



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

Communication and dissemination plan

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Abbreviations

PedCRIN	The Paediatric Clinical Research Infrastructure Network
CYP	Children and young people
ADRs	Adverse drug reactions
ECRIN	European Clinical Research Infrastructure Network
YPAG	Young person advisory groups
eYPAGnet	The European Network of Young person advisory groups
FSJD	Fundacio San Joan de Deu
VSOP	voor zeldzame en genetische aandoeningen
EPCT-RI	Paediatric Clinical Trial Research Infrastructure

Revision History Log

Revision	Date of release	Author	Summary of changes
0.1 - DRAFT	31.03.2017	FSJD	Initial draft
1.0	20.04.2017	FSJD	Inclusion of the logo of the project
2.0	03.05.2017	FSJD	Inclusion of the brochure and social media profiles screen-shoot

1. Background of the project: Paediatric clinical trials in Europe

The Paediatric Clinical Research Infrastructure Network (PedCRIN) is a four-year project funded by the European Union's Horizon 2020 programme, launched on 1 January 2017. PedCRIN will effectively bridge paediatricians and other partners across Europe (and internationally) to combine resources and expertise to conduct and manage robust clinical trials, while minimising risk and protecting the child participants.

Around 21 % of the European population (or more than 100 million people) is comprised of children and young people (CYP). Historically the needs and specificities of CYP have not received the right answer in terms of clinical trials and drug development. There are relevant data that confirm the necessity to change this reality and develop specific projects to ensure the right procedure to increase the studies and their quality:

- Medicines used for children are often off-label and unlicensed (45-60 %) and in preterm & neonatal population (90 %)
- Non-availability of appropriate paediatric formulations and inaccurate dosing
- Many paediatric diseases are rare diseases (80 % genetic) and this requires an investment in the research, development and authorization of orphan drugs. Most of the clinical trials addressed to paediatric patients are for the most prevalent diseases
- 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.

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. This will be achieved, in part, through the optimization of the capacity of the European Clinical Research Infrastructure Network (ECRIN) to support multinational paediatric clinical trials, using the tools developed through PedCRIN.

ECRIN is a public, non-profit organization that links scientific partners and networks across Europe to facilitate multinational clinical research. They provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration.

In this context, PedCRIN envisions the design, development and assessment of a European network that allows the conduct of non-commercial clinical trials among CYP.

2. Introduction to PedCRIN communication and dissemination plan

2.1. General purpose

In the context of PedCRIN, communication and dissemination will include both internal activities (involving partners of the project) and external activities (involving the greater scientific community and patients/society).

The purpose of the current communication and dissemination plan is to ensure that the information about the project arrives on time and to the right target groups. It will also ensure that all activities are aligned with the goals of the project and contribute to achieving them.

2.2. Internal and external objectives

The external objectives of the plan are to:

- **To increase awareness of the PedCRIN project** and its activities among relevant external stakeholders including children, parents and families, industry, regulatory authorities, policymakers, health care providers and other relevant stakeholders
- **Share best practices** for multinational collaboration on non-commercial paediatric clinical trials.
- **Spread the word about the activities** regarding the voice of patients and families in the development of paediatric drugs
- Inform all the stakeholders that **patients and their carers have a voice in the development process of PedCRIN**. They are a member of the paediatric community and their experience, expertise and voice is as valuable as that of the other members
- **Share information** about all the activities that are being performed to make sure patients and their parents have a voice in the development process of PedCRIN
- **To include the social media as a mean of communication** to achieve the general population and to educate about the empowerment of patients. This communication channel is also relevant to disseminate different milestones of the project

The internal objectives are to:

- **Ensure that internal stakeholders are aware of the appropriate way** to communicate about the project
- **Ensure that internal stakeholders are informed** of project progress, achievements, challenges, and any other considerations
- **Promote dialogue and information sharing** between work packages
- **Ensure that lessons learned are communicated** to the entire group

3. Definition of different target groups and audiences at local, regional and European level

The communication activities of the project will be addressed to main stakeholders (targets) involved in paediatric drug development. In order to ensure the impact of the dissemination and to promote a participatory process for performing clinical trials, it is essential to involve all stakeholders in these activities.

