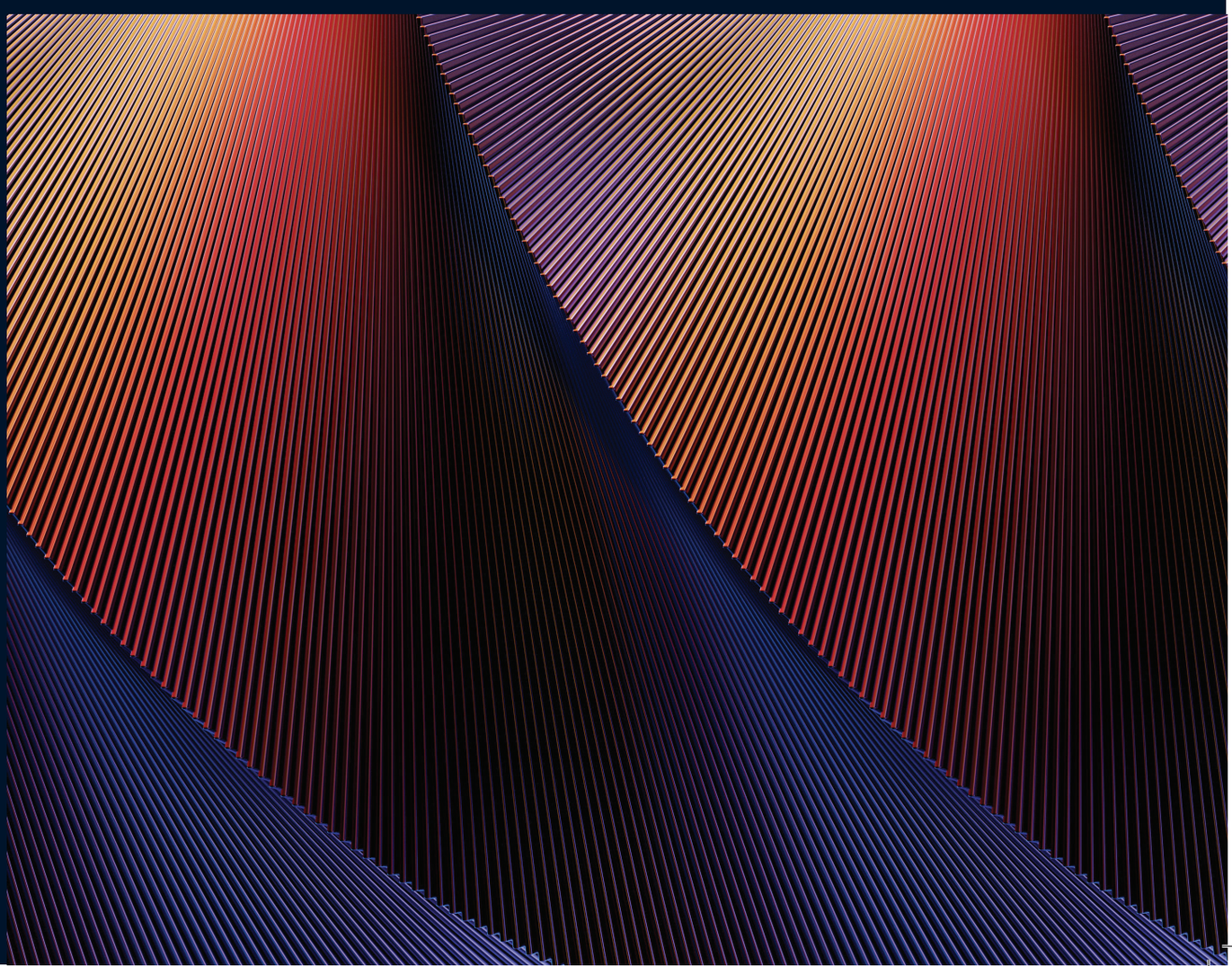
Aarthi Raghavan

ASIA HOUSE
RESEARCH

ASIA'S DIGITAL HEALTH INNOVATIONS:

The role of cross-border health data sharing



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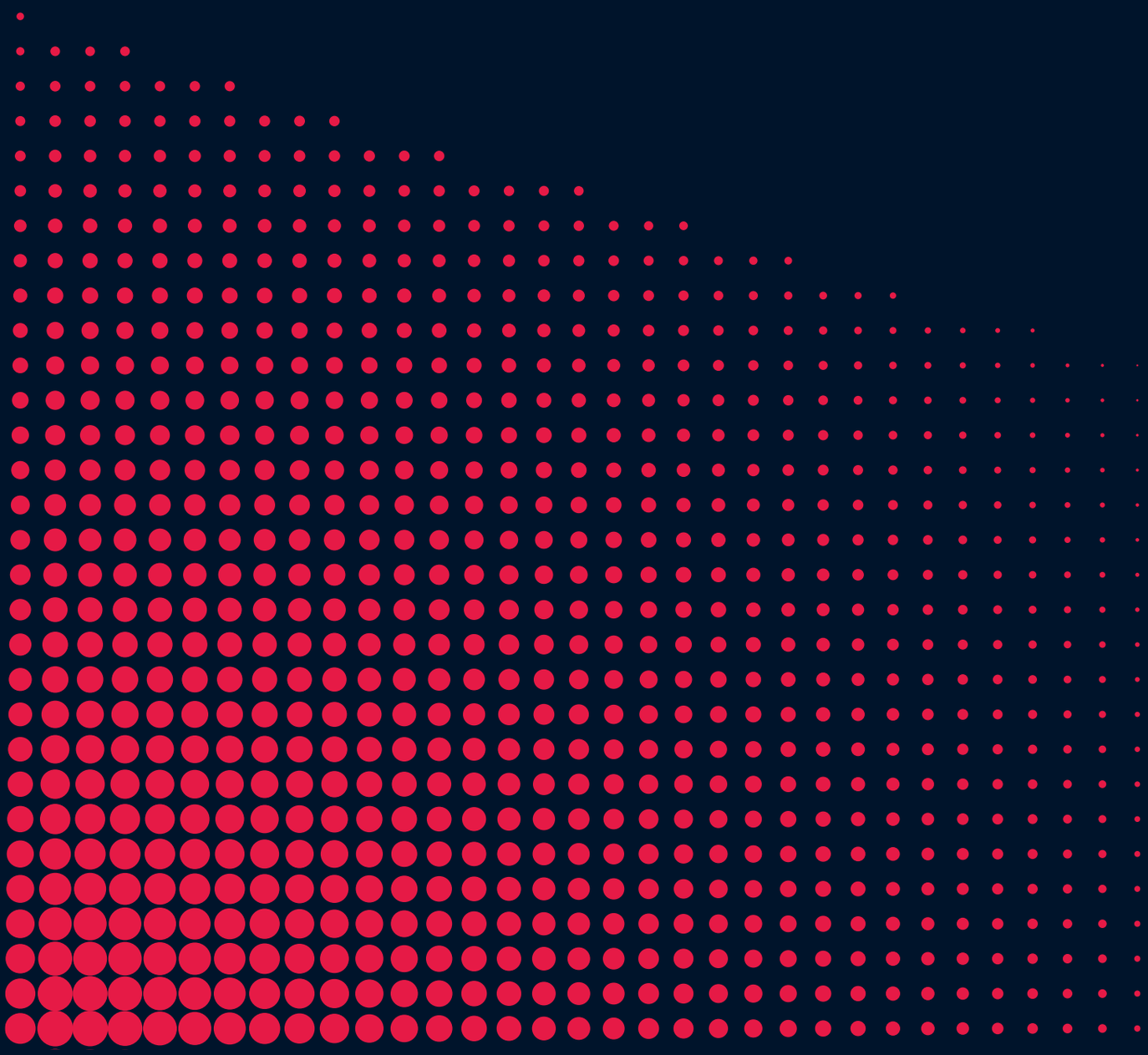

EXECUTIVE SUMMARY

Cross-border sharing of health data is essential for the modernisation of Asia's healthcare and the development of the digital health innovations that go with it. But it is not without snags. While Asia's public and private stakeholders are upbeat about sharing its potential benefits, they are acutely aware of the barriers preventing it from happening. Asia is hampered by differences in regulatory regimes, digital infrastructure, healthcare systems, cultures and languages, and capacities to innovate.

This research paper explores the current impact and future promise of cross-border sharing of health data on innovations across five Asian countries: China, India, Indonesia, Malaysia and Singapore.

The overall findings are:

- Sharing health data in Asia continues to be restricted by the lack of a common platform, and by differing national regulatory regimes, unequal digital infrastructures, and shortages of healthcare and IT staff.
- Governments are responding (to varying degrees) and healthcare startups are lining up to develop necessary innovation.
- The main barriers remain concerns over sharing citizens' data, worries about cyber threats, and cost.

At the country level, the findings are:

- **China** faces significant challenges to sharing health data because of its highly decentralised healthcare system, and the concern of both government and citizens about data security. Despite this, a less restrictive and more proactive regulatory approach has fuelled a market-based digital health innovation landscape. This has helped local startups and technology companies to scale up their innovation in the local market within shorter timelines. As a result, digital health startups in China have become increasingly attractive for global investors.
- **India's** healthcare systems, which are highly decentralised in terms of governance, have also created structural inefficiencies in sharing health data. The government is implementing the Ayushman Bharat Digital Mission to overcome these challenges and enable health data interoperability – essentially linking tech systems – across public and private healthcare systems, as well as in urban and rural areas. The country recently passed the Digital Personal Data Protection Act 2023, which is more open to cross-border sharing

of data and places strict conditions on the protection of health data during such transfers.

- Inefficiencies in health data collection and sharing have plagued digital health innovations in **Indonesia**. As such, the government is trying to combine existing health data systems onto a single platform called SATUSEHAT, and calling for startups to participate. In terms of cross-border sharing of health data, while the data protection law allows it, subsequent regulations for implementation are expected to become more restrictive due to strict government oversight.
- **Malaysia** has a robust and centrally regulated healthcare system, but government efforts to build comprehensive electronic health records (EHR) have been largely unsuccessful so far. It is currently banking on the Malaysia Health Data Warehouse to overcome existing challenges by bringing more hospitals and clinics together to actively share health data. The government provides abundant funding and support for digital health startups and has recently identified five hospitals to collaborate with them. Malaysia does allow cross-border data sharing, but in limited situations based on strict compliance with personal data protection legislation.
- **Singapore**, an early adopter of EHRs, has an advanced healthcare system, and the government actively encourages digital health startups and supports them with world-class facilities and funding. Health data sharing at the institutional levels and by means of active business-to-consumer (B2C) models has enabled unique innovations in healthcare. Yet data security remains a challenge. Hence, the government is planning to introduce enhanced regulations to protect personal data, prompting healthcare providers, technology companies and startups to be especially cautious and avoid cross-border sharing of health data as much as possible.

Country-wide EHRs are a crucial element in better healthcare. While digital health startups and technology companies tend to remain focused on serving urban, tech-savvy populations, government-led initiatives to create national records generate true data value. This allows for startups and technology companies to glean the more detailed and specific data they need for the health issues their innovations are trying to address.

The report identifies a *quid pro quo* for governments with national databases. In exchange for providing the conditions needed by startups – funding, regulatory sandboxes, etc. – governments can expect the digital health innovators themselves to contribute their own data to the national database, making it broader and more accurate. Additionally, the more digital health startups participate in the process, the more governments will be able to amend regulations in a way that enables them.

For the startups themselves, a key benefit of participating in national electronic health databases is that they can more easily expand from business-to-business (B2B) to B2C activities, depending on the kind of solution they are offering.

As things stand, higher regulatory restrictions tend to lead to digital health startups preferring a B2B over a B2C model. The latter requires use of personal data and attracts more regulation; the former tends to operate by partnering with experienced stakeholders who are already compliant with regulations, reducing the burden for startups.

The paper notes, however, that national EHRs can enable more digital health startups to offer consumer-facing solutions. A less restrictive

approach by governments to digital health startups can enable innovations to increase in size and depth. Conversely, an uncertain regulatory environment may push startups to adopt a cautious approach, limiting innovation and growth.

When it comes to cross-border health data sharing, concerns about the misuse of data are the main barrier to digital health innovation. Stakeholders are especially worried about regulatory repercussions if health data is breached or misused in the process of cross-border sharing. For digital health startups that are still small, this is a huge impediment as they lack the bandwidth to comply with complex regulations.

This all leads to a contradiction. Governments want to attract global innovations in local healthcare systems, but also want to restrict cross-border health data sharing because of privacy issues. They find this a viable model to encourage local innovation. But the governments that are able to innovate also want to share their innovations with other countries to exert their expertise regionally and globally.

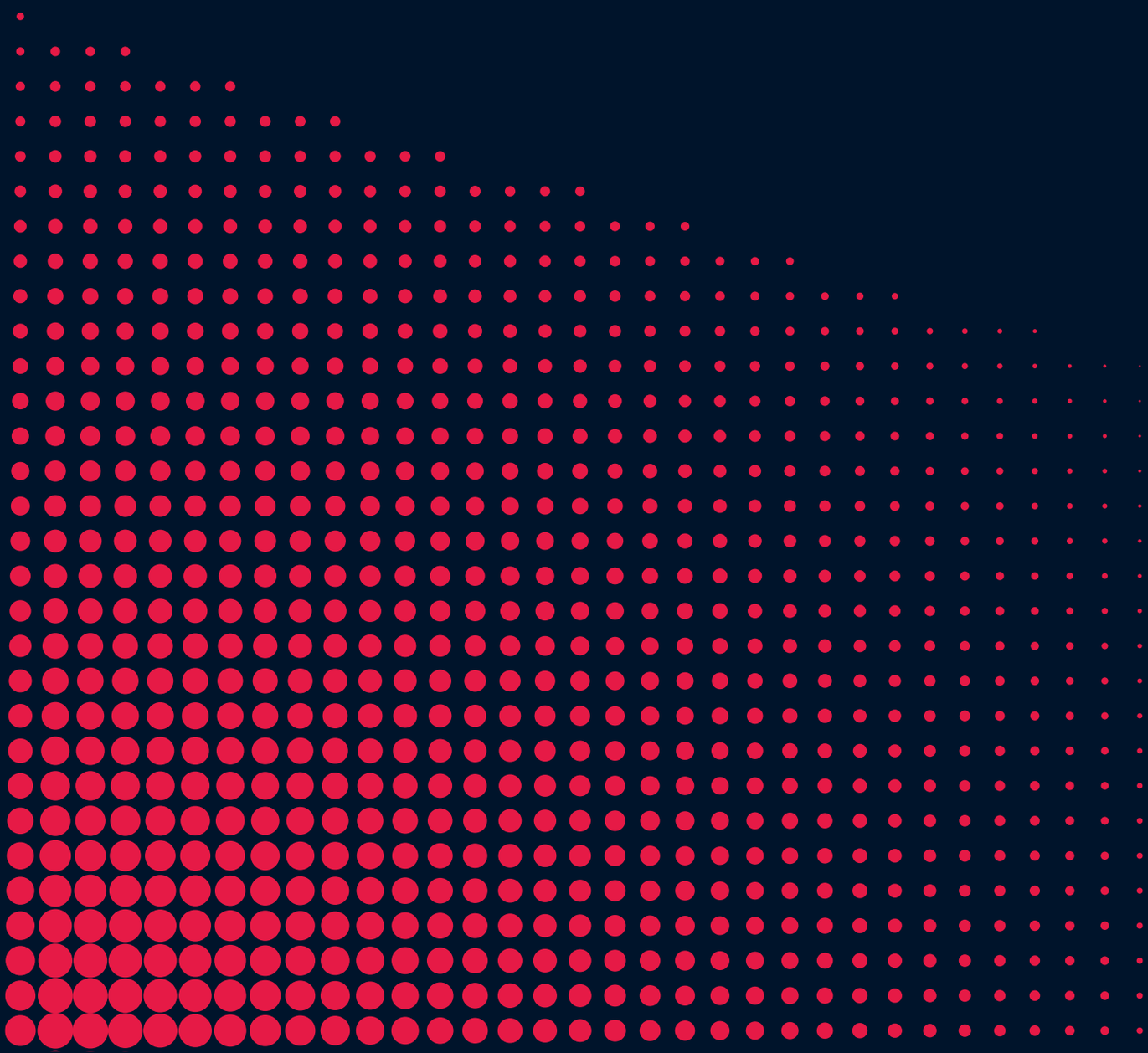

Table of contents

Executive Summary 1

List of Figures 6

List of Tables 6

Acknowledgement 7

Section 1: Introduction 8

- **1.1** What is health data sharing and why is it important? 10
- **1.2** Digital health as an opportunity for Asia: COVID-19 and beyond 12
- **1.3** How Asia is placed vis-à-vis global health data sharing 12
- **1.4** Efforts by Asian governments to enable cross-border data sharing in general 13
- **1.5** Drivers of cross-border health data sharing in Asia 14
- **1.6** Barriers to cross-border health data sharing in Asia 18

Section 2: Country cases 22

- **2.1** China: A robust yet relatively closed digital health ecosystem 23
- **2.2** India: An evolving and increasingly open digital health ecosystem 34
- **2.3** Indonesia: A fast-growing digital health ecosystem that's strongly protected 46
- **2.4** Malaysia: A regional front-runner in digital health, with ambitions to expand 55
- **2.5** Singapore: A regional leader in digital health innovation 63

Section 3: Sharing health data leads to digital health innovations in Asia 71

- **3.1** Electronic health records are important for digital health innovations at the country-level 72
- **3.2** Impact of cross-border sharing of health data on digital health innovations 76

Section 4: Policy recommendations 81

Section 5: Conclusion 84

List of figures

Figure 1 Thematic map of drivers of cross-border health data sharing in select Asian countries

Figure 2 The four levels of health data interoperability

Figure 3 Thematic map of barriers of cross-border health data sharing in select Asian countries

Figure 4 Timeline of key regulations related to health data sharing in China

Figure 5 Framework for the digitaliszation and sharing of health data in China

Figure 6 Timeline of regulations for health data sharing in India

Figure 7 Framework of the Ayushman Bharat Digital Mission

Figure 8 Timeline of regulations for health data sharing in Indonesia

Figure 9 Time of regulations for health data sharing in Malaysia

Figure 10 Future ICT architecture overview

Figure 11 Time of regulations for health data sharing in Singapore

Figure 12 Application of the NEHR in health data interoperability

Figure 13 Movement of B2B and B2C startups before and after EHR integration

Figure 14 Framework for Digital Health Innovations (DHI) in Asia

List of tables

Table 1 The impact of regulatory sandboxes on digital health innovations

Table 2 Examples of deep innovations Asian healthcare

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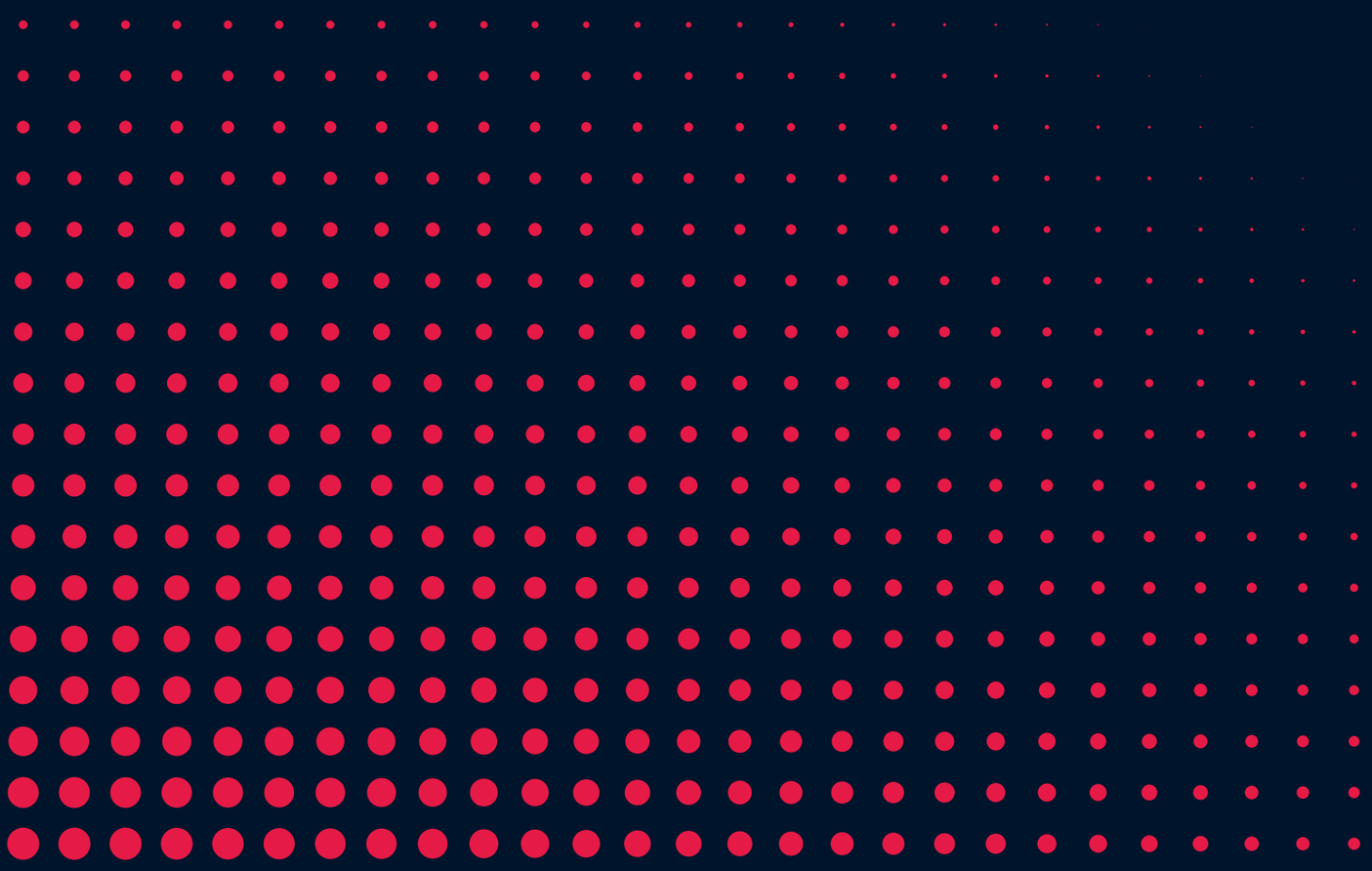
Aarthi Raghavan
Asia House Fellow 2022–23

1

INTRODUCTION



Technology has enabled Asia's healthcare providers to improve the access, affordability and quality of care to patients. Digital health applications, in particular, have reduced the time taken to access health data (Sujith, et al., 2022), cut the cost involved in this process, and eased the processes by which data can be accessed in healthcare settings (Wang, et al., 2022). As a result, healthcare organisations that adopt digital health applications (and that have embraced digitalisation overall) have a better view of their patients' needs.

Digitalisation helps healthcare providers to identify the bottlenecks in healthcare delivery and, crucially, to address them (see box). They can use this data to provide innovative healthcare services to patients, leading to positive longer-term outcomes (Long, et al., 2021; Matsuthita, 2020).

Digital health innovation: Three examples from the pandemic

→ During COVID-19, public and private technology companies in China designed artificial-intelligence (AI)-based 'doctor' chatbots to extend healthcare consultations to rural communities. These chatbots helped citizens access healthcare advice from homes and on time, while easing the stress on doctors and healthcare facilities.

→ Using data from across the country's medical facilities, vaccine stocks, and other resources, India's government designed and deployed the COVID-19 online vaccination portal. The portal made vaccination more efficient as citizens could easily register and instantly download certificates upon receiving the dose at the nearest designated facility.

→ In March 2020, Singapore launched the Trace Together digital application to identify potential new cases of COVID-19 in the community. The COVID-19 trace application relied on the communication between Bluetooth-enabled devices, which collected data on the proximity and duration of a user's contact with others, including a known case of COVID-19. This was used to prevent new infections and contain the disease more effectively.

Asia is a leader in digital innovation in healthcare. But with a fast-growing population of nearly 4.76 billion[1] people, Asia is faced with an increasing burden of healthcare needs. The region also faces significant inequalities in healthcare access and infrastructure between urban and rural areas, across socioeconomic levels, and across countries themselves (Nakhooda, et al., 2021).

This paper aims to examine the following emergent themes in the context of Asia's five major economies: China, India, Indonesia, Malaysia and Singapore:

- → The key drivers and barriers to sharing health data across borders.
- → Country-specific challenges faced by healthcare organisations in sharing health data.
- → The impact of sharing data on digital health innovations in Asia.

It is evident that the key factors shaping healthcare provision in the region are Asia's ageing populations and their increasing demand for healthcare; regional disparity in healthcare infrastructure and services; limited human and financial resources; and the continuing impact of COVID-19 (Nakhooda, et al., 2021). More than 1 million people lost their lives in the region due to the pandemic – 17.56 per cent of the global total.[2] Hospitals and doctors were placed under extreme stress during the period with many unable to undertake their fundamental role of care delivery. This has focused governments on the need for resilience in their healthcare sectors (OECD/WHO, 2022).

The first section will discuss why digitalisation in healthcare is important for Asia and the role it plays. This is followed by a discussion of how it is an opportunity for Asia, aided by the experiences gained from the COVID-19 pandemic. The section then discusses the drivers and barriers of cross-border health data sharing in Asia.

The second section consists of five country cases, outlining the opportunities and challenges for sharing health data and digital health innovations, the regulatory landscape for sharing, and the impact of electronic health records (EHRs) on digital health innovations at a national level.

The third section is about the findings from the research and covers the impact of EHRs on digital health innovation and the impact of cross-border health data sharing on digital health innovations in Asia. This is followed by a brief section on successful digital health innovations that have managed to expand at the regional as well as global level despite regulatory complexities. After this, the paper outlines a framework on digital health innovations in Asia followed by policy recommendations and the conclusion.

1.1 What is health data sharing and why is it important?

Health data is the information that a patient generates as she/he moves through the healthcare system to receive treatment. Depending on how it is used, it can be categorised as primary or secondary health data. While primary health data is used by healthcare providers to deliver care to a specific patient, secondary data is anonymous and used for research and policymaking (WHO, 2021). The sharing of health data (primary and/or secondary) is formally known as health data interoperability. It is the ability of different information systems, devices and applications to communicate with each other. It enables the access, exchange, integration and cooperative

1 The population of Asia as of September 10, 2023 is 4,759,279,795, based on the latest United Nations estimates (Worldometer, 2023).

2 Calculated using the COVID-19 cumulative death statistics as of June 19, 2023 (WHO, 2023).

use of data across organisations, regions or countries to optimise the health of individuals and populations globally (HIMSS, 2023).

Sharing health data enables healthcare providers, patients, public health authorities, universities and research institutions to get a complete understanding of health challenges, to develop solutions, and to make evidence-based decisions (WHO, 2022). It can enhance the quality of healthcare services, provide continuity of care for patients, build a knowledge base on social determinants of health,[3] improve research effectiveness, help in the application of emerging technologies such as artificial intelligence (AI) and big data analyses (WHO, 2021), and lead to new digital health innovations (Schwalbe, et al., 2020; Matsushita, 2020).

How beneficial can the sharing of health data be?

A study conducted across hospitals in the United States (US) suggested that sharing health data (at the national level in this case) can improve the cost of care by 44 per cent, patient experience by 38 per cent, care coordination and patient health outcomes by 36 per cent, access to care by 33 per cent and value-based care by 28 per cent (Biel, et al., 2019).

Although it started at the patient level – that is, using personal data for personal healthcare – the importance of health data has expanded. Health data in digital form can be shared across borders and contribute to global public healthcare (Groza, 2020). According to the World Health Organization (WHO), health data can have an unprecedented positive impact on the health and wellbeing of large populations globally (WHO, 2021). This is mainly because, when health data is pooled across countries, it tends to have greater value than the sum of the health data of individual countries.

Combining large datasets in healthcare increases sample sizes, leading to greater statistical power, which in turn increases the ability of researchers and policymakers to detect rare events and identify patterns (Oderkirk, et al., 2019). With the use of technology (AI, machine learning, etc.), health data when shared can generate valuable public health insights in real-time that can drive positive health outcomes for populations, help countries achieve universal health coverage, and build resilience towards future public health emergencies (Schwalbe, et al., 2020).

However, health data is sensitive personal information and hence requires well-designed data-protection safeguards at national and international levels. Greater collaboration is key as it not only enhances the coverage of these benefits of sharing health data but alsoboosts the capacity of regulatory bodies to thwart cyber threats in healthcare (Oderkirk, et al., 2019).

3 Social determinants of health are the non-medical factors that influence health outcomes. These can be the conditions in which people are born, grow, work, live and age. They also include economic policies and systems, development agendas, social norms, social policies, racism, climate change and political systems (CDC, 2022).

1.2 Digital health as an opportunity for Asia: COVID-19 and beyond

The COVID-19 pandemic has led to a mindset shift among Asia's governments and healthcare organisations with respect to health data sharing (Amit, et al., 2021; Nageshwaran, et al., 2021) and the adoption of digital health applications[4] (Liu, et al., 2022). Data sharing became a useful tool for policymakers to understand the scale of the COVID-19 virus within nations and across borders. In some instances,it helped to mitigate the economic impact of the pandemic.

Cross-border health data sharing guided scientists and researchers to identify patterns of the disease, to note the emergence of new variants, and to recommend precautions (Li, et al., 2022) and preventions (Merten, et al., 2020). It also aided in the development of vaccines, their supply across the world, and the ability to observe their efficacy across populations (Gao, et al., 2020).

In this sense, the pandemic offered an opportunity to understand how cross-border data flows enable digital innovations across the world (WTO, 2020). In Asia, governments used the sharing of health data to enable domestic as well as international travel by means of digital health passports and health codes (Guan, 2021). Digital health innovations such as contact-tracing applications and the issuance of digital vaccination certificates also emerged (Amit, et al., 2021).[5]

Since the pandemic abated, Asia's governments have been deploying digital health applications more actively (Sust, et al., 2020). This has had a knock-on impact on primary healthcare, on secondary healthcare, and on digital health startups (Gudi, et al., 2021). Public and private hospitals' interest in emerging technologies such as AI, machine learning, cloud computing and the Internet of Things has significantly increased, thus opening up innovations (Chandra, et al., 2022).

Crucially, Asia's policymakers have increased their efforts to build and launch national EHRs (Liang, et al., 2021) to build resilience in their healthcare systems (Garg, et al., 2023). India, China and Association of Southeast Asian Nations (ASEAN) have announced policies that promote digital health innovations (Ang, 2023; Wang W. Y., 2023; WHO South-East Asia, 2021) and aim to use digital health as a launch pad for economic recovery post COVID-19 (Asian Development Bank, 2021).

1.3 How Asia is placed vis-à-vis global health data sharing

Globally, the European Union (EU) and the US have implemented advanced mechanisms for sharing health data at, respectively, cross-border and national levels (Oderkirk, et al., 2019). These provide lessons for Asia.

The European Health Data Space aims to develop fully interoperable EHRs for diagnosis, treatment, research and disease prevention, with policies promoting effective sharing of health data for scientific discovery and precison medicine (Oderkirk, Wenzl, & Slawomirski, 2019). The region is also aligning its data sharing with investments in digital health innovations that use cloud technology to develop AI-based applications that can help improve treatments (Oderkirk, Wenzl, & Slawomirski, 2019).

