Smarter Reviews: Trusted Evidence

DistillerSR

DistillerSR Reduces Clinical Evaluation Report Time by 30%

Four of the top 5 global medical device companies trust DistillerSR

"Before DistillerSR, the literature review process was manual, laborious, and inconsistent. Reporting was difficult and we could not arrange the data in a way that was straightforward and organized."

— DR. BONNIE H. WEINER

DistillerSR™ Accelerates Literature Reviews to Meet Looming EU MDR requirements.

Market Readiness

According to KPMG and the Regulatory Affairs Professionals Society (RAPS), 66% of medical device manufacturers do not "have a strategy in place to sustain compliance to EU MDR requirements."

Keep Up With Client Demand

It takes 200-250 hours to complete a CER with many medical device companies often underestimating the time it takes to complete them.

Be Audit Ready and Compliant

For EU MDR submissions, one of the most pressing requirements is a repeatable and transparent review process. DistillerSR utilizes project and form templates so you can complete consistent CER literature reviews across your medical device portfolio.

“DistillerSR brings to the table efficiency, organization, and quality. Doing a literature review any other way is archaic.”

— DR. BONNIE H. WEINER

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Dr. Bonnie H. Weiner has used Evidence Partners' DistillerSR for more than four years to reduce the intensive manual work for literature reviews. Evidence Partners provides DistillerSR to pharmaceutical and medical device companies, contract research organizations, as well as universities, governments, and NGOs. The cloud-based platform combines AI and intelligent workflows that automate the management of researchers' systematic collection of secondary data to produce transparent, audit ready and compliant literature reviews faster and more cost effectively.

Using the software has helped Dr. Weiner reduce literature review times by approximately 30% and enabled the expansion of client offerings. Dr. Weiner provides FDA consulting services for early-stage companies and creates clinical evaluation reports (CERs) as a key part of her growing practice.

Keeping Up With Client Demand

Dr. Weiner estimates that using DistillerSR decreased the production time to produce a CER by about one-third. But the process is still time-intensive, taking about 200-250 hours. According to Dr. Weiner, clients often underestimate the work involved with preparing a CER, so expectations run high. “Before DistillerSR, the literature review process was manual, laborious, and inconsistent. Reporting was difficult and we could not arrange the data in a way that was straightforward or organized,” said Dr. Weiner. “As a consultant, clients want things done as efficiently as possible in both time and cost.”

Dr. Weiner's main focus of work is clinical evaluation reports (CERs) and literature reviews, which are a critical component for medical device companies' regulatory submissions under the new EU MDR requirements, which take full effect May 2021.

Be Audit Ready and Compliant

A critical benchmark for a successful CER is transparency and auditability - fundamental to EU MDR requirements. With DistillerSR, Dr. Weiner is able to generate accurate reports with the simple click of a button.

“The categorization of inclusions and exclusions really caught my attention,” she said. “The logistics of trying to develop processes around the counting of references and PRISMA diagrams is very challenging. Doing it manually is incredibly difficult; counts never come out right and we always had to figure out the problem. With DistillerSR, it's all integrated and automatically generated, including PRISMA diagrams. It's the click of a button and it would not have been at all possible if we were doing it manually.”

Reconciling References When the Data of Interest Changes

For Dr. Weiner and her team, a frequent challenge involves what happens when the data of interest changes. Dr. Weiner gives the example of starting a review only to discover that the protocol needs to change due to unforeseen details or different data may be needed. DistillerSR's “Reconcile References” capability enables Dr. Weiner to modify or add a variable, if needed, on screening or data extraction forms, reconcile the data, and easily capture the new data in references already screened.

Previously, this task would be a time-consuming burden to complete manually. More specifically, it would be nearly impossible to know if the data was captured correctly. DistillerSR's version control and audit trail means that such amendments remain auditable, systematic and reproducible - a critical EU MDR requirement.

Better, Faster Reviews Enabled New Services

By using DistillerSR, Dr. Weiner leverages the time and money saved to launch a new service: writing CERs. “DistillerSR brings to the table efficiency, organization, and quality. Doing a literature review any other way is archaic,” said Dr. Weiner.