



SUPPORTING CLINICAL RESEARCH ACROSS BORDERS



ECRIN - Supporting Multinational Clinical Trials

HOW ECRIN WORKS WITH NATIONAL PARTNERS

The European Clinical Research Infrastructure Network (ECRIN) is a sustainable, non-profit, distributed infrastructure with the legal status of a European Research Infrastructure Consortium (ERIC).

ECRIN supports multinational clinical trials in Europe, which provide increased access to patients, resources and expertise. In particular, ECRIN offers investigators and sponsors with the support they need to overcome the obstacles to multinational trials in Europe (e.g. regulatory and ethical requirements, management and funding issues). ECRIN is also involved in activities to enhance the ability of European sponsors to successfully conduct multi-country clinical research (e.g. tools/database development, data centre certification).

Moreover, ECRIN is involved in infrastructure development projects that aim to further develop the European clinical research community and facilitate multinational trials.



ECRIN IN NUMBERS

60+

NUMBER OF TRIALS (CURRENT/PAST) IN ECRIN'S PORTFOLIO

6

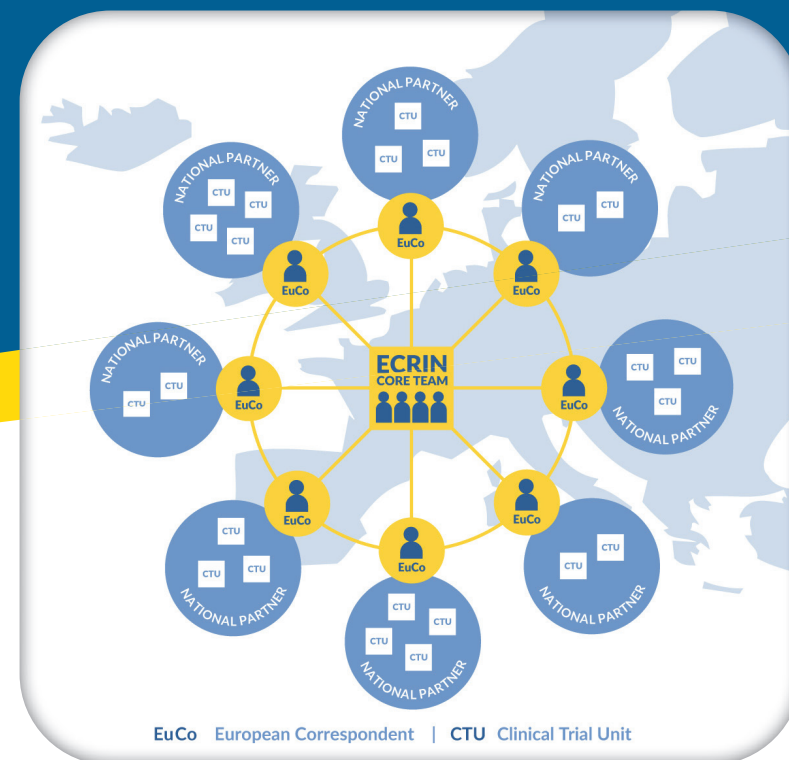
AVERAGE NUMBER OF COUNTRIES PER ECRIN-SUPPORTED TRIAL

2013

YEAR ECRIN WAS AWARDED ERIC STATUS

12

NUMBER OF ECRIN MEMBER/OBSERVER COUNTRIES (AS OF 2020)



HOW ECRIN WORKS WITH NATIONAL PARTNERS

ECRIN's organisational model is based on country membership. ECRIN has 9 member countries (Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Portugal and Spain) and 3 observer countries (Poland, Slovakia and Switzerland).

Each member and observer country hosts a European correspondent (EuCo). EuCos are clinical research experts with extensive knowledge of the national and European clinical research landscape. They manage the clinical trial portfolio and coordinate with the national scientific partner (i.e. a network of clinical trial units, CTUs), with support from the Paris-based core team.

WHAT WE DO: CLINICAL TRIAL OPERATIONS

ECRIN's core activity is clinical trial operations. ECRIN provides support to investigators and sponsors in ECRIN member and observer countries for the preparation of European funding applications and the validation of study protocols.

Provided that projects meet ECRIN's eligibility criteria, ECRIN can also provide various trial management services to sponsors and project coordinators.

As part of its operations activities, ECRIN contributes to the development of tools designed to facilitate multinational clinical research.