The US, on the other hand, is hampered by diverse standards across different EHR systems, by a lack of patient identification

4 Digital health application is the use of technologies like computing platforms, connectivity, software and sensors for healthcare and related uses. The broad scope of digital health includes categories like mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalised medicine (FDA, 2023).

5 Nageshwaran, et al., 2021; Amit, et al., 2020; Kapoor, et al., 2020; De Guzman, et al., 2020.

across health information exchanges, by poor data sharing due to insurance companies not participating, and by high integration costs (Healthcare Weekly, 2022) (CDC, 2022).

There is currently no comprehensive regulation that covers all Asian countries with respect to sharing health data across borders. However, there are some multilateral, regional, bilateral and national initiatives.

The Asia eHealth Information Network (AeHIN), for example, is a regional grouping comprising experts from South and Southeast Asia to promote health information technology to improve health outcomes in the region. AeHIN has put forward a framework for cross-border health data sharing that includes guidelines for data privacy and security (Liverani, et al., 2018).

In addition, WHO has revised its International Classification of Diseases for digital health records. It was endorsed by the World Health Assembly in 2019 and has come into effect globally since 1 January 2022 for national and international reporting of mortality data (Oderkirk, et al., 2019). This is starting to provide some standardisation, including in Asia.

What WHO wants

In 2022, WHO's Research for Health department launched a new policy requiring data sharing in all health research projects funded by the organisation (WHO, 2022).

In 2021, WHO published 'Global strategy on digital health (2020-2025)', aimed at creating a shared understanding of the need for interoperability and the resources required to enable it (WHO, 2021). The strategy highlights steps that governemnts can take to put in place national EHRs while ensuring patient privacy (WHO, 2021).

WHO's Digital Health Competency Framework, meanwhile, aims to strengthen digital health capacity and comptency at the country level and among digital health policymakers, project planners or managers, health practitioners, and the patient/people/population. It also guides stakeholders across the ecosystem who are implementing digital health solutions, systems and services (WHO, 2023).

All this applies to Asia as much as to the rest of the world.

1.4 Efforts by Asian governments to enable cross-border data sharing in general

Asia benefits from broad frameworks that may also apply to cross-border sharing of health data. The Asia-Pacific Economic Cooperation (APEC) Cross-Border Privacy Rules is an umbrella framework that applies to member countries[6] by requiring a minimum level of data protection wherever there is a lack of domestic regulations (although it does not displace domestic laws if there are any) (GSMA, 2018).

The ASEAN Data Management Framework and the Model Contractual Clauses for Cross Border Data Flows were approved by the 1st ASEAN Digital Ministers' Meeting in January 2021. The framework aims to promote sound data governance practices by helping organisations identify what datasets they

6 Australia, Brunei Darussalam, China, Indonesia, Malaysia, Philippines, Singapore, South Korea, Japan, Taiwan, Thailand and Vietnam are member countries of the APEC block (GSMA, 2018).

have, assign them to appropriate categories, manage the data, and protect them accordingly (ASEAN, 2021).

The ASEAN Model Contractual Clauses offer a template of contractual terms and conditions that may be included in the binding legal agreements between businesses transferring personal data to each other across borders (PDPC, 2021).

So far, there has not been much progress on the implementation of the frameworks, meaning the effect on cross-border health data sharing in Asia remains to be seen.

There have, however, been some notable developments with respect to developing global principles for data governance in Asia. Japan has proposed the concept of 'Data Free Flow with Trust' as an organising principle for the global approach to data governance (Goodman, et al., 2021).

Similarly, Singapore has tried to build cross-border data sharing as part of digital economic agreements. The 2020 Singapore-Australia Digital Economy Agreement is a binding trade agreement that mandates some form of data sharing between the countries (Goodman et al., 2021).

In the same year, Singapore joined New Zealand and Chile to launch the Digital Economy Partnership Agreement

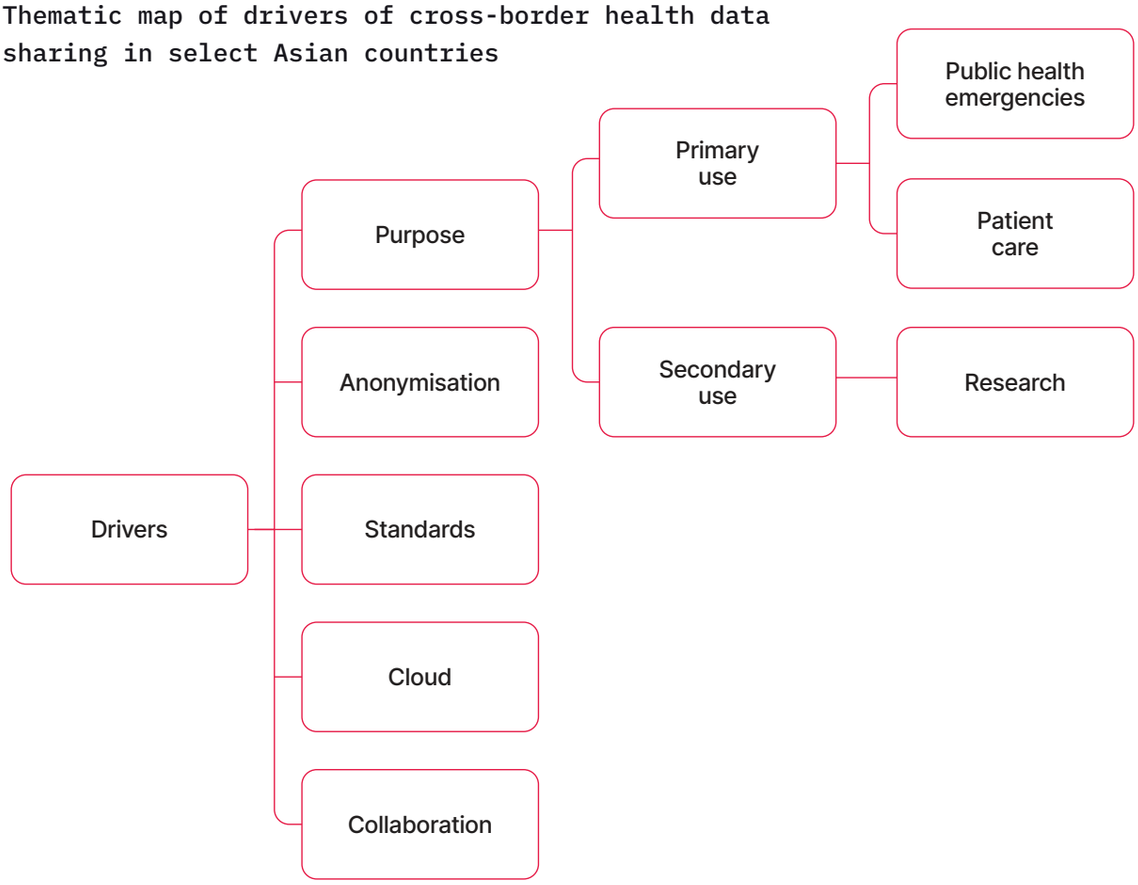
1.5 Drivers of cross-border health data sharing in Asia

The **purpose** of sharing health data across borders must be clear before countries can agree to engage in the process. An ASEAN-based study found some agreement. The value of health data sharing was recognised by governments for 1) public health emergencies, 2) the better understanding of disease epidemiology, and 3) for the exchange of good practices and experiences (Liverani, et al., 2018).

Similar findings have been identified across interviews conducted by Asia House for this paper, where participants noted that there must be a shared understanding among governments in the region about the purposes for which sharing health data is required and mutually beneficial.

- Data sharing for **public health emergencies** (Dye, et al., 2016), research, and innovation (WHO, 2021) is widely accepted by governments. That's why, during COVID-19, there was a wider agreement among governments with respect to cross-border health data sharing. One example is how the Malaysian Government shared the code for the MySejahtera application on GitHub, which is an open-source platform online. The MySejahtera app was mainly used to contact-trace potential new COVID-19 infections among the Malaysian population. Given the scale of the pandemic, and its impact on other countries in the region, the government decided to share it for wider use (Microsoft, 2021).
- **Patient care** is a key driver for cross-border health data sharing in Asia when patients seek care in another country. Governments are also open to sharing anonymous data in the case of communicable diseases. While most countries are hesitant to share the personal health data of patients across borders, aggregated data sharing may be possible for disease surveillance and for understanding better treatment options for patients in a targeted manner.
- **Medical tourism** can also be a catalyst for health data being shared between countries. For example, Malaysia is aiming to use its current brand as a medical tourism destination to further develop its capabilities and reputation for being the Fertility Hub of Asia, Cardiology Hub of Asia, and Cancer Care Centre of Excellence (ITO,

Figure 1:
Thematic map of drivers of cross-border health data sharing in select Asian countries



Source: Author's interviews (see Appendix 1)

2023). There are also ongoing discussions within ASEAN regarding medical tourism between countries which may potentially drive cross-border health data sharing.

However, a key driver is the **anonymisation** of health data when it is shared across borders, which has also been recommended by WHO. This is so that a patient cannot be re-identified at any point of the process while also achieving the goal for which the data is shared. Some governments already require healthcare organisations, technology companies and digital health startups working with AI and machine learning to anonymise and aggregate data before it is shared across borders to protect patient privacy. Others require encryption as an additional requirement, so that health data cannot be stolen or misused during transit from one country to another.[7]

→ **Data aggregation** involves large volumes of data from multiple sources being combined, compiled and organised into a unified format. This can then be used by healthcare providers to identify risk factors and develop strategies to reduce the risks for their patients (Chia, 2023). Since

7 It is also important to note that anonymised data cannot be easily used for patient care purposes. For instance, in some situations, organisations may find it hard to share the data overseas to get it analysed by AI and then bring it back to the origin country to inform the patient of a certain health risk. In such cases, anonymisation can become technically challenging for organisations (Interviews).

aggregated data does not include patients' personal information, it is easier to share and has fewer restrictions.

- During COVID-19, Indonesia was the only country in ASEAN that shifted from granular to aggregated data sharing, due to data privacy concerns, a high number of cases, and a lack of resources to report granular patient data in real-time (Amit, et al., 2021).
- **Secondary use** of health data involves anonymous health data being shared and used for research, innovation, public health and policy purposes. Currently, secondary use of health data is not clearly defined in many Asian countries, although there have been attempts to do so. Singapore is planning to introduce a Health Information Bill in the second half of 2023 to facilitate proper collection, use and sharing of health data across healthcare facilities (Abdullah, 2023). The law also defines the purposes for which secondary health data can be shared within the country as well as across borders.
- **Research** is a secondary use that is widely recognised across countries and multilateral institutions based in Asia. Most of the health data shared for research purposes is anonymous. This is perceived as beneficial by some countries who use and share healthcare research, especially with respect to improved treatment methods and innovation. For example, Singapore is a leader in research but it has a very small population. On the other hand, countries such as Malaysia, Thailand and Vietnam have larger populations that can provide a larger sample size for research activities.
- **Cloud service providers** such as Amazon Web Services, Google Cloud and Microsoft have built their business model around the efficient and secure sharing of health data for healthcare organisations.
- **Federated data platforms** – software processes that allow multiple databases to function as one – facilitate interoperability and information sharing between autonomous, decentralised organisations. By means of such platforms, data remains within the country of origin but the broader metadata[8] becomes centralised and searchable (Alvarellos, et al., 2023).
- The World Economic Forum has been actively exploring **the potential of federated data networks to enable cross-border health data sharing.** Federated data platforms are recommended as a viable alternative that should be adopted by governments around the world to enable more innovation in healthcare (WEF, 2020).
- Cloud service providers are enabling healthcare organisations to set up federated data platforms with **automatic anonymisation and encryption** of health data. This process is being increasingly recognised as an enabler in cross-border health data sharing globally, and is starting to be used in Asia (Alvarellos, et al., 2023; Pisani, et al., 2022).
- Some countries, however, have **restricting regulations** regarding the cloud. The Chief Government Security Office in Malaysia, for example, requires data to be anonymised and encrypted before it is uploaded and processed on the cloud and shared with relevant entities.
- **Health data standards** also play a crucial role in sharing between countries. Their use has increased given that many of the standards are globally recognised, such as Health Level 7 (HL7) and its Fast Healthcare

8 Metadata can be defined as information that describes and explains data. It provides context with details such as the source, type, owner and relationships to other datasets, thus helping the user to understand the relevance of a particular dataset and guiding its usage (Atlan, 2023).

Interoperability Resources (FHIR) element.[9] They provide a common language and a common set of expectations that enable interoperability between systems and/or devices. As such, they permit doctors, labs, hospitals, pharmacies and patients to share data regardless of application or market supplier (HIMSS, 2023).

- The standards relate to international patient conditions and access, cross-border care, and the continuum of care. The standards, however, are not yet being widely implemented from the perspective of cross-border health data sharing.
- Countries have agreed on **structural interoperability**, but **semantic interoperability** – the process of creating a common meaning for the data for different people, regardless of which system they happen to be working in (see Figure 2) – remains a challenge.

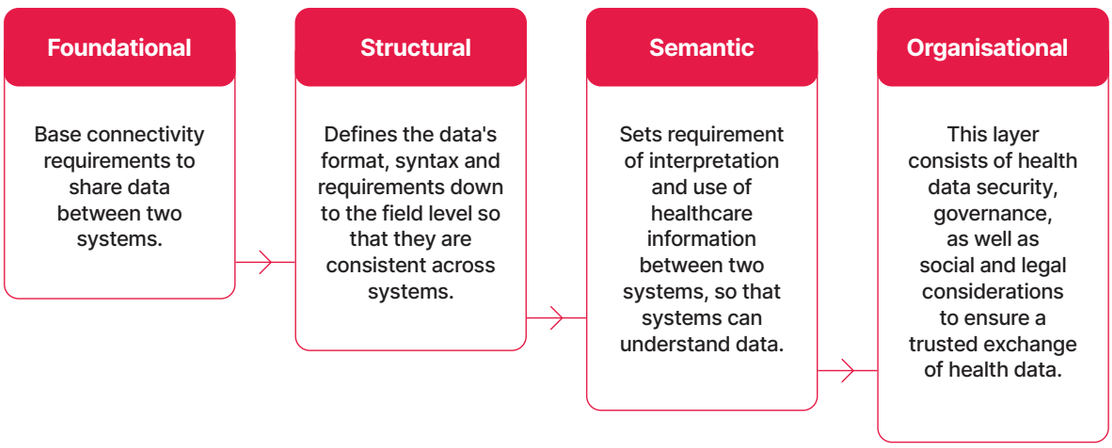
The ultimate goal is to achieve organisational interoperability of health data, which requires all stakeholders to collaborate, including governments, regional as well as multilateral bodies.

Our research, meanwhile, has found general agreement on the **need for a coordinating organisation** to help develop consensus among governments on the type of health data that can be shared, its purposes, and the process by which it can take shape. WHO's Programme for International Drug Monitoring was cited as one such initiative; under it, the safety of medicines and vaccines is assured by means of reliable and timely exchange of information across countries.

- The programme has established a central monitoring centre (the Uppsala Monitoring Centre), which receives information from various national centres regarding drug safety. This process is enabled by standard reporting mechanisms to promote rapid identification of cases (WHO, 2002).
- Another key initiative is the Global Alliance for Genomics and Health which is a non-profit alliance that aims to enable effective and responsible genomic and health-related data sharing by cultivating common frameworks and approaches (WEF, 2020).

9 There are different types of standards. If HL7 is a content standard (relating to data content), the FHIR is a transport standard that addresses the format of the messages exchanged between systems (HIMSS, 2023).

Figure 2:
The four levels of health data interoperability



Source: Author's interviews (see Appendix 1)

1.6 Barriers to cross-border health data sharing in Asia

Data sovereignty is a key barrier for sharing health data between countries. In Asia, countries do allow data exchange for patient care, including when their citizens are moving to another country to seek care. The challenge is when it comes to holding the health records of a citizen outside of the country. It is here that the issue gains a political colour and becomes important from a policy perspective for governments. One chief technology officer in a Singapore healthcare group summed it up as follows:

> **"The barrier is sending data over the place, putting your servers in some other country, when the patients are in other country, these are the policy objections of holding data overseas. Not data sharing, it's about where you store your data. "**

Countries reinforce this data sovereignty through **data localisation** requirements. Specific clauses in data protection policies mandate healthcare organisations, technology companies, digital health startups and even research institutions to store health data in the country of origin, especially when it includes patients' personal data.

→ Data localisation is less strict and easier to comply with when the data is anonymised, encrypted and/or aggregated in its form when shared across borders. Governments can also mandate that even after anonymisation of health data, re-identification of the patient is prohibited.

Data ownership is a key aspect of sovereignty, especially when governments believe that they are the custodians of the health data that originates within their jurisdiction. As a result, they enforce policies that require foreign companies collecting domestic health data to have part of their shareholding be owned by a

local company. The head of strategic planning at a Ministry of Health said:

> **"They cannot access our data. Data needs to be in the country, and we cannot allow them to access our patient data."**

A **data protection policy** is a baseline element that most countries in Asia have adopted, albeit in different forms and primarily in terms of sovereignty. These policies specify that medical data – including laboratory reports, genomic sequencing, X-rays, diagnoses and medical notes – consists of citizens' personal information and hence is a matter of sovereignty.

- The sovereignty component has a significant impact on governments' political will to engage in cross-border health data sharing. It is generally held that sharing of health data across borders can be a national threat.
- The geopolitical environment in the region seems to have a direct influence on the approach taken by governments with respect to data protection (The Economist, 2023).
- While countries like China and Indonesia are going the GDPR way, India took a less restrictive turn when it enacted its data protection policy in August 2023.

After data sovereignty, **cybersecurity risk** is the second-most-commonly agreed barrier to cross-border health data sharing. Healthcare organisations in Asia have seen an increase in cyberattacks in recent years (and, unlike in developed countries, governments in the region are lagging in terms of implementing protective measures (Kandasamy, et al., 2022)). Cybersecurity risks are real; despite the adoption of highly secure cloud services for storing health data, there have been cases where cyberattacks have infiltrated hospital IT systems and sensitive health data has been stolen.

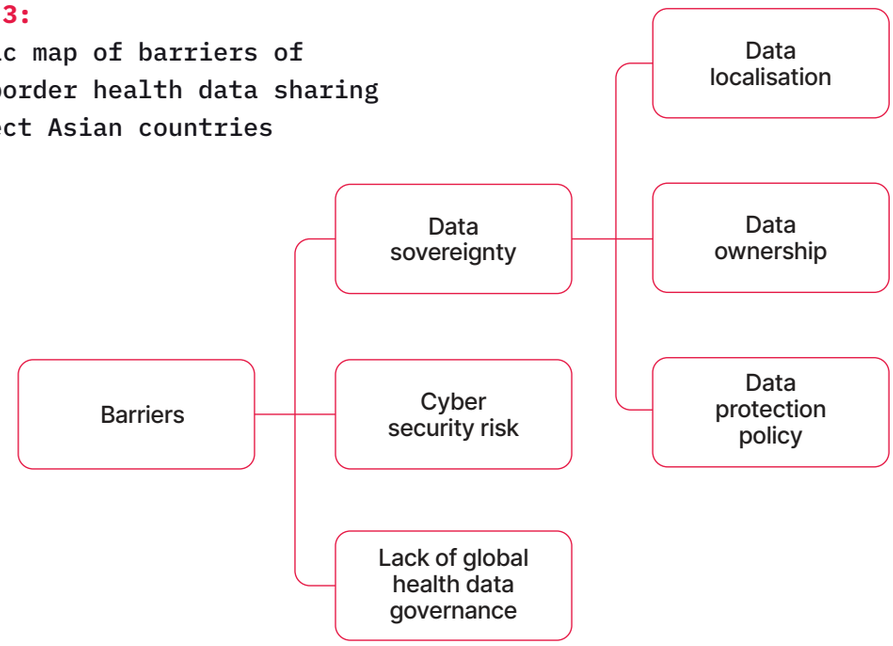
- In 2022, a cyberattack on the All India Institute of Medical Sciences compromised the personal health data of nearly 40 million citizens (Srivastava, 2022). Cyberattacks on healthcare systems have taken place across Asia, and different levels of healthcare. For example, in 2021, the Eye & Retina Surgeons specialist medical clinic in Singapore was hacked and the personal health data of 73,000 people was exposed (Raj, 2021).
- Hackers usually steal this data to demand ransom from governments and/or healthcare organisations. If demands are not met, the hackers leave the sensitive personal information of patients exposed on the dark web.[10] This was the case in 2022, when hackers stole the health data of nearly 9.7 million patients from Medibank – an Australian health insurance company – and, not receiving payment, posted it on the dark web (The Straits Times, 2022).

Such attacks can originate internally as well as externally. In some cases, hospital staff have copied and downloaded data. In 2018, the personal data of 1.5 million Singaporean citizens, including that of Prime Minister Lee Hsien Loong, was stolen from SingHealth's[11] cloud health database through a malware attack on a single computer which exposed the whole network to hackers. Cybersecurity

10 The dark web, also known as the deep web, refers to websites that are not indexed by and accessible via search engines. It is intentionally hidden and requires a specific browser to access data, which is mostly used for illicit purposes. While the size of the dark web is not known, it is usually where stolen medical records are made freely available and can be misused for financial gains.

11 Singapore Health Services is commonly referred to as SingHealth and it is one of the country's largest groups of healthcare institutions.

Figure 3:
Thematic map of barriers of cross-border health data sharing in select Asian countries



Source: Interviews

risks affect the trust of patients in accessing and sharing their health data by means of digital health applications.

The third major barrier to sharing health data across borders is the **lack of global governance for health data**. On an individual level, cross-border sharing of health data is still very manual. The doctor or a patient must make a special request to their respective governmentto enable the data sharing to take place. This is time-consuming and highly inconvenient for patients, healthcare organisations and researchers. It also poses significant compliance burdens on the technology companies and digital health startups involved in this process.

- In the case of communicable diseases, countries are required to report to WHO once a month. Yet it takes between one to two weeks for the data to be analysed and for the results to be shared with countries. Such delays, especially in the case of communicable diseases, can leave countries unprepared to mitigate the risks that are emerging quickly and in real-time.
- With a lack of global or regional agreements on health data sharing, governments in Asia rely on local regulations to share data with other countries. This further strengthens data sovereignty – a key barrier for cross-border health data sharing.

2

COUNTRY CASES

This section will discuss the policy landscape of health data sharing at the national and cross-border levels in five Asian countries: China, India, Indonesia, Malaysia and Singapore. It will offer an overview of the healthcare systems in each country, and the opportunities and challenges for digital health innovations, national EHRs, and regulations. The challenges faced by healthcare organisations in each country will also be addressed.

2.1 China: A robust yet relatively closed digital health ecosystem

China has the world's largest number of senior citizens, with nearly 250 million people over the age of 60. Nearly 400 million people and rising in the country are suffering from chronic conditions such as cardiovascular diseases or diabetes. This puts immense pressure on China's healthcare system (Ping An, 2021).

As a result, China's healthcare expenditure is expected to rise from RMB 6 trillion (US$ 928 billion) in 2019 to RMB 16 trillion (US$ 2.4 trillion) in 2030 (Huld, 2023). The country also needs an additional 700,000 general practitioners and 10 million nursing staff to handle the rising burden of diseases (Ping An, 2021).

Chinese President Xi Jinping has placed healthcare at the core of his policymaking programme. The **Healthy China 2030** policy blueprint, launched in 2016, aims at disease prevention and producing a comprehensive overhaul of the healthcare system. In 2017, **the National Population Health Informatization Development Plan** was released, containing fundamental policies on digitalisation and modernisation (Li, et al., 2019). Between 2018 and 2020, the government released a number of guidance documents to effectively integrate digital health as part of mainstream medical services in the country (see Appendix 1).

In 2021, the Ministry of Industry and Information Technology, the Ministry of Civil Affairs and the National Health Commission jointly issued a five-year action plan for the development of digitalisation in the elderly care sector. Private sector participation in healthcare has been encouraged to steer digital health innovations (including emerging technologies such as health monitoring devices, robots for home services, and telemedicine), which has been identified as a core area of service innovation (Chen, et al., 2022).

China has nearly 1 billion internet users (Ghosh, 2021), which is the highest of any country in the world. Partly as a result, there is active adoption and use of digital health applications among the population. The country also houses a vibrant technology ecosystem which is conducive for digital health innovations to be developed and launched into the market quickly and efficiently. As a result, the digital health system attracts significant investments (Deu, et al., 2022).

China, however, is a closed market in terms of sharing health data, which is highly restricted and regulated. There is active sharing of health data between the provinces and the central government, but health data sharing between provinces is negligible. There is also lack of health data sharing between primary and secondary healthcare institutions, as well as between hospitals at the secondary and tertiary levels of healthcare. This is the main barrier to health data interoperability in China, which has been recognised by the government.

As a healthcare industry expert said in an interview:

> **"Cross-provincial health data sharing is non-existent; for instance, there is no communication between a hospital in Beijing and one in Shanghai."**

2.1.1. China's internet hospitals

The Chinese Government has encouraged and invested in 'internet hospitals' since 2015. These are virtual centres that provide medical advice and prescribe medicines. The first internet hospital was the Wuzhen Internet Hospital in Tongxiang City in Zhejiang province, which is a collaboration between the Tongxiang Municipal Government and internet technology company WeDoctor Group (Sun, 2022). The programme led to large-scale implementation of an online platform where patients can obtain medical advice and drug prescriptions and, when required, make follow-up appointments at any hospital (Sun, 2022).

Internet hospitals have been instrumental in increasing collaboration between medical experts across different regions and in providing equitable access to quality healthcare for citizens living in rural and remote areas (Sun, 2022). The innovative approach has been widely adopted across the country and, as of 2021, there were more than 1,600 internet hospitals in China, 500 of which were established in the first half of 2021 alone (Xinhua Net, 2021).

This is mainly driven by backend regulatory support from the Chinese Government. Since 2019, the National Healthcare Security Administration launched the electronic medical insurance system. This has helped regulate the prices and insurance policies for better integration of internet-based medical services to be covered as part of the overall medical insurance system in the country.

For more vertical integration, the National Health Commission, since May 2020, has encouraged provincial governments to establish their own online regulatory platforms to regulate online medical providers and accelerate the market access of internet hospitals (China Briefing, 2020).

2.1.2. China's digital health innovations

The private sector is the key driver for digital health innovations in China; it has already led to the development of unique healthcare solutions such as one-stop virtual care platforms, cloud-based medical image diagnoses (Kharpal, 2020), and AI-assisted screenings (Braun & Hausle, 2019). The sector has been highly profitable for digital health startups, which have witnessed significant growth in profits in recent years.

Demonstrating the point, the total revenue of Beijing-based JD Health International Inc. for the first half of 2021 was US$ 2 billion, representing an increase of over 50 per cent year-on-year (China Internet Network Information Centre, 2022). The high potential for profitability, and active support from the government both at the central and provincial levels, is attracting many more technology enterprises to enter the digital health space,

creating industry unicorns – i.e., startups valued at more than US$ 1 billion (Deloitte, 2022).

A health technology expert at a digital health company noted:

> **"The Chinese provinces have a keen interest to have these startups so they typically provide free or highly subsidised research labs, office space where these companies can move into (and) they can receive funding."**

Some of the leading platforms in the country are AliHealth, Ping An Good Doctor, WeDoctor, and JD Health. These applications offer services in telemedicine and e-pharmacies and are used by millions. Being business-to-consumer (B2C) in nature, they have been able to collect user data on a massive scale, helping them improve their services significantly. The COVID-19 pandemic was a significant catalyst for these applications, as their usage increased tremendously. These applications were especially useful during the strict lockdowns that were implemented in China between 2020 and 2023 (Bu, et al., 2021; Cheng, 2020).

> **"Citizens use digital apps to store their health records which they can carry when they move from one hospital toanother."**
>
> **– Industry expert, a healthcare consultancy**

One example is Shanghai-based software Ping An Good Doctor, which allows patients to see a doctor online in minutes; it is a sharp contrast to hours of waiting at the hospital with no guarantee of an appointment (Bu, et al., 2021). Sensing demand, many applications started offering free consultations during the pandemic, which further increased adoption. Some saw more than 1 billion visits during the peak of the pandemic, with online consultations rising significantly (Bu, et al., 2021).

Digital health startups and companies in China work very closely with the Chinese Government for easier access to health data. Many of the leading digital health applications have partnered with internet hospitals, boosting use among the population (Cheng, 2020). Government support for digital health adoption has also been a key driver.

AI

Use of AI-based applications and automation systems in China's healthcare has increased sharply, significantly boosting efficiency in healthcare organisations (Olcott, 2022).

The potential for AI in healthcare has attracted nearly 4 billion RMB (US$ 567 million) in venture capital for Chinese digital health startups, while other stakeholders are also adopting AI-based applications, including for diagnoses. AI is being used for early screening of cancer patients and for diabetes management systems to be used after hospital discharge (Bu, et al., 2021).

2.1.3. China's fragmented data systems

Despite the progress made, health data sharing is still not as seamless as the government anticipated. This is mainly because of the uneven distribution and inefficient use of resources at provincial levels. Notably, of all hospitalised patients in China, 23 per cent are in top-tier hospitals, which account for only 0.3 per cent of the total number of hospitals (Ping An, 2021).

Secondary healthcare –being referred to specialists elsewhere – is the first choice for patients rather than primary care. This is due to China's weak primary healthcare system (Yip, et al., 2019), which has contributed to widespread mistrust among patients about the quality of doctors. As a result, leading hospitals are overcrowded with increased waiting times (Cheng, et al., 2022).

This has serious implications for the sharing of health data between primary and secondary healthcare systems. Complicating the situation is the existence of two core IT systems in primary healthcare. Furthermore, clinical IT systems in primary healthcare are not centralised and, as a result, there is lack of health data interoperability between primary services and the hospitals (Li, et al., 2020). Primary healthcare and secondary healthcare in China are also financed, governed and managed separately, creating barriers for coordination (Li, et al., 2020).

In secondary healthcare, hospitals are largely independent in China and they can choose to use their own IT systems and data standards for collecting, storing and analysing patient data. This means health data cannot be shared seamlessly between hospitals (Jin, et al., 2020).

Lack of health data interoperability within China is a bottleneck that is difficult to solve and is affecting the service quality and cost of healthcare. The increasing cost of care due to inefficiencies makes it challenging for insurance companies to cover treatments (Wu, et al., 2022; Ping An, 2021). Public hospitals provide most of the care and the government covers most of it. As of 2017, 82 per cent of inpatient care was provided by public hospitals (Meng, et al., 2019).

The government provides rural and urban resident-based health insurance, funded mainly by the government subsidies (about 70 per cent of the total funds). Otherwise, healthcare tends to be paid for by employee-based health insurance.

Private health insurance coverage accounts for only 6 per cent of total insurance coverage in the country (Meng, et al., 2019). As a result, private insurers have very little influence over government policies and have limited potential to expand their services in the country (Ping An, 2021).

