



APAC *Med*

The voice of MedTech

Advancing Real World Evidence in APAC

KEY CONSIDERATIONS FOR POLICYMAKERS

Examining Real World Evidence in APACMed's Digital Health Committee

The Asia Pacific Medical Technology Association (APACMed) launched its Digital Health Committee in 2020. To date, it has produced analytical research and supporting policy documents on a broad spectrum of topical issues, ranging from regulatory approaches for software as a medical device (SaMD), digital health reimbursement, interoperability and cybersecurity.

Recognizing the foundational role of evidence-based, data-driven decision-making to Asia's medical device landscape, the Committee launched a working group on Real World Evidence in 2021. The group collated industry perspectives through monthly meetings, supplemented by desk research and a literature review. The group also sought to engage regulators and other policy stakeholders, with efforts culminating in a public-private virtual dialogue in November 2021.

These efforts — and this paper — are intended to be a *first* step in understanding the landscape for RWE utilization by the medical device industry, and its regulatory and policy stakeholders, in the Asia-Pacific. The research and foundational conversations held in 2021 are meant to identify trends and highlight best practices emerging in the region, along with challenges to further implementation. These are, of course, complex topics, and APACMed plans additional work in the future to delve into more technical considerations and explore evolving issues with regional stakeholders. Above all, APACMed recognizes that this is a developing, evolving field, and our efforts must therefore be agile and adaptable.



Accordingly, APACMed has identified an initial set of recommendations – all of which fall within the broader areas of potential public-private collaboration, listed below – that policymakers and regulators can undertake to aid the evolution of the RWE ecosystem in national healthcare systems:

➤ Promote Public-Private Partnerships to Build Awareness, Capacity, and Expertise

➤ Embrace RWE's Potential to Improve Patient-Centric Healthcare Decision-making

➤ Enable Access to, and Quality of, Health Data

➤ Build Technical and Human Capacity

➤ Promote International Regulatory Collaboration and Harmonization

Contents

Examining Real World Evidence in APACMed's Digital Health Committee	02
Real World Evidence: Driving Innovation for the MedTech Industry Across Asia	05
Utilizing RWE for Regulatory and Reimbursement Decisions	07
Why RWE Matters for Asia	08
The Current Landscape	10
Key Policy Considerations for Promoting an Enabling Environment for RWE Utilization in Asia	12
Promote Public-Private Partnerships to Build Awareness, Capacity, and Expertise	14
Embrace RWE's Potential to Improve Patient-Centric Healthcare Decisionmaking	16
Enable Access to and Quality of Health Data	20
Build Technical and Human Capacity	26
Promote International Collaboration Among Regulatory Officials	30
Conclusion	32
Appendix: The U.S. FDA's Real World Evidence Program	32
Endnotes	34
Authors and Contributors	36

Real World Evidence: Driving Innovation for the MedTech Industry Across Asia

The evolution of healthcare systems continues to move towards models that are patient-centric, evidence-driven, and value-based. These trends are being driven by innovations in healthcare delivery, digitization of health information systems, and innovative technologies that capture both clinical care and patients' experiences and outcomes. These advances are reshaping not only how patients, physicians, and providers interact at the point of care, they are revolutionizing how policymakers evaluate new therapeutic products for market entry, and inform decisions regarding access and coverage.

The net result for health policy officials who embrace such an evidence-driven approach is more tangible, timely, and actionable insights to enable more targeted policymaking – and to drive positive healthcare outcomes. It brings health systems and their stakeholders closer to what that U.S. National Academy of Medicine has envisioned as a “learning health system.”¹ And a key, fundamental element to advance this analytical, strategic approach to healthcare decision-making will be the broader acceptance and utilization of real world data (RWD) and real world evidence (RWE).

Real world data is the broad term to denote patient and healthcare data generated and collected from sources outside of traditional clinical trials.² With the rapid digitalization of healthcare, new data sources are emerging and there is an exponential increase in health data being generated. These “real world” data sources encompass a wide array of inputs, ranging from electronic health records (EHRs), insurance claims and administrative databases, and patient registries, to wearables and in-home monitoring, health survey data, and beyond.³

Real world evidence are the actionable, practical insights that can be derived from that data with a rigorous study protocol and the use of appropriate analytical methods. As RWD becomes more prevalent and the analytical methods more refined, RWE is becoming a valuable tool to inform policymakers. This paper offers suggestions, therefore, on a question of growing importance:

How can regulators and other policymakers best utilize real world data, and insights drawn from real world evidence, to inform their decision-making processes?

The value of utilizing RWE is well-documented.⁴ Greater utilization of RWE by the policy community and regulators can spur innovation in the healthcare field, particularly for the medical technology sector, and drive more patient-centric, responsive care. Among myriad other positive impacts, utilization of RWE can:

- **Generate practical, actionable evidence at greater efficiency (in terms of time and, often, optimizing overall cost), when compared to traditional clinical trials;**
- **Accelerate the delivery of innovative medical products to market, by informing regulatory submissions with evidence on the actual practice of medicine and health care delivery;**
- **Improve access to care by demonstrating the safety, efficacy, and effectiveness of medical products, particularly to support adoption, funding and reimbursement decisions;**
- **Uncover new indications and label expansions for medical products, where they may have significant potential impacts for patient care; and**
- **Paint a more realistic picture of how medical treatments and technologies perform in a practical, “real world” setting.**

Moreover, RWE can provide a richer context of the patient journey and how medical devices fit into that journey. Patients (and physicians) don't always use medical products in the exact way they were intended, or as they are utilized in clinical trials. And the formal endpoints in clinical trials may not always account for the full spectrum of patient perspectives. RWE can give a clearer perspective of patient behavior and use of medical devices in a practical setting, outside of the hospital or clinic.

Unlocking the benefits of RWE will be a key determinant for innovation in the next generation of healthcare policymaking. All healthcare stakeholders need to collaborate to shape these policies — from regulators and healthcare policy decision-makers, to industry, academia, providers and patient groups, and beyond. Countries in Asia, particularly, stand to gain from smart engagement and leadership related to this evolving trend in healthcare decision-making.

Utilizing RWE for Regulatory and Reimbursement Decisions

The utilization of RWE for many *post-market* applications is growing. This includes post-marketing surveillance and safety monitoring, and the review of conditional pricing decisions or to establish coverage regimes after products have successfully been marketed in a country. But to-date, regulators have generally proven less inclined to utilize RWE for premarket approvals and funding considerations.

