MDCG 2021-08

Clinical investigation application/notification documents

May 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

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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

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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.

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.

These documents include:

- Clinical investigation – application/notification form under the MDR
- Addendum to the clinical investigation application/notification form for:
  - Additional investigational device(s) (section 3)
  - Additional comparator device(s) (section 4)
  - Additional investigation site(s) (section 5)
- Clinical investigation supporting documents - Appendix of documents to attach
- Checklist of general safety and performance requirements, Standards, common specifications and scientific advice

Insofar as possible, the clinical investigation application/notification form includes same data fields to the EUDAMED system in development.

For further guidance with respect to the application of certain MDR provisions during the absence of EUDAMED please see MDCG 2021-1 Rev.1.[3] In the absence of EUDAMED, the Union-wide unique single identification number for a clinical investigation, which shall be used for all relevant communication in relation to that clinical investigation will be the CIV-ID which is currently used for Eudamed2, the electronic system which supports the medical device Directives.[4]

Use of templates

These documents are intended to be facilitative and their 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 planned to be conducted as to any specific national requirements. It is planned that these templates will be withdrawn once the EUDAMED module for clinical investigations is fully functional. Further operational guidance with respect to the use of the guidance may be provided in due course.

[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] MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional, May 2021.
[4] Council Directives 90/385/EEC and 93/42/EEC.

Annex - Templates

Title	Document
Clinical investigation – application/notification form under the Medical Device Regulation	 Clinical investigation_notificat
Additional investigational device(s) (section 3)	 Section 3 - Additional investigational device(
Additional comparator device(s) (section 4)	 Section 4 - Additional comparator device(s).
Additional investigation site(s) (section 5)	 Section 5 - Additional investigation site(s).pc
Clinical investigation supporting documents - Appendix of documents to attach	 CI supporting documents - appendi
Checklist of general safety and performance requirements, Standards, common specifications and scientific advice	 GSPR and list of standards applied.doc