Challenges to health data interoperability mean that data access is difficult in China. This is further accentuated by a system-wide weakness in cooperation between hospitals, pharmaceutical companies, equipment manufacturers and technology companies. This becomes a serious barrier for real-time data sharing (Wu, et al., 2022).

Data management and data ownership are also challenging, as stakeholders have their own interests and goals, which do not overlap. And while the health system is brimming with significant private players, health data remains largely siloed within institutions, affecting not just sharing but also digital innovations (Wu, et al., 2022).

Similar challenges have also been identified at the public health level, whereby there are parallel data systems that do not talk to each other. For instance, the Infectious Disease Reporting System and the Tuberculosis Information Management System do not share health data as they use different patient identification numbers (Li, et al., 2020).

2.1.4. Data privacy concerns

Government policies and the rapid growth of private digital health companies have catalysed digital health adoption in China. However, citizens' concerns over health data privacy and rights remain high (Wu, et al., 2022), so citizens and human rights advocates have called for the government to enhance the legal framework around data protection to protect the privacy of citizens (Sun, 2022; World Bank, 2021).

Underlining this privacy concern is a rise in incidents where citizens' personal data has been stolen (Zheng, 2022; He, et al., 2022). Scholars have highlighted that the rising use of health data as a commodity by private companies might ultimately exacerbate health disparities and hinder equal access to healthcare (Sun, 2022; He, et al., 2022).

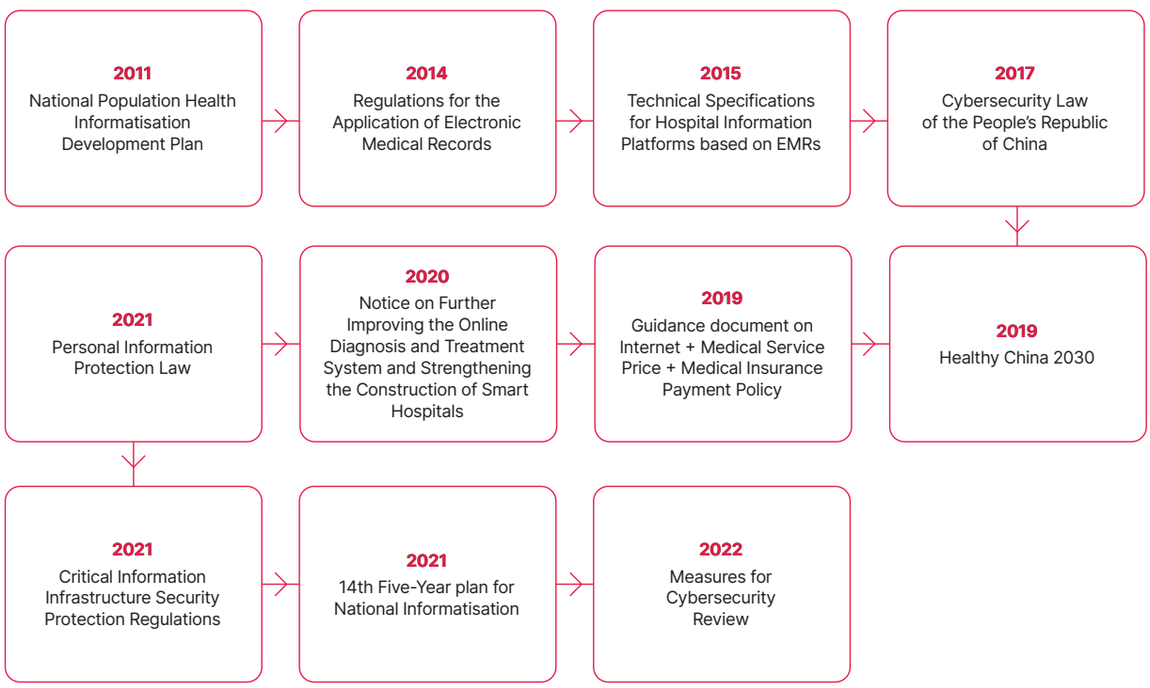
2.1.5. China's regulatory landscape for sharing health data

China wants to accelerate health data sharing as part of its 12th five-year plan, or economic blueprint. The governments perceive it as an important aspect of the ongoing reform in healthcare. In 2010, the National Health and Family Planning Commission (NHFPC) set up China's health informatisation road map (now upgraded and known formally as the 4631-2 Project (Li, et al., 2019).

The plan outlines the following:

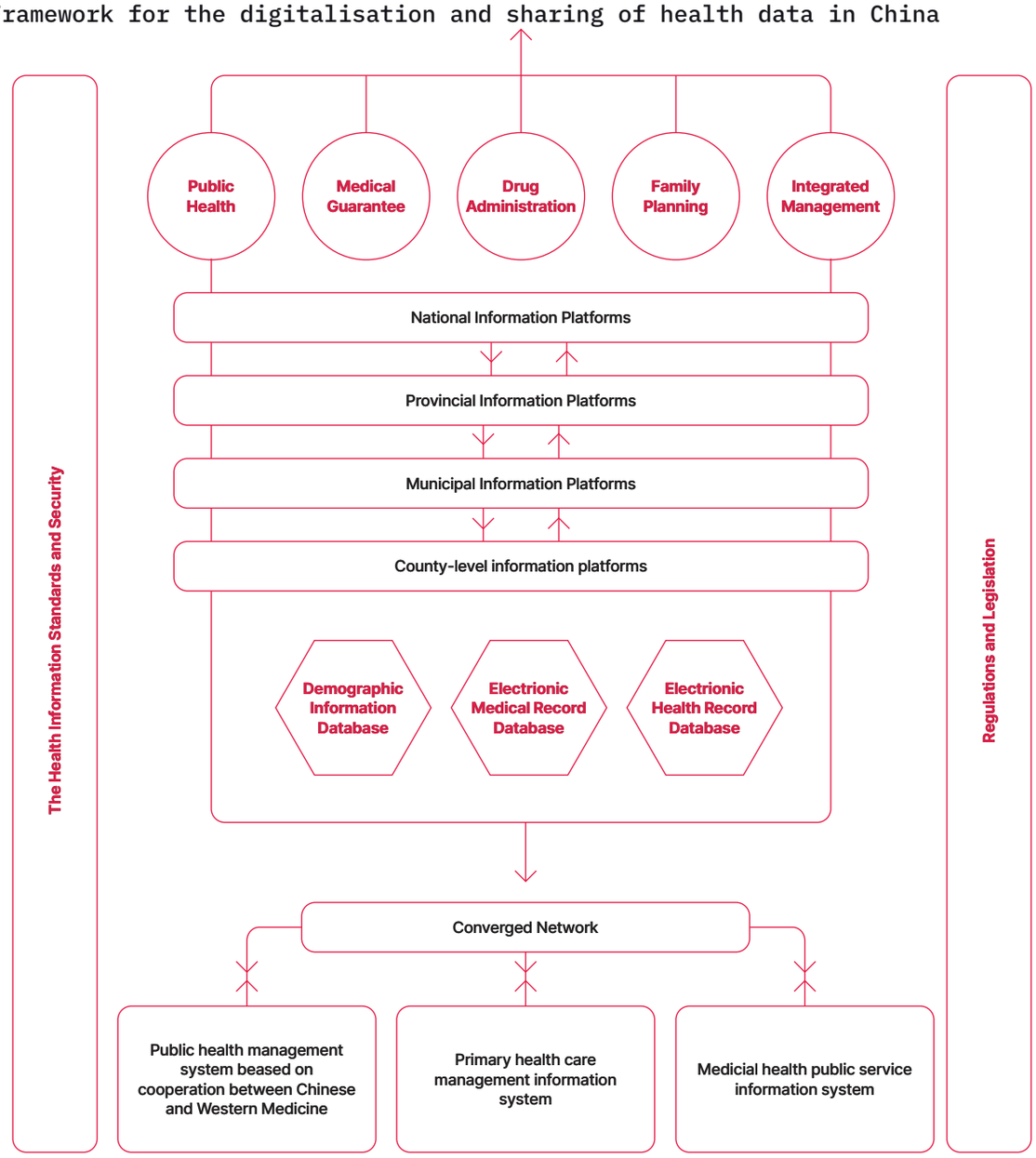
- Four **main information platforms** – national, provincial, municipal and county levels. On each of these platforms, the medical data from different regions is integrated and shared.

Figure 4:
Timeline of key regulations related to health data sharing in China



Source: See Appendix 2 for details

Figure 5:
Framework for the digitalisation and sharing of health data in China



Source: Li, et al. (2019)

- Six primary applications – public health, medical service, medical guarantee, drug administration, family plan and integrated management. These are deployed on each of the four main information platforms (NHFPC, 2013).
- Three demographic health information databases constructed on each of the four main information platforms – a demographic information database (DID), an electronic medical record databaseand an electronic health record database (EHRD) (NHFPC, 2013).
- The DID contains fundamental population information, family planning service management information, and floating population management information, etc.

- The EHRD stores information from the electronic health record (EHR). It is a lifetime record held for the purposes of supporting continuity of care, education and research. It is designed to ensure confidentiality at all times.
- One centralised network covering healthcare institutions at all levels (including Chinese medical institutions). It covers health information standards, security, regulations and legislation (Li, et al., 2019).

The 4631-2 Project is being implemented in three phases. The first covers improved health information technology infrastructure, the application systems of routine operations, and information standards and security systems. The second phase relates to the construction of regional information platforms with an eye to enabling data exchange between different regions and applications (PRC, 2017; China Digital Medical Network, 2014).

The third phase concerns big data technologies, AI, and Internet Plus[12] (State Council of PRC, 2015) to enable advanced applications such as predictive modelling, clinical decision support, disease or safety surveillance, public health, and research (PRC, 2017; China Digital Medical Network, 2014).

2.1.6 China's data protection policy

The main regulation that governs health data protection in China is the **Personal Information Protection Law (2021)**. The law defines personal data, the rights of individuals to control and process personal data, and the responsibilities of data processors (Guo, 2021). Health data is also regulated under certain specialised laws, regulations and policies.[13]

Patient privacy is largely protected by these regulations, although there may be exemptions to encourage the sharing of health data among various industries and institutions (Sun, 2022). In 2017, the Chinese Government issued the **Cybersecurity Law of the People's Republic of China and Regulations for the Application of Electronic Medical Records**. These essentially mean that health data can only be shared within China when the safety of patients' electronic data is ensured (Jin, et al., 2020).

> **"Cross-border health data sharing is not possible, and is highly restricted, especially with respect to the recent regulations."**
>
> **– Industry expert, a healthcare consultancy**

For cross-border health data sharing, stakeholders in the healthcare system or any other entity are required to comply with the **Regulations on Security Protection of Critical Information Infrastructure**. Specific conditions have been laid out for this purpose which include a security assessment organised by the relevant national network information department and a personal information protection certification agreed by professional institutions. Organisations are also required to enter into a government-approved contract with an overseas entity to stipulate the rights and obligations of both parties (Hu, et al., 2023).

There are detailed requirements for organisations that share health data; these mainly include an impact assessment, informed consent of the individual whose data

12 China's plan to manage its information superhighway.

13 For instance, Regulations on Infectious Diseases and Human Genetic Resources, and Policies on Promoting Big Data in Healthcare and Management of Population Health Information.

is shared, coordination with the recipient of the data on the purpose and use of the data, and supervision of how the data is used.

Recipient organisations must process personal data as agreed, return or delete it when the contract is over, not share it with others, and take necessary measures to protect it. Additionally, the **Measures for Cybersecurity Review (2021)** requires non-China-based organisations that hold personal data of more than 1 million Chinese citizens to apply for a cybersecurity review.

2.1.7 China's electronic health records

The key regulation that governs EHRs in China is **Technical Specifications for Hospital Information Platforms**, which was issued by the National Health Commission in 2015. It governs electronic medical records (EMRs), which are the hospital equivalent of broader EHRs. They are the complete and detailed clinical information resources created, stored and used electronically by medical institutions from visits by citizens to medical institutions (NHC, 2015).

Since then, the government has issued 31 national policies and 134 technical standards covering all aspects of medical care digitalisation, and built a digital medical security system (Liang, et al., 2021).

Since 2018, the National Health Commission has required EHRs to be categorised on a scale of 0 to 8 (Liang, et al., 2021).

- Levels 0 to 2 focus on data collection.
- Levels 3 to 4 concern data sharing within or between departments and simple clinical decision-making.
- Levels 5 to 8 relate to more complex clinical decision-making, cross-hospital data sharing, and patient self-service.

The Health Commission sets different deadlines for hospitals to encourage them to adopt greater levels for EHRs.

2.1.8 China's national electronic health record strategy

The Chinese Government has adopted different degrees of capital investment and policy guidance for different sizes of hospitals. For large – so-called Level III[14] – hospitals, which are responsible for over 46 per cent of outpatients in China, the government has focused on releasing management and other guidelines (Fu, et al., 2018) to promote hospital digitalisation with EHRs as the core. It has also encouraged private capital investments (Ting, et al., 2019).

For hospitals smaller than Level III, the government has opted for a strategy of direct finance and indirect guidance to promote EHR implementation gradually.

In 2019, the State Council of China stipulated that the construction of EHRs was a major indicator in assessing hospitals and the appointment of public hospital presidents (Ting, et al., 2019). If hospitals don't meet certain levels, they will be downgraded, which will greatly affect their reputation and income (Liang, et al., 2021).

China's EHR standards

EHRs within China are separated into two categories: Basic Architecture and Data Standard. Basic Architecture relates to basic EHR concepts, sources and contents. It consists of patients' consultation records, medical summaries, outpatient medical health

14 Chinese hospitals are classified into three tiers based on their ability to provide medical care, to provide medical education, and to conduct medical research: primary hospitals are Level I; secondary hospitals are Level II; and tertiary hospitals are Level III (Long, n.d.).

records, inpatient medical health records, legal medical certificates and reports, health examination records, and health institution information (Owusu-Marfo, et al., 2019). Data Standard concerns data quality, technology, and security and privacy. Since 2010, 283 national health informatisation standardisation projects have been approved and initiated, ranging from data acquisition and exchange to information management, storage, cataloguing and security (Li, et al., 2019).

2.1.9 China's organisational factors for sharing health data

Three potential organisational roadblocks to health data sharing in China are:

Data security concerns

IT departments in hospitals can be hesitant to share patient-related data with doctors unless they adhere to full procedures to obtain it. They worry that they will be responsible for data leaks and they are not aware of how doctors will use the data. As a result, strong security concerns generate complicated approval procedures for data access, leading specialty departments to use an external company platform to manage their data (Jin, et al., 2020).

Data format

For doctors, EMR data is not easily accessible and usable since laboratory test or imaging data is stored in PDF format or image files that have to be manually transcribed. Other EMR data is only stored in the system for a set period and then exported from the EMR system to PDF files (Jin, et al., 2020). These file formats lead to extraneous efforts involving manual transcription and high lag times for data retrieval for any purpose other than patient care (Jin, et al., 2020).

Lack of skilled IT professionals

In comparison with the increasing number of medical professionals, the number of IT professionals in China is relatively low, limiting the efficacy of IT departments. In one study, only 7 per cent of hospitals had more than 20 full-time IT staff members, which is not enough to meet needs. Some 76 per cent of medical institutions noted a lack of IT staff and the difficulty of recruitment (Li, et al., 2019).

2.1.10 The impact of data sharing on China's digital health innovation

Sharing health data is expected to have a significant impact on the potential for digital health innovations. Centralised health data via the national, provincial, municipal and county platforms enables data convergence, in turn boosting the application of advanced technologies such as big data and AI in healthcare. The application of these technologies creates new opportunities to improve healthcare delivery (Ping An, 2021).

A good example of this virtuous circle is digital health company Ping An, which works closely with healthcare institutions. It has developed extensive health databases over time, based on the services it has offered in collaboration with public hospitals. This, in turn, has enabled the company to develop solutions such as Ping An Smart Healthcare[15] and Ping An Good Doctor,[16] in addition to developing advanced AI-based innovations in collaboration[17] with leading research institutions in China (Ping An, 2021).

15 It provides tools to manage public healthcare, empowers providers, and improves medical resource accessibility and patient disease outcomes. For example, the company's intelligent image analysis system enables doctors to shorten diagnosis time from 15 minutes to 15 seconds.

16 It provides online consultations with AI-assisted medical teams and integrates seamlessly with offline medical services within the ecosystem. Users can search for basic information for free, with consultations and treatments available at a cost.

17 The company has collaborated with China's National Clinical Research Centre for Metabolic Diseases to develop an advanced type 2 diabetes management tool powered by AI and its health databases.

Platforms like Ping An and others like Haodf.com, WeDoctor and Chunyu Doctor act as third-party enablers to patient-provider interactions; in the process, they gain access to large amounts of data which they use to further improve their services. One key innovation is how these platforms have developed reputation systems whereby user feedback helps other users to assess the quality of services provided and which providers they should choose for their healthcare needs (Cheng, et al., 2022).

2.1.11 Conclusion: China offers a robust yet locally restricted digital health ecosystem driven mainly by the private sector

China offers a complex market for health data sharing which has helped to catalyse a budding market for digital health innovations. Comprehensive teleconsultation applications that are driven by technologies like AI and machine learning are actively being used by citizens for consulting doctors as well as for buying medicines online. There is also a widespread adoption of wearable devices in China that has led to huge generation of data and services. Digital health startups are aimed at making healthcare services accessible for consumers, especially the ageing population (Zhou, et al., 2021).

The government allows digital health startups to actively work with the public healthcare sector to develop and implement new innovations. By means of systematic incentives, it has been investing in and enabling a vibrant digital health ecosystem which has attracted significant inward investments. However, there remain deficiencies with respect to provincial level implementation of health data sharing mechanisms, especially with respect to primary healthcare facilities, which continue to lag behind in data sharing due to poor implementation of policies.

In secondary healthcare, hospitals are largely independent in choosing their IT systems and whether they want to share data with other hospitals. As such, they mostly prefer not to share health data for fear of misuse and lack of incentives for interoperability. They are required, however, to share data with the government since they are mostly public-funded institutions.

In this environment, digital health startups have been able to gain access to large-scale health data, given the wider scale of their services across the country. The startups have benefitted highly from the Internet Plus healthcare approach adopted by the Chinese Government – its drive for widespread internet integration – because this has involved the active participation of large internet providers, insurance companies and pharmaceutical companies. This is especially true for AI-based digital health startups which are exploring areas including disease prediction, clinical decision support systems, and AI-based imaging for diagnoses (He, et al., 2022; Interviews).

While China encourages data sharing at a national level, the government largely restricts the sharing of health data with other countries. If unavoidable, especially in cases of patient care for Chinese citizens abroad, the government regulates the process closely to ensure that the data sharing is compliant with its policies. This continues to have an impact on cross-border digital health innovations.

Within China, however, health innovation is strongly supported by the government and new supportive policies are to be expected. With increasing numbers of citizens demanding intelligent, personalised and efficient healthcare services, the market size of China's digital healthcare industry is expected to exceed 1.5 trillion RMB (US$ 210 billion) by 2025 (He, et al., 2022).

2.2 India: An evolving and increasingly open digital health ecosystem

By some accounts, India became the world's most populous country in 2023, with more than 1.428 billion people (the majority being below the age of 60) (UNFPA, 2023). With this young and dynamic population, India has both significant opportunities and significant challenges.

On the plus side, the Digital India initiative has led India over the past eight years to the cusp of a major digital transformation. With high penetration of low-cost smartphones, affordable data, and a competitive telecoms market, India is posited for widespread digital adoption in segments of the population that have previously been highly underserved (Balasubramanian, 2022).

On the other hand, healthcare in India is facing structural challenges such as a shortage of healthcare professionals, high out-of-pocket costs, and a very low doctor-to-patient ratio, estimated at one doctor for every 854 people in the country (Balasubramanian, 2022). Quality of care, accessibility, and affordability of healthcare services, medicines and diagnostics are thus problematic (Selvaraj, et al., 2022).

Overall, India offers a mixed healthcare system that started to be dominated by private healthcare in the 1980s. Some 70 per cent of outpatient and 58 per cent of inpatient visits are provided by for-profit or not-for-profit private healthcare organisations (Selvaraj, et al. 2022).

Indian public health standards require that all public sector health facilities from primary upwards should be equipped with an internet-connected computer. However, the implementation of this at the primary levels is not known. There are a number of parallel data systems such as the Mother and Child Tracking System and web portal, the District Health Information System (which reports data from districts to regional and state headquarters), and disease-specific platforms including the National Anti-Malaria Management Information System and the Strategic Information Management System for HIV/AIDS.

In 2004, India launched the Integrated Disease Surveillance Programme (IDSP) with assistance from the World Bank. It was the first digital health data platform implemented by the Ministry of Health and Family Welfare (MoHFW). Up until 2015, 97 per cent of districts in the country were reporting data to the platform across primary and secondary healthcare, across public and private hospitals, at a national level (Selvaraj, et al., 2022). However, a monitoring report in 2015 recommended that the IDSP be redesigned, limited to specific diseases, and integrated with other disease surveillance platforms (MoHFW, 2018).

By 2018, the first phase of the new programme – the Integrated Health Information Platform – was launched across seven states: Karnataka, Andhra Pradesh, Himachal Pradesh, Odisha, Uttar Pradesh, Telangana and Kerala (MoHFW, 2018). By 2021, the platform had been implemented across the remainder of the country. It is a web-based platform to provide near-real-time data to government and public health officials to detect, monitor and respond to outbreaks of more than 30 diseases across the country (WHO, 2021).

Another initiative is the Health Management Information System, which is a web platform for upgrading and pooling national health data from primary and secondary healthcare organisations, both private and non-profit. The initiative, however, has faced implementation challenges with gaps in data collection processes and the capacity of healthcare workers implementing the programme. There has also been a duplication of efforts and waste of resources due to the continuation of traditional paper-based processes (Selvaraj, et al., 2022).

To overcome these challenges, the government plans to support and develop national electronic records via the National Digital Health Mission (also known as the **Ayushman Bharat Digital Mission (ABDM)**) (Gudi, et al., 2021).

2.2.1 CoWIN: Winning over COVID-19

India's recent success in digital health innovation is the COVID Vaccine Intelligence Network, or CoWIN. It is a cloud-based platform developed by the government and supported by the United Nations Development Programme (UNDP). The platform facilitates registration, immunisations and appointments, and issues digital vaccination certificates. The

portal has a simple user interface to register and select a convenient facility, with an option to choose the vaccine type. As soon as the vaccination is completed, a digital vaccine certificate is delivered in a QR code via a text message or a printed copy at the healthcare facility.

The platform also allows vaccinators to verify registered beneficiaries, enter the vaccine doses, and record any adverse effects following immunisation (Pant, 2022). The platform can be used by people without access to the internet or an identity card by walking into any health facility and getting registered on CoWIN. Immunisation levels in rural areas have been higher than the national average and the dashboard allows programme managers to visualise and break down demographic data on vaccine coverage, consumption and wastage.

As an additional feature, the app can be used to link passports to CoWIN and generate vaccination certificates for international travel, and for sharing vaccination status on social media. The platform is also open to foreign nationals who register to get vaccinated; it has also been offered to other countries for open use.

Using CoWIN, India vaccinated more than 960 million people against COVID-19. That comprises 64 per cent of the total population, 73 per cent of which were from rural and hard-to-reach areas (Pant, 2022).

India's G20 push for a global digital health ecosystem

India has proposed the G20 Framework for Systems of Digital Public Infrastructure (DPI) – a voluntary and suggested framework for the development, deployment and governance of DPI.

In light of this, India has also welcomed the establishment of the Global Initiative in Digital Health within a WHO-managed framework to build a comprehensive digital health ecosystem in compliance with respective data protection regulations (G20, 2023).

2.2.2. Digital health innovations in India

India has 7,128 digital health startups offering targeted solutions aimed at addressing existing gaps in healthcare services (Gupta, 2022). Some of the leading companies are Novartis, Edwards Lifesciences, Centura Health, Hologic, PharmEasy, cult.fit, Innovaccer, Tata Digital Health and Practo (Singh, et al., 2022).

As an example, Tata Medical and Diagnostics, owned by Tata Group, is focusing on innovations to improve patient care by means of optimised healthcare testing, diagnostics and treatment capabilities. They are integrating AI, machine learning and other emerging technologies into their solutions (Balasubramanian, 2022).

Similarly, private hospital chain Apollo Hospitals has launched a telehealth capability (the ability to access healthcare without an in-person visit) across Asia. They became the second healthcare provider in the world

to attain Stage 6 DIAM[18] certification, which recognises the safety and capabilities of digital imaging modules. In addition, they have created a wide range of advanced patient care tools, including innovative patient communication portals, clinical care mapping software, and even augmented and virtual reality solutions (Balasubramanian, 2022).

Practo, meanwhile, seeks to fill healthcare needs where hospitals cannot. For instance, the app provides 24/7 medical assistance for serious as well as non-serious health conditions by means of a comprehensive built-in medical dictionary. The app also provides online appointment booking, online consultation, subscription-based health plans, diagnostic tests through Practo Associate Labs, medicine delivery and more.

PharmEasy provides access to health products. Patients can upload their prescription on the web, where it is then verified and sent to a pharmacy in the vicinity. The pharmacy can then deliver the products quickly (Beatrice, 2021).

The government is actively supporting the private sector in its attempts to digitalise healthcare access in India. For instance, the India Digital Health Accelerator programme – an initiative from within the Department of Biotechnology – aims to develop innovations that digitise screening, monitoring and telehealth for faster diagnoses, better patient surveillance, and improved healthcare delivery for large populations in India and abroad. It is supported by a cluster of investors, technology companies and knowledge partners from across India and the US, and is expected to create a successful model for cross-border ecosystem collaborations (Banerjee, 2022).

2.2.3 India's insurance market as an enabling mechanism for data sharing

The Indian Government launched the world's largest government-funded health insurance programme – the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) – in September 2018. It provides up to INR 500,000 (US$ 6,055) per family per year for secondary and tertiary hospitalisations (MoHFW, 2021). Run by the National Health Authority, it has led to the following benefits:

1. The PMJAY has been able to use the available public digital infrastructure to provide end-to-end services through a digital platform that helps identify beneficiaries when they are admitted and treated in hospitals until they get discharged.
2. The authority plans to use the PMJAY to expand the reach of digital health to all citizens and develop an open and interoperable health management system to empower patients, doctors, policymakers and researchers to improve healthcare delivery (MoHFW, 2021).

18 The Digital Imaging Adoption Model (DIAM) is a certification that healthcare organisations can use to measure their capabilities for secure medical imaging. The Healthcare Information and Management Systems Society (HIMSS) DIAM helps organisations improve patient safety, quality of care, and efficiency (HIMSS, 2023).

2.2.4 Public versus private healthcare

Public healthcare operates differently from private healthcare in India. While private healthcare has better infrastructure and good human resources, public healthcare has larger data. The private sector is ahead in terms of digitalisation, although it does not benefit the widerpopulation. Some private sector entities have implemented EHRs, hospital management systems, electronic claim management systems and longitudinal integration, which stores health data on independent systems. Moreover, they do not actively share health data amongst themselves or with the government-funded national programmes. Large private hospitals consider health data as an expensive and valuable asset and want to extract maximum benefit from it.

There is evidence that larger private hospitals are concerned about the implications of sharing internal digital systems and data, given the possibility of security breaches of confidential customer data (Sharma, 2023). Some smaller private hospitals also perceive health data sharing as a liability in terms of being taxed. This resistance originates in their outlook towards digitalisation as an additional cost rather than a worthy investment. They are reluctant in this regard to avoid regulatory scrutiny (Sharma, 2023; Interviews).

As a result, the MoHFW finds it challenging to get health data from private hospitals and clinics. As a result, the government had to make health data sharing mandatory for priority diseases such as tuberculosis, especially for private healthcare organisations.

2.2.5 India's fragmented health data systems

Currently, the sharing of health data in India is highly fragmented due to different administrative systems, financial restraints and policy goals. The responsibility of collecting health data is divided among different ministries and institutions, which makes health data interoperability difficult due to financial and administrative challenges. As a result, the health data that is collected fails to provide meaningful insights to stakeholders to design appropriate public health interventions. There are such a variety of data sources that there can be different interpretations (Nagarajan, et al., 2018).

The founder of an Indian digital health startup said:

> **"The sharing of health data is a challenge and also not a challenge. Not a challenge for us because we have figured out how to do it. It might be a challenge for a larger ecosystem because (of) the diversity with which data is stored into the systems and how they perceive the data."**

As one example, the National Family Health Survey and the National Health Mission provide similar data, but the former is reported by users and conducted at irregular periods, while the latter is collected from primary health centres, community health centres and hospitals annually (Nagarajan, et al., 2018). As a result, the data is incompatible.

At state level, there is wide variation in the process and quality of the data collected. Some states have different combinations of paper-based and electronic collection systems. The state of Haryana collects 10 data elements, but Bihar and Jharkhand have more than 200 fields. The protocols for data quality and updating are also varied, from few checks to very sophisticated ones to assure quality and accuracy

This is because of a lack of a standard mechanism at the state levels for procuring the necessary software for data collection. The National Informatics Centre, which might otherwise ease the situation, has been constrained in terms of funding and training across states (Nagarajan, et al., 2018).

2.2.6 India's digital infrastructure gaps

There are significant gaps in India's digital infrastructure. Southern states, for example, generally have better digital infrastructure than northeastern states. Moreover, states also vary in terms of capacities and human resources for capturing health data at the grassroot level. With the population increasing, state governments are likely to be further burdened with rising healthcare demands amid dwindling or inadequate resources.

> **"[For] actual delivery of healthcare, digital has to be one of the infrastructures that you have to enable. And if you don't do that then you're going to... have severe struggles in delivering care."**
>
> **– Digital innovation change leader, international non-profit based in India**

The COVID-19 pandemic has been a significant eye-opener for state governments that struggled to contain cases and deliver care. Healthcare systems were overburdened and collapsed at many levels. In certain parts of the country, states are failing to roll out digital applications developed by the central government. And, in cases where they do roll out the applications, they face challenges with respect to data quality, human resource capacities, availability of health resources, etc.

Moreover, many primary healthcare facilities and, in some states, even hospitals lack digital systems to capture health data in the digital form.

Lack of health data interoperability clouds infrastructure and resource gaps. As a result, policies are not aligned with the needs of healthcare at state levels. There are also parallel data systems – such as in the pharmaceutical industry – that are not centralised and hence cannot be used for broader public health purposes.

2.2.7 Regulatory landscape for sharing health data in India

Currently, India allows cross-border health data sharing but with conditions, as outlined below. At the national level, the ABDM is being scaled across public and private sectors to enable health data interoperability. However, given the scale of the country and the fragmentation of existing systems, the government may need more time for nation-wide integration.

India's data protection policy

The Government of India passed the Digital Personal Data Protection Act 2023 on August 11, 2023. The law requires healthcare providers to obtain explicit consent from patients before collecting, using or sharing their health data online. It classifies health data as sensitive personal data and hence places stringent restrictions on its sharing, with the exception of medical emergencies, epidemics and public safety matters where data may be shared without consent (Nakashe, 2023).

Healthcare providers will now be required to implement robust data encryption, access controls and audit trails to ensure the data security of patient health data. The Act necessitates hospitals to invest in advanced cybersecurity infrastructure to build resilience to cyberattacks. This is likely to enable safe

sharing of health data at the national as well as cross-border levels.

