

Navigating the Landscape of Digital Health

Singapore



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Please cite this report as follows: Mandyam, N.K., Tromp, J., 2022. The Singaporean Digital Health Landscape, Singapore: Saw Swee Hock School of Public Health, National University of Singapore.

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Disclaimer – This report is a product of a study lead by HITAP to understand the digital health landscape in Australia, England, India, Indonesia, Singapore, South Korea, and Thailand. The study was supported by the Access and Delivery Partners (ADP) and the Health System Research Institute (HSRI) on behalf of Ministry of Public Health Thailand (MoPH). The views expressed in this document are solely those of the authors and do not necessarily reflect the views of their affiliated or the partner organisations. In particular, the findings, interpretations, and conclusions expressed in this work neither necessarily reflect the views of funder organisations the HSRI, Thai MoPH and ADP nor do they guarantee the accuracy of the data included in this work.

More information on this project is available here: <https://www.hitap.net/en/research/183722>

Disclosure –

JT has received consulting or speaker fees from Daiichi-Sankyo, Boehringer Ingelheim, Roche diagnostics and Us2.ai, which owns patent US-10702247-B2. No conditions or limitations on SSHSPHs independence in research including data collection, analysis, reporting and resultant conclusions, recommendations, and publications are attached to any funding received.

Cover image designed by Pattama Nualpenyai, HITAP

Acknowledgements

We would like to thank the following people and organisations for their input and/or review of this report.

Tan Si Ying, Research Fellow at Leadership Institute for Global Health Transformation (LIGHT) at Saw Swee Hock School of Public Health

Kwong Hoe Ng, Head of Health Technology Evaluation, Utilisation Review and Adoption at Agency for Care Effectiveness (ACE)

Jeremy Lim, Director at Leadership Institute for Global Health Transformation (LIGHT) at Saw Swee Hock School of Public Health

Pin Sym Foong, Research Fellow at TeleHealth Core at Saw Swee Hock School of Public Health

Wee Hwee Lin and Jeremy Chan Wei Han, Faculty at Health Intervention and Policy Evaluation Research (HIPER) at Saw Swee Hock School of Public Health

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Abbreviations and definitions

ACE, Agency for Care Effectiveness
AI, Artificial Intelligence
AI-MD, Artificial Intelligence Medical Device
A-STAR, Agency for Science, Technology, and Research
BRAIN, Business Research Analytic Insight Network
CHAS, Community Health Assist Scheme
COVID-19, Coronavirus disease 2019
DAC, Drug Advisory Committee
DHIs, Digital Health Interventions
ECEG, Ethical Code and Ethical Guidelines
EDBI, Singapore Economic Development Board
HBRA, Human Biomedical Research Act
HCSA, Healthcare Services Act
H-Cloud, Health Cloud
HITMAP, Health IT Master Plan
HPB, Health Promotion Board
HSA, Health Sciences Authority
HSS, Horizon Scanning System
HTA, Health Technology Assessment
IMDA, Infocomm Media Development Authority
IHIS, Integrated Health Information Systems
ITU, International Telecommunication Unit
LEAP, Licensing Experimentation and Adaptation Program
mHealth, Mobile Health
MCI, Ministry of Communications and Information
MOE, Ministry of Education
MOH, Ministry of Health
MTAC, Medical Technology Advisory Committee
NEHR, National Electronic Health Records
NTG, National Telemedicine Guidelines
PDPA, Personal Data & Protection Act
PHC, Primary Healthcare Services
PHMCA, Private Hospitals & Medical Clinics Act
PMO, Prime Minister's Office
SaMD, Software Medical Devices
SDO, Singapore Digital Office
SNDGO, Smart Nation and Digital Government Office
TPLC, Total Product Life Cycle
UHC, Universal Health Coverage

Executive summary

Singapore has established itself as a medical hub in the region and is a favourable destination for medical tourism. The government of Singapore is working onto improve the nation's infrastructure and services including digital health interventions. Digital health interventions (DHIs), including electronic decision support tools, telemonitoring, and mobile health apps, are playing an increasingly larger role in the Singaporean health system. The Singaporean Health Sciences Authority defines digital health as *“the usage of connected devices, wearables, software including mobile applications, and artificial intelligence to address various health needs via information and communications technologies”*.

The Singaporean digital health landscape is rapidly evolving. It involves numerous stakeholders from the private and public sectors, including healthcare providers, hospitals, larger industry actors and start-ups, regulatory bodies, and universities.

Since 2014, the Smart Nation initiative has accelerated the digitisation of Singapore's government strategies. As part of the Smart Nation initiative, the Smart Health initiative introduced digital health to the health system. Specifically, this initiative promoted activities such as telehealth consultations, a centralised data platform for citizens to manage appointments and medication refills, and the introduction of a National Steps Challenge.

The regulatory landscape of digital health products is rapidly evolving. A regulatory sandbox, Licensing Experimentation and Adaptation Program laid the groundwork for the regulation of telehealth consultations. Separately, the Health Sciences Authority issued specific guidelines for subcategories of digital health, including artificial intelligence, electronic decision support tools, and telehealth consultations.

Digital literacy remains an important challenge in Singapore. Several government programs target vulnerable groups, including the elderly and low-income households. Despite these programs, a significant proportion of the elderly in Singapore does not use the internet or have access to mobile phones or tablets, reducing their access to digital health services.

There are limited reimbursement pathways for DHIs in Singapore. The horizon scanning system of the national health technology assessment agency, the Agency for Care Effectiveness, is designed to pick up and evaluate potential cost-effective technologies early. However, the lack of clear reimbursement for cost-effective DHIs remains a critical weakness.

Overall, Singapore's agile digital health ecosystem and economically strong environment make it an attractive hub for digital health. The country is taking active strides to address the current regulatory, digital literacy, and financial challenges in this space.

Background

Digital health interventions (DHIs), such as electronic decision support tools, telemonitoring, or mobile health (mHealth) apps, have the potential to address health system challenges that limit the achievement of universal health coverage (UHC).¹

Regional economic development and a growing ageing population have put significant strain on the sustainability of the Singaporean health system. These developments increased the demand for health services yet decreased the workforce supply.² The coronavirus disease 2019 (COVID-19) pandemic has significantly accelerated the development, implementation, and adoption of digital health technologies.^{3,4} These technologies have shown the potential to empower patients⁵ and providers⁶, promote universal health services coverage, improve long-term patient outcomes, and reduce healthcare costs.

Unfortunately, fundamental barriers can prevent implementation and access to DHIs.⁷ Health system governance (e.g., national privacy regulations, internet access), health provider (e.g., digital literacy, perceived effectiveness), patient (e.g., age, sex, socioeconomic factors), and technological (e.g., a context-specific adaptation of technology, interoperability) factors can affect the implementation of new DHIs.

To better understand the unique challenges and opportunities of DHIs in Singapore, this report analyses the Singaporean digital health landscape, including its legal frameworks, processes involved in conducting health technology assessment (HTA) of digital health technologies, stakeholders, and lessons learned.

1. The Singapore health system

Singapore's healthcare system is designed to ensure that everyone has access to different levels of healthcare in a timely, cost-effective and seamless manner. Singapore finances its health system using direct government subsidies of health services and the "three M's" i.e. "Medisave", "Medishield", and "Medifund". The government subsidises most in-hospital bills for citizens by up to 80%. Medishield Life, lifelong basic insurance, covers in-hospital and selected outpatient costs.⁸ Medisave, a compulsory individual medical savings account, partially covers out-of-pocket payments through mandatory personal and employer salary contributions.⁸ Medifund, a public endowment fund, covers the remaining costs for selected in-hospital services for citizens without enough Medishield Life and/or Medisave coverage after strict means-testing.⁸ In Singapore, mainstream health providers comprise a hybrid of public and private actors. Sixteen public hospitals are responsible for most secondary and tertiary care services. Individual private practitioners offer 80% of primary healthcare services (PHC). A mix of public government-owned facilities and private providers provide intermediate and long-term care services.⁹ Singapore is known for its good governance, consistently placing in the highest category (>97th percentile) globally for almost all governance indicators.¹⁰

2. Overview of the digital health ecosystem

2.1. Definition and classification of digital health

The Health Sciences Authority (HSA) oversees the regulation of health products, secures Singapore's blood supply, and conducts forensic and applied sciences for the nation. HSA is also the regulatory body for digital health in Singapore. It defines digital health as "*the usage of connected devices, wearables, software including mobile applications, and artificial intelligence to address various health needs via information and communications technologies*". This means that digital health products can include diverse categories, like telehealth, mobile health, wearable devices, health information technologies, and personalised medicine.¹¹ The HSA recognises several subcategories in digital health by issuing specific guidelines. These subcategories include applications involving artificial intelligence (AI)/machine learning¹², telehealth¹³, and recently a draft guideline on electronic decision support tools¹⁴ (**see Appendixes for guidelines**). Although in Singapore telemedicine is sometimes used interchangeably with the term 'telehealth', both describe a wide range of services where doctors may interact with other healthcare professionals, providers, caregivers, and/or patients virtually i.e. over a distance with the use of information communication technologies (ICT) such as video, audio or text. Additionally, there exists guidelines for both telemedicine and telehealth with the former focusing on services while the latter focuses more on medical devices and products.⁷²

