TAIWAN DIGITAL HEALTH

Considerations for fostering the best ecosystem

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PREFACE

At the time of writing, Taiwan is experiencing its largest COVID-19 outbreak so far.
It was a major achievement to keep the virus at bay for almost 17 months, but on May 16, 2021, Taiwan entered a level three (out of four) lockdown. At the same time, hospitals and the entire healthcare system are stretched thin under the rising number of patients in emergency wards and deaths from COVID-19 related complications.

This new reality for Taiwan is one most countries have been and continue to grapple with. Looking post-pandemic, the Healthcare industry across the globe is adamant that it will not return to the "old ways;" innovations that may remain include remote monitoring of clinical studies, the use of digital endpoints, legalizing telemedicine and ePrescriptions, and patients' newly discovered "superpowers" as they embrace new technologies and co-own aspects of health-related decision-making. Around the world, industry and users looking back at the way things were done up to 2019 are unimpressed and hungry for transformation, a digital transformation.

If the painfully long months of the pandemic were to be remembered in any "positive" light, the incentive to innovate and take risks would be at the very top. The outcome of such urgency was unprecedented systemic and institutional flexibility but also self-discovery and appreciation of the range of the possible.

As the pandemic fades away, the desire to relax back into normalcy notwithstanding, it is crucial to continue the efforts to make digital health products more accessible. These solutions have the potential to help alleviate other, equally significant, public health crises such as mental health, chronic diseases, and degenerative diseases.

EXECUTIVE SUMMARY

Taiwan occupies a unique position in the Asia-Pacific region. As a middle-income society, it is a suitable environment for incubating novel digitalization concepts. The market size is ideal for a first launch in Asia, the population well versed in technology, internet access is considered a human right, and open data governance is one of the many expressions of local policies promoting transparency, accountability, and value creation. In addition, there is consistent and continuous government support for digitization and digitalization through funding, new policy making, or cross-agency collaboration.

The island is particularly well positioned to lead the region in breakthrough, patient-centric, and evidence-based digital health solutions. For the past two decades, Taiwan has maintained very high satisfaction rates for its National Health Insurance program. The local regulatory agency, the Taiwan Food and Drug Administration (TFDA), is a trusted industry partner and the information and communications technology (ICT) industry, one of the largest in the world, is quickly expanding into digital health innovation. Nonetheless, so far Taiwan has not been able to build a true competitive advantage and differentiate itself from regional and international players. Local digital health innovators are looking with envy to Singapore and South Korea, while Venture Capital and large multinational partnerships and investments into digital health remain slow to come.

This white paper discusses missing links in existing structures and efforts that would be required to propel the digital health industry in Taiwan. Most importantly, recommendations based on initiatives taken in leading digital health markets such as the US, Germany, France, and the UK are presented as approaches worthy of consideration for accelerating digital health transformation.

The points below summarize the article's key recommendations:

- Creation of a cross-agency advocate for digital health within the government
- Creation of an e-Health platform, a one stop shop where manufacturers, regulators, insurers and other players can work together to support digital health innovators
- Establishment of a road map for development, certification, approval and reimbursement specific to digital health solutions
- Definition of pre- and post-market regulations designed to support the quick launch of digital solutions while ensuring patient-centricity

TAIWAN, THE HEART OF ASIAN INNOVATION

Digital health encompasses several modalities of information and telecommunication technologies used to deliver medical care, enhance access, improve value, and reduce gaps in care by allowing patients to access doctors remotely, which reduces the number of high-cost visits and/or emergency hospital admissions [1].

Following the expansion of digital health as a result of the COVID-19 crisis, it is predicted that the sector will see significant growth in the next few years with up to $250 billions of current US healthcare spend having the potential to be made virtual. By 2025, global spending on digital health is predicted to reach $1 trillion, while digital products and services will grow to a market share of 12% [2].

The Asia-Pacific region is home to 4.5 billion people, two thirds of the global population. The region is expected to drive the next decades in global GDP growth, innovation, and human development [3]. As such, Taiwan has a distinct leadership role to play in digital health with its home-grown expertise in both information and communications technologies (e.g., electronic, and optical component manufacturing and software services etc.) and medical care.

In recent years, government efforts have concentrated on establishing large innovation clusters such as the National Biotechnology Research Park, inaugurated in 2018, and the Hsinchu branch of National Taiwan University Hospital, which opened in 2019. In addition, several industry plans were put in place to promote multidisciplinary innovation, with Biomedicine as a key focus area, including the "Five plus Two" innovative industries plan and the “Six Core Strategic Industries” program. These initiatives will help Taiwan transition from contract manufacturing to high-value-adding services and build on its established data technology and telecommunications expertise [4]. Furthermore, Taiwan intends to advance its health maintenance, disease prevention, diagnostics and therapeutics programs as well as take early advantage of the global post-pandemic supply chain transformation to position itself as a key player in the world economy [5].

A tech-savvy population

According to the Taiwan Network Information Center, in 2019 the internet penetration rate stood at 93% of the population, with 98% of users connecting to the World Wide Web through a mobile phone. In addition to a higher than the global average e-commerce use rate, the annual market growth rate of online shopping is also on the rise from 12.4% in 2017 to an estimated 16.5% in 2020 [6]. As a percentage of all sales transactions in Taiwan, e-commerce accounts for 9% of all transactions, similar to levels in the United States and Germany [7]. These are all indicators of Taiwan’s readiness for a digitalization level comparable to that undertaken by top global healthcare systems (See Table 1).

