Medical Devices Industry Trend Report: Leveraging Data Reuse for More Efficient Evidence Management Throughout the Medical Device Lifecycle

Executive Summary

- Literature reviews that support medical devices safety & performance claims are known to require substantial resources and effort. The process involves comprehensively searching for, appraising, and extracting data from references before subjecting them to rigorous analyses. Compared to previous guidelines, current EU MDR and FDA requirements specifically emphasize the use of clinical and evidence-based data to support medical devices claims. In addition, the collection of clinical and evidence-based data is expected to occur continuously via post-market surveillance for all devices used in clinical settings.

- The burden of continuously performing the same literature searches and extracting the same data for different stages of the medical device lifecycle, from pre-market approval to post-market surveillance activities can create inefficiencies and unnecessary cost for manufacturers. This is compounded when manufacturers end up performing the same searches and extracting the same data for medical devices with similar intended purposes, especially as the overall volume of evidence-based data grows exponentially every year.

- Data reuse is the collection and curation of data that can be mined and shared among stakeholders within an organization and can result in operational efficiencies when performed properly.

Leveraging these capabilities can create a competitive advantage for companies that understand how to best capture the value of quickly identifying studies that have been previously vetted during the literature review process. Standardizing processes also lead to consistent results, even when multiple users may perform the same literature reviews, which means the data feeding into regulatory submissions will also be consistent. Further to the increased number of literature reviews, notified bodies expect manufacturers to be consistent with their own data collection, access and reuse practices in order to streamline their job of reviewing the data in a uniform manner.

- Reusing evidence-based research data can save valuable time and resources while reducing operational costs. Large companies with diverse portfolios can share data across business functions seamlessly and create a centralized approach for data collection and analysis, from R&D to patient safety, throughout the medical device lifecycle. Concurrently, smaller companies can benefit from the ability to rapidly review and justify their product portfolio by leveraging high-quality data through data reuse.

- Implementing software solutions that help manufacturers standardize data research, collection, curation and reuse processes early in the product design project ensures every business function involved in the medical device lifecycle is dynamically managing evidence and avoiding operational inefficiencies.

Introduction

Literature reviews play an integral role in the development of healthcare technology, from the initial stages of opportunity and risk analysis through post-market surveillance.

Even after a successful launch, however, manufacturers face numerous challenges when remediating product portfolios should regulatory bodies change their policies and licensing requirements.

Case in point: many global medical device manufacturers are still struggling to comply with regulations laid out in the European Union's Medical Device Regulation (EU) 2017/745 and In Vitro Medical Devices Regulation (EU) 2017/746 guidelines, otherwise called "the MDR" and "the IVDR," respectively. Among the recently introduced requirements is the need for literature reviews that provide thorough evaluations of the research landscape related to justify product performance and safety. This assessment of the scientific literature for each product under evaluation, which is a time-consuming, laborious, and expensive exercise.

As seen in Figure 1, both systematic literature reviews and SOTA reviews are continuous, living documents that require regular and sustained updates. Work tends to be done in silos with repeated screening and data extraction of the same references. Siloed reviews and updates fail to leverage the screening and data extraction work done by different groups on products with similar intended purpose at different stages in the regulatory approval process.

When team members do not recognize that they have previously identified and extracted data from references, operational inefficiencies result and can lead to avoidable errors. It is important to note that these errors do not only occur while manufacturers prepare regulation deliverables.

Rather, they can happen in the literature review processes of medical device products and scientific research processes of pharmaceutical products entering any global market. Therefore, the ability to reuse data previously extracted in a systematic literature review process represents a powerful operational advantage that leads to increased efficiencies with respect to saving time and money while improving quality over the long run for companies that properly reuse data.

Defining "Data Reuse" and Factors That Influence It

Literature reviews are known to require a substantial amount of resources and effort.