2.2. Purpose and target users

The standard definition of digital health technologies by the HSA refers to technologies that "*address various health needs*" as a purpose and can include individuals/patients and care providers as the target group. Generally, if applications are used for "*investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy, or physiological process*", digital health products are considered medical devices regulated by the HSA's Health Products (Medical Devices) Regulations 2010.¹⁵ The key guiding definition of a regulated medical device is included in the First Schedule of the Health Products Act.¹⁶

Regarding the specific subcategories, the HSA considers the purpose of AI/machine learning tools as "*solutions which are intended to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy, or physiological process. AI-MDs (artificial intelligence medical devices) typically have a direct impact to patient safety*".¹² The guidelines are not explicit about target users but, based on the definitions, likely include healthcare practitioners as target users and patients as "*clients*". For telehealth products, the intended use should be "*for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy, or physiological process to fall under the HSA's regulatory control*".¹³ Target users for telehealth products are healthcare practitioners and patients.¹³ Similarly, clinical decision support tools intended for "*medical purposes such as investigation, detection, diagnosis, prevention, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process*" are considered medical devices subject to regulatory controls by HSA.¹⁴ DHIs that do not fall within the medical devices scope do not have well-established or official regulatory, legal, and financing pathways.

2.3. National digital health strategy

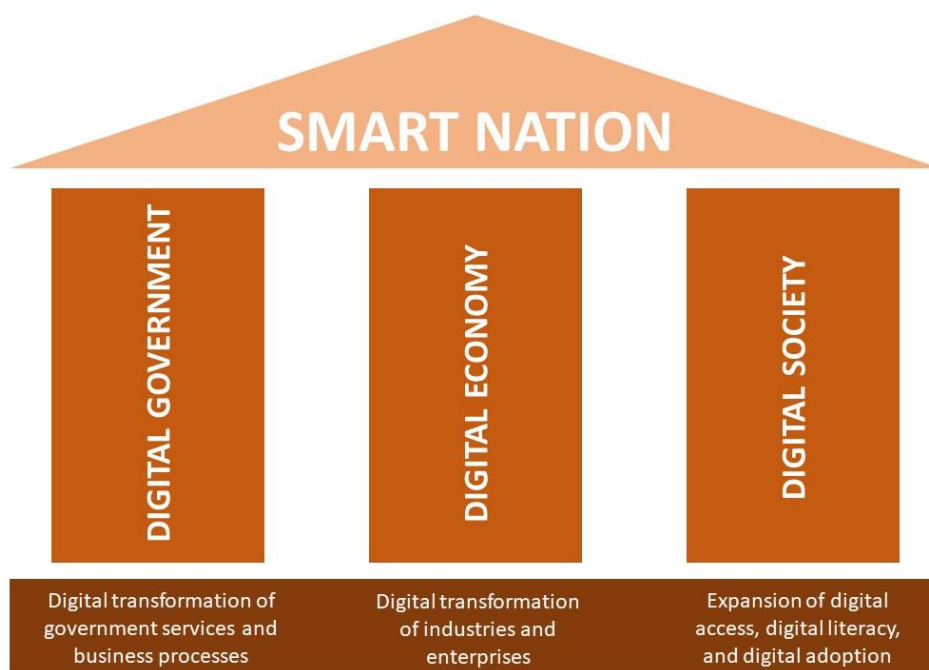
Smart Nation

In 2014, Singapore launched the Smart Nation digital initiative¹⁷. This initiative aims to transform Singapore through technology and create a digital-first country. The Smart Nation and Digital Government Office (SNDGO) leads this initiative under the Prime Minister's Office (PMO). Smart Nation has three key pillars and five domains.

The three pillars include:

1. Digital government: the Digital Government Blueprint highlights key attributes of this initiative (**Appendix 1**)¹⁸, which aims to achieve digital transformation of government services and business processes.
2. Digital economy: the Digital Economy Framework for Action highlights key attributes of this initiative (**Appendix 2**)¹⁹, which aims to digitalise industries and enterprises to make them competitive and resilient.
3. Digital society: Key attributes of this initiative are highlighted in the Digital Readiness Blueprint (**Appendix 3**)²⁰, which aims to make technology more accessible and improve digital literacy to increase digital adoption among Singaporeans.

FIGURE 1: KEY PILLARS OF SINGAPORE'S SMART NATION STRATEGY



Smart Nation is an important initiative that will enable Singapore to harness the power of technology, strengthen its capabilities, and stay at the forefront of regional and global competitiveness. The Smart Nation initiative helps Singapore achieve this by enabling a culture of innovation and experimentation while safeguarding cybersecurity and data privacy. The five domains of the initiative include transport, urban living, finance, education, and health.

Smart Health

As part of the Smart Nation program, Smart Health initiatives aim to introduce digital health to the health system.¹⁷ Initiatives include a specific focus on promoting and enabling telehealth consultations, introducing a centralised data platform for citizens to manage appointments and order medication refills called HealthHub, launching the National Steps Challenge, promoting daily exercise, and introducing assistive technologies.¹⁷ The National Steps Challenge aims to empower individuals to lead healthier lives by providing feedback on their daily exercise.²¹ The HealthHub platform expanded services, including providing national digital vaccination certificates and access to smoking cessation, diet control, and mental health services.²²

Health IT Master Plan (HITMAP)

HITMAP²³ is the Health IT Master Plan created by Integrated Health Information Systems (IHiS), the IT leader in charge of Singapore's public healthcare ecosystem. The plan was developed in 2013 in consultation with 850 stakeholders and has been revised and updated regularly to incorporate advancements in the field.²³

The three objectives of HITMAP are encapsulated as the "3 Beyonds". *Beyond hospital to community* refers to the concept of bringing the services provided in the hospital to the home to improve health access and minimise frequent hospital events to reduce the strain on hospitals. *Beyond quality to value* refers to delivering value and sustainability through efficient allocation of clinical resources. *Beyond healthcare to health* encourages a holistic approach to healthy living, focusing on mental health, physical health, preventive health, etc. Singaporeans are encouraged to become healthier and less dependent on medical care, so shifting the focus from remedial health to preventive health is essential.

FIGURE 2: OBJECTIVES OF HITMAP. ADAPTED FROM²³



To achieve these three objectives, seven programs revolving around big data and healthcare digitalisation have been deployed.²³

- Population profiling: harness unique insights about the Singaporean population by sharing and integrating data sources from healthcare and non-healthcare settings. One of the enabling platforms is Business Research Analytic Insight Network (BRAIN).

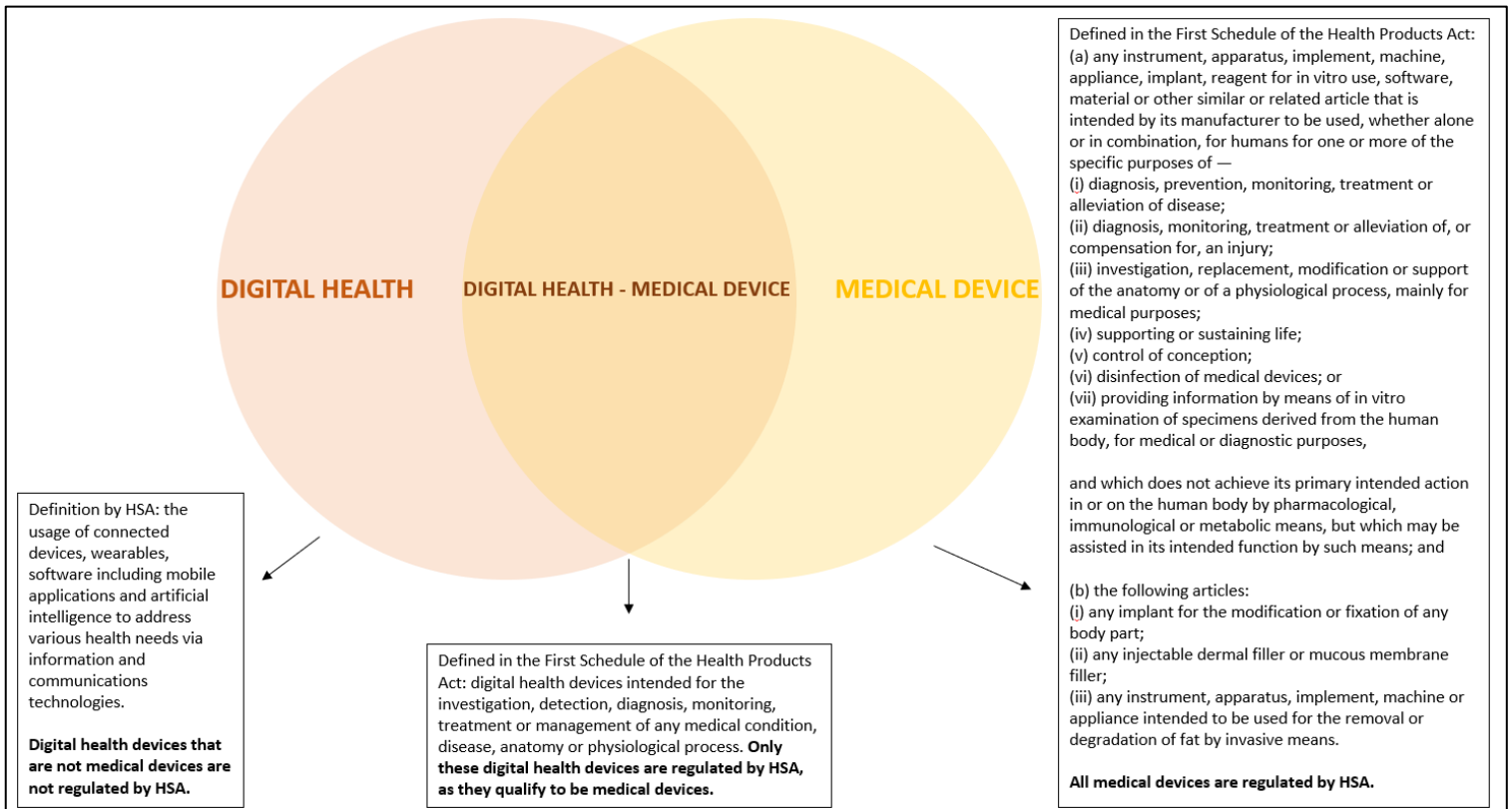
- Population enablement: create a platform where patients and providers can seamlessly connect, share data, and conduct patient education. An example of this is HealthHub.²²
- Prevention and continuity of care: harness digital capabilities to roll out prevention programs and integrate IT systems across healthcare providers to enable hassle-free continuity of care for patients. The enabling platform for this is the National Electronic Health Records (NEHR).²⁴
- Provider care and operations excellence: equip primary, secondary, and tertiary healthcare providers with essential IT systems to improve efficiency. An example of this is GPConnect, an integrated IT system for GPs.
- Healthcare financial excellence: ensure affordable healthcare for patients and be cost-effective.
- Policy and public health workbench: digitalise capabilities to collect and analyse large amounts of data that support public policy and public health.
- IT foundation and resiliency: develop core IT capabilities that can be leveraged cross-sectorally. The enabling platform for this is Health Cloud (H-Cloud).

