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
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.

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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)).
3. MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional, May 2021.
### Annex - Templates

<table>
<thead>
<tr>
<th>Title</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical investigation – application/notification form under the Medical Device Regulation</td>
<td><img src="Clinical_investigation_notification.png" alt="Clinical investigation notification" /></td>
</tr>
<tr>
<td>Additional investigational device(s) (section 3)</td>
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<tr>
<td>Additional comparator device(s) (section 4)</td>
<td><img src="Section_4.Additional_comparator_device.png" alt="Section 4 - Additional comparator device(s)" /></td>
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<tr>
<td>Additional investigation site(s) (section 5)</td>
<td><img src="Section_5.Additional_investigation_site.png" alt="Section 5 - Additional investigation site(s)" /></td>
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<tr>
<td>Clinical investigation supporting documents - Appendix of documents to attach</td>
<td><img src="Clinical_investigation_supporting_document.png" alt="CI supporting documents" /></td>
</tr>
<tr>
<td>Checklist of general safety and performance requirements, Standards, common specifications and scientific advice</td>
<td><img src="GSPR_and_list_of_standards_applied.png" alt="GSPR and list of standards applied" /></td>
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