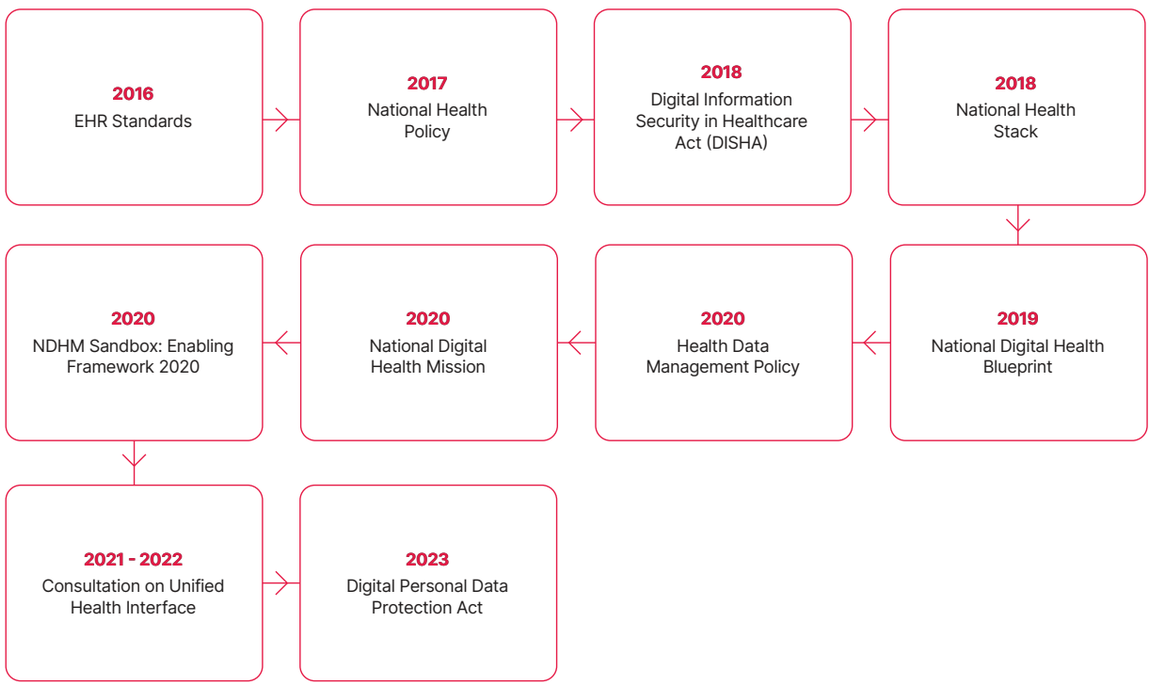
Clearly all this will help catalyse digital health innovations, since with clear regulations now being in place, researchers and innovators can better harness patient data for medical research and for the development of personalised treatments. Technology companies engaged in cross-border health data sharing will have to ensure that it is encrypted in transit and ensures patient privacy. In case of non-compliance, they may have to face legal repercussions, including penalties up to INR 500 million (US$ 6 million) (Nakashe, 2023).

The Digital Personal Data Protection Act allows cross-border data sharing where, in addition to patient consent, the recipient country should offer an adequate level of protection, and ensure that the data is stored in India. Section 16 of the Act states that the government may restrict sharing with certain countries which it will notify periodically (Amlegals, 2023).

2.2.8 Ayushman Bharat Digital Mission: India's national electronic health records initiative

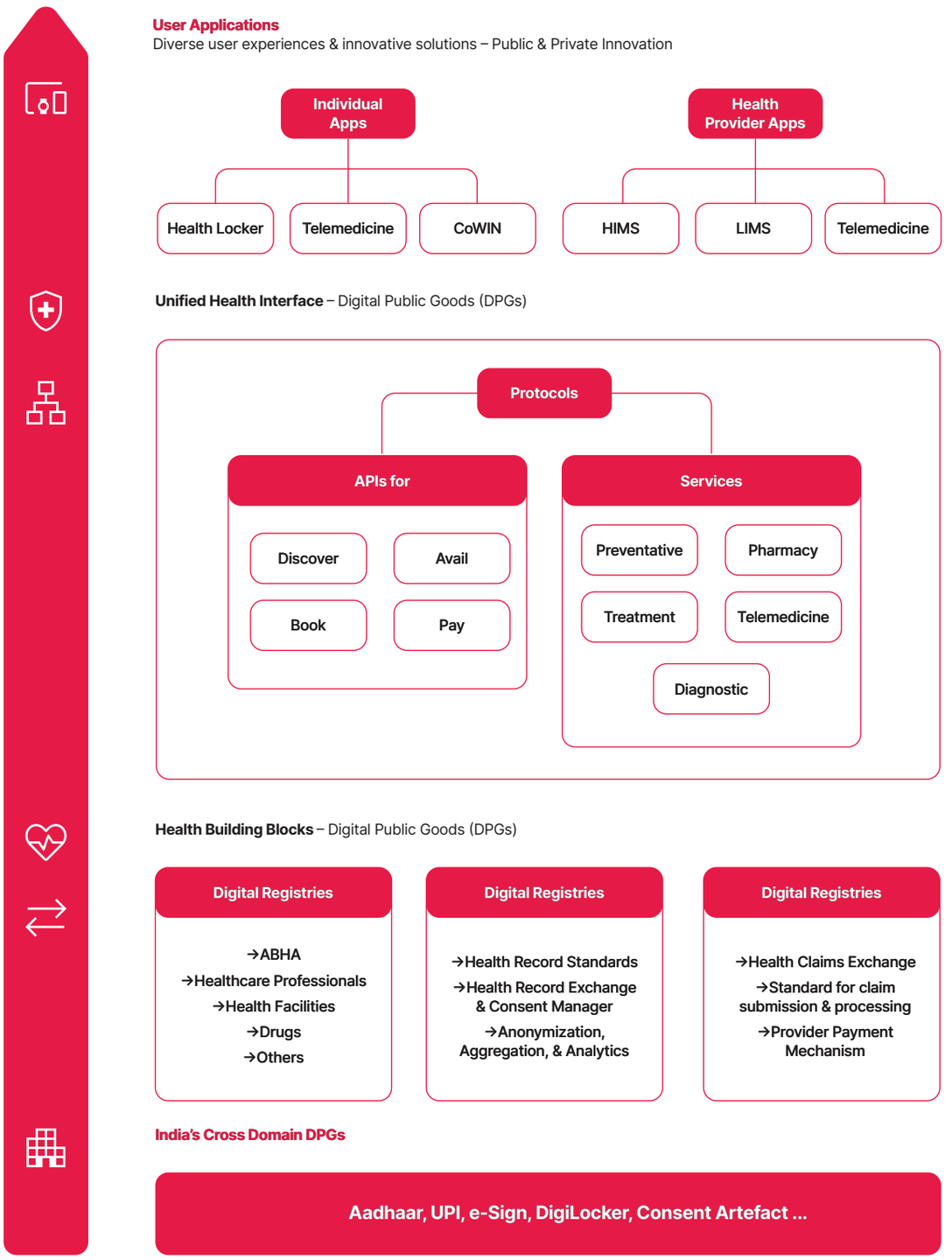
The **ABDM** seeks to develop a national digital framework to support an integrated digital health infrastructure in India. The vision for the ABDM was first laid out in the 2017 National Health Policy. Later in 2019, the National Digital Health Blueprint (NDHB) introduced the building blocks and action plan for pan-India implementation of digital health (NHA, 2023).

Figure 6:
Timeline of regulations for health data sharing in India



Source: See Appendix 2 for details

Figure 7:
Framework of the Ayushman Bharat Digital Mission[19]



Source: NHA, 2023

19 At ABDM-Insights, users can actively monitor the progress of the initiative in terms of the EHRs generated and the scale of interoperability achieved.

The NDHB identified implementation gaps for healthcare across India. Once the infrastructure and gaps were identified, the ABDM was officially launched in 2020. Following are its components (NHA, 2023):

- **Ayushman Bharat Health Account (ABHA) number**: A unique personal identifier for authentication and sharing of health records (based on informed consent) across multiple systems and stakeholders.
- **Healthcare Professionals Registry**: A comprehensive repository of all healthcare professionals involved in healthcare delivery. Doctors who are enrolled as part of this registry will be connected to the ABDM's digital health ecosystem.
- **ABHA mobile app**: An application to store personal health records based on an individual's account. Unlike the electronic health and medical records, it remains under the control of the individual. It is drawn from multiple sources and can be managed, shared and controlled by the individual.
- **Health Facility Registry**: A comprehensive repository of health facilities across different systems of medicine. It includes both public and private health facilities, including hospitals, clinics, diagnostic labs, imaging centres and pharmacies. Enrolling in this registry will help facilities connect with the country's digital health ecosystem.
- **Unified Health Interface**: An open network of end-user applications and participating health service provider applications. It will enable a variety of digital health services between patients and health service providers, including appointment booking and teleconsultation.

Regulations for EHRs in India

As per the Clinical Establishments (Registration and Regulation Act) (2010), hospitals in India are required to maintain an EMR for their patients. The MoHFW first released regulations for EMRs in 2013; they were updated in 2016 and made public (Singh, et al., 2022). However, these regulations were not successful in enabling health data interoperability.

As such, the National Health Authority announced the Health Data Management Policy (2022) on April 23, 2022. It is a digital-friendly data protection framework that lays the legal foundation of EHRs in digital form by enabling "interoperability across all players of the National Digital Health Ecosystem)" (NHA, 2022).

The framework gives citizens complete control over their health data and allows them to share, or prevent sharing, as per their needs and personal preferences. It specifically outlines the technical and policy requirements for sharing health data in aggregated form, and to prevent re-identification of anonymised data. While the framework does not specifically identify or define secondary health data, it recognises its use in facilitating medical research and innovations (NHA, 2022).

2.2.9 Integration of India's data systems

The ABDM offers an opportunity for the government to improve the larger healthcare infrastructure, including avoiding duplication of data, improving the quality and number of doctors, and preventing fraud and abuse. It also encourages innovation by attracting startups to the ecosystem by giving them access to a larger pool of health data. However, small and medium startups need to be incentivised more for them to participate actively in the ABDM.

The aim is eventually to provide health data storage and sharing at a national level while also enabling telemedicine services and using health data records to improve treatment outcomes for patients. As of December 17, 2022, nearly 40 million citizens had created their ABHA numbers (MoHFW, 2022).

For further scaling up the initiative, stakeholders observe that the government needs to introduce attractive incentives (and discourage disincentives) to get the stakeholders, including public as well as the private healthcare sector, to onboard the platform.

For private hospitals, getting new patients can be costly, so one incentive is to have the ABDM as a cost-effective solution to identify new customers. Integration can vary across urban and rural areas, since it affects the operational cost of the hospitals above other things. The ABDM incentivises more rural hospitals to participate in the programme than urban ones via pricing mechanisms.

An example of a disincentive would be barring hospitals that do not participate in the ABDM from national programmes including the PMJAY. Stakeholders observe that, in the future, the PMJAY may become a key source of revenue for hospitals and could be an enabler for greater adoption of the ABDM.

The ABDM has so far been able to incorporate more than 25,000 hospitals into its healthcare facilities network. This means all these hospitals are digitally equipped to participate in the ABDM ecosystem. Stakeholders note that the National Health Authority should clearly specify the advantages for healthcare facilities when they join the ABDM. Hospitals should also be enabled to synchronise their services with the ABHA app to improve their workflow.

For larger bodies in the healthcare system, integration of data can be challenging due to diversity in different IT systems and because of how data is perceived and used across systems. Although private healthcare organisations have digitised their data, they are not open to integration without the complete picture of who is going to use the data and for what purpose.

For example, large hospital chains such as Apollo do not have adequate incentives to participate in the ABDM and continue to function with their own systems. Primary healthcare is lagging behind compared with secondary and tertiary care facilities in terms of digitisation. There will also be state-level challenges including guaranteeing accurate, high-quality data. There is need for policy continuity to achieve this.

2.2.10 India's central versus state governments

The decentralisation of healthcare in India leads to fragmentation at the hospital level. For example, while state-owned hospitals are answerable to state governements, institutions in the state that are owned by the central government are answerable to it rather than to the state. For uniform implementation of the ABDM, all states should have equal kinds of resources in terms of digital infrastructure and human resources, and there should be better communication.

It is up to the central government to address this issue. Different states have different implementation units which partner with different consultants or private sector players. States also employ different professional services consultants. This leads to diversified implementation of the ABDM across states, while ideally, some stakeholders argue, it should be centrally controlled and monitored.

Sometimes states may hesitate to participate in the ABDM due to their political differences with the central government (e.g. West Bengal and Rajasthan, which are governed by

different political parties) and this affects the pan-India implementation of the programme. Some states, accordingly, may be reluctant to share data with the central government and may only share selective rather than comprehensive health data.

State governments are sometimes more interested in launching new projects than in looking at the sustainability and interoperability of projects. Over time,, projects suffer from lack of monitoring, delayed implementation and inadequate funding, which lead to them becoming burdens rather than achievements for state governements.

> **"[The PMJAY] is quite successful, but it will take time because there are still many states which are not able to onboard. Some have their own version. Some are central party ruling states and some are not. The latter are reluctant to join the mission by the prime minister and so on."**
>
> **– Health expert, leading private health insurance company**

The implementation of the PMJAY as a national health insurance scheme has become an enabler for the ABDM's digitalisation progress because the National Health Authority has taken initiative to ensure data portability between states that have enrolled for the programme. Maharashtra and Arunachal Pradesh states, for example, have enrolled in the PMJAY programme, which means that a patient moving between the two can continue to get PMJAY benefits.

Since insurance data can be rich and detailed, its integration with the ABDM can enable the government to identify gaps in healthcare infrastructure, delivery of services and uptake of the ABDM. States can also use this programme to improve digital infrastructure and human resources at the state levels. This is because most of the states are using the PMJAY as a national health insurance scheme and also as a base for state health insurance schemes. If states implement their own health insurance schemes, however, then they are not mandated to share data with the PMJAY and hence there is potential for duplication.

2.2.11 India's organisational factors affecting health data sharing and innovation

Private healthcare organisations in India have operated in silos for many years. As a result, they have been able to stay away from public sector regulations and have, over the years, invested and developed in-house innovations and digital health applications using their own gathered data. Some private hospitals have already implemented EHRs within their systems. They also have in place hospital management systems for increasing efficiency in their workflows. Many of these innovations, howerver, are not scalable given the limited scope of the data they are based on.

Data security and patient privacy are key concerns for all healthcare organisations. With the new data protection law in place, hospitals will have to allocate more resources to ensure that their systems are robust and well-protected from cyber threats. Currently, many hospitals also have limits when it comes to data storage. They are mandated to hold health data for a minimum of three years, but after that it can be destroyed. This means a loss of data that could have otherwise been used for generating valuable insights.

Another key challenge is the mindset and capability of doctors with respect to digital health. In India, given the extremely low doctor-patient ratio, doctors in most hospitals and healthcare facilities are overburdened with

their day-to-day handling of cases. As a result, they do not have the time to enter patient data into digital applications in real-time.

Doctors in India are also not trained in digital health, and many resist using digital devices for entering data, preferring handwritten notes. Identifying doctor availability and willingness to adopt digital health applications can be challenging for hospitals.

2.2.12 Impact of the ABDM on digital health innovations in India

In 2020, the MoHFW launched the National Digital Health Mission Sandbox Enabling Framework Guidelines, designed to enable technologies or products to be tested in a contained environment in compliance with government standards and with feedback from consumers. This helps organisations intending to be a part of the National Digital Health Mission (another name for the ABDM) to become one of its health information providers or users (ET Health World, 2023). Any digital health service provider or developer can register on the sandbox by following a pre-defined process of integrating and validating their software systems using the ABDM application programming interface.

As of July 2022, the sandbox had nearly 919 active participants – health information providers, health repository providers, health information users, and mobile health depositories, or health lockers. Of these, 52 digital applications have been successfully integrated with the ABDM, of which there are 20 public-sector and 32 private-sector applications (MoHFW, 2022). The National Health Authority also launched a Digital Health Incentive Scheme in January 2023, with incentives up to INR 40 million (US$ 485,200) offered to digital health stakeholders such as hospitals, laboratories and health technology companies (ET Health World, 2023). In addition, state-level EHRs have also integrated with the ABDM (ET Health World, 2023).

While the government prefers to engage all stakeholders equally as part of the ABDM, there is special preference for government innovations. For example, the government promotes e-Sanjeevani – which is also the National Telemedicine Service of India – to enable patients to easily access doctors (including specialists) across the country. Public-sector digital health innovations are less restricted by regulations as they are controlled by and implemented under the National Health Authority.

Moreover, since they are designed for thedigital public good, these applications are able to make services available for free, thus reaching a larger percentage of the population within a shorter time duration. This does not affect private digital health startups negatively since India has a vibrant domestic market – which, in addition to supportinggovernment policies, is leading to more startups entering the market. For example, the market is diversifying from curative to preventive healthcare solutions as witnessed by startups such as HealthifyMe, which uses AI to help individuals make healthier choices to prevent chronic illnesses like cardiovascular diseases, diabetes, etc. (Biswas, 2021).

2.2.13 Conclusion: Digital health innovation as a solution to India's healthcare challenges

India has an emerging and vibrant digital health innovation system alongside a large yet fragmented healthcare system. Healthcare in India is struggling to meet rising demand with limited resources for a vast and diverse population. Digital health innovations, therefore, are seen as a means to achieve universal healthcare while enabling structural reforms to make services more accessible, affordable and efficient.

The key drivers are the increased adoption of mobile devices in rural parts of the country, increasing access to affordable internet connectivity, and a societal change in digital adoption. India has the demand and supply for digital health innovations channelled by supportive government policies, in addition to increasing collaboration with global institutions and leading technology companies.

The active implementation of the ABDM programme will further enhance health data sharing domestically. For the private sector, the recently passed Digital Personal Data Protection Act 2023 has provided more clarity on data privacy rules, which will help technology companies and startups to effectively balance patient health data privacy with the need to share health data for developing new solutions.

With the current data protection law being more open to cross-border data sharing, India can enhance the potential for global collaborations in healthcare in safe and efficient ways. The coming five years are crucial for these developments on three fronts: 1) the successful implementation of the ABDM, 2) the implementation of data protection policy within healthcare, and 3) the impact of these initiatives and regulations on local as well as regional digital health innovations.

2.3. Indonesia: A fast-growing digital health ecosystem that's strongly protected

With a population of 278 million people, Indonesia has the largest and the fastest-growing population in Southeast Asia. It's a young country, with approximately 40 per cent of the population below the age of 25. The country also has 170 million (and growing) internet users, with 90 per cent of the users being below the age of 19 years (Cheung, et al., 2021; Taery, 2020). As per World Bank statistics, despite its economic growth, the country's GDP ranking has been stuck at 16th in the world since 2015 (Sato, et al., 2022).

One reason is the poor performance of the healthcare sector, which is calculated to be causing a loss of nearly 30 per cent in annual GDP. Communicable diseases such as typhoid and malaria account for 11 per cent of productivity loss while non-communicable diseases such as heart failure, respiratory problems and cancer account for 19 per cent (Lim, et al., 2019).

The country is especially challenged in delivering healthcare by geography; Indonesia's population is dispersed across some 17,000 islands. A shortage of healthcare professionals, gaps in digital infrastructure, and the paucity of digital health app use are key driving forces for digital health innovations in the country (Cheung, et al., 2021).

Since 2010, the government has been spending more to improve the healthcare sector by means of digitisation. In 2021, it allocated US$ 3.5 billion to fund universal health coverage, part of which was allocated for digitalisation (InCorp, 2021). Still, at 3.41 per cent of GDP, healthcare expenditure in Indonesia is below the regional average of 6.94 per cent (World Bank, 2023). Post-COVID-19, however, there is active enthusiasm in the sector to digitalise, with nearly 82 per cent of healthcare leaders aiming to invest more in AI, 49 per cent in telehealth, 47 per cent in digital health records and 44 per cent in clinical operations centres over the next three years (Preesman, 2022).

In light of such strong government spending, national health insurer BPJS Kesehatan (BPJS-K) has sought to make healthcare affordable for citizens (Sato, et al., 2022). Currently, 88 per cent of the population is covered by BPJS-K. Yet its impact has been unequal across urban and rural areas as well as across public and private healthcare sectors. In remote areas, despite having subscribed to BPJS-K, patients end up incurring out-of-pocket expenses for accessing healthcare services (Asante, et al., 2023).

The low quality of healthcare infrastructure is also a key challenge. Out of 34 provinces, 15 provide substandard public services and are in less than 70 per cent compliance with national standards (Sato, et al., 2022). Indonesia also suffers from a severe shortage of doctors: it has only slightly more than one doctor per 5,000 patients, which is far below the recommended 1:600 doctor-patient ratio (Hani, 2021). According to the Ministry of Health, Indonesia will need 160,000 doctors in the coming years (Cuaca, 2023).

To overcome these challenges, the Ministry, in partnership with the UNDP and with funding from Japan, launched the Blueprint of Health Transformation Strategy 2024 on December 16, 2021. It aims to lay the groundwork for digitalising healthcare in Indonesia. Its key goals include the digital integration of health data from patients and providers, and the integrated development of digital health infrastructure. The government aims to use digitalisation to attain universal health coverage (UNDP, 2021).

2.3.1 COVID-19 as a catalyst for Indonesia's digital health innovations

During the pandemic, the government developed an application called PeduliLindungi to collect research and laboratory data on COVID-19 testing. The data was combined into an integrated database by the Ministry of Health; this was the first time that the government had collected health data across healthcare facilities and integrated it into a single database.

One Ministry of Health official said:

> **"I think COVID really opened our eyes and also opened our willingness to do digital transformation, to do a centralised data approach."**

This initiative paved the way for the formation of a national health database. During the vaccination rollout, the government combined the use of unique identifiers, provided by the Ministry of Home Affairs, which helped the government to launch large information and communication campaigns for people to get vaccinated. Data collection during the vaccination rollout enabled the generation of vaccination certificates by means of the PeduliLindungi application.

There were digital health initiatives at the provincial as well as district levels, as regional governments developed their own digital platforms. Some examples include: 1) the open-source Pikobar initiative of the province of West Java, which enabled a COVID-19 monitoring system before the central government could deploy a solution nationally; and 2) the province of Bali deploying systems to predict the demand for oxygen tanks at the height of COVID-19 (Mun, 2022).

Provincial systems initially made COVID-19 reporting difficult, but this was soon resolved once the central government implemented a uniform system. In 2020 and 2021, Indonesia developed two national health systems as part of the COVID-19 management programmes. The PeduliLindungi and Vaccination Dashboard have been well-adopted for public health management with high traffic data exchange (Sato, et al., 2022). The PeduliLindungi application has been a huge success and has been downloaded more than 200 million times by citizens. The application was used to access COVID-19 test results as well as vaccination certificates.

The government also implemented barcodes for people to scan, which helped control the movement of people during the pandemic. The pandemic also increased digital adoption among citizens and boosted awareness about their rights to access their own health data. For example, citizens are now requesting child immunisation data be digitalised. Previously, this was recorded in a child immunisation book and if the book was lost then the data would be lost as well.

Healthcare facilities also developed a new feature for booking appointments online to prevent overcrowding. This has become a more common practice since the pandemic. Telemedicine also took off during the pandemic and several hospitals started providing their services remotely. Hospitals have also been collaborating with digital health startups to distribute medicines so that patients don't have to wait at the hospital.

Indonesia's drive for international COVID-19 vaccination certificates

As Chair of the G20 in 2022, Indonesia called for strengthened global health architecture to build resilience in the face of pandemics. Some specific issues taken up by the Indonesian Government were: equitable procurement of vaccines, medicines, and diagnostics, and harmonising international travel and health protocols (Guinto, et al., 2022).

Indonesia actively pushed for cross-border sharing of vaccination status and remains involved in the development of an international certificate standard for vaccination status. The country is also approaching other nations to adopt the DIVOC[20] and WHO vaccine standards, which are recognised universally.

2.3.2. Indonesia's insurance markets as an enabler for sharing health data

The BPJS-K national insurance organisation is recognised as a key enabler of digitisation in Indonesian healthcare facilities. It requires all primary care health clinics to use their web-based application to enter the health data of patients. Around 10 per cent of the facilities are not able to use this system in real-time due to difficulties in internet access and other digital infrastructure issues. But the remaining 90 per cent can enter the health data of patients directly into the BPJS-K system, where it can be accessed by other health facilities.

BPJS-K-member hospitals gainaccess through the Indonesian diagnosis-related groups system. Being members of the same insurance provider makes it easier for hospitals to share health data between facilities. If a patient in primary care is referred to hospital, the primary carer can use the system to refer the patient to the hospital, which may have been requested by the patient. Patients can thus access healthcare services at the referred hospital by means of a BPJS card or a national identity card, which will mainly be used for authentication and to check insurance eligibility.

The insurer also developed its own digital health application – Mobile JKN – to improve services to its members (Handayani, et al., 2021). An attempt to implement telemedicine services as part of this application failed at least partly because of a lack of doctors available on the platform.

The BPJS-K has also initiated digital services through collaboration with digital health startups. In 2019, for example, it partnered with Halodoc – a leading digital health startup – to provide doctor consultations while also creating a health information database (Halodoc, 2019). It was started as a free service and was widely used by citizens during the pandemic for ordering medicines. However, after the pandemic, its usage has reduced, as it now incurs some cost for users.

2.3.3 Digital health innovations in Indonesia fill existing gaps in healthcare

Halodoc, Alodokter, KlikDokter, Good Doctor, ProSehat, Dokter.id and YesDok are the leading digital health startups in Indonesia. Most of these applications connect patients to doctors by means of teleconsultations, provide informative health articles, and make

20 This stands for 'Digital Infrastructure for Verifiable Open Credentialing'. DIVOC is a Digital Public Goods Alliance listed public good that enables countries to digitally orchestrate large-scale vaccination and public health programmes using open-source digital infrastructure (DIVOC, 2022).

it easier for patients to search for hospitals, doctors and even specialists. They also help deliver medicines to patients directly, which was a highly used service during the COVID-19 lockdowns (Nurhayati-Wolff, 2021; Mime, 2020).

Most of these applications collect the health data of users to tailor their services as they evolve. The startups also actively collaborate with both public and private hospitals in the existing healthcare system (Anand, 2023).

2.3.4 Unequal adoption of digital health across urban and rural areas

The government has been trying to implement digital health solutions since before the pandemic, but the project has not been overly successful. Some of the challenges are technological, such as lack of health data interoperability, unequal distribution of infrastructure, security concerns, and system quality. Others, however, are related to people and healthcare organisations, including lack of IT experts, resistance of healthcare providers to health information systems, lack of top management support at hospitals, and changes in strategic government planning and policy (Harahap, et al., 2021).

The absence of a uniform digital infrastructure between urban and rural areas is a particular challenge. The digital infrastructure is good on major islands such as Kalimantan, Sumatra and Java, but on others – such as Ambon, Papua and East Nusa Tenggara – there are fundamental issues, including the availability of consistent electricity. Availability of skilled IT professionals also remains a challenge in remote and lightly populated cities and regions. In 2019, 62 per cent of Indonesians in urban areas were connected to the internet, compared with only 36 per cent in rural areas (World Bank, 2021).

There can also be low adoption in urban areas. While the use of telemedicine was good during the pandemic, its usage dropped after the pandemic subsided. Many people still prefer to meet a doctor in person instead of using digital applications to consult them.

One of the concerns expressed by stakeholders during this research was that digital health may accelerate Indonesia's urban- and age-bias, widening the inequality in access to healthcare. While digital health applications such as PeduliLindungi are helpful for people with good internet connectivity and access to mobile gadgets, widespread adoption may hinder healthcare access through the app for those lacking such technology.

Human resources challenges exacerbate existing gaps in digital adoption

Healthcare workers in primary healthcare are not adequately skilled to harness the benefits of digital health. This is because the number of healthcare workers with an education or background in health informatics or in medical records is low. 74.4 per cent of health informatics experts working in the country do not have a background in the field. As a result, there is a mismatch between education and the job market in healthcare, especially in terms of technological expertise (Interviews).

Hospitals also face similar challenges with respect to human resources. This is because 22 per cent–26 per cent of all healthcare providers work in large cities like Jakarta, which comprises 3 per cent of the total population of the country. The shortage of healthcare professionals was especially grave during the COVID-19 pandemic and the government had to recruit 2,785 volunteers to handle the rising number of cases across provinces (Mahendradhata, et al., 2021).

2.3.5 Indonesia's fragmented data systems

The Ministry of Health currently has 400 applications which are used for administration, disease monitoring, health monitoring and other functions. Many of these applications have been actively collecting data for the last 5–10 years. However, they exist in silos and are not integrated. There are also challenges with respect to the identification of cases in these data systems as some parts of the data have not been attached or have been incorrectly attached to the patient's unique national identification number. The key challenge for the government is cleaning and integrating the data. Indonesia's integrated national health platform, Sistem Informasi Kesehatan Nasional is equipped with a national health dictionary as a standard, but integration with local systems is limited (Sato, et al., 2022).

The government initially assigned the development of a national health information system to the Ministry of Health's Center for Information, Communication and Technology. However, each regional government is leading its own development initiatives, so the integration between national and regional platforms has been very limited. In recent years, the government switched the job to the Ministry of Health's Digital Transformation Office (DTO), which is more focused on integrating and developing the national health platform. However, the process of integrating national and regional platforms remains complex (Sato, et al., 2022).

2.3.6 Indonesia's regulatory landscape for sharing health data

Indonesia allows cross-border sharing of data in general but does not specify how health data should be treated during such transfers. At the national level, health data sharing remains fragmented. With the enactment of the Personal Data Protection Law and the launch of the SATUSEHAT initiative, health data sharing in Indonesia is starting to open up to new possibilities.

