials. PedCRIN is a four-year project funded by the European Union's Horizon 2020 programme, launched on 1 January 2017<sup>1</sup>.

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.

### **Lack of medicinal product testing on children: consequences**

Many medicinal products have not been adequately tested on children or authorised for use on this population. The lack of paediatric drug testing has several consequences:

- Non-availability of appropriate paediatric formulations;
- Medicines used are often off-label and unlicensed;
- Children may receive ineffective treatment;
- Children may be given inaccurate dosing;
- Warnings of possible adverse drug reactions (ADRs) and adverse events are insufficient for medicinal products used in children;
- New and innovative medicines are available with a paediatric indication, but with no evidence of long-term benefit and risk, e.g. the biological agents.

### **Differences between children and adults**

The paediatric population often responds to drugs and other therapeutics differently than adults do. Children differ from adults in anatomical and physiological ways and in the types of diseases from which they suffer; moreover, the manifestations of those diseases are different between children and adults. Children may respond differently to medicinal products, which have the potential to impact their growth and maturation and affect them psychosocially. It is also possible that a neonate may respond differently than older infants and children, and simply adjusting the dosage does not (always) solve the problem. Paediatric clinical trials are therefore essential to ensure that children receive appropriate, safe and effective treatment and care.

Clinical trials in children are more challenging than those in adults and the pool of eligible children for trials is often small. Children must have at least the same rights as adults regarding access to high quality and evidence-based medication and health care services.

### **Need for paediatric clinical trials**

Paediatric clinical trials have novel complexities due to the safety concerns of testing medicines in children, ethical considerations, informed consent, lower prevalence of disease, the need to test different age groups, the possibility of late adverse effects, the requirement for tailored study design and the need for child-appropriate medicine formulations. To improve clinical care of children, more clinical trials are needed focussing on children's health with the goal of developing treatments, drugs, and devices specific to children. Paediatric clinical trials are necessary to test the efficacy of a medicinal product if it is:

- For diseases that affect children exclusively or have different symptoms and development in children;
- Intended to treat diseases occurring in adults and children for which there is currently no treatment;
- To treat a disease occurring in adults and children for which treatments exist, but where there is insufficient knowledge of efficacy or toxicity in children.

### Non-commercial multinational trials

Commercially sponsored clinical trials are responsible for developing new medicines that can treat various disease areas. It is important to note, however, that these clinical trials only assess the activity of drugs that are chosen by a commercial entity that funds the entire process. Non-commercial or academic trials allow researchers to refine indications of available treatments and to optimise therapeutic strategies.

However, non-commercial trials face an increasing number of challenges, including a lack of funding, inadequate infrastructure to facilitate academic collaboration, and a lack of platform to discuss and solve issues related to academic trials.

### PedCRIN: developing capacity for the management of multinational paediatric clinical trials

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.

#### Project design

The four-year PedCRIN project builds on five work packages:

- Project coordination and implementation;
- Business strategy and governance structure;
- Development of tools specific for paediatric and neonatal trials: trial methodology, (patient-centred) outcome measures, adverse event reporting, bio-sample management, ethical and regulatory database, monitoring, quality and certification;
- Provision of operational support to selected pilot trials;
- Communication to target user communities and policymakers and aiming to empower patients and parents.

### Putting patients first

The children and their families have a critical role to play in clinical studies. Based on their personal experience, they can indicate which outcome measures are essential, when informed consented material is comprehensive, and which ethical aspects are important to them. As such, their role in the PedCRIN project is essential, and they will be placed at the centre of PedCRIN's work. Patient advocacy groups and young people's advisory groups (YPAGs) will give feedback on a presented protocol and they will be consulted to identify the role of children, young people, parents and caretakers during the management of multinational paediatric trials.

More information about PedCRIN can be found here: [www.ecriin.org/activities/pedcrin](http://www.ecriin.org/activities/pedcrin)

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