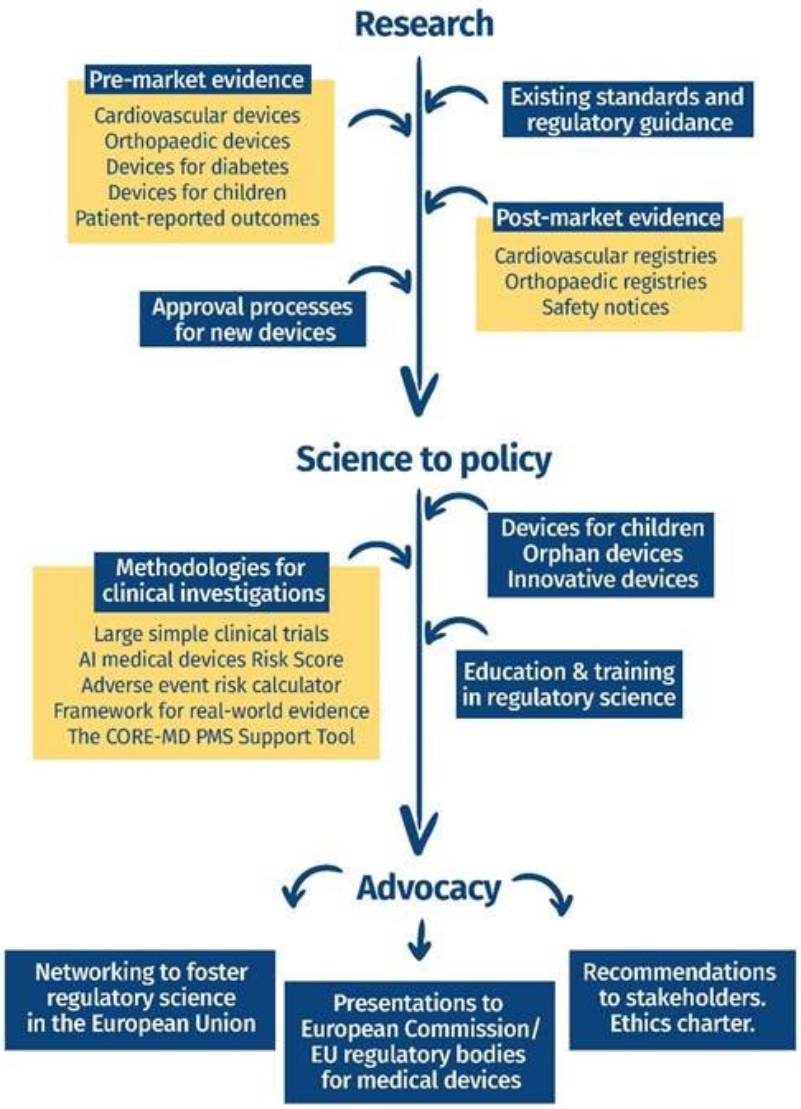
CORE-MD Methods And Tools

CORE-MD output	Envisaged exploitation routes
AI MDSW risk scoring system: This is a simple point-scoring system that can be used to estimate the overall risks associated with the use of a machine-learning algorithm or other AI MDSW in order to direct the level/depth of the pre- and post-release requirements for clinical evaluation. From a clinical perspective three parts of evidence are required, namely, valid clinical association, technical performance, and clinical performance, and for each the CORE-MD consortium has proposed scores from 1 to 3, relevant to the characteristics of the AI tool and its application, where lower values are associated with lower risk benefit. Further details are available in the public deliverable D2.4 and in the related peer-reviewed publication (under revision).	Further refinement while the AI Act is being implemented; Development of an IT-based tool for automatic risk score calculation (subject to resources/funding availability); Investigating opportunities for and barriers to its use by regulators and notified bodies, within the work of MDCG CIE Work Package 28.
Statistical tool: Due to the high-risk nature of many implantable devices, and to the absence of specific guidance about sample sizes or minimum cumulative follow-up required, limited sample sizes are common. However, this practice implies substantial uncertainty of the resulting risk estimates. We aimed to provide a practical tool to give insight into the relation between sample size and the implications for the level of risk that is accepted. The source code and the dataset used to test the tool on data comparing the Bioresorbable Vascular Scaffold (BVS) device to the Everolimus drug eluting stent (EES) are openly available on Zenodo.	Conducting further testing on the utility and usability of the tool on other datasets; Performing a statistical review of methods for applying objective performance criteria which was not possible due to lack of funding in the CORE-MD CSA.

Decision framework: Post-market surveillance (PMS) is essential for monitoring the performance of high-risk medical devices; no implantable device can be guaranteed to be completely free of risks over the long term. PMS is the responsibility of manufacturers, but the best quality data are collected by medical professional associations which conduct comprehensive registries. It is anticipated that EU regulators will consider the recommendations prepared by CORE-MD in its 'Decision framework' (Deliverable 3.1), as the basis for developing a system for recognizing which registries and other sources of post-market clinical follow-up can be used to provide reliable information that will be accepted for regulatory purposes.	Consideration by CIE WP28, and then by EU regulators at CIE and MDCG, to convert the framework in a checklist to be potentially Incorporated into or referenced in future EU guidance. In addition to be included in the respective publicly available deliverable, the framework has also been submitted for peer-reviewed publication, so it will be available for all stakeholders.
Web-scraping tool: The CORE-MD PMS Support Tool (Deliverable 3.2) has been designed to be useful to members of Expert Panels, regulators, and evaluators in notified bodies, whenever they wish to find out if problems have been reported with a particular device or with a particular type of advice. That information will not be available in EUDAMED until it has been fully operational for some years, since it will not include any historical data. The Tool may be useful also for manufacturers when they wish to summarize the 'state of the art' relevant to a certain device.	The tool has been demonstrated to DG SANTE, the EUDAMED software team, EMA, notified bodies, and various manufacturers (see list of relevant meetings and events, Section 7.2, Table 10). Further sources of funding have been explored, so that the tool can be maintained and developed. Options for commercialisation, if necessary, or for it to be supported by regulatory bodies, will be reviewed further with WP28, as a priority.

Overview of CORE-MD Main Outputs



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