	Taiwan	France	Germany	UK	US
Smartphone penetration rate[1]	98.7%	77.6%	77.9%	78.9%	81.6%
Universal healthcare coverage	Yes	Yes	Yes	Yes	No
Healthcare system	Largely funded by the government	Largely funded by the government	Private (PKV) and Public (GKV)funding	Largely funded by the government	Largely private with federal and state programs
Healthcare spending as part of GDP[2]	6.5%	11.6%	11.43%	10%	16.89%

Table 1 : Comparison of smartphone penetration, type of healthcare system and expenditure as part of GDP

HEALTHCARE FOR ALL

National Health Insurance: A well-managed and reliable system

Taiwan adopted a single-payer care system in 1995. The National Health Insurance System is funded by the government, employers and the insured based on their income. It is a system with low costs at the point of care and is accepted by the majority of Taiwanese as well-managed and reliable [8, 9].

With a universal health coverage of 99.9% [10], Taiwan's NHI is one of the most comprehensive social welfare programs in Asia. It offers extensive population coverage with high accessibility, reasonably low cost with unlimited freedom of choice, over 25,000 healthcare providers, and short waiting times. It takes only a couple of weeks to get a major surgery at a location of the patient's choice. The agency also runs a national health insurance databank used for planning, monitoring, and evaluating health services.

Amidst the outbreak and spread of COVID-19, the experience and capabilities of Taiwan's healthcare industry have been critical to the commendable and globally praised response. Taiwan's leading position in data management and use for clinical and public health purposes was of great help in this regard. NHI's MediCloud System was at the heart of Taiwan's successful first

[1] www.statista.com
[2] The world bank and NHIA

COVID-19 response. In the early stage of the outbreak of COVID-19, NHIA quickly turned the MediCloud System into a platform to share the travel and contact history of subscribers (see Figure 1).

Figure 1 : NHIA's MediCloud System[3]

This is an excellent example of digital health helping care providers efficiently and cost-effectively aggregate and analyze data, facilitate care coordination, and enable patient communication, self-management, and education. However, despite NHIA's great healthcare achievements, the system continues to vary in quality of care across the country, while weak gatekeeping processes contribute to increased financial pressures [9].

[3] Taiwan's Experience: Medical Information Sharing, Prof. Po-Chang Lee, NHIA, presented at the France-Taiwan Forum on Digital Health organized by La French Tech Taiwan and BPIPO on May 5, 2021.

Rising Health Expenditure

As life expectancy increases and chronic conditions become the norm, moving from reactive to proactive illness prevention is an inevitable transition for most mature healthcare systems. These conditions will exacerbate existing gaps like shortages in supplies and healthcare professionals, outdated infrastructure and the lack of agile policies easing the move from patient-focused healthcare systems to population well-being.

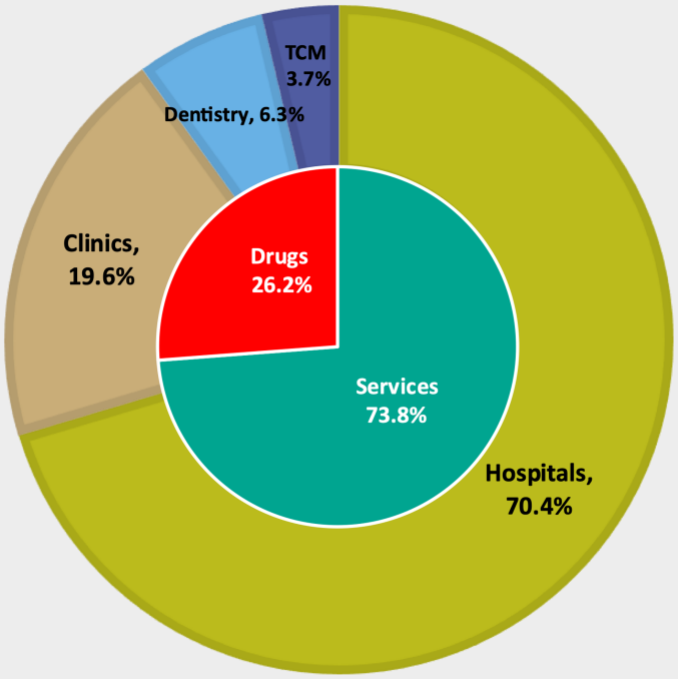

Figure 2 : NHIA's expenditure breakdown - Services and drugs budget[4]

Although NHIA has maintained a high satisfaction rate, with an average level of over 80% since its creation, a rapidly aging population and very low fertility rate of 1.07 births per woman in 2021, in combination with hospitals being the dominant resource for drugs and services (See Figure 2), health expenditure is on the rise and NHIA's reserve fund at its lowest since the program's inception (See Figure 3).

According to the 2019 NHIA report, renal disease, diabetes, and hypertension are among the top ten most expensive health conditions in Taiwan. The spending for these chronic diseases alone is around 14.5 % of the total annual national health expenditure (NHE) (See Table 2).

[4] NHIA 2021 budget announcement

Ranking	Diseases	No. of patients (k)	Amount (Unit: million Euro)	% In NHE
1	**Acute renal failure or chronic renal disease**	**422**	**1586**	**7.01**
2	Oral or Salivary gland disease	11829	1365	6.04
3	**Diabetes**	**1655**	**986**	**4.36**
4	Acute Upper Respiratory Tract Infection	14110	777	3.44
5	**Hypertension**	**2578**	**712**	**3.15**
6	Malignant neoplasm of digestive organs	179	616	2.72
7	Cerebrovascular disease	426	589	2.61
8	Ischemic heart disease	580	585	2.59
9	Influenza and pneumonia	2038	504	2.23
10	Persons encountering health services for specific procedures and health care	297	443	196

Table 2 : Top 10 diseases of the National Health Expenditure in 2019[5]

