Current Landscape for Global Regulatory Acceptance of Real-World Evidence for Medical Devices

Perspectives from the RAPID Global Regulatory Acceptance Group.

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Although traditional protocol-driven clinical studies play an important role in evaluating novel medical devices, real-world evidence (RWE) is also valuable for understanding device safety and effectiveness under broader conditions of use and with potentially less commitment of time and resources. Because of these potential benefits, there is ongoing interest in developing methodologies suitable for leveraging RWE that are relevant and reliable for regulatory uses.

The Center for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA) has included such efforts in recent strategic plans and published guidance on RWE use in 2017.[1] In addition, since its initiation in 2015, CDRH has actively participated in the Registry Assessment of Peripheral Interventional Devices (RAPID), a multi-stakeholder collaboration involving clinicians, academia, regulators, and industry intended to promote the collection and utilization of vascular device data across real-world data (RWD) sources. Completed RAPID projects included developing a minimum core data set to support consistent data collection, utilizing RWE to develop contemporary objective performance goals for peripheral interventions, and convening stakeholders to evaluate a safety signal.

This article summarizes RAPID's recent work in elucidating the current landscape for global regulatory application of RWE. By gathering information on successful and unsuccessful industry experiences using RWE in different regulatory jurisdictions as well as the availability of region-specific RWE guidance,[1-26] our goal is to identify areas of opportunity for global RWE application, as well as gaps where additional outreach or education may be beneficial.

FDA REPORT: EXAMPLES OF RWE USED IN MEDICAL DEVICE REGULATORY DECISIONS

FDA released a report in March 2021 summarizing 90 device submissions supported by RWE.[27] The FDA report identifies submission number, sponsor, device, RWD source, premarket or postmarket use, and whether RWE was the primary clinical evidence source.

Regulatory submission types included premarket approval (PMA), de novo, 510(k), and Humanitarian Device Exemptions supported by a variety of RWD sources (eg, national/international registries, sponsor registries, claims data, and medical records). Premarket examples supported original device approval, indication expansion, and changes to labeling or instructions for use. Postmarket examples satisfied postapproval commitments and PMA conditions of approval. In some cases, these data sets were also used to meet non–United States regulatory goals, including continued marketing in Europe under the Medical Device Regulation (MDR) and supporting cardiovascular device approvals in Japan.

TABLE 1. PREMARKET AND POSTMARKET EXAMPLES		
Description of Study	Evidence Source	Key Points
Premarket Examples		
FDA example #2: K173032 Scalp cooler - expand indication	Primary	National OUS registry (Dutch Scalp Cooling Registry)
FDA example #4: K173860 Vascular imaging system – modify indication	Primary	National OUS registry (SCAAR)
FDA example #12: P970003/S207 VNS therapy system – expand indication	Primary	National OUS registry (Japan VNS) + sponsor adverse event data
FDA example #22: K190779 ProVue retriever – modify labeling and instructions for use	Primary	Sponsor OUS registry
FDA example #28: P160036 Total ankle replacement system – original PMA approval compared OUS registry data to performance goal. Satisfy PAS.	Primary	Sponsor OUS registry
FDA example #29: P160043 Drug-eluting stent – original PMA approval	Supplemental	Sponsor OUS registry
FDA example #36: P960043/S097 Suture-mediated closure system – indication expansion	Primary	Sponsor OUS registry + medical records
Recent example: DEN210024 Laser sheath to remove IVC filter – support for de novo request for classification	Primary	Retrospective RWE clinical study
Postmarket Examples		
FDA example #5: H170001 Scoliosis treatment for adolescents – RWE supported modification to indications and postapproval study requirements	OUS commercial use primary	Registry for postapproval study
FDA example #11: P070026/S004 Ceramic total hip system – collect and analyze device survivorship, revision, death rate	Primary	OUS national registries to support condition of approval (UK and Australia)
FDA example #33: P130024/S009 Drug-coated balloon – expand indications premarket and satisfy condition of approval study requirements postmarket	Primary	Sponsor OUS registry
FDA example #37: P160043/S012, P110013/S088 Drug-eluting stent – expand indications premarket and satisfy condition of approval study requirements postmarket	Supplemental	Sponsor OUS registry Supplemental evidence
Abbreviations: IVC, inferior vena cava; OUS, outside of United States; PAS, postapproval study; PMA, premarket approval; RWE, real-world evidence; UK, United Kingdom; VNS, vagus nerve stimulation.		

