



Systematic Literature Review for supporting regulatory document (CER)

Customer

Medical device company/
regulatory team

Objective

To conduct a systematic literature review in accordance with MDR and MEDDEV guidelines for the preparation of a Clinical Evaluation Report (CER).

Scope

Systematic literature review to identify, screen, extract, and summarize clinical evidence.

Approach



Protocol & Scope: Client shared protocol; SME team designed CER-specific workflow.



Multi-Database Search: Platform searched PubMed & Embase with automated deduplication.



AI-Assisted Screening: Title/abstract & full-text screening with traceability and explanations.



Double-Blind Validation: Two independent reviewers validated; conflicts were resolved via conflict resolver.



Data Extraction & Summarization: Key evidence auto-extracted into tables; SME validated.



Submission-Ready Output: Word document with citations, aligned with MDR & MEDDEV, ready for CER submission.

Result

Methodology	Volume	Project Timeline	AI Accuracy
AI-aided double-blinded Review	2,532	3 weeks	93%