Digital Health Regulatory Framework in Southeast Asia

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I. BACKGROUND

This is the era where the world's population is connected to one another because information, communication, and technologies (ICT) are important and integral to our daily lives. Like a blessing in disguise, the COVID-19 pandemic has again reminded us of the benefits of digitally enabling sectors and activities.[1] ASEAN (Association of Southeast Asia Nations) is no exception. The countries in the region have increased their use of digital services by between 10 and 50 per cent on e-education, e-shopping, e-banking, and e-health, especially during the COVID-19 pandemic,[2] and this effect is likely to persist in the long term.

ICT played a big role during the pandemic across all ranges of sectors, but especially in health.[3] E-health or digital health, as defined by the World Health Organisation (WHO), is the use of ICT in improving health.[4] It encompasses a broad range of technologies, from mobile health apps to telemedicine. Digital health is important as it can reduce healthcare costs to families, improve equitable access to quality services, efficiently link health systems with social protection programmes, and increase accountability and sustainability of health service delivery.[5] Digital health can also promote healthy lives and wellbeing for everyone and everywhere,

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1. EU-ASEAN Business Council. Webinar - Fit-For-Purpose Regulatory Frameworks for Digital Health Post Covid-19: Opportunities for ASEAN. 3 May 2022 .

2. ASEAN. 2021. ASEAN Digital Masterplan 2025, p. 10.

3. Accessed 10 August 2023. (https://datareportal.com/reports/digital-2022-global-overview-report).

4. Accessed 2 August 2023. (https://www.who.int/health-topics/digital-health#tab=tab_1).

5. Ibid.

as it creates efficient and sustainable health systems, enabling the delivery of high-quality, affordable and equitable healthcare.[6]

Mr. Ekkaphab Phanthavong, ASEAN Deputy Secretary-General for the ASEAN Socio-Cultural Community, said: "ASEAN has experienced first-hand how digitalisation enabled ASEAN Member States to be nimbler and more adaptive to the COVID-19 pandemic".[7] He further encouraged the use of digital technologies for social welfare and reducing inequalities, especially in finding solutions to some of ASEAN's public digital health challenges, namely in optimising the technology skill sets of health practitioners and users, eliminating regulatory barriers, improving digital and health infrastructure and some other issues like privacy, safety, and ethical considerations.

This paper will provide an overview of the development of digital health in Southeast Asia, especially the regulatory framework. Some best practices from the WHO and the European Union's E-health policies will also be provided as comparison. In the end, the paper hopes to improve the digital health regulatory framework in Southeast Asia.

II. DIGITAL HEALTH IN SOUTHEAST ASIA

As mentioned previously, digital health uses ICT in improving health. Digital health has transformed the health ecosystem in the Southeast Asian region, including via telemedicine and digital health applications, digital system and big data analytics, and artificial intelligence (AI). Various websites and mobile applications have been established for telemedicine with the coverage ranging from urban to rural areas. Some examples of digital health applications are Indonesia's "halodoc"[8] and Malaysia's "Doctor2U" and "Doc2Us".[9]

The ASEAN BioDiaspora Virtual Centre[10] stands as a testament to leveraging digital systems and big data analytics to effectively tackle public health emergencies (PHE) within the ASEAN region. Notably, Brunei Darussalam has embraced the

6. Ibid.

7. Accessed 15 August 2023. (https://asean.org/regional-cooperation-multi-stakeholder-partnerships-key-to-aseans-digital-health-transformation/).

8. Halodoc. (https://www.halodoc.com/).

9. Doctor2U. (https://doctor2u.my/); Doc2Us. (https://doc2us.com/).

10. ASEAN BioDiospora Virtual Center. Accessed 19 December 2023. (https://asean-phe.org/phe-mechanism/asean-biodiaspora-virtual-centre-abvc/).

"One Patient One Record" initiative through its BRU-HIMS system.[11] This innovative platform consolidates medical data from various sources, including government hospitals, outpatient services, treatment centres, and clinics, into a unified electronic medical record, streamlining healthcare delivery and enhancing patient care.

