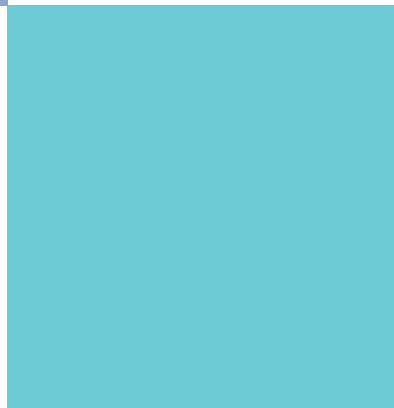
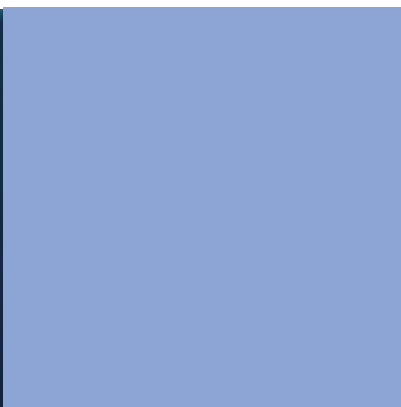




WEBINAR TRANSCRIPT

Productivity Improvements for Cost-Effective CER Writing and Maintenance

Shruti Sharma



Session Objectives

- A brief overview of the PMS reporting requirements under the EU MDR
- Understand some pain points that writers experience when we create and maintain these reports
- Learn to leverage technology to automate tasks and save our time and cost
- View a brief demo of CAPTIS™ that saves 20% of our team's time

PMS reporting requirements under the EU MDR

We have the clinical evaluation report, PMCF, SSCPs, risk management & PSURs. What I want to highlight is that these are the typical reports a manufacturer may need for one device. Now, most of these reports must be created for every device in the manufacturer's portfolio and all of them may have overlapping and redundant data.

PMS Reports – Data Sources

Now let's look at all that goes into these reports. On our left we see a list of all our internal data sources that is we have all our manufactured health data. This can include your device information, claims, internal testing, risk documents, PMS, FMEAs and device claims matrix. On our right, we have all the data that we collect from external sources that gives us all our peer review literature. We have multiple databases where we can get all this. We also have clinical trial registries and adverse event databases.

Remember all this data goes into documentation for one device back to for one cycle of these reports. These reports have to be maintained. That means you must repeat the process of data collection and analysis all over again when it's time to update these reports.

Manufacturers must invest time and resources to execute these and if you're only relying on traditional manual means to collect, you would have to deploy a lot of resources to meet your timelines. This could be a big challenge for all companies that cannot continuously add resources to their teams.

Key Pain Points

I want to touch upon the problems and pain points that could arise when we manually handle all our data sources.

Data collection: The biggest challenge with manual data preparation is that one or more people must take time out from their day to gather data, to use in any form of report. This could also mean that they are taking time away from analyzing this data and making an informed and timely decision. One will have to spend time devising some sort of a tracking system, maybe an Excel sheet or perhaps a pen and paper system. There's often no central repository for all this information. Manual data is tremendously time consuming, not really a value-added activity for someone like a PhD or a clinician in your team. The time and expertise of these highly skilled resources should be targeted towards actual data analysis versus collection or standardization of data.

Consistency: If your data isn't widely available, or if your business logic itself isn't centralized, your teams are reporting on different and conflicting data sets. One department or user may capture and calculate something one way while another calculates it entirely differently. This lack of a single source of truth can cause distrust in your actual data and it usually leads to more manual manipulation at a later point in time. Over time - This can lead to data silos. That means it becomes harder for cross-departmental agreement and collaboration. Problems with consistency could come from, for example, the way people regard their search strategies or mainly be how you capture your article details. Your templates could have inconsistency, or maybe a strategy change in your search protocol itself. We know this happens often and writers must spend additional time collating all this additional data and trying to make it look uniform so that it fits into your original data set.

Reporting: Your manual processes would inevitably mean inaccuracies or errors in calculations and reporting. Simple mistakes like a copy paste error or maybe you put in a wrong V look up formula in your Excel sheet. These compound over time, and these can go unnoticed before it's too late. Additionally, there can be problems with article traceability, referencing and variations in the report output from one user to another.

Maintenance: Now you remember all the reports that we saw earlier. All of those must be maintained periodically. For us to have consistency with the initial report, we need to ensure that we have everything that we need, right from the original plan, which means you need to have your older search strategy. You need to have all of your previous screening and appraisal data, all your previous reference articles, your source documents from your first report. If you have a lot of individual contributors out of which some of them may not be permanent employees. Their methodology or standardization may be different from what you follow internally and if all their work is not really stored internally in a safe place, then that means all that raw data could be a challenge when it finally comes to these reports at a later point in time.

