Supporting Clinical Trials Across Borders

EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK
(ECRIN)

ECRIN
EUROPEAN CLINICAL RESEARCH
INFRASTRUCTURE NETWORK

ECRIN — SUPPORTING MULTINATIONAL CLINICAL TRIALS

ECRIN is a non-profit organisation, working towards a society where all decisions in medical practice are made based on sound scientific evidence from high-quality clinical research. To achieve this goal, ECRIN supports the conduct of multinational clinical trials.

WHY WORK WITH ECRIN?

Difficulties in locating clinical trial units (CTUs), fulfilling local legal, regulatory and ethical requirements, and coordinating multi-country trial management deter many researchers from attempting multinational trials. This means that most independent trials are conducted in single centres, or multiple centres within one country. 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 soundness. 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. Find out more at *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. Find out more at *www.ecrin.org/activities/ecrin-on-board*

KEY FACTS AND DATES

40+ trials

Number of multinational trials in the ECRIN portfolio (current/past projects)*

Average 7 countries per trial

Each trial ECRIN is involved in covers on average 7 countries, with country counts ranging from 2 to 19

November 29th, 2013

ECRIN was awarded the legal status of European Research Infrastructure Consortium (ERIC) by the European Commission

*See publication list, p. 4

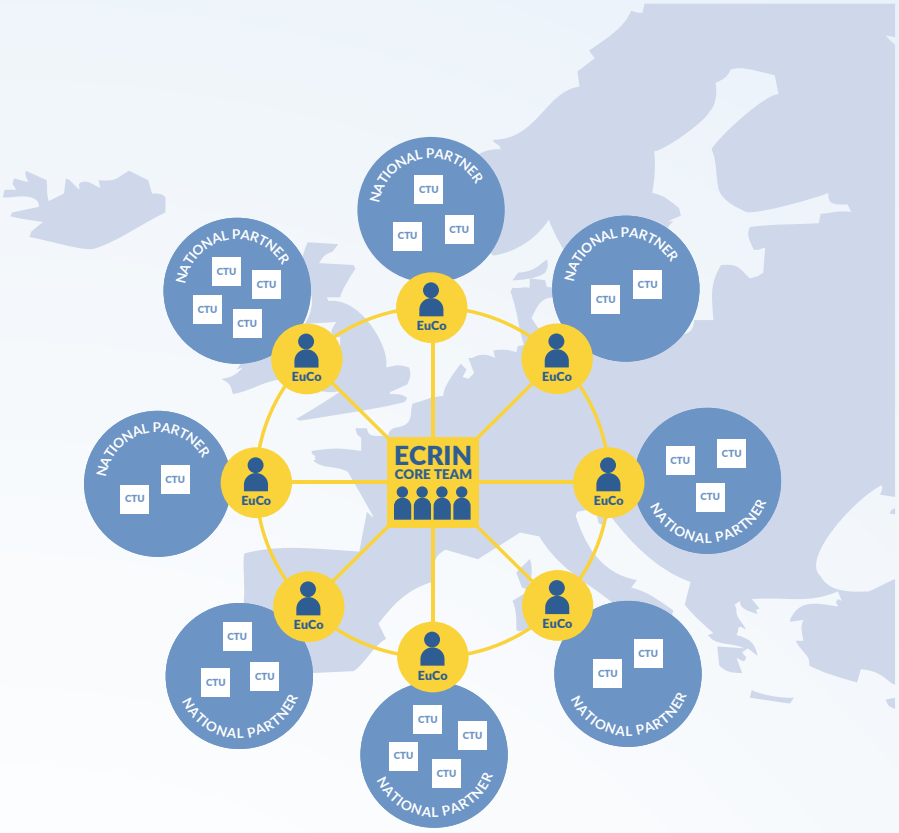
HOW ECRIN IS ORGANISED

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

Each 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.

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.



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

National networks

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

Q&A: MEMBERSHIP BENEFITS 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's Scientific Board and EuCos, respectively.*

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 & information

Funding advice

ECRIN advises on possible sources of funding as well as aspects of the structure of your funding application such as work package architecture, impact, management, governance, consortium composition, and multinational clinical trial management.

Site mapping & patient recruitment

EuCos can provide details of investigator sites and networks in their countries that can recruit participants for your study.

Selection of CTUs

EuCos can provide information on the location of CTUs and the services they provide.

Regulatory & ethical requirements

Requirements differ in each country. ECRIN guides you through the necesssary steps.

Insurance requirements

Find out from ECRIN the types of clinical trial-related insurance needed in different countries.

Protocol review

Scientific & methodological evaluation

When the time comes to write your full protocol, ECRIN supports you by providing methodological consulting and reviewing the scientific and methodological features of the full protocol. This work is done by ECRIN's Scientific Board, composed of independent clinical research experts.