3.1. The targets for external communication

3.1.1. Young Persons Advisory Groups (YPAGs)

Young person advisory groups are groups of children and teenagers who have been trained to collaborate in the design and development of clinical trials and other research initiatives addressed to the paediatric population. The aim of including these groups is to ensure that the perspectives and needs of the paediatric population are incorporated in the design of trials and and develop projects focused in their contributions (patient centered). The European Network of YPAGs (eYPAGnet) is going to be the most relevant stakeholder in dissemination activities in order to ensure that all groups in Europe are aware of the PedCRIN project.

On the other hand, parents of the members of YPAG can become good ambassadors of the PedCRIN project. Their involvement will not only show their influence on the clinical research but will also help in identifying and implementing needs of involving patients and families in the design of the clinical trials.

3.1.2. Patient associations

National and international patient associations will be involved in the communication activities. They will have an important role in shaping the (patient/family) advocacy activities that will be developed during the project. Members of eYPAGnet will also be involved in the development of such activities.

In order to identify the patient associations to be targeted by the project, a database of existing European organisations will be developed. This database will indicate in particular the specific diseases that the groups are involved in.

A database will be created about existing European organisations linked to specific diseases. Based on their disease focus, groups could be contacted to be involved in the PedCRIN-supported multinational paediatric clinical trials.

3.1.3. Neonate population

Neonates represent a group of patients which are much more vulnerable than children and young patients and therefore their needs must be prioritised. For this purpose, parents and the specific associations that work for the rights of the neonates are going to be targeted for communication activities of PedCRIN so as to make sure that they are aware of the PedCRIN project and its activities. A database of the organisations associated with neonatal patients will be created.

3.1.4. Paediatric community

The paediatric community comprises of healthcare providers, researchers, academics, regulators, and policy and decision makers at national and European levels.

Such groups are going to be approached through interaction with project partners and will be invited to receive the news about the project through the subscription of the newsletter. An active campaign will be performed during the month 4-5 of the project to inform these stakeholders about the newsletter in which project information will be shared.

3.2. The target for internal communication

The 15 project partners are the primary target for internal project communications. These organisations include:

1. European Clinical Research Infrastructure Network - ERIC
2. The University of Liverpool
3. Consorzio per Valutazioni Biologiche e Farmacologiche
4. Radboud University
5. Institut National de la Santé et de la Recherche Médicale
6. Hospital District of Helsinki and Uusimaa
7. Fundacio San Joan de Deu
8. Swiss Clinical Trial Organisation
9. Karolinska Institutet
10. Helse Bergen HF Haukeland University Hospital
11. Tartu Ulikool
12. Aristotelio Panepistimio Thessalonikis
13. OKIDS GmbH
14. The National Children's Research Centre
15. Vereniging Samenwerkende Ouder – en Patientenorganisaties

It is critical that these internal stakeholders have a clear understanding of the project aims, achievements, progress, etc. That's why they will act as the main project ambassadors to external stakeholders.

In a survey conducted at the start of the project, they already indicated their willingness to support external communications and in particular the dissemination of project news. This will be done by forwarding information to their contact databases or posting information on their websites and social media profiles (Facebook, Twitter, etc.).

Contacts of different countries involved in the project and at European level would be another important target for the communication activities. For this purpose

- ECRIN's contact database will be used
- National contacts will be approached through the contact database of project partners.

4. Tools and methods for internal and external communication

4.1. Internal communication

4.1.1. Tools

ECRIN has established an own e-mail address for the project (PedCRIN.communication@ecrin.org). This email address will be connected with the contact formula on the project website and will be placed on all reports. Specific project inquiries will be forwarded to the affected work package leaders. A statistic of all email inquiries will be provided regularly with the updated Dissemination and Communication Plan.

4.1.2. Frequency

Relevant information will be circulated at any time available without a pre-defined timeline.

4.2. External communication:

4.2.1. Tools

4.2.1.1. Mini-website

Mini-website of the project is expected to be launched by the end of month three. It will be embedded within the existing website of ECRIN. The main language of this tool is going to be English. The most relevant information of the project is going to be translated to the main languages of the European Community, such as the factsheet (*Appendix 1: Structure of architecture of the content of the mini-website*)

FSJD is responsible for this task which includes writing, editing and updating the information in the mini-website.

4.2.1.2. Logo

A logo will be developed to identify the project and will be included in all sorts of communication materials (mini-website, brochure, factsheet, etc.). This logo needs to be aligned with the logo of ECRIN but with paediatric features (*Appendix 2: Logo*)

VSOP is responsible for this task.