What if there was a solution to all these challenges while also improving your team productivity, report quality and help you with compliance?

What if technology could help you with bulk import of search data, maybe automatic import of free full-texts, article audit trails give you customizable data collection forms, also give you a centralized repository for all your reusable data, help you with data modularization? This is important because one manufacturer may have different devices, which pretty much follow the same therapeutic area and the disease conditions that treat them are also similar. They can leverage data from one report to another, maybe content like your clinical background, your state of the art, some of the sections from the state of the art, that is maybe a guideline section something about the alternative therapies. All of this can be leveraged for other devices also if they fall under the same therapeutic area.

What if technology could also help you optimize your entire data collection and storage process, and give you automatic triggers for report updates? The answer is YES, it can help you with all of that and it has.

CAPTIS™

I want to introduce all of you to CAPTIS™. CAPTIS™ is a proprietary technology that we've built that allows our team to reduce manual effort and reduce higher quality CERs in a lesser amount of time.

The goal is to have one place where the righter processes, both internal and external data sources in order to create the final report. Now since MDR requires the various reports to be updated on a regular basis. You will always have a high level of effort going into maintenance of these reports.

By working with Celegence and getting access to this solution, you can seamlessly maintain your reports on a regular cadence going forward.

Let me show you CAPTIS™ in action now. This is CAPTIS™. This is your reports overview page. This is where you'll get to see a brief summary of what's happening in your project. You'll get to see if you have any pending actions against all the articles that you retrieve for your DUE searches or for state of the art (SOTA) searches. We also have a little notice board at the bottom where you can leave comments for yourself. Maybe you need to follow up with someone, or if you have any collaborators on this project, they can also leave comments for you.

CAPTIS™ - Search Home Page

This is where all your searches get stored. We see a couple of searches that I've run already. To conduct a new search, you click on the search option, and we see a couple of databases listed. Now PubMed, Europe PMC and Google scholar are directly integrated with CAPTIS™ that means any searches that you do on these platforms, you can conduct them on CAPTIS™ directly.

The next three databases Embase, Cochrane and Prospero. You can search the parent websites and import all your article details into CAPTIS™.

Now let's run a sample search for PubMed. The first data field that we see here is something called SEARCH NAME, where you can assign a name to your search. Whether you're doing a particular string for your clinical background, maybe you're doing a search for your alternatives. All of them can be captured here. So, we have our search strings here and what you see in black and in bold like competitor, alternative therapies, your clinical background, you can capture all your search objectives here itself. Meaning because you have multiple strings within the same project. It can get confusing. If you can't remember why you chose a particular set of keywords or why you ran a particular string with a particular set of filters, you can assign names to yourself so that you can easily identify the objective.

Let's go back to our search page. Let's do a very simple search. I have a very basic set of keywords with me here. I'm going to call it a test search. Let this be a search for DUE. Now CAPTIS™ allows you to set your preference. That means do you want to do a search for your device under evaluation? Are you only looking for safety and performance data for your device? or are you doing a search for state of the art? You can choose either of these two options from here, you can assign a search category because we are running a particular full string. We will assign it as a scientific search. You can then set your date range. Let's just choose one year for now. You can even choose article types, just like you can on PubMed. Let's say we are only looking for clinical trials for now.

You can even choose your languages and CAPTIS™ also has a species filter like PubMed. You can select and hit search, we got 243 articles on CAPTIS™. We can verify this. If I go here, this will expand the string, like the way PubMed expands the string and then I can hit the globe icon here it'll take me to my PubMed page. We see the same number of articles.

When you've run your search, you can quickly browse through your results to see if these look relevant to your search objective and then if they do, you can simply hit save and CAPTIS™ will save your search. Let's go back to our screening homepage. So, this is the string that we just ran, and it has captured all our details. But if you look closely, CAPTIS™ has also captured which filters were used when you were running the search.

It has captured the string obviously and we also see which search objective was it that the search was conducted for. We also see which database the search was conducted on and what time, what date range was used. So this is essentially your entire search strategy in one place. This really helps us with traceability of our articles, and it also ensures that we record the correct information on our search protocol in our CERs or any other report pages that you're writing. This will also eventually help you with your reviews. If your team performs your searches and their reviews on CAPTIS™, the reviewer can just log onto this page and then see what kind of searches were done, what kind of search strings were used. They can go and verify the results.

