



## Real-world data coming into play in the medical device world: What medical writers need to know

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The integration of real-world data (RWD) into healthcare decision-making has transformed various aspects of clinical research, regulatory approval, and post-market surveillance. As the healthcare landscape continues to evolve, the use of RWD within the context of medical devices has garnered increasing attention from regulatory agencies, industry stakeholders, and the scientific community. With RWD now more available than ever before, clinicians and regulators alike are realising the benefits it offers: enhancing the relevance and applicability of research findings, improving patient outcomes and care, and supporting regulatory decision-making.

Medical devices, ranging from in-vitro diagnostics to therapeutic technologies, are subject to rigorous clinical assessments before reaching the market. However, while clinical investigations are essential for establishing initial safety and efficacy, these may not fully capture the complexity of real-world usage and long-term outcomes and may not be feasible for lower-risk devices. In Europe, the Medical Devices Regulation 2017/745<sup>1</sup> and In-Vitro Diagnostics Regulation 2017/746<sup>2</sup> introduce enhanced requirements for Post-Market Clinical Follow-up (PMCF) of all medical devices, requiring that data be continually collected and appraised throughout the entire lifetime of the device. In the United States, there are similar regulations and statutes (e.g., 21 CFR Parts 814 and 822 and the Federal Food, Drug, and Cosmetic Act Section 522) establishing post-market studies and surveillance requirements. In addition, in

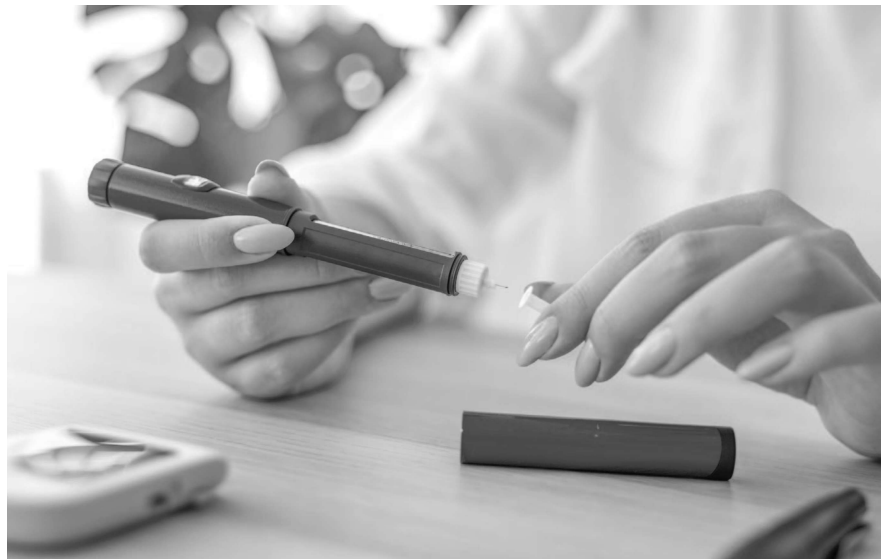


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recent years, several key initiatives and publications have focused on harnessing RWD to complement traditional clinical trials and provide more comprehensive insights into the performance, safety, and effectiveness of medical devices in diverse, real-world settings. By leveraging RWD, researchers and regulators are better equipped to address gaps in evidence, improve post-market surveillance, and guide product development in a more patient-centred manner.

This article explores 3 publications and 1 initiative surrounding the use of RWD in the medical device sector that medical writers would benefit from being aware of. We identified these through a targeted literature search (see Table 1). These publications highlight key regulatory frameworks, emerging methodologies for data integration, and real-world case studies that demonstrate the transformative potential of RWD. Medical device writers need to be aware of these initiatives and proposals in order to

### Real-world data (RWD)

refers to observational data collected from sources outside of traditional clinical trials, such as electronic health records, claims data, and patient-generated data used to understand patient health and healthcare delivery<sup>3</sup>. RWD offers a richer, more diverse data pool compared to controlled clinical environments.<sup>3</sup>

### Real-world evidence (RWE)

is clinical evidence regarding the usage, and potential benefits or risks, of a medical product derived from the analysis of RWD.<sup>3</sup>