As part of its review of its use of RWE for the regulation of medical devices, Australia's Therapeutic Goods Administration (TGA) recognized this aspect, noting that while RWE “already underpins TGA's post-market safety work on medicines, vaccines, and medical devices there is a less well-developed understanding both internally and externally of how it can be used in pre-market approval of products.”⁵

Enabling greater use of RWE at earlier stages of the regulatory engagement process – for both regulatory approvals and access/reimbursement decisions – could yield significant impacts, including:

- **Streamlining the approval process by delivering patient- and market-centric insights into the value and clinical utility of technologies for specific populations;**
- **Providing insights into patient sub-populations that may not be reflected in the design and implementation of traditional clinical trials;**
- **Complementing and augmenting evidence from clinical trials by enabling the emulation of external control arms;**
- **Reducing or eliminating the need for lengthy and resource intensive clinical trials, especially for instances in which traditional clinical trials may be impractical or excessively challenging to conduct (e.g., ethical issues in conducting clinical trials with pediatric populations); and**
- **Accelerating speed to market and potentially reducing the cost of evidence development for devices and their modifications, which ultimately can reduce the cost of delivery to patients.**

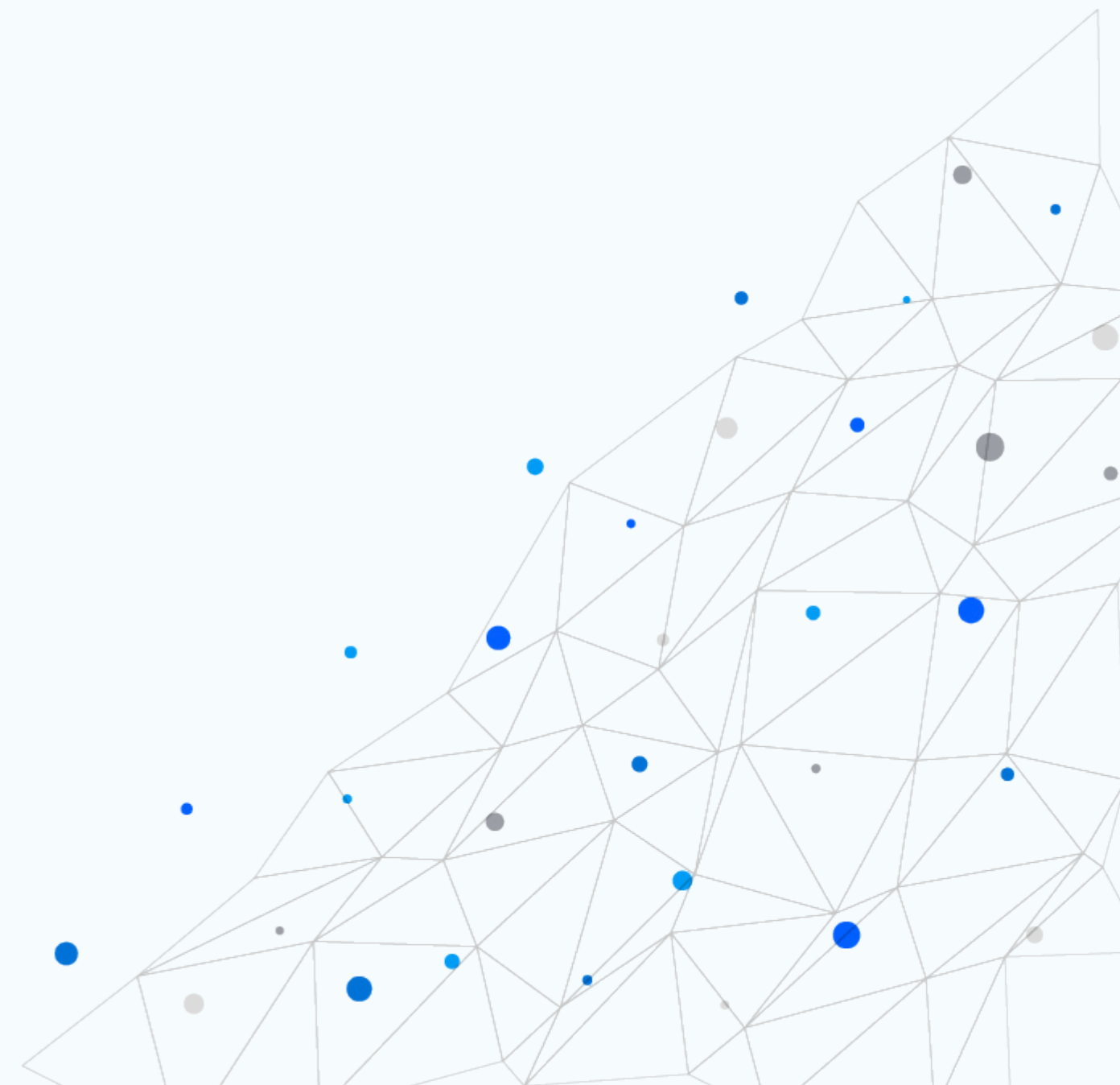
Why RWE Matters for Asia

Greater incorporation and utilization of RWE in Asia is a patient-focused imperative. At a macro level, such efforts will help bring innovative, life-enhancing and life-saving technologies to market faster, while also providing critical evidence to ensure such products and treatments are widely accessible to Asian patients. But importantly, the use of RWE can help inform regulators with more focused, actionable insights about the *specific patient populations* they are meant to serve. As noted by a group of academic researchers in assessing the landscape in Asia:

“RWD are particularly relevant in Asia where there is often a greater reliance on clinical effectiveness data from non-clinical trial sources (such as observational studies or disease registries) for regulatory and reimbursement purposes than in the United States or Europe for two reasons. First, only around 17% of the clinical trials are conducted in Asia due to barriers related to financial and human capacity, ethical and regulatory systems, lack of research environment, and operational issues. Second, there could be an under-representation of Asian population in pivotal RCTs. These reasons are crucial because medical treatments need to reflect the biological variations, for example, differences in body weight or pharmacokinetics and/or pharmacodynamics due to different genetic makeups between Caucasians and Asians, and the non-biological variations, for example, differences in local clinical practice guidelines driven by budget and resource constraints.”⁶

Diseases incubate, spread, and impact patients differently in Asia than in the U.S. or Europe. Not only are the vast majority of clinical trials conducted *outside of Asia* – for a litany of reasons, ranging from human capacity and training needs, to operational business concerns and legal and regulatory obstacles – but within those global studies, Asian patient attributes are often underrepresented. Further, results from large-scale clinical trials may not always fully capture the practical, “real world” implications of how medical devices operate in the field.

RWE can fill this gap for policymakers in the region, helping to ensure that the demographic, biological, genetic and other nuanced attributes of Asian citizens are considered when regulatory and policy decisions that impact this region are being made.





The Current Landscape

The utilization of RWE in the medical technology ecosystem – to include industry and manufacturers, as well as regulators, and other government policymakers – remains nascent in Asia. After reviewing available medical literature and other open-source writings on the evolving landscape for RWE, as well as conducting stakeholder interviews and through the discussion in the November 2021 virtual policy dialogue, the APACMed working group noted several topline themes:

The biopharmaceutical industry has traditionally been more active than the medical device industry in its use of RWE in regulatory and policy submissions

There is substantial documentation of RWE incorporated into regulatory submissions and considered for reimbursement and coverage actions related to pharmaceuticals. Despite the fact that the U.S. FDA published guidance on RWE for medical devices prior to its guidance for the pharmaceutical industry, publicly-available information and submissions related to medical devices that incorporates RWE is much more limited – particularly outside of the United States.

RWE integration for regulatory and policy decision-making is an emerging practice in the Asia Pacific

While also true in other regions, formal guidance and tangible case studies of medical device authorities relying upon RWE for review processes are hard to find within Asia, as are public-private initiatives dedicated to the advancement of RWE utilization. Asia lags in its development when compared to efforts in the U.S. and Europe. As discussed herein, certain factors – particularly related to data issues – present challenges in the Asian context.