Logistical assessment

As well as the science, logistics must be considered so that your trial runs smoothly. EuCos assess the practicality of plans in each country and give suggestions and alternatives where necessary.

1 PREPARATION

2 VALIDATION

*Published, completed trials include:

1. Perner, A. et al. Hydroxyethyl Starch 130/0.42 versus Ringer's Acetate in Severe Sepsis N Engl J Med 2012; 367:124.
2. Nielsen, N. et al. Targeted Temperature Management at 33°C versus 36°C after Cardiac Arrest N Engl J Med 2013; 369:2197.
3. Thorstensson, R. et al. A Phase I Clinical Study of a Live Attenuated Bordetella pertussis Vaccine - BPZE1 PlosOne, 2014; 9:1, e83449.
4. Holst, L.B. et al. Lower versus Higher Hemoglobin Threshold for Transfusion in Septic Shock N Engl J Med 2014; 371:1381.
5. Hyttel-Sorensen, S. et al. Cerebral near infrared spectroscopy oximetry in extremely preterm infants: phase II randomised clinical trial BMJ 2015; 350:g7635.

Trial management

Competent authorities & ethics committees

Submissions to regulatory and ethics authorities in participating countries can be managed by ECRIN, including organisation of on-time submissions to avoid delays.

Monitoring

All tasks related to monitoring such as training, on-site visits and reporting can be handled by ECRIN across country sites.

Adverse event reporting

ECRIN can support local reporting according to national requirements.

Data management

ECRIN can provide data management through its Certified Data Centres. These centres are audited and shown to fulfil ECRIN standard requirements, and are compliant with European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) standards.

Recommendations for health product and biosample management

ECRIN can provide contacts for medicine and sample handling across countries.

FACILITATING EUROPEAN CLINICAL RESEARCH

ECRIN is a public, non-profit organisation that links scientific partners and networks across Europe to facilitate multinational clinical research. We provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration.

We also contribute to capacity building projects with European and international partners.

OPENLY ACCESSIBLE CLINICAL TRIAL TOOLS

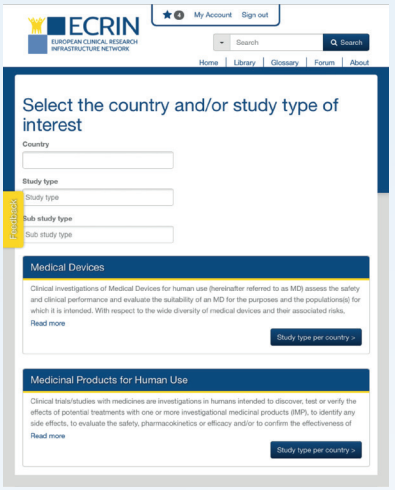
ECRIN provides and maintains freely accessible tools that facilitate research and organisation of clinical trials in Europe. Access the tools at *www.ecrin.org/tools*. They include:

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



Homepage of ECRIN CAMPUS

Medical Device Outcome Measure Database

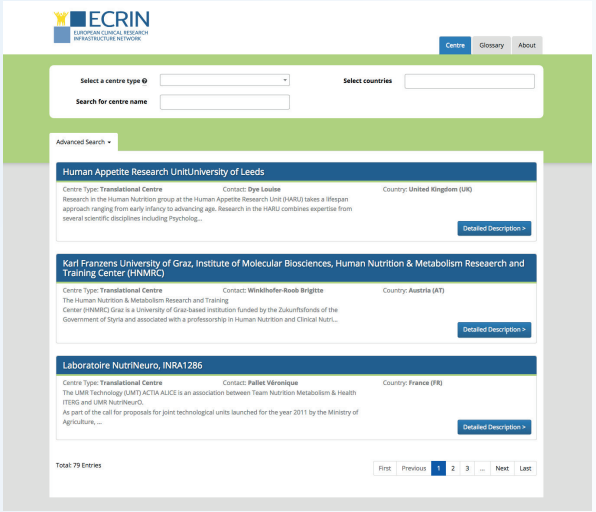
Browse outcome measures used in medical device research to assist in selecting appropriate outcome measures for your trial. Filter results by clicking on the device category, body system, intervention, risk classification or institution of interest. Select the filter relevant to your research to view medical devices and associated information (product names, risk class, disease, body system, intervention type and device category, outcome measures and source publication).

