MadeAi

Systematic Literature Review for supporting regulatory document (CER)

Customer

Medical Equipment Manufacturer/Clinical Research and Regulatory team

Objective

Conduct a systematic literature review to support CER for three devices and demonstrate state-of-the-art clinical safety and clinical performance in compliance with EU MDR requirements.

Scope

Systematic literature review to identify, screen, extract, and summarize clinical evidence supporting CERs for three vascular devices across neuro and peripheral interventions.

Approach

Protocol & Search: Client shared the objective; platform assisted SMEs in generating inclusion/exclusion criteria and search queries. Platform searched PubMed & Embase with automated deduplication.

AI-Assisted Screening: Title/abstract & full-text screening with traceability and explanations. Two independent reviewers validated; conflicts resolved via conflict resolver.

Data Appraisal & Data Contribution: Conducted data appraisal (quality, relevance, limitations) and data contribution (safety, performance, and benefit–risk evaluation) aligned with MDR & MEDDEV requirements.

Data Extraction: Platform extracted key data elements automatically; the SME team performed in-depth treatment-arm extraction for analysis.

Submission-Ready Output: AI-generated single-article, multi-article, and table summaries; SME validated; CER-ready literature summaries and evidence tables exported; validated by SMEs.

Result

Methodology	Volume	Project Timeline	AI Accuracy
AI-aided double- blinded Review	919	4 weeks	**94%**
	265	2 weeks	**88%**
	132	2 weeks	**92%**