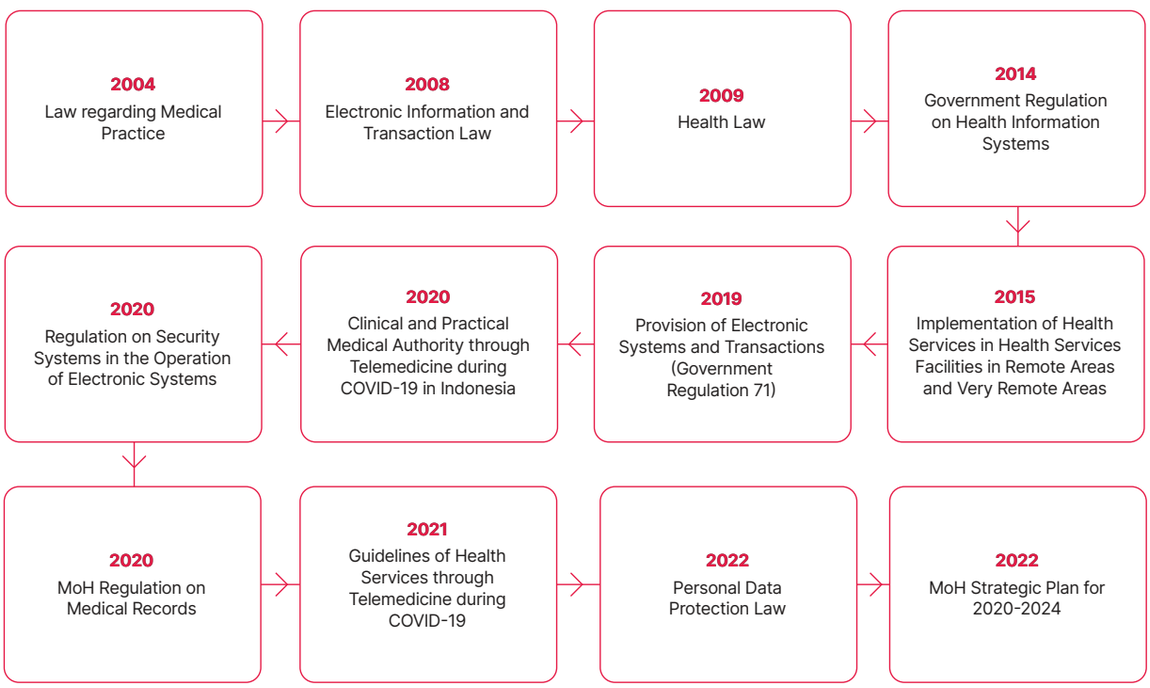
Indonesia's data protection policy

The Personal Data Protection Law No 27/2022 was signed into law on October 17, 2022. The law regulates personal data protection in both electronic and non-electronic form and applies extraterritorially to any personal data processing that has an impact on citizens outside of the country's jurisdiction. Despite being a comprehensive regulation, most provisions of the law require implementing regulations to be fully executed.. Starting from October 17, 2022, the law has provided a two-year transitional period for stakeholders involved in data processing activities to adjust their practices as per the requirements stated in the law (Rahmansyah, et al., 2023).

The law recognises health data as specific personal data, although it does not specify how the data processor should treat specific personal data differently from general personal data – which includes full name, gender, nationality, etc.

In terms of cross-border data transfer in general, Article 56 of the Personal Data Protection Law allows it given the condition that 1) the jurisdiction where the recipient of the data is located has an equivalent or higher data protection standard than the Indonesian law, 2) there is an adequate and binding personal data protection, and 3) the consent

Figure 8:
Timeline of regulations for health data sharing in Indonesia



Source: See Appendix 2 for details

of the patient has been obtained (Rahmansyah, et al., 2023).

As per the law, the government is expected to establish an independent authority for data protection. In the case of a data breach, the proposed Data Protection Authority (DPA) may exercise its powers by means of a written warning, the temporary suspension of processing activities, the forced deletion of personal data or administrative fines of a maximum of 2 per cent of annual revenues or sales of the processor.

However, currently, due to lack of implementing regulations and the formation of the DPA, stakeholders are required to abide by the Ministry of Communication and Informatics (MOCI) Regulation 20/2016. This law requires that organisations that engage in cross-border data sharing should get the patient's consent as well as coordinate with the MOCI before and after a cross-border data transfer.

Currently, entities engaged in cross-border data sharing are required to submit a form via email to the MOCI stating their name, the recipient of the transferred data, the personal data that's being transferred, the purpose and the destination of the transfer. However, the implementation is further complicated by sectoral regulations, lack of awareness among organisations, and the entity's willingness to comply with it (Rahmansyah, et al., 2023).

A healthcare expert at a think tank noted that the law was about data privacy rather than sharing:

> **"Given that we have enacted the data protection policy, I think it will become stricter."**

This is because the requirements for cross-border data sharing under the Personal Data Protection law is similar to that under the GDPR law, which is known for its strict rules.

2.3.7 The SATUSEHAT (One Health) initiative

In July 2022, the Ministry of Health launched the SATUSEHAT platform for the transformation and data integration of national health services. The initiative aims to transform healthcare services in Indonesia through digitalisation. SATUSEHAT will provide health data connectivity, analysis and services to support the integration of existing applications and health facilities (Govt of Indonesia, 2022).

SATUSEHAT was developed through extensive planning and consultation with experts and was tested across hospitals, laboratories, pharmacies and private clinics. It was tested first at 41 government hospitals and second at 31 diverse institutions (Govt of Indonesia, 2022). The platform sets up uniform standards that are expected to prevent misuse of health data (Dharma & Adji, 2023).

The SATUSEHAT database is now available as SATUSEHAT Mobile, presenting data from medical entities (KMS, 2022) and making it accessible for citizens to access and share (Arlinta, 2023). The data is not shared unless the patient gives their consent. Consent is also required for patients' data to be shared with SATUSEHAT.

The application is expected to reduce the workload at primary healthcare clinics and hospitals that have sometimes had to input the same health data across multiple applications. In some cases, primary healthcare workers currently have to enter patient data into 30 different applications depending on the type of cases they see at the clinic. For TB patients, they have the SITB (Sistem Informasi Tuberkulosis) application; for AIDS cases, they have the SIHA (Strategic Information on HIV and AIDS) database; and for malaria, there is a separate application. The health workers then need to aggregate the data and upload it to the national early warning and health monitoring system. SATUSEHAT will help avoid this process and duplication by creating a single depository.

SATUSEHAT also plans to integrate with the national insurer's BPJS Health application. More recently, the application has integrated three new features as part of the SATUSEHAT mobile application – these remind users to take their medication, record their health condition, and find the nearest doctors (Kenzu, 2023).

Indonesia's rules for EHRs

The Ministry of Health has new regulations set to cover EMRs across all healthcare facilities in Indonesia. They are expected to come into effect by December 31, 2023 (Endahayu, et al., 2022). The regulations stipulate that:

- All healthcare facilities must store health data in digital form; this is mainly to promote health data interoperability. The healthcare facilities that have been included are doctors' offices, public healthcare centres, clinics, hospitals, pharmacies and laboratories.
- Healthcare facilities must have a dedicated working unit to managethe medical records.
- Facilities may hire private technology service providers, but the health data must be stored within Indonesia, and the private service provider has to be first approved by the Ministry of Health.

→ Healthcare facilities may use the Ministry of Health's electronic system by submitting a written request.

Indonesia's strategy for EHRs

The DTO is currently developing generic health information systems for each healthcare provider tier – primary healthcare, hospitals, laboratories and clinical management. It is also developing an application for healthcare workers who work in communities and outside of healthcare facilities. Healthcare providers will be able to connect to SATUSEHAT by means of these applications.

The DTO is also seeking to have private vendors comply with SATUSEHAT standards, thus allowing hospitals wishing to choose an IT system from a private vendor to remain compliant with SATUSEHAT. Conversely, hospitals that have limited financial resources can opt for the Ministry of Health's free information management platform.

To persuade healthcare staff to input data into SATUSEHAT, the ministry is planning to offer professional credits that will be added to their qualifications. And to encourage hospitals, the ministry will mandate health data sharing into the SATUSEHAT if they want to claim funds from the BPJS-K national insurance system.

One risk facing the SATUSEHAT initiative is that it is primarily the brainchild of Minister of Health Budi Gunadi Sadikin and therefore could be affected (discontinued or restructured) if a new minister is elected in the 2024 elections. Accordingly, the Ministry is seeking to quickly develop and implement its systems to gain sufficient momentum and stakeholder support such that it would remain viable even if there is a change in political leadership (Interviews).

Indonesia's standards for EHRs

The DTO is currently adopting different international reporting standards for diagnostics, laboratories and medical examinations (ICD-10, LOINC, and ICD-9M, respectively). The SATUSEHAT platform is adopting HL7 of the FHIR for health data sharing.

Certain provinces, however, do not report under the international standards, so the DTO is working on integrating the systems. While centrally the SATUSEHAT will be implemented in the Indonesian language, at the provincial level the governments can develop applications in their own local language.

2.3.8 Indonesia's organisational factors that affect health data sharing

Many hospitals in Indonesia have very limited IT departments with which to transform their local hospital information management systems into centrally standardised ones. This is a human resources issue. But for hospitals that use hospital information systems from vendors, the main problem is funding. Meeting the December 2023 deadline for adopting SATUSEHAT will therefore be tight (Interviews).

There are also different attitudes to the process. While some private hospitals aren't willing to integrate their health data, others see it as an opportunity to attract more patients to their hospitals.

The current lack of data sharing is actually beneficial to hospitals since it discourages patients from moving from one hospital to another to seek better care. Patients worry that if they change hospitals then they would have to retake expensive tests. However, with the implementation of SATUSEHAT, this is expected to change as public and private hospitals can access patient data for their previous treatments and this will enable them to provide care continuity (Interviews).

2.3.9 Impact of the SATUSEHAT platform on digital health innovations

Currently, the focus of the Ministry of Health is to collect data and integrate all the existing data systems as part of the SATUSEHAT. Once the data is collected, stored and standardised as part of the platform, the Ministry plans to use the data to predict populations at high risk of communicable diseases. Recently, it has also issued **Decree (SK) No. HK.01.07/ Menkes/1280/2023** concerning the development of digital innovation through a regulatory sandbox using the same format as with the financial sector (Firdaus, et al., 2023). The initial focus is on digital health startups offering telemedicine services.

The Ministry's DTO says the regulatory sandbox will assess the reliability of business processes, business models, technology, regulatory management and service providers to innovate and analyse risks to society while developing regulations that support implementation in the health sector. It is also expected to help hospitals strengthen their data protection mechanisms and to enable healthcare workers to adopt new technology. For startups that pass through the regulatory sandbox, the government will issue temporary regulations in the form of recommendations and guidance (Firdaus, et al., 2023).

2.3.10 Conclusion: Indonesia is racing to achieve health data interoperability

With high demand and increasing adoption across the country, Indonesia is an attractive regional market for digital health innovations. The government recognises that the current healthcare system is highly fragmented, with lack of comprehensive data for policymaking. As a result, it is actively implementing the SATUSEHAT initiative, which aims to enable health data interoperability and drive digital health innovations. A key challenge, however, is the short timeline within which this policy is being executed, and the capacity of the key healthcare stakeholders to comply with the regulations promulgated by the government. Inefficient implementation might exacerbate existing challenges if the government is not careful.

On the positive side, the initiative has significant potential to enable local digital health startups to spread and grow quickly across the country once cleared through the new healthcare regulatory sandbox. While this bodes well for domestic innovation, significant challenges for Indonesia remain with respect to regional and global digital health innovation. Although the government has passed a data protection law, its implementation with respect to cross-border health data sharing is unclear.

Despite strict data laws and complex regulations, however, Indonesia overall offers an attractive option for regional digital health startups to scale their solutions into its vast market.

2.4 Malaysia: A regional front-runner in digital health, with ambitions to expand

Malaysia has a vibrant digital economy and manages one of the best healthcare systems in the world (Jebaraj, 2021). Public healthcare is led by the government and funded by the taxpayers, along with a private healthcare system that is a top destination for international patients (Jebaraj, 2021). With nearly 10 per cent of its population over the age of 60, senior care is a key focus for Malaysia (ITO, 2023).

The government is expected to double the country's healthcare expenditure by 2028, driven by the increasing prevalence of non-communicable diseases such as cardiovascular diseases and diabetes (ITO, 2023). Malaysians have the highest rates of diabetes in ASEAN, affecting one in five adults (ITO, 2023). This is likely to threaten the financial sustainability of Malaysia's healthcare system going forward (Razali, 2023).

The government has identified health data interoperability as a key part of providing quality healthcare services that are accessible and affordable. The current lack of such health data interoperability makes it challenging for patients to seek healthcare continuity across the country. For example, many patients have to retake tests when they move from one hospital to another, adding to out-of-pocket expenditures (Interviews).

This is the case across the public as well as private healthcare systems, which operate in parallel without much communication. Public healthcare is more affordable, but busy; private healthcare can be more convenient, and is highly digitised (Interviews).

Citizens in Malaysia are increasingly seeking virtual health services such as home doctor services through digital applications, internet pharmacies, teleconsultation, etc. However, currently there is no mechanism to ensure that patients obtain these services without risks (associated with confidentiality and ethics). Increased adoption of digital health applications post-COVID-19 has increased concerns about the safety, privacy and confidentiality of patient health data (Jebaraj, 2021).

The Malaysian Government has been a regional front-runner in adopting digital health[21] as a potential solution to the country's challenges. Aware of the gap between application adoption and data protection, the Ministry of Health launched the Malaysian Health Data Warehouse (MyHDW) in 2017. It aimed initially to collate the health information of approximately 2.5 million patients from public as well as private hospitals, with more data to be collected in subsequent phases of roll out (Rohaidi, 2017).

The MyHDW aims to help healthcare professionals and caregivers make more educated decisions about treatment. It was designed with data security in mind, ensuring that the personal information of patients was not publicly revealed (Rohaidi, 2017).

In 2021, the **Malaysia Digital Economy Blueprint** was published, setting out the government's MyDIGITAL initiative to transform the country into a digitally driven, high-income nation that is also a regional leader in the digital economy. The initiative also outlined a framework for the digitalisation of healthcare and the accelerated use of MyHDW by means of blockchain technology (Soraya, et al., 2022).

21 The country saw one of the earliest adoptions of telemedicine in 1997 (GSMA, 2022), with pilots of tele-primary care in early 2000s in rural Sibu in the Sarawak state. The pilots connected patients in rural clinics with specialists in the main Sibu hospital, thus allowing patients to access specialist care (HMA, 2023).

2.4.1. Malaysia's public versus private healthcare

The escalating cost of private healthcare in Malaysia is a major concern. This has spillover effects on public healthcare, which is adding pressure on government health spending through high medical costs for treatments.

The public-private mix, meanwhile, is leading to wealth-based inequality in healthcare access (Balqis-Ali, et al., 2021). In 2017, for example, out-of-pocket expenditures by citizens accounted for a significantly high 38 per cent of the total expenditure in healthcare (Jebaraj, 2021).

There are also disparities between the public and the private healthcare in Malaysia, with the private sector offering shorter waiting times and personalised care. In one survey, 21 per cent of the population reported high waiting times in public hospitals, compared with a mere 3.2 per cent that did so for private hospitals (IPH, 2015).

Private hospitals are also more advanced in terms of digitisation, with some having their entire systems digitised. They have built their own ecosystem, which also includes pharmacies, and hence the health data collected by them is more comprehensive (Interviews).

2.4.2 Malaysia's insurance market: Low coverage raises personal costs

Insurance can be a key enabler in health data sharing, with insurers well connected to healthcare organisations and collecting significant amounts of health data as part of their claims settlement. Insurers can also enable more coordination at the primary and secondary healthcare levels, and across public and private healthcare (Interviews).

Malaysia offers good quality universal healthcare through public healthcare facilities which includes public, military and university hospitals, and primary healthcare centres. However, income inequality is pushing more people towards private healthcare. People from the middle 40 per cent and top 20 per cent of income groups are increasingly accessing private healthcare to avoid long waiting times in public hospitals. The bottom 40 per cent, however, rely solely on public hospitals for their treatments (Shahid, 2022).

Insurance coverage is low, which further increases out-of-pocket expenditures for the majority of Malaysians not covered by private health insurance (Balqis-Ali, et al., 2021). Only 22 per cent of Malaysians have private health insurance, with 43 per cent finding it unaffordable (Shahid, 2022).

Lack of insurance coverage affects the effective adoption of digital health applications in healthcare settings as well as data sharing. Some 63 per cent of doctors surveyed during COVID-19 stated that lack of insurance reimbursement for digital health applications, including telemedicine, deterred its usage in an urban, private healthcare context (Shahid, 2022).

The MyHDW targets both public and private healthcare systems, and should empower policymakers to better understand the bottlenecks faced by the healthcare ecosystem and find ways to solve it.

2.4.3 Digital health innovations in Malaysia

There are fast-growing private digital health startups in Malaysia such as Naluri (an online psychology-based preventive health platform), BookDoc (a teleconsultation platform), ThoughtFull (a mental health care platform for employees, individuals and insurers), Health Metric (letting companies manage employee health online), and DoctorOnCall (a medical video consultation platform) (Virtualspirit, 2022).

The largest among them is DoctorOnCall, which is a digital healthcare platform by Health Digital Technologies Sdn. Bhd., and offers telehealth services and delivery of medicines. The platform allows users to store and share their medical records, as prepared by the doctor during the teleconsultation. These can then be used for follow-up consultations. The startup has been able to partner with established hospitals and pharmacies in Malaysia such as Qualitas Medical Group, CARING Pharmacy, Pharmaniaga, and Thomson (Tech Collective, 2020).

The startup has also signed a memorandum of understanding with Celcom, Malaysia's oldest mobile telecommunication provider, to explore innovations in digital health such as embedding DoctorOnCall into Celcom's digital offerings like Business Suite for Retail (Koh, 2020).

Blockchain innovation for heart health

Doc2US and Data8 are digital health startups in Malaysia that offer to store patient health data from wearables, home-based health tests and healthcare centres. Patients can access their data, share it with doctors and use the application to book online consultations.

Data8 has been working with the Digital Health Research and Innovation Unitof the National Institute of Health to develop this centralised database under the cHeart platform. As part of the initiative, health data is anonymised, standardised and integrated. This solution is currently being tested at the Kuala Lumpur Hospital and the Sungai Buloh Hospital in Selangor.

Source: GSMA, 2022

During COVID-19, the government implemented the MySejahtera app for tracing cases of the disease in the communities. The app has evolved to deliver other digital health services like health screening, telehealth and digital health data records. The government subsequently used the app as part of the National Health Screening Initiativeto screen 250,000 people. MySejahtera has now transitioned into a multi-purpose national digital health tool enabled by sector-wide partnerships between public and private healthcare stakeholders (GSMA, 2022).

2.4.4 Lack of adequate funding and adoption

Budget constraints have been a key challenge for the government's health digitisation initiatives in the country, in addition to inconsistent policy implementation (Allaudin, 2014).

An integrated hospital information system was introduced in the early 1990s to collect, store, retrieve, and display patients' data and information in public hospitals (Ismail, et al., 2015). This was followed in 2005 by a cloud-based system – the Teleprimary care and Oral Health Clinical Information System (TPC-OHCIS) – that allowed healthcare providers at public health clinics access to patient records through a centralised database. In 2008, the government also set up Malaysian Health Information Exchange (MyHIX), , a health information exchange to electronically transmit patient information between government hospitals and clinics using the two systems.

But by 2020, only 25 per cent of 146 public hospitals and 9 per cent of 1,090 public clinics had implemented either the hospital system or TPC-OHCIS. In addition, only 10 public hospitals and one public health clinic had successfully integrated MyHIX (Parliament of Malaysia, 2020).

While the high cost of the MyHIX programme was the main cause for its failures, unequal

focus on secondary versus primary healthcare is also a challenge (Ismail & Abdullah, 2017). Another key factor is the challenges that hospitals are facing in uploading and integrating data. Private hospitals have their own systems that do not integrate with MyHIX, and they lack the incentives to enable such integration (GSMA, 2022).

2.4.5 Inconsistent policy implementation

In 2018, the government announced plans to expand the two data systems in all government hospitals and clinics, predicting a cost of RM 1.5 billion (US$ 330 million) over the next five years. Malaysia's 2020 Budget also dedicated a portion of an RM 31 million allocation to conduct a pilot rollout project involving nine hospitals in different districts (Jaafar, 2019; Koh, 2018). However, in July 2020, under new government rules, the Ministry of Health announced that this pilot would be replaced with a phased-in implementation plan.

The new plan was expected to start in one state, Negeri Sembilan, across seven public hospitals, 44 public clinics and 12 dental clinics, with its success dictating the rollout of a nationwide system. The aim was to integrate the hospital and TPC-OHCIS systems with the MyHIX platform to create a Master Patient Index and Lifetime Health Records (Parliament of Malaysia, 2020).

This change in strategy was in line with WHO recommendations for developing countries with limited resources (WHO, 2006). As of October 2022, the Ministry of Health was still trying to scale the TPC-OHCIS systems (MOH, 2022).

2.4.6 Malaysia's regulatory landscape for sharing health data

Malaysia does not actively encourage health data sharing owing to lack of public trust. The country has been facing a significant increase in cybersecurity incidents since 2020 (GSMA, 2022). At the national level, the government is trying to implement health data sharing by means of the MyHDW, with previous efforts facing lags due to funding issues and the inability to catch up with technology advancements.

Cross-border health data sharing is allowed if the recipient country where the data is being transferred is in the 'white list' – countries that are recognised as having adequate and comprehensive data protection laws in place – or subject to other conditions, as shared below.

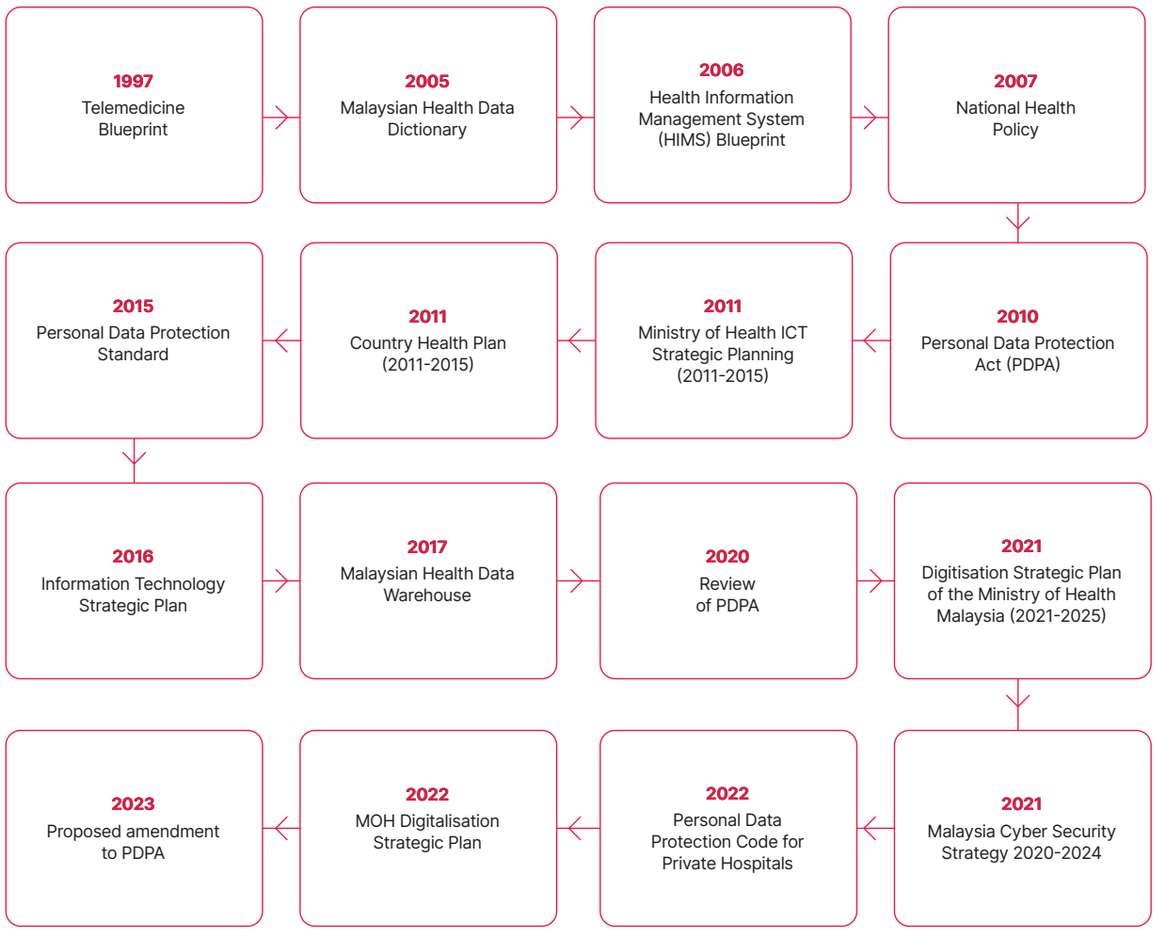
Malaysia's Data Protection Policy

The **Personal Data Protection Act 2010** is Malaysia's first comprehensive personal data protection legislation. It came into force on November 15, 2013 and aims to protect the personal data of Malaysian citizens. Health data is not specifically defined in Malaysia's Personal Data Protection Act (2010), but it is considered 'sensitive personal data' and so is subject to the law's more stringent provisions (Ping, 2022).

The informed consent of patients is necessary for collecting, storing and using data for clinical purposes (Soraya, et al., 2022). Organisations that process health data in Malaysia are required to be registered with the Personal Data Protection Department. In theory, cross-border health data is possible if the country has been specified and recorded in the Official Gazette (also known as the 'white list'). However,as of June 2022, none had been (Allen, et al., 2022).

There are some exceptions where health data can be shared with patient consent, and/or if the sharing is necessary as part of a contractual obligation between concerned entities, including healthcare institutions. The law requires healthcare organisations or other stakeholders to keep and maintain a record of health data processed by them and also

Figure 9:
Timeline of regulations for health data sharing in Malaysia



Source: See Appendix 2 for details

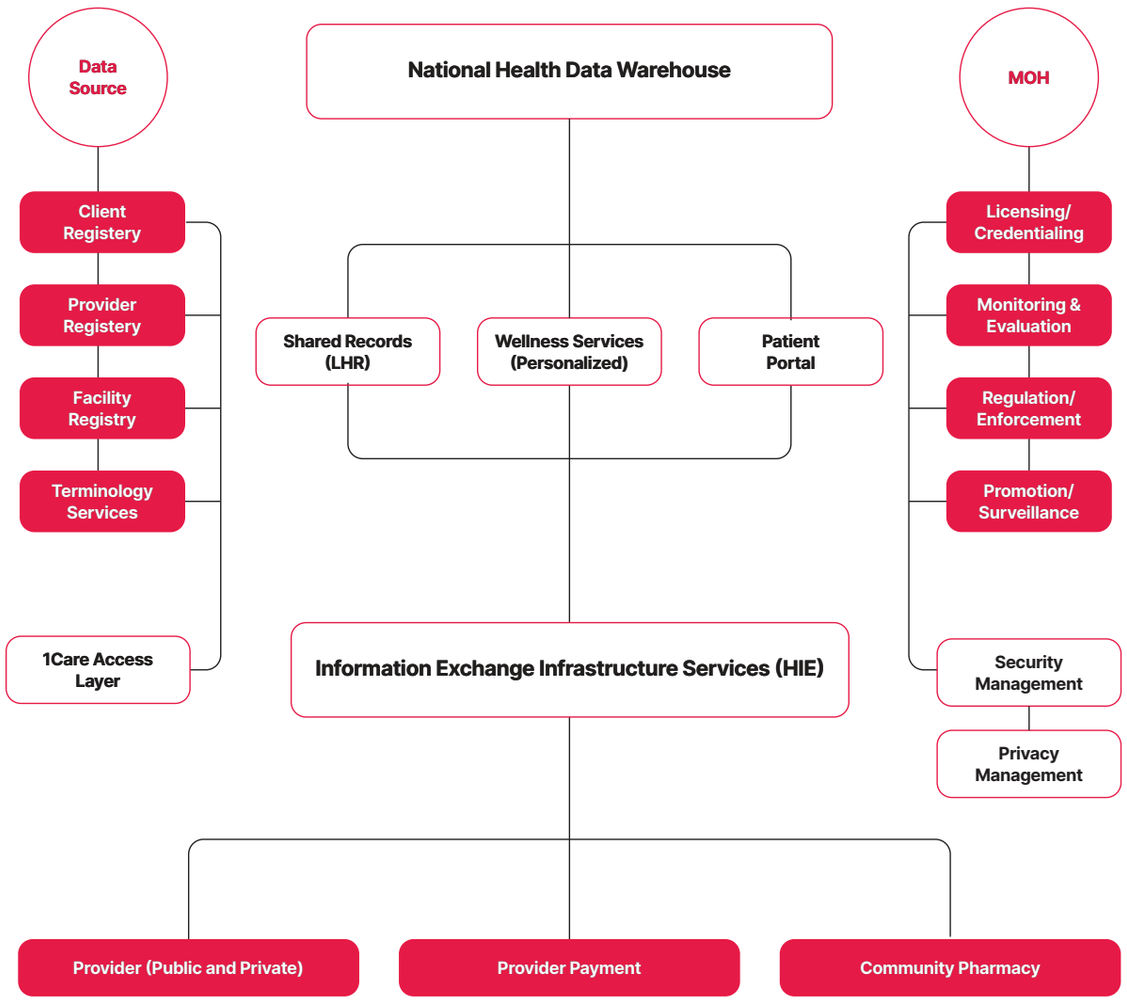
to document records of consent, disclosures to third parties, and their security policy. The obligation to ensure protection of patients' personal data lies primarily with the healthcare practitioner, but liability could also extend to digital healthcare platforms (Soraya, et al., 2022).

2.4.7 The Malaysian Health Data Warehouse

The MyHDW is expected to act as a trusted source of comprehensive healthcare data structured for query and analysis purposes (MyHDW, 2016). As shown in Figure 8, once operational, the MyHDW will pool together data from registries (client, provider and facility) alongside the Ministry's regulatory functions to form a comprehensive Health Information Exchange (HIE). The HIE will be used by healthcare providers, insurance companies and pharmacies to accurately capture a patient's journey along the care continuum.

The MyHDW aims to bring health data to public and private healthcare institutions across primary, secondary and tertiary levels of care. This will enable continuity for patients as they move across facilities and seek care, without having to retake tests or repeat case histories (Koh, 2020). The MyHDW requires:

Figure 10:
Future ICT architecture overview



Source: MOH, 2022

- Political support at all levels of government, national and regional.
- Effective and overarching governance to coordinate all e-health-related activities, ideally involving the highest levels of government or its representatives. National and regional activities must also be aligned and should involve all key stakeholders.
- Agreement on standards and other requirements. A national health informatics standards body is needed.
- A national infrastructure that supports data sharing.
- An endorsed and well-thought-through communication strategy for all relevant stakeholders.
- Legislative and legal frameworks to allow sharing of data. This includes a clear approach to consent and privacy.

2.4.8 Challenges faced by Malaysian healthcare organisations with respect to health data sharing

In primary healthcare, doctors continue to use paper-based methods for collecting and storing health data, and there is a degree of resistance to adopting digital tools. This resistance affects training of staff at hospital level, and creates a logistical nightmare for staff to export or transform paper-based documents into digital records. Doctors have to spend extra time and effort to understand the new system. However, due to high workloads, doctors are less motivated to undertake such training (Qian, 2022).

One public official said:

> **"In Malaysia, we are not 100 per cent fully computerised facilities. Only 30 per cent of our hospitals have been computerised, and 10 per cent of our government healthcare clinics are computerised. As a result, so far only these have been integrated into the MyHDW. The others have to manually enter the data into our system. And that's the biggest obstacle for them to enter the data."**

The high cost of digitalising is also a challenge; it includes hardware, software set-up costs, implementation assistance, staff training, ongoing network fees, and maintenance. Hospitals and particularly primary healthcare clinics don't have access to skilled IT professionals to enable the transition. Data privacy remains a key concern for the patient community as well as the providers. Any data breach is difficult for hospitals to handle and mitigate (Qian, 2022).