**Table 1. Key messages of the analysed publications**

Publication	Key messages
<p>McDermott O, Kearney B. The value of using real-world evidence as a source of clinical evidence in the European medical device regulations: a mixed methods study. <i>Expert Rev Med Devices</i>. 2024 Jan-Feb;21(1-2):149-163. doi:10.1080/17434440.2023.2291454 Epub 2024 Feb 4. PMID: 38041629.</p>	<ul style="list-style-type: none"> <li>● RWD for PMCF studies and clinical evaluation reports can aid in adhering to the European Medical Device Regulations.</li> <li>● Manufacturers can bridge gaps in clinical evidence by using RWD.</li> <li>● RWE supplements clinical evidence from pre- and post-market clinical investigations, reducing the costs associated with these studies and supporting the manufacturer's benefit/risk conclusion.</li> <li>● How the medical device industry could utilise RWE and proposes an initiative in the EU similar to the FDA-sponsored NESTcc partnership.</li> </ul>
<p>Wang C, Rosner GL, Bao T, et al. Leveraging real-world evidence for determining performance goals for medical device studies. <i>Stat Med</i>. 2021 Dec 20;40(29):6577-6589. doi: 10.1002/sim.9199. Epub 2021 Sep 24. PMID: 34561895.</p>	<ul style="list-style-type: none"> <li>● The authors of this publication propose a methodology for integrating unstructured data (e.g., text, images) into regression models, addressing challenges like measurement error and high dimensionality.</li> <li>● They introduce a one-step estimation strategy that combines information retrieval and topic modelling to generate variables from unstructured data, which are then used in regression analysis.</li> <li>● The one-step strategy substantially reduces bias in simulations. The method has quantitatively important effects in a leading application using Chief Executive Officer time-use data. The approach can be readily adapted by applied researchers.</li> <li>● Implications: This methodology enhances the ability to incorporate unstructured data into regression models, improving the accuracy and reliability of statistical inferences in various fields.</li> </ul>
<p>Shi L, Xuan D, Jakovljevic M. A review on the evolving environment of medical device real-world evidence regulation on market access in the USA. <i>Cost Eff Resour Alloc</i>. 2024 Oct 25;22(1):75. doi:10.1186/s12962-024-00582-9. PMID: 39456032; PMCID: PMC11515808.</p>	<ul style="list-style-type: none"> <li>● The FDA's CDRH oversees medical device approvals, which have evolved from the Medical Device Amendments (1976) to more recent policies, such as the 21st Century Cures Act (2016) and the Food and Drug Omnibus Reform Act (2022).</li> <li>● Since 2017, the FDA has increasingly recognised RWE/RWD as part of the evidence package for medical device approval, particularly for post-market surveillance, breakthrough devices, and alternative approval pathways.</li> <li>● Issues such as data availability, reliability, harmonisation, and interoperability remain barriers. The NEST was a database established to synthesise RWE from clinical registries, EHRs, and claims data.</li> <li>● The future of RWE in medical device regulation will focus on improving data transparency, standardisation, and analytical methods to enhance regulatory confidence. Advancements in AI and machine learning will help analyse large-scale RWD, bridging the gap between clinical research and real-world applications.</li> <li>● Expanding RWE beyond safety and efficacy to include cost-effectiveness and patient-centred outcomes will further support its role in regulatory decision-making and health technology assessments.</li> <li>● While regulatory acceptance of RWE is growing, the disparities in affordability of the different treatments, connected with the related reimbursement policies may compromise patient access to innovative medical devices.</li> </ul>

produce robust quality documents for regulatory submissions and post-market surveillance.

### Real-world data and clinical evidence

A review has been published highlighting the opportunities that exist in medical device regulations for manufacturers of legacy devices to conduct real-world evidence (RWE) studies to bridge gaps in clinical evidence.<sup>4</sup> The primary value of RWE lies in its ability to provide an accurate and, therefore, more reliable measure of

device safety and performance. This is due to the fact that often RWD mirror routine cases and provide bigger amounts of data compared to clinical studies run for market approval of a given device. RWE supplements clinical evidence generated from pre- and post-market clinical investigations, reducing the costs associated with these studies and supporting the manufacturer's benefit/risk conclusion.<sup>4</sup>

### Relevance for medical writers

The regulatory framework of medical devices is continuously evolving. Medical writers need to be proactive in adapting to the changing frameworks that may leverage RWE more extensively in the future, with the possibility of having a clone initiative to the FDA-sponsored National Evaluation System for Health Technology (NEST – <https://nestcc.org>) partnership in the U.S. in other regions in the world. Medical writers should understand how RWE can

**Table 1. cont.**

Publication	Key messages
<p>Baumfeld Andre E, Gee M, Magnus C, Greeman S, White P, de Mars M, Spring B. The Open Hand Initiative: Facilitating the use of real-world evidence in regulatory submissions through collaboration and transparency. <i>Clin Pharmacol Ther.</i> 2025 Apr;117(4):1072-1077. doi:10.1002/cpt.3539. Epub 2024 Dec 24. PMID: 39716998; PMCID: PMC11924146.</p>	<ul style="list-style-type: none"> <li>● RWD is increasingly used to support regulatory decisions, but its integration in IVD approvals remains complex due to data quality, availability, and regulatory clarity issues. The Open Hand Initiative was piloted to address these challenges in transitioning SARS-CoV-2 serology tests from EUA to full market approval.</li> <li>● Participants identified difficulties related to data access, standardisation, and interoperability, as well as limitations in using retrospective data for regulatory submissions. The COVID-19 pandemic also introduced unique barriers, such as shifting diagnostic criteria, evolving patient populations, and rapid technological advancements in test development.</li> <li>● The initiative emphasised the need for clear regulatory expectations for RWE, improved data collection and validation processes, and better alignment between study design and FDA requirements. Ensuring data privacy compliance and leveraging existing RWD sources were also highlighted as critical factors for successful submissions.</li> <li>● The Open Hand Initiative demonstrated the potential for collaborative regulatory science, where industry and regulators work together to refine RWE standards. While initially focused on IVDs, the model could be expanded to broader medical devices and pharmaceuticals, improving the integration of RWD in premarket and post-market decision-making.</li> </ul>

Abbreviations: CDRH, Center for Devices and Radiological Health; COVID-19, Coronavirus disease 2019; HER, electronic health record; EU, European Union; EUA, Emergency Use Authorization; FDA, Food and Drug Administration; IVD, In-vitro diagnostics; NEST, National Evaluation System for health Technology; RWD, real-world-data; RWE, real-world evidence.

