SUPPORTING CLINICAL RESEARCH ACROSS BORDERS
The European Clinical Research Infrastructure Network (ECRIN) is a non-profit, intergovernmental organisation with the legal status of a European Research Infrastructure Consortium (ERIC).

ECRIN supports multinational clinical trials in Europe. Multinational trials provide increased access to patients, resources and expertise and, in turn, generate potentially more robust trial results and greater public health impact.
40+ TRIALS

NUMBER OF MULTINATIONAL TRIALS IN THE ECRIN PORTFOLIO (CURRENT/PAST PROJECTS)

AVERAGE 6 COUNTRIES PER TRIAL

EACH TRIAL ECRIN IS INVOLVED IN COVERS ON AVERAGE 6 COUNTRIES, RANGING FROM 2 TO 16

ERIC STATUS

ECRIN WAS AWARDED THE LEGAL STATUS OF EUROPEAN RESEARCH INFRASTRUCTURE CONSORTIUM (ERIC), AN INTERGOVERNMENTAL ORGANISATION, BY THE EUROPEAN COMMISSION, ON 29 NOV. 2013
HOW ECRIN IS ORGANISED

ECRIN’s unique organisation enables it to link the resources and capacities of national networks across Europe and to access patients and medical expertise throughout Europe.
A PAN-EUROPEAN INFRASTRUCTURE

ECRIN’s organisational model is based on country membership. To date, ECRIN has 8 Member Countries (Czech Republic, France, Germany, Hungary, Italy, Norway, Portugal and Spain) and 2 Observer Countries (Slovakia, Switzerland).

Each Member or Observer Country hosts a European Correspondent (EuCo) who manages the clinical trial portfolio and coordinates the services provided by the national scientific partner (i.e., network of clinical trial units, CTUs), with support from the Paris-based Core Team.

EuCos are at the heart of ECRIN’s unique ability to successfully work across borders, coordinating CTUs and other stakeholders from multiple countries. Typically seconded to ECRIN by their local research institution, these clinical research experts are familiar with the national clinical trial landscape and ensure efficient coordination of multinational trials.
WHY WORK WITH ECRIN

ECRIN provides a pathway through Europe’s fragmented health and legal systems with its pan-European infrastructure. This infrastructure is designed to support multinational clinical research through integrated and coordinated operational services for trial management.
BENEFITS OF WORKING WITH ECRIN

Access to expertise and facilities
Running your trial in multiple countries - with ECRIN's support - increases its effectiveness by pooling resources. Multinational collaboration also opens up access to a wide range of facilities and expertise in different CTUs, increasing the scope and potential impact of your trial.

Scientific excellence and medical expertise
Independent protocol peer review by the ECRIN Scientific Board ensures scientific, ethical, medical and methodological relevance. In addition, multisite and multinational collaboration reduces bias and improves generalizability.

Access to trial participants
Multinational trials have the advantage of access to higher numbers of potential trial participants, and faster recruitment means faster completion of your trial. Reaching your target participant number ensures robustness of results, and multi-country trials also offer greater participant diversity for more meaningful trial results.

Quality Services
CTUs in ECRIN Member Countries can apply for ECRIN Data Centre Certification, which awards an independent certificate of quality after a successful audit. Certified centres are preferentially recommended for data management in ECRIN trials.

www.ecrin.org/activities/data-centre-certification

ECRIN-On-Board right from the start
ECRIN countries are eligible for the ECRIN-On-Board initiative, which offers support to multinational, clinical research projects preparing European funding applications (e.g., Horizon 2020 or E-Rare). Supported applicants receive methodological advice, logistics and operations consulting, and advice on the structure and content of the application.

www.ecrin.org/activities/ecrin-on-board
Q&A: MEMBERSHIP AND ELIGIBILITY FOR ECRIN SUPPORT

Q. What services do Member and Observer Countries receive?

A. ECRIN Member and Observer Countries can benefit from the full range of ECRIN services for multinational trial preparation, protocol evaluation and/or trial management.

Advice and information are freely provided by the ECRIN Core Team and EuCos.

Trial management services are provided at not-for-profit rates.
Q. Are all trials in Member and Observer Countries automatically eligible for ECRIN support?

A. No. To be eligible for ECRIN support, projects must involve at least two Member or Observer Countries; the protocol and trial plans must be reviewed and approved by ECRIN.

Q. Can ECRIN support a trial conducted in a country that is not a Member or Observer?

A. Yes, ECRIN can provide support services even if the trial is conducted by a country that is not a Member or Observer, provided that the project involves at least two Member and Observer Countries. In this case, one of ECRIN’s EuCos or the Core Team is assigned to the trial coordination.
ADVICE AND COORDINATION FOR CLINICAL TRIALS

We provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration.
PLANNING
- Trial design and methodology
- Regulatory, ethical, and insurance requirements
- Funding sources and cost
- Strategies for site selection and patient recruitment
- Task distribution for multinational study management
- Funding application support
- Medical expertise and support

RISK ASSESSMENT
- Protocol peer review
- Feasibility and risk assessment

OPERATIONAL COORDINATION
- Study management and coordination
- Regulatory and ethical submission
- Selection and provision of qualified resources
- Monitoring
- Vigilance
- Data management
ECRIN provides and maintains freely accessible tools that facilitate planning and conduct of clinical trials in Europe. Tools are available on ECRIN's website at www.ecrin.org/tools.
ECRIN CAMPUS FOR REGULATORY AND ETHICAL REQUIREMENTS

ECRIN CAMPUS is a central resource for information about clinical trial regulatory and ethical requirements covering 22 European countries and multiple study types such as clinical drug trials, clinical investigations of medical devices, combination drug-device studies and nutritional studies.

