ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

PedCRIN call for multinational clinical studies in children and neonates

Supporting multinational extension of paediatric clinical studies funded in the coordinating country

Deadline for application: 2nd May 2017 at 17.00 CET

Context

Children are still an understudied patient population. Clinical studies are needed to generate evidence supporting medical practice in children and neonates, and international cooperation is critical to obtain rapid and robust results optimizing healthcare strategies. However, conducting multinational paediatric clinical studies requires adequate infrastructure. The PedCRIN project is funded by the European Commission [1] to upgrade the ECRIN [2] infrastructure, through the development of a paediatric module. Among other activities, PedCRIN includes a call supporting the management of multinational paediatric clinical studies.

Purpose

The present call for application is intended to select, based on scientific excellence and evidence for feasibility, multi-national investigator-initiated paediatric or neonatal interventional clinical studies on medicinal products. The funding of the study should be already secured in the coordinating country, including the study coordination tasks (study design, protocol development, statistical plan and analysis, data management, safety management, general coordination). The PedCRIN funding will therefore be used to support study management tasks in countries other than the coordinating country[3], enabling multinational patient recruitment.

Eligibility

- Multi-center paediatric or neonatal therapeutic interventional clinical studies on medicinal products
- Having secured funding in the coordinating country
- Investigator-initiated studies
- Studies conducted in at least three European countries, among the 18 members[4] of the PedCRIN consortium

[1] H2020 Infrastructure unit, GA 731046

[2] European Clinical Research Infrastructure Network, www.ecrin.org

[3] This corresponds to the "TransNational Access (TNA)" funding scheme of the H2020 infrastructure unit, whose objective is to provide infrastructure services in EU countries distinct from the investigator home country. Transposed in the area of clinical studies, this TNA scheme corresponds to the provision of study management services, as proposed by ECRIN, in countries other than the coordinating investigator's country. In the TNA scheme, funding is allocated to the infrastructures providing local services to study management, not to the study investigator / sponsor

[4] Austria, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, United Kingdom

Study management services provided

Projects positively evaluated under the scope of this call will be offered study management services for the implementation of the study in the countries other than the principal investigator's one. These study management services may include

- Interaction with ethics committees and competent authorities (submission and follow up);
- Support for insurance contracting;
- Translation, back-translation of relevant documents and adaptation of informed consent;
- Local site monitoring;
- Local support to adverse event reporting;
- Investigational medicinal project (IMP) management;
- In turn, this funding scheme does not cover
  - The cost of study management in the coordinating country;
  - The cost related to patient investigation

Evaluation criteria

The selection will be based on:

- Scientific excellence
- Quality of the methodology
- Medical relevance, impact on public health and ethical dimension
- Feasibility of the study within the timelines (typically study completed within 2 years [5]) and in line with the budget (including evidence for secured funding in the coordinating country)
  - Without obstacle to authorization by ethics committees and competent authorities
  - Evidence for rapid patient recruitment
  - Short follow-up period
  - Budget for services in the range of €300k to €500k
  - Appropriate risk assessment and risk mitigation strategy to overcome potential roadblocks
  - Each selected study needs to comply with the ECRIN acceptance criteria

How to submit your project

This call follows a single-step procedure, as the protocol should already be accepted for funding in the coordinating country. Applicants are required to provide the full study protocol, together with the nature of the services requested and the related cost estimates, the countries involved, the evidence for funding in the coordinating country, the expected study duration, and the patient recruitment strategy, an inventory of potential obstacles regarding the clinical study authorization, a risk assessment and risk mitigation strategy.

Applications should be submitted to pedcrin@ecrin.org, using the PedCRIN template (download here), no later than on 2nd May 2017, 17.00 CET.

[5] PedCRIN is a 4-years project. This includes the selection of the supported studies, the signature of contracts and insurance, and the study authorization by competent authority and ethics committees, the activation of sites, patient recruitment and follow-up. Applicant studies providing evidence for rapid authorization, secure strategy for rapid patient recruitment (max 1 year), and short follow-up (max 1 year) will therefore be considered as a priority.