AI's roles include monitoring and diagnostic systems, robotic services, and treatment through advanced technology. However, the adoption of AI is still in the early stages. Only a few systems are in the advanced stages of AI implementation; for example, Singapore utilises AI to support several services like pathology and medicine delivery.[12] Some other applications using AI-powered diagnostic and predictive systems to diagnose patients through chat include OneNUHS App and OneNUHS Health Chatbox.[13] AI is also used to help in the rapid diagnosis and early detection of high-risk patients. An Indonesian start-up named CekMata[14] used AI for detecting cataracts. In Thailand, IBM Watson supercomputer analytics[15] has been integrated into the oncology department at Bumrungrad International Hospital to advise doctors on the best treatment plans for cancer patients.

III. DIGITAL HEALTH REGULATORY FRAMEWORK IN SOUTHEAST ASIA

Digital health development in Southeast Asia has also been supported by national policies and frameworks.[16] As we can see in Table 1, some countries in Southeast Asia have already taken a further step towards digital health transformation through the implementation of digital health strategies, policies, or blueprints.

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11. BRU-HIMS. (https://www.moh.gov.bn/SitePages/Bru-HIMS.aspx).

12. ASCC. 2023. Transforming the Digital Health Initiative in ASEAN. (https://asean.org/wp-content/uploads/2023/02/ASCC_Policy-Brief_Issue_6_Jan2023.pdf).

13. OneNUHS App. (https://www.nuhs.edu.sg/For-Patients-Visitors/OneNUHS-App/Pages/default.aspx).

14. CekMata. (https://www.instagram.com/cekmata_ai/).

15. IBM Watson supercomputer analytics. (https://www.ibm.com/watson).

16. ASCC. 2023. Transforming the Digital Health Initiative in ASEAN. (https://asean.org/wp-content/uploads/2023/02/ASCC_Policy-Brief_Issue_6_Jan2023.pdf).

Table 1. Digital Health Strategy in Southeast Asia.

Countries	E-health Policies or Strategies
Cambodia	Cambodia Health Tech Roadmap (2022)[17]
Indonesia	Indonesia Digital Health Transformation Strategy 2024[18]
Lao PDR	Lao PDR Digital Health Strategy for 2023-2027 (in progress)
Singapore	Singapore Smart Health Initiative[19]
Thailand	Thailand Digital Health Strategy, Ministry of Public Health 2021-2025[20]
The Philippines	Philippines E-health strategic framework and Plan 2014-20*
Viet Nam	Viet Nam's Ministry of Health Decision No. 5316, 2020[21]

Source: Multiple (2023).
Note: * no information on the update.

The Cambodia Health Technology Roadmap[22] was endorsed by the National Council of Science, Technology & Innovation (NCSTI) on 8 July 2021. The roadmap is based on three interrelated and reinforcing visions, namely an integrated one health approach, multidisciplinary policy and governance and strengthening research and knowledge-sharing capacity. Cambodia's target for digital health is divided into three phases. In the short term, Cambodia may consider focusing investment on ensuring nationwide internet access and developing cloud computing facilities to support the increased digitisation of the health sector. In the medium term, targeted development of blockchain medical records and advanced telemedicine infrastructure will build on earlier technological upgrading to enhance service provision. The long-term ambition in 2030 is to create a health sector characterised by knowledge sharing and embodying the principles of One Health. This

17. National Council of Science, Technology and Innovation. 2022. Cambodia Health Tech Roadmap. (https://www.misti.gov.kh/public/file/202206301656579483.pdf).

18. Ministry of Health Indonesia. 2021. 2024 Digital Health Transformation Strategy. (https://dto.kemkes.go.id/ENG-Blueprint-for-Digital-Health-Transformation-Strategy-Indonesia%202024.pdf).

19. Smart Nation Singapore. 2023. Singapore Smart Health Initiative. (https://www.smartnation.gov.sg/initiatives/health/).

20. Thailand Ministry of Public Health. Digital Health Strategy. (https://ict.moph.go.th/upload_file/files/263bec94c161efb9d61d3b1116dee9a4.pdf).

