APACMed
The voice of MedTech

The Power and Promise of Health Data Value for Innovation, Quality, and Efficient Care

Advancing Data Access, Sharing, and Transfer Policies for the MedTech Industry in the Asia-Pacific Region

August 2023

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Section 2: Message from APACMed

Medtech and Health Data – A Mutually-Reinforcing Relationship

The future of healthcare will be underpinned by insights and outcomes derived from data, and the benefits of an interconnected healthcare ecosystem cannot be understated. Health data is needed to achieve a more sustainable, efficient, and equitable ecosystem, which is a top priority for governments in the Asia-Pacific region.

In order for health data to deliver on its maximum value potential, however, the ambition requires trust and partnerships between public and private sector. Recognizing this, APACMed, the voice of the medtech industry in Asia Pacific, formed a Digital Health Committee in 2020. The Committee has focused on shaping policies for more appropriate regulation and reimbursement of digital health technologies, including greater acceptance of the use of Real-World Evidence (RWE).

Now, recognizing the continuing need for greater standardization with respect to access, sharing, and transfer policies, APACMed, along with a multidisciplinary set of stakeholders, has embarked on a journey toward the value of health data. Data is critical for ensuring that medical technologies are safe and effective across a range of populations in the region. Data sets require sufficiently large and diverse pools to train the relevant analytical models, thereby transcending traditional healthcare ecosystem stakeholder and national boundaries. Put another way, the more data we are able to access, share, and transfer, in secure and ethical manners, the closer we move to bringing our health-for-all ambitions to fruition.

Yet, currently, the health data which exists is incomplete, preventing us from seeing the full patient picture. For example, and despite the growing penetration of Electronic Health Records (EHRs) in many countries, access to quality data remains constrained. In addition, another challenge is the complex protocols for sharing health data, even with safeguards in place. Limited interoperability has led to fragmentation, the lack of pooled patient insights from which is actually a detriment to, rather than protection of, public good. A compounding challenge is the blocking of data transfers, such as across borders, inhibiting innovation and, especially for medtech, failing to effectively detect, monitor, and treat patients in a real-time, personalized manner.

By bringing medtech innovation to Asia Pacific, it is our aim to deliver on the promise of improved population health. This will require a public-private collaboration model, which involves the construction of more impactful, seamless, data sharing ecosystems.

In this paper, we lay out the opportunity for health data in the region, as a case for policy intervention. We also provide industry examples and recommendations for regulators and policymakers to consider acting upon, including by right-sizing resource allocation to the topic. Ultimately, there is already a wealth of data across healthcare ecosystems in developed and developing countries alike. It is therefore our collective responsibility to harness the health data, and to unlock the full benefits for patients in the Asia Pacific.

Sincerely,

Harjit Gill
CEO
APACMed

Farhana Nakhooda
Board Sponsor
Digital Health Committee

Section 3: Foreword

No Patient (Data) Left Behind

We are in the midst of an explosion of health data. By 2025, the compound annual growth for health data will be 36% and 30% of all of the world's volume of data is now being generated by the healthcare industry.[1]

Patients are increasingly informed and tech-savvy. They are already using a combination of structured data – digital files, images, spreadsheets, management software; and unstructured data – physical files, physician or nurse advice, communication tools, apps – to manage their own health. Most of the digital health initiatives brought about by the challenges of the COVID-19 pandemic are here to stay, and provide impetus for further digitization, from virtual appointments to wearables to chat-based lab reports. These trends influence the patient journey, forcing all of us to adapt to and adopt the new care delivery paradigms.

Often, when we speak of health-for-all or patient-centered care, we neglect to capture the voices of those who matter most – the patients themselves. It is concerning and limiting that the data is not being sufficiently evaluated nor valued, in terms of how it can be used to better manage our health. The focus has traditionally been on driving efficiencies in healthcare, such as claims processing and hospital bed utilization. And, while these efforts remain important, we are missing the bigger picture about how patients can be empowered to take responsibility for their journeys, too.

Remember, no two patient journeys are the same. The insights from health data can help to create the frameworks needed to break down the silos that exist within the healthcare industry, including data that is being held by the patients themselves.

This requires a concerted effort in digital and data literacy by regional stakeholders, public and private sector alike. Especially in light of the reality that 40% of the population in the Asia Pacific is still considered to be unconnected.[2]

There remain major questions about data ownership for access, sharing, and transfer purposes. For the moment, countries around the region are moving ahead with their own frameworks. We need to foster more multi-stakeholder dialogue, incorporating the patient voice at the table so as not to further exacerbate the socioeconomic inequities which linger. It is a tough, yet necessary, conversation. Only then are we able to harness the potential of health data for improved, safe patient experiences and outcomes in the Asia Pacific.

It is time for a paradigm shift with respect to our discussions on health data. Patients, and the wider ecosystem, will not benefit from piece-meal approaches. Initiatives such as this whitepaper around maximizing the value of health data are timely to spur dialogue and debate on these critical topics.

Technological innovations are growing rapidly around us. Let patients be partners by ensuring that medtech and data solutions are enabled to deliver a more meaningful impact to population health. Health-for-all is only possible by leaving no patient, and no patient data, behind. Nothing about us, without us.

Sincerely,

Aparna Mittal
Founder & CEO
PatientsEngage

Section 4: Paper Context and Call-to-Action Executive Summary

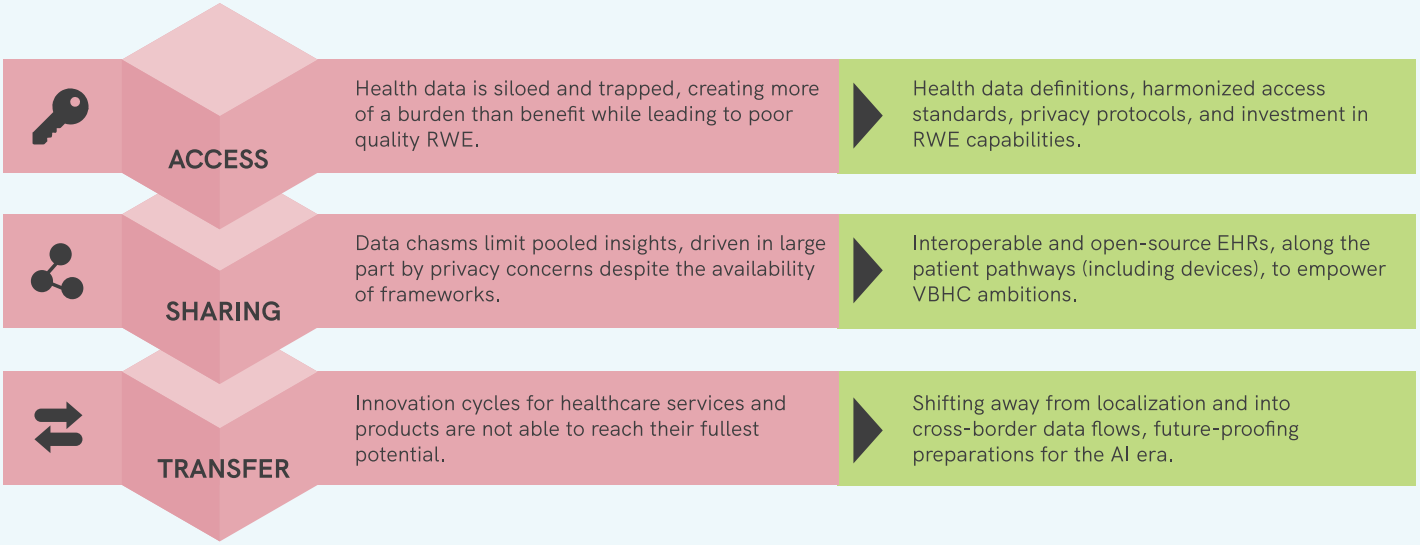
Since the launch of APACMed's Digital Health Committee in 2020, key priorities have included the regulation, evaluation, reimbursement, and cybersecurity of novel medical technologies seeking to enter Asia-Pacific markets. Focus has since shifted to the tremendous potential for modern healthcare systems to embrace the data being generated as a result.

In 2022, APACMed launched a Real-World Evidence (RWE) initiative to support policymakers and industry with frameworks for regulation and reimbursement decision-making. The whitepaper, recognizing multiple-source data as the bedrock of sustainable and interconnected healthcare systems, called for greater awareness, capacity, and expertise development efforts between the public and private sectors to work towards regulatory harmonization for RWE in the Asia Pacific. Engagement with policymakers and industry continues to progress RWE utilization in the region.

Now, to augment RWE efforts further, APACMed is emphasizing interoperability within and among healthcare ecosystems – ensuring that standards for data access, sharing, and transfer are enabling, rather than inhibiting, RWE and broader health transformation goals. The combination of RWE and data standards is fertile ground for emerging topics such as adoption of Artificial Intelligence (AI) to improve health care delivery and products. Following the undertaking of a global literature review (at a point in time, noting that literature continues to be produced at a rapid pace), interviews were conducted with multidisciplinary stakeholders, public and private sector alike, and industry use case examples were collected, in order to demonstrate the value of health data and to offer recommendations on policies to support its use in the Asia Pacific.

Accordingly, the following are the overarching takeaways for readers:

Awareness must increase about the value of health data across the care continuum in healthcare systems to support innovation, improved quality, and patient-centered care.



Policymakers require an actionable checklist in order to facilitate next steps for health data access, sharing, and transfer.

The health data revolution is here, and the time is now to mobilize public-private sector collaboration for its safe and effective use to improve patient outcomes and to maximize precious resources. We hope this whitepaper provides a frame for discussion about health data, and we welcome the opportunity of further dialogue on this exciting journey.

Section 5: Defining Health Data, Its Uses, and Value Therein

We found in our research that there is fairly common agreement amongst the literature and stakeholder sentiments about the definition of health data. Therefore, we adopt the following definition for this whitepaper, and outline in Figure 1 the examples of data types therein for the healthcare industry.