CAPTIS™ - Screening

Let's say we are doing a SOTA screening and let's go to level 1 (L1). So systematic literature reviews typically have two levels of screening. Level 1 (L1) is where we are looking at the title and the abstract only. Level 2 (L2) is where we look at the full text to decide. Right now, we are in L1 of my report, and I have a couple of article filters on my right here. Before we jump onto filters, now because we have multiple search strings, and we have multiple databases. It's quite likely that we will have duplicates. CAPTIS™ automatically identifies these duplicates. Like right now we have 52 articles that CAPTIS™ identified as duplicates and these are automatically excluded for you so that you don't have to de-duplicate anything on your own.

Now let's select a couple of filters. Let's say I want articles from PubMed, and I want all my articles that I'm yet to review. We see 536 articles here. To begin reviewing an article, you can simply click on it, and we see a new window pop up on our right. We see all our article details. We have the article title here; we see article authors. We also have other details like the DOI, PMID and all of these are clickable hyperlinks. You can click on any of these links, and it'll take you to the original PubMed search.

So, you can see the abstract below. You can read the abstract, take a decision. If this looks something that you want in your report, you can simply hit include here and that's it.

Let's jump onto our next article. To exclude an article, you can simply click exclude here and you get a dropdown list of exclusion reasons that you can choose. Now, this list is fully configurable. You can add as many reasons as you want, depending on the process or the template that you follow for your reports.

Let's say this is a different indication and I've excluded that. A cool feature that I really like about CAPTIS™ is article tags. Now let's say you're doing your state-of-the-art search and you know that there are multiple objectives that you need to fulfill. That means you have a section for clinical background that you need to write. You also have alternatives that you need to cover. Now, I look at this article in a way, I think this has some great content for my alternative discussion maybe. I can tag it for alternatives so that I remember later why I included this article. Now say this article also has some great content that can be used for my clinical background. I can also assign another tag clinical background and be good.

Let's also include this one now because we have two very distant objectives in our search. That is the DUE search that is for safety and performance, and this is device specific only. The second objective being state of the art (SOTA). Now, it's quite possible when you're doing a review of one objective, and you come across articles which fulfill another objective. Let's assume this is a SOTA review. Now this article has content for my device. I will not include this for state of the art (SOTA). Rather, I would include this for my device under the evaluation. So, I can exclude this article from this review using an appropriate reason, and I can push this off in my DUE search. CAPTIS™ will automatically push these articles into my DUE workflow, and I can review them as a part of my DUE set of articles.

Other things that you can do is edit article details. Let's take another article. Let's assume you did not get your entire information that you were looking for. You need to edit some links. You can always go to the options here and go to edit details, and you can edit any article identified from here itself.

CAPTIS™ - Keyword Filters

Let's go back to our L1. So here we see a couple of words highlighted or made bold in black, like the word brain here. These are keywords. Let's jump to our keywords filters below. Keywords are something that you can configure when you set up your project. So, keywords are basically you are telling CAPTIS™ to highlight something for you that you're interested in. So, all the words that we see in red here are all our negative keywords that we don't want perhaps. These also act as identifiers for you to quickly identify whether an article looks like it could be relevant for your search or not and all your blue words are all your positive keywords.

All the words in blue come up in bold and black and all the keywords that you've highlighted for your negative keywords come up like so. Let's search for say "hepatic" and let's also add a couple of other negative keywords. So now that I know these keywords appear in the title itself, I know that this is not going to be relevant for my review. I don't even have to look at the abstract because the title itself tells me that this is something that I don't need in my review. So instead of going to the full article details, I can simply select all these articles from this page itself. You can select as many articles as you want. Then you can go to selection and update.

CAPTIS™ - Update Articles

CAPTIS™ allows you to do a bulk update on these articles. You can update either article tags. If you want to add multiple tags to all of these articles, you can even remove any tags that you want removed from these articles. You can even do a bulk include or an exclude. Let's say I want to exclude all these articles because they are not in the indication that I'm interested in. You can select your reason and hit, okay. CAPTIS™ will ask you for a confirmation you hit, okay and all of them have been excluded from my list.

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CAPTIS™ - L2 Review

Once you're done with your L1 review, you can jump to your L2 review. Before you even begin your L2 review, it's important that you have the full text with you. Now CAPTIS™ has a feature where it can automatically download all full text for you if they are freely available and for the ones, for which it could not find the PDF. They come under this tag called missing articles. You can simply filter out all the articles which have a missing PD and then you can export this list out into an Excel sheet, and you can send it to your purchase department.