As medical device authorities in Asia are beginning to formalize their approaches for RWE, industry and stakeholder engagement will be critical

Leading regulators across Asia – including NMPA in China, Japan PMDA, Korea MFDS and Taiwan FDA – are beginning to issue formal guidance on how RWE will be utilized for review and coverage decision-making. Much of this guidance has come, however, just in recent years. New mechanisms and formalized public-private partnerships will be critical to positively impact this still-evolving regulatory and policymaking environment in Asia.

Key Policy Considerations for Promoting an Enabling Environment for RWE Utilization in Asia

Governments and regulators across Asia are at different stages of their journey with respect to utilization of RWE for regulatory and reimbursement decision-making. Some have already issued formal guidance and are advancing pilot projects to demonstrate RWE's benefits and capabilities; others are still at the early stages of those pathways. As this conversation evolves, policy interventions and recommendations must be tailored and fit-for-purpose for the individual markets, while also seeking opportunities to harmonize where appropriate.

Accordingly, the following are key policy considerations that governments should address on their journey to advance the utilization of RWE in healthcare decision-making. They are not meant as governmental or regulatory actions that can be implemented immediately. Rather, they reflect broader considerations – and fundamental questions – that will impact the evolution of the RWE ecosystem in national healthcare systems.

Importantly, policymakers can spur progress by recognizing these issues and committing to collaborate with a broad spectrum of stakeholders to address them. Clear, top-down signals to grapple with these challenges will incentivize a broader ecosystem to partner with government and, ultimately, offer innovative frameworks and solutions to these challenging questions.

To promote a national healthcare ecosystem that enables the utilization of RWE to its maximum potential, APACMed recommends that governments and policymakers:



➤ Promote Public-Private Partnerships to Build Awareness, Capacity, and Expertise

- Invest in, or promote innovative PPP models that convene diverse stakeholders to advance the development of an RWE “ecosystem”.

➤ Embrace RWE's Potential to Improve Patient-Centric Healthcare Decision-making

- Governments should issue clear, public commitments to explore greater utilization of RWE and issue formal guidance on the use of RWE in regulatory submissions and funding & reimbursement processes for the medical device industry.
- Policymakers should define real world data in a broad, inclusive manner that does not preclude the utilization of new and emerging sources of health data.
- Policymakers should incorporate RWE utilization into other regulatory and policy frameworks for digital health.

➤ Enable Access to, and Quality of, Health Data

- Develop standards and harmonized submission templates for healthcare data that can be submitted and utilized.
- Utilize best practices and reference models developed by international standards bodies and other policy-setting organizations.
- Encourage the development of codes of conduct and other voluntary frameworks to promote the trusted use of and access to health data.

➤ Build Technical and Human Capacity

- Promote investment in underlying health ICT infrastructure, and promote interoperability and sharing of data among national and sub-national systems.
- Recognize the importance of human capacity-building and skills development related to data proficiency.

➤ Promote International Regulatory Collaboration and Harmonization

- Engage in regional and global forums, societies and consortia, and formal collaborations dedicated to advancing sound policymaking through RWE – and, if needed, launch Asia-centric efforts aligned with this vision.

Promote Public-Private Partnerships to Build Awareness, Capacity, and Expertise

A foundational effort that all stakeholders within a national healthcare system should embrace is the promotion of unique, impactful public-private partnership (PPP) models, that focus on strengthening the ecosystem for generation and utilization of RWE. This is a critical first step that all countries – no matter where they currently stand on their ‘journey’ of RWE utilization – can immediately begin to implement.

Invest in, or promote innovative PPP models that convene diverse stakeholders to advance the development of an RWE “ecosystem”.

Given the rapidly evolving nature of medical technology, it is imperative that governments learn from industry, academia, and healthcare providers – and vice versa. Adopting an “ecosystem approach” that convenes relevant experts in a platform that provides for structured, ongoing dialogue and information sharing can yield tremendous insights.

The U.S. FDA’s engagement of the Medical Device Innovation Consortium (MDIC), a 501(c)(3) public-private partnership that promotes patient access to innovative technologies, to establish the NEST coordinating center (NESTcc) is a good example. The NESTcc was envisioned as a neutral, multistakeholder platform with a mission to “accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence and innovative research.”

NESTcc’s governing committee spans a diverse set of stakeholders, including government officials, patient representatives, clinicians, industry associations, health systems, and payers. Its work to-date has included research and demonstration projects to learn about “opportunities and challenges of using RWE to meet regulatory and coverage requirements,” as well as efforts to establish data quality standards, and the establishment of a shared “data network” to facilitate research among trusted collaborators.

The China Real-World Healthcare Data Collaboration (CRHEDO) project also promotes such a holistic, collaborative approach in this key market for medical technology. Sichuan University’s Chinese Evidence-based Medicine Center has engaged industry, regulators, trade associations and other stakeholders under the CRHEDO banner. The project draws upon databases from major

tertiary hospitals that serve more than 18 million patients, to assess the utility of RWE in enabling faster, more targeted policy, and medical decisions. As part of its workplan, the CRHEDO initiative has coordinated research among participating entities and has organized capacity building events, including RWE-related seminars.

Asia Pacific regulators would benefit from a regional partnership dedicated to advancing RWE utilization. National and sub-national programs provide a structured platform for research, collaboration, and sharing of best practices. Those initiatives could then feed into a regional APAC model to promote regional harmonization.

Asia Pacific regulators would benefit from a regional partnership dedicated to advancing RWE utilization. National and sub-national programs, like China’s CRHEDO project, are useful to convene stakeholders and provide a structured platform for research, collaboration, and sharing of learnings and best practices. Those national initiatives could then feed into a regional APAC model, perhaps modeled after the NESTcc structure, to promote regional harmonization and capacity building among Asian nations.

Embrace RWE's Potential to Improve Patient-Centric Healthcare Decision-Making

To help promote a regulatory and policy environment that will advance the utilization of RWE, policymakers should signal a clear commitment and vision for its use.

Governments should issue clear, public commitments to explore greater utilization of RWE and issue formal guidance on the use of RWE in regulatory submissions and funding & reimbursement processes for the medical device industry.

Clear framework/guidance and official announcements from policymakers that note the value and utility of leveraging RWE for healthcare decision-making will send an important signal to the market, and to the broader ecosystem of healthcare stakeholders. Such a commitment from Asian governments will help attract new partners, resources, and expertise that can collaborate to develop human capacity, incentivize investment in products or necessary information and communications technology (ICT) infrastructure, or launch new public-private initiatives.

Clear guidance and official announcements from policymakers that note the value and utility of leveraging RWE for healthcare decision-making will send an important signal to the market, and help attract new resources, expertise and partners to collaborate and launch new initiatives to advance RWE.



