

OPINION PAPER

# EUROPEAN CLINICAL TRIALS REGULATION 536/2014: CONCERNS AND PERSPECTIVES OF A MEMBER STATE

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**ABSTRACT:** The European Regulation 536/2014, entered into force on June 16, 2014 and not effective for several years for a delay in the development of a fully functional European portal, has represented a turning point in the legislation regarding clinical trials on medicinal products. Unlike other countries, Italy was unable to translate the multitude of decrees regulating clinical trials in one legislative act. The first step towards the alignment with Regulation 536/2014 was the Law 3/2018 that recognized the necessary changes that had to be made, the simplification of the submission and evaluation process by the Ethics Committees, the importance of infrastructure and support personnel in the conduct of clinical trials, among others. So far only three implementing decrees have been circulated one introducing the Coordination Center of Territorial Ethics Committees (CNOCE), one establishing two national ECs and a decree regarding observational and no profit studies. Certainly, further legislative measures will be needed to complete the implementation framework. There is a great deal of expectation with respect to the measure that will define the minimum requirements of clinical centers authorized for the conduct of clinical trials, as well as any other decrees necessary to address the critical issues described above.

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**Impact statement:** The paper provides an overview of the actions taken in a Member State to implement the European Regulation, some of which took a long time and continue to present multiple criticalities.

**Key words:** Clinical trial regulation; European Regulation; European Portal; Ethics Committees; research infrastructures.

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## INTRODUCTION

The European Regulation 536/2014 (1), entered into force on June 16, 2014 but not effective for several years for a delay in the development of a fully functional European Portal (CTIS), has represented a turning point in the legislation regarding clinical trials on medicinal products.

The previous legislation (2), in fact, despite being the first to include Good Clinical Practices in the European Law and having represented the first attempt to harmonize the local legislations of the different member states, had led to an increase in costs and lengthy timelines for study activation. Over the years, this has led to a reduction in trial authorization requests and notable disparities among Member States (3, 4).

The Regulation introduces novelties aimed at optimizing the process of regulatory approval for Clinical Trials, first and foremost the new authorization process, that sees the introduction of one authorization at European level (Part I) and leaves at each Member State the possibility of accepting or not accepting this decision. The new process, tackled the issue of high costs from the previous legislation, drastically cutting down timelines, and was meant to represent an opportunity for Member States like Italy, for a long time restrained by the complex bureaucracy and the need to undergo multiple evaluations by the competent authority and the various Ethics Committees (ECs), to increase their performance (5, 6).

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**Thomas Griffiths**



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