"Health data is typically personal information that relates to the health status of an individual, including but not limited to doctor referrals and prescriptions, medical acts and examination reports, laboratory tests, and medical imaging. Data is generated by interactions with healthcare facilities as well as medical devices and digital applications. Health data is frequently considered highly sensitive." [4,5]

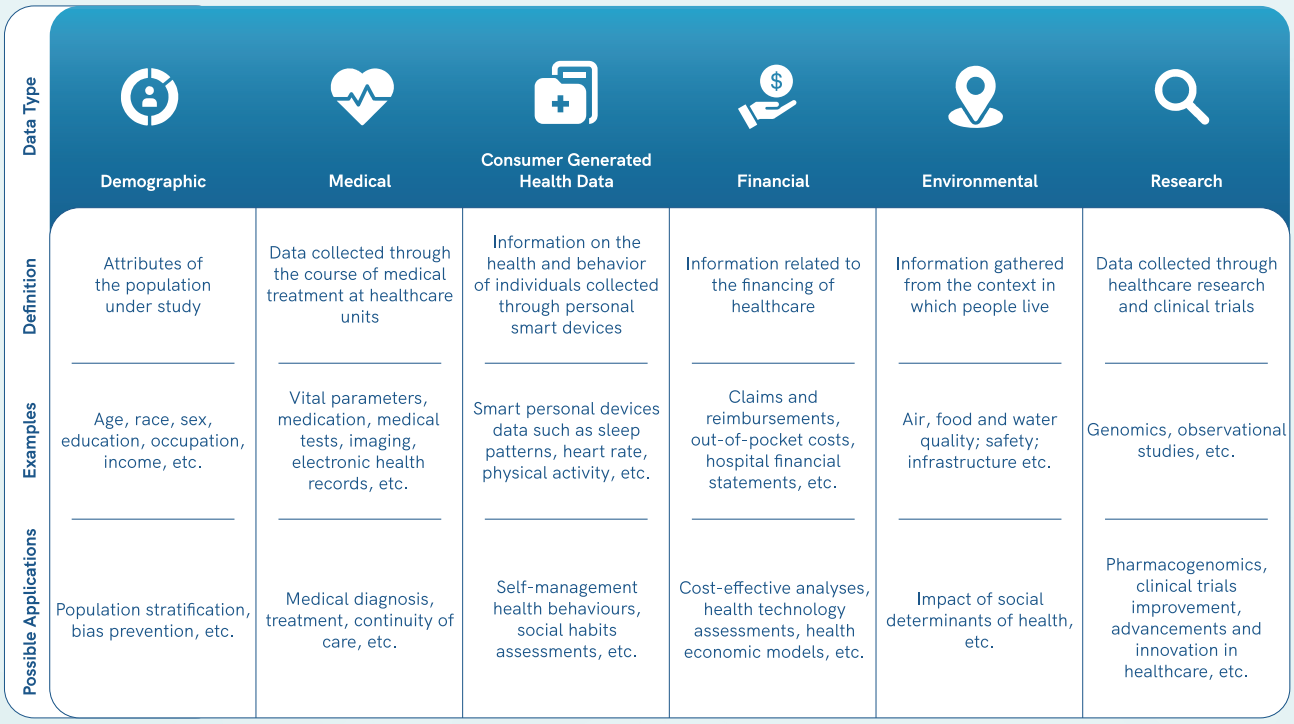


Figure 1: Illustration of data types in healthcare. It is critical to have a holistic view of the patient journey to support improved outcomes and efficient use of resources.[6] Image reproduced from National University of Singapore.

From a multi-stakeholder perspective across the Asia Pacific, though, there are often subtle yet important differences in the understanding of health data. While most governments seem to adopt a standard definition which is not too dissimilar from the above, other stakeholders from the ecosystem still need to be involved in the discussion, including clinicians, care providers, academia, and patients.

"We do not see official health data definitions as widely accepted as would be desired and are thus having to clarify the terms with stakeholders during every interaction," said representatives from the Tohoku Medical Megabank Organization (ToMMo) in Japan. "Awareness of the importance of aggregating large-scale data sets has improved, but we need to engage stakeholders in achieving a basic level of agreement on the definitions being used."

"We have started to see greater acceptance of data-driven activities across health-related R&D, treatment, and delivery contexts, and are keeping a close eye on national legislation for the same adopted around the world," said Joseph Whitlock, Executive Director of Global Data Alliance. "That said, there is still more work to be done to achieve common cross-border standards which can deliver on our promise of improved patient outcomes."

Health data now constitutes one-third of all data generated globally. And while the majority of healthcare leaders can see the value in collection of health data, 97% of health data produced by hospitals remains unused and 46% of healthcare leaders view data as a major burden to manage.[7] There are challenges but also opportunities surrounding health data, which will be explored in this whitepaper. However, the inherent tension arises from the ongoing difficulties of building "data sharing ecosystems" for healthcare.[6]

The COVID-19 pandemic accelerated interest and action in health data to help track cases and plan the response. Many policies and reforms were implemented at pace, a unique phenomenon in healthcare. The Philippines government, for example, was able to enact a number of health data and privacy reforms born out of contact tracing, in consultation with the private sector and wider public, such as the Advisory on the Guidelines for Workplaces and Establishments Processing Personal Data. In Singapore, public officials noted a greater openness to health data sharing yet also see the window of opportunity closing for policies that promote research and innovation. While health data privacy and misuse concerns remain, key is to leverage momentum to build responsible and compliant data pathways.[1]

"People experienced the value of sharing vaccine-related data as helpful during a crisis, but we are now once again facing restrictions in terms of data sharing across borders or in disease areas beyond infection control, including related to genetic information," said Dr. Clive Tan, Assistant Chief for Integrated Care and Population Health, National Healthcare Group in Singapore. **"We must seek to better leverage the infrastructure that was built during the pandemic, such as inter-country data sharing agreements."**

The status of health data sharing ecosystems in Asia Pacific varies by level of Health IT (HIT) adoption, national policy, and data handling capabilities. Essential health data is considered by stakeholders as already being available in developed as well as emerging country archetypes, a kind of prerequisite to support ongoing healthcare transformations, and there are efforts underway to offer best practices and regulatory harmonization across borders.[8] For example, effective and efficient governance of the data lifecycle is driven by FAIR (Findable, Accessible, Interoperable, Re-usable)[9] and G7 DFFT (Data Free Flow with Trust)[10] principles, which help to enable interoperability for RWE and AI.[11]

Yet, while a basic level of healthcare digitization has taken place in the Asia Pacific, unlocking the value of health data requires further policy reforms and adoption (see Figure 2). "The era of healthcare digitization is already underway, and patients are experiencing the data revolution through care provider institutions, such as registration, teleconsultations, and lab reports, as well as in their day-to-day lives with wearable devices, mobile apps, and social media," said Aparna Mittal, Founder & CEO of PatientsEngage. "But much of this data is still siloed, so we are missing an opportunity to harness the potential of activated and informed patient communities."

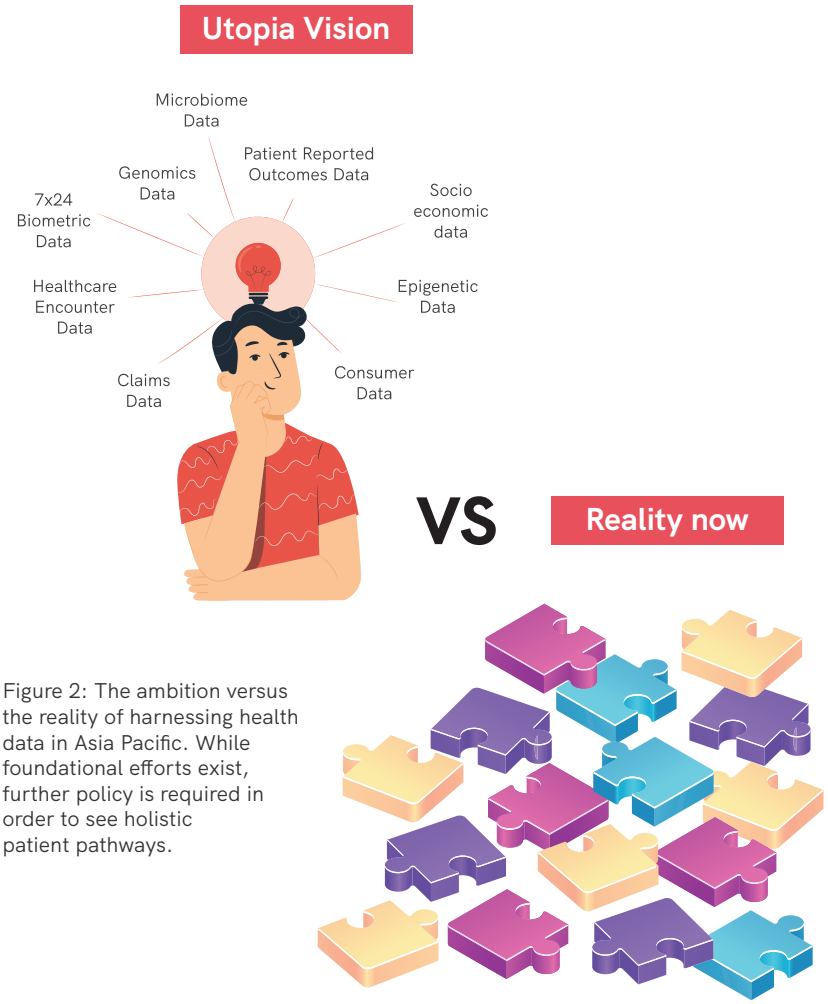


Figure 2: The ambition versus the reality of harnessing health data in Asia Pacific. While foundational efforts exist, further policy is required in order to see holistic patient pathways.

