

Creating a single European area for clinical research

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Clinical trials - the tests of medicines, medical devices and treatments - are costly and complicated to carry out, especially when they involve groups in different countries.



[2]

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Project:

European Clinical Research Infrastructures Network - Integrating Activity

The burden of recruiting and researching the patients and volunteers, managing the trials, and meeting the legal requirements to ensure they are safely conducted means that often only the best-resourced groups can afford them. But a more appropriate European framework is being developed for researchers thanks to a European project that aims to facilitate multinational clinical studies and trials by providing specialised services and infrastructure.

The European Clinical Research Infrastructures Network (ECRIN) is designed to bridge the patchy organisation of European clinical research and to develop an integrated European Union (EU)-wide clinical research infrastructure.

“ECRIN is part of the roadmap of the [European Strategy Forum on Research Infrastructures \(ESFRI\)](#) [3] or a pan-European infrastructure designed to support multinational clinical research,” says Jacques Demotes-Mainard, the project coordinator. *“The aim is to make Europe a single area for clinical studies, taking advantage of its population size to access patients, and unlocking latent scientific potential.”*

Despite various EU-wide efforts to simplify regulations, Europe is still divided in the biomedical area and most research-driven clinical trials are conducted at national level. *“Fragmentation of the health*

and legislative systems and funding sources in Europe represent major bottlenecks to multinational collaboration,” says Demotes-Mainard, who works at Institut National de la Santé et de la Recherche Médicale (INSERM) in Paris. “But people now realise it is better to collaborate than compete. That would give better access to resources and expertise. And with 500 million people and high healthcare standards, Europe is potentially the best place in the world for clinical research.”

ECRIN is currently supported by the ECRIN-IA project that involves networks from 24 countries and will expand the consortium to 9 new countries. ECRIN-IA supports services for multinational clinical trials on rare diseases, medical devices and nutrition. It also develops tools for risk-adapted monitoring and will upgrade data management tools. The four-year project is backed by a €8 million European Commission grant.

ECRIN contributes to the structuring of clinical research capacity both at the national and European levels by developing common standards and tools, and pushing towards better harmonisation of procedures. *“Multinational cooperation in clinical trials requires not only generic tools to support study management, but also common procedures and standards,”* says Demotes-Mainard. *“We would like to develop a common pan-European culture among the clinical research professionals and patient communities.”*

This requires training and communication policies to build common awareness for a new generation of clinical research professionals. It should, Demotes-Mainard says, be based on common tools for patient investigation, and require a disease-specific instead of a generic approach.

Demotes-Mainard says that creating a single area for clinical research in Europe will ensure easy patient recruitment and allow industry to directly access multiple research sites. *“It will strengthen the attractiveness of Europe for industry trials through the creation or maintenance of national infrastructures sharing common tools, standards and procedures”* he says. *“That will build up Europe’s scientific competitiveness and improve healthcare”,* he adds.

ECRIN-IA

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