The RAPID Global Regulatory Acceptance working group reviewed the report in detail and identified 11 examples of international RWD used to support FDA regulatory decisions. During the May 2022, RAPID Think Tank meeting, the working group presented the 11 FDA international examples and one additional recent example (Table 1).[28] During a panel discussion, the RAPID Think Tank participants noted limitations in the visibility of examples in which RWE was accepted or not accepted by global regulators. The panel discussed success in using Japanese surveillance data (high quality with up to 8-year follow-up) and Chinese use of RWE for novel technologies in the Hainan region. Think Tank participants were polled to understand the range of RWE experiences. Most RWE experience has been from the United States, Europe, and Japan, and examples and information around the use of RWE within and among these regions would be helpful to industry (Figures 1 and 2). Based on the polling results,
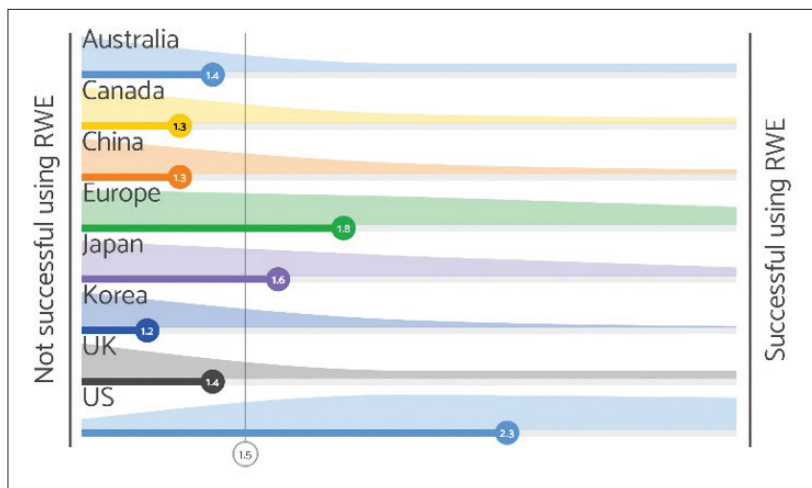
Figure 1. Results of poll regarding participants' experience with successful RWE submissions across regions.

the RAPID Global Regulatory Acceptance working group focused on reviewing global guidance documents and collecting additional examples of successful and unsuccessful use cases.

AVAILABLE GUIDANCE IN USE OF RWE FOR REGULATORY APPROVAL

The working group also looked at available guidance documents for use of RWE. Although regulatory approval of medical devices has traditionally been obtained through prospective clinical trials, the rise of electronic capture of medical data through electronic health records and registries has increased the availability of RWD. As a result, it was recognized that a framework could be developed to allow for use of RWE for regulatory decision-making. Over the last decade, RWE guidance documents have been released by regulatory agencies from different regions including the United States, Japan, China, Canada, Australia, the European Union (EU), and the United Kingdom (see appendix).[1-26]

Fortunately, these guidance documents share more similarities than differences. Many of these provide clear definitions of what constitutes RWD, when and how it can be used, and potential issues that could arise. Furthermore, the guidance documents define how RWD can be used to generate RWE for various purposes, including the use of RWE to support premarket submissions, postmarket surveillance studies, and pediatric marketing applications. Many of the documents have a strong focus on the quality of data used to generate RWE, noting that only high-quality data can be used for regulatory approval. Although that may seem obvious, there is no clear definition of high-

quality data, and many documents go in-depth when discussing where shortfalls in RWD may exist, with some discussing methods to mitigate risk inherent in RWD.

In addition to guidance documents released by government agencies, the International Medical Device Regulators Forum (IMDRF) released a guide to assist manufacturers in using RWD. The IMDRF documents go into significant depth in using RWD, including assessing data quality from registry-based data, linkage of data sources, methodologies for use of registry data, finding signals in data, and much more. The IMDRF documents expound on frameworks that are present in other documents and can serve as an important adjunct source of information when using RWD.

Despite the many similarities, there are also some differences between guidance documents. For example, the Japanese and EU guidance documents emphasize registry data, the Canadian documents focus on pharmaceutical approval, and the EU and United Kingdom documents discuss using RWD clinical trials in greater depth. However, it is important to note that these differences should not impact the fundamentals of RWD usage for regulatory approval and can therefore be viewed as additional information based on the area of interest or approach being considered. Overall, the documents demonstrate agreement across regions on the ability to use RWD for regulatory approval.

