ItaCRIN

ITALIAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

www.itacrin.it | Istituto Superiore di Sanità | Viale Regina Elena, 299 Rome

ECRIN

OBJECTIVE AND ORGANIZATION

The European Clinical Research Infrastructure Network (ECRIN) is a non-profit and public organization. ECRIN's mission is to support and facilitate the management of multinational clinical studies by providing researchers from Member and Observer countries, with a variety of advice, management services and tools.

ECRIN's organizational model is based on a Core Team located in Paris that coordinates with all European Correspondents (EuCo), who serve as primary points of contact in their affiliated country. Currently, ECRIN has nine Member Countries (France, Germany, Ireland, Italy, Norway, Portugal, Czeck Republic, Spain and Hungary) and three Observer Countries (Poland, Slovakia and Switzerland). Each Member and Observer Country establishes a National network of Clinical Trial Units (CTUs) and Contract Research Organizations (CROs) that represents the National scientific partners of ECRIN.

Each EuCo manages the clinical trial portfolio and coordinates the activities provided by the National network of CTUs/CROs with the support of the Core Team. Member and Observer Countries can benefit from all the services offered by ECRIN during multiple phases of multinational clinical studies from protocol evaluation to study management.

ECRIN was awarded by the French standards association (AFNOR) the ISO 9001:2015 Certification on the 30th of November 2020 for its capacity to provide high-quality operational services.
The Certification is applied to ECRIN's three principal services: the coordination of operational services to the management of multinational clinical trials in Europe, the capacity development through the participation in infrastructure development projects and the Certification of Data Centres (quality as a service). These services all have proven effective processes to enable the best possible results to enhance our customer satisfaction.

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OBJECTIVE AND ORGANIZATION

As ECRIN Member, Italy has its own National network of CTU and CRO partners called ItaCRIN. The mission of ItaCRIN is the promotion of high-level non-profit clinical research focused on the identification of innovative therapeutic strategies to the benefit of public health.

Since 2013, after the signature of the Memorandum of Understanding (MoU), the National hub of ECRIN in Italy is located at the Istituto Superiore di Sanità (ISS) in Rome.

Currently, the Italian network consists of eleven CTUs and CROs distributed across several Italian regions.

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ACTIVITIES AND SERVICES

CONSULTING AND INFORMATION

- Multinational clinical trial design
- Methodology
- Identification of necessary activities for study management
- Resourcing and cost evaluation
- Contributing to the identification of Clinic Centers in Italy and Europe
- European and International funding opportunities
- Regulatory, ethical, and insurance requirements

REVISION

- Protocol feasibility
- Scientific evaluation and protocol methodology
- Study design evaluation

CLINICAL TRIAL MANAGEMENT

- Coordination and management support of the clinical trial
- Regulatory activities
- Monitoring
- Pharmacovigilance
- Data Management
- Biological sample management

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ADVANTAGES OF COLLABORATION

Access to multinational clinical studies
The involvement of ECRIN in multinational clinical studies provides access to a variety of services and CTU/CRO experiences from different participating countries. This participation increases the impact and efficacy of the clinical studies.

Scientific excellence and medical competence
ECRIN Scientific Committee (Scientific Board) reviews the clinical protocol and ensures scientific, ethical, medical, and methodological relevance.

European Networking
The European Network ensures the proper Clinic Center and a fast-paced achievement of the Milestones from subject recruitment.

Quality Services
CTU/CROs in ECRIN Member Countries can apply for Data Center Certification, which gives an independent certificate of quality after a successful audit procedure.

ECRIN Scientific Board
After the first preparation steps of clinical studies involving European Countries, scientist from the ECRIN Member and Observer Countries can avail from the support of ECRIN Scientific Board. This service is guaranteed by an expert Committee that offers, without any additional cost, advice on methodologic, logistics, management design advice and study content for European call proposals (Horizon 2020 (H2020), Horizon Europe, the Innovative Medicines Initiative (IMI), the European Research Area Networks (ERA-Net) for rare diseases (E-Rare), cancer (ERA-Net TRANSCAN), neurosciences (ERA-Net NEURON), Personalized Medicine (ERA PerMed), etc).

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HOW TO BE PART OF THE CTU/CRO ItaCRIN NETWORK

Self-Assessment Sheet (SAS)

One of the main objectives of ItaCRIN is to provide service for the International Multi-center clinical study guidance by following GCP, as ICH E6 R2. To be part of the network, ECRIN requests to CTU/CRO to complete SAS.

The SAS offers to CTU/CROs the opportunity to certify its own experience, quality, resources, and capacity. The SAS has the validity of three years and it is confidential.

Data Center Certification

ECRIN also offers the opportunity to the Member Country CTUs to apply for Data Center Certification. This Quality certification is obtained through audits performed by internal and external ECRIN experts, and has the primary objective of warranty secure and efficient clinical research data management based on published ECRIN data.

The selection of Data Centers that provides the certification is made by the National Project Management team (ItaCRIN) and submitted from EuCo to ECRIN independent Certification Board, to answer the call launched annually.

(www.ecrin.org/data-centre-certification-validate).

Both of the above procedures do not involve any cost from the CTU/CROs.

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General Information
www.itacrin.it
www.ecrin.org

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