21. Viet Nam's Ministry of Health Decision No. 5316, 2020. (https://vanbanphapluat.co/decision-5316-qd-byt-2020-medical-digitalization-program-until-2025-and-orientation-to-2030).

22. General Department of Science, Technology, and Innovation. 2023. Cambodia Health Technology Roadmap. LinkedIn. (https://www.linkedin.com/pulse/cambodias-health-technology-roadmap-/).

objective will be achievable through the adoption of crucial technologies. Cambodia has recognised the interlinked relationships between health, social and economic outcomes, and is thus committed to improving health with the support of technologies as part of its future prosperity and economic development.

The Indonesian Ministry of Health formulated the 2024 Digital Health Transformation Strategy, a blueprint which is based on the spirit of creating an *"Indonesia Sehat"* collaboratively with the entire ecosystem of health industry players in a *SATUSEHAT* platform (Indonesia Health Services). The Indonesia digital health blueprint focuses on the Indonesian digital health situation and challenges, digital technology transformation (technology, ecosystem, data, and governance), and health platform and architecture. The Ministry of Health is currently preparing the Digital Health Transformation Strategy (DHTS) 2025-2029 as a continuation of the health technology transformation being conducted from 2021 to 2024. The goal of the DHTS 2025-2029 is to ensure that the programme or the movement is sustained and continues to achieve its ultimate goal, namely improving public health.[23]

Previously, the Lao People's Democratic Republic (Lao PDR) had formulated an E-health strategy spanning from 2017 to 2021, but it did not receive endorsement from the Ministry of Health (MOH) of Lao PDR. Subsequently, the MOH sought assistance from the World Health Organisation (WHO) to revise this strategy to align with current needs and circumstances, engaging relevant stakeholders in the process. In January 2022, the MOH conducted a Dissemination Workshop on its Digital Health Strategy for 2023-2027. The workshop served to scrutinise key elements of the strategy, involve stakeholders, and disseminate it in both printed and digital formats to national and international audiences.[24] At present, there are no updates available regarding the progress of the digital health strategy development.

Singapore is at the forefront of embracing key digital health technologies, with notable advancements in artificial intelligence (AI), telemedicine, mobile health, data analytics, and integrated healthcare systems. Central to these efforts is the Singapore Smart Health Initiative, which aims to empower individuals with the knowledge and tools necessary to manage their health effectively, leveraging technology and robotics in healthcare delivery. Supporting this initiative are various digital health programmes and policies, including the Singapore one-stop health

23. Muhamad Sean, Raka Adji. 2023. Ministry Prepares Digital Health Transformation Strategy for 2025-2029. Antara News. Accessed 18 December 2023. (https://en.antaranews.com/news/298719/ministry-prepares-digital-health-transformation-strategy-for-2025-2029).

24. AeHIN. 2023. Lao PDR holds Digital Health Strategy (2023-2027) Dissemination Workshop, 13 February 2023.

portal known as HealthHub, the National Steps Challenge™ & Healthy 365 App, Project Pensive, aimed at early detection of dementia through technology, and tel-ehealth services designed to bring healthcare directly to homes. These initiatives underscore the Singaporean government's commitment to revolutionising health-care through digital innovation.

Thailand has demonstrated a steadfast commitment to advancing digital health, continuously striving to expedite and expand its digital health transformation to effectively tackle the challenges and capitalise on the opportunities presented by healthcare in the 21st century. The Thailand Digital Health Strategy serves as a pivotal mechanism for enhancing the national health system, encompassing a paradigm shift, restructuring digital technology operations, and fostering health innovation across all sectors. This strategic approach underscores Thailand's dedi-cation to modernising healthcare delivery and improving health outcomes through digital innovation.

Drawing from the Philippines eHealth Strategic Framework and Plan 2014-20, the Philippines aimed to foster extensive access to healthcare services, health information dissemination, and secure sharing and exchange of client data. This initiative aimed to bolster the provision of safer, high-quality healthcare, foster-ing a more equitable and responsive health system for all Filipino citizens. The overarching goal was to revolutionise the utilisation of information in planning, managing, delivering, and monitoring health services. While there is no explicit update on the plan for the upcoming years, continuity from the previous agenda is expected, reflecting the nation's commitment to advancing healthcare through digital innovation.

