SUPPORTING CLINICAL TRIALS ACROSS BORDERS

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN
SUPPORTING MULTINATIONAL CLINICAL TRIALS

The European Clinical Research Infrastructure Network (ECRIN) is a non-profit, intergovernmental organisation that supports multinational clinical trials in Europe. Multi-country trials provide increased access to patients, resources, and expertise, and, in turn, potentially more robust trial results and greater public health impact.

50+ TRIALS

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

UNTIL 19 COUNTRIES PER TRIAL

EACH TRIAL ECRIN IS INVOLVED IN COVERS ON AVERAGE 7 COUNTRIES, WITH COUNTRY COUNTS RANGING FROM 2 TO 19

2013 NOV 29TH

ECRIN WAS AWARDED THE LEGAL STATUS OF EUROPEAN RESEARCH INFRASTRUCTURE CONSORTIUM (ERIC) BY THE EUROPEAN COMMISSION

HOW ECRIN IS ORGANISED

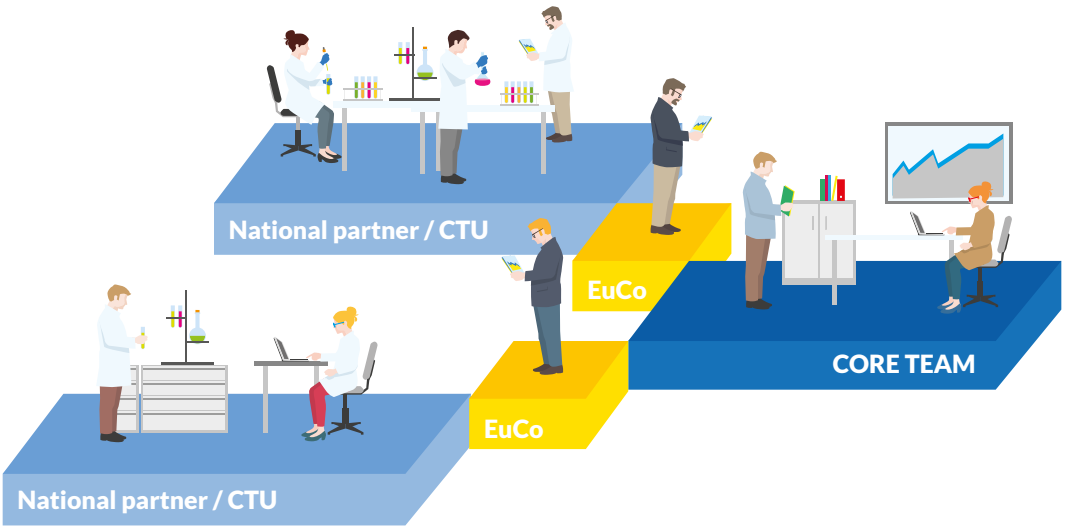
ECRIN's unique organisation enables it to link the resources and capacities of national networks across Europe and to create optimal combinations of sites and expertise for multinational trials.

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 1 Observer Country (Switzerland).

