Resources for Researching Medical Devices Using Publicly Available Databases

Speaker

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By Thi Nguyen, BS

The clinical evaluation of medical devices marketed in the European Union (EU) is influenced by guidance from the Medical Device Coordination Group (MDCG) and still-relevant sections of MEDDEV 2.7/1 Rev 4 (Medical Devices Document 2.7/1 Revision 4; June 2016). In her presentation at the 2022 AMWA Southeast Regional Conference, Sara VanWyk provided an overview of relevant guidance on the clinical evaluation report, publicly available databases for literature searches, and content and release information for summaries of safety and clinical performance (SSCPs).

Background

Historically, requirements for medical device regulation in Europe were established by the Medical Devices Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD). As of late, the requirements have been transitioning to follow the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

To show evidence of having met the EU MDR general safety and performance requirements, manufacturers plan and report on the clinical evaluation of medical devices marketed in the EU; such evaluations align with the MEDDEV and MDCG guidance documents, including MEDDEV 2.7/1 Rev 4, MDCG 2020-6, and MDCG 2020-13 (among others). The first relevant guidance is MEDDEV 2.7/1 Rev. 4 (June 2016), which offers manufacturers and notified bodies guidance on clinical evaluation under directives 93/42/EEC and 90/385/EEC. The second guidance is MDCG 2020-6, which explains sufficient clinical evidence for legacy devices.

The third guidance is MDCG 2020-13, which offers a template for the clinical evaluation assessment report (CEAR). Each section of guidance contains pearls of wisdom regarding the device characteristics and evidence described in a clinical evaluation report, including the device description, published literature, clinical investigations, and clinical experience. This information may additionally be described in an SSCP, depending on the type of device.

Device Description

Methods for describing the device under evaluation are outlined in MDCG 2020-13 Section C. To locate a device description, one can use the manufacturer's website, the United States (US) Food and Drug Administration (FDA) 510(k) Premarket Notification Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm), the FDA Premarket Approval (PMA) database, or the Therapeutic Goods Administration (TGA) Australian Registry of Therapeutic Goods (ARTG) database.

Published Literature

What literature qualifies for evaluation depends on the associated data, which can be categorized as either pivotal data or other data according to Section 9.3.2 of MEDDEV 2.7/1 Rev 4. Pivotal data must directly demonstrate adequate safety and performance (of sufficient quality and generated with the device under evaluation or the equivalent), whereas other data only play a supportive role. The same guidance also offers examples of data that lack scientific validity in Appendix A6. In terms of where to find published literature, many options exist, and Ms Vanwyk highly recommends PubMed, Embase, and the Cochrane Database for Systematic Reviews. However, other databases such as Europe PMC and Google Scholar can also be viable options.

Clinical Investigations

In addition to searching published literature, writers are also encouraged to search data from clinical investigations. This search can help writers identify data that are not found by other means. To find clinical investigation data, writers can use clinicaltrials.gov, the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), and Cochrane Central, although the EU Clinical Trials Register can also be a good resource.

Clinical Experience

Clinical experience includes data on suspected device-associated deaths, serious injuries, and malfunctions that can feed into medical device reports (used in the US) and medical device vigilance (used in the EU). In the US, the FDA can use clinical experience to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Data can be compiled from mandatory reporters (eg, manufacturers, importers, and user facilities) and voluntary reporters (eg, health care professionals, patients, and consumers).

It is important to note that clinical experience can have limited utility because of passive surveillance. Many clinical experience databases exist throughout the world, with the US having the most databases. Available databases per country are as follows:

- **US** – FDA Manufacturer and User Device Experience (MAUDE), FDA Recalls, and FDA Total Product Life Cycle (TPLC) databases

- **Canada** – Health Canada Medical Device Incidents and Health Canada Recalls and Safety Alerts databases
- **United Kingdom** – Medicines and Healthcare products Regulatory Agency (MHRA) database
- **Germany** – Federal Institute for Drugs and Medical Devices (BfArM) Field Corrective Actions and BfArM Recommendations databases
- **Switzerland** – SwissMedic Field Safety and Corrective Actions (FSCA) and SwissMedic Recalls databases
- **Australia** – TGA Device Adverse Even Notification (DAEN) and TGA System for Australian Recall Actions (SARA) databases

Other Resources

Other helpful resources include SSCPs, which provide publicly accessible, up-to-date summaries of clinical data and other information about the safety and clinical performance of a medical device. SSCP information can be accessed through https://ec.europa.eu/tools/eudamed/#/screen/home.

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Think Like an Editor: Improving Document Quality for Regulatory Submissions

Speaker

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By Paris Karr, PharmD

Quality control (QC) is an integral part of ensuring accurate and consistent regulatory writing submissions. QC can be essentially defined as a process of checking consistency against a standard. However, in a writing context, QC is more specific than just "review."

Considering different types of reviews (data, subject matter expert [SME], and editorial), the omission of each kind can have different implications. Data and SME reviews can be critical for regulatory submissions, whereas an editorial review is often necessary for document appearance.

In her presentation at AMWA's 2022 Southeast Regional Conference, Callie Compton, Senior Technical Editor at Certara Synchrogenix, identified common issues in the QC process and discussed strategies for regulatory medical writers to ensure a successful QC process.

Common Issues

Compton began by outlining several examples of document inconsistency. Such instances can include (but are not limited to) a document not aligning with sources, inconsistent terminology and style conventions, and errors in grammar, punctuation, and/or spelling. Furthermore, she also identified issues that may arise downstream in the QC process, such as inadequate time allotted for QC, vague, unclear expectations and/or instructions, and misplaced expectations for role/review type.

Document Consistency

Compton suggested that identifying specific standards that govern the document is a crucial step for QC. However, before the actual process of QC, regulatory medical writers should consider asking the following questions to ensure document consistency:

- Does my writing align with its source(s)?
- Is my writing easy to navigate?
- Do I write about the same content in the same way?
- Do the same components in my writing look the same?

Regulatory writing may often require checking external sources such as a tables, listings, and figures document or a clinical study report. To ensure that the writing is aligned with external content, it is important to clearly identify sources in the document and to keep them organized. Compton illustrated that source references should specify document identifiers, such as the study identification, version number, or date, if applicable.

Consistent terminology and style conventions are also critical for regulatory documents. Compton pointed out that a style guide can be an important tool to help maintain uniformity when there can be many acceptable writing conventions. A style guide may specify, for instance,

- use of company/drug name
- preferred template/toolbar
- abbreviations/terminology, and/or
- usage (eg, patient vs subject).

Compton elaborated that "style" may refer to 2 different things: writing composition or formatting. In discussing the latter, a QC checklist can help guide the medical writer to consistently perform specific assessments, line edits, and spelling checks as a process.

QC Process

Given its deadline-oriented and collaborative aspects, regulatory writing requires effective time management. Compton pointed out that inadequate time allotments for QC during development stages or at the end of a project can lead to considerable quality risk. For that reason, the start of