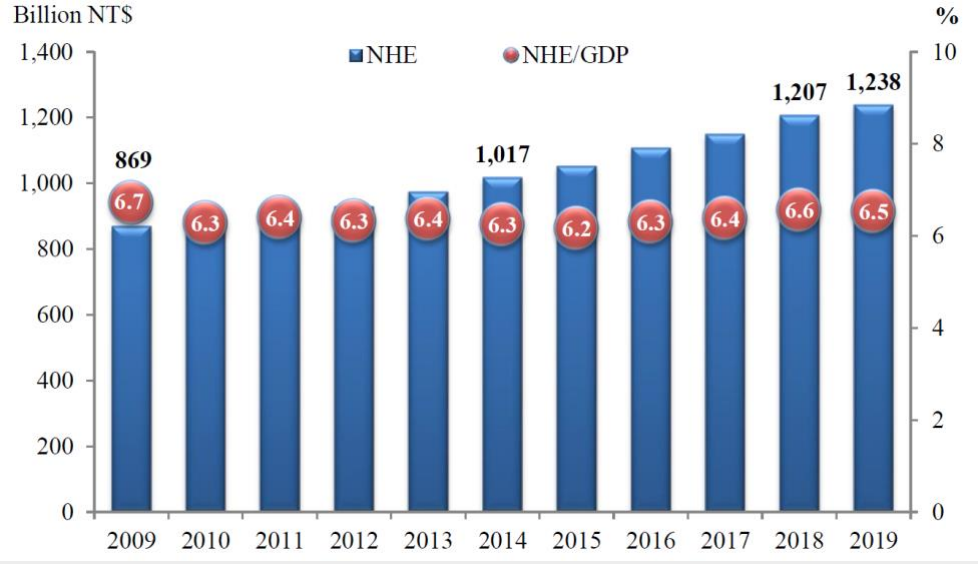

Figure 3 : NHE increase and NHE/GDP ratio from 2009 to 2019[6]

[5] 1 EURO=34.19 NTD, NHIA report 2019
[6] NHIA budget 2021

A sensible way of addressing the expenditure gap, estimated to an average yearly increase[7] of 4-5%[8] over the past decade, could be through better chronic disease management, currently accounting for almost 15% the yearly expenditure (see Table 2), a path many advanced countries have undertaken by enabling evidence-based digital health solutions.

This can be achieved by empowering patients and their families, peers, and caregivers with shared decision making (SDM) tools. The digital health solution is no longer a simple platform to monitor patients, instead it becomes a long-term communication bridge between healthcare providers and patients, moving the point of care from the hospital to the patient. Moreover, digital health for population health management recognizes wider determinants of health: individual behaviour accounts for 40-50% of a person's (or population's) relative health, physical and social environment for 20%, genetics 10-20%, and medical care 10-20% [11, 12].

Digital health is also an opportunity to move from cost-based payment systems to outcome-based systems. A single health insurance system has many advantages, it is more stable than private insurance and guarantees baseline healthcare service for all citizens equally. However, as the sole health insurance system available, it is highly unlikely that subscribers will get new, non-reimbursable drugs or new medical devices and technologies. As such, digitalizing the healthcare system ensures lower costs, better outcomes for patients, improved patient satisfaction, and better cost control.

FROM DIGITAL DIVIDE TO DIGITAL CONVERGENCE

So far, NHIA has demonstrated a clear understanding of the necessity of using digital solutions to address public health crises. In the latest COVID-19 outbreak, the institution entrusted patients and healthcare professionals with absorbing and adhering to new digital tools.
For example, NHIA allowed patients to register virtual visits and get ePrescriptions, something that was not legal under the Physicians Act. Prior to the pandemic, a physician could not treat, issue a prescription, or certify a diagnosis unless the patients were seen by the physician in person, except for patients in remote areas or in urgent circumstances. This effort was complemented by the establishment of an NHIA code, "ViT-COVID-19", for doctors to use [13]. As a result, NHIA expanded the reimbursement of virtual visits and prescriptions for patients under quarantine, chronic diseases, and unmet needs for a total of 4012 healthcare providers [14]. These initiatives are, however, set to expire once the public health emergency is lifted.

Taiwan is one of the very few examples of centralized healthcare databases for a population of over 20 million people. NHIA has tracked healthcare data for Taiwan's entire population since its inception over 25 years ago. As of July 2019, a total of 2.47 billion medical examination reports had been collected. To manage this large amount of medical expenditure data and improve review accuracy, Taiwan's Ministry of Health and Welfare allowed access to its medical imaging database to biotechnology and healthcare firms as well as use AI-based tools to review health insurance benefits [12, 15]. However, this data can only be accessed on-site, and must be part of projects

[7] Yearly NHIA budget data
[8] NHIA annual budget announcements

undertaken in collaboration with local Professors and/or research institutes[9]. While a great step towards digitalization, such siloed efforts can become hurdles that slow down digital health innovation.