Now, remember those article tags that I showed you earlier. This becomes helpful for you to do a quick focused search. That means say today I want to tackle my alternative section in my state-of-the-art review. I can always filter by the tag and I see all the articles that I included for my alternative discussion. Then I can do a very focused review having only this objective in my mind that I need to screen for all my alternative therapies. So once I'm done with this set of articles, I move on to the next set of articles, which could be, say my clinical background or my guidelines. You can use tags in all kinds of ways. You can use tags to assign articles to certain people. You can assign tags to articles that you aren't really sure about. You need a second opinion. You can use this option. You can even configure specific disease states or say specific outcomes that you're interested in, and you want to categorize articles. Tags essentially work like buckets for you to categorize your information in the possibilities.

Now let's do a L2 review. I'm going to filter by all my articles, which have a PDF, and which have an action pending against them. I see two articles here. Let's jump to one of these. So, I see all my articles details again here, I click on this button here and this will open the full text for me. We will also start our review simultaneously. On our left, we have the full text article. This window can be toggled into a larger view. So as and when you read the articles, you can start answering your L2 questions. These questions were configured using the IMDRF guideline. This is optional. You can choose not to configure questions also. If you want a simple dropdown list, like the way we have in our L1, that is also something that you can do.

Let me answer a couple of questions here. Other things that you can do on this stage is create your article summaries. Now you can create your tabular summaries from this page itself. Any data that you extract from these articles, all of these are free text boxes. Now all these boxes have also been configured by me when I was setting up this project. You can configure as many boxes or as many buckets of information as you want. I'm just adding some sample text here. You can even add notes for yourself or add comments for another collaborator.

CAPTIS™ - Article Details

Now let's say you're reading one article and you come across some content, which you think you can use in some other section of your CER that means you want to highlight content in your article. Let's say this

section has great content for my risk discussion in my CER, I can always highlight the section and I can assign it a tag. Maybe let's assign it as a risk. Let's also assign it as a safety tag. You can add as many tags as you want. All of these tags are also configurable. You can add more custom tags in your project configuration then hit, OK And that is saved. Now let us complete our review.

All the article highlights that you make, all of these can be accessed here under the Snippets. So here I see all my article highlights that I made for any of my articles. You can filter these highlights to jump to a particular set. You can even go back to the parent article if you need more information on the highlights, that's also possible.

CAPTIS™ also allows you to export your entire list to help you reference articles. That means I can filter all my included articles from my L2, and I can export this list out into a reference manager. We have Zotero integration, you can use the same kind of export for EndNote also, or any other referencing software that you're using. Now, once you're done with your entire review, there are a couple of reports that CAPTIS™ automatically generates for you.

CAPTIS™ - SoTA Reports

Let's go to our SoTA reports. An example of these reports would be say your L1 exclusion summary. This gives you a list of all your exclusion reasons that you use. Also, the count of each of these exclusion reasons and how many articles did you finally include after your L1 screening.

Other examples of reports can be L2 review summary. You can see all your article gradings and your entire appraisal here itself. All of these reports can be exported out into an Excel format. You also have something called an article data sheet where you have all the data that you extracted from these articles. This is the article that we did together in this demo. Now all these column headings can be configured based on the kind of data that you want to extract from these articles.

We also have a search parameter, which is essentially your entire search strategy. Now, this was automatically captured by CAPTIS™ when you were doing the search. That means there is no error in your entire search strategy in terms of capturing data. If you were to manually record this information in an Excel sheet or a word document, it's quite possible that you miss out some filters perhaps, or maybe you miss out a parenthesis somewhere, and that could lead to errors in terms of repeatability of the search strategy. Now, because this software automatically captures all your details. You can be assured that there will be no errors in capturing any of this information. Now all your reports can be exported together using this button "export" and you will get to an Excel sheet.

Let me quickly show you the Excel sheet. So, this is how the export looks like. You have your article flow in

your first tab, which is basically how many articles came in, how many went out in which level and how many were finally included in the CER. We also see our L1 exclusion summary that we saw earlier, and our L2 review summary, where we have all our gradings. We have all our article details in this column. Your article data sheet has all your extractions from each of these articles.

CAPTIS™ automatically generates your appendix for you. In case you want to use this information in your CER, this works like evidence that you did in order to conduct a systematic literature review. And you have details from all the articles that came up from your search. You have all your authors, titles and sources. You also have the decisions for each of these articles.