RWE LANDSCAPE

The working group created a mind map of the RWE landscape (Figure 3) based on the findings in the global regulatory guidance documents, which were additionally supported by the RWE examples from FDA. The mind map served as a summary of the RWE landscape and was central to organizing key concepts. The usage of RWE in the regulatory domain supports product development/research, premarket decisions, and postmarket activities. In addition, RWE supports other business processes outside the regulatory domain such as economic analysis, reimbursement, and public health surveillance.

The types of studies that utilized RWE were identified as feasibility planning, registry-embedded, external control of clinical trials, and pragmatic trials. The following characteristics were noted for RWD as the source of
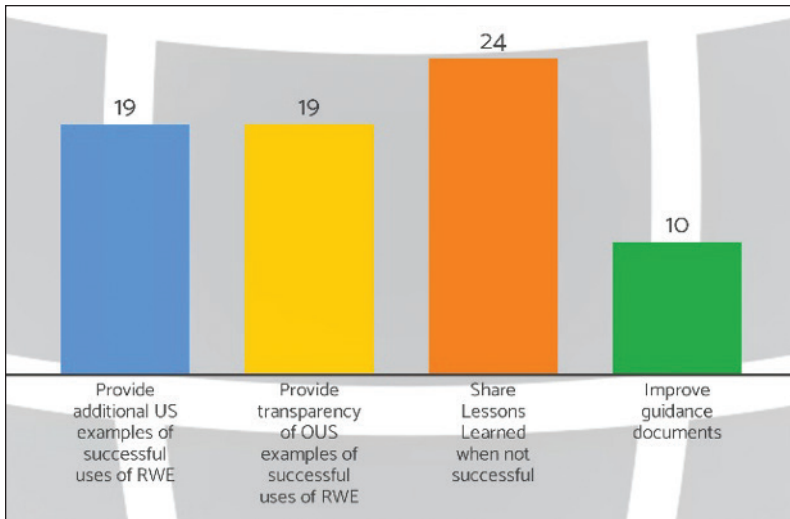
Figure 2. Results of poll to gauge options for improving industry's understanding of submitting RWE.

stand RWE experiences and the uses of RWE for regulatory decision-making by gathering information on both positive and negative experiences with RWE to support regulatory decisions. A total of 37 RWE experiences were submitted between September 7, 2022, and October 14, 2022.

For the majority of submissions, the United States (n = 23) was the primary region in which RWE was used, along with Europe (n = 7) and Japan (n = 5), with single experiences reported in Canada and China. Aortic valve devices (n = 8) and coronary drug-eluting stents (n = 6) were the most common device types. Additional devices included angioplasty balloons, peripheral drug-coated balloons, peripheral bare-metal stents, peripheral drug-eluting stents, covered stents, peripheral atherectomy devices, mitral valve devices, and thrombectomy devices. RWE was used as the primary source of data in most cases (n = 30), with one additional submission utilizing RWE as both primary and supplemental data. Sources of RWD included society registries, electronic health records, manufacturer/sponsor registries, national registries, literature reviews, claims data, retrospective studies, health care databases, and physician-sponsored

RWE: validity, completeness, data quality, and fit for purpose. Each of these characteristics are important to the relevance and reliability of RWD for use in regulatory decision-making as evidence to support premarket decisions as well as postmarket commitments.

