Smarter Reviews: Trusted Evidence

DistillerSR

NuVasive Streamlined Literature Reviews for More Efficient CER Submissions with DistillerSR

NuVasive, Inc. is the leader in spine technology innovation, with a mission to transform surgery, advance care, and change lives. The company's less invasive, procedurally integrated surgical solutions are designed to deliver reproducible and clinically proven outcomes. NuVasive operates in more than 50 countries.

Consistent, Repeatable Processes

DistillerSR enabled a consistent, repeatable literature review management process that can be replicated across multiple projects.

Audit-Ready CER Submissions

Every literature review conducted in DistillerSR is audit ready, which means every decision is recorded in an audit log throughout the entire review process.

Always Available Data Company Wide

DistillerSR has become a centralized, living archive for every medical device in NuVasive's portfolio. Everyone has access to the data they need, when they need it.

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> SENIOR MEDICAL WRITER AT NUVASIVE

Monique Liston is a senior medical writer at NuVasive. A librarian by training, she is part of a team in North America supporting products in the European market with clinical evidence for device safety and clinical performance (SSCP) requirements under the European Union's Medical Devices Regulation (MDR).

Process improvement is also part of her mandate. And that's how DistillerSR came into play.

"I came across DistillerSR while I was doing research to apply for this job at NuVasive. It seemed like a platform that could truly streamline the collection and analysis of clinical data," she noted.

That was in November 2018. She was hired in January 2019, and a few months into the job, it became clear that using Excel spreadsheets to conduct literature reviews manually was not sustainable. "The whole process was manual and inefficient," Monique pointed out. "Relying on spreadsheets as the sole mechanism to track clinical evidence is error prone, not easily reproducible and inconsistent. In the back of my head, I knew DistillerSR would present us with scalable solution and a better path forward."

Standard Protocols Drove Better Quality Control, Transparency, and Efficiency

NuVasive currently markets class I instruments, class IIb devices, and class III implantables. The main driver to implement DistillerSR was the need for a consistent, repeatable process that reduced subjectivity in the literature review process. In addition, the medical writing team required a platform that enabled more transparency while seamlessly dealing with large volumes of clinical data in an organized manner. Since implementing DistillerSR, NuVasive's medical writers have been working from a standardized list of questions for inclusion and exclusion criteria. Every literature review conducted in DistillerSR is audit ready, which means every decision is recorded in an audit log throughout the entire review process.

"DistillerSR displays the pathway for the entire body of clinical evidence for each device. Everything is clearly documented for the clinical evaluation report (CER) submission," stressed Monique. As a result of implementing DistillerSR, the team was able to successfully transition the process of collecting and analyzing clinical data from a contract research organization (CRO) to an in-house group.

All CER submissions are subject to tight deadlines, and time is critical for a team striving to get devices to the market safely for patients whose lives have been severely impacted by a spine-related disability or pathology.

"Some people would argue that using Excel spreadsheets to track the pathway for a clinical evaluation is sufficient," Monique said, "I would rather go into my DistillerSR projects to retrieve all the clinical evidence for each included study, export my data, and instantly produce a PRISMA diagram."

Using DistillerSR's Datarama, they are able to export data easily, build customized reports and select specific sets of references and data elements to be displayed. Reports can then be viewed in DistillerSR or downloaded as various file types.

The ability to keep stakeholders informed is also key for the NuVasive team. DistillerSR's reporting functionality allows Monique and her team to do just that by scheduling automated email updates to ensure everyone is aware of their review projects' progress.

The team has grown to six medical writers since implementing DistillerSR. "We have a running order that every new medical writer has to work in DistillerSR. In a way, they are born into a more efficient process."

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What once was a completely manual process is now fully automated. DistillerSR has enabled the medical writing team at NuVasive the efficiency and reproducibility they needed.

Distributed teams can collaborate more effectively and improve productivity using DistillerSR. Medical writers can rely on standard processes and reduce the overall administrative burden of literature reviews. Reviewers are automatically assigned and notified of new work, regardless of the number of projects they are working on. Meanwhile, project managers can monitor progress in real-time and gain insight into the team's workload, performance, and quality.

Data Reuse for Post-Market Surveillance (PMS) Requirements

DistillerSR's add-on module CuratorCR is a research knowledge center that centrally and dynamically manages an organization's evidence-based research, allowing medical researchers to continuously collect, curate, share, and reuse data across literature reviews and teams.

"With CuratorCR, I'll know immediately if a colleague has already retrieved clinical data related to a particular device and won't waste any time on that task. It will be a huge time saver for our team," said Monique.

For Nuvasive, CuratorCR is expected to simplify the data collection process for monitoring similar competitive devices placed on the market, as part of the EU MDR post-market surveillance (PMS) requirements managed by the company.

Always Accessible Data

In the past, the team's clinical evaluations were kept in multiple folders. Now, everything is centralized within DistillerSR and everyone in the team can easily access the data they need, when they need it.

"The purpose of DistillerSR goes beyond simply conducting systematic literature reviews," Monique noted. "I store everything in there – it's become a living archive for my entire device portfolio. With every project, I have a snapshot in time I can refer back to. I can then look at the data and pivot as necessary for the next one."

DistillerSR has become the fundamental first step of the process for all NuVasive's CER submissions once establishing their search parameters. ⌘

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