http://outcome-measure.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



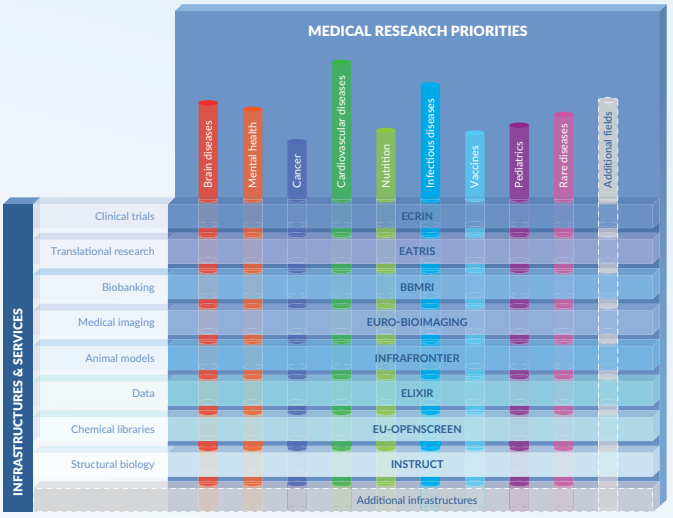
Translational, Interventional and Epidemiology Centre Locator for Nutrition

Created by the ECRIN Nutrition Network, the Translational, Interventional and Epidemiology Centre Locator details European translational and interventional research centres, whose work transfers science knowledge to clinical and health settings, and epidemiology centres that research nutritional and disease epidemiology. Locate research centres, and narrow down your selection according to your study type of interest.

http://nutrition.ecrin.org

SHAPING BIOMEDICAL RESEARCH WORKFLOWS

ECRIN manages multinational, independent clinical trials irrespective of the disease under study. At the same time, ECRIN maintains strong ties to health and life science focused investigation networks and specialised scientific communities to promote collaboration on multinational clinical research and facilitate access to patients and medical expertise.
Medical researchers require a range of integrated services and expertise including clinical trial services, translational research, imaging, biobanking, animal models and data management. ECRIN participates in initiatives that link research infrastructures, including the CORBEL project (supported by the European Union's Horizon 2020 programme, grant agreement no. 654248) and the Biological and Medical Sciences Research Infrastructures strategy board.

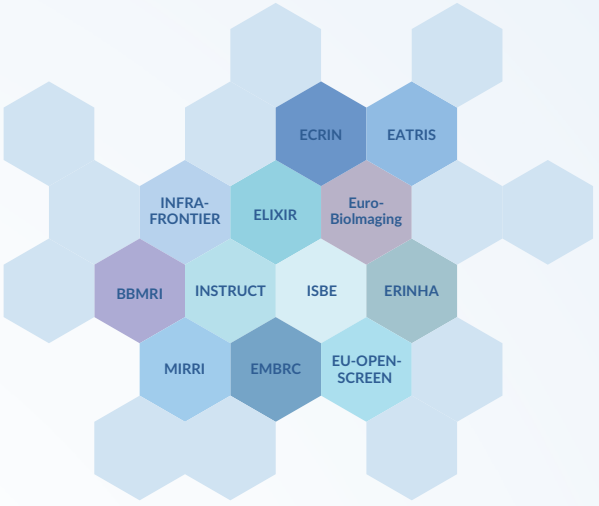


ECRIN works across health and life science fields. ECRIN also collaborates with other research infrastructures to create integrated biomedical research workflows.

BMS RIs

BIOLOGICAL AND MEDICAL SCIENCES RESEARCH INFRASTRUCTURES

ECRIN | clinical trials
EATRIS | translational research
EuroBioImaging | cellular and medical imaging
ELIXIR | bioinformatics
BBMRI | biobanks
INSTRUCT | structural biology
INFRAFRONTIER | mouse models
ISBE | systems biology
ERINHA | high-security laboratories
MIRRI | microbial collections
EMBRC | marine biology
EU-OPENSCREEN | chemical libraries and screening



ECRIN was created following the recommendation of the European Strategy Forum on Research Infrastructures (ESFRI) roadmap and is one of 12 ESFRI BMS RIs.

GLOBAL PARTNERS

ECRIN has established collaboration agreements with disease-oriented investigator networks and organisations outside Europe to support the conduct of international trials. These partners include Therapeutic Innovation Australia (TIA), Korea National Enterprise for Clinical Trials (KoNECT), the Foundation for Biomedical Research and Innovation (FBRI) in Japan, the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) in the U.S., and the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil.

Management office

5-7 rue Watt, 75013 Paris, France

www.ecrin.org

Contacts

Jacques Demotes, MD, PhD, Director General
jacques.demotes@ecrin.org
Christine Kubiak, PharmD, PhD, Operations Director
christine.kubiak@ecrin.org

European Correspondents for ECRIN Member and Observer Countries:
www.ecrin.org/contact/eu-co