RWE INDUSTRY SURVEYS

The RAPID Global Regulatory Acceptance working group conducted an industry survey to better under-
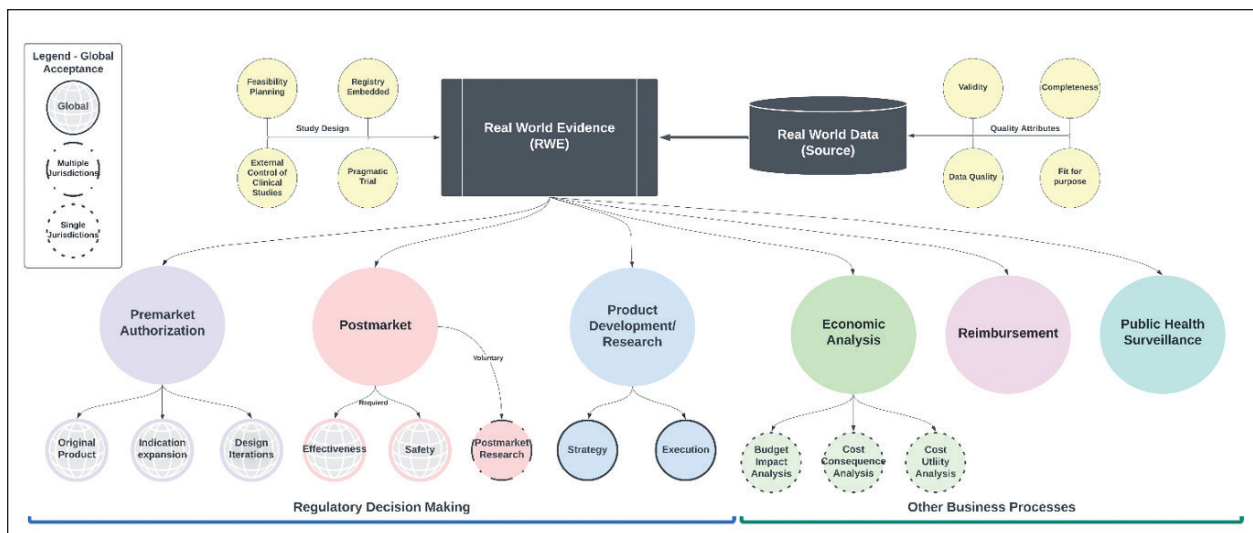

Figure 3. Mind map of the global RWE landscape. The diagram depicts the most commonly cited quality attributes in RWD that may be used as evidence in the various types of studies throughout the global RWE landscape. Note that not all of these were represented in each region that was assessed. Also depicted are the business processes supported by RWE, which include regulatory activities (eg, premarket authorization and postmarket surveillance and research) as well as nonregulatory activities (eg, product development/research, economic analysis, reimbursement, and public health surveillance).
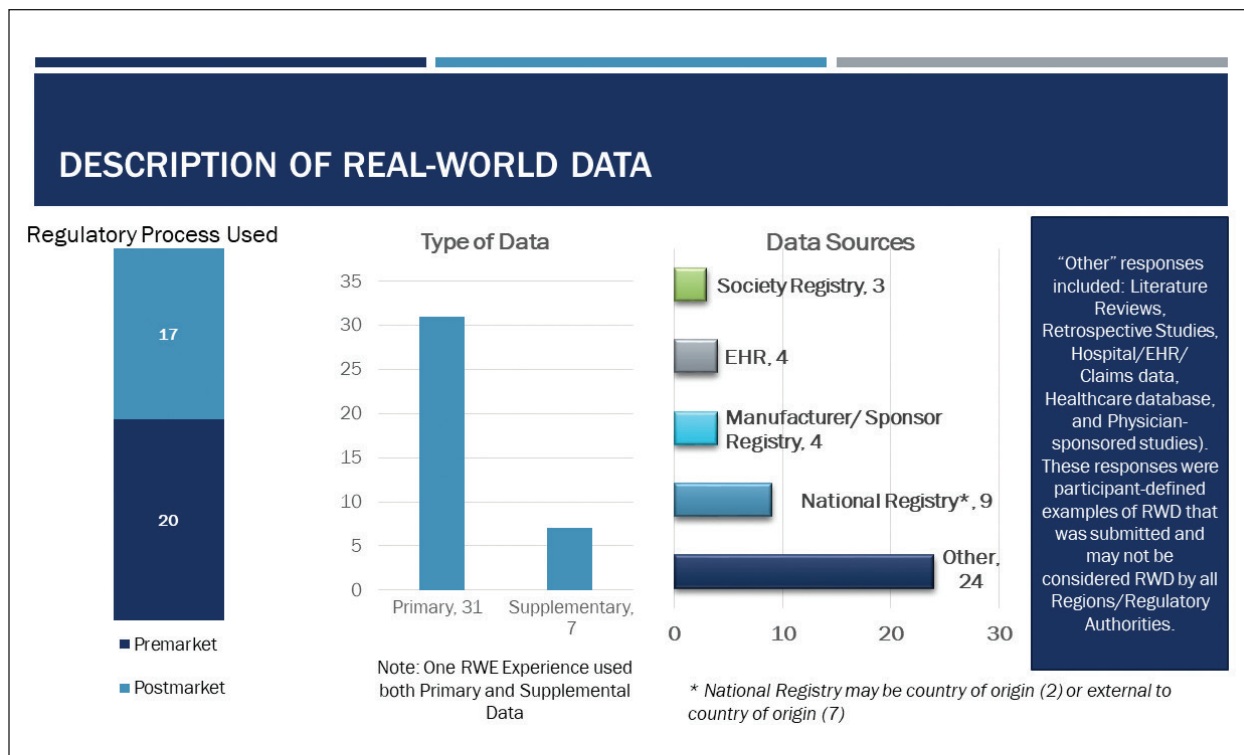
DESCRIPTION OF REAL-WORLD DATA