The process involves comprehensively searching for data, screening them, and extracting them from reference lists before subjecting them to rigorous analysis. In addition, compared with the previous guidelines, the MDR specifically emphasizes the use of clinical and evidence-based data to support medical device claims. The collection of clinical and evidence-based data is expected to occur continuously via post-market analysis for all devices used in clinical settings.

This burden can create inefficiencies for manufacturers who are forced to perform continuous studies on similar product portfolios. As a result, a recent trend present in all stages of the systematic literature review process is the reusing of data that have already been extracted from references found in previous studies.

"Data reuse"—or the collection and curation of data that can be mined and shared among researchers within an organization can be a strategic asset when performed properly.

Leveraging data reuse capabilities in an efficient manner can therefore create a competitive advantage for organizations that know how to best capture the value of quickly identifying studies that have been previously vetted during the systematic literature review process.

As the overall volume of evidence-based data in literature articles grows each year, performing efficient literature review searches becomes increasingly challenging. As search queries must be performed in a larger pool of potential articles, finding strong evidence for product commercialization becomes more challenging. This can lead to literature searches that take longer, yield poor-quality results, and are not performed efficiently or effectively.

Changes to regulatory requirements may prompt the need for an increased number of systematic literature reviews, which can ensure there is justification for the further pursuit of product research, commercialization, or use.

Under the MDR, evidence is continuously needed to support post-market surveillance activities. As knowledge and publications continue to increase, these requirements will ensure that more literature searches are performed in an increasingly complex data landscape. Regulatory changes that require more stringent evidence will only add to the challenges manufacturers face when performing searches.

Further to the increased number of literature reviews, regulatory bodies are also pushing to standardize the collection, access, and reuse of data.

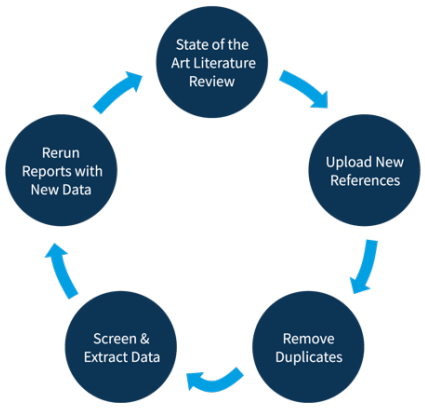

Figure 1: The Living Review Cycle
Source: Mitchel, LW, O'Blenis, P. Best Practices and Literature Review Using DistillerSR. DistillerSR.com. Published 2020.

With literature sources, medical technology, and the digitization of healthcare practices all on pace to grow consistently over the next few years, the need for regulatory bodies to review data in a uniform manner is increasingly important.

The more consistent manufacturers are with their own data collection and reuse practices, the easier this process will become for regulatory bodies.

Consistency also aims to reduce the duplication of efforts, thereby increasing efficiency in evidence-based data collection practices, all while ensuring that professional standards are met and maintained. With inconsistent practices, multiple users may perform literature reviews that yield the same results.

These results, however, may be collected or interpreted differently, or they may be missed entirely despite the duplicated effort.

Data reuse can help reduce variability in literature searches and can also maintain a specific level of professional standard from one literature review to the next.

Specific to the European regulations, there is a need for systematic and continuous documented searches for clinical literature that supports clinical evaluation reports (CERs) and performance evaluation reports (PERs).

As a result, there is an embedded need for manufacturers to use and reuse the data that they determine are relevant for their products under evaluation. The regulatory guidelines mandate that companies must perform a robust effort to review all clinical data relevant to each product under review.

Furthermore, industry guidelines outline the best practices to support clinical and performance evaluation documents. It is imperative that literature-search processes leverage these guidelines while promoting efficiency in data collection and reuse. Underlying the factors that influence the need for and best practices surrounding data reuse is quality.

In essence, the requirements laid out in the MDR and IVDR seek to elicit a comprehensive review of high-quality data that support claims against the safety and performance of market-bound products.

Why Reuse Research Data?

