



CASE STUDY

Leveraging Technology to Optimize MDR Compliance Outsourcing & Partnership

A Case Study on Acumed's Success through Strategic Outsourcing and Partnership with Celegence and **CAPTIS**





Partnership Background

Acumed reached out to Celegence learn more about the CAPTIS technology solution in search of more efficient pathways to optimize their current literature review process, which was manual and cumbersome.

They were impressed by the demonstration of CAPTIS and promptly started a trial. During this time, they were pleased to discover the additional advantage of being able to harness Celegence's medical writing expertise while working collaboratively within the platform.

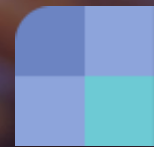
Ultimately, subscribing to CAPTIS and utilizing the services of Celegence's Medical Writing Team resulted in considerable productivity gains for the Acumed team. The blend of technology and services added significant efficiencies to the collaboration.



Project Deliverable

Literature Review Report

Acumed's Experience with



CAPTIS

Technology is about making mundane tasks easier and allowing you to do more with less.

Sundar Pichai



01 Easy Collaboration

Real-time Reviews

Celegence collaborated on projects with Acumed to set up the system with the necessary databases, exclusion criteria, screening questions, and article tags.



CAPTIS enabled Celegence writers to leave **notes**, **comments**, and **tags** on their articles, eliminating the need to share excel sheets back and forth.



CAPTIS allowed Acumed's team to not only track the thought process of their writers, but also to collaborate and comment as they moved towards finalizing which articles to include, improving the efficiency of the entire review process.





02 Quick Implementation of mid-project Changes

As Acumed learned more about what data is sufficient from Notified Bodies, they were able to implement changes to their data collection process in order to clearly demonstrate the safety and efficacy of their products.

CAPTIS enabled easier implementation of mid-project process changes, such as modifying exclusion criteria, through filtering and sorting of article tags and notes.



Tags in the system made it easy to re-sort and improve search strings over time.



Team at Celegence was flexible in changing the process midstream.



CAPTIS is robust enough to cater to changes as the project is being executed.





03 Simplified Content Management

CAPTIS facilitates the entire literature review process from start to finish.



Acumed found it incredibly beneficial to utilize CAPTIS, as all their literature reviews, accompanying data, and supporting files were organized in a **single, convenient platform**.



Acumed's project lead was able to **quickly access and share data** with internal clinicians, instead of having to laboriously search for literature or evidence.



CAPTIS made the whole process **less people dependent**, creating more workflow efficiencies.



04 Data Ownership Access Control

Data is secured on CAPTIS for as long as the client has an active subscription, regardless of any changes in the team, making it easier to bring maintenance work in-house, if necessary.



Literature review data could be shared easily, even with independent consultants who may want to review work.

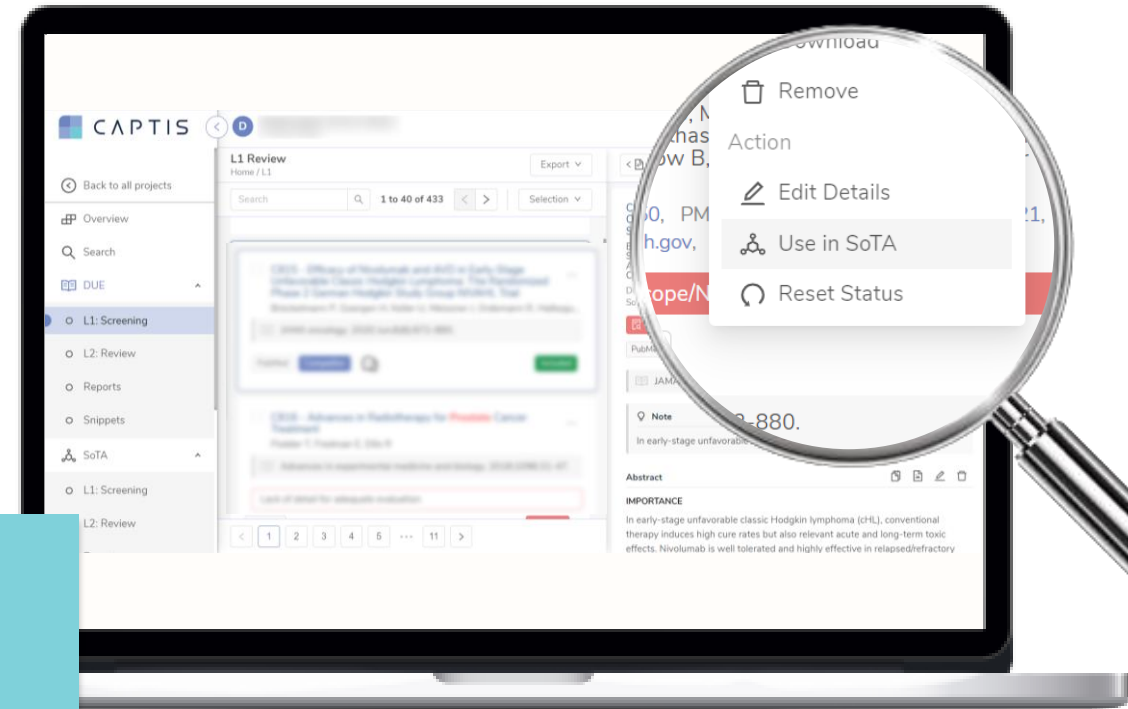


Assigning and revoking access was easy.



