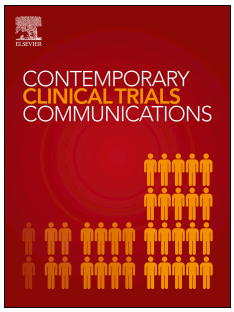
Accepted Manuscript



Main changes in European Clinical Trials Regulation (No 536/2014)

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PII: S2451-8654(18)30010-3

DOI: 10.1016/j.conctc.2018.05.014

Reference: CONCTC 258

To appear in: *Contemporary Clinical Trials Communications*

Received Date: 22 December 2017

Revised Date: 7 May 2018

Accepted Date: 16 May 2018

Please cite this article as: E. Tenti, G. Simonetti, M.T. Bochicchio, G. Martinelli, Main changes in European Clinical Trials Regulation (No 536/2014), *Contemporary Clinical Trials Communications* (2018), doi: 10.1016/j.conctc.2018.05.014.

Main changes in European Clinical Trials Regulation (No 536/2014)

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Abstract

The new Regulation (EU) No. 536/2014 for clinical trials of medicinal products for human is part of a European regulatory framework in which the European Commission has wished to give a strong impetus to scientific research and industrial progress. It is a new regulation that fills a series of regulatory gaps in the Clinical Trials through the creation of a uniform framework for the authorization of clinical trials by all interested Member States with a single assessment of the results. The Regulation thus facilitates cross-border cooperation to make the clinical tests wider and encourage the development of special treatments, for example for rare diseases, but above all streamlines the rules on clinical trials acrossEuropean Union (EU), introducing simplified rules for experimentation so-called 'low level of intervention', on which much has been discussed and still arouses concern, providing for authorized medicines or used off-label in the presence of scientific evidence published on efficacy and safety and to benefit from they will be mainly the pediatric and oncological therapeutic areas. The applications and any communication will be submitted paperlessly via a new electronic EU portal. The complex processing procedures and shorter time limits are to be stressed in comparison to the previously valid regulations. This is a major challenge for all stakeholders, but on the other hand it should contribute to the future role of the EU in the development of innovative medicines.

Abbreviations:

EU (European Union), EC (European Commission), MA (Marketing authorization**),** CI (Informed Consent), MS (member states), rMS(reporting member state),

Keywords

Clinical trials, new regulation, reporting member states, interventional study

Introduction

The number of applications for authorization to clinical trials in EU decreased by 25% between 2007 and 2011; the clinical costs of conducting clinical trials increased and the average waiting time for clinical trials increased by 90% to 152 days [1]. The current provisions of Directive 2001/20 / EC seem to have hindered the conduct of clinical trials in EU On 17 July 2012, for the first time, the European Commission proposed a new Regulation on Clinical Trials for Medicines because it considered that a Regulation was the best tool to promote robust data generation and in line with the requirements of medication research, at this time of globalization and potential loss of Europe's attractiveness for clinical trials, which are at the same time an opportunity for economic development and early access to innovative medicines while ensuring maximum patient protection in respect for the principles of ethics and the safeguarding of individual rights. Following a complicated and sometimes controversial process of negotiation, the Regulation was adopted in April 2014 by the European Parliament and published on 27 May 2014 in the Official Journal (OJ)