A CLOSER LOOK AT CLINICAL TRIAL OPERATIONS

ECRIN primarily provides support for the management of multinational clinical trials, as well as for preparation and protocol evaluation. The illustration below provides a more detailed look at ECRIN's clinical trial support services.

1. PLANNING



We offer advice on:

- Trial design and methodology
- Regulatory, ethical, data protection and insurance requirements
- Strategies for site selection
- Task distribution for multinational studies
- Cost evaluation
- Funding opportunities

2. RISK ASSESSMENT



We conduct:

- Independent protocol peer reviews
- Logistical evaluations of project plans

3. OPERATIONAL COORDINATION



We coordinate services for:

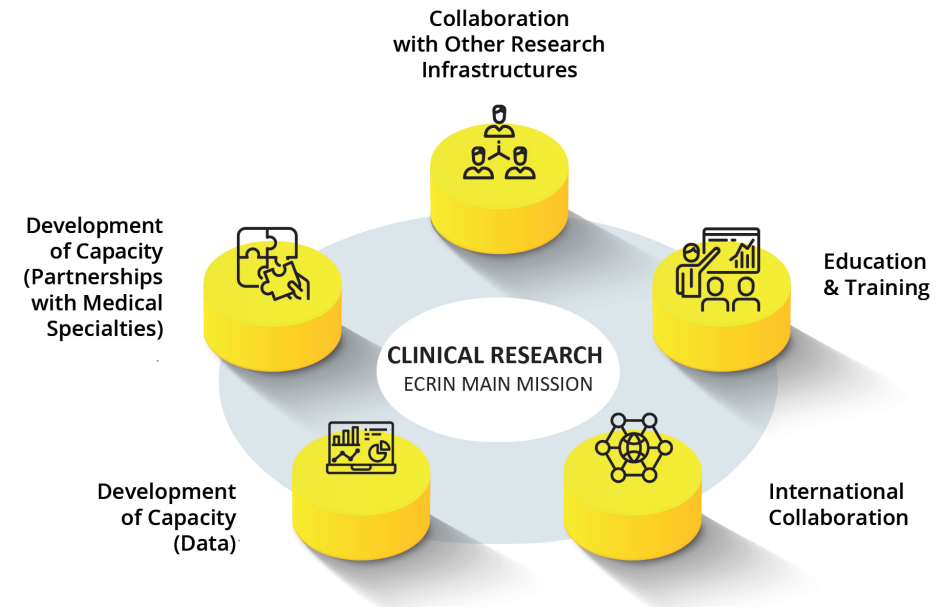
- Study management
- Regulatory and ethical approval
- Study monitoring
- Vigilance
- Data management



HOW TO ACCESS ECRIN SERVICES FOR MULTINATIONAL TRIALS

ECRIN members and observers can benefit from the full range of ECRIN services for multinational trial preparation, protocol evaluation, and/or trial management.

Trial management services are provided at not-for-profit rates to academic sponsors, provided that projects are validated by ECRIN's Collaboration Committee. In particular, ECRIN charges the non-profit cost of the distributed services carried out by the national scientific partner (in its member/observer countries). This budget is then redistributed to the final service provider (i.e. the national scientific partner).



WHAT WE DO: INFRASTRUCTURE DEVELOPMENT PROJECTS

ECRIN is an active player in European infrastructure development projects. These projects aim to develop and upgrade ECRIN's capacity, tools and services.

Some infrastructure development projects may involve other European research infrastructures (RIs) working across a wide range of areas and offering diverse services.

The goal of these partnerships is to link RIs to develop tools, services, training, landscape analyses, and/or resources, as well as to increase the visibility of the RIs.



LEARN MORE:
[www.ecrin.org/activities/
access-cost-policy](http://www.ecrin.org/activities/access-cost-policy)

WHAT WE DO: QUALITY

ECRIN has a quality management system (QMS), which is fit-for-purpose and has been adapted to its distributed infrastructure. It follows a risk and process-based approach, which is founded on the recommendations of the ISO 9001:2015 standard and the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP E6 (R2)).

The QMS aims to coordinate and structure the organisation's activities to meet customer and regulatory requirements, and to improve effectiveness and efficiency on an ongoing basis.

ECRIN is currently pursuing certification of its QMS with ISO 9001:2015.

Data Centre Certification

ECRIN also offers 'quality as a service' through its Data Management Centre Certification programme.

The 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.

An on-site audit is performed to assess the centre's data management activities and IT infrastructure using published ECRIN data management standards.



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