3. Regulatory framework

3.1. Legal frameworks/mandates

The Health Products Act²⁵ and the Health Products (Medical Devices) Regulations 2010¹⁵ require medical devices to be registered with HSA before placing them on the Singapore market unless they are exempted. According to the First Schedule of the Health Products Act¹⁶, a digital health device intended for medical purposes such as “*investigation, detection, diagnosis, monitoring, treatment, or management of any medical condition, disease, anatomy, or physiological process*” will be classified as a medical device subject to HSA’s regulatory controls. If a DHI is not considered a medical device, it does not fall within the authority of HSA.

FIGURE 3: DIGITAL HEALTH DEFINITIONS AND HSA SCOPE



Other relevant legal frameworks:

- Personal Data & Protection Act (PDPA) and Guidelines (including Advisory Guidelines for the Healthcare Sector): obligations regarding the protection, collection, use, disclosure, and access of personal data.
- Private Hospitals & Medical Clinics Act (PHMCA) and Guidelines: licensed healthcare institutions and services under the PHMCA must comply with its requirements and licensing terms and conditions.
- Healthcare Services Act (HCSA): the broader and more flexible regulatory regime for healthcare services that will progressively supersede the PHMCA from 2022.
- Professional Registration Act and Ethical Code: law regarding the registration of medical practitioners.
- Civil Law (Amendment) Bill: statutory tests determining healthcare professionals' duty in providing medical advice.
- The Human Biomedical Research Act (HBRA) and Ethical Guidelines for Human Biomedical Research: standards and requirements for research and development activities with human data.

3.2. Governance structure, process, and core functions

HSA has guidance documents which provide detailed overviews of the regulatory processes.²⁶ DHIs that are considered medical devices are subject to regulatory controls, including (1) product registration, (2) dealer's licensing, (3) post-market requirements, and (4) any other applicable regulatory requirements and guidelines.

Product registration

- **Risk-based regulation.** The medical device's risk class determines its regulatory requirements. HSA classifies medical devices into four categories based on expected risk, the nature of the device, and its intended functions. Class A devices are low risk, class B devices are low to moderate risk, class C devices are moderate to high risk, and class D devices are high risk. HSA requires all medical devices to be registered, except for low-risk class A devices.
- **Confidence-based regulation.** Product registration of Class B, C, and D medical devices can be conducted via one of several evaluation routes (e.g., full evaluation route, abridged evaluation route, expedited evaluation route, immediate evaluation route etc.). The abridged, expedited, and immediate routes are based on a confidence-based approach. They leverage prior approvals by HSA's formal reference regulatory agencies and prior safe marketing history. Reference regulatory agencies include the Therapeutic Goods Administration Australia, Health Canada, the US Food and Drug Administration, European Union Notified Bodies, and Japan's Ministry of Health, Labour and Welfare.

TABLE 1: EVALUATION ROUTES AND CRITERIA

Full Evaluation (Class B, C, and D)	Abridged Evaluation (Class B, C, and D)	Expedited Evaluation (Class C and D)	Immediate Evaluation (Class B Medical Devices and Standalone Medical Mobile Applications)
No reference agency approval	1 reference agency approval	<u>Class C and D</u> <ul style="list-style-type: none"> • 2 reference agencies approval • No prior rejection/withdrawal from any reference agency/HSA <p align="center">OR</p> <u>Class C</u> <ul style="list-style-type: none"> • 1 reference agency approval • 3 years marketing history • No major safety issues globally • No prior rejection/withdrawal from any reference agency/HSA 	<u>Class B</u> <ul style="list-style-type: none"> • 2 reference agencies approval • No prior rejection/withdrawal from any reference agency/HSA <p align="center">OR</p> <ul style="list-style-type: none"> • 1 reference agency approval • 3 years marketing history • No major safety issues globally • No prior rejection/withdrawal from any reference agency/HSA <u>Standalone Medical Mobile Applications</u> <ul style="list-style-type: none"> • 1 reference agency approval • No major safety issues globally • No prior rejection/withdrawal from any reference agency/HSA

All product registration applications must adhere to submission guidelines, including accurate labelling, the grouping of devices, marketing, risk analysis, provision of clinical and safety evidence, etc. Refer to GN-15: Guidance on Medical Device Product Registration²⁶ for detailed guidelines on product registration.

Dealer’s licensing

Manufacturers, importers, and wholesalers of medical devices need to hold valid licenses and adhere to the required quality standards set out by HSA. For further information, refer to GN-02: Guidance of Manufacturers, Importers, and Wholesalers of Medical Devices.²⁶

Post-market requirements

Licensed medical device companies must notify HSA of any changes to their medical devices, adverse events, device recalls, and field safety corrective actions. Refer to GN-05: Guidance on Reporting of Adverse Events²⁶ and GN-10: Guidance on Medical Devices Field Safety Corrective Action²⁶ for more information.

Other guidelines

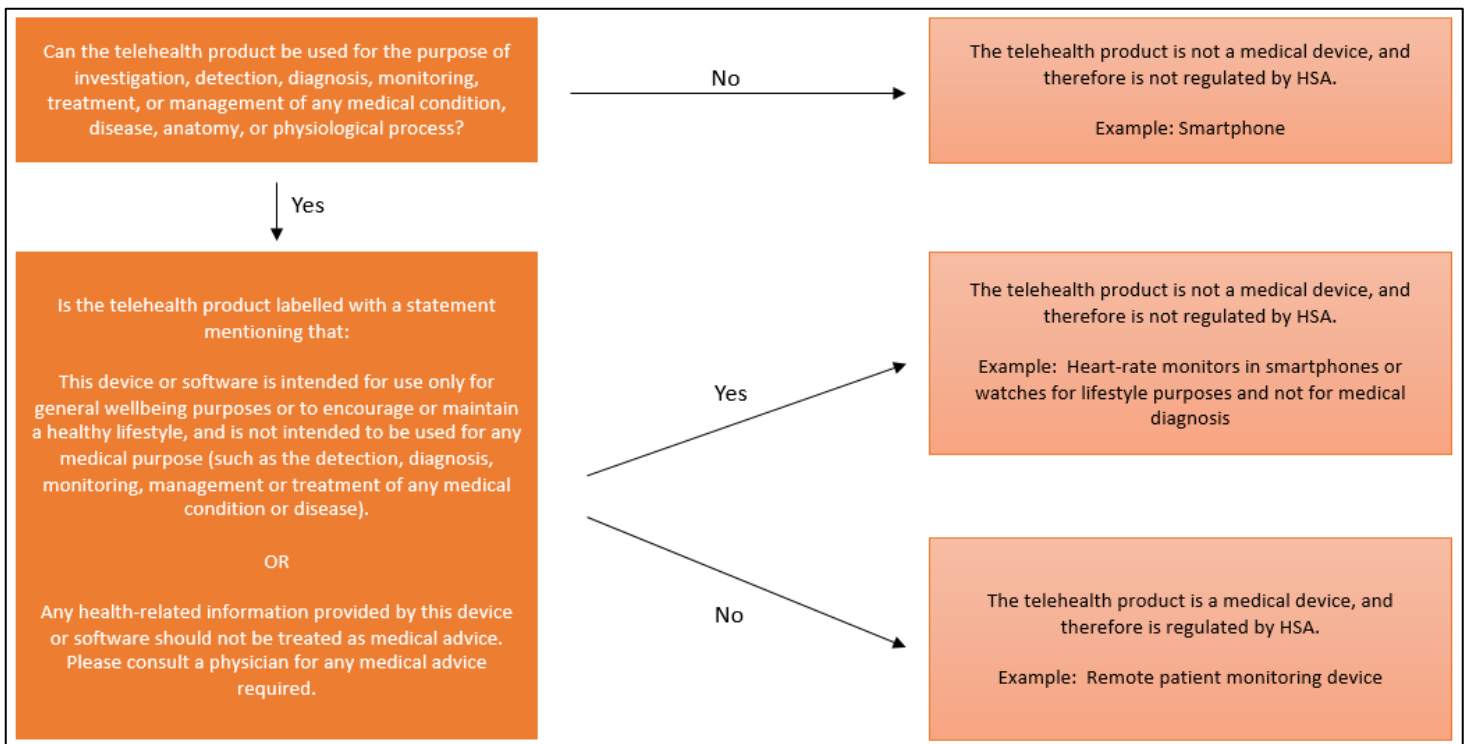
The HSA has specific guidelines for applications involving AI/machine learning¹², telehealth¹³, and electronic decision support tools¹⁴ (see **Appendixes for Guidelines**).

