



Paediatric Clinical Research Infrastructure Network (PedCRIN)

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Contact: Jacques Demotes
ECRIN-ERIC Director General
European Clinical Research Infrastructure
Network
BioPark, 5-7 rue Watt
75013 Paris, France
Tel: +33 180058646
Jacques.demotes@ecrin.org
www.ecrin.org



PedCRIN support for multinational clinical studies

PedCRIN support for the studies resulted in the start of two of the three studies that were accepted for support. The PedCRIN staff facilitated the drafting of contracts and agreements. More [information](#) about the recent developments and about the studies: The [WE-study](#) and the [POPART-study](#)

PedCRIN poster

A [PedCRIN poster](#) was presented at [18th World Congress of Basic and Clinical Pharmacology in Kyoto, Japan, July 1-6, 2018](#) by WP3 members Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF). In PedCRIN project WP3 is dedicated to develop tools specific for neonatal and paediatric multinational, non-commercial paediatric clinical trials. The conference was focused on the theme of “Pharmacology for the Future Science, Drug Development and Therapeutics” CVBF participated in the event and presented the poster describing the preliminary results of the PedCRIN project.

Patient involvement in the clinical trials of PedCRIN

Fundació Sant Joan de Déu in Barcelona (Spain) performed an advice session with the members of the group [Kids Barcelona](#). This is a Young Persons Advisory Group linked to the Clinical Trials Unit of [Sant Joan de Déu Children’s Hospital](#)

The activity was focused on the patients and parents documentation of the WE study. The meeting was held May 30, and led by a pediatric neurologist with expertise in clinical trials addressed to paediatric patients with cerebral palsy. The outcomes of the session will improve the current version of this documents and facilitate that they will be more patient friendly. New YPAGs around Europe will contribute soon to the project doing the same consultation activity. The results will be part of a final report about the patients’ involvement in PedCRIN project.

The Vereniging Ouder en Patiëntenorganisaties (VSOP, the Dutch Patient Association for Rare and Genetic diseases) held a parent meeting on the POPART study. The parents had experience with neonatal care, because their children had been admitted to a neonatal intensive care unit and were ventilated. Relevant (preliminary) outcomes of the meeting where: (1) if they where asked, they would participate in a study like POPART (2) they think it is imported to inform parents about the

randomization process and (3) they thought that the conversation with the physician about the trial was more important than the written informed consent documents.

EMA Workshop 'Paediatric Regulation'

EMA organized a workshop '[How to better apply the Paediatric Regulation to boost development of medicines for children](#)'. Among the topics that were discussed was the advice to support the conduct of clinical trials, to ensure sustainable infrastructures and funding, the involvement of young persons in research. The EC and EMA, including the Paediatric Committee (PDCO) are working on an action plan for the next 2 years, which will be shared with stakeholders by mid-2018.

EMA Workshop 'Development medicinal products'

EMA organized a workshop on 'Development of antibacterial medicinal products for paediatric patients' on 21-22 June. More information can be found [here](#)

Interviews with the Principle Investigators

The partner Fundació Sant Joan de Déu in Barcelona interviewed the principle investigator of the WE study (The [WE Study: Finding a way to palliate the symptoms of Cerebral Palsy in children](#)). This is one of the studies that is supported by PedCRIN as mentioned above. The transcribed interview can be found [here](#).

What's PedCRIN?

PedCRIN project is to enhance ECRIN capacity for the management of multinational multicentre neonatal and paediatric clinical trials and to develop tools to facilitate the academic or investigator initiated 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). 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. More information about the PedCRIN project on the website, Facebook and Twitter.





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Our mailing address is:

ECRIN (PedCRIN)
5-7 rue Watt
75013 Paris, France

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