Paediatric Clinical Research Infrastructure Network (PedCRIN)

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Project Website

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Working Package: WP5 (FSJD)

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PedCRIN Mini Website

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ABOUT PedCRIN

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 (EPCT-RI) 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?

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.
The PedCRIN consortium is led by ECRIN and composed of 14 other organisations:

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**Project coordination**
The PedCRIN project is organised in six work packages (see WP activities). The diagram below illustrates the lead organisation(s) for each one.

Contact

For general project inquiries, please contact: pedcrin@ecrin.org
For communications inquiries, please contact: pedcrin.communication@ecrin.org
Overview

The PedCRIN project builds on five work packages:

1. Project coordination and implementation
2. Business strategy and governance structure
3. Development of tools specific for paediatric and neonatal trials
4. Provision of operational support to pilot trials
5. Communication to target user communities and policymakers and aiming to empower patients and parents
6. Ethics

1. Project coordination (WP1)

Objective:

To manage the PedCRIN project, coordinate work package activities, and implement governance decisions

Key activities:

Management of the project including the coordination of the work package activities by the project coordinator organisation, with support from the governance bodies:

- Management Board, composed of the project beneficiaries
- Steering Committee, composed of the work package leaders
- Advisory Board, composed of the major stakeholders in global paediatric and clinical research

Partners: European Clinical Research Infrastructure Network (ECRIN)

2. Governance & Sustainability (WP2)

Objectives:

- To establish the conditions for the sustainability of an upgraded ECRIN research infrastructure that can provide specific tools and services to paediatric clinical trials
- To involve government representatives and scientific partners in project governance through participation in a Sustainability Board

Key activities:

- Development of a strategy plan – defining challenges, strategic options, objectives and actions – to enhance ECRIN’s capacity to support multinational paediatric clinical trials
- Establishment of a Sustainability Board to develop the project’s statutes and business plan and to contribute to the financial management of the project
- Drafting of reports on decisions related to strategy
- Ensure that children, young people, parents and caretakers are at the heart of PedCRIN

Partners: University of Liverpool (ULIV)
3. Tools for neonatal & paediatric clinical trials (WP3)

Objectives:

- To develop or adapt tools to be used for multinational paediatric clinical trials; this entails upgrading tools already developed by participants, especially ECRIN, taking into consideration paediatric specifications
- To disseminate tools to PedCRIN and ECRIN partners
- To train and support partners on the use of the tools

Key activities:

- Survey targeting paediatric and neonatal users as well as patient communities to identify the needs of paediatricians in terms of infrastructures and tools for clinical trials.
- Gap analysis to detect missing tools and services to support paediatric and neonatal trials
- Upgrade, maintenance and sustainability of tools for paediatric trials (ethical and regulatory database, pharmacovigilance, etc.)
- Upgrade, maintenance and sustainability of tools for neonatal trials
- Dissemination of the tools to PedCRIN and ECRIN partners
- Development of a procedure to enable access to individual patient clinical trial data

Partners: Consorzio Per Valutazioni Biologiche E Farmacologiche (CVFB)  
Institut National de la Sante et de la Recherche Medicale (INSERM)

4. Trial Support (WP4)

Objectives:

- To select various trials, which already have funding in the coordinating country, to serve as PedCRIN pilots to assess the tools for paediatric and neonatal trials developed in WP3 To provide access to ECRIN trial management services (e.g. support for regulatory and ethical submissions, trial monitoring, pharmacovigilance, insurance, trial product and bio sample management) to the PedCRIN pilot trials
- To provide support for the extension of the pilot trials to other ECRIN Member or Observer Countries, and/or countries represented in the PedCRIN consortium

Key activities:

- Management of a call for applications for the clinical trials to be supported by PedCRIN
- Selection of the pilot trials with the inclusion of at least one neonatal trial if it meets the quality criteria
- Provision of operational services to multinational paediatric and neonatal trials selected by the peer-review procedure

Partners: Radboud University (RUMC)  
Hospital District of Helsinki and Uusimaa (HUS-FI)  
European Clinical Research Infrastructure Network (ECRIN)
5. Communication (WP5)

Objectives:

- To communicate about PedCRIN with children, parents and families, industry, regulatory authorities, policymakers, healthcare providers and all the relevant stakeholders
- To ensure that children, young people, parents and families are included in PedCRIN activities
- To educate and empower young patients and their families during the entire process of a clinical trial (recruitment, development, etc.)
- To evaluate the impact of the education and empowerment activities on different target groups

Key activities:

- Development and implementation of a communication and dissemination plan to promote the different activities, goals and deliverables of the project
- Development of a mini PedCRIN website on the ECRIN website and a newsletter to ensure that project stakeholders and the interested public have information about PedCRIN including project updates/news
- Development and dissemination of communication materials targeted at different types of audiences
- Consultation with patients, parents, patient advocates, advocacy groups and Young Persons’ Advisory Groups (YPAGs) to identify the role they have during the management of multinational paediatric trials by, for example, giving active feedback on trial protocols and informed consent material
- Report of the activities performed regarding patient engagement, perspective integration and impact assessment of the empowerment activities

Partners: Fundació Sant Joan de Déu
Vereniging Samenwerkende Ouder – en Patientenorganisaties (VSOP)

6. Ethics (WP6)

Objectives:

- To set out the “ethics requirement” that the project must comply with

Key activities:

- Provide details on the procedures and criteria that will be used to identify/recruit research participants
- Provide detailed information on the informed consent procedures that will be implemented for the participation of humans
- Provide templates of the informed consent forms and information sheets when requested
- Providing information on the procedures that will be implemented for data collection, storage, protection, retention, and destruction and conformation that they comply with national and EU legislation

Partners: Radboud University (RUMC)
European Clinical Research Infrastructure Network (ECRIN)
TOOLS
For now this will be a basic page with a brief presentation of PedCRIN tools and links to tools. However, the technical specifications will be provided at a later date.

NEWSROOM
This section will have two tabs (i) News articles & (ii) PedCRIN publications.

Under News Articles:
It will include news articles that have been “tagged” as PedCRIN.
To date, two news articles are included: PedCRIN press release and PedCRIN call for multinational neonatal and paediatric clinical studies

Under PedCRIN Publications
1. The PedCRIN factsheet (http://www.ecrin.org/sites/default/files/PedCRIN/PedCRIN%20factsheet.pdf) and its multiple translations will be provided
2. The (future) PedCRIN brochure
3. The (future) PedCRIN newsletter

For subscription of the newsletter a separate subscription link/button will be added on the website

RESOURCES
This section will be published in coming few months and will provide:
- Educational resources
- Information for children

CALL FOR PROJECTS
This page is dedicated for providing the information regarding the funding opportunities for investigators