Regulatory Process Used

Type of Data

Data Sources

"Other" responses included: Literature Reviews, Retrospective Studies, Hospital/EHR/ Claims data, Healthcare database, and Physician-sponsored studies). These responses were participant-defined examples of RWD that was submitted and may not be considered RWD by all Regions/Regulatory Authorities.

Note: One RWE Experience used both Primary and Supplemental Data

* National Registry may be country of origin (2) or external to country of origin (7)

Figure 4. Survey results for RWD characteristics.

studies (Figure 4). Experiences included both premarket (n = 20) and postmarket (n = 17) submissions.

Of the 37 submissions, 31 RWE experiences were identified as successful. Estimated time savings using RWE compared to traditional independent industry studies varied, with eight respondents estimating 0 to 6 months, six estimating 6 to 12 months, seven estimating 12 to 24 months, and five estimating 2 to 5 years. Estimated cost savings ranged from $500K to $20M.

There were six RWE experiences that were identified as unsuccessful (5 United States submissions, 1 Japanese submission). Reported issues identified by regulators related to these unsuccessful submissions included access to data, data completeness, data quality, and inability to demonstrate conformance to Good Clinical Practice. However, despite these unsuccessful attempts, when asked what would encourage submitters to consider the use of RWE in subsequent regulatory submissions, many reaffirmed the importance of consultation mechanisms, development of clear regional guidance, increased transparency of data availability by RWD holders, and direction from regulators as to when the use of RWE should be considered.

Concerns reported in the survey that diminish enthusiasm for using RWE to support regulatory submissions include the perceived inability to use the same data across regions, lack of guidance from regulators, and concerns with data confidentiality. Moving forward, key considerations that may enhance the likelihood of successful submissions include formal and/or informal communication with regulators, ongoing discussions with regulatory bodies about RWE, and creation of a reusable infrastructure to answer multiple questions about real-world medical device safety and effectiveness.

DISCUSSION

The review of global RWE guidance documents revealed no apparent substantive discrepancies or conflicts between regulatory bodies regarding the use of RWE for regulatory decision-making. However, many guidance documents provide general conceptual information about RWE without describing specific details or examples on the use or application of RWE within a certain jurisdiction. This higher-level focus is likely due to the relative novelty of RWE as a key component of the medical device regulatory landscape. Although many regulatory bodies support and encourage use of RWE, the mechanism of how specifically to incorporate RWE into a submission and what sources may qualify as high-quality RWD are provided broad latitude. This flexibility can be positive by allowing both regulators and industry to determine an appropriate use scenario

that fits individual situations but also presents a challenge due to a lack of clarity on what may be acceptable for a given situation. Therefore, early discussion with regulators is especially important when considering the use of RWE to support a regulatory submission.

The 90 RWE cases shared by FDA provide examples of the conditions under which RWE was able to support a regulatory submission in the United States and can be used as a guide by industry. However, when considering use of RWE in other regions, there are limited examples available for industry to reference. Regulatory bodies and industry can help address this challenge by providing additional examples of the successful use of RWE to support regulatory decisions globally.

Another gap identified is the lack of examples around unsuccessful RWE submissions. These unsuccessful experiences can be valuable learning opportunities, often more so than successful examples, and can be used to identify challenges or limitations that still exist for RWE. By analyzing specific scenarios to identify and share common problem areas, industry and regulators can work together to identify pathways for overcoming remaining challenges, leading to more frequent and successful use of RWE in the future.

The potential benefits of RWE use were clearly identified through the industry survey, finding that RWE resulted in direct cost savings of $500K to $20M and time savings ranging from months to years. The primary risk of RWE usage in regulatory submissions is a lack of acceptance by the regulator. This risk may be mitigated by early and open communication between industry and regulators to identify concerns or questions about the proposed use of RWE and working collaboratively to identify the best path forward and minimize uncertainty.