As highlighted by each of the above factors influencing the need for data reuse, there are several reasons why learning effective methods for reusing data is in the strategic interest of a medical device or in-vitro diagnostic manufacturer. One of these drivers is that leveraging reused evidence-based research data can save valuable time and resources. Implementing a rigorous program to leverage data reuse can therefore translate into more efficient business practices and a reduction in operational costs. Another important driver relates to the cost of data collection and processing, which often represent a huge investment of company resources and are plagued by inefficiencies when performed manually.

For small organizations that perhaps hire only a handful of employees to address regulatory needs, the ability to leverage high-quality data through data reuse translates into the ability to rapidly review and justify the entire product portfolio.

At the same time, large manufacturers with entire departments that support the regulatory compliance of only one business unit or product family can benefit from efforts performed elsewhere in the organization.

The European device regulations clearly require manufacturers to own and employ best practices in literature reviews that support products under evaluation. This includes a need to proactively and consistently procure SOTA clinical data. Requirements set forth in these regulations are consistent with those in many other medical device and pharmaceutical markets across the globe.

Many product families are related, which provides ample opportunities to reuse data that supports claims of safety and performance from one product family to another. Evidence-based data are heavily leveraged throughout the construction of literature reviews and CERs as well as post-market surveillance-reporting requirements.

Reusing research data is therefore imperative to the successful completion of medical device and pharmaceutical regulatory reporting processes.

Who Reuses Data?

There are numerous consumers of reused data, including organizations that continuously monitor and manage literature for regulatory submissions, such as medical device companies or pharmaceutical companies.

As previously stated, regulatory bodies mandate that companies continuously maintain and document how developments outlined in scientific literature impact any claims made against medical product or pharmaceutical safety and performance. The FDA, for example, mandates that such data be maintained for the entire market lifetime of a product and for no less than 2 years. Companies similarly need to meet local regulatory requirements, which may involve storing data for long periods or replicating research and may provide an opportunity to reuse data in an organized and methodical manner.

Another example of a group interested in reusing data is a research consortium, which can be composed of separate research institutions or, as is increasingly prevalent, a combination of public and private organizations. For collaborative research or development projects that involve multiple institutions, there might be an opportunity to leverage data that have been previously researched by other members of the consortium. For example, citations of seminal research papers that have potential impacts across the spectrum of the involved research disciplines can benefit from a centralized solution that quickly outlines whether other group members have also recently cited the study.

Similarly, research projects within an organization often involve cross-functional personnel.

These interdisciplinary initiatives can benefit from an organized method of reusing data that will ensure that workflow efficiencies are maintained among the various groups involved. Examples of this type of project include multiple departments supporting a preclinical submission for a medical device. In such a project, there may be a need for both clinical affairs, regulatory, and R&D department staff to perform scientific-literature reviews. In this scenario, it would be beneficial for a software program to notify staff when other team members have previously cited a study or have at least reviewed a paper and considered it within their workflow.

Finally, researchers looking to avoid reusing previously referenced data–as in the cases of student and professional researchers–can be assisted by solutions that clearly define when research has been cited early on. Therefore, there are many groups that could benefit from a software solution that directly addresses data reuse.

Requirements and Challenges for Data Reuse

In addition to the previously mentioned challenges associated with data reuse, there are several requirements for successfully implementing data reuse best practices within an organization. One key requirement for the successful execution of literature reviews is that data must be collected and curated in a standardized manner. If two researchers working on related literature reviews perform their data collection using different methods, their organization may struggle to ensure that the results of its literature review are based on apples-to-apples comparisons. At minimum, an organization must have standardized processes for performing literature reviews to ensure uniformity among team members' data collection. This is true within organizations such as the medical device or pharmaceutical companies previously mentioned as well as within interdisciplinary research partnerships.

