

ECRIN ERIC



European Clinical Research Infrastructure Network

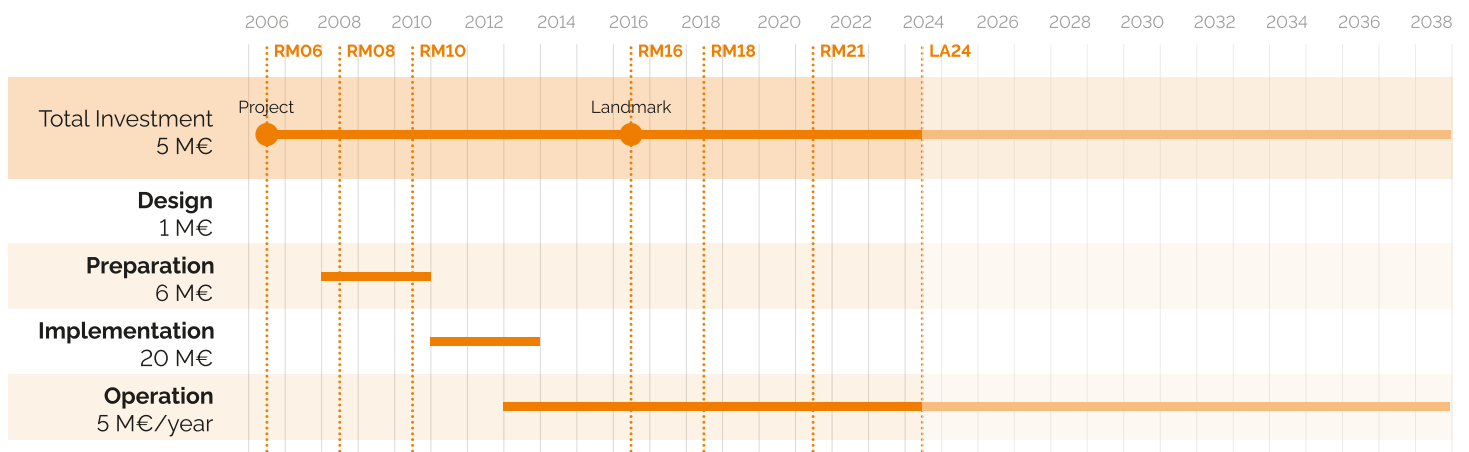
Website	Headquarters	Legal Status	Type	Access
http://www.ecrin.org	ECRIN ERIC Paris, France	Established (ERIC, AISBL, GmbH, Others)	distributed	remote, physical

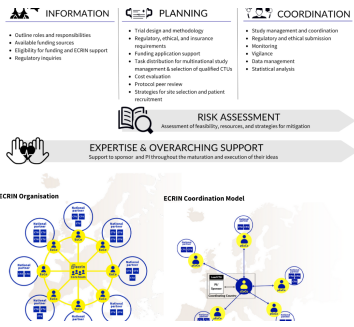
DESCRIPTION

The European Clinical Research Infrastructure Network (ECRIN) is a sustainable, non-profit, distributed infrastructure whose mission is to support clinical research in Europe, and in particular multinational clinical studies. ECRIN assists academic investigators and sponsors, as well as SMEs, to overcome the obstacles associated with multinational studies in Europe. Multi-country studies provide increased access to patients, resources, and expertise, and, in turn, potentially more robust study results and a greater public health impact. Difficulties in coordinating clinical trial units, fulfilling local legal, regulatory and ethical requirements, and coordinating multinational study management deter many researchers from attempting multinational trials and studies. This means that most independent studies are conducted in a single centre, 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 the European clinical research capacity. ECRIN started in 2004 by connecting research facilities at multiple sites in countries across Europe and providing services for top-level clinical research. It was officially awarded the status of European Research Infrastructure Consortium (ERIC) in November 2013 it has undergone an independent scientific evaluation in 2019 and the first round of ESFRI monitoring in 2023. ECRIN works to fulfil its vision to generate scientific evidence to optimize medical practice by accompanying the different actors from advice and preparation, through to the setup, and management of a

multinational study. Its expertise is disease agnostic and can be applied in any field (see services section). ECRIN's organisational model is based on country membership. ECRIN currently has 13 Member and Observer countries (Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Spain, Slovakia, and Switzerland) covering 361M citizens and more than 80% of the European population. Each Member and Observer country hosts a European Correspondent (EuCo). EuCos are national ECRIN staff, who are clinical research experts with extensive knowledge of the national and European clinical research landscape. Together they coordinate the clinical study portfolio and work closely with the national scientific partners (i.e. a network of clinical trial units, CTUs) and with their colleagues based at the Paris headquarters. ECRIN's national partners unite over 130 CTUs all providing high-quality support and services for clinical research from study planning to preparation of the final report. The CTUs work in a broad range of medical fields, and some have specific expertise, for example, in paediatrics and vaccines. They can cover clinical studies for the development of new drugs, medical devices, or therapeutic strategies, as well as repurposing or comparative effectiveness. These CTUs, all ECRIN partners, are selected for a given study based on their resources and areas of expertise. They have also demonstrated their compliance with ECRIN quality standards. Currently, ECRIN's clinical trial portfolio counts over 75 multinational studies with an average of 6.5 countries per clinical study.