The 21st Century Cures Act, enacted by the United States Congress in 2016, provides a clear example. The Act required the U.S. FDA to create a program to evaluate the use of RWE to: (a) help support the approval of a new indication for an already-approved drug; and (b) help support or satisfy post-approval study requirements. The Cures Act also mandated that the U.S. FDA publish a framework to implement the RWE Program for drugs and biologics that describes: (a) the sources of RWE; (b) the gaps in data collection activities; (c) the standards and methodologies for collecting and analyzing RWE; and (d) the priority areas, remaining challenges, and potential pilot opportunities. And when releasing its 2017 guidelines for RWE and medical products, the U.S. FDA stated that, "By recognizing the value of RWE as an important contributing factor for understanding and regulating medical devices, we hope to encourage the medical community to learn more from routine clinical care than we do today."⁷

Within Asia, several regulatory authorities have been first-movers with respect to formal guidance. Korea's Ministry of Food and Drug Safety released early guidance in 2019. And in 2020, China's National Medical Products Administration (NMPA) issued its Technical Guideline on Real World Data Used in Medical Device Clinical Evaluation. The Guideline offered: (a) definitions of real world data and real world evidence; (b) advantages and limitations of real-world research; as well as (c) common sources and considerations for quality of such data, along with eleven common situations where RWE can be utilized for clinical evaluation processes. Importantly, under the Technical Guideline, RWE still may only serve as supplementary data for regulatory submissions; but this action by NMPA, along with other support for the RWE ecosystem, marks an evolution in the regulatory approach in China's healthcare system.

Promoting the utilization of RWE within legislation and formal regulation should be the goal; but governments need not wait for such formal processes to play out, before signaling their intent in the field – policy statements and initiatives can also have meaningful impact. In the United Kingdom, the National Institute for Health and Care Excellence (NICE) issued a statement of intent to work on RWE guidance, thus sending a message to its regulated entities and stakeholders that it was serious about developing the RWE ecosystem in the U.K.

While reviewing its regulatory landscape related to RWE utilization and patient-reported outcomes in the regulation of medical devices, the Therapeutic Goods Administration (TGA) in Australia has noted the need to sharpen its messaging regarding RWE – and provided a clear signal that it intends to work with stakeholders, both domestic and international, to do so. The TGA's 2021 review of RWE utilization found "there is ambiguity (internally and externally) surrounding our usage of RWE, which potentially limits its adoption" and that stakeholders sought clarity of communication on how TGA accepts and use patient-reported outcomes.⁸ The TGA committed to improve its communications and transparency regarding its use of RWE, as part of its ongoing reform efforts.

Policymakers should define real world data in a broad, inclusive manner that does not preclude the utilization of new and emerging sources of health data.

There is no standardized, commonly-accepted definition for what constitutes real world data in the healthcare context.⁹ Most offered definitions reference data that is generated and collected outside of the scope of randomized controlled trials (RCTs). The U.S. FDA, for example, defines RWD as “data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources”. It also makes a distinction between RWD and RWE, which is considered “the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD”. As noted above, China’s NMPA has outlined its own definition of RWE in its 2020 Technical Guideline. But there is no harmonized, consensus definition that clarifies exactly how far the scope of real world data should reach.

Policymakers should endeavor to be inclusive of the broadest possible range of potential real world data sources for regulatory and policy uses. Such a formal definition should not only incorporate “traditional” sources of RWD, but also new sources of data emerging from the digital health revolution.



Formal guidance, policy documents, and RWE initiatives by policymakers should endeavor to be inclusive of the broadest possible range of potential real world data sources for regulatory and policy uses. Such a formal definition should not only incorporate “traditional” sources of RWD – e.g., disease or product registries, EHRs, insurance claims databases, and public health data – but should also be welcoming of new sources of data emerging from the digital health revolution. This includes data from mobile devices and wearable technologies, in-home digital solutions, telemedicine and other emerging technologies. Categorization of RWD sources should, to the extent possible, be written in an adaptive manner so that new sources of health data can be accommodated as they come online and into the marketplace.

Policymakers should incorporate RWE utilization into other regulatory and policy frameworks for digital health.

When developing regulatory guidance and policy frameworks for other aspects of digital health, policymakers should recognize the critical role that RWE can play in validating the performance of digital-intensive medical products in the marketplace. Australia’s TGA, for example, has noted that RWE utilization “is a critical and necessary component to understanding and enhancing the performance” of emerging technologies, such as gene, cell and tissue therapies, as well as software-based medical devices. And for software as a medical device (SaMD) technologies in particular, RWE can provide ongoing, adaptive validation to support agile change management procedures, as part of a holistic, “lifecycle approach” for regulation of such products.¹⁰

The formulation of risk-based approaches for digital health regulation should allow for greater utilization of RWE by health policy decision-makers. Providing clear pathways for market entry and coverage decisions for digital health products, while ensuring robust safeguards to balance patient privacy concerns, will help generate more actionable data and RWE insights to understand how devices perform in actual care settings, strengthen the delivery of patient care and, ultimately, move toward the concept of a “learning health system.”¹¹

Enable Access to, and Quality of, Health Data

The digital health revolution and new medical technologies are contributing to a wealth of newly-generated health data, including from patient-recorded mechanisms and non-traditional sources. This enables new insights into the patient journey, and informs policy processes accordingly. But to enable the effective, trusted use of RWE by authorities, standards need to be established regarding the sources of data, acceptable data quality, and analytical methods that may be used to derive RWE-driven insights.

There is a rapidly-growing body of research and academic literature dedicated to health data and its utilization by regulators. Much of this complex discussion is beyond the scope of this paper. Further, much of the policy and regulatory complexities are within the purview of data protection authorities, and the broader global data privacy conversation.

That said, regulators and healthcare policymakers should engage with stakeholders to address two fundamental challenges that pose hurdles to greater utilization of RWE: access to health data in a standardized, consistent format, and quality of the health data intended to be used for regulatory and reimbursement decisions.

Efforts must be made to ensure that relevant health data can be accessed and utilized to drive more personalized care and more targeted policy interventions. Government has a top-down function here, in clearly articulating what kind of data is sought, how it will be used, and how sponsors should submit such data.

Stakeholders must address the quality gap by ensuring that the data submitted for regulatory and policy needs is fit-for-purpose for use by authorities.



Once those sources of data are identified and integrated into the RWE ecosystem, all stakeholders must address the quality gap by ensuring that the data submitted for regulatory and policy purposes is fit-for-purpose for use by authorities – that is, the data must contain all the critical factors needed for proper evaluation by medical authorities. Standards need to be set to ensure that all stakeholders understand the criteria to ensure the data they utilize is “regulatory grade.”

As a starting point, policymakers may seek to address these challenges by collaborating with experts and stakeholders to advance the following goals:

Develop standards and harmonized submission templates for healthcare data that can be submitted and utilized.

Policymakers should begin by clarifying what types of real world data, and the evidence drawn from such data, will be used to support premarket regulatory decision-making – e.g., to establish patient characteristics, evidence of interventions, comparators between products, or for outcomes (including patient reported outcomes) related to effectiveness and safety. Harmonized, consistent approaches – including through reference to international standards – would advance the ability of the medical technology industry to collect, assess, and utilize relevant data in its regulatory and policy submissions.

While technical considerations regarding the development of such standards are beyond the scope of this paper, this is an area ripe for engagement and collaboration between government and industry.