At minimum, personnel performing literature reviews must have some baseline knowledge about the existence of data in order to perform their queries appropriately. This includes understanding the literature review process and data landscape, including the identification of appropriate databases, an awareness of how to appropriately use search criteria, and knowledge of all relevant research domains. Given that collected data are not stored in a vacuum, a basic understanding of the regulatory requirements that guide the literature reviews themselves is similarly beneficial. Furthermore, personnel should have knowledge of whether team members have previously located specific data in order to optimize efficiencies and results within any given literature review.

Once data have been located via a literature review, it is critical that they undergo some type of validation to verify their authenticity and relevance to the product in question. Ultimately, this includes validating the source of information, the quality of the study and any evidence found within it, the relevance of the study to the device or devices under regulatory evaluation, and the degree of alignment between literature review results and claims against the product's safety and performance; equally important is safeguarding against false heuristics that can occur if a specific study has already been used.

In the latter cases, previous literature review findings may not have been initially validated and may have no actual value to the current literature review. Some personnel may simply reuse poor quality studies because those studies have been used previously, and low-quality evidence can be passed on from literature review to literature review without being properly evaluated.

When reusing evidence-based data, building trust into literature review processes is an important step in this journey. Validating data is one way to build trust into literature review processes, and establishing robust research processes can similarly build trust in literature review results. Further, being able to quickly determine whether colleagues have previously used high-quality studies is a way of ensuring that high-quality data make it through the literature review process, further bolstering trust in the results. As outlined in medical device and pharmaceutical regulations, the manufacturer is ultimately responsible for ensuring that literature reviews are accurate, up to date ,and relevant to the products under evaluation.

The ability to systematically determine if an article has already been reviewed is therefore a real benefit to individuals and organizations performing literature reviews. While organizations can unofficially track these results with shared spreadsheets, software applications that directly address this challenge are more beneficial. Software platforms such as DistillerSR have the ability to track status changes in real time, allow users to quickly access data, and increase efficiency in workflow processes by giving users the ability to leverage prior efforts and effectively reuse data. DistillerSR's add-on module, CuratorCR, goes one step further to proactively identify previously collected data for a particular reference and actively present results the reviewer can include in their research.

Benefits of Data Reuse as a Business Strategy

There are many benefits to reusing data as a strategy when performing literature reviews. Data reuse capabilities allow an organization to build on the findings of previous research. In doing so, researchers can dramatically accelerate the pace at which they work.

Data reuse solutions improve existing MDR data collection efforts in multiple ways. Similarly, evidence-based data collection efforts across the healthcare product and scientific service spectrum can benefit from these solutions.

First, from an efficiency point of view, data reuse solutions allow researchers to avoid the unnecessary duplication of efforts.

By clearly tracking whether references have been previously used, researchers can leverage the work their colleagues have already accomplished, thereby increasing workflow efficiency and overall productivity.

One further benefit here is the ability to reproduce or replicate the process of researching findings for related literature review queries for medical devices with similar intended purpose, for example. Improvements in data quality and consistency also make the verification and/or validation of research findings easier.

Finally, in the event of interruptions to research efforts and staff turnover, organizations are able to maintain research continuity if they leverage data reuse processes.

Data reuse further enables savings in the time and resources needed to perform similar tasks. Rather than performing queries leading to the same literature review results, valuable time is saved by reusing data.

This practice results in cost savings because it prevents organizations from losing money by committing additional personnel to achieve the same results, and it increases the value of an employee's efforts because they can be saved rather than duplicated.

Cross-functional collaborations with interdisciplinary partners benefit from data reuse by leveraging the expertise of personnel in other groups. For example, a cross-functional literature review performed by regulatory affairs, clinical affairs, and R&D departments can see strengthened results if all groups agree to reuse data results.

Reusing data can also benefit an organization by increasing the likelihood that new tools, methods, or approaches will be discovered. This can lead to the curation of these methods, which can result in the creation of intellectual property over time, thereby increasing value to the organization.

Finally, as processes become more consistent and data are reused, trust and validation are both likely to increase over time. The standardized adoption of best practices for literature reviews within an organization, leads to better outcomes, cost savings, and a more efficient workflow.

