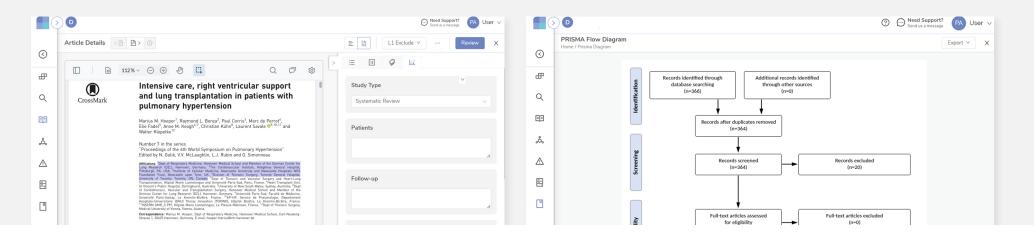
CAPTIS

The only software dedicated to EU MDR / IVDR Compliance

CAPTIS[™] is a secure, user-friendly web-based application that assists medical writers with the laborious process of creating regulatory documentation for EU MDR / IVDR compliance such as CEP/CER, PEP/PER, SVR, PMCF Plan/Report, SSCPs and more.

CAPTIS[™] has been developed in collaboration with our experienced and qualified team of medical writers to address the real time challenges in medical writing and EU MDR / IVDR compliance.



Systematic Literature Review

- Integration with medical research databases such as PubMed and Google Scholar with automatic citation data and full-text retrieval.
- Ability to import search results from additional health databases so that all articles are in consolidated for end-to-end assessment.
- Multi-stage screening support with a customizable review process.
- Separate workflows for both device under evaluation & state of the art searches.
- Automatic duplicate detection, configurable review questions and keyword highlighting.

Al assisted literature data extractions & summaries using CAPTIS Copilot.

Adverse Event Data Analysis

- Integration with major adverse event databases such as US FDA MAUDE and TPLC.
- Enhanced interface allowing users to search quickly and simultaneously for multiple product codes and brand names.
- Flexibility to review events on the platform or easily export all events on a single click to an Excel sheet.

Automated Report Generation

- Built-in report generation to automatically create complex reports required for final submissions.
- Integrate an up-to-date report with the click of a button to save significant time and reduce the chance of human error.



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2. Introduction			Ē	Hadeted Detiret Deckloses Configuration				
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3.1 Key sources relevant to innovation-friendly regulation and medical devices regulation	Executive summary	GD Linked document name Z Edit		Updated Patient Problems Configuration, results cut-off in Project 1 Risk Analysis	🔊 Alana Smith	P Pfiztech	Baxter	Octobe
3.2 Key considerations		f healthcare, ranging from the relatively simple and external (such table defibrillators, deep brain stimulators, etc). This is an area of		Updated Patient Problems Configuration,	SB Susan Bateson	TechMed	First Aid Equipment	Octobe

Collaboration & Review

- Communicate with your team and update project status.
- Designated roles and responsibilities with customizable review workflows.
- Work concurrently on various projects so that no time is wasted.

Source Document Management

- Upload source documentation such as IFUs on the device to ensure that the final report reflects the right information.
- Users can tag information from the source document to final reports.
- Notifications when new versions are uploaded by collaborators.
- Easy categorization, tracking and highlighting of each document.

Report Writing & Maintenance

- Link information from source documentation directly into your report.
- Align data and content across various PMS documentation for simplified maintenance.
- Record reused terms such as Indications for Use as a Data Dictionary entry to serve as a "Single Source of Truth" to ensure consistency.
- Seamless commenting, project progress and collaboration.
- Smart templates with effortless standard, example and guidance text set-up.
- Built-in Reference Manager with instant PDF downloads.



Why Choose CAPTIS™?

FEATURE	CAPTIS™	OTHER SOLUTIONS	BENEFITS
Improved data retrieval due to Google Scholar and Europe PMC integration	~	×	 Improved metadata + higher percentage of full text PDFs are retrieved by cross-checking against two databases (PubMed and Google Scholar)
Option for separate but intertwined SoTA (State-of-the-Art) and DuE (Device under Evaluation) workflows	~	×	 Run literature searches specific to State-of-the-Art data Seamlessly move articles between workflows
Customizable tables for summary reports	~	×	 Add new data fields for your projects as report formats change and as your team received Notified Body feedback
Source document management	~	×	 Ensures reports reflect accurate information from the latest internal documentation such as IFUs, device description, etc.
Audit trail & reproducibility	~	×	 Audit trail to understand details of past decisions have been made and how data has been extracted from various databases
US FDA MAUDE/TPLC adverse event database integration	~	×	Consolidated results for multiple product codesImproved interface allowing search by brand name
Writing Support & In-Built Regulatory Intelligence	~	×	 Ability to share workload with our writing team seamlessly and NB/Device Manufacturer intelligence regularly incorporated
Content Linking when drafting Reports	~	×	 Seamlessly link content from the referenced Technical Documentation One-click data verification for Reviewers
Plug Dynamic Literature Review Tables into Reports	~	×	 Easily plug literature tables generated from the Systematic Literature Review Dynamic tables which update automatically based on any updates in the Literature Review
In-built Reference Manager	~	×	 Cite included articles and Technical Documentation easily Save cost; no need for additional Reference Management Software subscription
Report Template Support	~	×	 Create custom guidance-based report templates for your team
Review Workflows	~	×	 Design custom review workflows with multiple review stages and progress tracking
Easy Project Maintenance	~	×	 Create timely maintenance reports for Regulatory Documents View literature reviews and linked content from previous reports Update information in multiple documents simultaneously

Ready to demo CAPTIS™ with your team? **CONTACT US!** info@celegence.com

