PRESS RELEASE

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RED: Your Central Resource for Navigating the Clinical Study Regulatory & Ethical Submissions Requirements in Europe

Sailing through regulatory hurdles is one of the toughest challenges in multinational clinical research – The Regulatory and Ethical Database (RED) is here to clear the path and give your research the tools to cross borders.

RED supports the European clinical research community

RED supports the European clinical research community by providing essential resources and guidance in the regulatory landscape. Whether preparing a proposal for a multi-country study or expanding an ongoing study outside national boundaries, RED ensures the provision of precise, up-to-date regulatory and ethical information to guide researchers through their submission process. This tool offers a wide range of information, organised into 750 easily searchable fields, to help clinical researchers and sponsors navigate the complexities of clinical studies across Europe.

With RED, clinical researchers can focus on their research question and remain compliant with Europe's regulatory and ethical standards for a variety of different study types.

A growing need in Europe to share regulatory information

Despite the efforts underway at European level, the lack of harmonisation of regulatory approvals continues to be one of the main challenges for investigator initiated clinical studies as highlighted by the ERA4Health partnership and recent literature (Gumber et al, 2024). This builds on the OECD Global Science Forum report “Facilitating International Cooperation in Non-Commercial Clinical Trials” highlighting the need for collaboration with international partners to address complex regulatory issues, share information and harmonisation for ethical, legal and logistical standards (2011).

The increasing number of investigator-initiated multinational clinical studies in Europe is leading to a growing need for tools to help sponsors and investigators plan and extend their research across countries. RED is one such tool, providing regulatory and ethical information coverage across an increasing number of European countries.

Regularly updated information for diverse study types and populations

Whether conducting research on pharmaceuticals, medical devices, or non-interventional studies, RED equips researchers with the critical information to step beyond their national boundaries and compare options to take their research to new horizons. Filters are included to quickly access content tailored to the unique regulatory and ethical considerations for vulnerable populations, allowing users to negotiate the additional complexities involved in including these specific populations.

The database is regularly updated by ECRIN's network of national experts throughout Europe. They continuously monitor for changes in national regulations and integrate them directly, translating key information and documents where necessary.

The best way to get to know RED and its functionalities is to visit the tool, available online now!

About ECRIN

ECRIN is the European Clinical Research Infrastructure Network, a public, nonprofit organisation that focuses on investigator initiated multinational clinical trials as well as clinical trials initiated by SMEs. It provides sponsors and investigators with advice, management services and tools to explore Europe's fragmented health and legal systems on clinical trials. ECRIN has national scientific partners in 13 countries covering more than 360 million citizens. Multi-country clinical trials mean greater access to patients, resources, and expertise, and in turn, faster and potentially more robust results.

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Access RED

Get started and browse the RED tool: https://red.ecrin.org/en

Contact information

For more information visit the RED webpage on the ECRIN website or contact ECRIN directly at media@ecrin.org.