2.4.9 Impact of the Malaysian Health Data Warehouse on digital health innovations

The National Technology and Innovation Sandbox (NTIS) – led by the Ministry of Science, Technology and Innovation (MOSTI) – is a regulatory sandbox that aims to encourage local digital innovations to scale. It was announced in 2020 by former Prime Minister Muhyiddin Yassin. Futurise Sdn Bhd – a wholly-owned subsidiary of Cyberview Sdn Bhd under the Ministry of Finance – has been appointed by MOSTI as the implementing agency for the NTIS initiative. It is part of the NTIS's Technical Committee as well as the Executive Selection Committee (Futurise, 2023).

In February 2022, the Ministry of Health partnered with Futurise to launch the Online Healthcare Service Regulatory Lab (OHS RegLab), a regulatory framework for Online Healthcare Services in the country. By means of the OHS RegLab, the Ministry of Health seeks to identify the right regulatory instruments and improvements to protect the rights of patients without inhibiting innovation.

As part of the OHS RegLab, digital health startups and technology companies will have the opportunity to engage with regulators closely. More than 50 digital health stakeholders from Malaysia are expected to participate in the OHS RegLab, which include private hospitals, clinics and technology companies (Ignatius, 2022).

In September 2022, MOSTI and the Ministry of Health announced that they have identified five hospitals as Health Technology Hubs under the NTIS. Three of these hospitals will be located in the city of Kuala Lumpur and the others will be based out of Pahang and Negeri Sembilan. The hospitals will be used to test and eventually commercialise digital health innovations in a safe and regulated environment. The hospitals will also receive funding and regulatory facilitation for increased collaboration between public and private sector stakeholders in healthcare (MRANTI, 2022).

The Health Technology Hubs will also be supported by the 10-acre Malaysian Research Accelerator for Technology and Innovation (MRANTI) Integrated Healthcare Cluster, which will provide capacity-building programmes, laboratories and research facilities for innovators to test digital health solutions through technology and equipment in a live environment. MRANTI will be the lead secretariat for this initiative. In 2022, the government allocated funding of more than US$ 7 million to MRANTI to further develop the cluster and support innovations in the country (MRANTI, 2022).

2.4.10 Conclusion: Malaysia can evolve into a regional hub for digital health innovations

Malaysia has been both front-runner and laggard in terms of digital health innovations. While the government has been trying to build EHRs for many years now, it has largely been unsuccessful due to funding issues. However, the MyHDW holds promise since it is being implemented by the Ministry of Health, a key regulating body for public as well as private healthcare organisations.

It remains to be seen how the MyHDW will enable digital health innovations in the future. However, given the synergy among the different key ministries in the Malaysian Government, there is potential for increased collaboration between MRANTI and the MyHDW.

Overall, the Malaysian Government is actively deploying policies with significant amounts of funding being channelled to digital innovations, including in healthcare. The country also offers a welcoming ecosystem for regional digital health startups to scale up their solutions in the regulatory sandbox that has been developed by MRANTI.

However, the government faces structural challenges with respect to driving digital health adoption in the two-tiered healthcare system, which is completely separated at this point. In addition, the lack of national health insurance and low adoption of private health insurance makes it challenging for the government to bridge the gap and encourage more health data interoperability.

The government has leverage in terms of attracting and supporting innovations, but not necessarily in terms of health data sharing. As a result, while the political and policy intentions are there, it is the stakeholder groups that the government needs to bring together.

On the other hand, the government seems to be more reserved with respect to cross-border health data sharing given the rising number of cybersecurity incidents in Malaysia in recent years.

2.5 Singapore: A regional leader in digital health innovation

Singapore has 2.3 doctors per 1,000 people, which is among the highest ratios in the region (OECD, 2020). It also has among the highest health spend per capita at US$ 4,100, dwarfing the Asia-Pacific average of US$ 1,090 (OECD, 2022). Healthcare spending as a percentage of national GDP increased steadily from 1.2 per cent to 2.2 per cent between 2010 and 2019 (Statista, 2023). This is mainly due to an ageing population that is increasingly susceptible to chronic diseases such as cardiovascular diseases and diabetes. The country has universal health coverage for its citizens through a mixed financing system.[22] It also has excellent healthcare infrastructure that is well planned and regulated (Swiss Business Hub ASEAN, 2021).

Institutionally, Singapore is well-placed as a launchpad for regional and global startups to scale-up in Southeast Asia and beyond. This is largely due to a combination of digital maturity, comprehensive national strategies, and expansive innovation capacities. In addition, Singapore is known for its advanced adoption of digital health data collection, making it easier and cheaper for the country to innovate. This was evident in the country's aggressive digital contact tracing during COVID-19 (Parry, 2022).

Singapore's main data sharing platform for health is the National Electronic Health Record, managed by Synapxe – previously known as the Integrated Health Information Systems – under the Ministry of Health (Leck, et al., 2023; Luk, 2018). It came after a series of earlier systems designed to increase interoperability between hospitals, clinics, pharmacies and researchers with the Ministry of Health (and other government agencies) (Manoharan, et al., 2018).

Indeed, Singapore launched its first national medical information network, also known as Medi Net, as early in the digital era as 1990. The government then implemented the National Patient Master Index in 1994, which was migrated to the Critical Medical Information Store by 2006 (Luk, 2018).

The Ministry of Health also ran the Electronic Medical Record Exchange (EMRX), allowing doctors to access and share patient data online. It brought in lab reports and medications and was extended to include national immunisation data, school health records and community hospital records (Luk, 2018).

But EMRX proved limited since it only allowed the sharing of health data. This culminated in the launch in 2011 of the National Electronic Health Record (NEHR), which aimed to reduce fragmentation in healthcare by means of improved analytical capabilities (Luk, 2018).

Despite the evident success of data compilation, however, Singapore faced a healthcare financing challenge. There is a rising shortage of acute hospital beds and intermediate and long-term care services, in addition to high out-of-pocket expenditures (Tan, et al., 2021). This is mainly due to the rapidly ageing population and its accompanying health issues (Liu, et al., 2020).

Diabetes alone is projected to affect more than 1 million people by 2050, which is more than double that of 2014, and the equivalent of a sixth of the current population (Liu, et al., 2020). In addition, hospitals are facing shortages of staff, especially nurses. Locals perceive nursing as having an uncompetitive salary, limited career advancement opportunities, and irregular work hours. As a result, Singapore is dependent on foreign workers or temporary employees to take up the role. This became especially more

22 Singapore's healthcare financing is known as the 3M scheme, which stands for Medisave, MediShield and Medifund. The government subsidises healthcare costs but the citizens also have to share the cost of healthcare services to keep the system sustainable (Lena, 2017).

challenging during COVID-19 due to travel restrictions (Tay, et al., 2021).

2.5.1 Digital health innovations in Singapore

Singapore has the third-largest digital health ecosystem in Asia, with more than 269 digital health startups, 20 of them prominent in size and revenue. The government has allocated SGD 19 billion (US$ 14 billion) to support digital health innovations (EDB, 2021). Leading digital health startups include Doctor Anywhere (a teleconsultation platform), Holmusk (a data-driven behavioural health improvement platform), EndoMaster (medical robotics), DocDoc (an AI-powered teleconsultation platform) and Docquity (a doctor support platform) (Tech Collective, 2021).

Most of these startups have plans to expand to other countries in the region. This is because launching in larger populations enables them to generate more revenue and expand their data-driven solutions more effectively. For instance, Doctor Anywhere has decided to use its recent US$ 27 million in funding to expand to the Philippines and Malaysia (Tech Collective, 2021).

Similarly, Holmusk is a mental health analytics provider which acquired London-based Otsuka Health Solutions to expand its operations in the United Kingdom. And Docquity has partnered with Novartis to expand its services to other countries in Asia, including Indonesia, Malaysia, the Philippines, Vietnam, Bangladesh and Thailand (Tech Collective, 2021).

The success of TraceTogether during COVID-19

GovTech, an agency of the Singapore Government, was able to indigenously develop and deploy the TraceTogether application for the contact tracing of infected persons. This supported the efforts of the government to quickly and efficiently contain the spread of COVID-19 in local communities.

The application used Bluetooth to facilitate community-driven contact tracing by identifying encounters between users. Built on BlueTrace protocol, the application was shared as open-source code on GitHub to provide transparency on data usage and to encourage co-creation of new technologies.

Source: Singapore Government Developer Portal (2023)

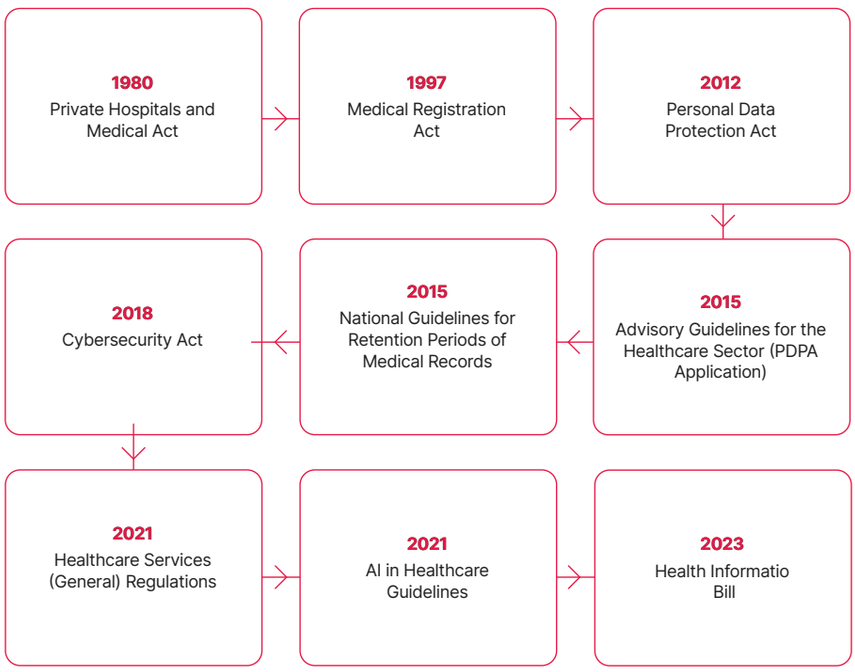
2.5.2 Singapore's regulatory landscape for sharing health data

Singapore does not encourage cross-border sharing of health data, although regulations allow it in certain circumstances. The government is highly cautious about the risk of health data misuse and this has enhanced regulatory oversight. At the national level, health data sharing has been advanced significantly due to consistent implementation of the NEHR platform.

Singapore's Data Protection Policy

The **Personal Data Protection Act (PDPA) (2012)** provides a baseline standard of protection for personal data in Singapore, and it is enforced by the Personal Data Protection

Figure 11:
Time of regulations for health data sharing in Singapore



Source: See Appendix 2 for details

Commission (PDPC). It comprises various requirements governing the collection, use, disclosure, access, protection, retention and transfer of personal data in Singapore (PDPC, 2023).

The PDPA requires organisations to seek consent from an individual before collecting, using or sharing her or his data. They are required to make reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks as stated in the law (Yeo, et al., 2022).

In 2020, the government introduced the Personal Data Protection (Amendment) Act, which introduced mandatory data breach notifications, an expanded consent framework, new offenses for the mishandling of personal data, the right of data portability, higher penalties for uncontained breaches (10 per cent of the annual turnover of an organisation in the country), and new grounds for processing data without consent in certain situations.

"We can't share clinical data, or patient information overseas for business, including when a company is having its application overseas. I think there are a lot of concerns about having your country's patients being overseas in another system in another country where you cannot assure them of the same level of security, and privacy, and confidentiality in the systems that are in those countries. So, the ... law which governs us in

> **Singapore allows information to be overseas except for when (it contains) what we call identifiable information. This is also only when they are of the same standard as an equivalent law."**
>
> **– Chief Technology Officer, a healthcare group, Singapore**

For cross-border health data sharing, the transferring entity must ensure that the recipient protects personal data with a standard of protection comparable to that under Singapore law. The types of personal data collected, used and disclosed, the purposes for which it is done, and the parties to whom the personal data will be disclosed must be clearly identified when obtaining consent from users. If there is to be any cross-border transfers of personal data, relying on contractual terms to comply with relevant data protection requirements is common. As a result, healthcare organisations, technology companies and digital health startups must comply with these requirements when entering the relevant contract (Goh, et al., 2023).

2.5.3 The National Electronic Health Record and attack on H-Cloud

The NEHR is a key enabler of the 'One Patient, One Health Record', astrategic vision of the government. It receives patients' key health information from different healthcare settings and consolidates it into a holistic picture of their healthcare history, thus enabling better decision making, accurate diagnoses, improved treatment and a patient-centric integrated care model (Synapxe, 2023).

It was implemented in two phases (Muttitt, et al., 2012). Phase one was by the second quarter of 2012 to allow for one-way sharing of health data with a limited number of integration partners, and the viewing of health information through the NEHR portal. Phase two was to reach, by 2015, objectives including increased integration, two-way health data flows, increased data sources, reconciliation services, and increased portal access (Lena, 2017).

In 2014, NEHR manager IHIS (now Synapxe) went further, launching H-Cloud (Healthcare Cloud), which allowed for the migration of existing health data to the cloud. By 2016, IHIS had standardised and consolidated over 500 applications used by the three layers of Singapore's health systems – SingHealth, National Health Group, and the National University Healthcare System – on H-Cloud. Initially, the adding of data was to be voluntary, but this failed to encourage public and private hospitals to contribute, and compulsory sharing was considered (Raghavan, et al., 2021).

In 2018, however, a major cyberattack led to nearly 1.5 million health records being compromised. This prompted the government to hold off on mandatory data sharing by hospitals, and instead to set up an independent external review into the safety and security of H-Cloud (Raghavan, et al., 2021).

As of December 2022, all public healthcare institutions and over 30 per cent of private MOH-licensed healthcare institutions in Singapore had access to the NEHR. This included over 90 per cent of private hospitals over 60 per cent of medical clinics (MOH, 2023).

The government is planning to introduce the Health Information Bill in the second half of 2023 to establish a framework for the safe and secure collection, access, sharing and use of health data across the healthcare ecosystem (MOH, 2023). The new bill will benefit patients, residents and healthcare providers by:

A) Increasing the functionality of the NEHR through the mandatory contribution of summary data to the NEHR by licensed healthcare providers.

B) Enhancing the legal framework to facilitate proactive data sharing across MOH entities. This will give healthcare providers a fuller picture of patient health for better monitoring and follow-up.

C) Putting in place safeguards for data sharing to protect patient confidentiality and respect patient autonomy.

D) Putting in place cybersecurity, data security and data protection measures to safeguard health data. This may include data security classification, requirements for proper data storage, transmission and disposal, and alignment with the Personal Data Protection Act.

2.5.4 Uses of the National Electronic Health Record

At the moment, the NEHR's main capability is to facilitate the consolidation, digital management, and sharing of patient information and records across both the public and private sectors (Goh, et al., 2023).

Since April 2011, it has incorporated National Health Identification Service data, which enables the matching of patient records from across Singapore's health system. Users can be identified by means of their national identification number, name, date of birth, address, and other demographic details. The NEHR provides a concise summary of the most recent clinical activities of a patient, including laboratory results, medications and the most recent health events. This enables doctors to navigate to more detailed data and documents.

The NEHR also includes role-based access, data sensitivity classification, and 'break-the-glass' emergency functionality which enables doctors to access patient information outside of normal security and privacy settings if needed. The system monitors use via full audit logging, showing who has accessed data, when, where, and how (HHM Global, 2023).

2.5.5 Challenges faced by healthcare organisations in Singapore

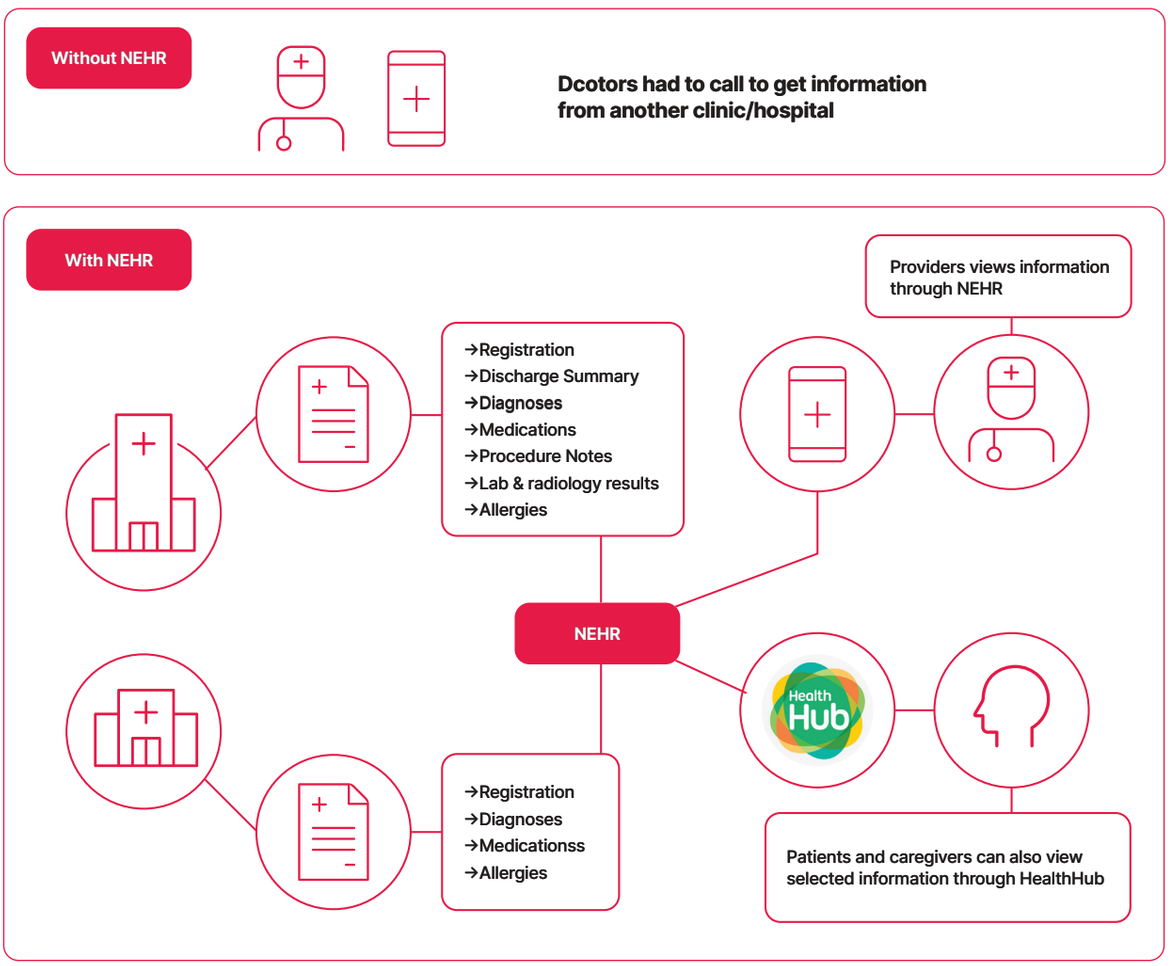
The health system in Singapore consists of more than 4,020 public and private hospitals, as well as residential and non-residential long-term care facilities which includes clinics and nursing homes (MOH, 2022). Private practitioners provide 80 per cent of primary healthcare services, with government clinics providing the rest. Some 80 per cent of hospital care is public (HHM Global, 2023).

Management of health data is among the key challenges for hospitals. Some 43 per cent of hospitals report difficulties in data management due to large volumes of health data and a lack of clarity around ownership (Philips, 2021). They are also concerned about potential mismanagement of data, improper access to patient data, and cybersecurity (Goh, et al., 2023).

Hospitals are especially wary of sharing health data with cross-border health data particularly worrisome given the strict regulations around data protection and the implications arising from potential misuse (Interviews). Understanding safeguards, legal responsibility and liability for breaches, as well as patient preferences to restrict the sharing of their data in the NEHR, are key issues (Goh, et al., 2023).

Healthcare providers' lack of experience with new technologies is another concern. Some 52 per cent of all hospitals in the country have cited lack of experience as a current impediment to data sharing, and 47 per cent of them have highlighted lack of training to be an impediment in digital health adoption in general (Philips, 2021).

Figure 12:
Application of the NEHR in health data interoperability



Source: MOH, 2023

2.5.6 Impact of the NEHR on digital health innovations

As part of the government's **Smart Nation initiative**, the Ministry of Health has been strategically shifting from curative to preventive health. To achieve this, it has promoted wearable technology, digital health applications, and digitised transactions such as payments and online registrations to track and ensure good health for citizens (Dhawan, 2021). For example, using machine learning, hospitals in Singapore are able to identify patients who may not show up for follow-up treatments, thus allowing hospital administrators to send them reminders or to allocate their appointment slot to another patient. This solution optimises clinical resources and time (Dhawan, 2021).

The Ministry of Health is taking a two-pronged approach to better innovate in the digital health space. The first is a top-down approach through a **National AI Strategy** which helps the country develop and use AI in healthcare by using it to analyse clinical and genomic data, medical images, and health

behaviours to better assess the risk profile of patients. The second is a bottom-up approach whereby the ministry has launched a Health Grand Challenge to encourage and support new ideas that adopt AI technologies and innovations in healthcare. This encourages the development of digital health innovations at the primary healthcare levels (Dhawan, 2021).

The Ministry's Office for Healthcare Transformation (MOHT) – an innovation office established in 2018 – and Synapxe (previously Integrated Health Information Systems) have been especially instrumental in developing the legal frameworks and implementation strategies to enable digital health innovations (Dhawan, 2021). The MOHT aims to mainly develop and experiment with game-changing system-level innovations in healthcare by partnering with relevant stakeholders and developing frameworks, methodologies and toolkits to successfully scale innovations in the Singaporean healthcare system (MOHT, 2023).

In January 2020, the Singapore Government passed the **Healthcare Services Bill** which enabled them to license and implement new models of healthcare. The Ministry of Health eventually created a regulatory sandbox regulated by the **Licensing Experimentation and Adaptation Programme**, alongside a strong set of guidelines to enable digital health innovations in the country (Robertson, 2020).

The sandbox was designed to enable the smoother transition of innovations as part of the regulatory environment so that they meet patient safety standards while also delivering innovative solutions to patients (Bhunia, 2018). It closed in February 2021, having been deemed to have met its immediate objectives (MOH, 2023). The Ministry of Health is taking a need-based approach to the use of sandboxes and for limited time durations. As such, there is no active sandbox that's being implemented at this point.

Outside of the sandbox approach, the government is supporting digital health innovations through the National Health Innovation Centre (NHIC) and Enterprise Singapore, which provide funding and capability support for digital health startups. The NHIC aims to accelerate innovations by collaborating with public health institutions, universities, research institutes and the private sector (Sunderland, et al., 2023).

2.5.7 Conclusion: Singapore is the regional hub for digital health innovations in Asia

Singapore has fostered digital health innovation by means of regulations that have brought together some of the best global technology companies, digital health startups, healthcare providers, research institutions, and talent to incubate new ideas which can then be easily developed and channelled into innovative startups. Singapore's economy especially benefits from this process. Its developed investment ecosystem spurs technology and knowledge transfer, which the policymakers can fine-tune to fill gaps in its economy and in its investment ecosystem.

Singapore implemented EHRs comparatively early, but the government is cautious about health data sharing. This is largely the result of the 2018 cyberattack in which hackers stole sensitive personal information from more than 1.5 million citizens. This paused the regulatory momentum for achieving health data interoperability across Singapore's different healthcare clusters and instead enforced a third-party review of the NEHR. As a result, Singapore does not allow cross-border health data sharing unless the data has been anonymised and meets other data protection protocols.

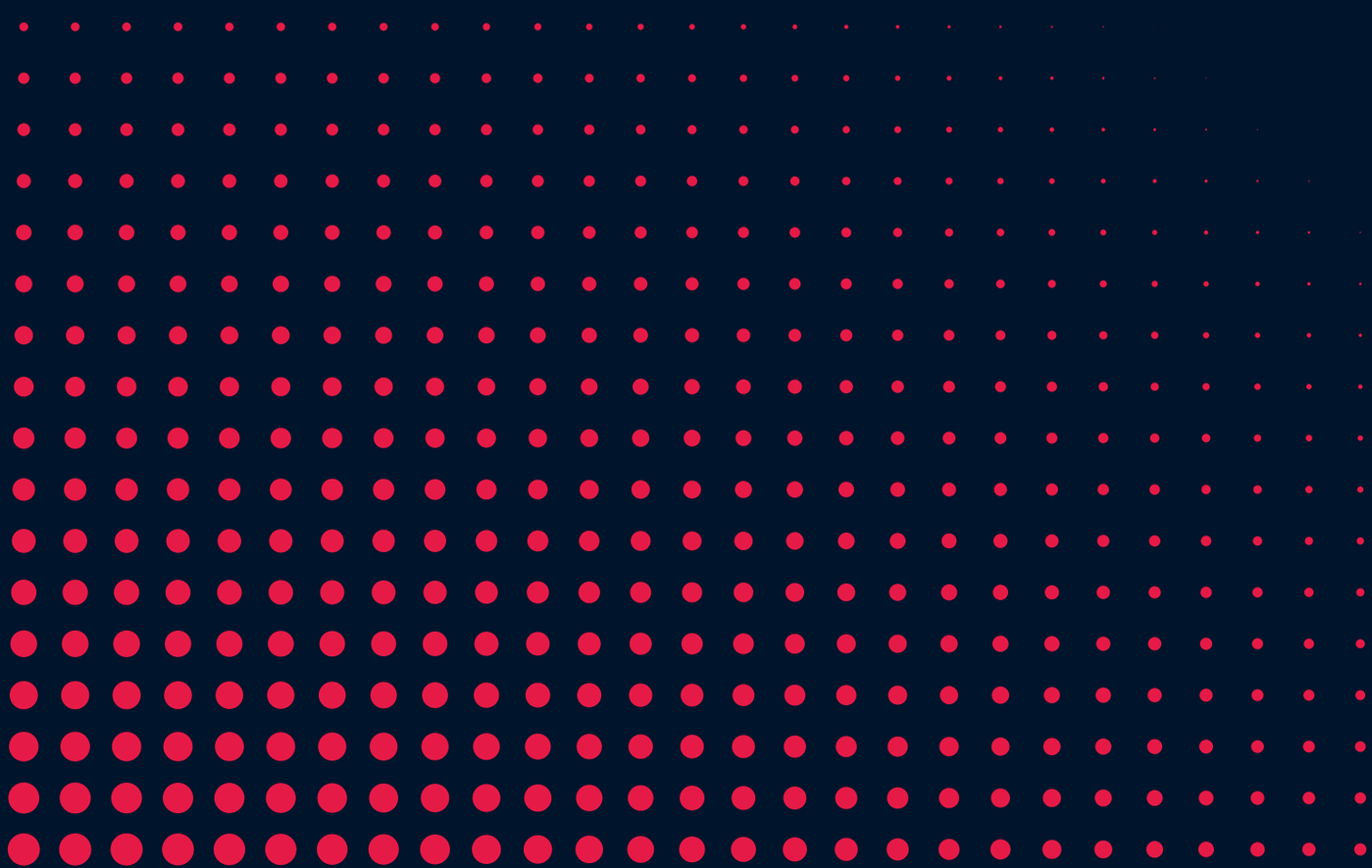
These restrictions, however, do not affect digital health innovations within Singapore. Startups typically partner with public-sector or larger private-sector players who have

security protocols in place for enabling innovations to work on sample or synthetic data.[23] Moreover, Singapore's relatively small population enables startups to use Singapore as a launchpad to expand their products and services to larger markets where they can generate more revenue. The country also serves as a test bed for startups from other countries to test their solutions in Singapore before engaging in cross-border expansion to other Asian countries.

23 Synthetic data generated from computer simulations or algorithms provides an inexpensive alternative to real-world data that's increasingly used to create accurate AI models (Andrews, 2021).

3

SHARING HEALTH DATA LEADS TO DIGITAL HEALTH INNOVATIONS IN ASIA



This section will discuss the links between the sharing of health data and the success of digital health innovation in Asia. The first section looks at national EHRs, while the second section focuses on cross-border health data sharing.

3.1. Electronic health records are important for digital health innovations at the country-level

EHRs are developed by countries to enable greater health data interoperability at a national level between the various healthcare organisations. Governments understand that it is vital for improving the health outcomes of patients, to optimise resources, to improve policymaking and to stimulate research and innovations. Asian governments are increasingly creating favourable regulatory environments to encourage local digital health startups, which also attracts more investments into their countries. Here's how the relationship between EHRs and digital health innovations work at the national level:

A) Improving access to the data that an innovation needs

Healthcare is a complex sector and the challenges it faces are multifaceted. For a long time, healthcare organisations have operated in silos within Asian countries without trying to take a broader system-wide approach to solving issues. EHRs try to solve this challenge by enabling health data sharing at national levels.

Good EHRs contain large amounts of data, and startups that integrate with them are likely to get easier access to what they need. Digital health innovations are based on the specific healthcare problems that they are trying to solve, and, at its most basic, health data helps define the problem for which the startups try and identify solutions.

As such, EHRs can form a common playing field for digital health innovations in Asia to take shape, mature and scale to effectively solve problems in healthcare.

B) A win-win situation for startups and governments

Technology is ahead of regulations, especially in Asia, but governments are increasingly recognising the success and usefulness of digital health innovations not just to improve healthcare (such as telemedicine, AI-based diagnosis tools, etc.), but also as an engine to drive economic growth.

While the COVID-19 pandemic taught valuable lessons to governments in terms of the benefits of digital healthcare, it also encouraged them to work closely with digital health startups. The process involves not only governments supporting innovation startups, but the startups contributing to the governments' efforts to improve healthcare as well.

Data is the key currency in this engagement, and the greater the success of a digital health startup in the domestic market, the more attractive it is for governments to engage with them as part of their national EHR initiatives.

So, by integrating digital health startups with their EHRs, governments in Asia are scoring

three valuable successes for the future of healthcare in the region:

- Transforming healthcare delivery through digital health innovations.
- Supporting local innovations to scale up and add value to the national economy.
- Scoring political gains through good policymaking and setting a precedent for the future.

C) EHR integration and regulatory sandboxes push innovations to scale

Governments in the region are starting to recognise the need for, and the importance of, preventive care, in addition to curative care, as part of the broader spectrum of healthcare services. As a result, integrating startups into national EHR systems provides an opportunity for them to add preventive healthcare (based on AI and other emerging technologies) to their offerings.

EHR integration is also a way for startups to be recognised as key mainstream players in the healthcare system. It not only enables them to work more closely with public as well as private healthcare organisations, but also to take their solutions to a larger segment of the population.

Such an approach can help countries attract significant amounts of investment in digital health, further encouraging innovation. However, given that EHRs in Asia are still in the developing phase in most countries (e.g., India, Indonesia and Malaysia), and are more strictly controlled in advanced countries (e.g., China and Singapore), the road to integration is not always clear.