Instead, a consolidated, collaborative and risk-based model to support digital health innovation could look as follows:

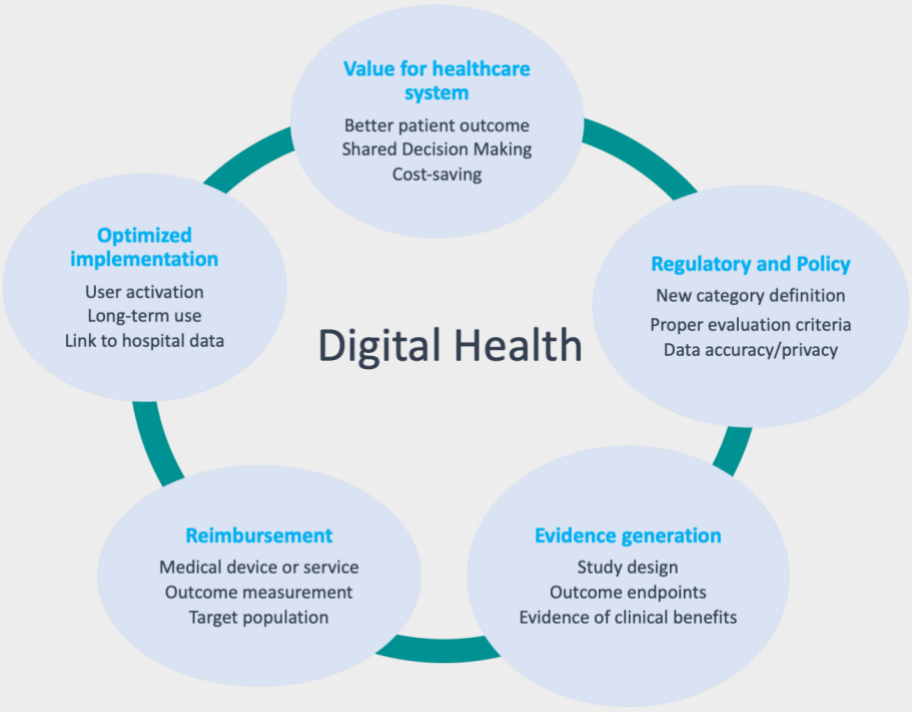

Figure 4 : A model for digital health innovation

Real World Evidence

RWE can be defined as "Insights generated from Real-World Data using appropriate scientific analytics with the intention to support a claim or belief, for which a hypothesis is usually formulated in advance" [16].

Digital health and RWE evolve interdependently from each other, whereby digital data is used to generate RWE and RWE further drives digital innovation and adoption. For example, Software as Medical Devices (SaMDs[10]), that make up a large proportion of patient facing digital health smartphone Apps, "learn" by using real world data to generate real world evidence. This data is first

[9] Leveraging Medical Resources in Taiwan, interview with Prof. Yu-Chuan Jack Li (李友專) at HealthForAll, October 2020

[10] IMDRF defines Software as "a Medical Device (SaMD) as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

consented by patients and caregivers, collected, stored, transmitted, aggregated, and analysed for evidence generation for stakeholders (payers, insurers, and regulators) decision-making process and use. Nevertheless, there are many challenges linked to the use of RWE in digital health, these range from patient ease with data sharing, to regulator/insurer position on "digitally derived endpoints" and lack of regulatory clarity regarding RWE requirements [16].

Some actions can be taken by regulators and payers to support the use of RWE, most directly achieved through clearer requirements and open access to past regulatory decisions. These will guide health developers when deciding the tools and criteria to conduct analysis, ensure that the techniques applied during analyses are rigorous and provide consistency across individual reviewers. This will also have the effect of increasing commitment to digital technologies by influencing future payer decisions through proven post-market effectiveness.

Placing Digital Health Solutions on the Market

According to ICLG, a platform for legal reference, there is no clear definition of "digital health" under Taiwan law. Similar to advanced markets, the manufacturing and sale of a medical device requires a market approval granted by Taiwan FDA [13]. In early 2020, Taiwan's congress passed the new Medical Device Management Act (MDMA) intended to separate the regulation of medical devices from the existing Pharmaceutical Affairs Act, which regulated both drugs and medical devices up to that point. The Act came into effect on May 1, 2021 [13].

To transform its healthcare system, Taiwan is relying on its complete semiconductor and ICT industry supply chain, in addition to investing in innovative digital health technologies using big data, artificial intelligence (AI)/machine learning (ML), biomedical chips and sensors. [15]. To support this effort, on May 7, 2021, the Taiwan Food and Drug Administration (TFDA) launched the Medical AI Preparatory Office, a new structure that aims to regulate and enable the commercialization of AI/ML-based digital health solutions with an advisory committee to accelerate review time, programs to train cross-industry talent, and integrated e-platforms.

These developments notwithstanding, so far only three Software as Medical Device (SaMD)-based digital health solutions were approved in Taiwan. In one example, DeepCT obtained approval in February 2020 for a technology to identify intracerebral hemorrhage in non-contrast CT (NCCT) scans and help prioritize urgent cases to alleviate the time pressure in emergency rooms. Interestingly, DeepCT obtained clearance by the US FDA, through a 510(k) process, six months prior to being approved in Taiwan. TFDA requirements are often perceived as more stringent which can have the unintended effect of preventing start-ups from first seeking approval in Taiwan. This is also exacerbated by a relatively new trend of investors requiring regulatory clearances or high degrees of confidence of obtaining one as part of the due diligence process. In other words, as a fund-raising strategy, digital health start-ups may have to first secure a US FDA clearance then use that to obtain Taiwan FDA approval.

TFDA is making efforts on this front: six months after the first SaMD was cleared, VeriSee DR, an AI-assisted solution for Diabetic Retinopathy (DR) identification developed by Acer Healthcare, was approved in September 2020 with no prior US FDA clearance. Furthermore, in May 2021 TFDA's

green light went to an AI-based COVID-19 diagnostic solution, which was granted special public health emergency authorization under the Medical Devices Management Act (MDMA) as a fast diagnostic tool to identify COVID-19 cases by detecting chest infections on X-ray images [17], intended for use alongside PCR or rapid antigen testing.

To summarize, the regulatory pathways for digital health device commercialization in Taiwan remain unclear. The same is true for reimbursement schemes and criteria. Further transparency around and user input into value-judgement decisions by regulators and insurers are needed to reduce uncertainty around regulatory pathways and reimbursement strategies.

