Services and support

STUDY PREPARATION

When planning an international clinical trial, it is important to consider the financial, scientific, regulatory and administrative aspects long before recruitment of the first patient begins. The organization supports and guides investigators, sponsors, project coordinators and other stakeholders through various aspects of international clinical trials.

Prior to the start of the clinical trial, support concerns:

- Funding - advising on possible sources of funding, as well as aspects related to preparing a funding application;
- Identifying sites and recruiting participants - European correspondents can provide details about the research network in their country - identify sites that can recruit participants for the trial;
- Selecting clinical trial sites - European correspondents can provide information on sites in their country that have the capacity and services needed to conduct the trial;
- Legal and ethical requirements - advice on legal requirements;
- Insurance requirements - information on the necessary insurance for international clinical trials in different countries;
- Costs - assistance in calculating the cost of clinical trial management services to help with budget preparation.

PROTOCOL REVIEW

In the phase immediately preceding the implementation of a clinical trial, the organization can provide the following services:

- Scientific and methodological evaluation - at the stage of writing or revising the full protocol, the organization provides support by providing advice and independent evaluation of the scientific and methodological value of the protocol. This evaluation is carried out by ECRIN's Scientific Council of clinical trial experts;
- Logistical evaluation - in addition to the merits of the project, its planning and logistics are equally important for the smooth running of the clinical trial process. European correspondents assess the practicality of the plans and make suggestions and alternative proposals if

necessary.

Important: scientific/methodological and logistical evaluation of projects is required to use the clinical trial management service provided by the organization.

STUDY MANAGEMENT

Support for clinical trial management across borders

Clinical trial management services for international studies are provided through local European correspondents, with the participation of their national partners (networks of research centers), which helps overcome obstacles that arise when working in different regulatory and legal systems. Researchers and project coordinators can use a variety of clinical trial management services when working with study sites.

Services in the study include:

- Submissions to CTIS - Submission of documentation to CTIS, meeting required deadlines;
- Insurance consulting -providing information on international clinical trial insurance or providing quotes for local insurance for international clinical trials;
- Monitoring - perform all monitoring tasks, such as training, monitoring visits and reporting;
- Adverse event reporting - support reporting as required;
- Data management - ECRIN-certified centers can be used for data management in international trials;
- Recommendations for the management of medicinal products and biological material - information on the handling of medicinal products and biological material in all countries.

How to access clinical trial management support?

Clinical trial management services are provided on a not-for-profit basis for projects approved by ECRIN's Scientific Council (scientific evaluation) - after prior logistical evaluation performed by European correspondents.

To learn more and/or to submit your project, contact your European correspondent and see the tab here (access and cost policy). It is necessary to send: a completed application form to the Scientific Council and read the Applicant's Manual.

Ensuring quality management

An effective quality management system (QMS) is a key component of research management and ensures the protection of research participants and the reliability of the results obtained. We design, develop and implement an effective system that offers a clearly structured, comprehensive approach to maintaining the highest quality standards.

For the organization's internal processes, quality is ensured by Standard Operating Procedures (SOPs), guidelines and training. For national scientific partners (i.e., clinical trial infrastructure networks), quality is achieved through compliance with ECRIN quality standards. These standards (e.g., site certification requirements) are used to confirm partners' ability to provide appropriate and effective clinical research services.

ACCESS AND COST OF SERVICES

Scope and cost of services

ECRIN members and observers can benefit from ECRIN's full suite of services for international study preparation, protocol evaluation and/or study management. Advice and information on non-commercial clinical trial projects involving two or more ECRIN members and/or observers is provided free of charge by the ECRIN core team and European Correspondents (EuCos).

To learn more about the terms and conditions of the available services and/or to propose a project, please contact your European correspondent and refer to the Instructions for Applicants and the ECRIN Scientific Council Application Guidelines (eligibility criteria).

Eligibility

To be eligible for ECRIN support, projects must involve at least two countries with member or observer status. Projects must be reviewed and approved by ECRIN (Collaboration Committee).

ECRIN can provide support services even if the country coordinating the study is not a member or observer, provided that the project involves, at least, two countries belonging to the organization. In such a case, one of the European correspondents or a person from the core team is, as it were, assigned to the study. Significantly - countries outside the organization's structure cannot benefit from support in the initial phase of the survey preparation.

Who to contact?

The first point of contact for clinical trial support services is your local European correspondent. If there is no European correspondent for your country, contact the ECRIN core team.