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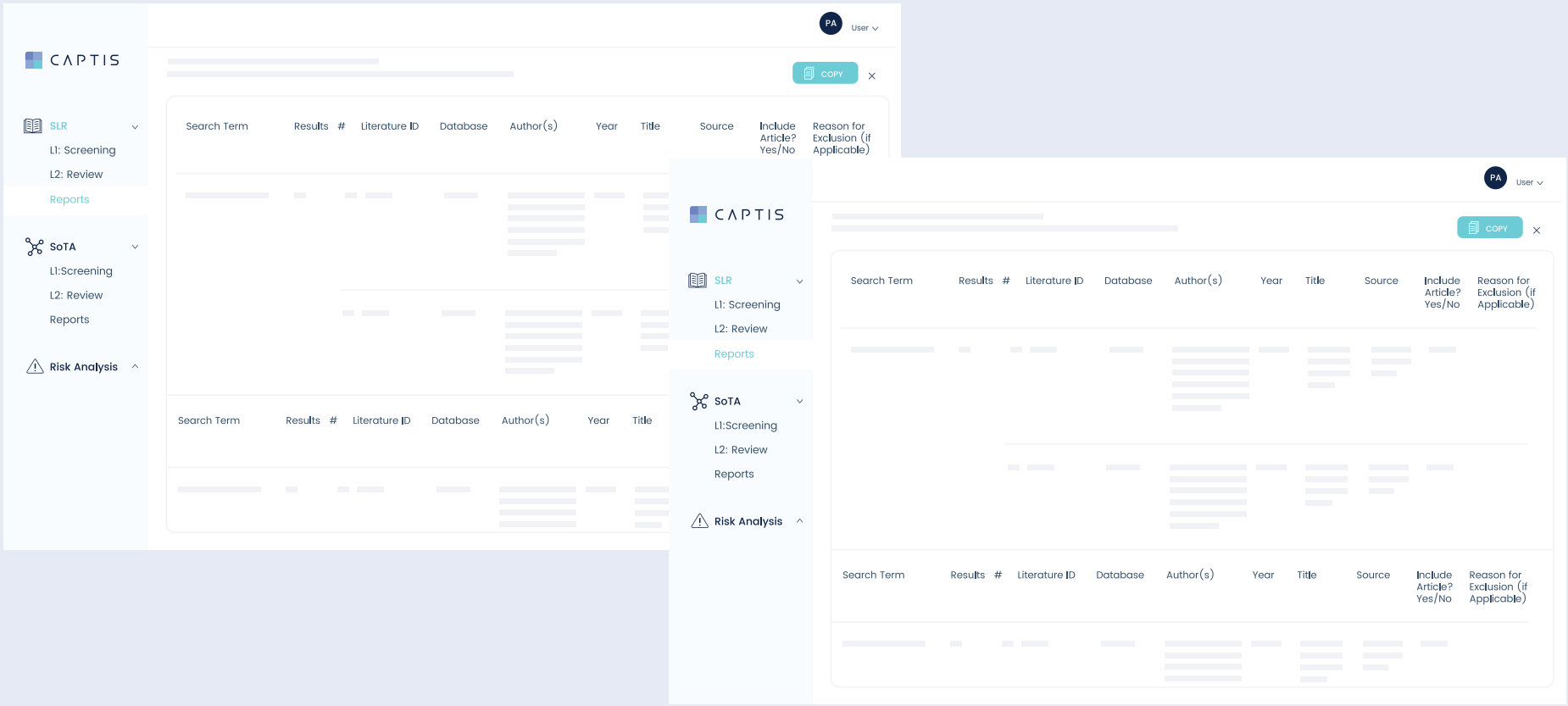
CAPTIS

EU MDR COMPLIANCE

The only software dedicated to EU MDR 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 compliance such as CERs/CEPs, PMCF plans, and SSCPs.