Uses of health data across the patient care continuum

Uses of health data span the lifecycle of patient pathways, from primary prevention through to diagnosis, treatment, and monitoring. Health data can, for example, be used to enable remote healthcare services, analyze patient conditions against global databases, monitor epidemiological patterns, and facilitate cross-border scientific research.[12,13]

Of increasing emphasis is the role medical technologies, including digital applications, play within the data generating and sharing ecosystem (see Figure 3). The WHO estimates that there are around two million different kinds of medical technologies already on the global markets, with many of them producing data. Medical technologies collect information (continuously or on-demand) from patients and possess the ability to transform this information into readable outputs for individuals, care providers, and systems at large. Going forward, there is a need to better integrate medical technologies, and the data therein, to the wider sharing ecosystems.[14]

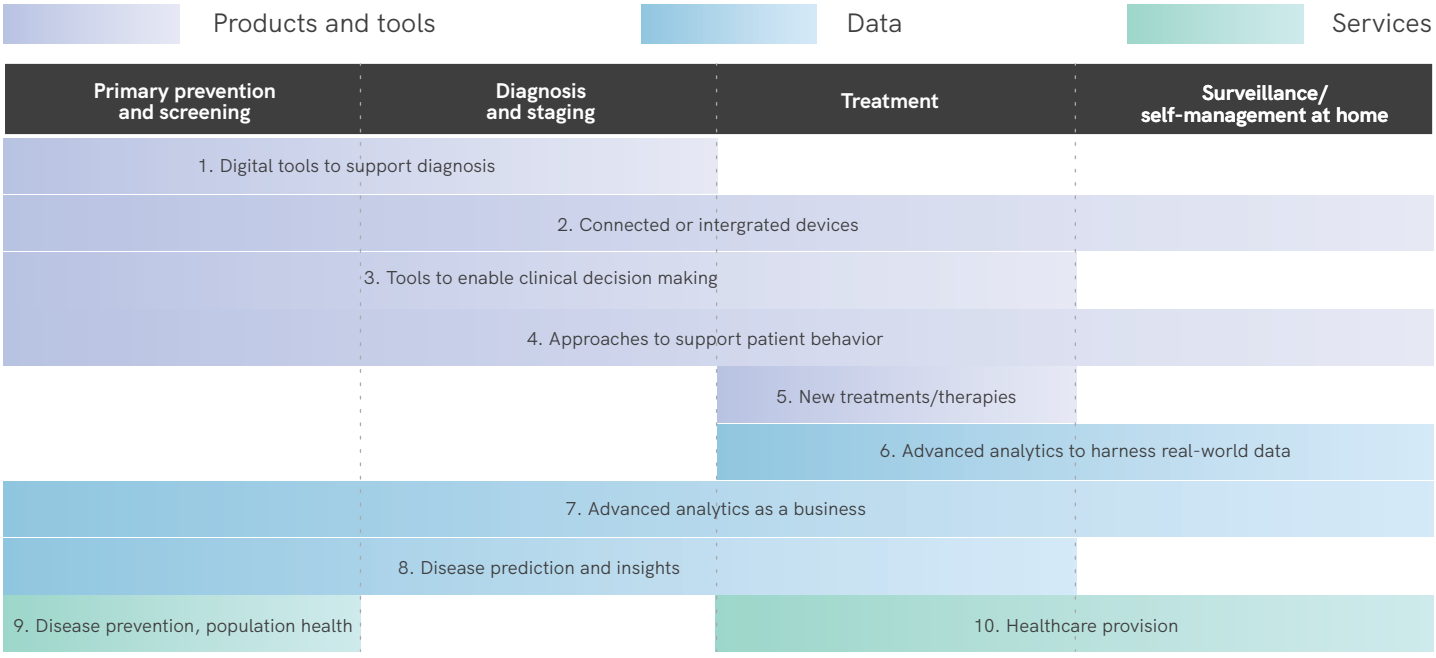


Figure 3: Opportunities for health data contributions across the patient continuum, especially as increasingly generated by medical technologies and digital health solutions.[15] Image reproduced from McKinsey & Company.

Uses of health data for research to improve care delivery and to develop innovative technologies

Health data is essential for research to improve the performance of healthcare services and of existing medical devices or in-vitro diagnostics, as well as to develop new and innovative technologies – a benefit to everyone. Additionally, health data can provide insights into patient populations suffering from common disease patterns, thereby enabling more targeted and personalized research.

One way to think about data is through a disease pathway lens. Figure 4 provides an example in oncology, in terms of opportunities for better data intervention across the continuum, ultimately driving improved patient experiences and outcomes while maximizing available resources.

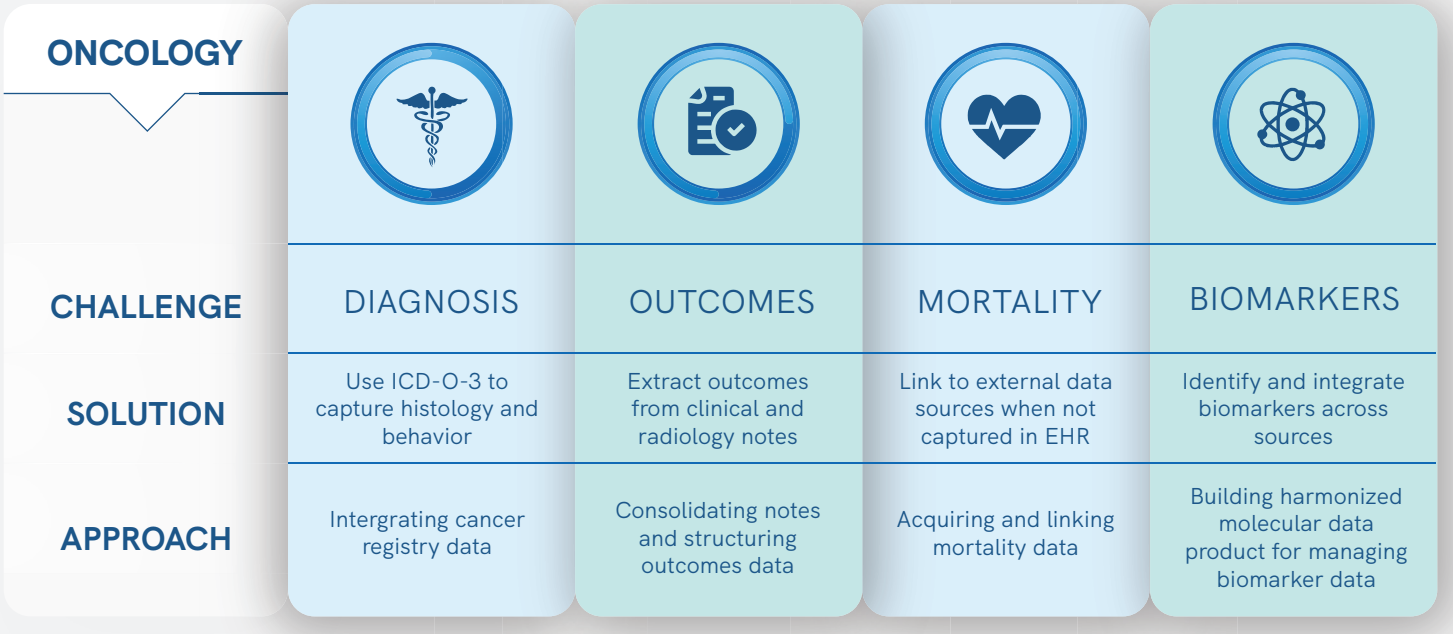


Figure 4: An example from Health Catalyst on how oncology data can be accessed and used to determine clinical areas such as diagnosis, outcomes, and mortality. This cancer data can then be leveraged from a preventative perspective as well as to improve health outcomes and resource efficiency.

To harness the full potential of health data for research, care delivery, and innovation, stakeholders in the Asia Pacific need to work together to build better mechanisms for its effective and efficient use. Implementation of best practices, such as the FAIR principles, for scientific data management and stewardship, can empower use of new and powerful analytical tools, like AI and machine learning, at scale.

"One major hurdle in the whole equation is the community of care provision," said Dr. Shankar Prinja, National Health Authority Executive Director of the Ayushman Bharat program in India. "We need to bring everyone on board to deliver on the expected benefits. At the moment, there is insufficient value perceived in changing behaviors toward the more digitized healthcare modes."

Uses of health data for evidence and decision-making

Health data in the form of RWE can help to provide answers about medical product and technology safety (including post-market), such as information about effectiveness based on patient behaviors in the healthcare system under consideration. There are many examples already underway in the region of leveraging large datasets, including the AI research hub concept in Singapore, next-generation electronic patient record standardization in Thailand, B-net in Japan, among other big data initiatives in the likes of Korea and Australia.[1]

In Australia, a recent population survey actually listed health data as the #1 concern with respect to the overall topic of digital health. While various local data governance frameworks do exist, such as the Australian Institute of Health and Welfare (AIHW) framework, it has not yet been implemented nor is legally binding. Similarly, while the Privacy Act 1988 provides a national law on data privacy, there remain a myriad of data governance standards across territorial governments, sectors, institutions, and ecosystem organizations. The increased complexity may be heightening the risk of data misuse.[16]

In India, data that is generated through research surveys and public health programs (e.g., for reproductive health) is now being consolidated through digitization of patient records under the Ayushman Bharat Digital Health Mission. The Ayushman Bharat Health Account establishes a unique identifier and, along with a "DigiLocker", better connects hospitals and community activities while giving control of the data to the patients. The common architecture allows for smoother claims management under the Universal Health Coverage (UHC) or public insurance schemes too. Eventually the idea is to better utilize the data for analytics, including to reform benefits packages. "The point of digitization efforts under the UHC ambition in India is more for public good than financial means, at this stage," said Dr. Prinja in India. "Policies are emerging with respect to data sharing, with ongoing public consultations."

In China, the COVID-19 experience has accelerated digitization of healthcare – online medical users jumped to nearly 250 million citizens in 2021. Yet, at the same time, and in accordance with the Personal Information Protection Law (PIPL), health data is considered sensitive data and therefore must be protected from "unlawful collection, transfers, and processing." Hence, there is an increased tightening of the rules, and therefore opportunities, to harness the health data being generated. For example, health data is required to stay localized within China, and it is perceived that alignment with the existing medical device regulations can be an arduous process. The medical data regulations in China currently cover everything from telemedicine to Software as a Medical Device (SaMD), digital therapeutics, AI, and robots.[17]

With health data as a foundation, RWE can support the assessment of medical product and technology safety and efficacy, to complement traditional randomized clinical trials or when such trials may be impractical. This could be due to small patient cohort sizes, ethical reasons, or sensitive studies (e.g., for severely debilitating diseases). Similar to the notion of using health data for research, policies which foster an environment of data sharing and collaboration are required in order to further maximize the potential of RWE for decision-making.

This whitepaper emphasizes Value-Based Health Care (VBHC) as a forward-looking transformation which will underpin key policies in the region, especially those which are going to require uses of health data across the patient lifecycle. Achieving VBHC will involve reliable measurements of outcomes, foundational healthcare technologies, and an ability to access quality data; in other words, overcoming lingering challenges of lack of data transparency.[18]

Therefore, health data is critical for VBHC. Data captured in electronic recordkeeping and other digitalized tools must be better leveraged. Stakeholders, public and private sector alike, must find common ground for interoperability. Access and transparency, including for patients and with consideration of their privacy, must be achieved.[19] "The value of health data is maximal when it is timely and aggregated, such as for VBHC ambitions," said Dr. Tan in Singapore. "Much work has already been done to improve the use of data for patient-care provider decision-making, so now the focus needs to be on harnessing its value at the population level."

