# ECRIN as a facilitator of multinational clinical research for rare diseases in Europe

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## Background

Investigator-initiated trials are conducted mainly as single-centre or multiple-centre setting in one country. This fact might bias studies' outcomes or limit trial initiation within one country. This last constraint is especially remarkable in the case of rare diseases (RD), considering the limited number of patients per country. The main hurdle for academic investigators is due to the fragmented health and legal systems within Europe. ECRIN's unique pan-European organisation enables to successfully work across borders, coordinating Clinical Trial Units and other stakeholders from multiple countries.

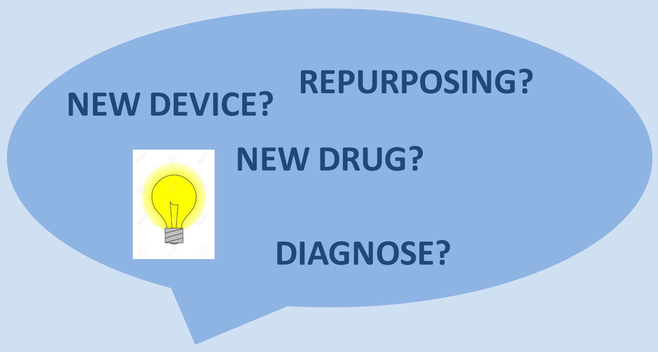
ECRIN can help to circumvent the challenges associated to RD clinical research by supporting European Reference Networks (ERN) investigators in design, planning and performing clinical studies:

1. Providing support to plan multinational clinical trials, through a Clinical Trials Helpdesk for Rare Diseases aiming to facilitate access to RD specific expertise, including design aspects, in the framework of the EJP RD project.
2. Providing support to perform multinational clinical trials (operational coordination), as part of ECRIN services.

## 1. Clinical Trials Helpdesk for Rare Diseases

**Request**

European Reference Networks




**Support**

EUROPEAN JOINT PROGRAMME RARE DISEASES

Pillar 4: Accelerating the translation of research& therapy development

### CLINICAL TRIALS SUPPORT OFFICE

**Clinical Trials Design Planning**:

- Innovative statistical design
- Methodology tailored to small populations
- RD experts mentoring

**Clinical trial Execution Planning**:

- Country selection
- Patient recruitment
- Regulatory and ethical
- Cost evaluation

*Clinical Trials Helpdesk (Task 20.2 Work Package 20 of EJP-RD)*

## 2. ECRIN-Supporting multinational clinical trials


***ECRIN organization***. ECRIN's devolved organisation model is based on country memberships. Each member country hosts an European Correspondent (EuCo) who coordinates the research collaborations and the services provided by the national scientific partners (i.e. networks of clinical trial units, CTUs) for the conduct of clinical trials, with support from the Paris-based Core Team. EuCos' profound knowledge of the local national research landscape and regulatory requirements ensures efficient and GCP compliant management of multinational trials.


***ECRIN support services***. ECRIN provides advice, consultancy and operations management for multinational clinical trials.

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**REFERENCES:**

**EJP RD project —grant agreement number** —825575

http://www.ejprarediseases.org/

**ECRIN**

http://www.ecrin.org/

European Commission