4.2.1.3. Brochure

A visual brochure will be created to summarise the project's background, objectives, planned work and project outputs. The brochure will be available online and printed and it will be distributed to key stakeholders. The target of this resource is the scientific community. Language: English (*Appendix 3: Brochure*)

VSOP is responsible for this task.

4.2.1.4. Factsheet

A factsheet has been developed in plain English for lay audiences to explain the importance of having paediatric clinical trials and a European Clinical Trial Network. The content will be available online and in the different languages represented for the different partners of the project (*Appendix 4: Factsheet*).

VSOP is responsible for this task.

4.2.1.5. Newsletters:

A newsletter will be produced and disseminated through the different lists of stakeholders and subscribers. The newsletters will be also published on the mini-website, and promoted by the social media profiles.

The software “MailChimp” is going to be the tool to edit, produce and send the newsletter through the different lists of contacts.

The newsletter will be produced every four months (or three times per year). The news of the project and other relevant content will be agreed upon by ECRIN and FSJD.

VSOP is the responsible for this task.

4.2.1.6. Press release:

One press release was launched at the beginning of the project. Partners will distribute it and post it on their websites as well as on their social media accounts. Efforts will be made to contact press and media to increase awareness of the project, both at local and European level (*Appendix 5: Press release*).

FSJD is the responsible for this task. All the partners are going to be encouraged to distribute the press releases through their contact databases.

4.2.1.7. Facebook profile:

A new profile regarding the PedCRIN project is going to be launched on Facebook. The page will be used to circulate information on:

- News of the project
- Newsletters
- Call for application
- Content to educate about paediatric clinical trials
- Content about children, young patients and relatives about advocacy
- Tools of the project
- Other relevant content about paediatric clinical trials

Questions and comments received in the Facebook environment are going to be answered from FSJD as a coordinator of this social media channel.

FSJD is responsible for this task, while ECRIN will provide quality assurance by approving content prior to publication (Appendix 6: Social Media)

4.2.1.8. Twitter profile:

The profile of ECRIN on Twitter is going to be used to spread the word about the project. The content that will be available on Facebook will also be disseminated through Twitter. Relevant information of the project published by other relevant profiles on Twitter are going to be curated (retweet, likes, etc.) (*Appendix 6: Social Media*)

FSJD is responsible for this task, and again, ECRIN will provide approval prior to publication

4.2.2. Methods and frequency

Tool	Owner	Deadline	Frequency of the dissemination
Mini-website	FSJD	M3	According to the news/outcomes of the project. At a minimum, one news article will be published per month
Logo	VSOP	M3	
Brochure	VSOP	M3	
			One brochure will be created and distributed throughout the course of the project (if needed, an update will be done, and the document will be reprinted and uploaded on the mini- website)
Factsheet	VSOP	M1	One factsheet will be created and made available via the mini-website throughout the course of the project. The factsheet will be available in different languages. If needed, an update will be done, and the document will be uploaded on the mini-website. Factsheet will be distributed during the activities with patients, families and patients' associations'
Newsletter	VSOP	M4	Quarterly
Press release	FSJD	M1	Mandatory one at the start of the project
			At least one at end of the project
Facebook profile	FSDJ	M3	2 publications/week
Twitter profile	FSJD	M3	2 publications/week

5. Key messages: Information and arguments needed to influence specific policy choices

- **News about the PedCRIN** project will be spread using mini-website, newsletter and social media (Facebook and Twitter)
- **An educative campaign about paediatric clinical research** and clinical trials will be initiated through social media (Facebook and Twitter). For this purpose weekly content will be provided to ECRIN and VSOP for broadcasting on Facebook and Twitter.
- **Key messages** of the project are going to be planned monthly and send to ECRIN to reach their approval.

6. Tracking and analytics of the activities

- ✓ The most significant statistics about the website and the social media profiles will be collected monthly, such as: visits, unique users, pages that users have visited, most visited contents, etc. The statistics about the website are going to be collected through Google Analytics. About social media the tools to recruit this information are going to be: Facebook Statistics and Twitter Analytics (*Appendix 7: Tracking and analytics Page No. 22*)
- ✓ This information is going to be saved in an Excel file updated in a Dropbox folder shared by the internal stakeholders involved in the communications work package (WP5). The reports are going to be shared with the Steering Committee. The analysis of the reports will be useful to know in detail about the public users of our social media and website with the aim to adapt to them the type of contents that are more interesting and that generate more impact.

- ✓ Information will be collected about the impact of the communication resources of the project: Factsheet and brochure. Quantitative and qualitative information are going to be collected:
 - Number of downloads through the web
 - Number of copies delivered in different events
 - Number and names of event where information about this resource will be distributed.Etc.