"The point of digitization efforts under the UHC ambition in India is more for public good than financial means, at this stage," said Dr. Prinja in India.

As it stands, healthcare transformations in Asia Pacific, like VBHC, are often slowed, rather than empowered, by a data sharing ecosystem. RWE could, for example, enable VBHC with measurements for outcomes-based payment models or clinical insights for more efficient, higher quality service delivery. Existing frustrations often include conceptual model variation by country and care setting, unnecessary regulatory complexities, and general fragmentation of strategies.[20] For health data to be truly harnessed, policy must keep pace with innovation.

A demonstration of considering the value of health data from the perspective of VBHC stakeholders working together lies in an initiative known as Value of Diagnostic Information (VODI).[21] As the COVID-19 pandemic raised awareness toward, the importance of diagnostic insights is critical to care pathway decision-making. The value of these insights is not from disparate sets of data coming from various devices and care pathway points. The value lies in the efforts to consolidate the data into more holistic patient pictures. There is still much more work to be done, but, as Figure 5 highlights, the concepts of VODI are well underway as an example of the power of health data from multi-stakeholder collaborations. APACMed is currently working on a related VODI whitepaper, initially tackling the rise of cardiovascular disease in the region, which promotes such data sharing ecosystems as a value-positive intervention for policymakers.

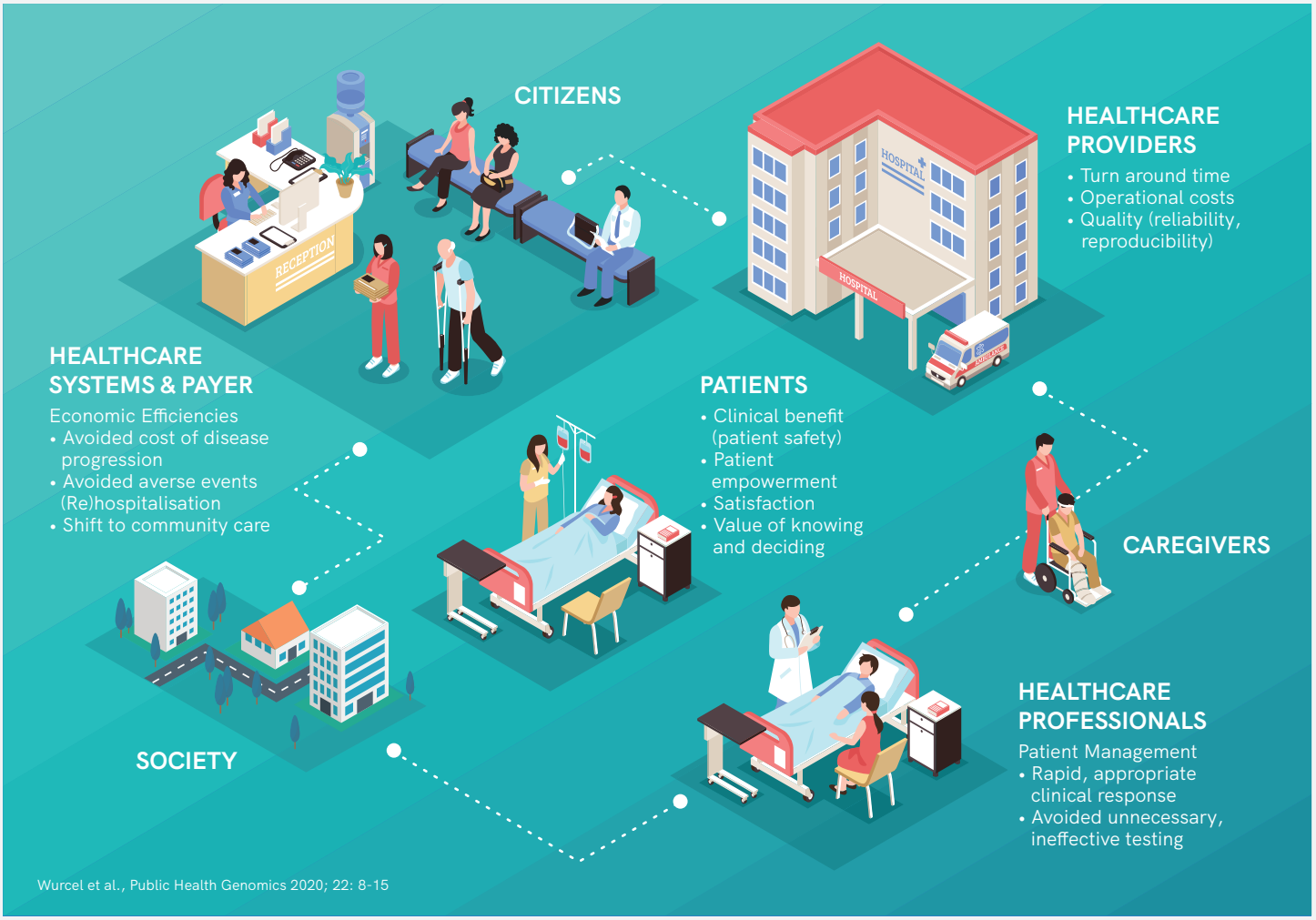


Figure 5: VODI illustration as an example of the power of multi-stakeholder health data collaboration. Such collaborations, and data sharing, are fundamental for enabling reform ambitions like VBHC.

Viewing value from the perspective of technology, this whitepaper proposes that there are a variety of possible VBHC-style benefits to be gained specifically by harnessing device-generated health data, such as from medical devices and digital applications. Table 1 provides a selection of health data value inflection points by device- or technology-generated category[21]:

Table 1: Device-Generated Benefit of Health Data by Transformation Category

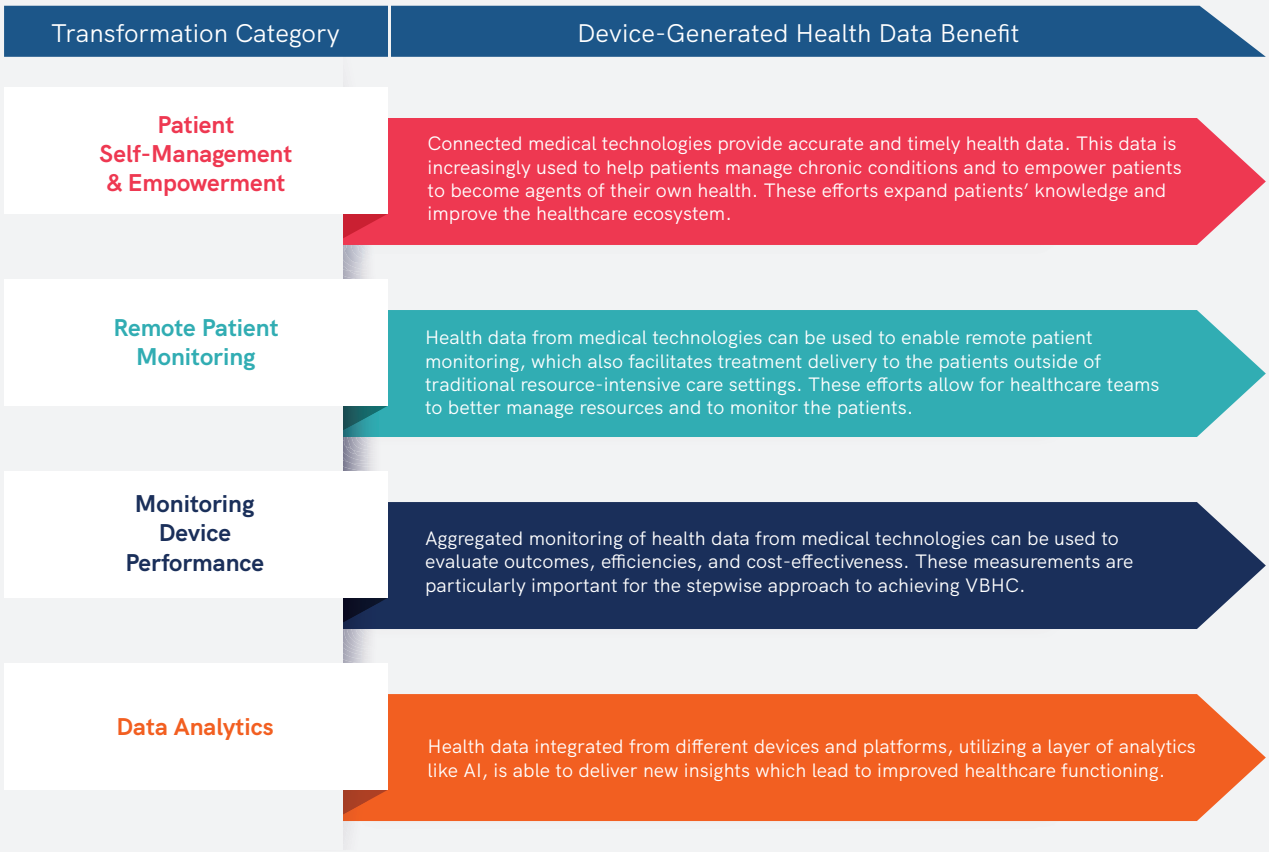


Image reproduced from MedTech Europe.

Summary of benefits offered by health data definitions and uses

We have provided a consistent definition of health data, described its various uses (and challenges therein), and illustrated several case examples happening around the region and globe. **Ultimately, the key message is that we must seek to better understand the value delivered by these efforts.** On the regulatory side, health data can help to ensure medical product safety and efficacy. Projects such as the United States Food & Drug Administration (FDA) Oncology Center of Excellence' s Project Orbis, in partnership with Australia, Brazil, Canada, Singapore, Switzerland, and the United Kingdom, support the regulation of critical products through cross-border collaborations. Similar approaches could be used for post-market surveillance and good pharmacovigilance practice. Cross-border health data sharing would allow for improved, more rapid reporting of any events (adverse, manufacturing inspection, clinical studies) across stakeholders and borders.