China's health data landscape is instructive. The country is rich in health data sources, spanning health data platforms from regional networks, to well established registries, EHR repositories, and claims databases. But observers have noted challenges in utilizing such data, including due to ambiguity around the approval process to access health datasets, as well as patient privacy and the evolving, often ambiguous, regulatory environment for data protection.

In its technical guidance on RWE, the NMPA explicitly highlighted challenges in ensuring data quality, including the lack of standardized sources of data, as well as issues including representativeness, completeness, accuracy, authenticity, consistency, and repeatability, as well as the potential for bias. All of these pose hurdles for the ability of RWE to ever supplant RCTs in their entirety for policymaking purposes.

One potential solution that has been proposed is the development of so-called “common data models.” The Observational Health Data Sciences and Informatics (OHDSI) program¹² is one initiative that has helped develop such a model, which is intended to help encode and store clinical data in a standardized manner. Use of common data models allows the same research queries to be addressed consistently across different sources, databases and geographies, drawing data from a large number of observed patients, thus improving the feasibility of large-scale international observational research.¹³ These models can also address patient privacy concerns by incorporating data use and sharing agreements, as well as access control measures. But common data models are not without their own challenges, such as lack of identification of specific medical devices (make/model), standardized definitions of outcomes/endpoints, and actual mapping to common terminology codes.

As a practical first step, regulators can encourage pre-submission meetings and communication with medical device applicants to discuss the inclusion of RWE.



As a practical first step – short of developing and / or recognizing formal data standards – regulators can encourage pre-submission meetings and communication with medical device applicants to discuss the inclusion of RWE. Australia’s TGA has committed to taking this step as part of its ongoing reform of RWE utilization, noting that such early conversations can help clarify what types of RWD are available and what insights and evidence from that data may be appropriate to use in a regulatory submission.

Utilize best practices and reference models developed by international standards bodies and other policy-setting organizations.

Regulators and policymakers do not have to undertake this challenging work on their own. There are numerous global organizations that are undertaking the challenging, yet critical work of developing frameworks for health data access, utilization, and security. Policymakers within the medical technology realm should engage with, and seek to learn from these efforts.

The ongoing body of work produced by researchers involved in the OHDSI collaborative mentioned above is instructive. An ongoing Special Task Force on RWE in healthcare decision-making, convened jointly by the Professional Society for Health Economics and Outcomes Research (ISPOR) and the International Society for Pharmacoepidemiology (ISPE), also has produced a wealth of research and resources. The joint ISPOR/ISPE task force was commissioned to recommend policies related to “the planning, execution, and dissemination of RWD studies that help to assure the public of the integrity of the research process and enhance confidence in the RWE produced from RWD studies.”

The NESTcc Research Methods Subcommittee is currently revising the *NESTcc Research Methods Framework – A Practical Guide to RWE for Medical Devices*. It is intended as a pragmatic, methodological framework or “living playbook” that can be used by all stakeholders across the NESTcc medical device ecosystem, aiding them in designing, executing, and evaluating pre- and post-market studies based on RWD and highlighting device-specific considerations in benefit/risk studies. The Research Methods Framework will emphasize two key principles in the design of RWE studies: (1) pre-specification of study design in order to avoid the fact or appearance of selective data mining; and (2) close attention to potential confounders and how they will be addressed in the study design. The Framework organized its content into the form of a study protocol in order to provide guidance in a practitioner-friendly, step-by-step fashion.

Similarly, the NESTcc Data Quality Subcommittee is currently revising the *NESTcc Data Quality Framework* to identify principles, standards, and best practices that will ensure consistent and appropriate assessment of data quality to assess fit-for-purpose in medical devices. This “living playbook” will identify standards to ensure consistency, accuracy, completeness, and traceability of the RWD source to be used by all stakeholders, including regulators and industry.

Finally, the concept of regulatory reliance may also play an important role in this setting, particularly for many Asian regulatory authorities that do not have the capacity or resources to develop their own frameworks. The TGA in Australia has explicitly referenced guidance published by the International Medical Device Regulators Forum (IMDRF), noting it “may be adopted as appropriate” for the Australian market, and committed to review and potentially adopt “select guidance documents from comparable overseas regulators,” rather than “imposing bespoke Australian requirements” on international manufacturers.

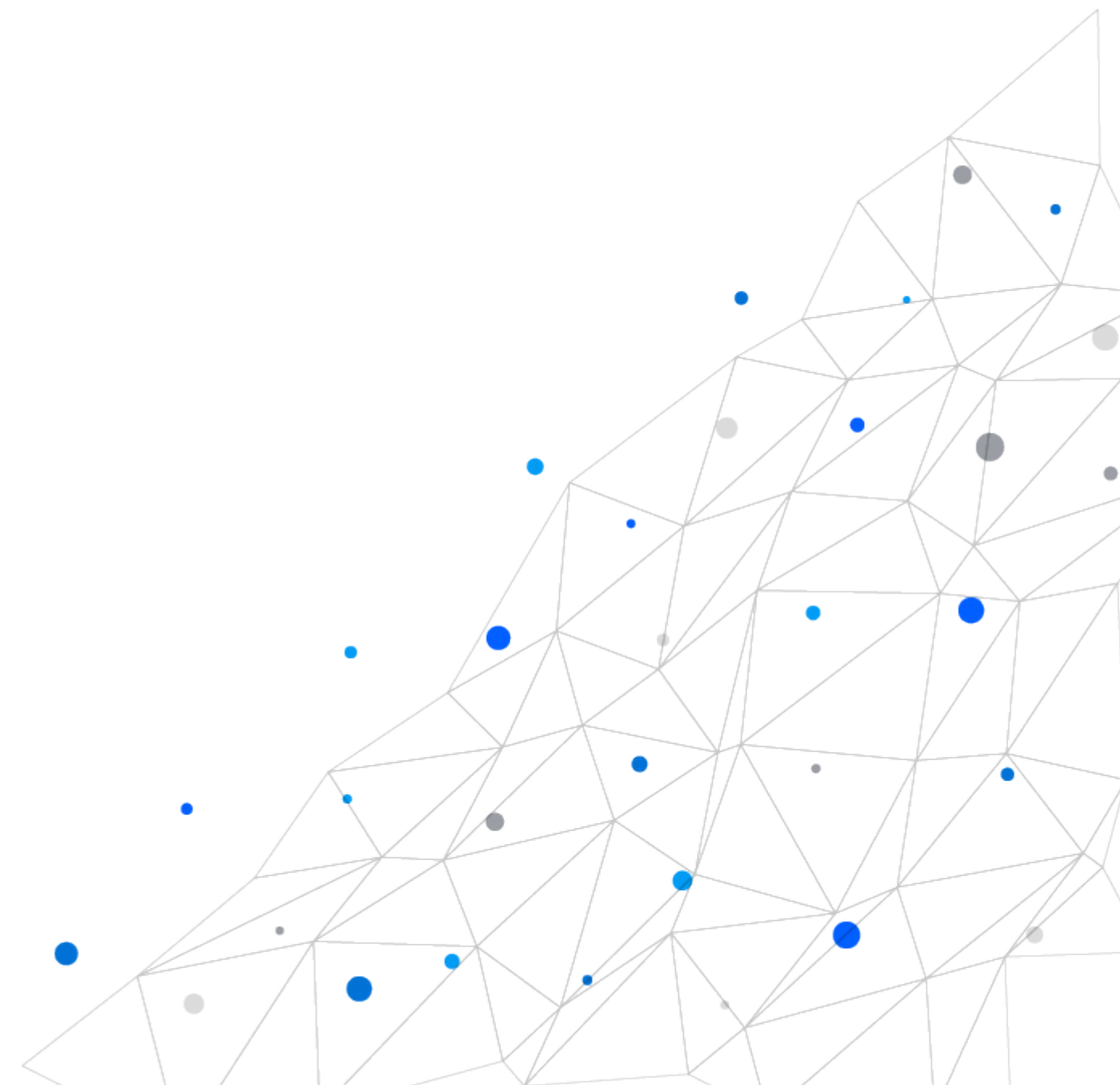
Encourage the development of codes of conduct and other voluntary frameworks to promote the trusted use of health data.

