



Supporting  
clinical studies across borders





## ECRIN IN NUMBERS

**2013** awarded the ERIC status

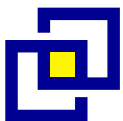
**13** ECRIN Member / Observer countries

**130+** clinical trial units

**70+** trials in ECRIN's portfolio

**6.5** average number of countries per ECRIN-supported trial

**50+** projects to develop ECRIN capacity, tools and expertise



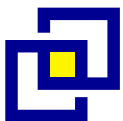
## SUPPORTING CLINICAL STUDIES ACROSS BORDERS

**Our vision:** to generate scientific evidence to optimise medical practice.

**Our mission:** to support the conduct of multinational clinical studies in Europe.

The European Clinical Research Infrastructure Network (ECRIN) supports sponsors and investigators to plan and conduct multinational clinical studies in Europe. We tackle the existing barriers that hinder investigator-initiated clinical studies across Europe so you don't have to.



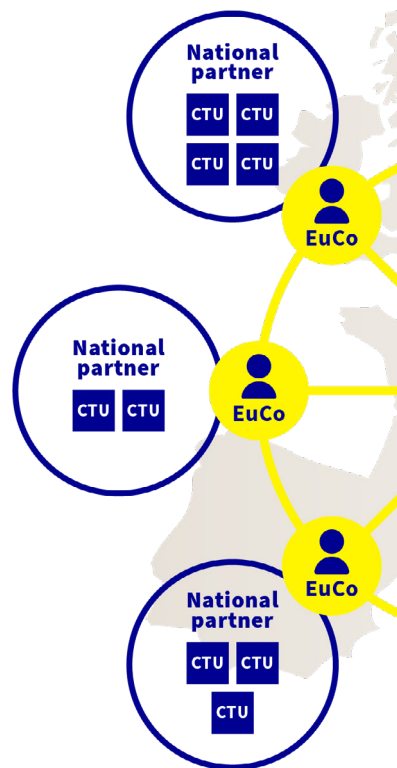


## ECRIN SUPPORTING EUROPEAN CLINICAL STUDIES

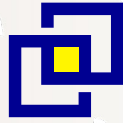
ECRIN is the European infrastructure that supports multinational studies. We bring together expertise, resources, and facilities across the continent. We work across all diseases including paediatric and rare diseases and support studies on medical devices and vaccines. With over 130 clinical trial units in our network and staff specialised in all the relevant fields, our services include:

- regulatory and ethical submissions
- monitoring
- vigilance
- data management
- statistics.

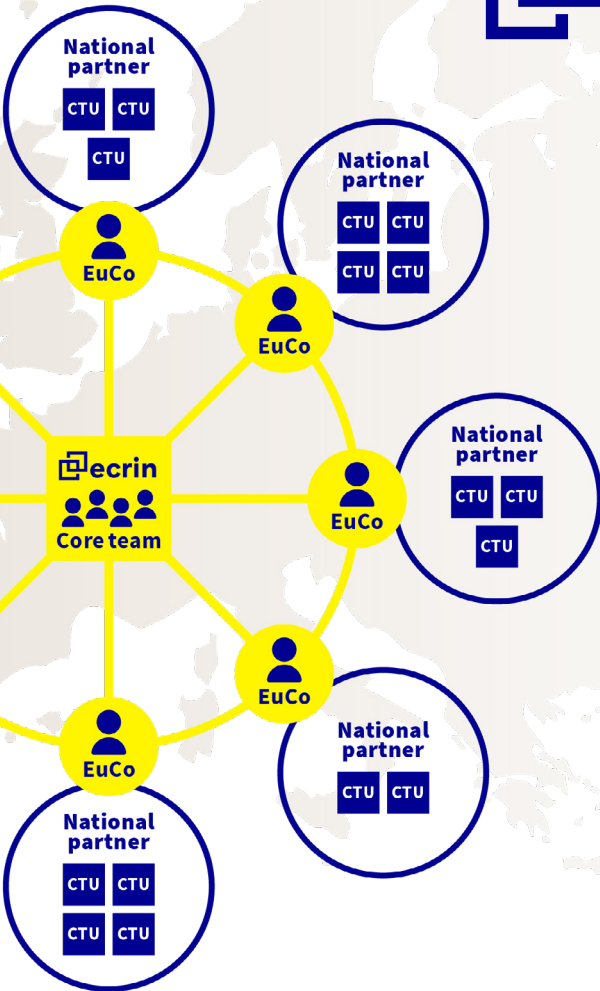
ECRIN maintains the ISO 9001:2015 certification to demonstrate its capacity to best support you with high-quality services. This applies to all our principal services, provided by ECRIN staff.



