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Case Study: Clinical Evaluation Report for Medical Devices

Objective

Our client approached us with a Clinical Evaluation Report (CER)assignment for a Class IIa medical device. We were required to prepare end-to-end document; however, the literature search strategy was prepared at the client end based on the search terms provided by us. The literature output and the access to full-text articles had to be provided by the client. We had to screen the articles based on our inclusion-exclusion criteria and appraisal criteria. We had to share the screened results with the client for their approval before moving forward.

Our Approach

We prepared a list of source documents that we needed from the client apart from the literature output and shared the list with the client. After receiving the source documents, we went for a kick-off meeting to clarify the expectations, the route of conformity, the submission timelines, and the requirement of source data (based on the route of conformity). After getting approval on the names of equivalent and similar devices, we analyzed relevant data (literature data, manufacturer's clinical investigation data, pre-clinical data, post-market surveillance data and data from public adverse event databases) to evaluate the following in conformity with the relevant GSPRs:

- if there was any new safety signal
- if the device was performing as per its intended use
- if the device and the technology used by the device was state of the art and
- if the benefits outweighed the risks.

The completed draft went through the internal robust (review and QC) processes before sharing with the client.

Outcome

We received positive feedback for the CER. The client approved the report and entered into a long-term association with us. To learn more about how we can help your organization

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