Codes of conduct¹⁴ and other voluntary mechanisms developed by industry and/or external stakeholders, which contain clear obligations for accountability, transparency, and security, can promote a more trusted ecosystem for the generation and use of real world data. When developed by consensus among a broad set of stakeholders, such frameworks can incentivize actors across the healthcare spectrum to more effectively manage privacy and security aspects of, and incorporate ethical considerations related to, patient-reported data. Elements of such codes of conduct could include efforts, for example, to ensure patient equities are represented when data policies are promulgated; to mitigate the potential introduction of bias into datasets; or to ensure patients exercise informed consent related to the collection, use, and sharing of their health data.

When developed by consensus among a broad set of stakeholders, codes of conduct and other voluntary frameworks can incentivize actors across the healthcare spectrum to more effectively manage the privacy, security, and ethical considerations related to patient-reported data.



Numerous global experts and organizations have called for the development of global norms and ethical standards regarding how health data can be safely utilized and leveraged for public health outcomes.¹⁵ This is another space where multi-stakeholder collaboration, bringing together government, academic, and private sector expertise and perspectives, is absolutely critical.



Build Technical and Human Capacity

Just as the sources, quality, and trust in the data, itself, are foundational to building an enabling ecosystem for RWE, so is a health system's ability to collect and understand that data. Without investments in the underlying health ICT infrastructure, including efforts to ensure interoperability between datasets held by varying stakeholders and custodians of varying datasets, countries will not realize the full benefits of RWE. Similarly, governments must take steps to ensure that the staff within the regulatory agencies and policy decision-making organizations have the requisite technical skills to properly understand, judge, and utilize the insights offered by such health data.

Promote investment in underlying health ICT infrastructure, and promote interoperability and sharing of data among national and sub-national systems.

Many countries are rapidly investing to modernize their health systems with technologies to better collect, store, analyze and share health data. As they do so, they must work to ensure that the data networks of various healthcare systems can be integrated – and interoperable – to allow the sharing of data across multiple care settings. Systems that can readily incorporate data across primary, secondary, and tertiary care settings, while also allowing for the intake of patient-reported data (e.g., from apps or wearables) and data from other devices and non-clinical sources, will set the standard for care in the coming years. APACMed has developed a report on medical device interoperability and recommendations for relevant standards and policy frameworks that health officials may use to promote interoperability.

The myriad technologies, solutions, and firms that aim to address the health ICT market are beyond the scope of this paper. Governments have a role, however, in promoting policy frameworks that will allow the responsible sharing of, and collaboration with the data collected by such systems. At a macro level, Singapore's "Health IT Master Plan," or HITMAP, is an example of a strategic health technology roadmap meant to guide national investments in the healthcare sector. One of HITMAP's seven pillars includes building a strong foundation for the use of data analytics in healthcare, including the infrastructure and governance models needed to unlock insights and drive more personalized patient care.

Regulatory sandboxes are one approach that are gaining increased attention. The French data protection authority ('CNIL') launched such a sandbox initiative in 2021 focused on innovative

startups and projects in the healthcare sector that utilize personal health data. The call for applications sought projects that tackle novel data protection issues, with a specific interest in those related to access to research data, the sharing of data between health professionals, and innovative AI solutions.

Certifying trusted intermediaries to manage the aggregation of, access to, and use of health data sets is another novel approach. Japan's 2017 "Medical Big Data Act" (or "Next-Generation Medical Infrastructure Act") enabled the creation of "certified medical data agents," which are private entities, accredited by the government to aggregate, store, and secure data sets provided by hospitals, clinics, employers and other health data custodians. Organizations – including those from industry, academic and research institutions, or administrative bodies – could apply to the medical data agent for access to the anonymized data for research purposes. This model is meant to encourage the safe, responsible use of health data for R&D, while ensuring oversight and guaranteeing that robust privacy and security safeguards are employed during the process.

A regulatory innovation that is foundational for the interoperability and sharing of health data produced by medical devices is the implementation and recognition of unique device identifiers (UDIs). Regulators must implement UDI systems in a harmonized, consistent fashion.



Another regulatory innovation that is proving to be foundational for the interoperability and sharing of health data produced by medical devices is the implementation and recognition of unique device identifiers (UDIs). The UDI system – adopted by the U.S. FDA, but with increasing global use and adoption – establishes a “dedicated global identification protocol to unambiguously identify medical devices in the healthcare supply chain.”¹⁶ The UDI information, in the form of a unique numeric or alphanumeric code, is displayed on the device as both human-readable data and machine-readable data; a centralized public database of registered UDI information was also developed to serve as a reference catalog and repository. As more products incorporate an UDI, driven by a regulatory mandate to do so, the ability to verify the origin and accuracy of many data sources will improve.

Regulators must implement the requirement for devices to have an UDI, however, in a harmonized, consistent fashion. This can be done through reference to internationally-accepted UDI coding systems (e.g., GS1, HIBCC, or ICCBBA) and labeling requirements. The IMDRF has made recommendations on how a globally-harmonized and automated UDI data submission process could be implemented.¹⁷ Importantly, all parties within the healthcare system must be encouraged to document the UDI for the devices they use – particularly at the point of care, and not just for supply chain applications – in order to realize the full promise of UDIs, and their ability to help promote robust health data ecosystems. Full implementation in this manner will require collaboration between government, industry, and health systems stakeholders (providers, hospitals, et al.).

Recognize the importance of human capacity-building and skills development related to data proficiency.

No matter how much high-quality health data is generated, insights from that data will not be utilized effectively without skilled practitioners in regulatory and policymaking bodies who understand how to effectively analyze and comprehend the data provided. Governments must therefore prioritize education and training initiatives to develop a regulatory workforce with the requisite skills to fully analyze real data. This public commitment must include the allocation of financial resources, where possible.

An APACMed member company representative in Japan reported anecdotally about the challenges in the market. The Japanese government has invested significantly to establish world-class, interoperable health data-sharing platforms. This includes high-profile efforts such as the Rational Medicine Initiative, launched in 2017 with the goal of ensuring Japan’s healthcare ecosystem is “strictly evidence-based”, as well as the Medical Information Database Network, or MID-NET, which was expected to contribute data analyses toward regulatory decision-making. Nevertheless, this

representative noted that regulators simply “don’t have the necessary knowledge or analytical know-how to utilize the data and make informed decisions” from it. Accordingly, the burden of proof has shifted to the private sector in Japan, to make the case for how certain real world data and insights should be utilized in the regulatory process.

