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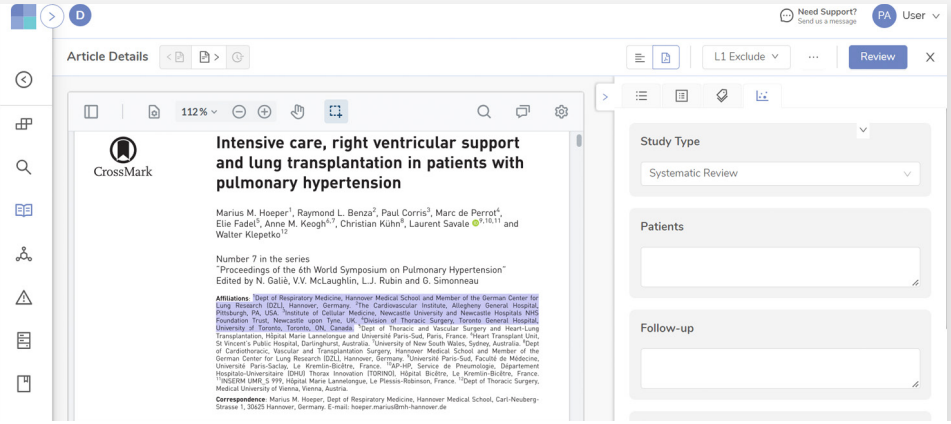
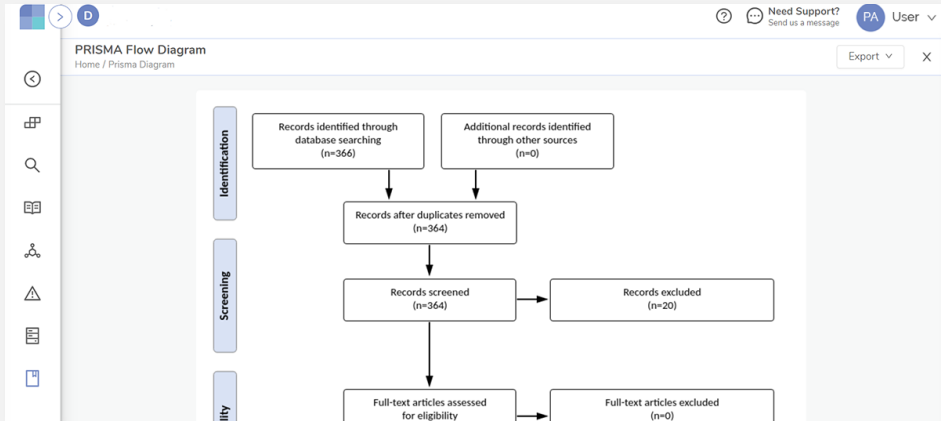
CAPTIS

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.

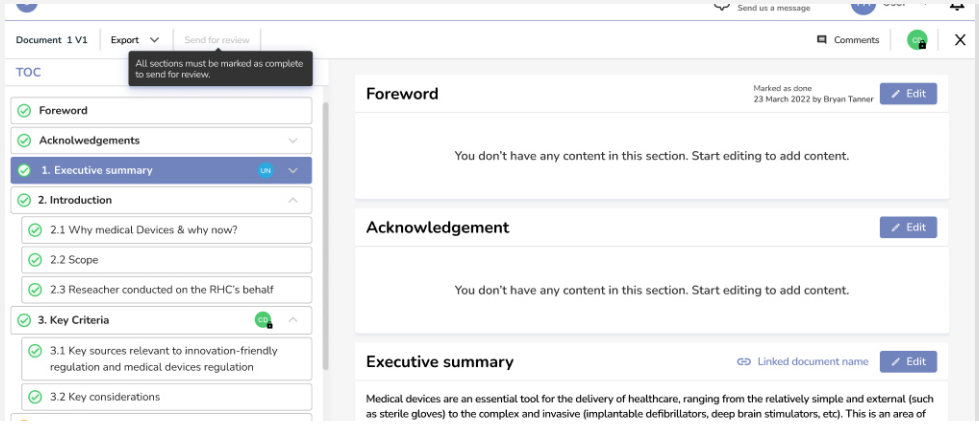
Adverse Event Data Analysis

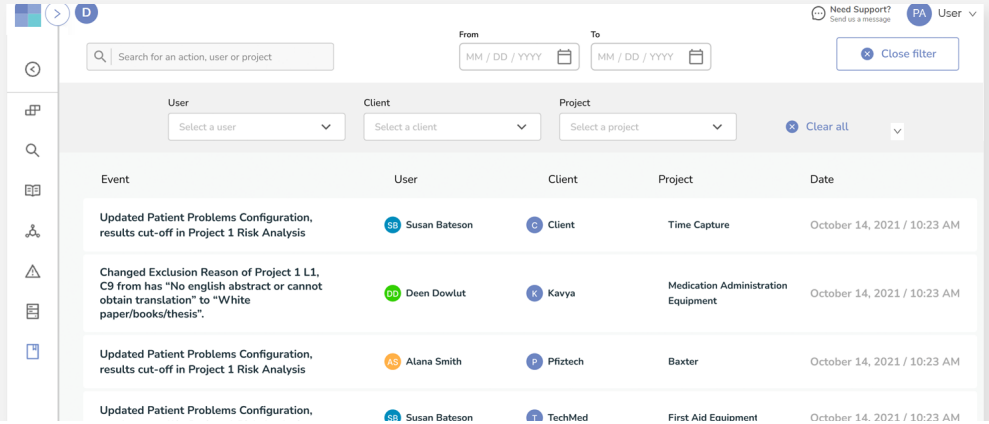
- Integration with major adverse event databases such as US FDA MAUDE and TPLC.
- Enhanced interface allowing users to search quickly and simultaneously for multiple product codes and brand names.
- Flexibility to review events on the platform or easily export all events on a single click to an Excel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

AI assisted literature data extractions & summaries using CAPTIS Copilot.





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 codes ▪ Improved 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

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