The regulatory and legal environment for telehealth

The HSA guidelines on telehealth (**Appendix 4**)¹³ were developed in 2017 to determine if a telehealth intervention is a regulated medical device under HSA and to understand the relevant regulatory requirements. HSA defines Telehealth as “the provision of healthcare services over physically separate environments via infoComm technologies, categorised into four domains: Tele-collaboration, Tele-treatment, Tele-monitoring, and Tele-support”. If the telehealth product is a medical device based on its intended use, the regulatory approach will be similar to other medical devices, including product registration, licensing, and post-market obligations.

FIGURE 4: FLOWCHART TO DETERMINE IF A TELEHEALTH PRODUCT IS A MEDICAL DEVICE REGULATED BY HSA. ADAPTED FROM ¹³

HSA covers telehealth products, not telehealth services.²⁷ Therefore, the National Telemedicine Guidelines (NTG) (**Appendix 5**)²⁸ were developed by the Ministry of Health (MOH) in 2015 to guide the delivery of Telemedicine services in Singapore with specific advice on clinical standards, human resources, organisational factors, and technology. In 2016, the Singapore Medical Council revised its Ethical Code and Ethical Guidelines (ECEG)²⁹ to include guidance on responsible telemedicine practices.



The Licensing Experimentation and Adaptation Program (LEAP) regulatory sandbox

MOH recognised the importance of telemedicine as a key feature of Singapore's healthcare landscape early. However, there was a lack of clarity on the guidelines for telemedicine to guide healthcare practitioners. The upcoming Healthcare Services Act will replace the present regulatory framework for telehealth services in 2023.³⁰ However, there was a need to identify the real and perceived risks of telemedicine in a controlled environment earlier on. The Licensing Experimentation and Adaptation Program (LEAP) sandbox aimed to 'demystify' telemedicine and help establish fit-for-purpose regulations for telemedicine in Singapore.³¹ The LEAP sandbox had a bespoke model reflective of the different risk and mitigation measures relevant to telemedicine. Mitigation measures included a clear escalation protocol for conditions unsuitable for telemedicine (e.g. chest pain or breathlessness). The MOH partnered with private telehealth providers during the sandbox model and evaluated the effects and necessary regulations on a quarterly basis using qualitative (e.g. necessary regulations, implementation barriers) and quantitative (e.g. adverse events) data. Furthermore, the LEAP sandbox had higher standards and more stringent organisational requirements than sandboxes used in other sectors like finance or the automotive industry.^{30,32} In 2021, the MOH gathered enough information for the new HCSA guidelines and the LEAP sandbox was closed.

The regulatory and legal environment for software medical devices (SaMD)

HSA issued "Regulatory Guidelines for Software Medical Devices – A Lifecycle Approach" (**Appendix 6**)³³ in December 2019. SaMD that falls under HSA regulation includes "*software intended for medical purposes such as investigating, detecting, monitoring, treating or managing any medical condition, disease, anatomy or physiological process*". Examples of such software include software embedded in medical devices, standalone software and mobile applications, and web-based software. All software medical device manufacturers are recommended to adopt a Total Product Life Cycle (TPLC) approach to manage and adapt to rapid technological changes. Similar to medical devices, SaMD regulatory processes include:

1. Product registration (includes requirements for incorporating a quality management system, risk assessment, software verification and validation, change management, traceability, and various aspects throughout a software's life cycle)
2. Dealer's licensing
3. Post-market requirements

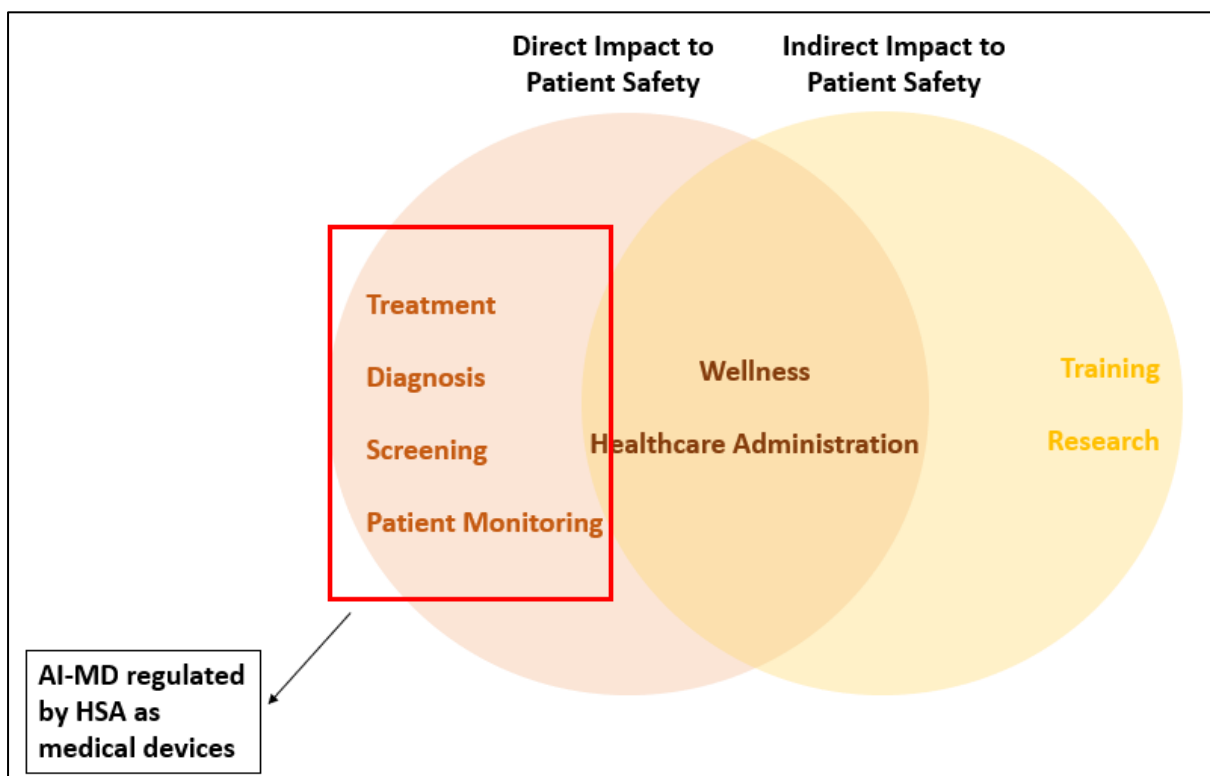
HSA has published guidance for standalone software and mobile applications - a subset of SaMD – as well.¹³ This technology refers to "*software and/or mobile applications with a medical purpose that are intended to function by themselves and are not intended for use to control or affect other hardware medical devices*".¹¹ If standalone mobile applications are not intended for medical purposes but can perform such functions (e.g. heart rate monitoring), the application must include a clarifying statement. All standalone medical mobile applications will fall under HSA's jurisdiction if the application is distributed in Singapore regardless of where the physical service

is located (local or overseas). These applications are subject to product registration, dealer’s license requirements, and post-market obligations like all other medical devices. Class B or C standalone mobile applications registered by one of HSA’s reference regulatory agencies may qualify for the immediate registration pathway.

The regulatory and legal environment for artificial intelligence

Currently, AI is regulated under the existing frameworks for medical devices or SaMD.¹¹ HSA defines AI-MDs as AI solutions intended “for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process”. MOH, HSA, and IHiS have also co-developed the MOH Artificial Intelligence in Healthcare Guidelines (**Appendix 7**)¹², which complement HSA regulations for AI-MDs and cover AI algorithms not covered under HSA related to wellness, administration, training, and research.