Fueling Digital Health Innovation

Healthcare systems culture and administrative boundaries can contribute to organizational and structural fragmentation. The global pandemic had a positive effect on the "distrust" that sometimes exists between health purchasers, care providers, and industry. The level of cooperation witnessed between the pharmaceutical and MedTech industry, regulators, and healthcare systems was unprecedented.

During the May 2021 forum organized by La French Tech Taiwan and the Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) on the theme "Fostering the Best Digital Health Ecosystem in Taiwan" key stakeholders and contributors joined the effort to establish a common understanding of digital health, its scope, potential and the regional landscape, underscoring the importance of adaptive policies for capability- and capacity-building in the region. At this meeting, NHIA reaffirmed its commitment to reimbursing all innovative technologies with proven clinical outcome regardless of "whether they are drugs or Software as Medical Device (SaMD)."

While Taiwan has one of the best healthcare systems in Asia, with extensive data management systems (e.g., the centralized database for the national health insurance), it has not yet put in place digital health specific regulations, funding schemes and platforms that bring patients, innovators, industry, and regulators together. This can only be achieved through significant investment programs to support digital health initiatives. Governments in leading digital health markets have been heavily investing in the field, with the latest coming from France where President Macron announced the "Health Innovation 2030" program, co-funded by private and public entities up to 7 billion euros, of which 600 million euros will be dedicated to supporting digital health initiatives [18]. This comes on top of an EU-funded program, EU4Health, of 2 billion euros to support digital health initiatives in France alone, including 600 million euros for organizational restructuring [19].

BUILDING ON BEST MODELS FOR DIGITAL HEALTH

Despite clear indicators of market maturity, Taiwan still lacks guidelines for digital health product registration, clinical evidence requirements, dedicated funding and reimbursement schemes, and integrated platforms. For example, TFDA's effort to create an office for assessing AI Medical Devices was not matched with insurance coverage. In 2021, NHIA allocated 100 million TWD (~3MEUR) to telemedicine; while this is a good starting point, other digital health solutions are still un-assessable and inaccessible. Digital health solutions being actively developed now, are likely to continue to

face funding and market penetration hurdles if the government fails to improve the reimbursement structure.

The remarkable digitalization steps taken by NHIA and TFDA in response to the public health crisis are set to be reversed once the public emergency ends. Returning to old "operating standards" would be a missed opportunity that Taiwan cannot afford. Instead, a far-sighted approach could build on the changes made during the public health crisis, learn from digital health leading markets, like Germany, the UK, France and the US, and integrate different aspects of the ecosystem in ways that center patients and innovators while defining value drivers for all stakeholders (see Table 3). This would have the effect of improving health outcomes in the long term (with reduced deaths or complications resulting from chronic conditions), reducing costs, increasing access to healthcare treatments and staff through remote monitoring/consultations, and enabling a fast-growing economic sector. It could provide employment, income, and support for skilled workers in the currently strained healthcare sector, and position Taiwan in a leadership role in the region.

Stakeholder	Primary Value Drivers	Secondary Value Drivers
Regulators	Safety; Effectiveness	Privacy; Security; Interoperability; Other minimum requirements
Policymakers	Quality of care; Financial stability	Health inequality reduction
Purchasers	Cost-effectiveness; Improved member experience; Effectiveness; Budget impact	Big data; Long-run cost management (macro-economic efficiency)
Healthcare Providers	Care quality; Patient relationships; Reimbursement	Targeted health care delivery; Chronic disease prevention; Self-management
Patients/Carers	User experience; Health gain	Credibility; Health benefits; Convenience

Table 3 : Stakeholder value drivers for the uptake of Digital Health for population health management[11]

Germany's DiGA: A Model for Integrated Digital Health Solution Assessment

In the DiGA model the ecosystem is an integrated platform where the paradigm shifts from a linear series of events that ensue from each other (e.g., design, evidence generation, safety and effectiveness assessment, market approval, value assessment, reimbursement) to using real world evidence and involving patients and users in value assessment, in view of obtaining reimbursement and final regulatory clearance.

This approach was successfully implemented in Germany under the DiGA Act, passed in December 2019. Under the Act, patient-facing digital health applications are allowed on the market provided

[11] Bibliography reference [21]

certain requirements of safety, interoperability, and medical content are met. These solutions can be immediately prescribed by doctors and be reimbursed, while generating evidence for a subsequent and final regulatory approval and listing on the national health insurance agency's list of approved codes. Under this model, regulatory clearance, and reimbursement feed into each other's decision-making process until the final listing and approval are obtained. To date, the DiGA process (see Figure 5) is the most integrated system for digital health regulatory clearance and reimbursement. More than 25 Apps have been approved as of this writing and it has been praised across the globe.