This is where regulatory sandboxes come in (except for China). Also known as anticipatory regulation systems,[24] regulatory sandboxes allow innovators to test products, services and business models in a safe environment to confirm their compliance with existing regulations before they can be scaled up across a given sector – in this case healthcare (Leckenby, et al., 2021). The following table highlights the status and impact of regulatory sandboxes on digital health innovations:

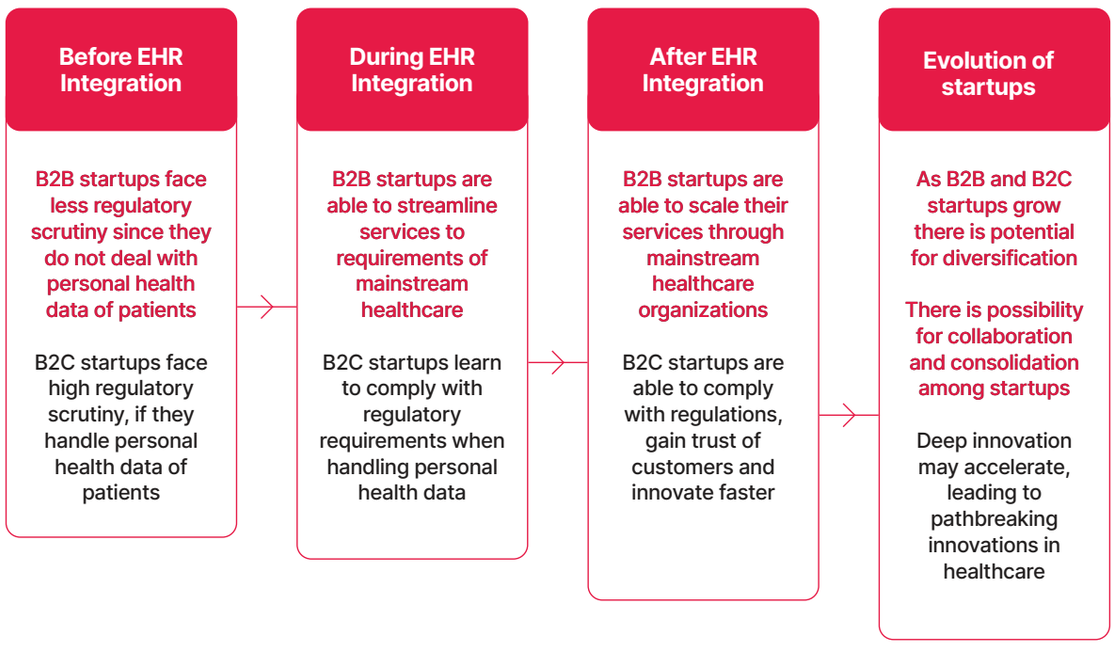
24 It is a new model for developing regulatory frameworks to allow technological developments while also ensuring the creation and implementation of effective regulation (Vogel, 2020).

Table 1:
The impact of regulatory sandboxes on digital health innovations

Country	Regulatory sandbox model	Launch year	Status	Impact on innovation
China[25]	None	-	-	Startups actively compete in the market with others to develop and scale new innovations. The uniqueness of the Chinese digital health ecosystem lies in its ultra-rapid development and iteration cycle, which leads innovations to enter the market in as little as three months (Deu, et al., 2022). However, recent attempts by the government to regulate leading Chinese technology companies have led to uncertainty (Bu, et al., 2021).
India	National Digital Health Mission (NDHM) sandbox	2020	Active	More than 100 digital health applications integrated with the Ayushman Bharat Digital Mission (ABDM), India's national EHR, after successfully clearing the sandbox environment (ET Health World, 2023). Furthermore, the Digital Health Incentive Scheme (DHIS) is also aimed at encouraging startups, providing ABDM-compliant digital health solutions to enable wider adoption by stakeholders across the healthcare ecosystem (NHA, 2023).
Indonesia	Ministry of Health regulatory sandbox	2023	Active	Currently accepting applications from digital health startups, especially in the telemedicine space, to participate in the sandbox (Firdaus, et al., 2023).
Malaysia	National Technology and Innovation Sandbox (NTIS)	2020	Active	The Ministry of Science, Technology and Innovation and the Ministry of Health have identified five hospitals as health technology hubs under NTIS. The hubs will enable startups to test their products and services using technology and facilities at the Malaysian Research Accelerator for Technology and Innovation (MRANTI) Integrated Healthcare Cluster (Digital News Asia, 2022).
Singapore	Licensing Experimentation and Adaptation Programme	2018	Closed	The sandbox has primarily been opened for telemedicine and mobile medicine applications to understand the risks associated with them and the mitigation measures required. The sandbox was used as a preliminary test bed prior to licensing of startups under the Healthcare Services Act (expected to be announced in 2023).

25 China offers a unique context where the government has been known to under-regulate digital innovations; as a result, some scholars perceive that a regulatory sandbox is not suitable for the Chinese innovation ecosystem (Liao, 2020).

Figure 13:
Movement of B2B and B2C startups before and after EHR integration



D) EHR integration helps innovations to evolve

Strict regulations with respect to health data sharing generally discourage startups from offering direct-to-customer (or B2C) products and services. This is especially true for startups that have not been able to move beyond their country of origin. Instead, they choose the direct-to-business (or B2B) model for their products and services to avoid strict data protection and cybersecurity regulations when developing their innovations in the initial stages of the startup.

But integrating with a national EHR system can make the hurdles smaller.

For instance, Biofourmis (based in Singapore) partnered with Novartis to apply its digital therapeutics solution to treat patients recovering from health failure in six countries across Southeast Asia. This helped them to rapidly scale the startup's exposure to patients across the region (Robertson, 2020).

Table 2:
Examples of deep innovations[26] in Asian healthcare

China	India	Indonesia	Malaysia	Singapore
AI – Tencent has started integrating AI into diagnostics and imaging technology; China's first neurosurgery robot, named Remebot, did more than 17 minor invasive surgeries in 2019.	**AI** – SS Innovations has developed India's first robotic system that can be used in a variety of surgeries.	**Digital health platforms** – Startups based in Jakarta are developing the world's most comprehensive one-stop solution for people to manage patients' health completely.	**Blockchain** – Data8 uses it to store patient data from local hospitals for easy transferability and documentation.	**AI** – The National University Health System has developed an Automated Diagnosis Engine which helps diagnose appendicitis using clinical notes.
Cloud-based hospitals - (Internet hospitals)	**3D printing** – has been used to create medical devices and aids.	**E-pharmacies** – Halodoc, Alodokter, Lifepack, Prixa, Diri Care and Rey are some leading startups offering the service.	**AI** – Qmed Copilot is an AI-powered clinical assistant that allows doctors to identify patterns in patient data and helps reduce diagnostic errors.	**Deep-learning tech** – EyRIS harnesses deep learning to detect diseases of the eye's retina, and provides immediate assessment.

With EHR integration, startups can learn to comply with regulatory requirements while they are participating in the regulatory sandbox. On 'graduating', they can freely launch their services in the market without having to struggle with regulatory uncertainties. This will allow them to freely design their services for healthcare organisations, technology companies or other entities (B2B) or for customers (B2C).

Getting certified by the government is also a benefit for startups as it will help them to project credibility to their clients and customers and compete fairly in the market.

3.2. Impact of cross-border sharing of health data on digital health innovations

Cross-border health data sharing is a complex challenge in Asia, given that most countries in the region do not actively support it. The sensitive nature of health data and governments' concerns about protecting privacy and the confidentiality of citizens have created barriers that directly affect digital health innovations at a regional level. However, some key themes have emerged with respect to the impact of cross-border health data sharing on digital health innovations:

A) Concerns about data misuse make innovation cumbersome

Data misuse is a valid global concern, but countries in Asia appear to be especially vulnerable. For example, research suggests that countries in the Asia-Pacific region experienced the highest number of cyberattacks in recent years (Petrosyan, 2023). Asian countries are also lagging in

26 Deep innovations, or deep tech innovations, are innovations that are grounded in science and technology and have the potential to dominate the future in many ways, since they require new or adapted approaches to their founding, growth and support (Apodaca, et al., 2022).

terms of data protection and data security laws that may enable them to deal with such attacks.

As a result, cross-border health data sharing is discouraged directly or indirectly through regulations (data protection and cybersecurity laws) that increase compliance burdens for digital health startups and technology companies.

> **"They (governments) want to ensure that certain things are in place, (that) you get the protection and everything else. Now yes, does it stifle innovation? Yes."**
>
> **– Chief Technology Officer, a healthcare group, Singapore**

B) Data-sharing restrictions limit innovations from achieving scale

Limits on cross-border sharing can block off a startup's ability to grow. Startups, for example, need good data penetration, particularly in Asia, given the diversity of the region in terms of cultures, languages, development status, governance structures and most importantly the needs of the specific local healthcare systems.

Since data in one country may not be relevant in another, restrictions on cross-border health data sharing can limit startups from developing relevant solutions. It may require startups to establish a physical presence in different countries to test, launch and scale digital health innovations. This in turn increases the cost for startups and may discourage them from expanding to new markets.

However, interestingly, some startups are beginning to choose alternative solutions to bypass regulatory restrictions and achieve scale regionally.

- **Technological solutions:** Federated data platforms are emerging as a viable alternative since they facilitate secure data sharing without having to physically move the data from outside of its organisational and jurisdictional boundaries. These platforms are increasingly being used for global collaboration in genomic studies andhold promise for digital health innovations as well.

- **Business models:** Startups are taking a B2B approach to scale up regionally, and partnering with leading private hospital chains, technology companies and other key stakeholders who have a local presence. By doing this, they are able to bypass stringent data protection laws in some countries.

C) Restricting cross-border data sharing, but open to sharing innovations across borders

An increasingly common strategy among Asian countries is to not share data across borders, but instead encourage the sharing of innovations. This is happening in two ways: by inviting outsiders in, or by sharing applications with others:

- **Localising innovation:** Countries develop the required policy environment for innovation and attract startups globally to come and participate. For example, some countries are opening their regulatory sandboxes to regional and global startups. This enables a country to learn best practices and emerging uses of technology, and to encourage local startups to innovate in similar and/or more contextually relevant ways.

- Malaysia, for example, opens its sandbox to companies from other countries, according to one public sector official (Interview).

- **Globalising innovation**. Countries develop innovations in the public sector and make efforts to share them with other countries as a digital public good. For instance, during COVID-19, India, Malaysia, Indonesia and Singapore developed digital tools for contact tracing and vaccination which they shared via open-source platforms for countries and organisations globally.

3.2.1 Examples of cross-border digital health innovations in Asia

Despite strong concerns regarding cross-border health data sharing, and severe regulatory barriers, digital health startups, technology companies and healthcare providers have been expanding their footprint across the region.

The following three cases highlight some of the approaches that stakeholders are deploying to scale their presence across diverse jurisdictions.

Case 1:

Oncoshot – Startup innovating for cancer care

Singapore-based Oncoshot seeks to empower cancer patients to take control of their treatment by giving them access to the full extent of options. The platform helps patients, caregivers and oncologists identify clinical trials more efficiently and effectively. It generates leads for relevant clinical trials in minutes instead of the traditional approach that can take weeks.

As part of Project EISE (Project Enhanced Clinical Trial Initiation, Screening and Enrolment), Oncoshot connects cancer patients, public and private healthcare professionals, and pharmaceutical and biotechnology companies across Singapore to a one-stop shop (Oncoshot, 2022).

Data is protected by requiring analysis and research to be carried out withing the hospital system, conferring control to hospital administrators.

In 2022, the company received Series A funding to support the expansion of the startup into India and Australia. Seeking to set up nation-wide public-private clinical trial systems like Project EISE in Singapore, the startup has partnered in India with more than 30 hospitals and industry partners and four hospital networks in more than three cities, plus more than 20 hospitals in Australia (Oncoshot, 2022).

Healthcare gap

Clinical trials for cancer patients

Solution

Faster and efficient AI-based patient-provider match to enable clinical trials.

Approach

Federated data platforms that overcome current challenges related to cross-border health data sharing as the data never leaves the hospital premises.

Case 2:

Savonix – Startup innovating for elderly care

Savonix is a US-based digital health startup with a major presence in Singapore. It provides ranked personalised health recommendations for early screening and detection of dementia, based on evidence-based, clinically valid cognitive and emotional assessments.

The platform helps healthcare providers to improve treatment outcomes (EDB, 2021). The startup partners with companies working in

active ageing or cognitive health for the elderly to speed up regionalisation.

In 2020, the startup partnered with Lumen Lab to understand consumer insights and payer perspectives, co-invest, and speed-up localisation and network building. The startup decided to take regulatory opinion up front to proactively remove compliance-related hurdles along the way (EDB, 2021).

Healthcare gap

Early screening and detection of dementia

Solution

Cognitive and emotional assessment providing personalised health recommendations.

Approach

Partnership with larger companies working in the active ageing or cognitive health space to localise solutions in other markets.

Case 3:

Parkway Pantai – Innovation powered by a hospital chain

Parkway Pantai, part of IHH Healthcare, is a Malaysian hospital chain that operates more than 80 private hospitals in Singapore, Malaysia, India, Hong Kong, China and elsewhere. Headquartered in Singapore, its innovation office functions as a corporate venture arm to adopt innovative technologies, run innovation challenges, and invest in relevant startups (EDB, 2021).

- The hospital chain prioritises investment in its IT systems to integrate data across faculties and countries to gather data. This helps identify areas for innovation to facilitate better clinical decision making, patient experience, and operational models.
- It partners with startups instead of big tech companies, considering them more flexible and able to offer affordable solutions in low-income countries.
- Innovation challenges help the chain to foster an innovation mindset in its leadership and staff.

Healthcare gap

Clinical decision making, patient experience, and exploration of new operational models

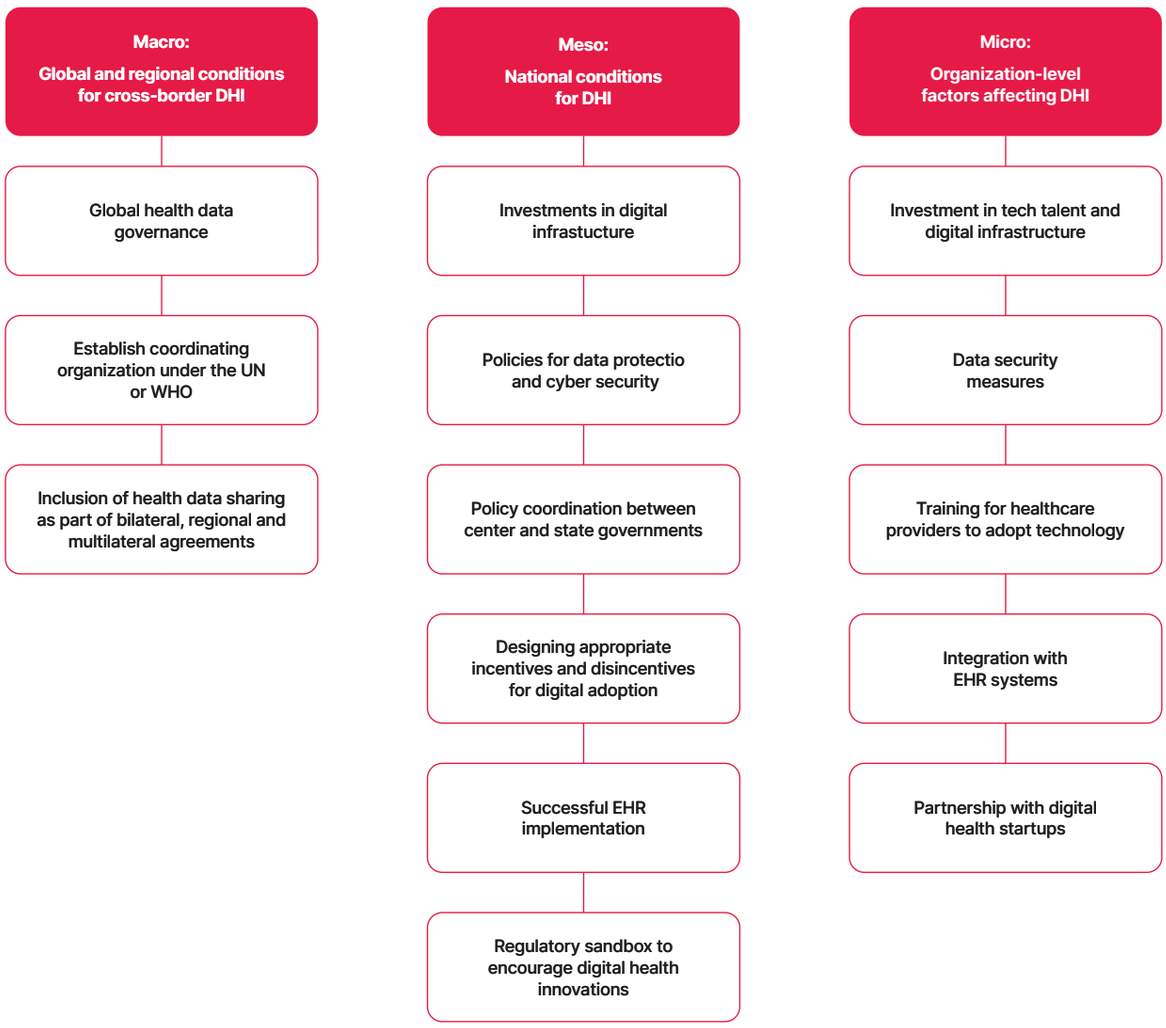
Solution

IT investments to integrate data across faculties and jurisdictions, actively partner with digital health startups, and conduct innovation challenges to encourage an in-house innovation mindset at organisational level.

Approach

Improving internal systems by increasing technology investments, bringing in new solutions by partnering with startups, and instilling provider motivation to adopt digital health.

Figure 14:
Framework for Digital Health Innovations in Asia



4

POLICY RECOMMENDATIONS

The following are recommendations for actions that countries and healthcare stakeholders should take to enhance the use of digital healthcare and the sharing of health data.

4.1 Global level

There is an urgent need for global health data governance, and it should be a priority in leading political, business and healthcare forums alike.

- Development of universal standards for health data security and interoperability will allow countries to share data for patient care, public health emergencies, research and innovation.
- A new coordinating organisation – under the UN or WHO – is needed to accelerate the development and launch of a standard set of principles for cross-border sharing of health data.

4.2 Governmental level

Electronic health records + data protection + cybersecurity = secure environment for health data sharing

- Governments should gather the health records of patients, while at the same time ensuring adequate standards, data privacy protection, and security from cyberattacks.
- The standards and protections should be superseding any rules currently used by organisations to secure sensitive patient health data.
- Such measures will be a catalyst for digital health innovations and efficient healthcare delivery, enabling the free yet secure movement of data.

Digital infrastructure and skill development

- Governments in Asia should prioritise the development of all-encompassing and efficient internet service infrastructures by telecom companies and broadband service providers to end the current urban-rural, public-private, provincial gaps in healthcare.
- Primary, secondary and tertiary healthcare providers should be connected nationally by means of fast and reliable internet connectivity and robust IT systems.
- Governments should ensure that digital health is a priority in medical education to prepare healthcare workers to adopt and efficiently use digital tools as part of care delivery.
- Governments should support tech experts from other sectors to learn about the sectoral nuances in healthcare by means of short courses and workshops. This can provide a reserve of technologically skilled professionals to work with digital healthcare when needed.
- Attractive pay packages are also necessary to bring in and retain tech talent in healthcare organisations.

Insurance

- National health insurance schemes can be enablers in digital adoption as well as in health data sharing. Governments should tweak policies to make digital adoption a requirement for healthcare organisations

and other stakeholders' participation in national health insurance schemes.

Regulatory sandboxes

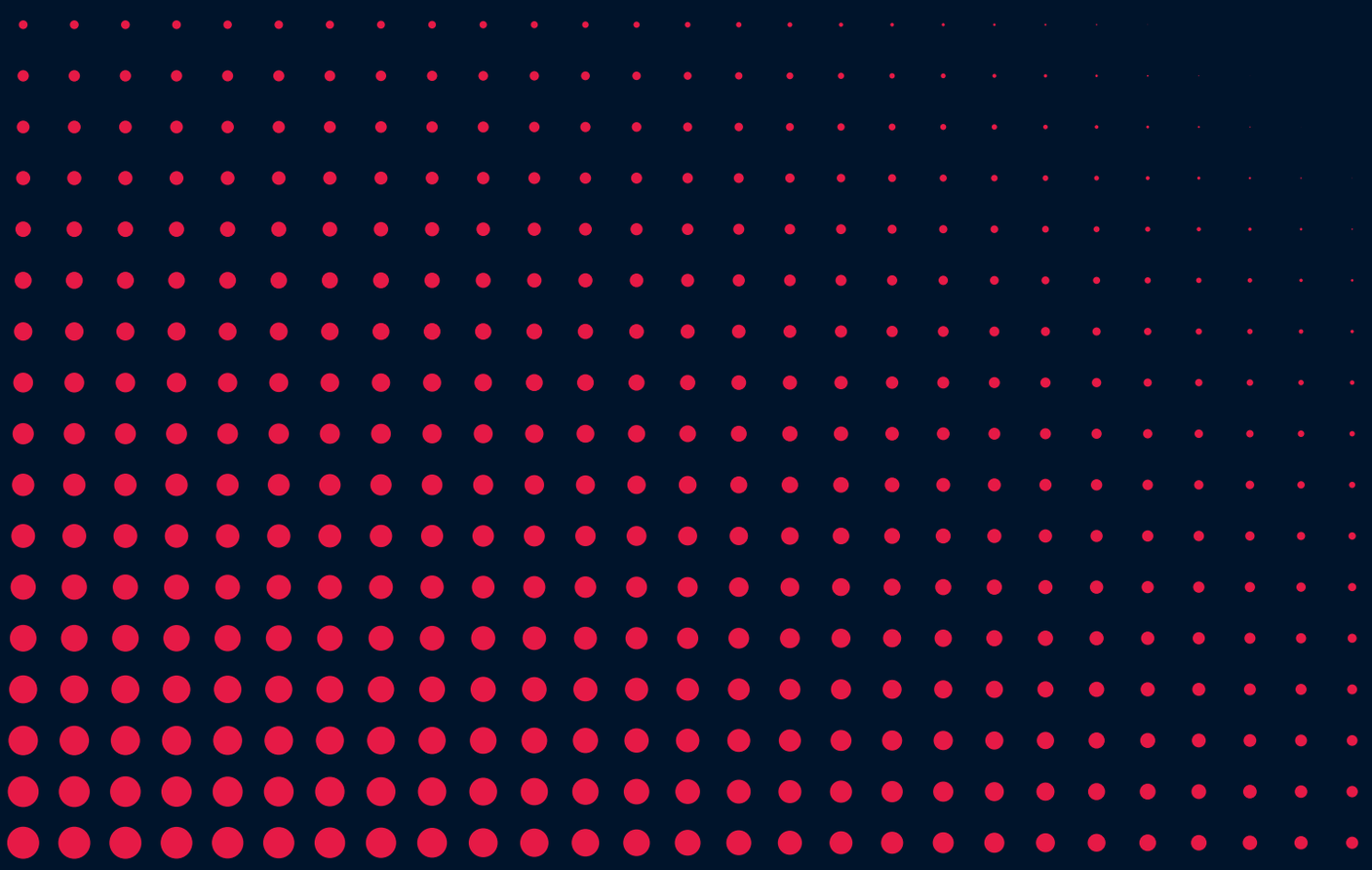
- Regulatory sandboxes – essentially test beds for startups to innovate under a regulator's supervision – should be encouraged as a way to build digital health technology and to help governments overcome their wariness about health data misuse by private companies.
- However, they should be used with care. Some countries lack the regulatory capacity to operate a sandbox effectively (namely resources, staff, expertise and tools). The sandbox approach may also compete with other regulatory priorities (Martin, et al., 2019).

4.3 Provider level

- Public as well as private healthcare providers should be actively encouraged to develop and participate in EHRs via well-designed incentives and disincentives.
- Focus should at first be on primary healthcare, later moving to secondary and tertiary healthcare. This is because primary healthcare clinics often lack financial capacity, IT systems and staff in comparison with larger organisations.
- Local networks of primary and secondary healthcare facilities could be created to optimise the sharing of health data.
- Partnership with digital health startups should be encouraged to help bridge the resource gaps experienced at the primary and secondary healthcare levels. As one example, Indonesian hospitals actively partnered with digital health startups to deliver medicines to patients during COVID-19 (Interviews).

5

CONCLUSION



The sharing of health data in Asia – and, hence, the adoption of digital healthcare – is hampered by diverse regulatory regimes, unequal digital infrastructure, shortages of healthcare and IT staff, and – overall – by the lack of a common platform on which the sharing can take place. This is exacerbated by the increasing threat of cyberattacks on healthcare organisations, breeding deep hesitancy about data storage and sharing.

Governments and providers view themselves as custodians of citizens' health data. In general, they do not trust sharing data outside because of the lack of a global framework or overseeing organisation.

Ranged against this, however, is the need for what digital health, including data sharing, can bring. The likelihood of future pandemics and rising demand for healthcare in ageing populations mean that structurally weak healthcare systems will struggle unless modernised.

This became clear to most Asian governments during the COVID-19 pandemic, leading to a shift in mindset. India, Indonesia and Malaysia have since been actively developing policies to enable the digital linking of healthcare data and systems, or interoperability. China and Singapore, two countries that had advanced health data interoperability in place before the pandemic, are making their systems more robust, including by encouraging private sector innovation.

To date, however, the focus has been on gathering health data but keeping it within national borders. This is seen as both ensuring safety and allowing the data to fuel local innovations which in turn can attract foreign investment.

The evolving national electronic health records initiatives across India, Indonesia and Malaysia are examples of this trend. India and Indonesia are also developing regulatory sandboxes, which allow startups to innovate under a regulator's supervision before expanding into the market. Such locally nurtured digital health innovations are not just seen as beneficial to improving local healthcare, since sharing innovations can also raise a country's regional and global influence (known as 'innovation globalisation').

To assuage some data sharing concerns, meanwhile, digital health startups are developing work-around strategies. They may, for example, rely on nationally linked (or federated) data platforms, which provide enough data without needing cross-border input. If they have a presence in other countries, the companies may also use cross-border, but in-house, data to feed their systems.

For the same reason, Asia's digital health startups tend to position themselves as B2B rather than B2C models. A highly regulated and restrictive policy environment may force some startups to choose B2B because

facing consumers directly exposes them to regulatory scrutiny.

Country by country

This report considered the state of digital health systems in five Asian countries: China, India, Indonesia, Malaysia and Singapore. It found progress, but large differences.

China, for example, has been able to capture massive amounts of health data that can be used to develop digital health innovations (e.g., internet hospitals). It is also actively seeking to digitalise its health system. This has meant that Chinese digital health startups find it easier to expand within than in other countries.

Digital health startups face greater challenges in India and Indonesia, both of which suffer from fragmented health data systems. But this may soon change. National electronic health records – the ABDM and SATUSEHAT, respectively – are taking root, while both countries are encouraging digital health startups by means of regulatory sandboxes. If the policies are successful, India and Indonesia can become leading hubs for digital health innovations in the next few years.

Malaysia is using its centralised healthcare system to collect data at a national level and is also mentoring local and global digital health startups to innovate. The MyHDW offers significant promise in enabling health data interoperability in the country, although its impact on digital health innovations remains unclear at this point.

Singapore shines as a regional hub for digital health innovations with an advanced regulatory regime, robust facilities and plentiful investment. An upcoming bill is expected to see Singapore take an interesting turn – a more decentralised approach to healthcare, delinking from hospitals and taking care to communities – by encouraging more health data interoperability across the ecosystem. However, it remains to be seen how this policy will actually pan out.

Overall, national-level health data sharing is evolving fast in Asia and is likely to encourage more local digital health innovations. Governments in the region are actively recognising and supporting digital health innovations. Policymakers have identified digital health systems as a solution to many of their existing challenges in healthcare, including increasing expenditures. As such, digital health innovations will continue to get regulatory support, and newer technological and business models are likely to evolve in the region that may help innovations to scale across countries quickly and more efficiently.

But the costs associated with this process will be high, since governments are likely to continue or even increase restrictions on cross-border health data sharing. There are also broad variances among stakeholders and countries when it comes to regulatory compliance, digital infrastructure, the maturity of EHRs, standards, data protection, cybersecurity measures, and political will.

In short, there is progress in Asia's embrace of digital health systems, but it is being held back by the region's diverse systems and governmental concerns over the cross-border sharing of data. Unless there is a multilateral effort towards shared health data governance, this situation is unlikelyto change any time soon.

6

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Appendix 1:
Research methods and data analysis

This report seeks to understand how different stakeholders in the Asian healthcare system think about the sharing of cross-border health data and its impact on digital health innovations. The three main questions that the research aims to explore are 1) the key drivers of and barriers to health data sharing, 2) the specific challenges that healthcare organisations face in health data sharing, and 3) the existence of a causal link between health data sharing and digital health innovations in Asia.

The research was undertaken in two phases, via surveys and via interviews.

Phase 1: Surveys

Survey participants were randomly identified through LinkedIn, based on their experience in digital health innovation and the healthcare sector across the countries under view. The participants were contacted via LinkedIn chat application to explore their interest in participating in the survey. While doing so, the intent and expected outcomes of the research were duly shared with participants, including the fact that the information gathered would not be used to identify them at any point during and after the research. To maintain anonymity, the name of the participants as well as their organisations have not been captured in the survey. Nine responses were received.

Survey questions:

1. How would you describe your role in the healthcare space?
2. Do you think cross border health data sharing contributes to digital health innovations?
3. Name three key drivers of cross border health data sharing in Asia
4. Name three key barriers to cross border health data sharing in Asia
5. How would you rank cross border health data sharing in Asia at this point?
6. How are public healthcare organizations placed in enabling cross border health data sharing in Asia?
7. Is the private healthcare sector better placed than public healthcare when it comes to cross border health data sharing in Asia?
8. Based on your experience, what can healthcare organizations/policymakers/ technology companies can do to improve cross border health data sharing in Asia?

The questions were designed using Typeform, Google Forms, and Microsoft forms, and the link to the form was shared using LinkedIn as well as by means of email to interested participants.

Phase 2: Semi-structured interviews

Since this research is qualitative in nature, semi-structured interviews were designed and administered to select participants who agreed to be interviewed. A key reason for choosing this method for the interview was because of the diversity of the participants roles and experience in the healthcare sector. Semi-structured interviews offer more flexibility in terms of questions and allow the researcher to adapt to the pace of the interviewee to elicit the most relevant responses to the questions of interest. Participants were selected based on their experience in healthcare and their knowledge and interest in health data sharing and its impact on digital health innovations.

Nearly 37 interviews were conducted with a set of stakeholders identified through online research based on their work in the healthcare sector and their interest and experience in digital health. LinkedIn was the main social media platform used to identify potential

interviewees, based on their education and work profile. The intent of the research and its goals were clearly stated, and permission was sought from each interviewee to record the interview for analysis purposes. The interviews were conducted by the researcher by means of the Zoom platform, which was also used to record the meeting. On average, the interviews ranged from 30 minutes to 1.5 hours in duration. Later, the interview recordings were downloaded to the computer and transcribed before being analysed.

Data analysis

Transcripts of interviews were analysed by means of ATLAS.ti 22, a Computer Assisted Analysis of Qualitative Data (CAQDAS) software. A desktop version of the software was used to upload the transcripts and code them. Thematic analysis technique was used to identify the broad themes and patterns in the interviews answering the key research questions. The country level codes were then grouped into themes which were then discussed as part of the case findings.