Viet Nam's Ministry of Health Decision No. 5316, 2020 approves the healthcare digital transformation scheme until 2025 and orientation to 2030, promoting the implementation of information technology and digital technology in all aspects of healthcare activities. The four key areas addressed in this scheme are state admin-istration, cashless payment and telehealth, disease prevention and primary care, and healthcare. Furthermore, Viet Nam's Ministry of Health is also focusing on three objectives in transforming healthcare, namely e-health infrastructure, elec-tronic medical records, and an online one-stop public health service system.

Despite the existence of national guidelines for digital health policy, Southeast Asian countries do not have any regional guidelines and standards. Although the health vision was indeed stated in the background for the ASEAN Digital Masterplan (ADM) 2025 creation and the health focus stated under desired outcome 1, the Masterplan was designed only to address COVID-19 pandemic-related global health

issues and the measures required to control it.[25] The ADM 2025, unfortunately, does not provide a clear strategy or outcomes that are specifically connected to the segment of digital health in the broad context.

Having a regional framework for digital health is important, especially in standardising and aligning data, harmonising digital systems, and improving interoperability, as it will leverage the potential for efficiently gaining electronic medical health records. For example, public and private hospitals in Southeast Asia (as part of ASEAN member states) may use different platforms and formats to encode medical data, which also come in different data formats, in recording a patient's medical history. Having the same data formats will allow all patients within Southeast Asia to easily share medical records in all hospitals within the region. In addition, patients need to feel safe and confident that the digital health services will be stored, used, and shared in a responsible manner. That said, hospitals and medical facilities in Southeast Asia must also comply with a set of standards and guidelines as provided at the ASEAN level to ensure that patient data records are safe and secure in whichever hospital they are going to within the region.

IV. INTERNATIONAL STANDARD AND BEST PRACTICES

World Health Organisation

The WHO[26] has four strategic objectives for digital health (Table 2 below). The four strategic objectives are intended to provide guidance and coordination on global digital health transformation and to strengthen synergies between initiatives and stakeholders to improve health outcomes and mitigate associated risks at all levels: "Promoting global collaboration and advance the transfer of knowledge on digital health, Advancing the implementation of national digital health strategies, Strengthening governance for digital health at global, regional, and national levels, Advocating people-centred health systems that are enabled by digital health."

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25. Ibid, p. 8.

26. WHO. Global Strategy for Digital Health 2020-2025. (https://apps.who.int/iris/bitstream/handle/10665/344249/9789240020924-eng.pdf).

Table 2. WHO Strategic Objectives for Digital Health 2020-2025.

Strategic Objectives	Outputs
1. Promote global collaboration and advance the transfer of knowledge on digital health	1) digital health is prioritised and integrated into health systems at global, regional, and national levels through dedicated bodies and mechanisms for governance. 2) multi-stakeholder groups are convened on a regular basis to support the appropriate use and scaling up of digital health and innovation to accelerate progress towards the health-related Sustainable Development Goals. 3) information centres for disease surveillance are established or strengthened at national, regional, and global levels.
2. Advance the implementation of national digital health strategies	1) a national digital health strategy or equivalent strategic framework exists, is integrated in the national health strategy, and is actively used to guide development and accelerate progress towards the health-related targets of the Sustainable Development Goals and in the context of digital transformation of health systems; and 2) a dynamic digital health maturity model assessment to guide prioritisation of national investment in digital health is made in support of primary health care and universal health coverage.
3. Strengthen governance for digital health at global, regional and national levels	1) governance exists, in accordance with Secretariat-led development of regulatory framework, to agree on global appropriate use of health data and on concepts such as health data as a global public good and to outline principles of equitable data-sharing principles for research, consistent metadata and definitions, artificial intelligence and data analytics, and primary and secondary use of data. 2) a voluntary guideline on global interoperability standards for digital health is developed in collaboration with stakeholders and adopted, that: a) tries to build upon results already broadly achieved, b) includes a list of commonly agreed use cases for the public health care sector, its functional requirements and a set of functional and technical specifications, standards, semantics and profiles derived thereof, c) defines requirements for a sound legal and regulatory framework with clearly defined roles for data governance and d) encompasses political leadership regarding public investment, procurement and standardisation to create an interoperable digital health ecosystem at the national and international levels; 3) global guidance on planning, development and use of digital hospitals, digital clinical trials and digital therapeutics is developed; and 4) a set of recommendations is developed for pseudonymisation and anonymisation of health data.
4. Advocate people-centred health systems that are enabled by digital health	1) improved digital health literacy in using and understanding digital health technologies and systems as well as health data is prioritised, and the validated tools are accessible by all populations. 2) a framework allowing individual feedback in validating the performance of digital health tools and services, diffusion of increasing digital health demand is implemented and used. 3) global minimum health data standards for prioritised digital health technologies and processes are established, adopted, and applied at national level; and 4) global guidance on personalised medicine is developed.