Governments should proactively invest in workforce skills initiatives that help provide regulatory and policy officials with the competencies needed to make informed, data-driven decisions. This can include establishing data science/data analytics bureaus within the relevant ministry or regulatory authority, as well as hiring experts with the relevant data proficiencies to supplement regulatory staff. Another useful resource is to commission an RWE Advisory Committee of external, expert stakeholders, who may counsel policymaking organizations on key issues related to RWE utilization and integration.

Governments – in partnership with other stakeholders – should proactively invest in workforce skills initiatives that help provide regulatory and policy officials with the competencies needed to make informed, data-driven decisions.

But the onus should not fall on government, alone. Partnerships with universities, associations and other expert groups, and industry programs can play a vital role. The U.S. FDA adopted such a collaborative approach with their unique “Experiential Learning Program.” This advanced training program aims “to close the knowledge gap between emerging and innovative technology and the pre-market review of the resulting medical devices,” by allowing regulatory review staff (within CDRH) to conduct visits to research, clinical, manufacturing and healthcare facilities to see how medical devices are designed and utilized. The ELP is intended to further CDRH’s commitment to “understanding current industry practices, innovative technologies, regulatory impacts and needs, and how patient perspective and quality systems management advances the development and evaluation of innovative devices and monitor the performance of marketed devices.”

Promote International Regulatory Collaboration and Harmonization

Finally, regulators and policymakers across Asia should collaborate with their global peers to share information and best practices related to RWE utilization. Engagement in regional and global forums on the topic is critically important. If government-to-government venues for engagement are not as robust in Asia as elsewhere, new initiatives and collaborations should be launched.

International regulatory collaboration is considered a foundational tenet of “good regulatory practices,” which are the systems, tools, and methods for improving the quality of regulations. *The ASEAN Guidelines on Good Regulatory Practices*,¹⁸ for example, list collaboration among regulators as a core principle. Such collaboration, information sharing, and capacity building engagement is particularly important for emerging topics such as RWE.

Engage in regional and global forums, venues, and collaborations dedicated to advancing sound policymaking through RWE – and, if needed, launch Asia-centric efforts aligned with this vision.

These government-led efforts can be bilateral. The U.S. FDA and the European Medicines Agency (EMA), have committed to collaborating on RWE, for example, by exchanging information and cooperating on methodologies to optimize the use of RWE to support regulatory decision making throughout the medical product lifecycle.

But regional and global initiatives provide the opportunity to collaborate at scale. Pharmaceutical regulators, working under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), provide a recent relevant example. Amid the global pandemic, the ICMRA – with leadership from Health Canada and EMA, alongside experts from the World Health Organization – launched a series of collaborative workshops to discuss “the importance of global collaboration and information sharing in relation to real-world evidence that can be used to facilitate regulatory decision-making on COVID-19 treatments and vaccines.”¹⁹ The participants noted that “closer collaboration between regulators worldwide allows timely sharing of data, knowledge and tools, which can benefit patients globally.”

Similarly, the National University of Singapore’s Initiative to Improve Health in Asia (NIHA) has led a robust workplan and convened regional regulators and experts to develop a landscape analysis

and recommendations regarding the use of artificial intelligence (AI) in healthcare. The resulting whitepaper²⁰ made several recommendations to address the gaps in regulatory capacity related to healthcare AI, including the need for coordination among national regulatory authorities in the Asia-Pacific in their approaches and frameworks for AI-based technologies.

Regional forums exist to advance pan-Asian collaboration, capacity building, and trainings on RWE. And where forums are lacking or not able to dedicate sufficient attention and resources to the understanding and promotion of RWE, new platforms may be launched.

Regional forums exist that can be leveraged for such pan-Asian collaboration on RWE. Relevant engagement can be advanced through the IMDRF or the Asian Harmonization Working Party, for example. The Health Working Group and Life Sciences Innovation Forum within the Asia-Pacific Economic Cooperation (APEC) forum are similar venues where capacity building efforts dedicated to RWE and related technical trainings could be launched.

Asian regulators and policymakers should actively participate and engage in these policy coordination venues, alongside their partners in industry, academia, patient groups, civil society, and elsewhere. And where forums are lacking or not able to dedicate sufficient attention and resources to the understanding and promotion of RWE, new platforms may be launched. The importance of RWE, and the potential benefits to Asian patients and health systems from its utilization, demands it.

Conclusion

Greater utilization of RWE – particularly in regulatory and policymaking processes – will accelerate the positive trend toward patient-centric, evidence-driven, and value-based healthcare decision-making. The acceptance of RWE in these processes, however, remains an emerging practice, with many challenging issues related to data quality and standards, stakeholder engagement, and medical technology regulatory practices and coverage assessments, among others, yet to be resolved. This is particularly true for governments and healthcare ecosystems across Asia.

As with many challenging policy issues, we believe a critical first step is to ensure that robust mechanisms exist for public-private dialogue and collaboration. Bringing together a wide spectrum of voices – from government to industry, inclusive of academics, providers, and patient voices – will help Asian healthcare stakeholders and ecosystems, collectively, to identify and implement best practices. And through such collaboration, ultimately, we may unlock the promise of RWE and see the development of true “learning health systems” to benefit patients and drive progress for health outcomes across the region.

Appendix: The U.S. FDA’s Real World Evidence Program

The U.S. Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) has consistently provided global leadership by developing sound guidance on innovative approaches, such as use of RWE, so that medical devices are more readily and speedily available to patients who need them. In 2017, the agency published guidance on the Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, which provides clarity on how RWD may be evaluated to determine suitability for generating the types of RWE that can be used in U.S. FDA regulatory decision-making for medical devices. Based on data from 2012 to 2019, it published an analysis of 90 examples of different types of regulatory submissions supported by RWE at the U.S. FDA’s Center for Devices and Radiological Health, titled, Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions.

The U.S. FDA has also led the way in supporting public-private partnerships to promote the use of RWE for regulatory decision-making. It provided the Medical Device Innovation Consortium (MDIC)

with a grant to establish the National Evaluation System for health Technology Coordinating Center (NESTcc) to evaluate the use of retrospective and active sources of RWD in medical technologies for regulatory decision-making. It integrates data from clinical registries, electronic health records, and medical billing claims to generate evidence of medical device safety and effectiveness. NESTcc, in collaboration with medical device stakeholders and FDA, published the NESTcc Methods Framework and the NESTcc Data Quality Framework as guides for using RWD to generate RWE in medical devices. Through MDIC, the FDA also partnered with industry to publish Real-World Clinical Evidence Generation: Advancing Regulatory Science and Patient Access for In Vitro Diagnostics (IVDs), the first such RWE framework focused on in vitro diagnostic devices. In addition, FDA officials are actively engaged in the Duke-Margolis Center for Health Policy RWE Collaborative, which works with stakeholders to improve the development and use of RWE/D to provide more options for patient treatment and improve outcomes.