TIMELINE & ESTIMATED COSTS





POLITICAL SUPPORT

Lead
FR

Member
CZ, DE, ES, GR, HU, IE, IT, NO,
PL, PT

Observer
CH, SK



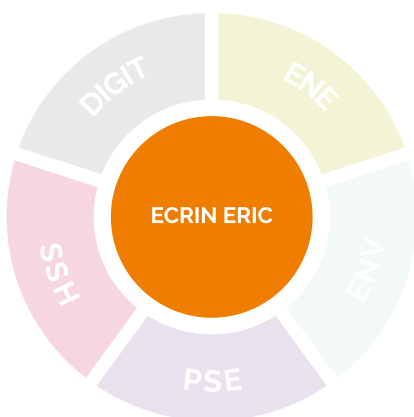
IMPACTS

ECRIN is a major tool to address the health Grand Challenge and has a significant impact on citizens and the economy. Clinical trials assessing the safety and efficacy of new products result in health innovation, with a strong positive impact on the health industry – medicines, vaccines, medical devices, diagnostics, and nutrition sectors. In addition to enlarging the health industry market, clinical trials exploring new indications for already authorized products, repurposing trials, have an impact on citizens' health. Clinical trials comparing authorized treatments, comparative effectiveness trials, result in an improvement in healthcare strategies, with a measurable economic impact on wellbeing and productivity, and in healthcare cost containment. Moreover, independent, multinational studies are key instruments for the optimisation of healthcare solutions and the promotion of evidence-based medical practice in Europe and globally. ECRIN works with its Member and Observer countries that do not yet have well established trial networks to support their development with an adapted approach to increase the national capacity and the number of investigator-initiated studies. It provides access to the ECRIN community which promotes the sharing of best practice across countries. It also provides training and resources to countries to support successful proposals for multinational investigator-initiated studies. To better ascertain the impact of ECRIN and its national partners, ECRIN will work with a group of experts on questions related to impact assessment. This assessment is particularly difficult as clinical trials take years to complete and the uptake of their results by the health authorities and the ensuing implementation into regular care, takes more time still.

SERVICES

ECRIN's principal services are all ISO 9001:2015 certified and enable the advancement of the clinical research community with direct support via our clinical operations services for clinical studies. Beyond this, ECRIN also offers data centre certification, freely available tools and relevant training to support the clinical research community. The clinical operation services support investigators and sponsors at all stages of the clinical study development. For example, ECRIN can provide general information on questions related to the setup of a clinical study, as well as, the types of available European funding and how to apply. ECRIN can support investigators and sponsors in ECRIN Member and Observer countries to prepare EU funding proposals, regardless of their level of experience with such applications for multinational studies. To ensure smooth implementation and management, ECRIN provides various study management services, accompanying sponsors, investigators and project coordinators all the way from protocol finalisation to study close out. ECRIN coordinates these services, performed by CTUs, in ECRIN's Member and Observer countries. ECRIN's expertise and overarching support are available at all times, and specific risk assessment services are available for planning and implementation. ECRIN's Data Centre Certification programme was developed to audit European, non-commercial data centres using ECRIN IT / DM standards, to confirm their ability to provide compliant, effective, and efficient data management services for clinical trials. Training is essential to ensure that best practices are shared across our user communities. ECRIN and its national partners develop dedicated training and webinars for different stakeholder groups. These range from ECRIN's CTU network, to principal investigators and sponsors, to consortia and affiliated partners in ECRIN supported projects. The ECRIN Tools to support clinical research in Europe are available on the ECRIN website. They include support to trial and study development for all communities, some focus on specific populations such as paediatrics and rare diseases, while others support new trial methodologies such as adaptive platform trials.

INTERCONNECTIONS



COOPERATION WITH OTHER RIS

ECRIN has signed a partnership agreement with BBMRI-ERIC (biobanking and biomolecular resources) and EATRIS-ERIC (translational medicine) creating EU-AMRI, the European Alliance for Medical Research Infrastructures. The three research infrastructures, provide complementary services to researchers in the field of biomedical sciences and support the development of personalised medicine. Through EU-AMRI the infrastructures support the biomedical community through education and advocacy. ECRIN also participates with other RIs in European cluster projects. Many of such projects focus on the EOSC and unite, for example, the life science RIs, who work together within the project to address issues related to data sharing and reuse, as well as, provide recommendations and develop tools to support the medical communities. ECRIN contributes to the ERIC-Forum project shaping and advancing the ERIC community. More largely in the health science sector, ECRIN participates in various methodological and disease specific cluster projects including ISIDORE for infectious disease and canSERV for cancer research.