

## Investigator-initiated clinical trials conducted by the Portuguese Clinical Research Infrastructure Network (PtCRIN)

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**Abstract:** Interventional clinical studies can provide the highest levels of evidence and generate significant results on specific investigational medicinal products or medical devices. In order to have powerful studies, attain unquestionable results and make significant discoveries, the number of patients enrolled must be high. Therefore, multinational, randomised clinical trials are necessary. The multicentre, multinational recruitment of subjects in investigator-initiated clinical trials (IICTs) increases their logistical burden, justifying the need for specific infrastructures to ease implementation.

Herein, we provide for the first time an overview of the facts and figures concerning IICTs, existing infrastructures' capacity for interventional clinical research, and scientific performance of investigators in a European country, Portugal. We aim to highlight the relevance and need for investing in European infrastructures such as the European Clinical Research Infrastructure Network (ECRIN) for multinational IICTs. A public, non-profit organisation, ECRIN facilitates the conduct of multinational clinical trials in Europe by coordinating scientific partners and their networks, and providing advice, management services and tools to enhance collaboration. Currently in Portugal, few multinational randomised IICTs are coordinated by national investigators. This is most likely due to the lack of human resources dedicated to clinical trials in clinical research centres (CRCs) as well as the scarcity of professional academic clinical trial units (CTUs) providing logistics and management services at non-profit rates.

With the data shown, we expect to trigger the development of similar studies in other European countries and stress the impact of government support for IICTs.

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