MDCG 2021-28

Substantial modification of clinical investigation under Medical Device Regulation

December 2021

Contents

Acronyms

EUDAMED	European database on medical devices
GSPR	General safety and performance requirements
NCA	National Competent Authority
PMCF	Post-market clinical follow-up
REC	Research ethics committee

Introduction

The sponsor of a clinical investigation is required to submit an application/notification[1] to the Member State(s) in which a clinical investigation is to be conducted, accompanied by the documentation referred to in Chapter II of Annex XV of Regulation (EU) 2017/745 (MDR).[2] The application/notification is required to be submitted by means of the electronic system referred to in Article 73 of the MDR.

Additionally, the sponsor of a clinical investigation is required to notify[3] the Member State(s) in which a clinical investigation is being or is to be conducted if it intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, within one week, by means of the same electronic system.

In the absence of the European database on medical devices (EUDAMED), a series of clinical investigation application/notification documents have been created to support clinical investigation procedures with respect to MDR – see MDCG 2021-8 and MDCG 2021-20 .

To add to these documents, a template for *'Substantial modification of clinical investigation under MDR'* is also provided.

Insofar as possible, the modification of a clinical investigation notification form includes same data fields to the EUDAMED system in development.

Use of the template

This document is intended to be facilitative and its use by the Competent Authorities and sponsors is encouraged, however it is important to check with the individual Member State in which the clinical investigation is taking place or planned to be conducted as to any specific national requirements. It is foreseen that this template will be withdrawn once the EUDAMED module for clinical investigations is fully functional.

[1] Clinical investigation application (MDR Art. 62(1)), PMCF investigation notification (MDR Art. 74(1)), other clinical investigation application/notification, i.e. a national application (MDR Art. 82(1)).
[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.
[3] Article 75 Regulation (EU) 2017/745

Annex - Template

Title	Document
Substantial modification of clinical investigation under Medical Device Regulation	 Substantial modification of clinica