FIGURE 5: HSA’S REGULATORY SCOPE OF AI. ADAPTED FROM ¹²



HSA’s device development consultation scheme

This scheme allows researchers, developers, and manufacturers of digital health technologies to seek advice and support from HSA about a future regulatory submission. This scheme is crucial for novel digital health products that do not fit naturally into current regulatory systems to expedite registration and facilitate early patient access to DHIs.

4. Digital health trends

4.1. Market size and trends

Singapore is an attractive place to introduce digital health solutions because there are low barriers to adoption. The revenue for the digital health market in Singapore is approximately US\$431.50 million in 2022, with an expected annual growth rate of 9.25%.³⁴ Forecasted growth is primarily driven by eHealth and less by digital fitness and well-being innovations.³⁴ The Singapore government committed to a 5-year budget of Singapore Dollar (SGD) 19 billion for both, the digital economy and health sciences, in 2016.³⁵ Marsh McLennan³⁶ and Accenture³⁷ conducted consumer surveys about digital health usage and adoption in Singapore, demonstrating that:

- There was strong demand for digital health in Singapore: 58% of consumers found the digital health vision exciting. In particular, there was high demand for wearable technology, integrated electronic health records, telemedicine, and apps that help patients identify the right doctors.
- There were varying attitudes towards technology depending on age: the elderly favoured human interaction while the youth favoured convenience and were more open to virtual care.
- Government and traditional healthcare professionals were more trusted and expected to deliver digital health solutions to Singaporeans.
- Consumers were generally tech-savvy and raised concerns about digital tools' privacy, security, and effectiveness.

4.2. Market opportunities

Artificial intelligence

As part of the Smart Nation initiative, Singapore has laid out a National AI Strategy.¹⁷ As part of this AI strategy, AI in healthcare is one of the seven national AI programs led by IHiS.³⁸ The 2030 vision for AI in healthcare focuses on AI's role in chronic disease management and prevention. Diabetes, for example, is one of the chronic diseases that Singapore is dealing with. The Singapore National Eye Centre's (SNEC) Singapore Eye Research Institute (Seri) and the National University of Singapore's (NUS) School of Computing have collaborated to create a deep learning system for detecting diabetic eye disease. Selena+ (Singapore Eye 2 van 3 Lesion Analyzer Plus) accomplishes this by scanning photographs for evidence of diabetic eye disease. Aside from diabetic retinopathy, AI technology can detect glaucoma and age-related macular degeneration. Accelerating drug discovery is another application of AI that is increasingly being used during the pandemic. Singapore's national drug discovery and development platform (EDDC) has collaborated with pharmaceutical company Auransa to use predictive AI to accelerate the discovery of new therapeutics for viral pandemics. A multidisciplinary team of NUS researchers created 'IDentif.AI,' a platform for identifying effective drug combinations and dosing for billions of different drugs used to treat infectious diseases.

Wearables and health promotion

The Health Promotion Board (HPB) has launched several health promotion initiatives, nudging Singaporeans to lead healthier lifestyles. One example is the National Steps Challenge.³⁹ Singaporeans use a steps tracker and mobile application to track their exercise progress and goals. Gamification and incentives motivate Singaporeans to participate. This HPB initiative has achieved impactful milestones, including motivating 82% of the participants to spend more time on physical activity than they did before the Challenge.⁴⁰ Another popular initiative is LumiHealth⁴¹ – a program designed by HPB and Apple. The Apple Watch with the LumiHealth app can monitor vital parameters and encourage users to take action to improve their physical and mental health.

Electronic health records

Since 2011, the National Electronic Health Record (NEHR) has supported the vision of “*One Patient, One Health Record*”. MOH owns the secure system managed by IHiS. NEHR allows providers to have a longitudinal view of a patient’s healthcare history and enables continuity of care. NEHR is regularly updated to improve usability and interoperability.²⁴

Mobile apps

Mobile apps help Singaporeans manage their health outside of the healthcare setting before and after consultations. HealthHub is a one-stop platform that integrates patient data into one location so patients can better manage their health by accessing their vaccination and test records, booking appointments, ordering medicines, and conducting other health-related services. HealthBuddy⁴², a commonly used mobile app, provides healthcare professionals’ latest advice, including healthy living tips, videos, and patient education. Healthy 365, a mobile application by HPB, encourages users to adopt a healthier lifestyle through gamification, wellness programs, and rewards.⁴³

Telemedicine

COVID-19 has accelerated telemedicine adoption in Singapore. Many private telemedicine providers - such as WhiteCoat, Doctor Anywhere, and MyDoc - and public hospitals have telemedicine operations. The MOH monitors the quality of care for all these providers. During COVID-19, the MOH extended patient subsidies to cover telemedicine consultations, increasing this rapidly growing technology user base. Singapore has rapidly tested novel digital innovations, like telemedicine, through its regulatory sandbox and has scaled up telemedicine services to extend its coverage to more citizens.

5. COVID-19 and digital health in Singapore

Singapore's general digital ecosystem across sectors matured before the COVID-19 pandemic, but technology adoption in healthcare accelerated because of the pandemic. With most in-person visits cancelled or put on hold, the use of remote services soared during the pandemic. Consumers are now more confident and comfortable with digital healthcare, and it is evident that the default care model is shifting towards virtual care as Singapore moves on to the post-pandemic era.

The Smart Nation and Digital Government Group used technology to respond swiftly during the pandemic. Since digital infrastructure was built up as part of the Smart Nation initiative, Singapore was able to react decisively and promptly to the COVID-19 pandemic. Digital health technologies such as mobile apps, electronic medical records, smartphones, GPS tracking, CCTV cameras, robots, drones, and digital health passports were used to manage COVID-19.⁴⁴

Below are some notable examples:

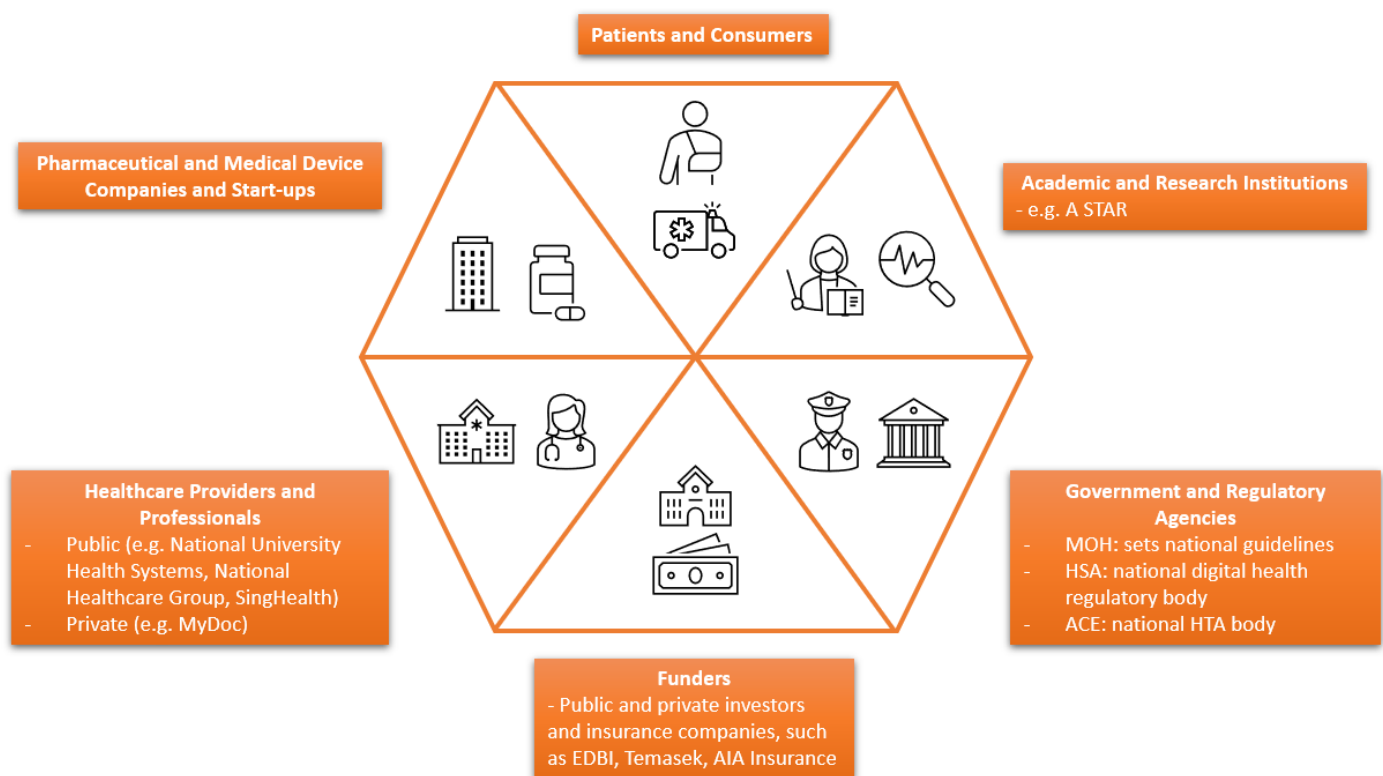
- Bluetooth contact tracing: TraceTogether and SafeEntry reduce the average time to identify and quarantine close contacts from 4 days to less than 1.5 days.
- Community preparedness: HealthCerts are globally interoperable COVID-19 test results and vaccine certificates that allow for accurate and easy verification when citizens are on the go.
- Verified information: The COVID-19 Situational Report Dashboard and the Gov. sg WhatsApp platform provide verified information and regular updates about the constantly evolving pandemic to keep the public well-informed.