So, what does it all mean? **For healthcare providers**, an ideal vision is to have access to the most relevant data, directly at the point of care. This enables real-time, more personalized treatment, increased medication efficacy, and enhanced efficiencies. **For patients (and citizens more widely)**, health data allows for managing one's own care journey. Connected medical devices can assist patients in monitoring their care conditions, empowering them to greater health and well-being. **And for governments**, ultimately responsible for health system sustainability and resiliency, health data identifies inequities, resulting in opportunities for improved decision-making in predicting and preventing disease burdens as well as maximizing precious resources therein. Health data can also address future needs as they arise, including urgent public health threats like a pandemic. Figure 6 summarizes these benefits, by stakeholder category.

What are the benefits of the use of health data for all stakeholders?

Figure 6: Non-exhaustive list of benefits, by stakeholder type, which can be derived from more supporting policies promoting the safe and effective use of health data.[14]
Image reproduced from MedTech Europe.

Of course, for the medtech industry itself, data generated could be better interconnected for benefits such as quality monitoring, research and innovation (throughout the product lifecycle) and improved delivery of healthcare. The ultimate benefit, for all stakeholders, comes in the form of a country's social and economic development. Known as an "open data society" (see Figure 7), in line with the data sharing ecosystems, there is indeed a level of investment required at the outset. However, as time goes on, the benefits for public and private sector alike are recouped. There is an opportunity for policymakers in the Asia Pacific to harness health data for not only goals like UHC and VBHC, but even bigger ambitions ahead. The value of an open data society across nine countries in Europe, in which public and private sector data are working together in unison, is estimated to have already created more than 100,00 jobs as well as €1.7 billion in cost savings through efficiency gains.[22]

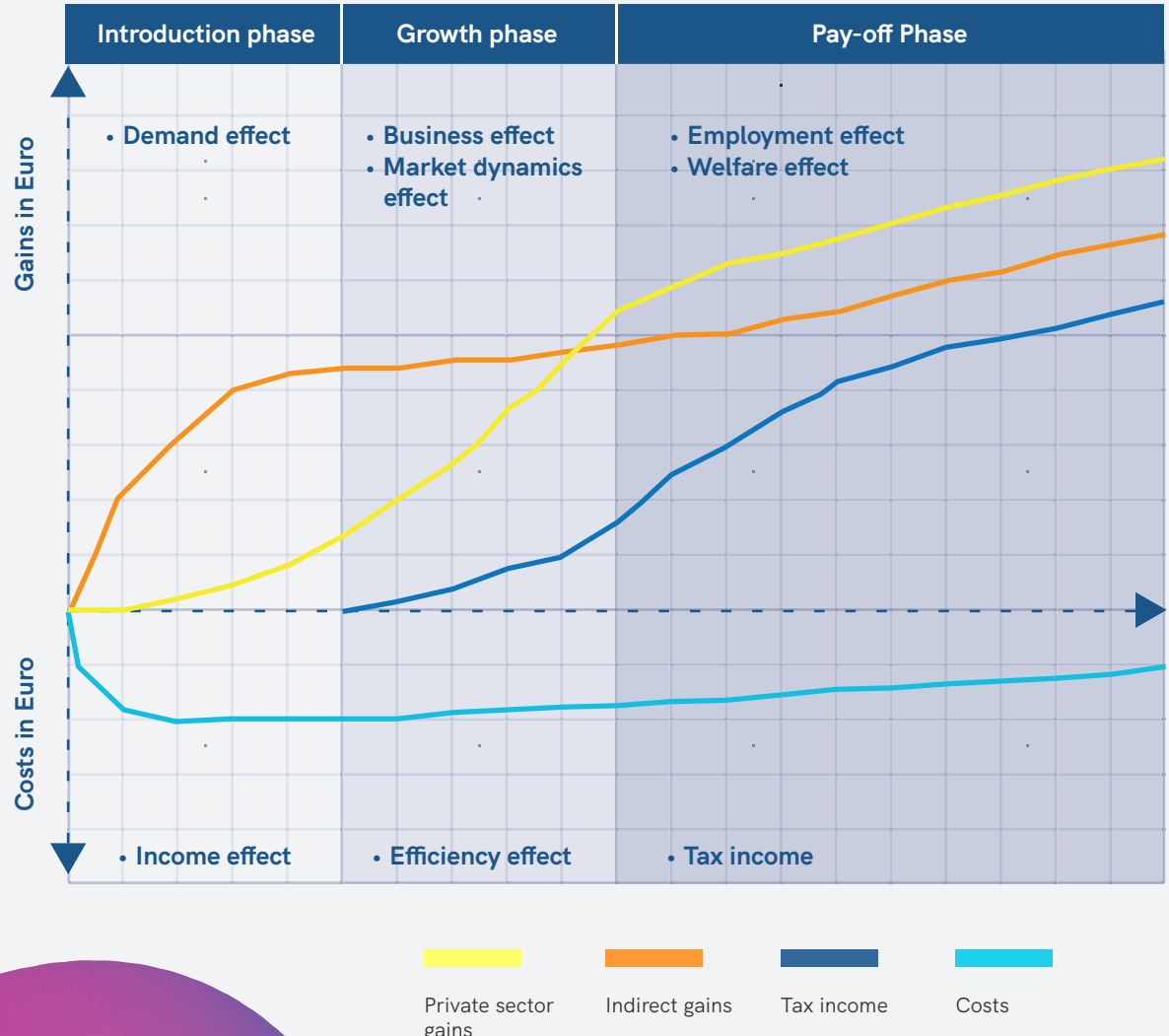


Figure 7: Concept of an open data society, and the value trajectory over time. Initially there is an investment required to harness data and then benefits are delivered for public and private sector.
Image reproduced from European Data Portal.

Section 6: Challenges and Best Practices for the Value of Health Data

Health Data Challenges

The major challenges for realizing the value of health data come in three forms – accessing the data, sharing it, and transfer protocols therein. We will touch on each challenge, then offer best practices for addressing them through real-world case studies.

"Most countries are unable to produce basic health statistics," said Dr. Steve MacFeely, Director of Data & Analytics at the World Health Organization. "If health data were properly valued, we could not only fulfill data reporting requirements but build upon even larger data sets for everyone's benefit."

The first challenge to harnessing health data comes in the form of accessing it

While great achievements have been made in the region with respect to the implementation of HIT like Electronic Health Records (EHRs), the data often becomes trapped and siloed.[19] One in two healthcare leaders currently see data as more of a burden than an asset. There is evidence to suggest that the difference between early and late adoption of healthcare transformation initiatives, such as VBHC and UHC, boils down to the ability to access data. These same leaders cite the need for streamlined and compliant data access, as well as data analysis capabilities, as a top factor in swinging their opinion in a more favorable view of health data.[23] Stakeholders are reluctant to furnish access pathways to the data, frequently due to legal concerns. These scenarios have a direct effect on our collective ability to use data for legitimate purposes like patient education.

"There is still the issue of who owns health data and, while in principle it is said to ultimately be for the patient, in reality that is far from the case in most situations," said Mittal of PatientsEngage. "Some patients are getting better about collecting and using their own data, now the policies need to catch up to empower this and to support all patients being included in the digital datasphere."

From a medtech industry perspective, these health data access challenges manifest themselves in a few ways. Due to unclear regulations, medical technologies, which are becoming smarter and also stewards of health data, are unable to contribute or exchange data with the sharing ecosystem. In addition, typical obligations for medtech companies, such as vigilance and safety reports for post-market surveillance, need to be modernized to align with the latest practices of data-driven technologies. Even within the Asia-Pacific region, the regulations which do exist are not harmonized and therefore create further data fragmentation across stakeholders and borders.[21]

Challenges with health data access are intertwined to quality issues, too. RWE, and future-looking topics like AI, suffer from data which is not always clean (e.g., from messy health registries and patient record systems). Health data completeness, reliability, and relevance is important for RWE, and access more generally, to provide insights about medtech product safety, effectiveness, and, ultimately, value. Standards for these data sources and their access are needed for quality improvement.

Beyond access, a second challenge is sharing the health data

While the prior decades have focused on building out HIT infrastructure, we now face a situation of limited interoperability. The fragmentation leads to data chasms which are not able to connect to each other nor to leverage the benefits of pooled insights.[24]

A key concern in data access is privacy. Various studies have shown that when asked to participate in research to advance science and to help progress the healthcare ecosystem, patients do generally support the sharing of their information. However, several high-profile examples of data leaks and inappropriate use have raised public concerns about the mechanisms in place to support their privacy. As a reaction, some countries have enacted legislation limiting data access which has unintentionally hindered broader healthcare ambitions, such as in research. For RWE to be maximized, stakeholders must collaborate to develop enhanced data governance for compliant and responsible sharing.[25]

Research has shown there is more benefit than harm which can be achieved through health data sharing, and modern mechanisms that exist can be put in place to facilitate appropriate safeguards. Harmonized regulatory frameworks, consent protocols, and cross-border, multi-stakeholder interface solutions are very possible. For example, by viewing the sharing of health data as a common public good, countries could better explore combinations of socioeconomic determinants with genetic factors, especially for disease burdens which require earlier prevention across various stakeholders, when designing their healthcare transformation ambitions.[26]

"Frameworks do technically exist, but often times it is too easy to find reasons not to share the health data which then becomes the default position," said Dr. Charles Alessi, former Chief Clinical Officer at HIMSS. "Therefore, the most common reason that health data is not shared is not due to technical issues, but rather political ones." "Health data is not easily shared due to the perceived sensitivities and lack of clear rules of engagement," concurred Dr. Tan in Singapore. "In fact, there is more guidance about what not to do than the other way around, which creates even greater risk of variance. We now face a situation in which the ambition behind shared data lakes has not materialized, and instead we see them becoming data vaults."

