MDCG 2024-15

Guidance on the publication of the clinical investigation reports and their summaries in the absence of EUDAMED

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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 it is chaired by a representative of the European Commission. 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.

1. Introduction

Article 77(5) MDR requires that the sponsor submits to the Member States in which a clinical investigation was conducted a clinical investigation report within one year of the end of the clinical investigation or within three months of the early termination or temporary halt, irrespective of the outcome of the clinical investigation. Furthermore, the clinical investigation report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by means of EUDAMED.

Article 77(7) MDR require that the summary and the clinical investigation report shall become publicly accessible through EUDAMED at the latest when the device is registered in accordance with Article 29 and before it is placed on the market. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission. If the device is not registered in accordance with Article 29 within one year of the summary and the report having been entered into EUDAMED pursuant to Article 77(5) MDR, they shall become publicly accessible at that point in time. These are the timelines for publication under this SOP.

MDCG 2021-1 Rev. 1 *"Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional"* indicates that concerning Article 77(5) "The upload of the relevant information should take place via the respective national procedures applicable to clinical investigations". Regarding paragraph 7 of the same Article it indicates that the "CI reports and the respective summary reports should be shared and published via the use of a **dedicated publicly available CIRCABC directory.**"

The Commission guidance on the content and structure of the summary of the clinical investigation report (2023/C 163/06) provides appropriate means of identifying the summaries of the CI reports. The same principles are used for identifying the CI reports.

2. Procedure for the publication of the clinical investigation reports and their summaries

2.1 Submission of the reports by the sponsors

According to article 77(5) and MDCG 2021-1 Rev. 1, the reports and their summaries will be submitted together by the sponsors to the competent authorities of the Member States in which a clinical investigation was conducted and will be published by the Commission in the form they are submitted to the Member States. No redaction will be performed by the Member States or the Commission, the sponsor bearing all the responsibility for the content of the documents including confidentiality and data protection. The relevant contact for the competent authorities to be used for the submission of the reports is the same as the one used for the application for the clinical investigation or the one indicated by the competent authority.

2.2 Labelling of the documents and tracking

The competent authorities will label the documents as follows:

- For the clinical investigation report: CIV-ID – CIR
- For the clinical investigation report summary: CIV-ID – SCIR

The CIV-ID will have been generated according to MDCG 2021-20 instructions for generating CIV-ID for MDR Clinical Investigations.

A tracking file will be made available and will include the following information[1]:

- Date of clinical investigation report & of its summary
- Title of clinical investigation
- Name and contact details of the sponsor of the study
- Name of the entity funding the study
- Single identification number (CIV-ID)
- Clinical investigation plan code or number
- Status – final, temporary halt, early termination

2.3 Management of the documents

The Member State which generated the CIV-ID will transmit to the Commission the two documents labelled as outlined above without undue delay after receiving them from the sponsor, indicating the date of receipt. Only the clinical investigations conducted according to MDR Articles 62, and 74(1) will be consistently transmitted. For clinical investigations falling under article 82 the CI reports and their summaries will be transmitted only if this is relevant due to the national reporting requirements. The contact point is represented by a dedicated functional mailbox.

Based on the CIV-ID, the Commission will verify that there is no duplication and then will update the tracking file and upload the documents in the dedicated CIRCABC directory one year after it has been submitted to the relevant Competent Authorities. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission.

2.4 Storage of the documents

The documents will be stored in a dedicated public CIRCABC directory called *"MDR Clinical Investigation reports and their summaries"* which may be found under the following link:
https://circabc.europa.eu/ui/group/5bfd5ece-dc70-468c-b47d-8f871fe8405d/library/affe24c8-db4e-4e81-aedb-b555a0b395a4

The Member States will publicise this link at the national level through appropriate means such as posting it to their respective websites. Supplementary, the link will be made available on the Commission medical devices website on the page dedicated to the MDCG documents, within the clinical section.

A dedicated tracking file listing the CI reports and their respective summaries uploaded in the library will be placed in the root of the dedicated CIRCABC directory and kept up to date by the Commission.

The membership of this directory is the same as for the MDCG CIE Working Group. For the general public, as the CIRCABC directory is publicly accessible, anybody interested in consulting and downloading its content will be able to do so without the need to become a member.

3. Validity of the document

This document will cease to be applicable, and become obsolete, once the use of the CI/PS EUDAMED module, which is relevant for the publication of the clinical investigation reports and their summaries, becomes mandatory.

[1] Section 2.1 Cover page of 2023/C 163/06 modified.