CONCLUSION

Overall, the use of RWE to support regulatory decision-making is supported by many global regulatory authorities. Increased communication between industry and regulators and increased sharing of both successful and unsuccessful RWE experiences can continue to overcome challenges, improve the quality of RWD, and advance the global acceptance of RWE for regulatory decision-making. ■

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APPENDIX. REFERENCES TO GUIDANCE DOCUMENTS[1-26]		
Region	**Guidance Title**	**Reviewed or Current**
United States	Submitting documents using real-world data and real-world evidence to FDA for drugs and biologics guidance for industry	Reviewed version: May 2019 Current version: September 2022
United States	Use of real-world evidence to support regulatory decision-making for medical devices	Reviewed (current) version: August 2017
United States	Data standards for drug and biological product submissions containing real-world data	Reviewed version: October 1, 2021 (*Draft)
United States	Real-world data: assessing electronic health records and medical claims data to support regulatory decision-making for drug and biological products	Reviewed version: September 1, 2021 (*Draft)
United States	Real world data: assessing registries to support regulatory decision making for drug and biological products	Reviewed version: November 2021 (*Draft)
United States	Considerations for the use of RWD and RWE to support regulatory decision-making for drug and biological products	Reviewed version: December 1, 2021 (*Draft)
Japan	Points to consider for ensuring the reliability in utilization of registry data for applications	Reviewed (current) version: March 23, 2021
Japan	Basic principles on utilization of registry for applications	Published March 23, 2021
Japan	Guidelines for the conduct of pharmacoepidemiological studies in drug safety assessment with medical information databases	Reviewed (current) version: March 31, 2014
China	Technical guideline for the application of real world data in clinical evaluation of medical devices	Reviewed (current) version: November 24, 2020
Global - IMDRF	IMDRF/registry WG/N42FINAL: 2017 methodological principles in the use of international medical device registry data	Reviewed version: August 2016 Current version: March 2017
Global - IMDRF	IMDRF/registry WG/N46FINAL: 2018 tools for assessing the usability of registries in support of regulatory decision-making	Reviewed (current) version: March 2018
Global - IMDRF	IMDRF/registry WG/N33FINAL: 2016 principles of international system of registries linked to other data sources and tools	Reviewed (current) version: September 2016
Global - IMDRF	IMDRF MDCE WG/N57FINAL: 2019 (formerly GHTF/SG5/N3:2010) clinical evaluation	Reviewed (current) version: October 2019
Global - IMDRF	IMDRF MDCE WG/N55FINAL: 2019 (formerly GHTF/SG5/N1R8:2007) clinical evidence	Reviewed (current) version: October 2019
Global - IMDRF	Post-market clinical follow-up studies	Reviewed (current) version: March 25, 2021
Canada	Optimizing the use of real-world evidence to inform regulatory decision making	Reviewed (current) version: April 2019
Canada	Guidance on clinical evidence requirements for medical devices	Reviewed version: November 2021 Current version: November 2022
Canada	Elements of real world data/evidence quality throughout the prescription drug product life cycle	Reviewed (current) version: March 5, 2019
Canada	Medical device real-world data and evidence in Canada: an environmental scan highlights	Reviewed (current) version: March 2020
Korea	Guideline on application of the real-world evidence (RWE) for medical devices	No translation available at time of review Current version: February 2019
EMA	Guideline on registry-based studies – draft proposal	Reviewed (current) version: September 2020

APPENDIX. REFERENCES TO GUIDANCE DOCUMENTS[1-26] (CONTINUED)		
Region	**Guidance Title**	**Reviewed or Current**
EMA	Post authorization (human regulatory)	—
Australia	Joint TGA-Medicines Australia guidelines for the design and conduct of company-sponsored post-marketing surveillance studies	Reviewed (current) version: August 24, 2021
Australia	Risk management plans for medicines and biologicals	Reviewed (current) version: March 29, 2019
Australia	Therapeutic Goods Administration international engagement strategy 2021-2025	Reviewed (current) version: July 26, 2021
United Kingdom (MHRA)	MHRA draft guidance on randomised controlled trials generating real-world evidence to support regulatory decisions	Reviewed (current) version: October 30, 2020
United Kingdom (NICE)	Evidence standards framework for digital health technologies	Reviewed version: December 10, 2018 Current version: August 9, 2022
Abbreviations: EMA, European Medicines Agency; IMDRF, International Medical Device Regulators Forum; MHRA, Medicines and Healthcare Products Regulatory Agency; NICE, National Institute for Health and Care Excellence. *Not for implementation until a final version is published.		

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