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ECRIN: making multinational clinical trials in Europe easier

Lea Stankovski, PhD; Christine Kubiak, PharmD, PhD; Jacques Demotes-Mainard, MD, PhD, MBA

The European Clinical Research Infrastructures Network (ECRIN) supports investigators and sponsors in the conduct of multinational clinical research with information and services.

Differences in the national legislation and healthcare systems in Europe have resulted in the fragmentation of clinical research. This hampers participant recruitment, scientific collaboration and negatively impacts on the cost of multinational research. This has led to a bottleneck in the initiation of international clinical trials in Europe, particularly by academic sponsors and investigators since they lack the support to interact with the different national regulatory and ethics committees, and to act as a sponsor in foreign countries.

EU Directive 2001/20/EC, the Clinical Trials Directive, was implemented with the objective of harmonising the regulatory environment in order to facilitate clinical research in Europe. However, after divergent transposition into national laws, this target was partly missed [1].

As a consequence, development of EU-wide infrastructure networks [2] and disease-oriented scientific networks [3] appears an appropriate solution to overcome these obstacles (see also the article from Meeus M et al. *Eur J Hosp Pharm Prac.* 2009;15 (5):23-5).

ECRIN development in three steps

With this in mind, the European Clinical Research Infrastructures Network (ECRIN) was initiated in 2004. This integrated clinical research infrastructure bridges the fragmentation of clinical research in Europe through the interconnection of national networks of clinical

research centres and clinical trial units. The ECRIN programme was funded by the 6th and 7th Framework Programmes of Research (FP6 and FP7) of the European Commission. The first step of the programme was an evaluation of the main bottlenecks to multinational cooperation on clinical trials. This highlighted the poor capacity of public institutions to act as a sponsor in multinational studies and helped to define a strategy: harmonisation of training, tools and practice; and providing services for sponsors in multinational studies [4–6].

The second step aimed at preparing guidance documents and procedures to support investigators and sponsors in multinational clinical studies in the EU. Transnational working groups focused on ethics, regulation, adverse event reporting, data management, monitoring, quality assurance, and developed a training programme based on this knowledge.

Currently ECRIN is in its third step (2008–2011), the preparatory phase of the European Strategy Forum on Research Infrastructures (ESFRI) roadmap. During this phase the network will become a sustainable European institution, with a legal status, and will start to provide support to multinational studies.

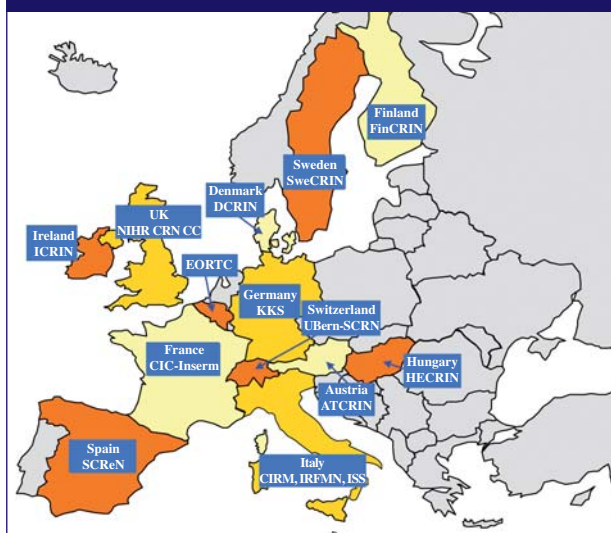
European extension

ECRIN currently connects national clinical research institutions and networks from 13 countries (see Figure 1): Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Spain, Sweden, Switzerland and the UK. ECRIN plans to extend to encompass all the EU Member and Associated States. With this approach ECRIN will stimulate the creation of national networks and hubs of clinical research infrastructures. The network also develops partnerships with clinical research infrastructures in other world regions.

Objectives and support

ECRIN is designed to improve the capacity of the EU to perform high quality clinical research, and to promote innovative pharmaceutical and biotechnology development, as well as the development of other interventions. ECRIN is based on the connection between national networks of academic clinical research centres and clinical trials units to support the conduct of multinational trials in Europe. The aim of the network is to facilitate access to patients, scientific interactions and to provide a 'one-stop shop' support to investigators and spon-

Figure 1: Map of countries participating in ECRIN



sors for any type of clinical research, in any medical field during the preparation and the conduct of a study. Support provided will include consultancy (such as information on regulatory and ethical requirements, consulting on centre selection, insurance) and services (such as interaction with competent authorities and ethics committees, study monitoring). Consultancy and services are provided or coordinated by the European correspondents working in each national hub, acting as interfaces between the national networks and the ECRIN coordination. For a given project, the European correspondent in the country hosting the sponsor is in charge of coordinating the activities of the other European correspondents and of the national networks in the countries involved.

Support from ECRIN is provided to projects successfully evaluated by the ECRIN Scientific Board and the coordination office. The ECRIN Scientific Board, composed of independent scientific experts in the field of clinical research, is in charge of the scientific and methodological assessment of the clinical trials submitted to ECRIN, whereas the feasibility of the study is evaluated by the coordination office. The ECRIN coordination office is also in charge of the executive management of the selected projects.

Impact of ECRIN

Besides facilitating clinical trials through information, consulting and services, ECRIN is also involved in the structuring of clinical research in the EU. ECRIN contributes to the discussion on the

2001/20/EC Directive and was a partner in the Impact on Clinical Research of European Legislation (ICREL) project [1], with the objective of improving the current legislative system. The network is also involved in education policies as it participates, with other ESFRI-biomedical research infrastructures and pharmaceutical companies, in the FP7 Innovative Medicines Initiative (IMI) EMTrain project to develop a pan-European education platform [7, 8].

Conclusion

ECRIN aims to make the EU an integrated area for clinical research, facilitating the conduct of clinical studies, which is particularly relevant for rare diseases. The network will benefit not only the academic scientific community but also small and medium size enterprises and pharmaceutical companies, therefore increasing the competitiveness and attractiveness of Europe. This will lead to the further development of innovative prevention, diagnostic and treatment options for the benefit of European patients and citizens.

Author for correspondence

Jacques Demotes-Mainard, MD, PhD, MBA
ECRIN Project Coordinator
INSERM, Institut Thématique Santé Publique
101 rue de Tolbiac
F-75654 Paris Cedex 13, France
jacques.demotes@inserm.fr

Co-authors

Lea Stankovski, PhD
French Correspondent for ECRIN

Christine Kubiak, PharmD, PhD
ECRIN Executive Manager

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