- ✓ A proposal of the statistics to be analysed is included in (*Appendix 7: Tracking and analytics Page No. 22*)

7. Conclusion

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. At European level PedCRIN will promote studies that need to be done across borders and thereby enhance the position of Europe as a place to conduct studies. The removal of barriers to trial management will speed up the evaluation of new and improved therapies and by reducing time and cost overhead of multinational studies will stimulate investigators and funders to conduct more multinational studies.

Promoting dissemination of interoperable standards will amplify the impact of the project. Communication with paediatric communities as potential users (academic and industry sponsors) will be a key success factor. An adequate dissemination and communication of the project objectives and results (tools and messages) to key stakeholders at local, national and European levels will promote the added value of using PedCRIN. Finally for PedCRIN the website and the newsletter will be the essential promoting and dissemination tool. Downloads and information will be available on the website. Announcements and news will be promoted via the newsletter and social media (Facebook and Twitter).

Appendix 1: Structure of architecture of the content of the mini-website

A. ABOUT PedCRIN

- Overview
- Consortium
- Project coordination
- Contact

B. WP ACTIVITIES

- Overview
- Project coordination
- Sustainability
- Tools
- Support to multinational trials
- Communication
- Ethics

C. TOOLS

D. NEWS

- News
- PedCRIN publications

E. RESOURCES

- Educational resources
- Information for children

F. CALL FOR PROJECTS

Note: The pages "Tools" and "Resources" are not yet published on the mini-website; they will be published once the content is available for each section.

Appendix 2: Logo



Paediatric Clinical Research Infrastructure Network (PedCRIN)

Towards better medicines for children: Enhancing research infrastructure to conduct
and manage more robust paediatric clinical trials

[Appendix 3: Brochure](#)

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 2017¹.

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 do we need PedCRIN?

Clinical research involving infants, children, and adolescents is, in some important aspects, more challenging than research involving adults. 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. These challenges deter many researchers from attempting multinational trials, which are not only important for new drugs but also for available treatments that need to be refined. Conducting clinical trials in children requires specific competences and infrastructure. To overcome complex challenges of pediatric research there is a need to develop an infrastructure which could be used as a tool for the support and management of multinational paediatric trials. To fulfill this need EPCTRI and ECRIN collaborated to develop PedCRIN, a common infrastructure for paediatric trial management and investigation.

ECRIN is a non-profit intergovernmental organisation that provides support to multinational clinical trials. Through PedCRIN, ECRIN will develop its capacity to support the conduct of robust, multinational, academic paediatric clinical trials.

The aims of PedCRIN

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.