There is the opportunity, through public and private sector collaboration, to establish a seamless, interconnected data sharing ecosystem which allows the information to flow along the patient journey and to maximize analysis, AI, and related tools for more efficient, personalized healthcare. Yet this vision will not be realized without addressing the interoperability and governance issues which remain. Resolutions to fragmentation and stakeholder buy-in are urgently needed in Asia Pacific.[27]

The third and final challenge pertains to the transfer of health data, especially across borders

Even by resolving the access and sharing hurdles, health data currently faces heavy restrictions due to transfer blocks and also localization requirements, thereby hindering the natural cycles of healthcare innovation which occur through cross-border collaboration of novel medical technologies. Remote healthcare services, for example, require secure, cross-border data exchange. Other top healthcare agenda items in Asia Pacific which necessitate improved data transfer protocols include cross-border epidemiological control and virtual consultations.[28]

For the medtech industry, cross-border data transfers are essential to detect, monitor, and treat disease in a safe, effective, precise, and timely manner. This data may include that which is collected in the normal use of medical devices, such as in hospital settings, as well as increasingly decentralized devices and consumer technologies. The data must be aggregated through transnational digital networks, safely and securely, in order to realize the benefits of connected healthcare. Patients seek improved real-time relationships with their care providers, irrespective of location and setting.

Cross-border data transfer involving medtech can help medical researchers better understand population patterns, promote collaborations amongst healthcare systems, and contribute to continued medical education. Examples include surgical image databanks which are recorded around the world and then transferred to respective educational institutions, as well as combining multi-ethnicity databases to ensure more inclusive and equitable representation in R&D.[29]

As ToMMo can attest to in Japan, the ambition behind collecting multi-institutional data for the benefit of a common biobank has faced setbacks in the form of lack of digitization and standardization. Pathways for health data transfer regulation, licensing, and Intellectual Property (IP) protection all call for a rethink.[30] In China, recent measures like the PIPL are even intended to have an extra-territorial effect. What this means in practice is that before any health data is transferred outside of China, for example, the exporting organization must undergo a security assessment by a government authority, obtain certification from a qualified institution, and enter into a data transfer agreement based on the government's standard contract.[31]

"Health data has significant potential for the purposes of improving worldwide care delivery and outcomes, but some national laws adopt a default policy position of restricting the ability to transfer the data across borders, undermining and frustrating the development of novel health interventions," said Whitlock of Global Data Alliance. "Public and private sector must avoid a default presumption that health-related data should not be transferred across borders; rather, we should be open-minded about the opportunities of such sharing."

Health Data Best Practices

The United Nations, G20, among others like APEC and IPEF, have been actively working to address the topic of data flows across borders, for transfer purposes and also inclusivity of access and sharing needs.[32] A G7 meeting held in April 2023 amongst the Digital and Tech Ministers, for example, recognized the critical role of data as an enabler for economic growth and social well-being, necessitating the further operationalization of frameworks like DFFT.[10] The core issues being lack of consensus on interoperability, as underpinned by data free flow and data sovereignty concerns. Data governance has increasingly become a "patchwork of frameworks" over time, at best lacking uniformity but often even contradictory.

"Health data can shine a light on patterns (anticipated or otherwise), help to document changes, and suggest relationships or associations," said Dr. MacFeely of the WHO. "If these data are open and accessible, then they can inform policy formulation and assessment." In the spirit of more consistent cross-border transfer protocols, Dr. MacFeely and the WHO team offer the Harmonized Health Facility Assessment (HFFA) course for capacity development via survey data analysis, which has already been deployed to a number of countries around the world.[33]

Many governments interviewed also grapple with how to effectively and efficiently monitor compliance of health data policies. While a one-size, fits-all solution may not be feasible in the near-term, it is not impossible to strive for finding common ground on topics such as privacy and localization expectations. Indeed, stakeholders generally agree that patients deserve the highest privacy and security standards; yet, without careful consideration, data protection and legal requirements risk being misapplied to the health sector.[4] The most important goal, according to the G20, being to "maximize the benefits of data flows and to ensure security and privacy involve a variety of interoperable regimes." There is already some solid policy ground to build on with the European General Data Protection Regulation (GDPR), United States Health Insurance Portability and Accountability Act (HIPAA), and Singapore Personal Data Protection Act (PDPA).

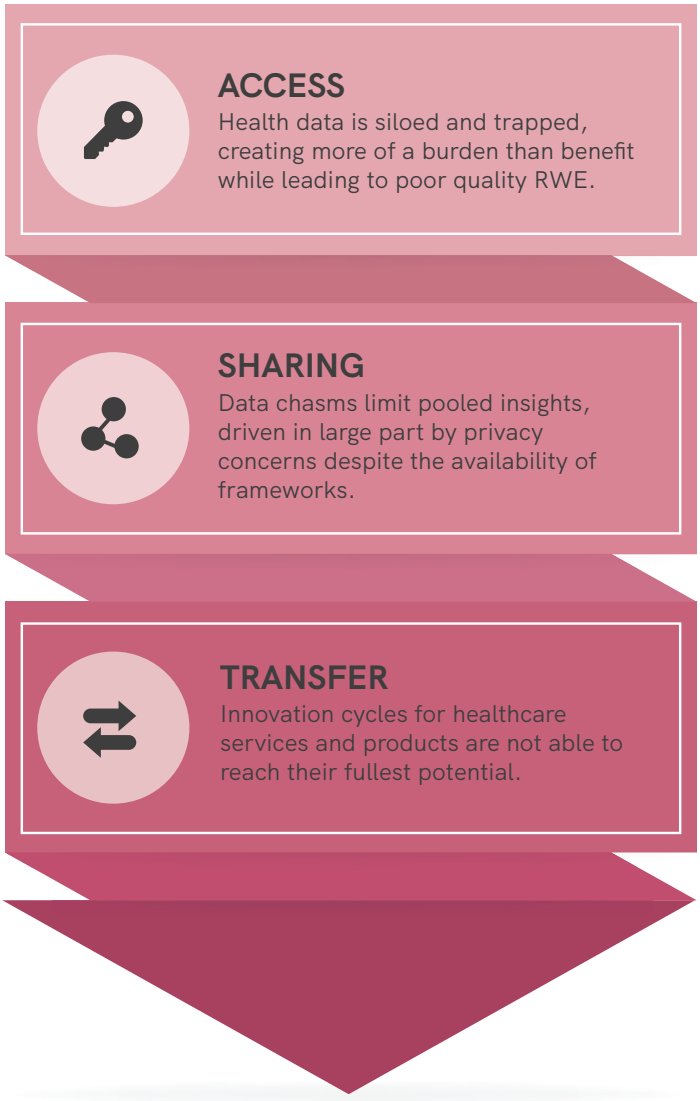


Figure 8: Summary of the health data access, sharing, and transfer challenges which remain in the Asia Pacific, as well as their intertwine therein. Progress has been made, but there is more work needed.

Fortunately for policymaker leaders in Asia Pacific, there are a number of industry best practices to learn from about health data. Much of the HIT infrastructure is already available, despite the fragmentation and interoperability challenges. Opt-in models engaging patients and care providers in their data journeys, effective data safeguarding protocols, efforts to standardize the frameworks, and data sharing ecosystems along the lifecycle can be found around the region and globe. An understanding of how to collaborate with health data stewards, therefore, in order to more seamlessly and securely access, share, and transfer the data, can be a win-win strategy for public and private sector partners.[11]

The following are three case studies provided by APACMed members (multinational medtech companies with operations in Asia Pacific), demonstrating best practices and learnings over time. Thereafter, we will summarize the consolidated set of policy recommendations to take forward.

Best practice case study 1: Leveraging clinical trial data for the benefit of patients, and beyond (Johnson & Johnson MedTech) [34,35]

Patient enrollment and engagement in clinical trials is a great opportunity for governments in the Asia-Pacific region to unlock the value being generated through ongoing research. Since 2014, Johnson & Johnson has partnered with the Yale University Open Data Access (YODA) project to enable a fair and unbiased approach for assessing external research proposals that require the use of clinical trial data as provided by the medtech industry. YODA, therefore, is essentially a health data sharing collaborative between public and private sector with the goal to enable scientists across the world to gain access to the company's clinical trial data assets while promoting strong scientific research and serving the public good.

A review of YODA after five years was published in *Nature*, highlighting the learnings from the experience. YODA's success in facilitating the merging of clinical trial data can be found in its controlled access model, requiring investigators to register and submit proposals that sufficiently detail the research methods before the data is shared. In addition, once the proposals are reviewed by the YODA team (a multi-stakeholder panel), the proposals are publicly posted. Investigators then gain virtual access to the secure data platform to conduct their analyses.

In terms of protocols, as outlined in Figure 9, any investigator is eligible to request data, including those who are employed by the medtech industry. Because the controlled-access model makes information as publicly available as possible, including clinical trial metadata, prespecified analysis plans, and the results of data-sharing requests, the process promotes transparency as well as the responsible conduct and reporting of research. Ultimately, by using a controlled-access model and a multi-stakeholder panel to review access requests, such a strategy prevents unwarranted data distribution and patient re-identification, while ensuring good stewardship by all parties involved.

