Smarter Reviews: Trusted Evidence

Compliant CER and PER Literature Reviews – Always Audit Ready

The new European Union Medical Device Regulations (MDR) and In Vitro Diagnostics Regulations (IVDR) demand, among other things, complete lifecycle traceability from product development through post-market analysis. Regulatory professionals can expect dramatic increases in the frequency and volume of documentation and more stringent traceability measures for MDR clinical evaluation reports (CERs) and and IVDR performance evaluation reports (PERs).

Used by 80% of the world's top medical device companies, DistillerSR leverages AI-powered automation, intelligent workflows, and data reuse to enable regulatory professionals and medical writers to evaluate literature in a faster, easier, accurate, audit-ready, and compliant manner.

A Single Source of Trusted Evidence

Highly manual, spreadsheet-based literature reviews lack enterprise-wide standards on how data is managed, shared, tracked, and distributed. With the increased frequency of submissions, this can result in increased demands on staff, which can lead to biases, omitted references, and user errors.

Fully Transparent, Secure, and Audit Ready

DistillerSR tracks all review activity and makes it easy to view the provenance of every cell of data. You can restrict access and ensure your data meets your organization's security standards through single sign-on (SSO) and user permissions.

Simplified Real-Time Oversight

Distributed teams can collaborate more effectively, with standard processes in place and reduced management overhead. Reviewers are automatically assigned and notified of new work, regardless of the number of projects they are working on. Project managers can view real-time user and project metrics to gain insight into the team's workload, participation, quality, and performance.

Always Up-To-Date Review Status

Schedule reports can be configured and sent to you (and your stakeholders) automatically via email. Reports can be configured based on rolling date ranges and distributed at specific time intervals.

This capability gives you the flexibility to track and share what's important in the progress of your review.

Do More Reviews Faster and Smarter

DistillerSR automates many of the traditional review tasks so you can produce work quickly, accurately, and cost-effectively.

Always Up-To-Date Reviews

By using auto-alerts from data providers such as PubMed, EBSCO, and Ovid, DistillerSR allows you to automatically update reviews with new references as soon as they become available. This means time spent rerunning searches for CER and PER scheduled updates is eliminated.

Simplified, Cost-Effective Full-Text Retrieval

Freely available full-text documents can be automatically retrieved and added to literature reviews, and teams can leverage their Article Galaxy and RightFind subscriptions to order full-text documents from within DistillerSR for the lowest possible cost.

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"After implementing DistillerSR, we were able to increase our annual literature review output by 30%. We would have had to hire nine additional full-time reviewers to achieve a similar output using manual processes."

– MEDICAL DEVICES DISTILLERSR CUSTOMER

Instant Access to Source Materials

Connect directly to source materials stored in your organization's eLibrary and through DOI.org. This eliminates the tedious task of searching for and uploading full-text documents.

Artificial Intelligence Reduces Screening Times and Improves Review Quality

Using DistillerSR's AI-powered automation and intelligent workflows enables medical writers to produce CER and PER literature reviews faster and more accurately.

Duplicate Detection and Quarantine

Using powerful duplicate detection built within your workflow, DistillerSR easily identifies and removes duplicate records. The literature review software also automatically tracks their removal for standard reporting and preserves them for future reference and retrieval.

Find Relevant References Faster

With the help of AI, DistillerSR allows you to find what you need quickly and easily sort through irrelevant materials. Its AI differentiates between relevant and irrelevant records, continuously reprioritizing the remaining, as-yet-unscreened records, and then presents them based on the likelihood of relevance. On average, you can find most of your relevant references 40–60% sooner than conventional screening.

Prevent Erroneous Exclusions

Confirm that you haven't accidentally excluded any relevant references. DistillerSR's AI double-checks your exclusions for errors, increasing your confidence in your screening decisions. Conflicts and disagreements between reviewers, meanwhile, are automatically identified and set aside for easy resolution.

Take Control of Your Reviews – the Way You Want

Manual literature review processes often rely on the varied experience of individual medical writers' talent and industry knowledge, which can lead to ad hoc, inconsistent, and inefficient methods that can't scale with growing submission requirements.

Create and Reuse Template that Fit Your Protocol

Extract, appraise, and report data in a way that fits your protocol. Furthermore, when you need to conduct similar research, you can instantly reuse your review process across multiple reviews by creating templates. These can be copied and modified as needed.

Eliminate Time Wasted on Data Cleaning

Reduce human error by requiring data validation at the time of extraction, for example by using prespecified acceptable ranges for numerical values. Configured to meet your requirements, DistillerSR's in-form data validation lets your team spend less time and effort acquiring analysis-ready data.

Easily Meet Global Standards

You can also easily follow globally recognized standards and compliance requirements. This includes auto-generating PRISMA flow diagrams, maintaining strict version control, and producing fully transparent and audit-ready results.

Reuse Data with CuratorCR

DistillerSR's CuratorCR module automatically notifies you if anyone in your organization has already collected data for a reference. This increases overall review efficiency as citations are linked to existing extracted data and can be reused for other projects.

CuratorCR eliminates unnecessary duplication of effort by easily finding, viewing, validating, and reusing already collected data and PDFs across reviews and teams.

1. **Reference Added to Review**

2. **You Begin Reviewing**

3. **CuratorCR Notifies You of Already Collected Data**

CuratorCR uses the DOI code and/or PMID to find matches.

4. **View Already Collected Data from Other Projects**

5. **Use Already Collected Data from Other Projects**

Copy and Paste

Regardless of the subject matter, the size of your team, or the scope of the project, DistillerSR provides you with the tools and flexibility to create a defensible, audit-ready, and fully compliant review process for CER and PER submissions.⌘

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Progressive roll-out of the new In Vitro Diagnostics Regulations (IVDR) is starting from May 2022

Device manufacturers whose products fall under this category will still need to develop a repeatable, transparent process for their PER literature reviews. Approximately 80% of IVD manufacturers will shift from self-certification to notified body oversight under these new regulations. It will be critical for IVD manufacturers to ensure their literature reviews are streamlined, audit ready, and compliant.

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For more information, visit distillersr.com.