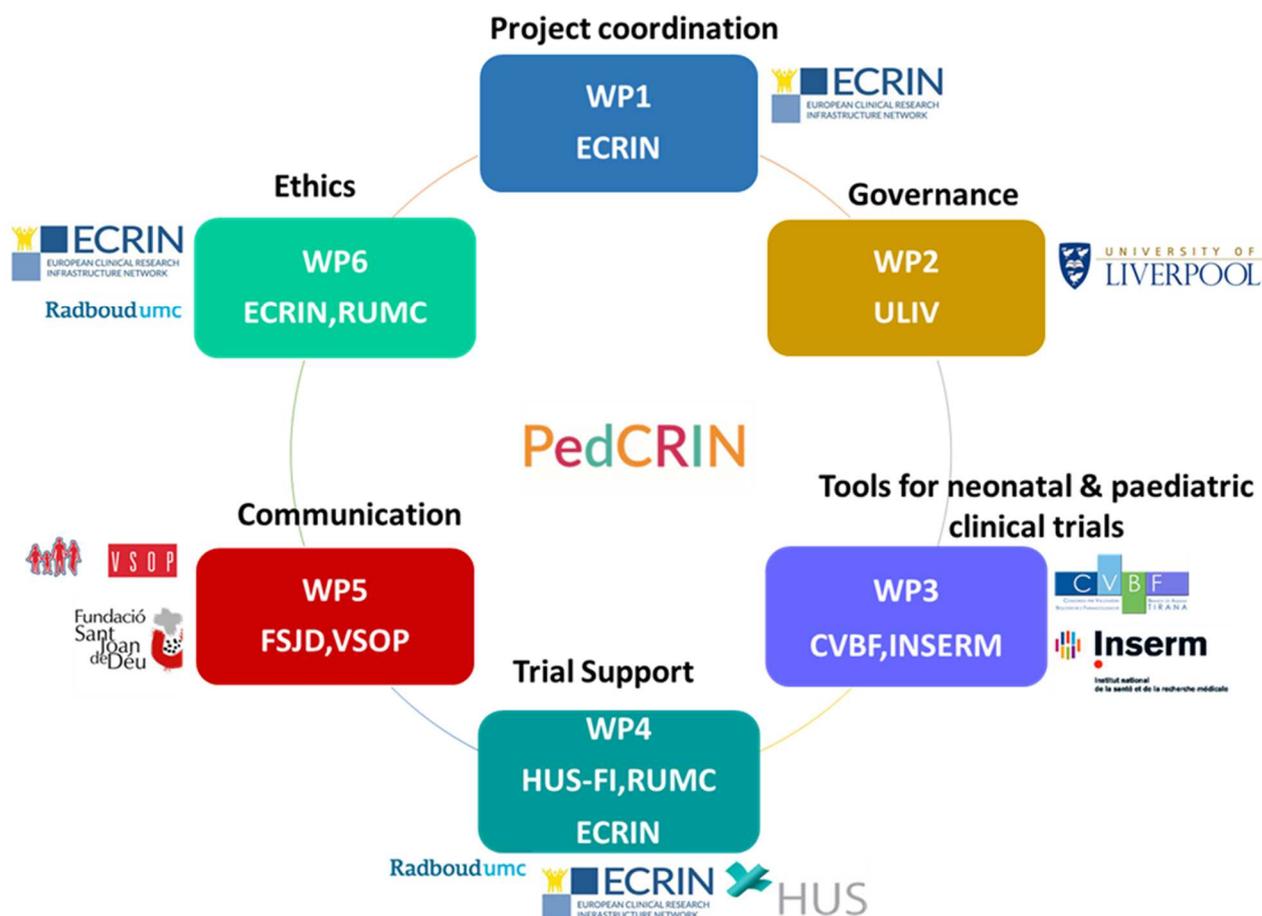
Project organization

The project builds on six work packages. The tasks and deliverables of the six work packages are being performed by fifteen project partners representing thirteen different countries of the European union (Table: participating organisations). In the project organization overview the cohesion between the work packages and the different work package leaders are being displayed.

The six work packages:

1. Project coordination and implementation ([ECRIN](#))
2. Business strategy and governance structure (sustainability) ([ULIV](#))
3. Development of tools specific for paediatric and neonatal trials ([CVBF](#), [INSERM](#))
4. Provision of operational support to pilot trials ([HUS-FI](#), [RUMC](#), [ECRIN](#))
5. Communication to target user communities and policymakers and aiming to empower patients and parents ([FSJD](#), [VSOP](#))
6. Ethics ([ECRIN](#), [RUMC](#))

Project organization overview



Participating Organisations

Participant organisation		Country
European Clinical Research Infrastructure Network (ECRIN)	ECRIN	France
The University of Liverpool	ULIV	UK
Consorzio Per Valutazioni Biologiche E Farmacologiche	CVBE	Italy
Stichting Katholieke Universiteit	RUMC	Netherlands
Institut National De La Sante et de la Recherche Medicale (INSERM)	INSERM	France
Hospital District of Helsinki and Uusimaa	HUS-FI	Finland
Fundacio Sant Joan de Deu	FSJD	Spain
Swiss Clinical Trial Organisation	SCTO	Switzerland
Karolinska Institutet	KI	Sweden
Helse Bergen HF Haukeland University Hospital	HUS-NO	Norway
Tartu Ulikool	UTarta	Estonia
Aristotelio Panepistimio Thessalonikis	AUTH	Greece
OKIDS GmbH	OKIDS	Austria
The National Children's Research Centre	NCRC	Ireland
Vereniging Samenwerkende Ouder- en Patientenorganisaties	VSOP	Netherlands



PedCRIN expected outcomes

More information and a complete overview of the objectives and activities in the six work packages can be found on the PedCRIN [website](http://www.ecriin.org/projects/pedcrin/wp-activities) (<http://www.ecriin.org/projects/pedcrin/wp-activities>). The main expected outcomes of PedCRIN are:

1. PedCRIN will contribute to a comprehensive European landscape of sustainable Research Infrastructures that respond to challenges in science, industry and society
2. PedCRIN will provide tools, infrastructures and services for academic and independent investigators for conducting multinational neonatal and paediatric clinical trials
3. The removal of barriers to trial management will speed up the evaluation of new and improved therapies
4. By reducing time and cost overhead of multinational studies will stimulate investigators and funders to conduct more multinational studies in Europe
5. Joint involvement in the management of multinational trials will therefore act as a hands-on training for the whole organization and the staff involved
6. PedCRIN will specify needs of including the engagement of children, young people, families and carers in the design and implementation of clinical trails

Want to know more about PedCRIN or get involved?