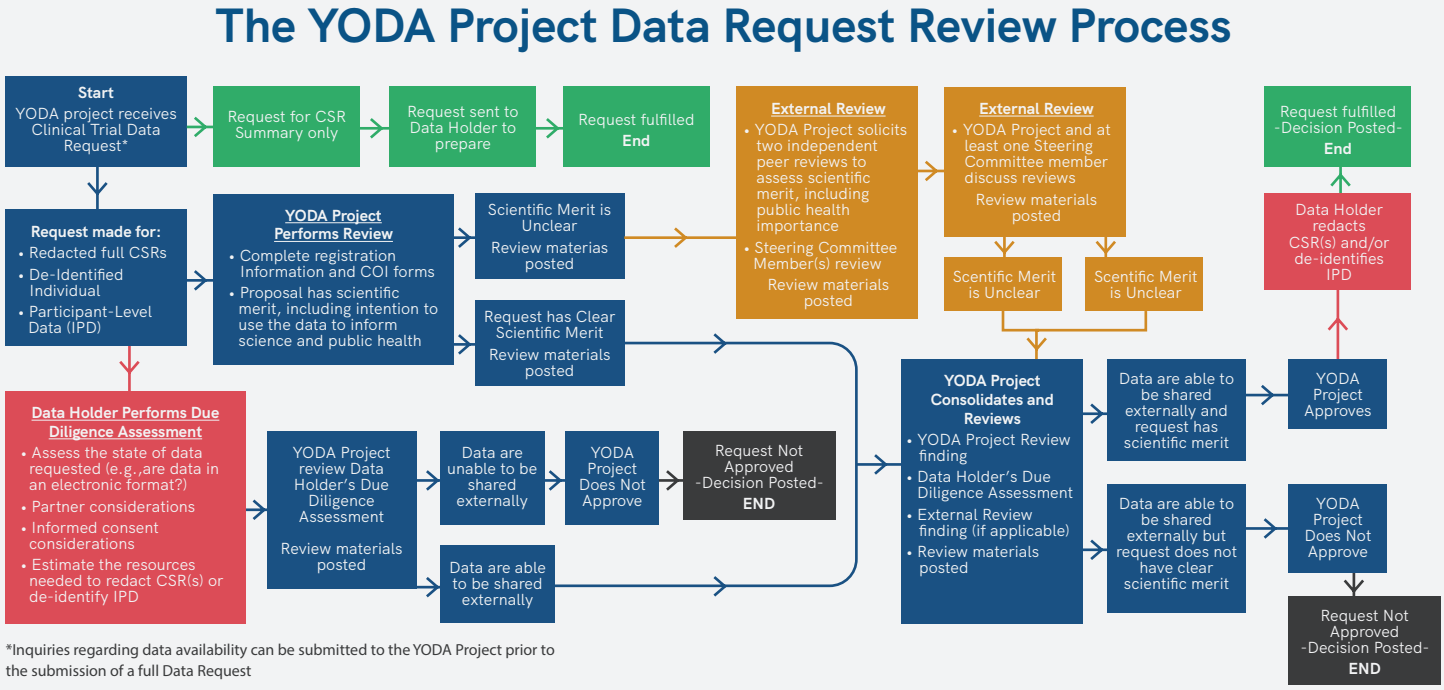


Figure 9: Schematic of the YODA project data request review process for a sharing collaborative. Image reproduced from Johnson & Johnson MedTech.

The lessons from the case study speak to the potential of data science more broadly in the healthcare industry on a few fronts – improving access to high-quality care when and where people need can be powered by data science; investments in workforce upskilling as well as population digital literacy that are required (e.g., training healthcare professionals to read, analyze, and interpret data, supported by a concerted training plan from governments); and citizens, likewise, must be empowered to manage their own data, to understand the benefits of data science, and to possess the tools to make informed decisions. Picture a surgery, for example, that features a combination of robotics, advanced imaging, and a connected digital ecosystem, in which the data is generated, aggregated, and processed in such a way as to reduce variability, no matter where in the world the patient is sitting. Good health data governance, like the FAIR principles, can serve to unlock these opportunities.

Best practice case study 2: Integration of hospital data to provide holistic patient support (Siemens Healthineers) [36]

By consistently bringing breakthrough innovations to market, Siemens Healthineers is enabling health workers with personalized care, operational excellence, and system transformation. But, how can a society as a whole become healthier? That would require preventing disease from happening in the first place and providing treatment that works, in a self-fulfilling financial loop. While this may sound like an ideological concept, it is ultimately the ambition of systems which are moving in the direction of VBHC. To be successful in VBHC endeavors, however, insights surrounding every aspect of care delivery – quality, cost, utilization, variations in care, patient behaviors, outcomes – are required. Data is one of the keys to obtaining such insights, and there is a wealth of untapped information being generated every day in healthcare. Without innovative, digitalized solutions, the data is disparate and not leveraged effectively, affecting future potential in areas like AI, too.

Seoul National University Bundang Hospital (SNUBH) in Korea is an example of making use of its patient data through an integrated sharing platform. Korea, like many countries, is facing a demographic crisis, to combat which the government is promoting VBHC through technology adoption. The SNUBH managing board grasped the opportunity, setting a committed strategy through digitalization, such as the integrated platform. The platform, which is AI-enabled, allows hospital staff to make evidence-based decisions for better patient care and operational outcomes. The platform offers a comprehensive view of the patient, which is then used for precise, prevention-oriented interventions to optimize available resources. As a result, top-line growth at SNUBH has increased more than 11-fold since adoption of the data-driven technique in 2003.

Figure 10 provides an illustration of SNUBH's data integration strategic framework. Core to the strategy was bringing caregivers and end users to the center of the hospital's digital transformation process, offering the right suite of tools while also aligning to international standards (e.g., HL7). The platform continues to grow over time, now integrating data from clinical, financial, medicinal, genetic, travel, and personal health record sources. Two engineers and one nurse are dedicated to managing the platform's data workstreams, a service which became heightened during the COVID-19 pandemic. Not only does the platform give health workers at the hospital an insightful picture, but SNUBH allows for decentralized and remote access to approved data.

Figure 10: SNUBH data integration strategic sharing framework, for innovation in Korea and beyond. Image reproduced from Siemens Healthineers.

As data was built and improved over time, the platform is an example of a truly longitudinal picture of a healthcare ecosystem, from diagnosis to therapy to follow-up activities. SNUBH's early decision to consider data as a strategic asset to the organization, and its investment in digital transformation as well as capability development, became critical in times of need like the pandemic. According to SNUBH, hospitals that want to succeed in the VBHC journey must be ready to integrate data from various sources and to harness the power of insights in order to provide optimal, cost-effective care.

Best practice case study 3: Health data that improves outcomes while maximizing resources (Health Catalyst) [37]

In the United States, like many countries globally, stroke remains the leading cause of long-term disability and the fifth leading cause of death, accounting for more than USD 34 billion in annual healthcare costs. Improving stroke outcomes requires early identification and intervention, yet remains a challenge due to incomplete patient data.

Thibodaux Regional Health System had implemented an evidence-based stroke care intervention in its emergency department. However, the organization was not meeting its targets. They lacked a standardized process for timely diagnostic testing and intervention. Thibodaux Regional also lacked actionable data – in other words, a data-driven approach that reduced mortality, minimized transfers, and provided high-quality patient care. For example, the health system faced discontinuous neurology coverage, necessitating a higher-than-desired volume of patients being transferred to other acute-care facilities and, therefore, disruption to the care continuum and patient satisfaction.

The emergency department providers, nurses, and technicians took ownership to improve the quality and timeliness of stroke care. Using data, Thibodaux Regional, working with Health Catalyst, enabled early warnings of the signs and symptoms of stroke, recognition of uncommon symptoms, and identification of high acuity patients requiring immediate transfers. The emergency department implemented a stroke assessment scale and order set, standardized stroke team notifications, and incorporated visual identifiers for patients with stroke in order to reduce intervention times. Algorithms for the data were designed to align to the new workflows, unlocking even larger health system value in the form of staffing optimization and performance monitoring (see Figure 11). The results speak for themselves – 34% reduction in mortality for patients who have had a stroke, 20% reduction in relative length of hospital stay, 24% decrease in variable costs, and, perhaps most importantly, a 25% increase in patient satisfaction scores with a ranking at the 99th percentile.

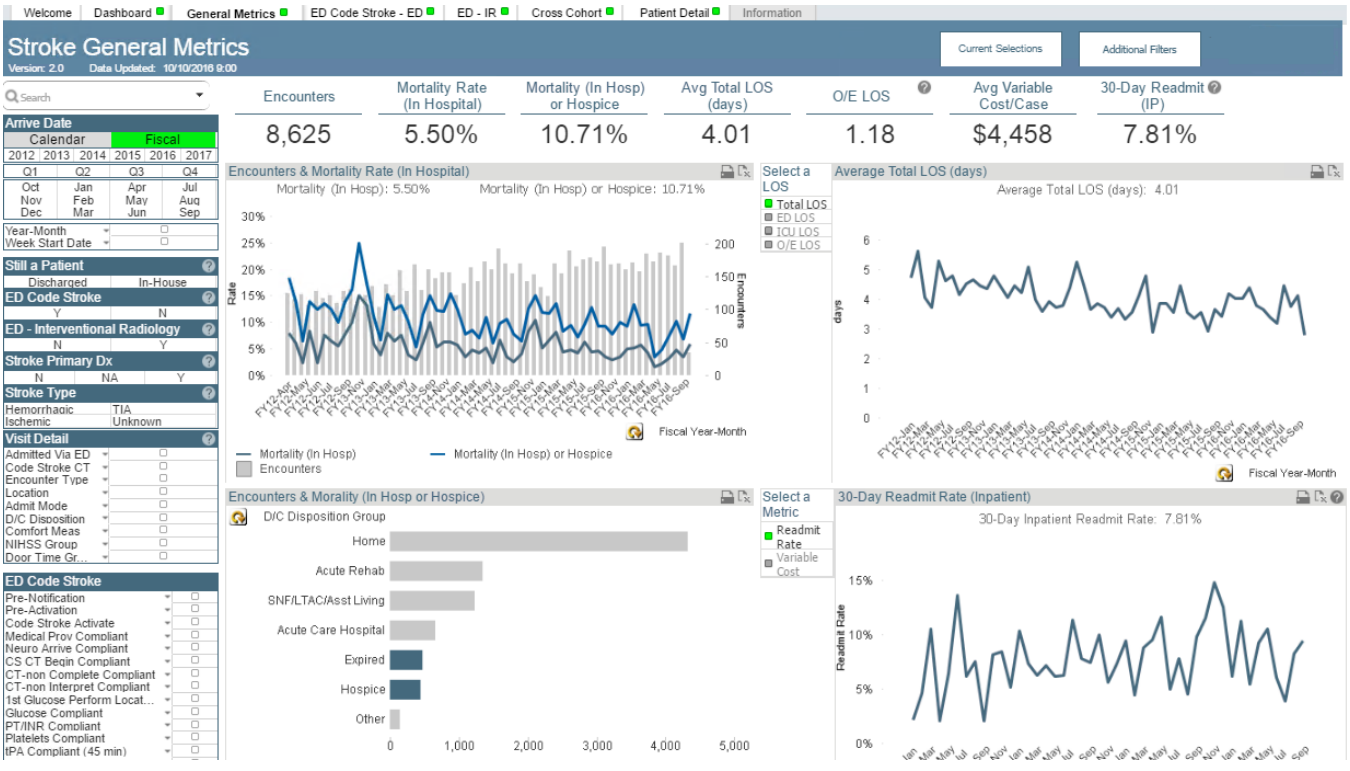


Figure 11: Demonstration of the Health Catalyst Stroke Analytics Accelerator visualization tool, utilizing data from the stroke improvement program to drive even greater clinical- and health system-wide benefits. Image reproduced from Health Catalyst.