Appendix 2: List of regulations

China

Year	Act	Key provisions for health data	Does it support digital health innovation?
2011	National Population Health Informatization Development Plan (Li, et al., 2019)	The plan aimed to establish a 4-levels of information platforms which will enable national health data sharing.	The plan identifies the need to use digital health for improving health outcomes. It promotes personalized healthcare services by means of digital health applications. It promotes innovation by means of technology application in healthcare to upgrade current systems and support key businesses in the process while also expanding healthcare services to the entire population. Since 2015, the government has been focusing on application of advanced technologies for predictive modelling, clinical decision support, disease or safety surveillance, public health and research.
2014	Regulations for the Application of Electronic Medical Records (PRC, 2014)	The regulation claims that the government is the custodian of health data and healthcare organizations are required to comply with existing regulations.	No
2014	Options on Promoting Telemedicine Service for Medical Institutions	This policy allowed online business-to-consumer health services.	Yes. This encourages established medical institutions to open up to digital health services.
2015	Outline of National Medical and Health Service System Planning (2015-2020)	It promotes the development of mobile internet and telemedicine services.	Yes. It is an enabling policy for digital health innovation in telemedicine.
2015	Technical Specifications for Hospital Information Platforms based on EMRs (Liang J., et al., 2021)	This law defines electronic medical records (EMRs) as complete and detailed clinical information that is created, stored and used in digital form by medical institutions and are generated and recorded for citizens as part of their visits.	No
2016	Outline of Health China Plan 2030	The State Council for the first time released a policy implementing Internet + Healthcare at a broad strategy level.	Yes. It sets the vision for digital health as a viable alternative to or part of regular medical services.

2017	Cybersecurity Law of the People's Republic of China (PRC, 2022)	The law puts in place the need to protect online data. It encourages network data security protection while opening up public data resources. Although, it does not specify health data.	The law encourages innovation by means of opening up of public data resources. Although it is not clear if this includes digital health innovation.
2018	Administrative measures to regulate telemedicine[27]	None	Enables healthcare organizations like hospitals to offer telemedicine services through an affiliated internet hospital. However, it does not include other stakeholders including digital health startups.
2019	Healthy China 2030 (Zhuang, n.d.)	The plan promotes the use of big data in health by building a national health data resources repository.	Yes. The plan encourages use of new business models for use of big data in health. It specifically mentions reforms and innovation as a priority for the Chinese government as a supportive mechanism to improve citizen health.
2019	Guidance document on Internet + Medical Service Price + Medical Insurance Payment Policy	This aims to include internet diagnosis and treatment as part of social insurance and officially removes the ban on online prescription and sale of medicines.	Yes. It enables the third-party service providers in the digital space to actively design and implement innovative services for the healthcare sector.
2019	Action Outline for Boosting High quality Development of the Health Industry (2019-2022)	The plan maps out 10 major programs to facilitate better cooperation between platforms for drug distributions, medical institutions and e-commerce enterprises.	Yes. Greater collaboration is key to innovation in the healthcare space given the diverse set of stakeholders who provider services.
2020	Opinions on Strengthening IT Support for the Prevention and Control of COVID Opinions on Internet + Diagnoses and Treatment for the Prevention and Control of COVID-19	These documents issued by the National Health Commission encourage medical institutions to leverage online healthcare to release the pressure of offline medical institutions.	Yes, since these approaches towards regulation have helped in promulgating greater adoption of digital health solutions during COVID-19.
2020	Notice on Further Improving the Online Diagnosis and Treatment System and Strengthening the Construction of Smart Hospitals	It calls upon provincial governments to set up regulatory platforms to oversee online medical services and accelerate the market access of internet-based hospitals and online medical service providers.	Yes. It helps in the vertical integration and penetration of digital health solutions from cities to provinces and remote areas of the country.

27 These measures include (i) Measures for the Administration of the Internet-based Diagnosis and Treatment; (ii) Measures for the Administration of the Internet Hospitals; and (iii) Measures for the Administration of Telemedicine (Wang K. , 2018)

2020	Law of the PRC on Basic Medical Care and Health Promotion	As part of the legislation, medical and health institutions were urged to establish and improve their systems for medical information exchange and information security. This is expected to effectively build an online and offline integrated medical service model.	Yes. It enables more mainstreaming of digital health solutions as part of the regular medical services in the country.
2020	Key Tasks for Deepening the Reform of Medical and Health System in the Second Half of 2020	This document prioritises the accelerated development of Internet + medical health information platforms, health management service models, promotes Internet + medical security and the application of new generation information technology in the health industry as one of the key policy agendas for the government.	Yes. It envisions better business models for digital health to be holistically integrated as part of the overall healthcare ecosystem. Thus, making way for innovations to take shape in the sector.
2021	Personal Information Protection Law (PRC, 2021)	Health data is categorized under sensitive personal data. Sharing of health data within country is strictly based on informed consent or in exceptional situations. For cross-border health data sharing the restrictions are stricter even in cases where the country has signed international treaties or agreements for data transfer.	It has a direct impact on digital health innovation that relies on personal health data that can identify the individual to whom the data belongs. It specifically places compliance requirements for healthcare organizations, technology companies and digital health startups who handle personal health data.
2021	Critical Information Infrastructure Security Protection Regulations (PRC, 2021)	Health data is not specifically mentioned in the regulation, however information systems in public services have been mentioned.	No
2021	14th Five-Year Plan for National Informatization (PRC, 2021)	The plan envisions comprehensive implementation of national health and medical big data resource catalogues.	The plan aims to strengthen and expand the application of AI, big data and other advanced technologies in healthcare. The government also aims to foster new digital health innovations to improve citizen health and well-being.
2022	Measures for Cybersecurity Review	It is applicable for data theft and cybersecurity risks associated with health data sharing.	No

India

Year	Act	Key provisions for health data	Does it support digital health innovation?
2000	Information Technology Act (Ministry of Law, Justice and Company Affairs, 2000) *Regulating body:* Ministry of Electronics and Information Technology (MeitY) *Status:* Implemented	Sections 43A and 72A of the act address damages for failure to secure data and penalties for disclosure of information that does not comply with law respectively.	Enables innovations by covering the legal issues which can arise with the utilization of open, value-based and distributive parts of digital solutions.
2002	Indian Medical Council Regulations (Medical Council of India, 2002) *Regulating body:* Medical Council of India (MCI) *Status:* Implemented	Doctors should keep patient identity private during medical care and operations.	No
2011	Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules of 2011 (MEITY, 2011) *Regulating body*: MEITY *Status:* Implemented	It ensures that businesses must get permission before sharing sensitive or personally identifiable information.	Not specified
2016	Electronic Health Record (EHR) Standards for India (MoHFW, 2016) *Regulating body:* MoHFW *Status:* Implemented	Security of health data is a key priority; Based on global best practices	Promotes technical innovation using adopted standards

2017	National Health Policy (NHP) (MoHFW, 2017) *Regulating body:* MoHFW *Status:* Implemented	Envisions the creation of a National Health Information Architecture for seamless health data sharing by creating the Meta Data and Data Standards and Electronic Health Records. It encourages collaboration with the private sector and advocates for scaling initiatives in telemedicine.	Encourages digital health innovations, including research collaboration with other countries in Global South to develop digital health innovations.
2017	Digital Information Security in Healthcare Act (DISHA) (MoHFW, 2017) *Regulating body:* MoHFW *Status:* Implemented	Aims to provide for electronic health data privacy, confidentiality, security and standardization, and provide for the establishment of the National Digital Health Authority and Health Information Exchanges.	Not clearly identified
2018	National Health Stack (NHS): Strategy and Approach (NITI Aayog, 2018) *Regulating body:* National Institution for Transforming India (NITI Aayog)[28] *Status:* Implemented	It puts forth a digital health framework that can be used across India, and will support the healthcare ecosystem in integrating digital solutions. The vision put forth a roadmap to implement digital health records for all citizens of India by 2022.	It encourages innovation while ensuring user privacy and control. The NHS puts forth the idea of publishing open datasets to increase transparency, accountability, civil society engagement and innovations in service delivery.
2019	National Digital Health Blueprint (NDHB) (MoHFW, 2019) *Regulating body:* MoHFW *Status:* Currently being implemented	Enables interoperability between digital health systems at the patient, hospital and ancillary level.	Recognizes the digital health innovations proposes development of sandbox environments, aim to implement AI enabled clinical decision support systems, health analytics platform, anonymization methodology for health data analytics, establishment of Security and Privacy Operations Centre (SOC), Network Operations Centre (NOC) and Privacy Operations Centre (POC), and a framework for value-added services.

28 The NITI Aayog is a policy research and development centre that works closely with the government to promote research and innovation, develop a policy vision for the government, and deal with contingent issues. It also works on developing policy guidance on sector-specific technology adoption, including in healthcare. (NITI Aayog, 2023)

2020	National Digital Health Mission: Strategy Overview (MoHFW, 2020) *Regulating body:* MoHFW *Status:* Currently being implemented	Aims to establish digital health systems to manage the core digital health data and the infrastructure required for its seamless exchange. Federated health data exchange system planned to enable data to be held closest to where it was created. Health records will be shareable by the patient with appropriate consent, and complete control of the records will remain with patient.	Encourages innovation while ensuring consent-based data sharing with strong data privacy and encryption. The NDHM will manage the develop and manage a core platform to manage the privacy and security of datasets, while digital health startups can develop new applications on top of it. This model is expected to help innovations scale faster and with contextual understanding since they can be used in multiple local languages and access devices.
2020	Health Data Management Policy (HDM Policy) (MoHFW, 2020) *Regulating body:* MoHFW *Status:* Implemented	It recognizes the entities in the data processing space, such as fiduciaries and data processors and sets up a permission framework for processing personal data in healthcare settings.	Not specified.
2020	NDHM Sandbox: Enabling Framework (NDHM, 2020) *Regulating body:* MoHFW *Status:* Currently being implemented	Health data sharing is allowed based on HDM Policy, Information Security Policy and Data Protection Bill. Only anonymized data can be shared by a healthcare provider. No data can be shared outside of the country and all health data must be stored physically within the country in local servers. Webservers are not allowed.	Provides an enabling environment for new digital health innovations to be tested and monitored, while containing potential risks. It will be a dynamic, evidence-based system that will learn from and evolve with emerging technologies. It promotes the idea of responsible innovation to promote efficiency and benefit consumers. Evidence-based approach will be taken to emerging technologies to assess their benefits and risks and will promote only those innovations that are useful in the Indian context and address healthcare challenges in a significant way. The sandbox will be overseen by the NDHM Health Tech Committee (HTC).

2020	Telemedicine Practice Guidelines (TPG) 2020 (MoHFW, 2020) *Regulating body:* MoHFW *Status:* Implemented	Health data sharing is an essential part of the telemedicine guidelines. It mandates that health data of patients seeking telemedicine will be retained by the healthcare provider and if misused the Indian Medical Council Regulations 2002 will apply.	Not specified.
2023	Digital Personal Data Protection Act *Regulating body:* Data Protection Authority (to be formed by end of 2023) *Status:* Enacted into a law in August 2023	Health data is considered 'sensitive personal data' and hence will be regulated under stringent data protection rules.	Yes, it provides clarity for digital health startups and technology companies dealing with personal health data in digital forms on the steps they need to take to protect the data while collecting, processing and sharing it at the national as well as cross-border levels.

Indonesia

Year	Act	Key provisions for health data	Does it support digital health innovation?
2004	Law of the Republic of Indonesia No.29 of 2004 regarding the Medical Practice (WHO, 2004)	It requires healthcare providers to maintain the confidentiality of patients.	No
2008	Electronic Information and Transactions Law (Law No. 11); amended by Law No. 19 of 2016 (Cyrilla, 2008) *Regulating body:* Ministry of Communication and Informatics (MCI) *Status:* Implemented	Sharing of personal data is subject to consent of the person whose data is being shared. Digital platforms in the country must 1) provide a standard protection procedure that guarantees security or confidentiality of patient data (in the form of electronic information or documents); 2) apply risk management in the event of any damage or loss arising out of operation of an electronic system; 3) provide and carry out procedures and facilities to protect an electronic system from interference and material and non-material loss; 4) provide a security standard covering procedures and systems to prevent and overcome any threat or attempted interference.	The law enables protection of health data from misuse on digital platforms and hence acts as a direction for digital platforms on steps they must take to protect health data. Although not stated explicitly, this may encourage responsible innovation.
2009	Health Law (Law No. 36); amended by Law No. 11 on Job Creation) (Apiycna, 2009) *Regulating body:* Ministry of Health (MOH) *Status:* Implemented	Provides protection to information of patients contained in medical records. Except in certain circumstances, medical records must be kept confidential by healthcare providers and may not be shared with other parties without approval of the patients. Use of anonymized data for research purposes has been allowed in this law (Hakim & Pardede, 2022)	The law encourages efforts to realize the highest possible health for the community. Hence, it may enable digital health innovations provided the patient is not harmed in any way (ILO, 2009).
2014	Government Regulation No. 46 of 2014 concerning Health Information Systems (HIS) (JDIH BPK RI, 2014)	It aims to build cooperation, coordination, and integration in continuous health development efforts.	Implementation process and applications are still poor and not optimal. Hence, it may not have a significant impact on digital health innovations

2019	Provision of Electronic Systems and Transactions (GR 71) (Pardede, 2019) *Regulating body:* MCI *Status:* Implemented	Health data constitutes personal data under this law. It states that health data sharing must be 1) at the consent of the data subject, 2) limited to the information that is relevant and in accordance with the purpose thereof, 3) conducted in a specific manner. This law applies to collection, use, storage, dissemination, and deletion of health data. It requires digital platforms and other technology service providers to maintain confidentiality, completeness, authenticity, accessibility, availability, and traceability of digital health data as per prevailing laws (Hakim & Pardede, 2022).	It enables cross border health data sharing under the supervision of regulatory bodies, or ministry (Triarianto, et al., 2020). This may encourage more innovation in digital health.
2020	Minister of Communication and Informatics (MCI) Regulation No.5 of 2020 on Private Electronic System Providers; amended with MCI Regulation No.10 of 2021 (Makarim & Taira, 2021) *Regulating body:* MCI *Status:* Implemented	Digital health platforms offering services in Indonesia both local and foreign are required to register in the country.	Not specified
2020	BSSN Regulation No. 8 of 2020 on Security Systems in the Operation of Electronic Systems	It specifies that subject to the risk level of an electronic system (or digital health platform), certain security standards must be implemented by the digital health platform.	Not specified
2022	Personal Data Protection Law (PDPL) *Regulating body:* Yet to be formed *Status:* Passed	This law establishes special rules for the processing of health data. It grants data subjects (patients in this case) extensive rights including the right to restrict data processing and the right to data portability, among others. Concerned persons should be notified within 72 hours of the breach. The law also limits cross-border sharing of data to only those countries that have an equal level of personal data protection (Data Guidance, 2022).	The law still allows cross-border data transfers, in addition to regulating national level data sharing. This will enable a conducive environment for digital health innovations in the country.

2022	MOH Regulation No. 24 of 2022 on Medical Records (Makarim & Taira, 2022) *Regulating body:* MOH *Status:* Issued	It underlines the digital transformation in Indonesian healthcare as it sets out detailed provisions on implementing the new EMR for healthcare facilities. This regulation will serve as a new legal framework for digital-based and integrated medical records, which is the SATUSEHAT platform (Schinder Law Firm, 2022). Healthcare organizations must connect with a health data sharing platform which is managed by the MOH.	This is a significant and important regulation to enable health data sharing within Indonesia. However, it does not specify anything about cross border health data sharing, although it does allow health data use for research and for public health emergencies (Endahayu, et al., 2022).

Malaysia

Year	Act	Key provisions for health data	Does it support digital health innovation
1997	Telemedicine Blueprint (MOH, 1997) *Regulating body:* Ministry of Health (MOH) *Status:* Implemented	This blueprint for telemedicine application puts in place an advanced model for creating a centralized health database and making it interoperable across hospitals and clinics in the country.	The blueprint encourages digital health innovations to improve healthcare services. It also envisions new business models for the innovations to take shape and how the MOH can support them.
1998	Private Healthcare and Facilities Act (MMA, 1998) *Regulating body:* Ministry of Health (MOH) *Status:* Implemented	A private hospital or clinic must report to the concerned authority regarding any data breaches.	Not specified
2005	Malaysian Health Data Dictionary (MOH, 2005)	This document aimed to provide a standard definition and description of data elements that would be used in the capture of health and health related data.	This enabled a key foundation for the Malaysian Health Data Warehouse which was implemented starting 2011. This document outlines innovation as one of the key outcomes of this effort.
2010	Personal Data Protection Act (PDPA) (Department of Personal Data Protection, 2010) *Regulating body:* Department of Personal Data Protection (DPDP) *Status:* Implemented	This regulation aims to safeguard personal data by requiring the users of data (which in this case can be healthcare organizations, technology companies, digital health startups, and the government) to comply with certain obligations and conferring certain rights to the data subject (the patient) in relation to their personal data (Ping, 2022).	Not specified
2015	Personal Data Protection Standard *Regulating body:* DPDP *Status:* Implemented	This includes security standards, and retention standards. This is a minimum requirement and will apply to all persons/ organizations who process, has control of, or allows the processing of personal data.	Not specified
2016	Information Technology Strategic Plan (PSTM) 2016 – 2020	Aims to direct digitalization in the healthcare sector by means of specific policy implementation, and supporting infrastructure for greater health data sharing.	The plan aims to encourage digital health innovations.

2020	Public Consultation Paper No. 01/2020 on Review of the PDPA (DPDP, 2020) *Regulating body:* MCMC *Status:* Not implemented, will be considered by the next government	Some of the potential amendments to the PDPA can be: 1) all organizations that collect, use, store and share data must appoint at least one Data Protection Officer (DPO), 2) introduction of a mandatory data breach notification requirement, 3) extension of the scope of application of the PDPA to data processors (which may include ISPs and CSPs – refer Appendix 3), 4) introduction of a right to data portability, which is the right of the person to obtain and reuse their data for other purposes across different services, and 5) introduction of a black-list regime whereby persons will be allowed to share data across borders subject to compliance with certain minimum criteria in the PDPA, except for countries that have been black-listed by the Minister of Communications and Multimedia (Rajah & Tann, 2022).	The amendment may enable cross-border health data sharing and hence encourage digital health innovations.
2021	Malaysia Cyber Security Strategy 2020-2024 (NACSA, 2021) *Regulating body:* National Cyber Security Agency (NACSA) *Status:* Implemented	It's an overarching strategy to protect the Critical National Information Infrastructure (CNII) which include healthcare.	Not specified
2022	Personal Data Protection Code of Practice for Private Hospitals in the Healthcare Industry (APHM, 2022) *Regulating body:* DPDP *Status:* Implemented	It allows health data to be shared with explicit consent of patients, however consent is not required when sharing health data for treatment purposes, and with the Ministry of Health in cases where it's used for reporting communicable diseases. Cross-border health data sharing is possible with the consent of patients, to undertake treatment abroad, or to get second opinion of a healthcare provider who is located overseas, in case where it is necessary to protect the vital interest of the patient, or in case of public interest as determined by the Minister of Health (APHM, 2022).	This enables better regulation of health data in the private healthcare organizations and may contribute to health data sharing between the public and the private healthcare sectors in Malaysia. This may also play a role in digital health innovations with respect to seamless data sharing, and scale-up of innovations within the healthcare ecosystem.
2022	Ministry of Health Malaysia Digitalization Strategic Plan 2021 – 2025 *Regulating body:* MOH *Status:* Released	Aims to direct the digitalization initiatives within the MOH to enable greater health data interoperability at the national level, as well as to oversee the successful implementation of the Malaysia Health Data Warehouse (MyHDW).	The strategic roadmap is aimed at enhancing digitalization of the healthcare systems in the country. This is likely to create a conducive environment for innovation.

2023	Proposed amendment to PDPA 2010 (Rajah & Tann, 2023) *Regulating body:* MCMC *Status:* Under consideration	Additional amendments considered include 1) increased penalties for misuse or data breach under the PDPA, and 2) increased enforcement powers and elevation of the DPDP as a Statutory Commission (Rajah & Tann, 2023)	Data breach is a serious concern in healthcare and hence strict regulation of the same will enable more trust in the safety of health data being handled by organizations. This may enable digital health innovations to take shape in a well-regulated environment.

Singapore

Year	Act	Key provisions for health data	Does it support digital health innovation?
2012	Personal Data Protection Act (PDPA) (first version, amended version below) *Regulating body:* Personal Data Protection Commission (PDPC) *Status:* Implemented	The PDPA accords overall protection to personal data of Singaporean citizens, however the PDPC has later issued sector-specific guidelines, e.g., for healthcare the advisory is listed as below.	Not specified
2015	Advisory Guidelines for the Healthcare Sector (first version, amended version below) *Regulating body:* PDPC *Status:* Implemented	The guidelines cater to health data protection in healthcare settings and mandates steps that healthcare organizations can take to ensure this.	Not specified
2015	National Telemedicine Guidelines (MOH, 2015) *Regulating body:* Ministry of Health (MOH) *Status:* Implemented	It set out requirements on the delivery of diagnostic quality images and audio for telemedicine services, reliability of medical and laboratory equipment, equipment calibration and other application-specific standards that will apply to telemedicine equipment in general. It also highlights that the use of telemedicine or any medical act outside of the traditional healthcare setting (e.g., video or audio recording of sessions or the use of data for research or educational purposes) should be made only with the explicit consent from the patient for each step (Hanson, et al., 2020).	Since telemedicine application requires health data sharing between different stakeholders involved in the case process, the regulation tends to enable health data sharing. This may enable new innovations in the healthcare sector in Singapore. The guidelines recognize the potential for innovation in telemedicine services.
2015	National Guidelines for Retention Periods of Medical Records (Ong, 2015) *Regulating body:* MOH *Status:* Implemented	The updated guidelines seek to standardize best practices and ensure that medical records retention practices meet all current medical and legal requirements, and enables electronic medical records.	Not specified.

2017	Advisory Guidelines for the Healthcare Sector (on the application of the PDPA to the healthcare sector) (Revised in 2017) (PDPC, 2017) *Regulating body:* PDPC *Status:* Implemented	The advisory enables healthcare organizations to decide on the security arrangements that may be reasonable and appropriate in a given situation. It takes into account the complex nature of healthcare as a sector and makes it essential to give adequate protections to health data.	The advisory which is in succession of the PDPA caters to the healthcare sector's requirements to collect, use, store and share health data of patients based on circumstances. The law enables trust and consent-based approach to health data sharing, which maybe an enabler for innovation. Although this is not specifically identified in the guidelines.
2018	Cybersecurity Act (Government of Singapore, 2018) *Regulating body:* Ministry of Communications and Information (MCI) *Status:* Implemented	Recognizes acute hospital care services and services related to disease surveillance and response as essential services. Hence healthcare has been categorized under critical information infrastructure under the act.	Not specified
2020	Medical Registration Act 1997, 2020 Revised Edition (MOH, 1998)[29]	Protects the confidentiality of health data	Not specified
2020	Private Hospitals and Medical Clinics Act (1980) (MOH, 2020) (2020 Revised version)	It mandates that confidentiality of health data of patients must be protected.	Not specified
2020	Healthcare Services Act (MOH, 2020) *Regulating body:* MOH *Status:* Implemented	By means of this regulation the MOH wants to expand the scope of healthcare services in regulation and included specific provisions for mainstreaming telemedicine as part of the healthcare services in Singapore	Not specified

29 This revised edition incorporates all amendments up to and including 1 December 2021 and comes into operation on 31 December 2021

2021	Healthcare Services (General) Regulations 2021 (MOH, 2022) *Regulating body:* MOH *Status:* Implemented	Patient health record has been defined as personal data and medical information of a patient that is maintained by a healthcare provider in relation to the healthcare service availed. It requires health data to be protected from unauthorized offline and online access. Transmission of health data to an authorized entity or individual is to be undertaken securely. It mandates healthcare organizations to provide adequate protection to health data such that it is not compromised in a manner that affects the safety, confidentiality and security of health data.	Not specified
2020	Personal Data Protection Act (PDPA) 2012, 2020 Revised Edition[30] (IMDA, 2020) *Regulating body:* Infocomm Media Development Authority (IMDA) *Status:* Implemented	Regulates collection, storage, disclosure and use of personal data and defines the rights of citizens with respect to their personal data.	The law acts as an enabler for digital health innovations since health data sharing can be more responsible and organizations have to ensure data privacy and security, which means that they can build more trust in the process.
2021	Artificial Intelligence in Healthcare Guidelines (MOH, 2021) *Regulating body:* MOH *Status:* Implemented	Share good practices with AI developers (e.g., manufacturers or companies) and AI implementers including healthcare institutions – hospitals, clinics, laboratories, etc.	These guidelines are a key enabler for AI-based digital health innovations. They give clear guidelines to AI developers as well as implementers, thus creating an enabling environment for innovations to take shape.
2022	Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (HSA, 2022) *Regulating body:* Health Sciences Authority (HSA) *Status:* Implemented	The guidelines present a risk classification of medical mobile applications and medical devices used in the healthcare setting. It prevents data conversion to other purposes like transfer of information.	Not specified.

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2022	Revised Guidelines for Retention Periods of Medical Records (MOH, 2022) *Regulating body:* MOH *Status:* Implemented	Requires health data to be stored in digital format and retained for a specific period of time for use in healthcare settings.	Health data storage norms can be important for healthcare organizations who are the first layer of users of the data in healthcare settings. However, the broader implication of this can be that health data in this format can be potentially used for innovation purposes at the organizational level.
2023	Health Information Bill *Regulating body:* MOH *Status:* Being discussed, may potentially be tabled in 2023	This law is expected to facilitate greater integration of the healthcare ecosystem. This will require licensed healthcare providers (including private providers) to input patients' medical records into the National Electronic Health Record ("NEHR"). This enables important patient data to be made accessible to various care providers and facilitate good continuity of care, and also enhances overall efficiency of the healthcare system (Goh, Ying, Yap, & Hsien, 2023).	This law is expected to regulate health data sharing more strictly, while also enabling such sharing for the purposes of digital health innovations by ensuring data privacy and security.

List of acronyms

ABDM	Ayushman Bharat Digital Mission
ABHA	Ayushman Bharat Health Account
AeHIN	Asia eHealth Information Network
AI	Artificial Intelligence
AIIMS	All Indian Institute of Medical Sciences
ADB	Asian Development Bank
ADGMIN	Association of South East Asian Nations' Digital Ministers' Meeting
APEC	Asia-Pacific Economic Cooperation
API	Application Programming Interface
ASEAN	Association of Southeast Asian Nations
B2B	Business to Business
B2C	Business to Consumer
BPJS-K	Badan Penyelenggara Jaminan Sosial Kesehatan
CBPR	Cross Border Privacy Rules
C-CAMP	Centre for Cellular and Molecular Platforms
CC	Cloud Computing
CDC	Centres for Disease Control and Prevention
CGSO	Chief Government Security Office
CMIS	Critical Medical Information Store
COVID-19	Coronavirus Disease 2019
CoWIN	Winning over Coronavirus Disease 2019
CSP	Cloud Service Provider
CTO	Chief Technology Officer
DBT	Department of Biotechnology
DEA	Digital Economic Agreement
DEPA	Digital Economy Partnership Agreement
DFFT	Data Free Flow with Trust
DHCF	Digital Health Competency Framework
DHI	Digital Health Innovation
DHID	Demographic Health Information Databases
DHIS	Digital Health Incentive Scheme
DIAM	Digital Imaging Adoption Model
DID	Demographic Information Database
DISHA	Digital Information Security in Healthcare Act
DIVOC	Digital Infrastructure for Verifiable Open Credentialing
DMF	Data Management Framework
DRG	Diagnosis-related groups
DTO	Digital Transformation Office (Indonesia)
EDB	Economic Development Board
EHRs	Electronic Health Records
EHRD	Electronic Health Record Database
EISE	Enhanced Clinical Trial Initiation, Screening and Enrolment
EMRs	Electronic Medical Records
EMRD	Electronic Medical Record Database
EMRX	Electronic Medical Record Exchange
ERS	Eye & Retina Surgeons
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GSMA	Global System for Mobile communications Association
H-Cloud	Healthcare Cloud
HFR	Healthcare Facilities Registry
HIE	Health Information Exchange
HIMSS	Healthcare Information and Management Systems Society
HIP	Health Information Provider
HIS	Hospital Information System
HIU	Health Information User
HL7	Health Level 7
HMIS	Health Management Information Systems
HPR	Healthcare Professionals Registry
ICD	International Classification of Diseases
IDHA	India Digital Health Accelerator
IDSP	Integrated Disease Surveillance Programme
IHIP	Integrated Health Information Platform
IHIS	Integrated Health Information System
IHS	Indonesian Health Services
INR	Indian Rupee
IoT	Internet of Things
IPHS	Indian Public Health Standards
IT	Information Technology
LEAP	Licensing Experimentation and Adaptation Programme
LOINC	Logical Observation Identifiers Names and Codes
MCC	Model Contractual Clauses
ML	Machine Learning
MMV	MassMutual Ventures
MOH	Ministry of Health
MoHFW	Ministry of Health and Family Welfare (India)

MRANTI	Malaysian Research Accelerator for Technology and Innovation
MyHDW	Malaysian Health Data Warehouse
MyHIX	Malaysian Health Information Exchange
NDHB	National Digital Health Blueprint
NDHM	National Digital Health Mission
NEHR	National Electronic Health Record
NFHS	National Family Health Survey
NHA	National Health Authority
NHC	National Health Commission
NHFPC	National Health and Family Planning Commission
NHG	National Health Group
NHIS	National Health Identification Service
NHM	National Health Mission
NIC	National Informatics Centre
NPMI	National Patient Master Index
NTIS	National Technology and Innovation Sandbox
NUHS	National University Healthcare System
OECD	Organisation for Economic Cooperation and Development
PAAS	Platform-as-a-service
PDF	Portable Document Format
PDPA	Personal Data Protection Act
PDPC	Personal Data Protection Commission
PDPD	Personal Data Protection Department
PHR	Personal Health Record
PMJAY	(Ayushman Bharat) Pradhan Mantri Jan Arogya Yojana
PRC	People's Republic of China
PRIS	Patient Registry Information System
Pusdatin	Pusat Data dan Teknologi Informasi
RM	Malaysian Ringgit
RMB	Renminbi
SADEA	Singapore-Australia Digital Economy Agreement
SGD	Singaporean Dollar
SIHA	Strategic Information on HIV and AIDS database
SIKDA	Sistem Informasi Kesehatan Daerah
SIKNAS	Sistem Informasi Kesehatan Nasional
SIMPUS	Sistem Informasi Perpustakaan UII
SIMRS	Sistem Informasi Manajemen Rumah Sakit
SingHealth	Singapore Health Services
SITB	Sistem Informasi Tuberkulosis
SMRP	Sistem Maklumat Rekod Pesakit
SPDI	Sensitive Personal Data and Information
TB	Tuberculosis
TPC-OHCIS	Tele Primary Care-Oral Health Clinical Information System
UHC	Universal Health Coverage
UHI	Unified Health Interface
UMC	Uppsala Monitoring Centre
UN	United Nations
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
US	United States
VPN	Virtual Private Network
WHO	World Health Organization
WTO	World Trade Organization

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