Source: WHO (2020).

In addition to the four strategic objectives for digital health, the World Health Organisation together with the International Telecommunications Union (ITU) released the National eHealth Strategy Toolkit.[27] The toolkit is a practical guide that provides governments, their ministries and stakeholders with a solid foundation and method for the development and implementation of a national eHealth vision, action plan and monitoring framework.

Table 3. WHO-ITU eHealth components.

Leadership and Governance			
Strategy and Investment	Services and applications	Legislation, Policy and Compliance	Workforce
	Standards and interoperability		
	Infrastructure		

Source: WHO-ITU National eHealth Strategy Toolkit (2012).

The most critical part in the toolkit is **leadership and governance** because adequate governance is important for encouraging the growth of the digital health industry. It will direct and coordinate national-level digital health, as well as multisector engagement and specification of roles. The next component in this toolkit is **strategy and investment**, which entails responsive strategy, planning, and financing for the digital health environment. These include identifying financing needs and sources, such as from the government, private sector, and donors. The **legislation, policy and compliance** component is described as the development and adoption of national policies and legislation aiming to establish trust and protection for digital health consumers and the industry, and includes: ensuring adequate service quality, data privacy, and reimbursement. Compliance to these regulations should be prioritised through periodic accreditation of digital health products and services. Furthermore, due to the digital divide across a country, ICT **infrastructure** represents another challenge in implementing telemedicine. The internet can be very costly due to the absence of competition. It is important to ensure service quality and to keep prices low by promoting competition. The **workforce** component entails the improvement of digital skills and literacy through education, technical cooperation, establishing relevant networks, and collaborations with the private sector. Digital literacy for the public is the aim and main focus of this component. It is also crucial to introduce **standards** that allow for accurate

27. WHO-ITU National eHealth Strategy Toolkit. 2012. Available at: (https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf).

and consistent data collection to exchange information across systems, so as to effectively transform the digital health landscape. The last component, **services and application,** involves brainstorming and working sessions to develop digital health products that can solve health issues.

European Union

The European Union (EU), as another regional organisation, has also been working to provide its citizens with access to safe and top-quality digital services in health and care.[28] The European Union's digital transformation of health and care centres on three core priorities. First, it focuses on ensuring citizens' secure access to their health data, both within their own countries and across borders, facilitating seamless access to health information throughout the EU. Second, it aims to advance personalised medicine by establishing a shared European data infrastructure, enabling collaboration among researchers and healthcare professionals across member states. Third, the EU prioritises citizen empowerment through digital tools, promoting person-centred care and fostering active engagement between individuals and healthcare providers.

The European Union's dedication to leveraging digital technologies to empower individuals, enhance healthcare services, and foster cross-border cooperation in the health and care sector is evident through its prioritised initiatives. With a focus on ensuring secure data access, establishing shared data infrastructure, and enabling citizen empowerment through digital tools, the EU aims to cultivate a more integrated and responsive healthcare ecosystem. This approach aims to meet the diverse needs of EU citizens while fostering a culture of innovation and collaboration among member states. Central to these efforts is the EU's unwavering commitment to prioritising the sharing of health data across borders. By facilitating seamless access to health information for EU citizens regardless of their location within the region, the EU seeks to promote continuity of care and facilitate informed decision-making. This commitment underscores the EU's vision of creating a unified healthcare landscape that utilises digital technologies to improve accessibility, efficiency, and quality of care while promoting greater cooperation and solidarity among member states.

