CORE-MD

Coordinating Research and Evidence for Medical Devices

Repository of trial designs for orthopaedic, cardiovascular and diabetic devices

Deliverable 1.2

Deliverable factsheet

Source Activity:	Work package 1, Task 1.1
Title:	Repository of trial designs for orthopaedic, cardiovascular and diabetic devices
Lead Beneficiary:	RCSI
Nature:	Other
Dissemination level:	Public
Editor:	André Frenk (BUH / Insel Gruppe AG), Robert Byrne (RCSI)
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Status:	Final
Date:	31/03/2024
Contractual Delivery Date:	Month 24

Version Log

Issue Date	Version	Involved	Comments
31/03/2024	1.0	Arjola Bano (BUH / Insel Gruppe AG), Anne Lübbeke (UOXF), André Frenk (BUH / Insel Gruppe AG)	Preparation of the datasets to be compliant with the FAIR principles for upload on Zenodo
30/04/2024	2.0	Arjola Bano (BUH / Insel Gruppe AG), Anne Lübbeke (UOXF), André Frenk (BUH / Insel Gruppe AG)	Finalization of the deliverables with URL and DOI of the three datasets

Note for the reviewers: the present deliverable was finalised towards the end of the project in order to add the relevant references and URL to the FAIR-compliant open datasets published onto Zenodo after submission of the corresponding manuscripts to the relevant publishers.

Executive Summary

The Task 1.1 within Work Package 1 focused on the conduct of systematic reviews of the scientific literature to evaluate the methodologies of studies and the types of clinical evidence available for high-risk medical devices approved for clinical use in Europe. Three medical fields using high-risk (Class III) medical devices were selected: cardiovascular, orthopedics and diabetics. Bern University Hospital performed the evaluation of the devices in the cardiovascular and diabetics fields. The review of the devices in the orthopedic field was performed by the Geneva University Hospitals and the University of Oxford.

The results of the three reviews are concisely presented in Deliverable 1.3 and discussed in detail in the respective submitted papers. Moreover, the methodologies used in the analyzed studies have been compared with the extensive summary of regulatory guidance provided by Task 1.4 in Deliverable D1.6. These, along with the outcomes of WP2 (analysis of new methods for clinical evidence generation) and WP3 (analysis of quality and utility of real-world data for post market assessment), have provided the basis for designing and building consensus on the final CORE-MD recommendations.

This Deliverable 1.2 compiles the relevant datasets generated within Task 1.1 for the conduction of the three systematic reviews thus providing an open access repository of the study designs and methodologies for clinical investigation of high-risk medical devices with approval for use in Europe.
In line with the FAIR principles that the CORE-MD project adheres to and the process established in the project's data management plan, the datasets have been made available through the dedicated Zenodo CORE-MD community.

For each dataset, two files have been made openly available to allow for reproducibility of the findings and performance of complementary analyses, i.e. a labels' dictionary and the full dataset, both in .csv format.

Here below the references and URLs to the three open datasets uploaded on the CORE-MD community within Zenodo repository are provided:

- Lübbeke, A. (2024). Clinical investigations to evaluate high-risk orthopaedic devices: a systematic review of the peer-reviewed medical literature [Data set]. In EFORT Open Reviews (Vol. 8, Number 11, pp. 781–791). Zenodo. https://doi.org/10.5281/zenodo.10623389.
- Siontis, G. (2024). Clinical investigations to evaluate high-risk cardiovascular devices: a systematic review of the peer-reviewed medical literature [Data set]. Zenodo. https://doi.org/10.5281/zenodo.10617117.
- Bano, A. (2024). Clinical evidence for high-risk CE-marked medical devices for glucose management: a systematic review and meta-analysis (Version 1) [Data set]. Zenodo. https://doi.org/10.5281/zenodo.10894441.

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CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

For more information, visit: www.core-md.eu