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

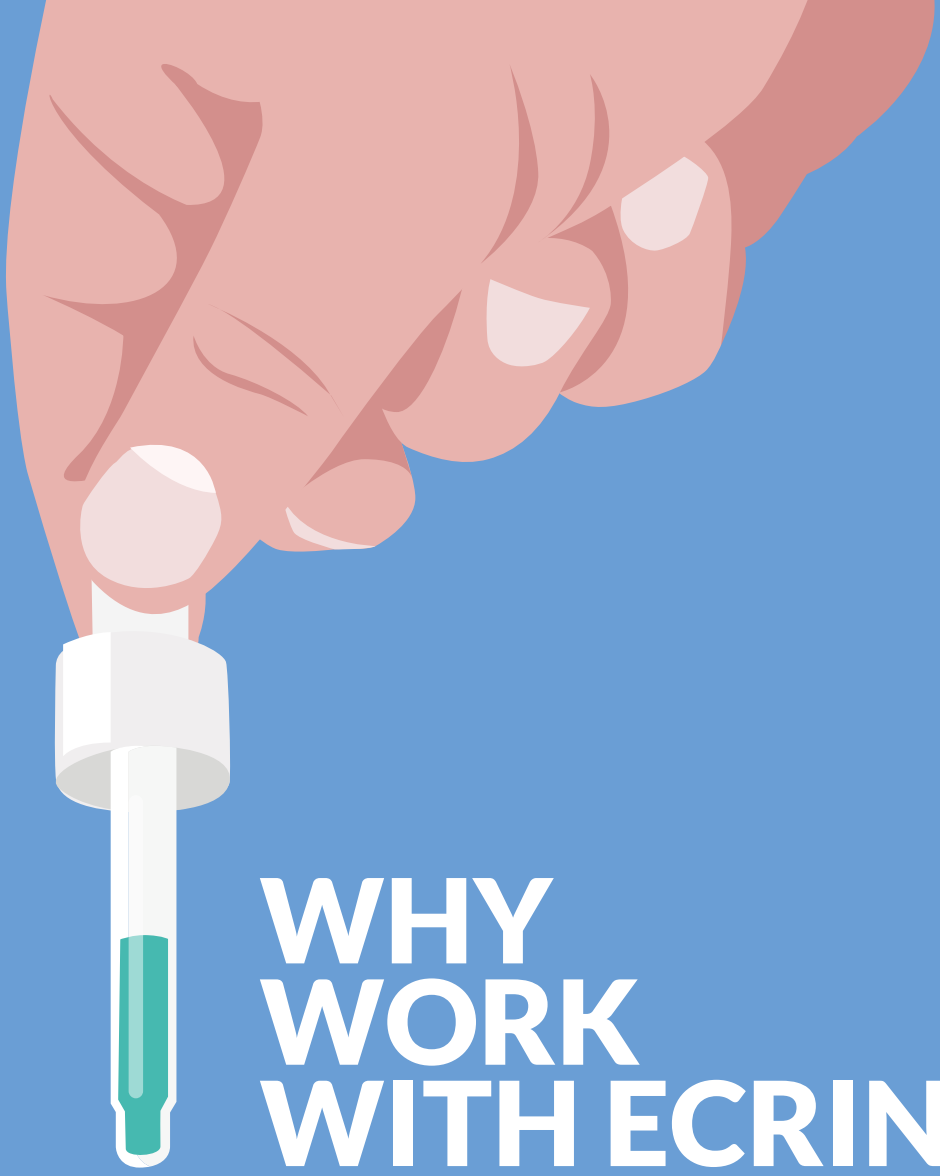
EuCos are at the heart of ECRIN's unique ability to successfully work across borders, coordinating CTUs and other stakeholders from multiple countries. Typically seconded to ECRIN by their local research institution, these clinical research experts are deeply familiar with the national clinical trial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



National partners
CH: SCTO
CZ: CZECRIN
DE: KKSN
ES: SCReN
FR: F-CRIN
HU: HECRIN
IT: ItaCRIN
NO: NorCRIN
PT: PtCRIN

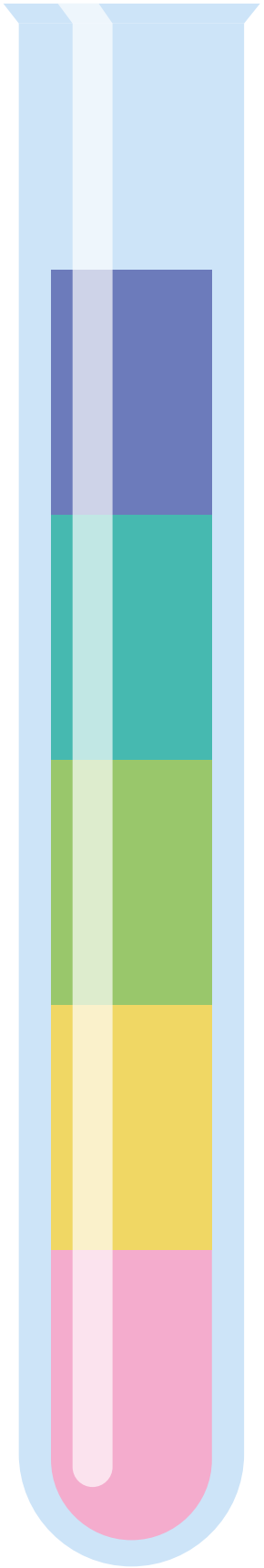
EuCo European Correspondent

CTU Clinical Trial Unit



WHY WORK WITH ECRIN

ECRIN provides a pathway through Europe's fragmented health and legal systems with its pan-European infrastructure that is designed to support multinational clinical research and unlock access to patients and medical expertise.



BENEFITS OF WORKING WITH ECRIN

Access to expertise and facilities
Running your trial in multiple countries - with ECRIN 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 relevants. In addition, multinational collaboration with broad scientific communities results in improved methodology and reduced bias compared with single-country / single-centre trials.

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.

Data Centre Certification
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 that is 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.

