R&D Solutions for Pharma & Life Sciences

MEDICAL DEVICE DEVELOPMENT

The EU Medical Devices Regulation: The role of scientific literature in clinical evaluations and post-market surveillance

Some immediate actions are required of medical device manufacturers to ensure readiness for the new European Union Medical Devices Regulation, which calls for much stricter clinical data and a continuous process of clinical evaluation. Based on analyses of MDR 2017/745 and MEDDEV 2.7/1 Rev. 4, systematic reviews of the scientific literature have a lot to offer in this process. We show how leveraging solutions like Embase can help.

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A challenging transition period

While the new European Union Medical Devices Regulation (MDR) will not become effective until May 2021 (after the recent postponement by one year), **some immediate actions are required of medical device manufacturers.**

We are currently in the transition period, but pressure is rising with demands for stricter compliance and an emerging shortage of expertise. Effective strategies must be prioritized if manufacturers are to be ready for the ISO 13485:2016 and the 2021 full enforcement of MDR.

Stricter clinical evaluations

The new MDR calls for much stricter clinical data and a continuous process of clinical evaluation. It also involves device classification and definition changes. Manufacturers must now consider whether their devices must be re-certified and prepare a plan for this.

It is also necessary to restructure their post-market surveillance strategy to align with the new regulations, which include a new periodic safety update report (PSUR) for Class IIb and Class III devices. **Clinical evaluation reports (CERs) must also be brought up to date so that they report on the safety, performance and clinical benefits devices throughout their life cycle.** This includes post-market surveillance (PMS) planning and post-market clinical follow-up (PMCF).

A year is not a long time to achieve this, but leveraging the scientific literature with the right research solution will certainly help.

Six major areas where systematic reviews will help

Based on analyses of MDR 2017/745, **systematic reviews of the scientific literature clearly have a lot to offer for clinical evaluations of medical devices.** There are six sections that propose using literature as the source of pre-clinical and clinical data required for:

- *demonstration of equivalence*
- *technical documentation* on product evaluation & validation and post-market surveillance, proving conformity of the new device to the regulation
- *requirements to be met by notified bodies* for examination, validation and verification of manufacturer's procedures, for literature searching, appraisal and analysis, it's documentation for reproducibility, and currency of the relevant literature
- *post-marketing clinical follow-up*
- *investigator's brochure*, in case any investigational devices were used for conducting clinical studies and thus collecting safety and effectiveness data from them
- *clinical investigation plan* with background literature review and the current state of the art

Why choose Embase

According to MEDDEV 2.7/1 Rev. 4 manufacturers must develop a system of literature review that covers the appropriate comprehensive sources (e.g., Embase, MEDLINE®, the Cochrane CENTRAL trials register); uses an objective methodology and has an auditable protocol.

In fact, MEDDEV 2.7/1 Rev. 4 and the Cochrane Collaboration also recommend Embase as a comprehensive source for systematic reviews. Embase also has the advantage of a dedicated feature for building PICO (Patient/Population/Problem, Intervention, Comparison, Outcome) framework-based systematic reviews. This is a highly recommended objective methodology for this type of study.

Its dedicated Medical device search form can help easily discover the adverse events required for post-marketing surveillance. Embase also enables easy export of searches, making it simple to audit the protocol whenever necessary, and alert creation to remain up to date with the most recent information, necessary for CER updates and also to perform a pro-active PMCF.

Leveraging Embase for obtaining pertinent clinical data, as required in these six sections will help medical device manufacturers in CER and PMCF creation, and their update to get ahead on a major part of their preparation for MDR. Elsevier has extensive experience in preparing scientific literature for critical tasks in drug and medical device development, and continually work to ensure that Embase is ready to serve the needs of our customer base.

Embase

Embase helps customers improve literature monitoring strategies and systematic reviews with the world's most comprehensive biomedical literature database and dedicated query forms for PICO and medical device searches.

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