



Paediatric Clinical Research Infrastructure Network (PedCRIN)

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What's PedCRIN?

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. 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 Call outcome: 3 trials selected

In February 2017, PedCRIN call for application was launched to fund investigator-initiated paediatric or neonatal interventional clinical studies on medicinal products to support study management tasks in countries other than the coordinating country. In **response to this call 13 applications were received** from (6) different EU countries. Of these studies **(3) were neonatal, (7) paediatric and (3) both neonatal and paediatric (3)**.

Project Title	Country
Project 1: The WE-study: Walking Easier with cerebral palsy Project Synopsis: WE Study Website: https://otbb3.nu/WE-studien	Norway France Poland (Zagorz)
Project 2: A randomised trial of prophylactic oropharyngeal surfactant for preterm infants: the POPART trial Project Synopsis: POPART	Iceland Denmark Sweden Norway Italy Portugal Czech Republic
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) Project Synopsis: OTBB3	France Belgium Italy Netherlands Germany

In total **3 studies where selected to participate** in the PedCRIN-project as pilot trials. These 3 studies are:

- **Project 1:** The WE-study–Walking Easier with cerebral palsy
- **Project 2:** A randomised trial of prophylactic oropharyngeal surfactant for preterm infants: the POPART trial
- **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): OTBB3 Trial

10 years of regulation on paediatric research

Ten years ago the EU adopted a new regulation on pediatric research to enhance the development of paediatric medicines: 'Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December

2006 on medicinal products for paediatric use, OJ L 378, 27.12.2006'.

Recently a report about this regulation was published.

The **Pediatric Regulation** has three main objectives:

- To encourage high-quality research on medicines for children,
- To ensure that most pediatric medicines are specifically authorized with age-appropriate forms and formulations,
- To increase the availability of high-quality information about medicines used by children.



For PedCRIN it is important that the regulation acknowledges the importance of researcher initiated research – annex to research by pharmaceutical companies – and underlines the importance of the creation of networks and the consultation of children and parents about ways to conduct pediatric research.

Why this newsletter?

The PedCRIN Newsletters will keep you informed about the progress of the PedCRIN project. If you want to **subscribe to the PedCRIN Newsletter**, please do so through the link in the right column of the PedCRIN website. When receiving the PedCRIN Newsletter, do not hesitate to forward it to your contacts that might be interested in information about PedCRIN and the project.

Upcoming events:

- **Advisory Board** on the 27th of February 2018 in Paris (France)
- **PedCRIN annual Meeting** in Bergen (Norway) on the 23th and 24th of April 2018



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