Use ECRIN CAMPUS to locate country-specific competent authorities and ethics committees, consult the summary of requirements for each country, and browse related documents, such as applicable regulations and guidelines. Easily search by country, study type, or a combination of both, to find information relevant to your trial. To support your information search, you can always contact your local EuCO.

http://campus.ecrin.org

RISK-BASED MONITORING TOOLBOX

The Risk-Based Monitoring Toolbox enables researchers to create a risk-based strategy appropriate for their study and needs. Choose tools for assessment, monitoring and study conduct to find relevant tool names, institutions where they are used, links and user feedback.

www.ecrin.org/tools/risk-based-monitoring
ECRIN offers valuable information on trial design and methodology. Resources (notably a series of publications, listed below) draw on the methodological expertise of the ECRIN Scientific Board, its experience in reviewing multinational study protocols, and the know-how of the methodology task force of the ECRIN Integrating Activity (ECRIN-IA, a project financed by the European Union’s Seventh Framework Programme under grant number 284395).

Papers address barriers to randomised clinical trials in general and in regards to trials on rare diseases, medical devices and nutrition in particular.

"Barriers to the conduct of randomised clinical trials within all disease areas"

"A systematic literature review of evidence-based clinical practice for rare diseases: what are the perceived and real barriers for improving the evidence and how can they be overcome?"

"Specific barriers to the conduct of randomised clinical trials on medical devices"
https://bit.ly/2I8UhU8

"Evidence-based practice within nutrition: what are the barriers for improving the evidence and how can they be dealt with?"
OTHER TOOLS

Centre Locators for Medical Medical Device CTUs or CTCs

Centre Locators for Translational, Interventional and Epidemiology centres for Nutrition
http://nutrition.ecrin.org/

Medical Device Outcome Measure Database
http://outcome-measure.ecrin.org/
CAPACITY ACTIVITIES

To develop its capacity, improve the landscape for clinical research in Europe and provide the scientific community with the most relevant services, ECRIN leads or is involved in several capacity /structuring projects and activities.
DEVELOPING CAPACITIES

PEDCRIN

To improve evidence-based medical care for children, more clinical trials are needed focussing on children’s health with the goal of developing treatments, drugs, and devices specific to children. However, clinical trials in children are more challenging than those in adults and require specific expertise and resources. Through the Paediatric Clinical Research Infrastructure Network (PedCRIN), a project funded by the European Union’s Horizon 2020 programme, ECRIN is strengthening and developing capacity for the management of multinational paediatric non-commercial clinical trials. PedCRIN effectively bridges 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.

DATA CENTRE CERTIFICATION

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IMPROVING CLINICAL RESEARCH PRACTICE

DATA SHARING

Data sharing and optimal reuse of data is a key issue for the clinical research community, as investigators now have to include provisions on data sharing as part of the data management plan. ECRIN published, in the context of the H2020 CORBEL project, a consensus document on
clinical trial data sharing recommendations and principles, with the objective of facilitating and harmonizing practice for multinational studies.


**MIROR**

Reducing waste and increasing value of research represents a major societal challenge, and one that ECRIN is committed to tackling. It is doing so through its participation in the H2020 project Methods on Research on Research (MiRoR). MiRoR is an innovative and ambitious joint doctoral training programme funded by Marie Skłodowska-Curie Actions (under grant agreement 676207), dedicated to Methods in Research on Research in the field of clinical research, involving 15 early-stage researchers (ESRs, i.e. PhD students). The objective is to develop creative solutions to transform clinical research practice and increase its value. It will tackle the different steps of a clinical research project (planning, conduct, reporting and peer-review), the various study designs (observational or interventional studies, systematic reviews) and the various study questions (therapeutic, diagnostic, and prognostic evaluation).

**GLOBAL PARTNERSHIPS**

ECRIN also promotes global collaboration in clinical trials to facilitate access for European investigators to patients and medical expertise worldwide, which is particularly relevant for rare diseases. As a follow-up of the Organisation for Economic Co-operation and Development (OECD) Council, the Clinical Research Initiative for Global Health (CRIGH, www.crigh.org) was launched in January 2017 with 40 Members and Observers, including the OECD and World Health Organisation (WHO) as partners. The CRIGH secretariat is shared between the US National Institutes of Health (NIH) and ECRIN. CRIGH covers various aspects of international cooperation – infrastructure funding, training, ethical review, patient involvement, comparative effectiveness research, and socio-economic impact.

FACILITATING EUROPEAN CLINICAL RESEARCH

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