Stakeholders in Singapore's digital health landscape

1. Definitions and roles of stakeholders

There are several stakeholders relevant to the development of DHIs in Singapore.⁴⁵ Technology and medical equipment companies together with start-ups and academia are key players throughout the lifecycle, involved in R&D, DHI supply, and funding. Investors play an important role in driving digital health innovation and providing seed funding for early development. Government players, like the Singapore government's investment arm, the Singapore Economic Development Board (EDB), provide critical early-stage investments for early-phase start-ups.⁴⁶ Universities and research institutions, such as the Agency for Science, Technology, and Research (A-STAR), provide early investment grants to commercialize and pilot academic innovations. Singapore has several digital health incubators to stimulate innovation.⁴⁷ Regulatory bodies, like the HSA, play a key role to provide guidelines and regulations during the development stage. Continued investments during the development phase are critical and include (semi)-governmental parties like EDB or Temasek (Singapore's sovereign wealth fund) and commercial investors. The Agency for Care Effectiveness (ACE) is the national HTA body assessing the value of DHIs. Decisions on the adoption and funding of DHIs are made by MOH and end-users (e.g. health systems/practitioners or patients/clients).

FIGURE 6: STAKEHOLDERS IN SINGAPORE'S DIGITAL HEALTH ECOSYSTEM



Digital literacy in Singapore

1. Digital readiness blueprint

The Singapore Digital Office (SDO) set up under the Infocomm Media Development Authority (IMDA) - a statutory board of the Ministry of Communications and Information (MCI) - aims to accelerate digital adoption in Singapore. A vital aspect of the Smart Nation initiative is the government’s commitment to improving digital literacy, which is covered in the Digital Readiness Blueprint (**Appendix 3**).²⁰ This blueprint focuses on three key areas: digital access, digital literacy, and digital participation. It also covers aspects of fostering digital inclusion through DHI design.

TABLE 2: SUMMARY OF THE DIGITAL READINESS BLUEPRINT. ADAPTED FROM²⁰

	Digital Access	Digital Literacy	Digital Participation	Inclusion by Design
Strategic Outcomes	Every Singaporean has the means to transact digitally.	Every Singaporean has the skills, confidence, and motivation to use technology.	Every Singaporean makes use of technology to achieve a better quality of life.	Every digital product or service is designed for easy and intuitive use by all Singaporeans.
Strategic Thrusts	Expand and enhance digital access for inclusivity	Infuse digital literacy into national consciousness	Empower community and businesses to drive widespread adoption of technology	Promote digital inclusion by design
Recommendations	<ul style="list-style-type: none"> Make access to basic digital enablers as widespread as possible Customise access package for those with specific needs 	<ul style="list-style-type: none"> Identify a set of basic digital skills Strengthen focus on information and media literacy Ensure that Singaporean youth grow up learning to use technology to benefit their communities 	<ul style="list-style-type: none"> Encourage private and people sector to help Singaporeans adopt technology Provide one-on-one assistance to make it easy to adopt technology Provide support for projects that create enable community participation 	<ul style="list-style-type: none"> Encourage organisation to design for inclusion Ensure relevant digital services are made available in vernacular languages

2. Measurement of digital literacy

In Singapore, MCI defines digital literacy as “*having the knowledge, understanding, and attitudes to use technology safely, meaningfully, and responsibly*”. The Digital Media and Information Literacy Framework^{48,49} aims to guide creators of digital literacy programs about the critical skills to incorporate into curriculums to create a digitally literate and digitally-savvy population.

IMDA’s 2019 Survey on Infocomm Usage in Households and by Individuals reveals that 89% of houses have computer access, and 98% have internet access.⁵⁰ Singaporeans are generally regarded as being digitally savvy; however, there remain gaps, as demonstrated by several studies. In 2020, the Institute of Policy Studies

conducted a study to determine how susceptible Singaporeans are to false news.^{51,52} Results revealed that nearly 6 out of 10 participants trusted incorrect information and news articles when presented to them. Additionally, the lived realities during the COVID-19 pandemic brought the issues of Singapore's digital divide to the forefront. Vulnerable groups, such as the elderly, disabled, migrant workers, and low-income communities, are digitally excluded due to barriers to access and are more susceptible to cybersecurity scams.⁵³ While there does not seem to be transparent and concrete information about how the government measures digital literacy among Singaporeans, many independent studies by external bodies in Singapore have attempted to measure this, revealing the high rates of susceptibility to misinformation and the poor digital skills among vulnerable communities – two of the key areas that the government is targeting to improve digital literacy.

3. Programs to improve digital literacy

While there are a plethora of initiatives to improve digital literacy, some current and common initiatives include²⁰:

- SkillsFuture credit and courses for employees and the public cover basic digital skills such as searching for information online, accessing government e-services, and transacting digitally.
- Digital For Life program aims to create a digitally inclusive society by making digital learning a lifelong pursuit by spreading knowledge on cyber-security, media literacy, and mitigating the risks of online harms.⁵⁴
- Ministry of Education's (MOE) implementation of a cyber-wellness curriculum so that Singaporean youth grow up understanding the risks of the online environment.
- Scholarships and fellowships, like the Smart Nation Scholarship, encourage young citizens to build their IT skills.
- MOE's National Digital Literacy Program aims to refresh student curriculums and incorporate critical digital skills at all stages of education.⁵⁵
- Seniors and low-income citizens are key target groups for improving digital literacy. Some initiatives targeted to these audiences include delivering bite-sized IT courses, deploying Digital Ambassadors to provide customised support, and launching the Seniors Go Digital and Hawkers Go Digital initiatives.⁵⁶
- Inmates are also targeted to learn digital literacy skills as this will help this vulnerable community reintegrate with society, be accepted, and get employed after prison.⁵⁷

Overall, Singapore ranks first for digital inclusiveness among 82 countries worldwide, according to Roland Berger's Digital Inclusion Index 2020, and is taking proactive steps to ensure everyone can cross the digital divide.⁵⁸

Health technology assessment (HTA) and reimbursement process of digital health technologies

1. HTA methods and process guidelines for digital health

The Agency for Care Effectiveness (ACE) is the national HTA agency.⁵⁹ ACE conducts HTAs for drugs or medical technologies, which inform funding and coverage decisions made by MOH's Drug Advisory Committee (DAC) and MOH's Medical Technology Advisory Committee (MTAC), respectively. The general HTA process can be summarised in three steps:

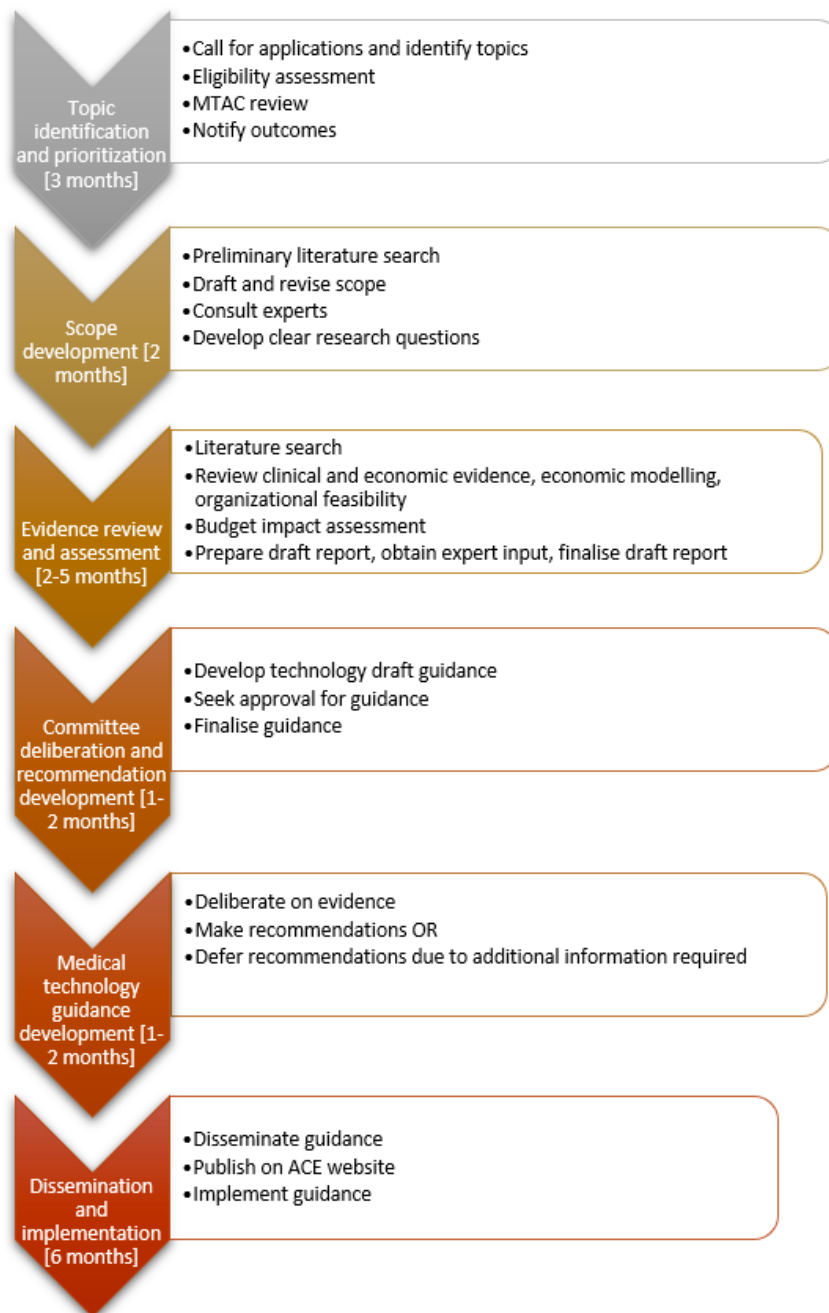
1. Topic selection: Public healthcare organisations submit topics for HTA and subsidy consideration, which ACE, DAC, and MTAC then select.
2. Technical evaluation: ACE conducts the HTAs and may request public healthcare organisations to submit supporting evidence.
 - Full evaluation: costly technologies with a high budget require a full evaluation. A budget of SGD 2 million per year is considered high. A full evaluation includes a systematic review and economic modelling to ensure the technology is clinically safe and can be cost-effective.
 - Expedited evaluation: An expedited evaluation can be conducted for technologies with a low budget impact and existing published literature on clinical safety and cost-effectiveness.
3. Decision-making: ACE, DAC, and MTAC make their collective decisions about financing technologies based on several parameters, including clinical needs related to the disease under investigation, clinical safety of the technology, the cost-effectiveness of the technology, and organisational feasibility.

2. Comparison of HTA for digital health with other HTA

HTA for medical technologies

Medical technologies can include but are not limited to medical devices, diagnostics, and medical services or procedures. There is no HTA process specific to digital health in Singapore; however, some DHIs may fall under the medical technology HTA route. Below is a detailed overview of the medical technology evaluation process.

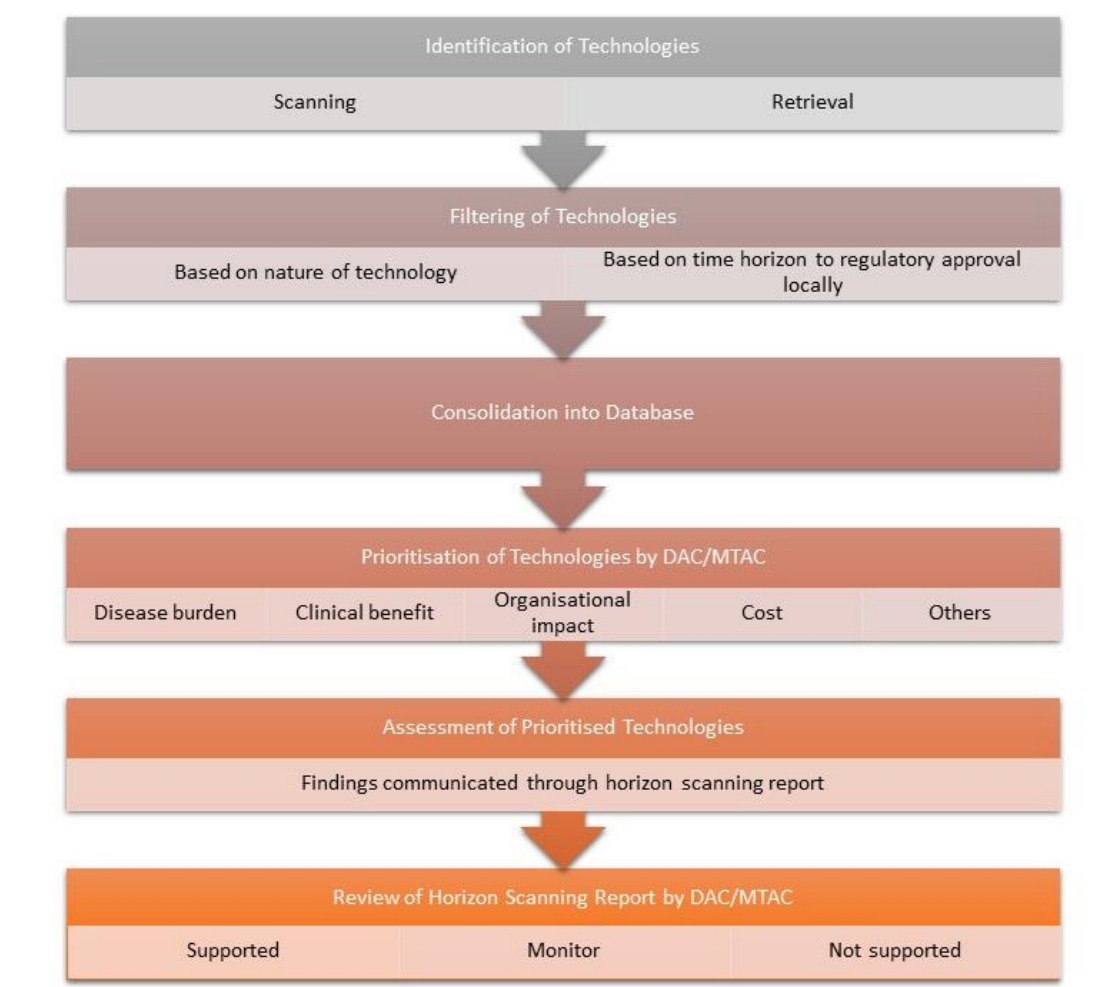
FIGURE 7: HTA PROCESS FOR MEDICAL TECHNOLOGIES. ADAPTED FROM⁶⁰



Horizon scanning system

For emerging technologies that are new, have high potential and impact on healthcare systems, and are of great interest to be further studied, ACE established a horizon scanning system (HSS) in 2019⁶¹. HSS represents a continuum of HTA and serves as an avenue for conducting early HTA.

FIGURE 8: HORIZON SCANNING SYSTEM. ADAPTED FROM⁶⁰



Given that ACE's horizon scanning program is still in its infancy, the framework will continue to evolve to ensure relevance. In 2019, telemedicine⁶² and AI⁶³ were nominated as potential topics of interest for horizon scanning.

Case study on ACE's horizon scanning of telemedicine ⁶²

About: Telemedicine is the remote delivery of healthcare services using information and communication technologies. Telemedicine models include store-and-forward telemedicine, hospital-based real-time telemedicine, and home-based telemedicine.

Regulatory landscape: As provided in HSA's telemedicine guidelines, HSA regulates telemedicine products that are considered medical devices. MOH released the National Telemedicine Guidelines to guide telemedicine services. The Healthcare Services Act will provide further regulatory and licensing measures for telemedicine in 2023. Nevertheless, regulation of cyber-security risks, international licensing, and cross-institute credentialing have not been addressed.

Current development in Singapore:

TABLE 3: STAGE OF DIFFUSION OF TELEMEDICINE IN SINGAPORE. SOURCE: ACE

Clinical application	Stage of diffusion
Tele-monitoring	Newly entered
Tele-stroke, tele-rehabilitation, tele-consultation	Nearly established
Tele-ophthalmology	Established

Case study continued on next page

Clinical evidence:

TABLE 4: EVIDENCE CATEGORIES FOR TELEMEDICINE TOPICS IN SINGAPORE. SOURCE: ACE

Category	Topic
A	Remote patient monitoring for chronic conditions
A	Communication and counselling for chronic conditions
A	Psychotherapy for behavioural health
B	Consultation for various clinical reasons
B	Applications of telehealth for acute/ICU care including remote patient monitoring and tele-monitoring
B	Maternal and child health
C	Triage for urgent and primary care
C	Applications in paediatrics (managing chronic serious conditions)
C	Applications related to the integration of mental and physical health
C	Impact of tele-dermatology on patient outcomes
C	Impact on cost and utilisation

Category A

- Sizable quantity of evidence, including several systematic reviews
- Consistent conclusions supporting the effectiveness of telemedicine; unlikely that future studies will disprove these conclusions

Category B

- Topics that would benefit from additional systematic reviews but have enough primary studies to constitute a body of evidence

Category C

- Topics with few primary studies conducted; unlikely to constitute a body of evidence
- Systematic reviews would risk being small and inconclusive until further primary research is conducted

Impact on cost: While there may be an initial high cost for set-up, telemedicine may be cost-effective due to improved patient outcomes due to increased preventive care and better allocation of healthcare resources. Nevertheless, there is a need for more studies on telemedicine's economic evaluation and cost-effectiveness.