*EuCo: European Correspondent  
CTU: Clinical Trial Unit*



## ECRIN UNITES NATIONAL PARTNERS

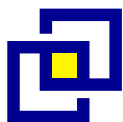


ECRIN is based on country membership and integrates its service with the existing national networks. We currently have 13 Member and Observer countries (Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Slovakia, Spain, Switzerland).

A European Correspondent (EuCo) is located at each national hub. EuCos are local ECRIN staff members, they are:

- clinical research and methodological professionals
- national and European clinical research experts
- your first point of contact.

They manage the clinical trial portfolio and coordinate with their national scientific partner (i.e. network of clinical trial units, CTUs), with support from their colleagues at the Paris-based core team and across Europe.



## CLINICAL OPERATIONS

**ECRIN's core activities are the provision of general information, planning, risk assessment and operational coordination of investigator-initiated multinational studies. At the heart of the ECRIN service offer is the underlying expertise that our staff provide to the sponsor and investigator at every step of the development of their clinical study.**

ECRIN supports investigators and sponsors in ECRIN Member and Observer countries starting from their initial idea. Our collaboration can begin from the inception of the research question or the preparation of European funding applications and later include the review of study protocols. Once a study is funded, ECRIN and its partner CTUs provide various services to support operational coordination ensuring the successful rollout of the clinical study in different countries. Figure 1 provides an overview of the services offered through ECRIN's clinical operations services.





## GENERAL INFORMATION

- Outline roles and responsibilities
- Available funding sources
- Eligibility for funding and ECRIN support
- Regulatory inquiries



## PLANNING

- Study design and methodology
- Regulatory, ethical, and insurance requirements
- Funding application support
- Task distribution for multinational study management and selection of qualified CTUs
- Cost evaluation
- Protocol peer review
- Strategies for site selection and patient recruitment



## OPERATIONAL COORDINATION

- Study management and coordination
- Regulatory and ethical submission
- Monitoring
- Vigilance
- Data management
- Statistical analysis



## RISK ASSESSMENT

Assessment of feasibility, resources, and strategies for mitigation

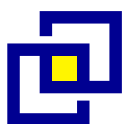


## EXPERTISE & OVERARCHING SUPPORT

Support to sponsor and investigator throughout the maturation and execution of their ideas

**Figure 1.** ECRIN Clinical Operations Services





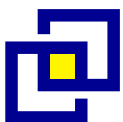
## **ACCESS ECRIN SERVICES FOR MULTINATIONAL STUDIES**

**Investigators and sponsors in ECRIN Member and Observer countries can benefit from the full range of ECRIN clinical operations services pending approval by the ECRIN Scientific Board.**

Operational coordination is provided at not-for-profit rates to academic sponsors. This includes the distributed services carried out by our national scientific partners (in our Member / Observer countries).







## ADDITIONAL ECRIN SERVICES



### DATA CENTRE CERTIFICATION

The Data Centre Certification programme certifies non-commercial data centres from ECRIN Member and Observer countries which have demonstrated that they can provide safe, secure, compliant and efficient management of clinical research data. The goal is to enhance high-quality data management services in non-commercial clinical trials, and to contribute to the harmonisation of European practice in data management.



## **DEVELOPMENT OF TOOLS, TRAINING AND COMMUNICATION**

At ECRIN we work continuously to develop our knowledge, capacity, tools and services to better support our user community.



### **Tools**

ECRIN develops, contributes to, and maintains freely accessible tools for the benefit of the European clinical research community, which are available on the ECRIN website. The tools include but are not limited to: tools on regulatory and ethical issues, risk-based monitoring, support for the paediatric and rare disease communities, the identification of clinical trial objects, data sharing, and more.



### **Training**

Training is essential to ensuring that best practices are shared across our user communities. ECRIN develops dedicated training and webinars for different stakeholder groups including its CTU network, investigators and sponsors as well as its consortia and affiliated partners in ECRIN supported projects.

### **International Clinical Trials Day**

ECRIN launched International Clinical Trials Day (ICTD) in 2005 to commemorate the day James Lind started his famous clinical trial on scurvy on 20 May 1747. ECRIN's annual celebration of ICTD brings together patients, health policy actors, health authorities, clinical researchers, health professionals and citizens from Europe, and beyond to discuss relevant topics as they relate to clinical research.

## Dissemination

Advancement of science relies on broad dissemination of ideas and results. ECRIN contributes to this process through the publications of scientific articles, white papers and policy briefs.





## **CONTACT**

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