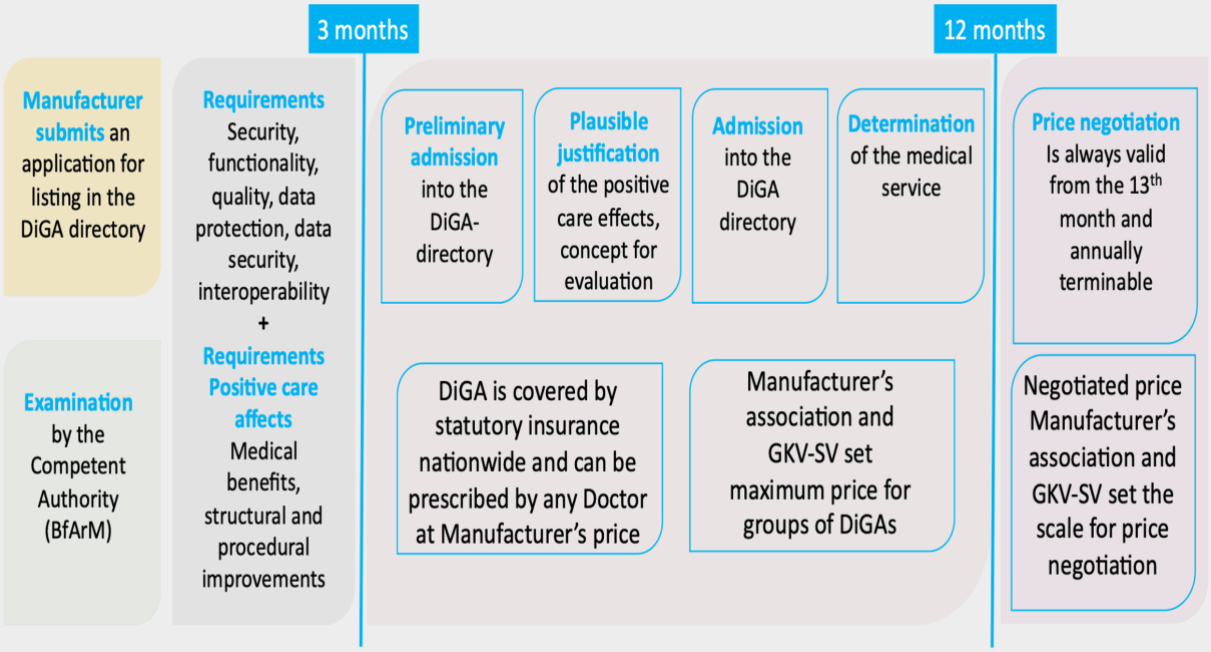

Figure 5 : Diagram of the DiGA process[12]

[12] www.BfArm.de, DiGA Fast Track Procedure

The UK's Functional Classification: Tiers of Clinical Evidence

In the UK, a functional classification was developed with the intention of providing a pragmatic approach to differentiating the digital health technologies that are expected to be most widely developed and used on the basis of function.

Classifying digital health technologies by function (see Figure 6) allows them to be classified into evidence tiers based on the potential risk to users. The evidence level required is proportionate to the associated risk to users presented by the technologies in each tier. This classification is independent of whether the digital health technology in question is approved under the Medical Device Regulation or not.

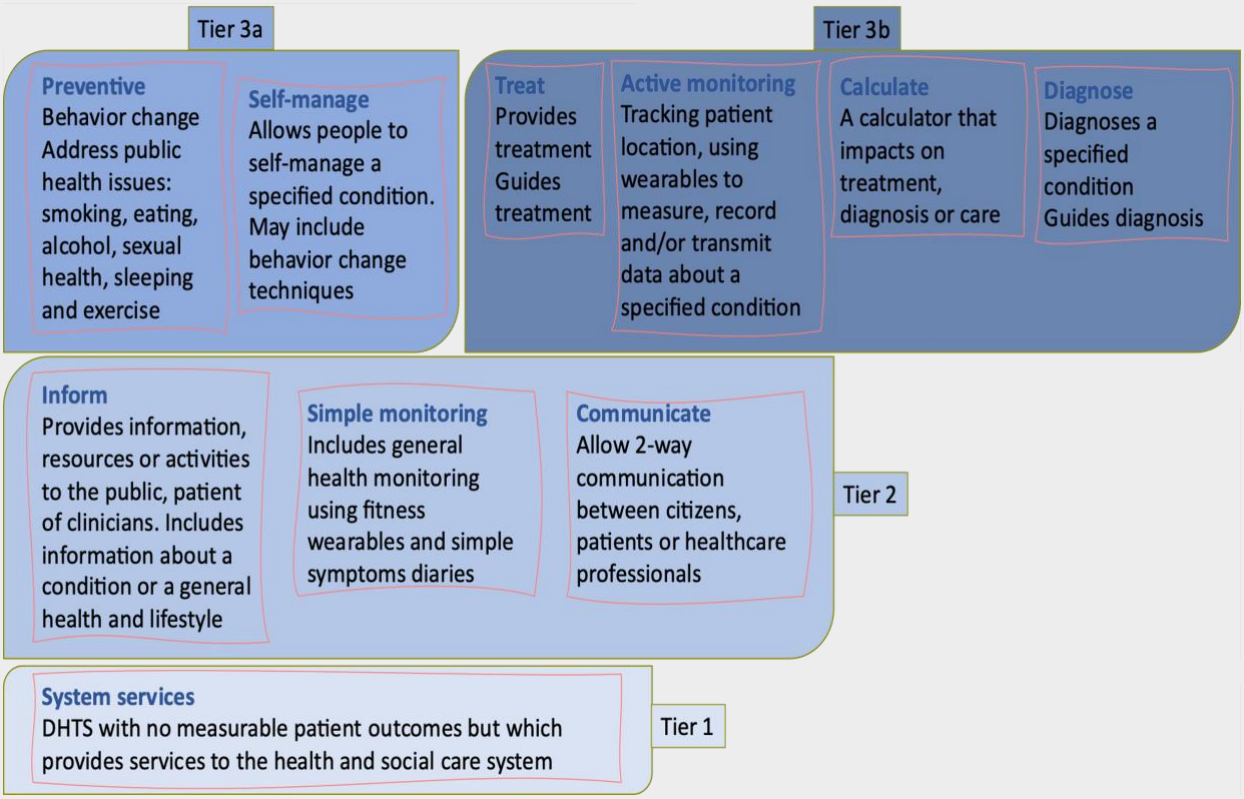

Figure 6 : UK functional classification and evidence tier system[13]