Important as well for this case study is the role of leadership. The transformation program had the support of the most senior executives at Thibodaux Regional. In addition, an interdisciplinary stroke care transformation team was assembled with representation from the medical director, nursing, emergency department, intensive care staff, quality improvement experts, unit coordinators, educators, and frontline staff. Strong leadership, supported by data and analytics, unlocked the stroke care transformation as a mechanism to find opportunities for meaningful improvement.

Section 7: Policy Action Checklist to Take Forward

We can imagine a near-term future in the Asia Pacific, like Figure 12, from Health Catalyst, where health reform ambitions are enabled, rather than hindered, by data. Effective policy will be key to ensuring health data is used safely and ethically, to avoid further fragmentation in regulation, and to establish a social contract which strikes the balance between innovation and public good.[38]

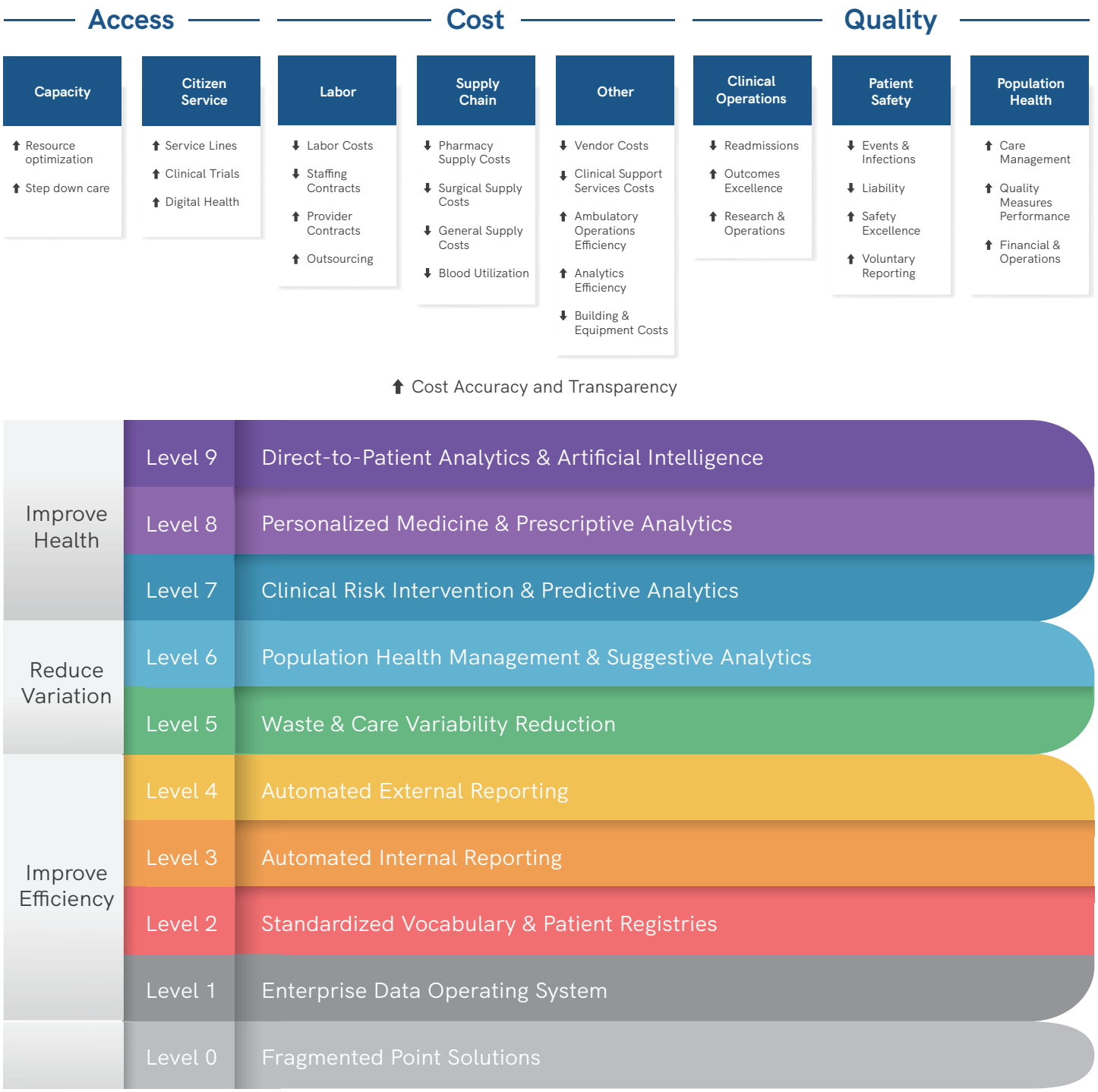


Figure 12: At top, a data-driven approach to addressing core health reform issues in order to improve access, cost, and quality. At bottom, an adoption model for analytic maturity. Frameworks provided by Health Catalyst, the latter in collaboration with HIMSS.

Table 2 provides a policy action checklist, as derived from literature, field discussions, and APACMed members' own experiences, organized around the challenge themes of data access, sharing, and transfer.[39] The opportunity to harness a generational impact on health data is more a concern of "when" rather than "if"; we hope further dialogue can be held, public and private sector working hand-in-hand, to deliver on the promise of visions like RWE and AI in the region.

Table 2: Health Data Policy Action Checklist for Asia Pacific

Challenge	#	Policy Recommendation (Sequential Order)
1. Data Access: Lawful basis for processing health data, as well as its openness, transparency, and security safeguards.	1.1	Take stock of the existing degree of HIT infrastructure (and data) available, while also benchmarking with other countries and stakeholders. This includes aligning on what health data means (including RWE) and capturing evolving innovations happening in data generation and collection, such as federated, unstructured, as well as synthetic data. Importantly, seek to distinguish health data from other consumer data, in terms of its outcomes and legitimate use. Data domain areas may include diagnosis, treatment, research, public health, reimbursement, operations, quality improvement, post-market surveillance, and outcomes evaluation.
	1.2	Adopt clear, harmonized rules on permitted national and international data access and use, while ensuring protection of patient privacy through a predictable legal framework in which stakeholders, including civil society, are involved in designing through public consultation. These rules should apply to access and use of data in the delivery of healthcare, as well as in research and innovation.
	1.3	Establish consistent approaches to protecting patient privacy, such as rules around data de-identification and informed consent. At the same time, encourage use of patient health data, especially for secondary purposes like research and decision-making.
	1.4	Invest in capabilities (people, tools) and communications (stakeholder-relevant information) for health data. This means a robust health data security framework, including obligations for critical infrastructure, network, and information systems, as well as minimum required security standards in the healthcare sector, such as protection for hospitals and health systems. Such a framework requires global cooperation to harmonize the standards for improved data control.

"Countries are moving ahead with their own frameworks, but patients cannot and will not accept a piece-meal approach," said Mittal of PatientsEngage. "Are governments and industry ready to lean into the necessary paradigm shift for health data access solutions which are more meaningful for the average patient?"

Challenge	#	Policy Recommendation (Sequential Order)
2. Data Sharing: Health data minimization, individual participation, and accountability.	2.1	Address the legalities of privacy issues for data sharing such as data processing, consent, anonymization, and any exceptions therein for public interest. This includes supporting adoption of interoperable EHRs with standards for data entry, and investing in infrastructure to enable the quality, use, and sharing of EHR data.
	2.2	Create a seamless, interconnected ecosystem that allows for health data to flow and be analyzed (e.g., with AI) throughout the patient journey. This includes development of common standards, such as open-source health data and interoperability of health information systems at national levels. This also includes functional, technical, and semantic interoperability, as building blocks to ensure any data exchanged across devices and systems is rightly understood and interpreted.
	2.3	Review how insights from the above sharing ecosystem are able to empower broader reform initiatives underway, including UHC and VBHC. A critical step is to ensure data systems are interoperable by encouraging the adoption of existing open technical and data exchange formats for EHR (semantic) standards for all health-related data, such as clinical data and patient-generated health data.
	2.4	Continue to conduct transparent communication campaigns, especially patient awareness and regarding the use of data for research purposes.

"With the public's increasing use of HIT, data frameworks and policies should ensure that appropriate and reasonable security measures are in place to protect health data from unauthorized processing," said Leandro Aguirre, Deputy Privacy Commissioner of the National Privacy Commission in the Philippines. "These frameworks should promote accountability for those who process health data, as well as fairness for those who own the health data being used."

Challenge	#	Policy Recommendation (Sequential Order)
3. Data Transfer: International health data exchanges.	3.1	With access and sharing underway, put in place strong health data governance arrangements, based upon core principles and legal frameworks that are in compliance with privacy regulations, covering the ways in which patient data can be transferred, with standardization, transparency, and ethics, across borders. Advocate the benefits of allowing health data to move responsibly in contrast to restrictive data localization laws. For example, centralized servers may be preferred by stakeholders in order to ensure maximum investment in secure data hosting solutions (versus duplicating servers in every country, which may be impractical for the medical technologies and actually increase risk of breaches).
	3.2	Engage in cross-border protocol dialogue on best practices, within the region and further abroad such as the likes of the UK (common identifier) and Nordics (policy rigor). Privacy safeguards should be in proportion to the risks, aiming to allow secure and controlled exchange of information while supporting innovation. Push for harmonization of data transfers, security measures, and interoperability between different regulatory systems.
	3.3	Revisit privacy protocols for sharing to ensure they meet international standards for the certification of cross-border health data transfer. Privacy safeguards should be proportional to the risks, allowing secure and controlled exchange of information while enabling innovation. This means eventually mandating data transfer and security measures for interoperability which are harmonized among regulatory systems. Move away from country-specific rules requiring data to stay local and preventing cross-border data flows, including more consistent and harmonized classification.
	3.4	Adopt a transfer policy which respects local sovereignty needs while also positioning guidelines for promoting a multi-stakeholder data ecosystem. Any rules impacting cross-border health data transfers should adhere to good regulatory practices, including transparency and privacy, be non-discriminatory, be necessary to achieve a legitimate objective (rather than imposing greater restrictions than necessary), respect accountability models aligned with international best practices, and be harmonized and interoperable with legal frameworks in other jurisdictions. Any regulations must also be future proofed to account for data transfer requirements to develop innovative technologies.

"The policy approach to health data should evolve beyond just collection and into utilization too," said representatives from ToMMo. "There is much to be learned from and integrated into cross-border health data transfer, in the Asia Pacific region and also beyond."

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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, please visit: www.apacmed.org