Harnessing real-world data: An advantage for medical device manufacturers

Crispin Bennet, Heidi Chapman and Laura C Collada Ali of **Trilogy Writing & Consulting** explore how it's time for medical device manufacturers to harness the full potential of real-world data to strengthen regulatory submissions and post-market strategies.

The integration of real-world data (RWD) into healthcare decision-making is reshaping how medical devices are developed, assessed and monitored. With RWD becoming increasingly accessible, manufacturers, regulators and clinicians are recognising its value in enhancing the relevance of research findings, improving patient outcomes and supporting regulatory decisions.

Medical devices – from in vitro diagnostics to therapeutic technologies – undergo rigorous clinical evaluation before market entry. However, traditional clinical investigations may not fully reflect real-world usage or long-term outcomes, especially for lower-risk devices. In Europe, the Medical Devices Regulation (EU MDR 2017/745) and In Vitro Diagnostics Regulation (IVDR 2017/746) mandate continuous Post-Market Clinical Follow-up (PMCF), requiring manufacturers to collect and assess data throughout the device's life cycle. Similarly, in the US, regulations such as 21 Code of Federal Regulation Parts 814 and 822 and Section 522 of the Federal Food, Drug and Cosmetic Act establish post-market study and surveillance requirements.

Recent initiatives and publications have focused on leveraging RWD to complement clinical trials and provide deeper insights into device performance, safety and effectiveness across diverse patient populations. For manufacturers, this means better tools to fill evidence gaps, strengthen post-market surveillance, and guide product development with a more patient-centric approach.

This article reviews three key publications and one collaborative initiative that highlight how RWD is being used in the medical device sector. These resources offer practical insights into regulatory frameworks, data integration methodologies and real-world applications that manufacturers should be aware of to optimise their regulatory strategies and product life-cycle management.

RWD reflects routine clinical practice and typically includes larger, more diverse patient populations than traditional trials. This makes RWE particularly valuable for supplementing pre- and post-market clinical investigations, supporting benefit/risk assessments, and reducing the financial burden of conducting new studies.

Legacy devices – those already on the market but lacking comprehensive clinical data – can benefit significantly from RWE. Regulatory frameworks now offer pathways for manufacturers to use RWD to strengthen clinical evidence, especially under the EU MDR. This approach aligns with initiatives like the Food and Drug Administration's National Evaluation System for Health Technology, which promotes the use of RWE in regulatory decision-making.

"Manufacturers should explore diverse sources of RWD, including hospital records, electronic health records, registries and even social media listening."

Manufacturers should explore diverse sources of RWD, including hospital records, electronic health records, registries and even social media listening. These sources can provide insights into device performance across varied clinical settings, helping to build a robust evidence base.

Leveraging RWE for legacy devices

As regulatory expectations evolve, RWE is becoming a powerful tool for medical device manufacturers, especially those managing legacy devices. A recent review (McDermott & Kearney. 2024; Expert Rev Med Devices) highlights how RWE can help bridge gaps in clinical evidence, offering a more accurate and cost-effective way to demonstrate device safety and performance.

Defining clinical endpoints using RWD

A novel methodology has emerged that uses RWE to define meaningful endpoints

What are real-world data (RWD) and real-world evidence (RWE)?

- RWD refers to observational data collected outside traditional clinical trials – such as electronic health records, insurance claims and patient-generated data – used to understand patient health and care delivery.
- RWE is clinical evidence about the use, benefits, or risks of a medical product, derived from the analysis of RWD.

for device evaluation (Wang et al. 2021; Stat Med). This approach applies entropy balancing, a statistical technique that adjusts for differences between real-world and study populations. By aligning treatment and control groups more accurately, manufacturers can reduce bias and improve the reliability of conclusions drawn from RWD.

This method is particularly useful when designing clinical investigations or updating performance and safety parameters. It helps manufacturers overcome challenges related to limited or inconsistent data, ensuring that endpoints are relevant and reflective of actual clinical use.

Market access and regulatory submissions

RWE is increasingly recognised by regulators as a valid component of market access strategies. A recent review of the FDA's framework outlines how RWE can support regulatory approvals, highlighting key legislative milestones and future directions (Shi et al. 2024; Cost Eff Resour Alloc).

For manufacturers, this means that integrating RWE into submission dossiers can enhance the credibility of clinical evidence and potentially accelerate approval timelines. Understanding how to align RWD collection with regulatory expectations is essential for successful submissions.

Collaborative initiatives: the open hand approach

The Open Hand Initiative (Baumfeld Andre et al. 2025; Clin Pharmacol Ther), a collaboration between the FDA, manufacturers and the Medical Device Innovation Consortium, exemplifies how industry and regulators can work together to improve the quality and transparency of RWE. This initiative encourages manufacturers to share insights from regulatory interactions, fostering a more consistent and effective use of RWD in submissions.

Participating in such initiatives can help manufacturers stay ahead of regulatory trends, improve data quality and ensure that their devices meet evolving standards.

As the medical device industry continues to shift towards evidence-based regulation, RWD offers manufacturers a strategic advantage. Whether supporting legacy devices, defining clinical endpoints, or facilitating market access, RWE provides a cost-effective and reliable way to strengthen clinical evidence.

Key messages of the analysed publications

Publication	Take-home messages for manufacturers
McDermott & Kearney (2024) Expert Rev Med Devices	• RWD can support PMCF and clinical evaluation under EU MDR. • Helps fill evidence gaps and reduce study costs. • Suggests EU initiative similar to FDA's NESTcc.
Wang et al. (2021) Stat Med	• Introduces a method to use unstructured data (e.g., text/images) in performance goal setting. • Reduces bias and improves reliability of statistical models. • Useful for enhancing endpoint selection and study design.
Shi et al. (2024) Cost Eff Resour Alloc	• FDA increasingly accepts RWE for approvals and surveillance. • Key challenges: data quality, interoperability, and regulatory clarity. • Future focus: AI-driven analysis, cost-effectiveness and patient outcomes. • Reimbursement disparities may affect access to innovative devices.
Baumfeld Andre et al. (2025) Clin Pharmacol Ther	• Open Hand Initiative promotes collaboration to improve RWE use in In Vitro Diagnostic approvals. • Highlights need for better data access, standardisation and alignment with FDA expectations. • Model could extend to broader device categories for more robust submissions.

Note: these four publications were identified as most relevant for medical device manufacturers involved in writing regulatory documents for medical devices upon the following search string on PubMed on 24 February 2025: ("real-world data"[Title] OR "real-world evidence"[Title]) AND ("medical device"[Title] OR "in-vitro diagnostic"[Title]) AND (2020:2025[pdat])

"Manufacturers should actively engage with emerging methodologies, regulatory frameworks and collaborative initiatives to ensure their devices are backed by robust, relevant data."

Conclusion

Manufacturers should actively engage with emerging methodologies, regulatory frameworks and collaborative initiatives to ensure their devices are backed by robust, relevant data. By doing so, they can enhance patient outcomes, streamline regulatory processes and contribute to the future of healthcare technology.

Medical writers are uniquely positioned to support medical device manufacturers in navigating these evolving challenges and opportunities, thanks to their deep understanding of regulatory landscapes, clinical evidence generation and strategic communication.

References available on request.

The content of this article was first published in the European Medical Writers Association Medical Writing Journal in September 2025.

https://trilogywriting.com