[13] www.nice.org.uk, Evidence Standards Framework

France's G_NIUS: A One Stop Shop Platform for e-Health

Innovative regulatory and reimbursement assessment methods would remain unnavigable if not provided on one central platform where manufacturers can obtain critical guidance for their application, submit regulatory and reimbursement dossiers, and obtain information on similar devices. To date, TFDA continues to rely heavily on face-to-face meetings or one-on-one phone calls to address manufacturers' questions. A more efficient and enabling way would be to create a bi-lingual, user-friendly e-Health platform. G_NIUS (Guichet National de l'Innovation et des Usages en e-Santé) is the French government's digital health portal designed with innovators in mind. It addresses their most common questions from regulatory processes to funding. In addition, the platform works to foster an online community through specialized content sharing, educational webinars, regular newsletters, and podcasts where innovators share their insight on securing regulatory and reimbursement clearances in France and elsewhere.

Figure 7 : G_NIUS platform developed to fuel the digital health ecosystem in France[14]

US Pre-Cert Program: A Post-Medical Device Quality Management System (QMS)

The uncoupling of the Taiwan Medical Devices Act from the Pharma Act was long overdue and creates the need for a split between the regulation of medical devices and that of digital health. As previously discussed, digital health innovation in Taiwan is likely to come from ICT manufacturers

[14] www.gnius.esante.gouv.fr

and local software start-ups most of whom are not experienced in the medical field and can be discouraged by the level of scrutiny required to place a health solution on the market.

The US FDA Pre-Cert program is a highly innovative approach under which the regulatory oversight is shifted from the product to the manufacturer's processes and quality culture. Software updates, often a regulatory bottleneck, can under pre-defined conditions be released to the market without prior review or approval from local authorities. Whilst highly praised for its paradigm shifting approach, the Pre-Cert program is still in its early phase. This should not, however prevent Taiwan from developing a similar process and recruiting candidates for a pilot program based on the US Pre-Cert adjusted to the local industry's needs.

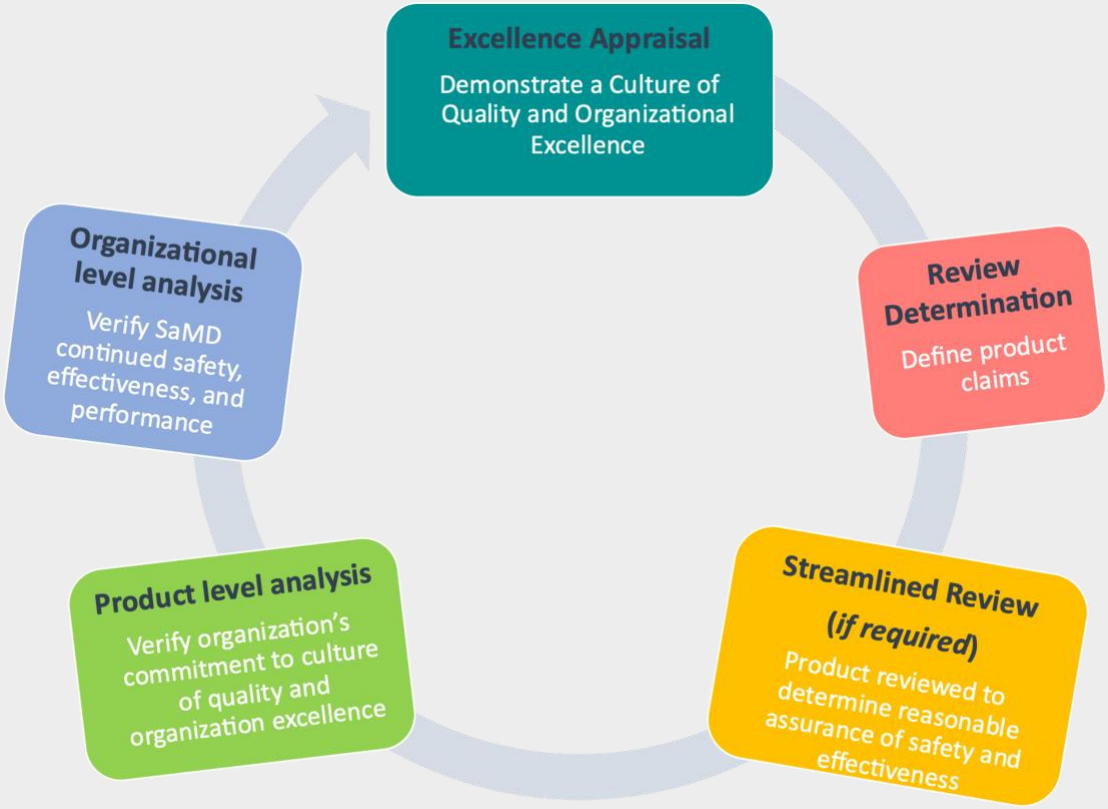

Figure 8 : The US FDA Pre-Cert Program - Total Product Lifecycle (TPLC)[15]

[15] FDA, Digital Health Software Precertification (Pre-Cert) Program

CALL TO ACTION

Taiwan healthcare system, telecommunications infrastructure and population's technological proficiency is at par with leading digital health markets such as Germany, France, and the US. Yet, the island is lagging in terms of reimbursement and regulatory policy reforms.

The latest COVID-19 outbreak clearly shows that undertaking digital health transformation in Taiwan is no longer an option, it is a necessity. Doing so will require preparedness of health systems at local, regional, and national levels and a willingness to engage with stakeholders and novel digital technology developers.