Barriers to implementation: Implementation challenges include medico-legal liability, infrastructure and interoperability, data protection, cost, financing, and digital illiteracy.

Conclusion: The demand for and supply of telemedicine is increasing. While the financial and implementational challenges of rolling out telemedicine on a public scale

need to be addressed, telemedicine is of interest and will be continued to be monitored.

3. Examples of reimbursed digital health technologies

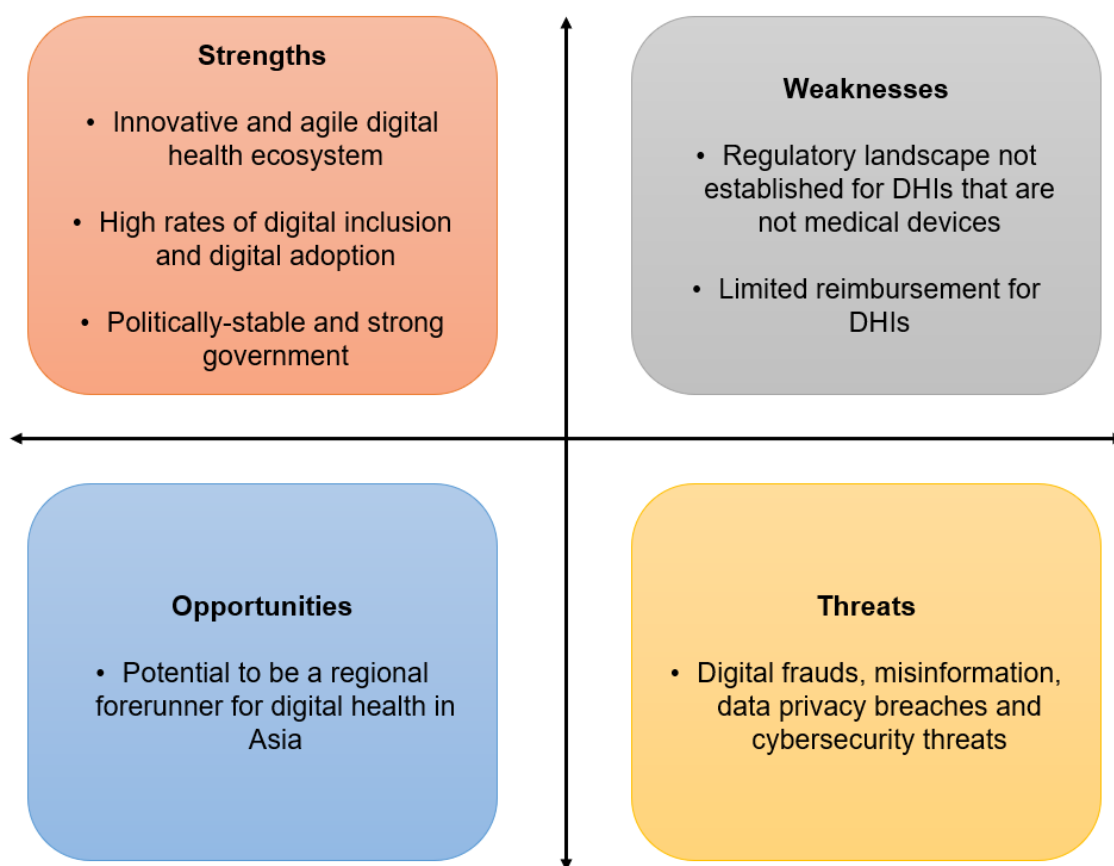
There are currently no established reimbursement pathways specific to DHIs. However, some technologies can benefit from already existing systems.

Under Phase 3 of the HCSA, which will come into effect at the end of 2023, telemedicine providers that meet MOH's requirements and safety guidelines will be licensed and may qualify for reimbursement.^{64,65} In the interim, MOH has listed telemedicine providers who currently meet MOH requirements. Telemedicine video consultations for regular follow-ups of all twenty chronic conditions listed under the Chronic Disease Management Program conducted by these listed providers can now be reimbursed using Community Health Assist Scheme (CHAS) subsidies and MediSave. This coverage expansion started in 2020 in response to COVID-19 to allow patients to receive care without physical visits. Findings from this coverage expansion will likely inform MOH's future reimbursement decisions for telemedicine.⁶⁶

During COVID-19, MOH also expanded patient subsidies for COVID-19 patients who requested telemedicine care; however, these subsidies will be progressively withdrawn in 2022 as Singapore enters the post-pandemic phase.⁶⁷

Lessons learned

FIGURE 9: SWOT ANALYSIS OF DIGITAL HEALTH IN SINGAPORE



1. Strengths

The digital health landscape is constantly evolving. To be receptive to these changes, Singapore has fostered an innovative and agile ecosystem for digital health.⁶⁸ For instance, regulatory sandboxes allow Singapore to pilot emerging technologies in a controlled environment to better understand their regulatory issues and risks. HSA's device development consultation scheme will enable manufacturers and researchers of DHIs to consult HSA regarding the regulatory guidelines to follow, thereby expediting patient access to novel technologies. This is important for DHIs which do not have an established and official regulatory process in Singapore. ACE's horizon scanning system has also been beneficial in identifying new technologies early and assessing their value, cost-effectiveness, and impacts. Such schemes allow for a flexible regulatory and financing digital health system, facilitating the supply of novel and beneficial DHIs in the Singaporean market.

On the demand side, Singapore is the most digitally inclusive country in the world and is equipping its population with tech-savvy and digitally literate skills. There is a high rate of digital adoption in Singapore, and the demand for wearable technology, integrated electronic health records, telemedicine, and mobile apps is also high. With the rising supply and demand for DHIs, Singapore is leading the way in championing digital health in the region.

Another factor that strengthens Singapore as a potential digital health hub is the presence of a proactive, politically stable, and strict government; a strong economy; and a safe business environment. These factors attract investors, private players, and other stakeholders in the digital health and innovation space to enter the Singapore market.

2. Weaknesses

The DHI landscape can be complex, involving regulatory, financial, and evaluative hurdles to cross.

The regulatory landscape in Singapore is well-defined with laws and guidance for digital health technologies that fall under the purview of medical devices. However, the regulatory and legal landscape for the many DHIs that do not fall under the medical device category is not established. In addition, Singapore's HSA has been put under the spotlight for not providing sufficient clarity about whether a DHI falls under the medical device category, making it difficult for manufacturers to navigate the regulatory requirements.⁶⁹

Regarding HTA and financing, there is no separate HTA committee or process for digital health. Currently, very few DHIs are publicly reimbursed. In addition, the transparency about reimbursement decisions by MOH needs to be improved so that stakeholders in the DHI market have more clarity on the processes followed and are more informed.

The WHO International Tele-communication Unit (ITU) National e-Health Strategy Toolkit recommends establishing a national e-health vision, developing an e-health action plan, and implementing monitoring and evaluation processes.⁷⁰ While Singapore has made progress in laying out a nation's digital health vision and plan through the Smart Nation initiative and HITMAP, processes to monitor and evaluate digital health tools need to be effectively implemented.

3. Opportunities

WHO's global strategy on digital health recognises the transformative potential of technology and the urgent need to harness technology to improve health equity.⁷¹ Through the Smart Nation initiative, Singapore has positioned itself firmly by building its digital capabilities early and integrating them into healthcare. Singapore's strategic geographical location, combined with its strong information technology infrastructure

and a favourable climate for innovation as a result of strong government support, makes it an ideal destination for an Asia-Pacific digital healthcare hub. Global multinationals, accelerators, and startups are increasingly interested in establishing the country as a base for addressing the emerging digital healthcare needs of people across several countries in the region.⁷³

4. Threats

While Singapore is rated as the most digitally inclusive country, there remain gaps. In particular, digital literacy among vulnerable communities is low and the spread of misinformation is high. The government needs to take active steps to address these gaps so that the proliferation of digital health serves as a boon and not as a bane in the form of increased cybersecurity threats and digital fraud.⁷⁴ The threat to individual data privacy is also a major concern, as evidenced by the COVID-19 contact tracing applications launched by the government to combat the pandemic. Later, it was revealed that the data originally collected for contact tracing was also being used by the Ministry of Home Affairs to police for criminal investigations. This resulted in a loss of public trust, as well as a decrease in the use of such digital health applications.

While this SWOT analysis aims to summarise the key points, it is in no way exhaustive or comprehensive. Overall, the demand and supply of DHIs in Singapore are high, putting the country on track to achieve its national digital health goals and emerge as a strong regional forerunner. Nevertheless, gaps exist in terms of specific regulatory, financial, evaluative, and literacy challenges.

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Appendixes

1. Digital Government Blueprint
2. Digital Economy Framework for Action
3. Digital Readiness Blueprint
4. Regulatory Guidelines for Artificial Intelligence
5. MOH National Telemedicine Guidelines
6. Regulatory Guidelines for Software Medical Devices and AI MD
7. Regulatory Guidelines for Artificial Intelligence