1

PREPARATION
STUDY PLANNING

- Trial design and methodology
- Regulatory, ethical, and insurance requirements
- Funding sources and cost
- Strategies for sites selection and patient recruitment
- Task distribution for multinational study management
- Funding application support
- Medical expertise and support

2

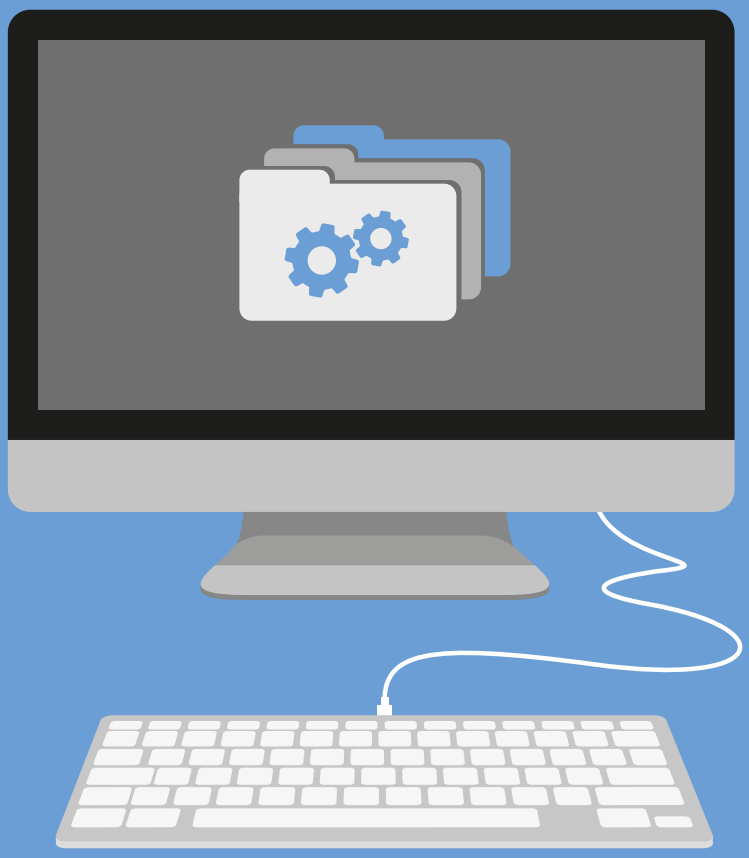
VALIDATION
STUDY RISK

- Protocol peer review
- Feasability and risk assessment

3

IMPLEMENTATION
STUDY COORDINATION

- Study management and coordination
- Regulatory and ethical submission
- Selection and provision of qualified resources
- Monitoring
- Vigilance
- Data management



OPENLY ACCESSIBLE TOOLS

ECRIN provides and maintains freely accessible tools that facilitate research and organization 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 risk assessment, monitoring adaptation or study conduct tools to find related tool names, institutions where they are used, links and user feedback.

www.ecrin.org/tools/risk-based-monitoring

DESIGN AND METHODOLOGY

Taking advantage of the methodological expertise of the ECRIN Scientific Board, of its experience in peer-reviewing multinational study protocols, and on the know-how developed by the methodology task-force during the ECRIN-IA project, a series of recommendations on trial design and methodology was published

Recommendations
https://www.sciencedirect.com/science/article/pii/S0953620516300401
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2099-9

Special focus of challenges raised by trials on rare diseases
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2287-7

On medical device
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2168-0

On nutrition
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2160-8

OTHER TOOLS

Centre Locators for Medical Devices CTU or CTC
http://www.ecrin.org/sites/default/files/Medical%20device%20mapping/20150915_ECRIN_Mapping_Results.xls

Centre Locators for Translational, Interventional and Epidemiology centres for Nutrition
http://www.ecrin.org/tools/centre-locator-for-nutrition

Medical Device Outcome Measure Data base
http://www.ecrin.org/tools/medical-device

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.

DEVELOPMENT OF PAEDIATRIC CAPACITY

To improve clinical care of 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 developping 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 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.

Ohmann C. et al., Sharing and reuse of individual participant data from clinical trials: principles and recommendations.BMJ Open. 2017, 7(12):e018647. doi: 10.1136/bmjopen-2017-018647

IMPROVING CLINICAL RESEARCH PRACTICE

Reducing waste and increasing value of research represents a major societal challenge. MIROR is an innovative and ambitious joint doctoral training programme funded by Marie Skłodowska-Curie Actions, dedicated to Methods in Research on Research (MIROR) 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 studies, randomised trials, systematic reviews) and the various study questions (therapeutic, diagnostic, and prognostic evaluation).

GLOBAL PARTNERSHIPS

ECRIN also promotes global cooperation in clinical trials, with the objective to facilitate, for European investigators, access to patients and to medical expertise worldwide, which is particularly relevant for rare diseases. As a follow-up of the OECD Council Recommendation on the Governance of Clinical Trials, 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 WHO as partners, and the CRIGH secretariat is shared between the US NIH and ECRIN. CRIGH covers various aspects of international cooperation – infrastructure funding, training, ethical review, patient involvement, comparative effectiveness research, socio-economic impact.

Demotes-Mainard J, Melien O, Sgard F, Bouësseau MC, Trimble ET: Global health: Boost multinational clinical research. Nature 545:289 (2017) doi:10.1038/545289b

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