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.

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About ECRIN:

The European Clinical Research Infrastructure Network (ECRIN, 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.

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