Barriers to Data Reuse

There are two categories of barriers that prevent data reuse from being used effectively during literature reviews: mechanical and attitudinal.

The mechanical barriers to data reuse include the overall lack of centralization of a service that supports data curation, documentation, and comparison to previously used studies.

Currently, many organizations' reviewers spend hours screening literature databases, extracting references that may seem relevant to literature review objectives, screening abstracts and references for keywords that are potentially of value, evaluating whether a reference should be considered high quality, rejecting low-quality references, and passing data on to the literature review's results.

Without employing commercial software, there is no central source that automatically performs these tedious processes and, more importantly, no central source of comparison between previously used studies and those currently under evaluation. This lack of centralization can be thought of as a mechanical obstruction to efficient workflows in literature reviews.

While some software platforms offer support to some of the processes mentioned, many organizations face the lack of a comprehensive solution that streamlines the literature review and data-reuse processes.

Ultimately, businesses that invest in critical infrastructure to help support their literature review efforts are likely to find greater results. There is a need for technology solutions that can make it easier for reviewers to search, retrieve, and reuse evidence-based data in an organized, efficient, and methodical manner.

Although organizations face a lack of cost-effective and time-saving tools, there are some solutions that encourage organizations to perform careful curation and reuse data during literature reviews.

The other type of barrier that exists is attitudinal. This barrier pertains more to the cultures of businesses, how they choose to operate, and whether they employ processes that support the effective practice of data reuse to streamline regulatory efforts.

Attitudinal differences in organizations can range from a simple lack of awareness of the need to employ data-reuse practices to an awareness unmet by active investments in resources to establish best practices (including investments in infrastructure).

Additionally, some organizations attempt data reuse but employ ineffective practices and end up not fully realizing the potential benefits of successful data reuse.

Recommendations

There are several recommendations worth considering when deploying best practices for the efficient reuse of data, including the following:

- Investing in data curation early in project design
- Promoting infrastructure solutions
- Providing shared tools and services
- Ensuring data-discovery mechanisms

Investing in data curation processes early in the project design ensures that an organization reaps the benefits of data reuse and avoids the operational inefficiencies of ineffective reuse practices.

Challenges with Research Data	Business Problem	Business Impact			Data Reuse Benefits
Multiple Systems	Centralizing all data to support a medical device from pre-market approval through post-market surveillance is difficult to achieve	Repeat Questions from Notified Bodies	Regulatory Delays	Costly Management of Evidence	Quickly identify previously reviewed, screened, and appraised data
Massive Volume		Misalignment of Evidence and Outcomes	Duplicated work between departments	Inconsistent results between departments	Continuously updated to keep up with latest evidence
Inconsistent Structure	Misalignment of efforts and failure to leverage research data that may be ongoing in other departments		Lengthy Reimbursement Profitability	Compromised Data Integrity	Save time and effort in regulatory compliance process
Fragmented Management		Lack of Data Traceability	Inadequate Payer Support Pricing		Evidence database that can be reused for medical devices with similar intended purpose

Table 1: Benefits of Data Reuse in Literature Reviews

By planning to standardize how data are researched, collected, curated, and reused, organizations can optimize their chances of success.

Organizations should similarly promote infrastructure solutions to support these initiatives. While it is possible to methodically track data that have been reviewed during previous literature review efforts, proper infrastructure, including software platforms that track and trace research studies and citations, significantly simplifies and standardizes these efforts.

Software that directly aims to ensure a positive and effective workflow experience for researchers who are looking to leverage data reuse will go a long way to ensuring worker satisfaction and the achievement of desired outcomes.

Once an organization has invested in infrastructure, providing shared tools and services that enable collaboration is essential. By sharing resources, organizations not only promote process standardization but also maximize software target capabilities. Training can be simultaneously performed for multiple users, and organizations can ensure they are all making use of evidence-based data for their own purposes.