28. EU. 2023. Shaping Europe's Digital Future. (https://digital-strategy.ec.europa.eu/en/policies/ehealth); EU. 2023. (https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en).

To realise the full potential of the health data, the European Commission presented a proposal to enact a regulation to set up the European health data space.[29] This proposal advocates for empowering individuals to manage their health data autonomously, facilitating greater autonomy and agency in personal healthcare decisions. Additionally, it advocates for leveraging health data to enhance healthcare delivery, spur research advancements, foster innovation, and inform policy-making processes. By promoting the safe and secure exchange, utilisation, and reuse of health data, this initiative positions the EU to fully capitalise on the potential inherent in harnessing health data for the collective benefit of its citizens and the advancement of healthcare systems.

V. CONCLUSION AND RECOMMENDATIONS

ASEAN member states have made significant strides towards digital health transformation at the national level, with many countries having already established their own comprehensive strategies, policies, and blueprints. Examples include Cambodia's Health Tech Roadmap (2022), Indonesia's Digital Health Transformation Strategy 2024, and Singapore's Smart Health Initiative, among others. However, while countries like Laos are in the process of developing their digital health strategies, there remains a lack of uniformity in the current landscape of digital health readiness across ASEAN member states. Despite individual efforts, the ASEAN Digital Masterplan 2025 (ADM 2025) currently lacks a clear strategy or outcomes specifically linked to digital health. This highlights the need for a regional framework that standardises and aligns data, harmonises digital systems, and improves interoperability. Such a framework would facilitate efficient access to electronic medical health records and enhance the overall effectiveness of digital health initiatives across the ASEAN region. By addressing these challenges collectively, ASEAN can leverage the full potential of digital technologies to improve healthcare delivery and outcomes for all its citizens.

Aligned with the WHO Digital Health Framework, digital health policies across Southeast Asian countries underscore a commitment to collaboration and knowledge sharing, aiming to propel the effective implementation of digital health strategies. Furthermore, within ASEAN, member states collectively prioritise enhancing governance structures at both national and regional levels. Leveraging

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29. European Commission. 2022. Regulation of the European Parliament and of the Council on the European Health Data Space. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197).

resources such as the WHO and ITU's National eHealth Strategy Toolkit, ASEAN can systematically evaluate and gauge the readiness of countries in embracing digital health initiatives. This comprehensive approach serves as a guiding framework to identify areas for improvement and to advance all facets of digital health within each member state. By adopting a holistic perspective, ASEAN stands poised to optimise the potential of digital health technologies, fostering innovation and enhancing healthcare delivery across the region. Through collaborative efforts and informed governance, member states can leverage shared resources and best practices to bolster their digital health infrastructure. This collective approach not only facilitates the assessment and enhancement of digital health readiness but also fosters a conducive environment for sustainable progress and equitable access to healthcare services throughout Southeast Asia.

Looking beyond the ASEAN region, the European Commission's proposal to establish a regulation for the European health data space offers valuable insights for ASEAN countries as they develop their own regional digital health service framework. This EU initiative, which focuses on standardising a digital health framework within Europe, emphasises the safe and secure exchange, utilisation, and reuse of health data to maximise its potential benefits for citizens and healthcare systems. The promotion of such practices can serve as an encouraging example for ASEAN to explore opportunities for exchanging health data across the region.

In drafting a regional framework for digital health services, ASEAN can draw inspiration from the European Commission's approach while considering the unique needs and challenges within the ASEAN context. By prioritising data security, interoperability, and collaboration among member states, ASEAN can create a robust framework that facilitates seamless exchange and utilisation of health data for the betterment of healthcare delivery and outcomes across the region. Additionally, leveraging lessons learned from the EU's efforts can help ASEAN navigate the complexities of digital health governance and foster greater trust and cooperation among member states.

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