05 State-of-the-Art Workflow

With workflows tailored for regulatory submissions, CAPTIS allows users to tag articles relevant for State-of-the-Art (SoTA), and even conduct separate SoTA systematic reviews.



With a dedicated State of the Art workflow, articles can be moved from the Device under Evaluation (DUE) workflow to the SoTA workflow and vice-versa, easily.



Celegence writers facilitated the SoTA workflow by helping Acumed identify relevant articles and decide if more searches were necessary.

The partnership between Celegence and Acumed was a resounding success, attributed to the perfect blend of

PEOPLE, PROCESS, and CAPTIS!



Collaborative Approach



Flexibility and Quick Adaptation



Simple Content Management



Data Ownership



Optimized Workflows



CAPTIS



Capabilities Overview and Key Benefits

CAPTIS Modules



Technology solution to support high-quality, sustainable, cost-effective compliance for the device and diagnostic industry

- Time and cost-effective report development and maintenance
- Consistency and quality in compliance
- Enhancing collaboration & project oversight

1

Literature Review

Literature search, review, and reporting, all in one place

2

Adverse Events

Enhanced US FDA MAUDE and TPLC Integration

3

Source Documents

Central Repository for Project Related Documentation

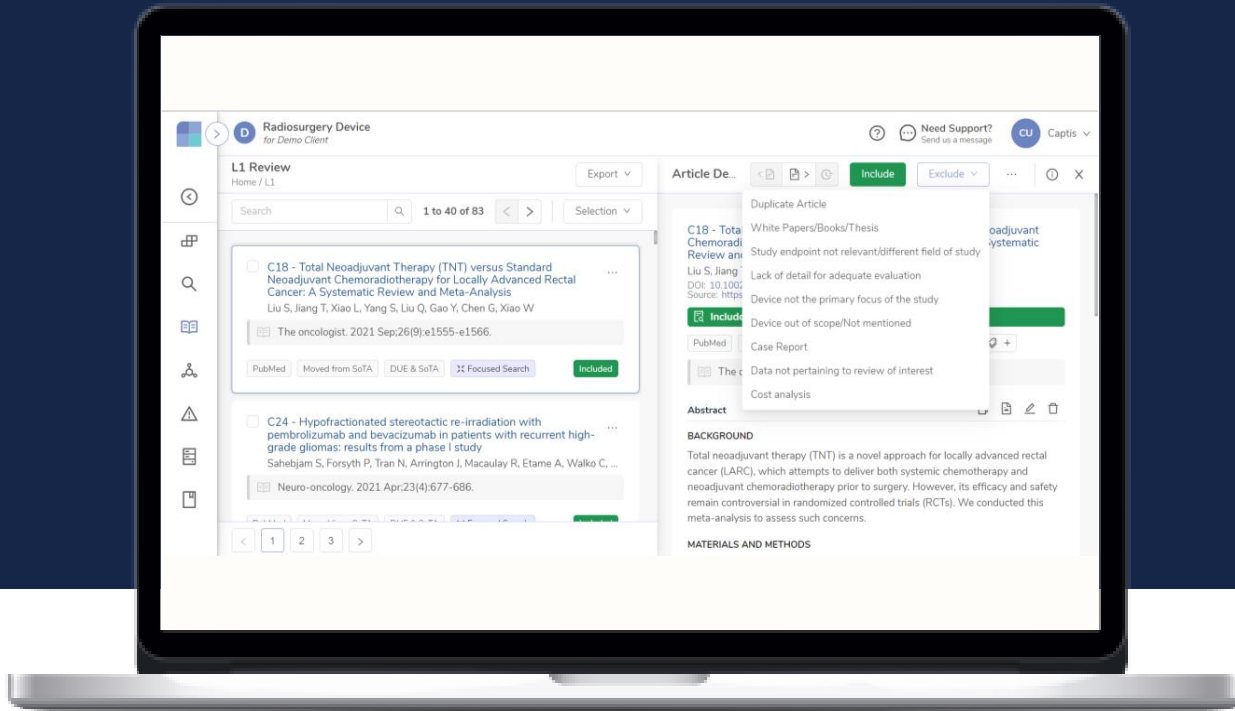
4

Report Writing

Enhanced Report Creation experience

Get more out of Literature Reviews

Manage Your Literature Review & Documentation Effortlessly



- ✓ Bulk Import of Search Data
- ✓ Automatic import of free full-texts
- ✓ Customizable Data Collection Forms
- ✓ Automated data summaries with improved consistency across documentation
- ✓ Reduce rework for maintenance reports
- ✓ Article audit trails
- ✓ Nearly 30% reduction in the time taken for the overall literature review process
- ✓ Effortless updates to the literature search strategy