Note: These 4 publications were identified as most relevant for medical writers involved in writing regulatory documents for medical devices upon the following search string on PubMed on Feb 24, 2025: ((“real-world data”[Title] OR “real-world evidence”[Title]) AND (“medical device”[Title] OR “in-vitro diagnostic”[Title])) Filters: from 2020 – 2025 (“real-world data”[Title] OR “real-world evidence”[Title]) AND (“medical device”[Title] OR “in-vitro diagnostic”[Title])) AND (2020:2025[pdat])

support the clinical evidence required under the Medical Devices Regulation, reduce costs, and contribute to ongoing benefit/risk profile evaluations, particularly, for legacy devices. They should also be aware that there are multiple sources of RWE within the medical devices world: from hospital charts to social-media listening, for example.

### Using real-world data to define clinical investigations endpoints

A new method has been developed leveraging RWE to propose meaningful endpoints for assessing devices.<sup>5</sup> The method applies entropy balancing (a data processing method for matching treatment and control observations) to address possible patient dissimilarities between a study’s target patient population and existing real-world patients, taking into account operational differences between clinical studies and real-world clinical practice. Applying this method reduces the risk of biased conclusions to be drawn on a set of different sources, as it is often the case with RWD. The publication is technical but presents a practical case.

### Relevance for medical writers

Even if medical writers are not responsible for the statistical methodology, it is important that they

understand how RWE can be applied to aid selection of relevant performance and safety endpoints for device studies and assessments.

Safety and performance parameters are used in different steps of the clinical evaluation of a medical device; e.g., when defining the state-of-the-art and when designing endpoints for a clinical investigation. However, it is challenging to determine performance or safety parameters when the amount of reliable, relevant, and available data are limited.

Medical writers need to be careful when using unstructured data to draw conclusions on the safety and performance data of a given device, as the risk for a biased conclusion is high.

Weighting different formats and sources of data is not an easy task, but statistical methodologies applying new methods like the one presented in this publication can play an important role in producing a robust body of data, from which conclusions can be drawn safely. We should be aware of these methods and work in collaboration with statisticians to analyse and

assess data. Adopting robust methodologies can ensure more accurate clinical evaluations and support the validity of regulatory documentation.

**Medical writers need to be careful when using unstructured data to draw conclusions on the safety and performance data of a given device, as the risk for a biased conclusion is high.**

### Can RWD facilitate market access?

A recent review explores the role of RWE and RWD in the regulatory approval of medical devices within the U.S. FDA framework.<sup>6</sup> The review highlights key legislative milestones, challenges in integrating RWE into regulatory decisions, and potential future directions.

### Relevance for medical writers

It is important for medical writers to be aware of the value of integrating RWE into

submission dossiers for devices and what the regulatory framework is for doing this. This article provides valuable information on evolving guidelines and best practices for utilising RWE. By applying these medical writers can support teams in producing applications that draw more robust conclusions about the need for the device at hand.

## An all-hands initiative: When manufacturers and regulators come together to leverage real-world data

The Open Hand Initiative presents an innovative approach to integrating RWE and RWD into the regulatory approval process for in-vitro diagnostic (IVD) devices.<sup>7</sup> The Open Hand Initiative, a collaboration between the FDA, device manufacturers, and the Medical Device Innovation Consortium (MDIC), promotes transparency by encouraging manufacturers to share insights from regulatory interactions to improve the quality and applicability of RWE.<sup>7</sup>

### Relevance for medical writers

This article provides further valuable insights into the evolving regulatory landscape for medical devices, particularly the role of RWE in FDA submissions. Medical writers involved in regulatory documentation, clinical investigation design, and evidence synthesis can benefit from understanding how to align RWD collection with regulatory expectations to improve the quality of data and transparency of the types of data supporting submissions. Addressing regulators' expectations in terms of the content of the documentation to be submitted may shorten time to response from the authorities and lead to a more successful submission.

### Conclusion

As the regulatory landscape continues to shift, understanding the role of RWD in medical device development will be crucial for ensuring better patient outcomes and driving the future of healthcare technology. RWE use in the medical device sector continues to expand, and it offers valuable opportunities to strengthen clinical evidence, enhance post-market surveillance, and support regulatory submissions. Medical writers

must stay informed of emerging methodologies, evolving regulatory frameworks, and collaborative initiatives like the Open Hand Initiative.<sup>7</sup> By doing so, they can help ensure that medical device documentation is robust, relevant, and aligned with current standards – ultimately contributing to more effective, evidence-based healthcare.

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### Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employer or EMWA.

### Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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