The COVID-19 pandemic has served to accelerate the FDA’s engagement and collaboration on the utilization of RWE. Newly available data is used to update emergency use authorizations for COVID-19 tests, initially based on limited / preliminary information. The FDA also is participating in the COVID-19 Diagnostics Evidence Accelerator which allows analysis of both diagnostic and clinical data in real time and helps with evaluation of diagnostic tools and medical interventions for COVID-19.

FDA RWE Regulations for Drugs and Biologics

A broader RWE Program was published in 2018 as a framework to evaluate RWE in the context of regulating drug and biologics (but not medical devices) to support approvals of new indications for previously approved drugs, and to support or satisfy post-approval study requirements. In 2021 alone, the FDA published numerous relevant draft guidance for drugs and biologics, covering assessment of EHR’s, registry data, data standards for product submissions, as well as Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.

Endnotes

¹<https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/>

²“Real world data” generally refers to the raw data collected from a range of sources outside of randomized clinical trials (RCTs), while “real world evidence” connotes the insights and inferences that may be drawn from such data and utilized in healthcare decision making. The terms are often used somewhat interchangeably, though RWE is generally more applicable to the policymaking and regulatory setting. Unless specifically noted, this paper will refer to the use of real world evidence by policymakers.

³This is not an exhaustive list. RWD sources include those mentioned here, along with other non-clinical data such as supply chain inputs, hospital charge master data, laboratory and radiological imaging data, patient-generated health data (e.g., patient reported outcomes, wearable and digital apps captured outcomes), public health databases (e.g., birth and death registries, surveillance) and registries (e.g., national/clinical society/sponsor), among other sources.

⁴The Real-World Evidence Collaborative at the Duke Margolis Center for Health Policy is an excellent resource for a practical introduction to RWE and its benefits – available here: <https://healthpolicy.duke.edu/projects/real-world-evidence-collaborative>. For RWE’s specific application to the medical device industry, the NEST Coordinating Center, under the rubric of the Medical Device Innovation Consortium (MDIC), has numerous excellent primers – available here: <https://nestcc.org/>. (Both last accessed February 28, 2022.)

⁵Australian Department of Health, Therapeutic Goods Administration, “Real world evidence and patient reported outcomes in the regulatory context” (November 2021), available at <https://www.tga.gov.au/sites/default/files/real-world-evidence-and-patient-reported-outcomes-in-the-regulatory-context.pdf>

⁶Lou J, et al (2020). Real-world data for health technology assessment for reimbursement decisions in Asia: current landscape and a way forward. International Journal of Technology Assessment in Health Care.

⁷Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices: Guidance for Industry and Food and Drug Administration Staff, p. 6; (published 31 August 2017; last accessed 18 January 2022), available at <https://www.fda.gov/files/medical%20devices/published/Use-of-Real-World-Evidence-to-Support-Regulatory-Decision-Making-for-Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.pdf>

⁸<https://www.tga.gov.au/review-real-world-evidence-and-patient-reported-outcomes>

⁹See, e.g., <https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/OIT-RWE-Report-Oct-2020-FINAL-MA-VERSION.pdf> at p. 3, noting “A study on the consensus definition of RWD/E (or lack thereof) uncovered a high degree of disparity in definitions adopted by various stakeholders.”

¹⁰For example, the U.S. FDA has discussed the concept of “Real-World Performance” (RWP) analytics (“FDA believes organizations can show excellence toward continuous improvement through proactive monitoring of RWP data related to their SaMD products”). See here, <https://www.fda.gov/media/119722/download>, at pp 37-43.

¹¹See, e.g., <https://www.nap.edu/catalog/11903/the-learning-healthcare-system-workshop-summary>

¹²OHDSI is a multi-stakeholder, interdisciplinary collaboration among an international network of researchers, with a central coordinating center at Columbia University, New York, USA. Find out more here: <https://www.ohdsi.org/>

¹³Zou KH, Li JZ, Imperato J, Potkar CN, Sethi N, Edwards J, Ray A., Harnessing Real-World Data for Regulatory Use and Applying Innovative Applications, J Multidiscip Healthc. 2020.

¹⁴For one relevant example, see the code of conduct developed by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), created to promote scientific independence and transparency throughout the research process. ENCePP is supported by the European Medicines Agency (EMA). More information is available here: https://www.encepp.eu/code_of_conduct/index.shtml. (Last accessed February 28, 2022)

¹⁵See, e.g., Statement from the Science Academies of the Group of Seven (G7) nations, Data for international health emergencies: governance, operations and skills (March 2021), available at <https://royalsociety.org/-/media/about-us/international/g-science-statements/G7-data-for-international-health-emergencies-31-03-2021.pdf>; see also discussions from the Drug Information Association (DIA) 5th HTAi Asia Policy Forum, available at <https://globalforum.diaglobal.org/issue/january-2018/universal-healthcare-in-asia-hta-and-real-world-data-overcoming-barriers/> (last accessed 17 January 2022).

¹⁶[https://www.futurebridge.com/blog/unique-device-identification-udi-for-medical-devices/#:~:text=The%20Unique%20Device%20Identifier%20\(UDI,data%20and%20machine%20readable%20data](https://www.futurebridge.com/blog/unique-device-identification-udi-for-medical-devices/#:~:text=The%20Unique%20Device%20Identifier%20(UDI,data%20and%20machine%20readable%20data)

¹⁷See, e.g., <https://www.imdrf.org/consultations/unique-device-identification-system-udi-system>

¹⁸Available at <https://asean.org/wp-content/uploads/2017/09/ASEAN-Guidelines-on-Good-Regulatory-Practices2.pdf>

¹⁹<https://www.ema.europa.eu/en/news/advancing-international-collaboration-covid-19-real-world-evidence-observational-studies>

²⁰Available at https://www.duke-nus.edu.sg/docs/librariesprovider5/default-document-library/niha_white_paper_ai-in-healthcare_vfinal-23102020.pdf?sfvrsn=1c5e2636_0

Lead Authors and Contributors

Clark Jennings, C&M International

Mugant M, C&M International

Roberta Sarno, APACMed

Varun Veigas, Roche Diagnostics and Co-Chair, APACMed Digital Health Committee

Anh Bourcet, Abbott Laboratories and Co-Chair, APACMed Digital Health Committee

Experts' Roundtable Participants

Heather Colvin, Director of Regulatory Affairs, Evidence and Outcomes Policy, Johnson & Johnson

Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division, Therapeutic Goods Administration, Australia

Flora Sandra Siami, Senior Vice President at Medical Device Innovation Consortium (MDIC) and Head of National Evaluation System for health Technology (NESTcc)

Jack Wong, Founder, Asia Regulatory Professionals Association

Asst Prof Sean Lam, Head of Data Science, SingHealth Duke-NUS Academic Medical Centre and Assistant Professor, Signature Programme in Health Services and Systems Research, Duke-NUS, Singapore

Dr. K. Arnold Chan, Director, National Taiwan University Health Data Research Center and Director, National Taiwan University Hospital Clinical Trials Center

Asst Prof Clive Tan, NUS Saw Swee Hock School of Public Health and Group Head of the Force Health Group, Singapore Armed Forces Medical Corps



About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. In 2020, APACMed established a Digital Health Committee to support its members in addressing regional challenges in digital health.

For more information, visit: www.apacmed.org