30%
Efficiency Gain

01 Quicker Literature Reviews

02 Traceable Evidence Gathering

03 Simplified Notified Body Reviews

CAPTIS Subscription & Service Delivery Models



In-house

Your team completes all work in the CAPTIS platform; save time and reduce manual effort of your medical writers



Collaborative

Celegence's team works with yours together in the CAPTIS platform; benefit from collaboration features and access to all project data



Outsourced

Celegence's expert team completes all work in CAPTIS; you maintain ownership & access to all project data



Which CAPTIS Subscription Model did Acumed choose?

Acumed initially adopted the **Collaborative** model for their projects, and upon completing the project, they transitioned to the **In-house** model to continue working on the remaining reports.

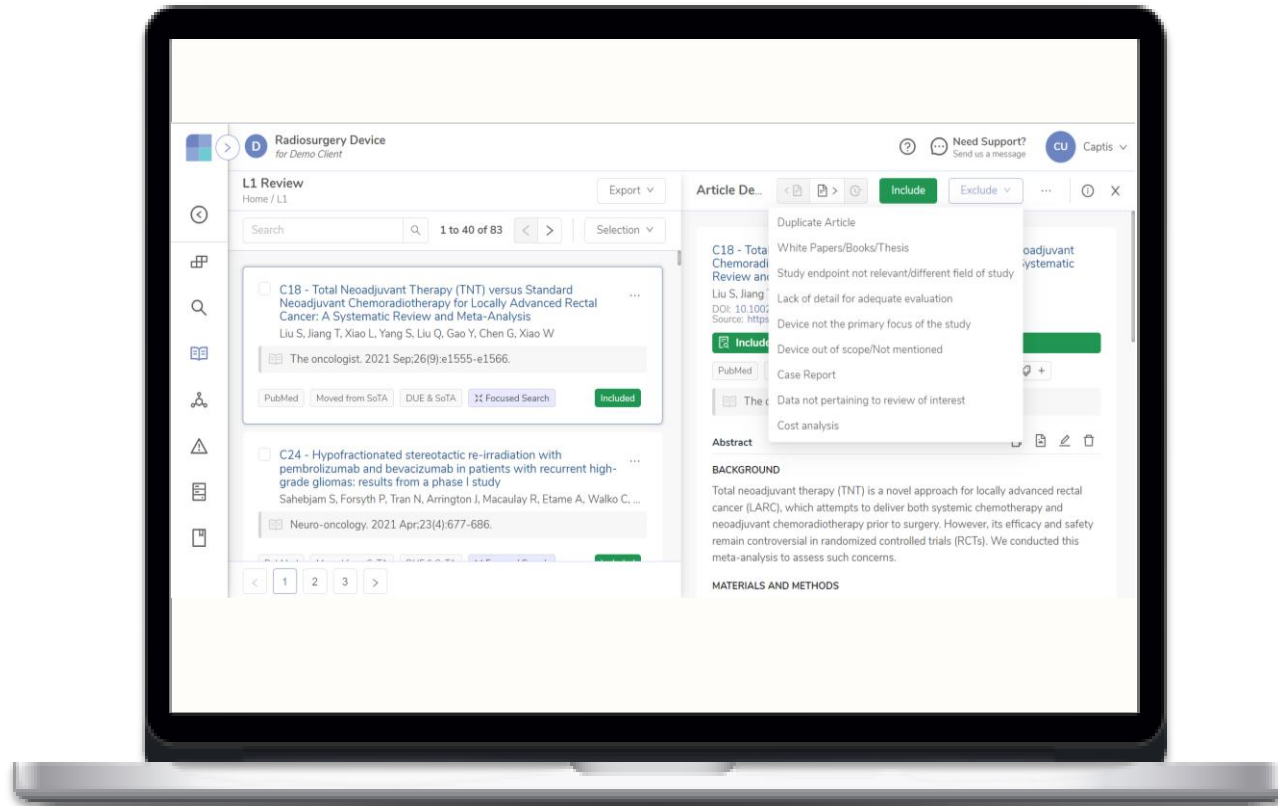
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A CAPTIS subscription involves personalized training, extended support, and regular updates. Your ideas, our inspiration. Join now for a transformative experience!



Examples of Ideas from our Clients

- Publication Date Filter
- In full text evaluation, moving articles from DUE to SotA and vice-versa
- Conditional Level 2 Appraisal; multiple full-text appraisal questionnaires in the same project.
- Article tag-based customized literature reports



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Literature
Review



Adverse
Events



Source
Documents



Report
Writing

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