Now, all these articles right now say No because by default, all of them are No. As in, when we take an action against them, CAPTIS™ will update the reasons for us like article number 18 was an exclusion. And this was the reason that we used. So, all this data can be copied from this Excel sheet into a table in your word document. You also see the search parameters here, all the strings that were used, all the filters that were used for each of these strings. We also get to see how many articles were included or excluded from the string and we also see how many exclusion reasons were used.

CAPTIS™ - Upload Source Documents

You can upload all your source documents on CAPTIS™, and these have been preconfigured to match the kind of data that we collect for all our regulatory documents. All of these are preconfigured categories. You can drop information into each of these categories. What more you can do is you can add bookmarks. So, you may come across a document, say a technical file, which is say a thousand pages long and there's a lot of information that you need from it but all of it is jumbled in different pages, and you might maintain some sort of a tracker, maybe an Excel tracker where you save which page had which information. On CAPTIS™ you can do that using the bookmarks feature. Say this is a piece of information that I really need for my report, and I can bookmark it. Let's bookmark all this content.

Let's call it "pRE-preoperative", let's test for now. You can assign it a category, which category of information has fallen. Maybe this is your let's say product information and this added into your list of bookmarks that you have. You can jump between pages, between bookmarks and you can even jump between different documents.

Now, that was just a small subset of features that we have on the platform. There's a lot more to show, and we can do that in a longer demo. Now you eventually be able to draft entire CERs on CAPTIS™ and if you have created your initial CER on CAPTIS™, creating and maintenance of CER is easy.

You can select sections, which you want to carry forward to your newer documents based on any newer reports that you have on any new updates in your source documents. You can also set the date range for the new report because CAPTIS™ conducted your previous search that means it already has all your search parameters. All you now must do is put in the start and the end date of your maintenance report and CAPTIS™ will automatically run these searches for you.

Maintenance CER Template

You'll also be able to draft entire CERs on the platform, and this is how the drafts will look like. If you see the table of content on the left, we see some of these sections have been marked in red. That means this is CAPTIS™ telling you that, "Hey, you did mention that you have updates in these sections because you have newer documents in these sections". So CAPTIS™ is giving you a prompt that you must update these sections based on the newer documents that you've uploaded. On the right, we see all our reports from our literature workflow. Any reports which are created in the literature workflow can be used directly into your reports in CAPTIS™. You'll also be able to highlight and comment in case you're collaborating with multiple people here.

Case Study: MDD to MDR CER Remediation Done Through CAPTIS™.

The client of ours was a manufacturer of a standalone software, which was used for imaging and visualization of cardiac anatomical structures.

- **Challenges:** The challenge that we had, this was the first MDR CER that we were doing for them, and this had overlapping date changes with the previous submission that was done on CAPTIS™. Now, this device is widely used. It had been out for decades, and a popular device and we know what that means. A popular device usually means we have a lot of data to sort through, which is not necessarily a bad thing in terms of evidence. It's just a lot of effort sorting through a lot of data. So, we had about a thousand articles reported for the one device,

- **Solution:** The previous MDD literature review was conducted on CAPTIS™ and because the date ranges were overlapping, our writers could leverage screening decisions for over 800 articles. We only had to screen about 150 of them, which were published in the gap period.

That means the search gave us 950 articles, and we only ended up screening about 150 of them this year. Now 950 versus 150, that is a significant difference in the number of articles to review and the efforts required to screen all these articles.

- **Business Impact:** Our medical writing team could save over 120 hours of effort in literature, retrieval and screening. That means we had to deploy lesser resources to do the same project.

This is just one of the examples of the benefits you get when you leverage technologies in your report. Imagine the cumulative savings in total effort and overall cost when utilized technology for all of your maintenance of CERs. Now we have other customers who are using it for their own writers and they get the same benefit that our team has been getting for the past two years.

Ways to Utilize CAPTIS™

There are different ways you can utilize CAPTIS™. Now we offer an in-house model where your team utilizes CAPTIS™ for all your in-house medical writing needs. You can also have a collaborative model where your team and our medical writers collaborate on projects and communicate via CAPTIS™, or you can outsource your entire medical writing projects where our medical writers can create your reports on your behalf, and you will get full visibility and review options on the platform.

Schedule Your CAPTIS™ Demo

Due to demand and interest from the industry, we have devised an easy onboarding process for new clients migrating away from other solutions to CAPTIS™.

If you want more information on CAPTIS™, or if you have any questions on harmonizing your current process to the platform free to get in touch to

info@celegence.com

and our team will be happy to set up an in-depth demo.

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