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



Systematic Literature Review

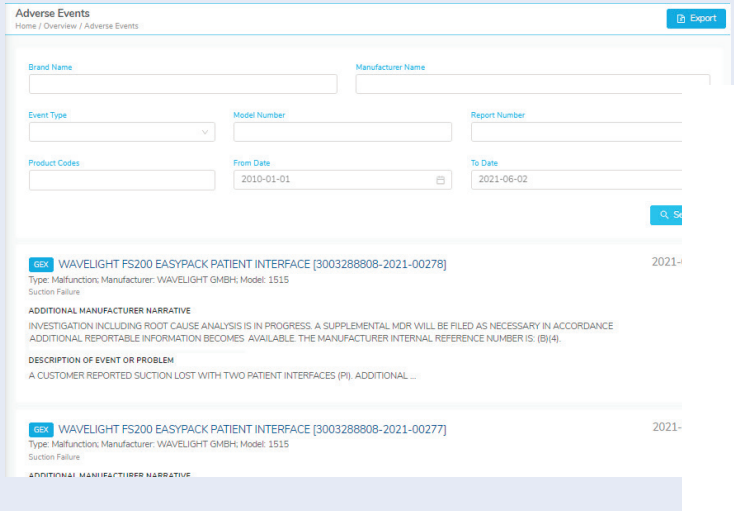
- Integration with medical research databases such as PubMed and Google Scholar with automatic citation data and full-text retrieval.
- Ability to import search results from additional health databases so that all articles are in consolidated for end-to-end assessment.
- Multi-stage screening support 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.

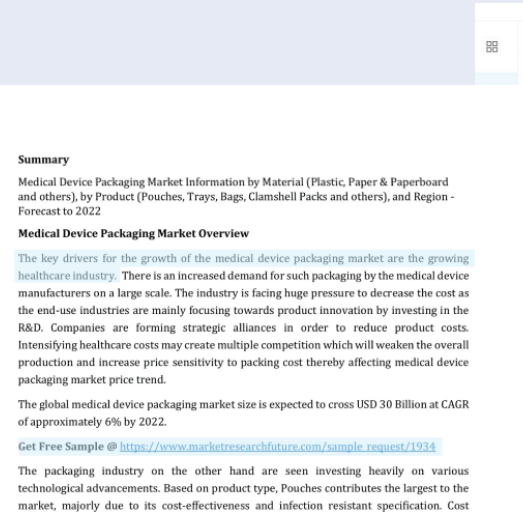
Adverse Event Data Analysis

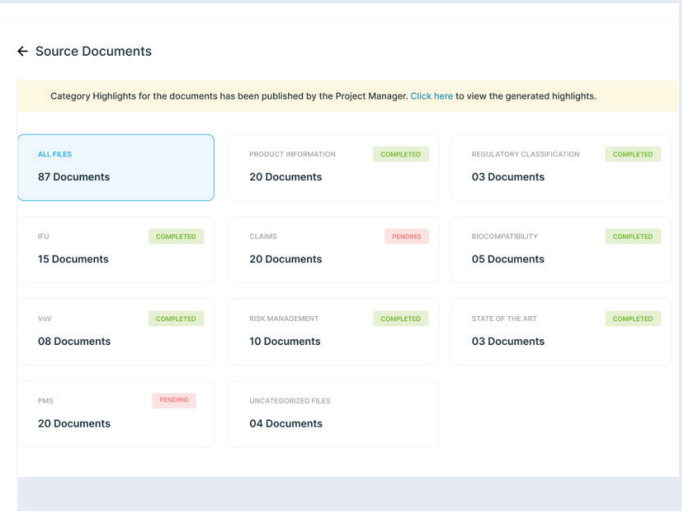
- Integration with major adverse event databases such as US FDA MAUDE and TPLC.
- Enhanced interface allowing users to search quickly and simultaneously for multiple product codes and brand names.
- Flexibility to review events on the platform or easily export all events on a single click to an Excel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







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.

Why Choose CAPTIS?

- ✓ Reduce the time spent by your medical maintaining EU MDR documentation by an average of 20%.
- ✓ Ensure high quality reports are developed the first time by lessening the chance of human error.
- ✓ Track report due dates and deadlines based upon the risk classification as per MDR requirements.
- ✓ Improve compliance by implementing Notified Body feedback into future submissions.
- ✓ 100% cloud-based, allowing for fast and simple implementation.

Ready to demo CAPTIS with your team?

CONTACT US!

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