Finally, ensuring there are adequate data discovery mechanisms optimizes data reuse within organizations. This includes providing access to scientific literature databases that house high-quality, evidence-based data as well as providing all team members with adequate resources to properly perform searches.

Leveraging software to allow team members to reuse data also improves the overall output of a team's performance and is therefore a recommended course of action.

CuratorCR: DistillerSR's Solution for Data Reuse

DistillerSR has developed a solution for data reuse that directly solves many of the challenges outlined above. CuratorCR is a research knowledge center that dynamically manages an organization's evidence-based data by consistently collecting, sharing, updating, and reusing them, thereby serving as a single source of truth for reviewers.

Integrated seamlessly with DistillerSR, CuratorCR centrally manages and dynamically enriches literature review data to ensure they are continuously accessible and consistently reusable for analysis across the organization.

This solution provides multiple users with the ability to rapidly and reliably leverage data reuse practices, ensuring more efficient preparation of evidence-based research efforts for healthcare and scientific products.

Among its many benefits, CuratorCR does the following:

- Provides a standard way of dynamically managing evidence-based research to ensure the continuous availability of trusted review data as opposed to the current status quo of ad hoc, unorganized, and static storage of data
- Actively promotes the reuse of previously collected data to reduce research time and improve reviewer productivity by proactively identifying available data and making suggestions ("Answer Suggestions") to reviewers in real time
- Allows reviewers to access shared references from different review projects to lower publication subscription costs

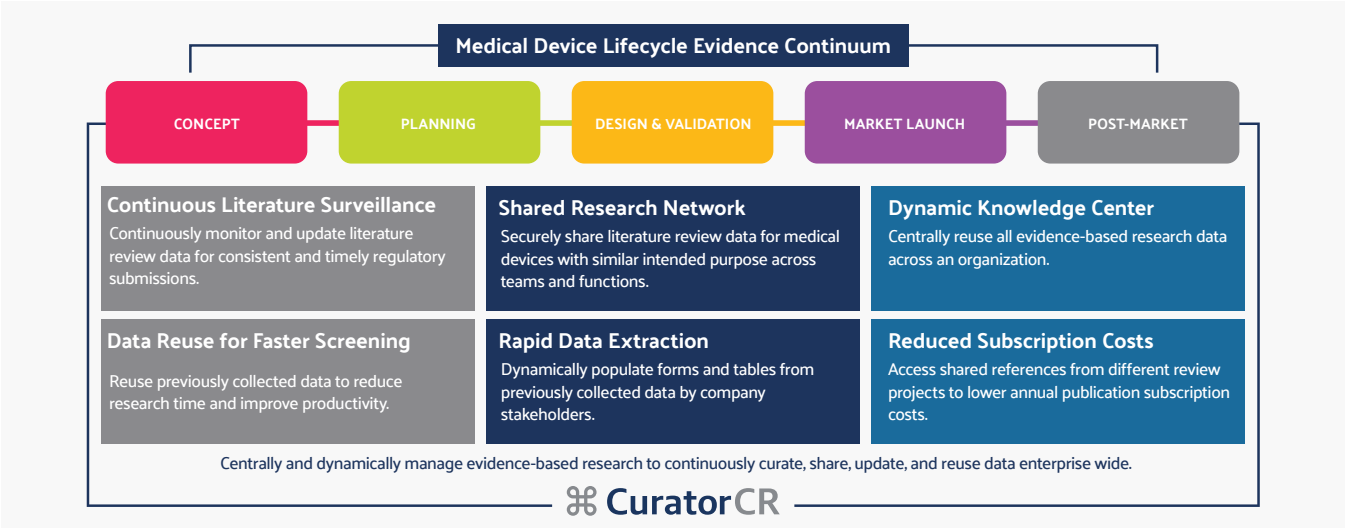

Table 2: Creating a Dynamic Knowledge Center to Continuously Manage Evidence-Based Data Enterprise Wide.

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