More information about PedCRIN can be found on the [website](http://www.ecriin.org/projects/pedcrin) (<http://www.ecriin.org/projects/pedcrin>). If you have any ideas or questions about PedCRIN, please do not hesitate to contact the PedCRIN team at: Pedcrin.Communication@ecrin.org

Additional contact information:

Begonya Nafria, Patient Advocacy Manager, FSJD
Pedcrin.Communication@ecrin.org

Kim Karsenberg, Policy officer Rare diseases, VSOP
Pedcrin.Communication@ecrin.org

Salma MALIK, PedCRIN Project Manager
salma.malik@ecrin.org

Appendix 4: Factsheet

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 2017ⁱⁱ.

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

[Appendix 5: 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.

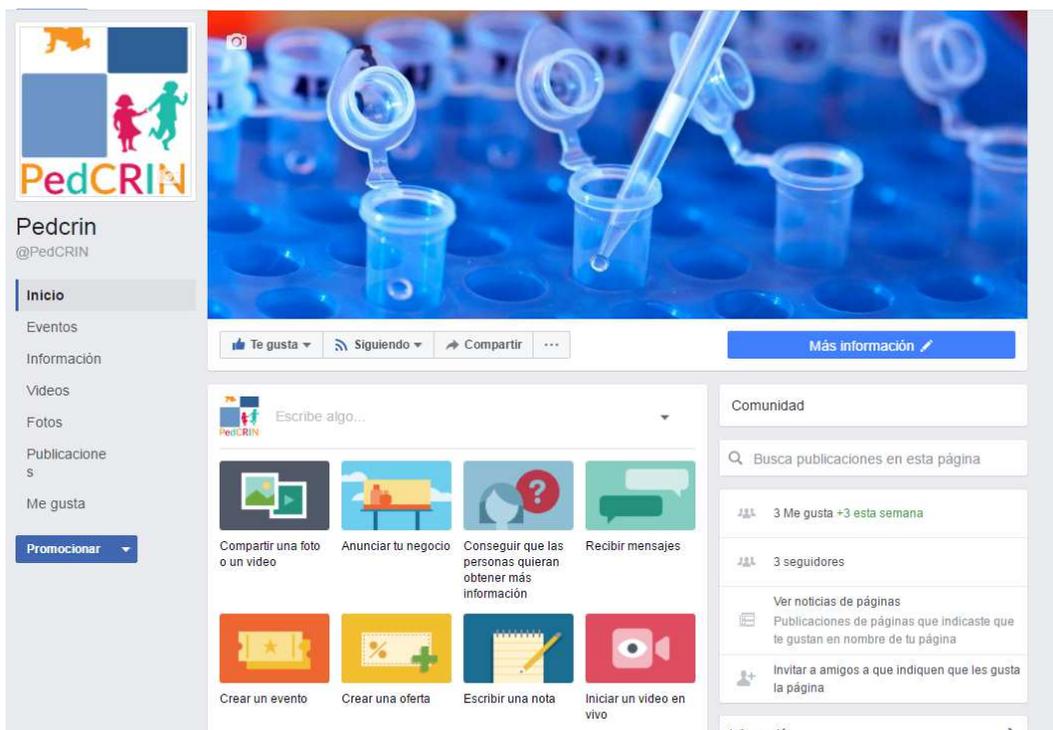


PedCRIN has received funding from the European Union’s Horizon 2020 programme (INFRADEV-3 call) under grant agreement number 731046.

Appendix 6: Social media



Twitter profile



Facebook profile

Appendix 7: Tracking and analytics

Mini-website PedCRIN
Visits Unique users Pages that the users have visited Pages by visit Temps by visit Bounce rate Newsletter visits Mobile traffic From Smartphone vs. from table
Page level data /Key metrics
Followers New followers Unsubscribed followers Unique visitors Scope during the month
Contents and participation of the users (Post level data/Talking about this post)
Post published Likes Comments Missages in the wall Negative comments Questions Shared posts

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