Smarter Reviews: Trusted Evidence

DistillerSR

From Quantitative to Scoping Reviews: How Terumo BCT Built a Defensible Clinical Evidence Practice with DistillerSR

"DistillerSR didn't just digitize our process; it enabled a fundamental shift in our methodology, allowing us to evolve from resource-intensive quantifiable reviews to more appropriate scoping reviews that fit the available literature"

– AUGUSTA TALLMAN, SENIOR MANAGER, GLOBAL CLINICAL REGULATORY SUPPORT AT TERUMO BLOOD AND CELL TECHNOLOGIES

By shifting from quantitative to scoping reviews and integrating AI-enabled screening, the team now manages a **multitude of CERs including Class I, IIa, IIb and III products**, and has maintained few follow-up queries from notified bodies.

Better Methodology, Not Just Better Tools

The team's most important shift was moving to scoping reviews that fit the available literature – DistillerSR's flexibility made that transition possible.

Faster Screening Without Compromising Rigour

Classifiers, Rerank, and AI-enabled screening dramatically reduce front-end burden; documented human review of outputs maintains rigour and regulatory credibility.

AI Disclosure to Reduce Regulatory Friction

Clearly disclosing AI use alongside transparent verification protocols has helped the team maintain few follow-up queries.

The Future of Clinical Evidence is Continuous

Enhancing annual project cycles toward continuously-updated databases with cross-functional access is the next milestone for teams looking to achieve long-term efficiency.

"Features like AI-Enabled Classifiers and Rerank screening are major time savers, eliminating a significant front-end burden and making it straightforward to keep all our data in one place for our CERs"

– SARAH MORTON, GLOBAL CLINICAL REGULATORY SUPPORT SPECIALIST AT TERUMO BLOOD AND CELL TECHNOLOGIES

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About Terumo Blood and Cell Technologies

Terumo Blood and Cell Technologies (Terumo BCT) is a subsidiary of Terumo Corporation, a global leader in medical technology founded in 1921 and headquartered in Tokyo. Founded in 1965 in Lakewood, Colorado, Terumo BCT specialises in blood component collection and processing, therapeutic apheresis, and cell and gene therapy technologies. With a portfolio that includes Class III devices requiring rigorous, audit-ready Clinical Evaluation Reports (CERs), maintaining high-quality clinical evidence is a core regulatory requirement.

The Starting Point: A Solid Foundation, A Methodology Ready to Evolve

When the current clinical team at Terumo Blood and Cell Technologies came together, they inherited a DistillerSR environment that had already been in place for several years. The platform gave them a solid foundation – a centralised, structured approach to literature review that was far more manageable than the Excel files and printed references that had come before.
But as the team dug into the work, a more fundamental question emerged: were they using the right methodology for the literature available to them?

The team had been conducting quantifiable literature reviews – designed for meta-analysis and the kind of large, comparable evidence bodies that approach requires. In practice, however, the available literature for their device categories rarely supported that level of quantification. Cochrane guidance, too, pointed toward quantifiable reviews being appropriate less frequently than the team had been applying them.

The conclusion was clear: scoping reviews were a better fit. And making that shift – methodological, not just procedural – turned out to be where DistillerSR's flexibility became most valuable.

The Shift: Reconfiguring for Scoping Reviews

Making the transition from quantitative to scoping reviews required more than a change in mindset – it required rethinking the extraction forms themselves. The team adapted their forms to capture themes rather than numbers, making them more generic and broadly applicable across device types rather than tailored to specific quantitative endpoints.

The result was a review process better matched to the evidence landscape they actually worked in: one that could surface meaningful clinical insights across a body of literature without forcing a false precision that the data couldn't support.

Today, the team uses DistillerSR to conduct a multitude of CERs including Class I, IIa, IIb and III products – all conducted through the scoping review approach they have refined over time.

AI Features That Made the Difference

Alongside the methodological evolution, the team has progressively integrated DistillerSR's AI features into their workflow – and the impact on efficiency has been significant.

- Classifiers and Rerank are deployed at the start of each project, dramatically reducing the front-end screening burden and allowing clinical staff to focus on higher-value analysis rather than initial triage.
- AI screening is used to accelerate reference categorisation, with results reviewed and verified by the clinical team before any decisions are made.
- A centralized data repository replaced fragmented files with a single, searchable record of all screened articles – making it easier to maintain consistency and audit trails across review cycles.

“Our next strategic step is to enhance our annual project cycles into a continuously updated database and build a cross-functional knowledge base. We envision a user-friendly interface that allows other departments – like Medical Affairs, Quality, and Regulatory Affairs – to query the system and access information without extensive training, which would eliminate the need for our clinical team to manually pull data for them.”

– AUGUSTA TALLMAN, SENIOR MANAGER, GLOBAL CLINICAL REGULATORY SUPPORT AT TERUMO BLOOD AND CELL TECHNOLOGIES

Transparent Communication with Notified Bodies and Auditors

In order to maintain transparent communication with our notified bodies and auditors, the team drafts standalone literature review plans and reports that detail the systematic literature review process and document when and how AI is used to facilitate review.

Looking Ahead: From Annual Projects to a Living Knowledge Base

The team’s strategic vision extends well beyond the current annual review cycle. Two priorities are driving their next phase of development.

First, they are actively evaluating DistillerSR’s Smart Evidence Extraction (SEE) feature, which they believe would add particular value for synthesising peer-reviewed published articles – with any new capability validated across a subset of projects before broader deployment.

Second, and more ambitiously, the team aims to transition from point-in-time annual project cycles to a continuously maintained literature database – and to build a cross-functional knowledge base that allows colleagues in Medical Affairs, Quality, and Regulatory Affairs to query and access evidence independently, without requiring clinical team involvement for every data request. ⌘

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