Taiwan is well positioned to leverage its existing ICT industry and digital health companies that could support the development of tools to act as gatekeepers to care and channel patients into and within the health system, attending to underserved populations and facilitating transitions between self-management and primary care or between primary and secondary care.

During the digital health forum organized by La French Tech Taiwan and BPIPO on May 5th 2021, several interested parties including international pharmaceutical companies, local digital health start-ups, foreign and local government agencies, and insurers expressed interest in collaborating on different aspects of regulatory and reimbursement policy by identifying key barriers and bottlenecks and exploring essential stakeholder motivations.

A survey of key ecosystem players conducted from the 29th of July to the 11th of August 2021 showed over 60% of respondents[16] (see Figure 9 and Figure 10) are currently developing digital health solutions most of which are disease management APPs. Based on this survey, about 65% are regulated by TFDA, while over 90% indicated their solutions are not currently covered under any NHIA scheme.

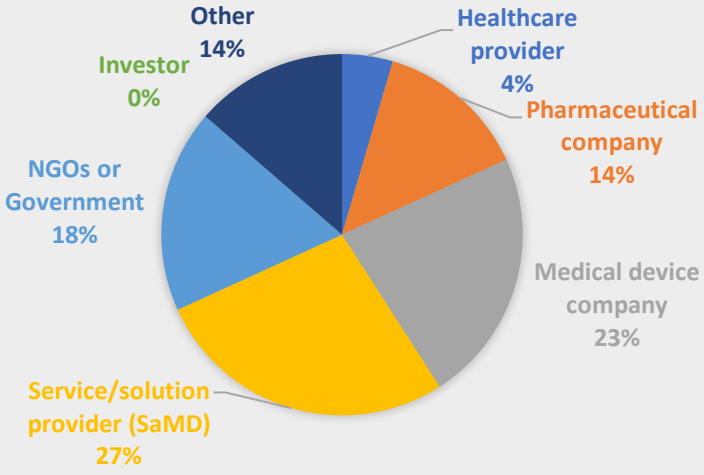

Figure 9: Respondents' role in the Taiwan digital health ecosystem

[16] A total of 22 responses were collected

Participation and integration of clinical medical systems (27%) as well as regulations (18%) came at the very top of challenges faced by the industry (see Figure 11). Interestingly, when asked about immediate bottlenecks facing Digital Health innovators in Taiwan compared to advanced markets like the US, the percentage of respondents who see regulations as a major hurdle rose from 18% to 26% (see Figure 12).

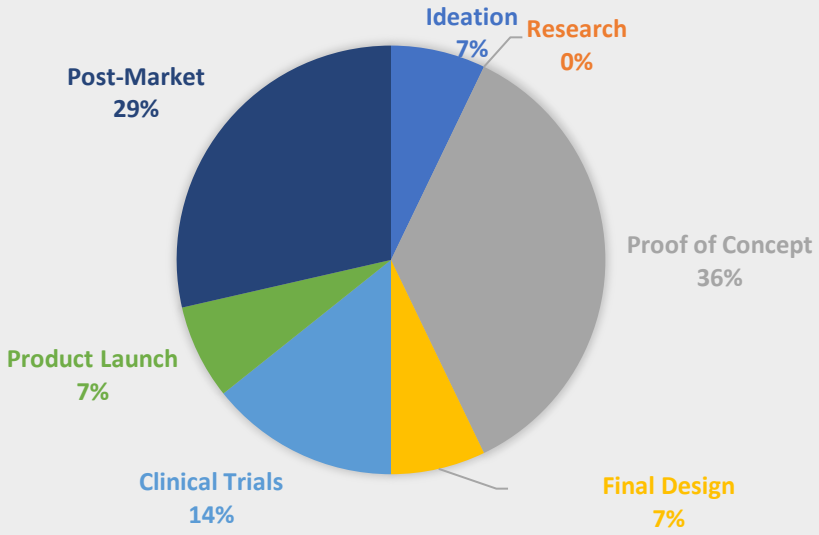

Figure 10: Respondents' current product development stage

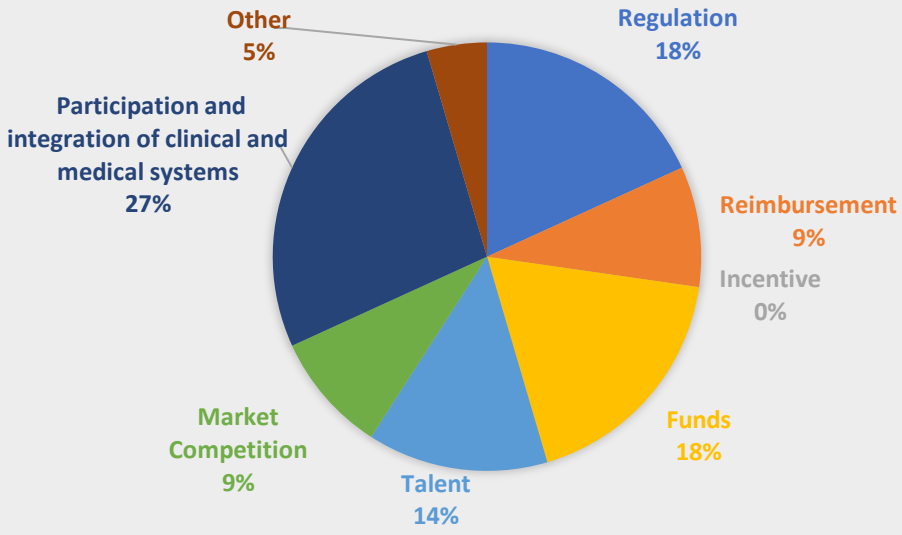

Figure 11: Greatest challenge facing companies developing digital health solutions in Taiwan

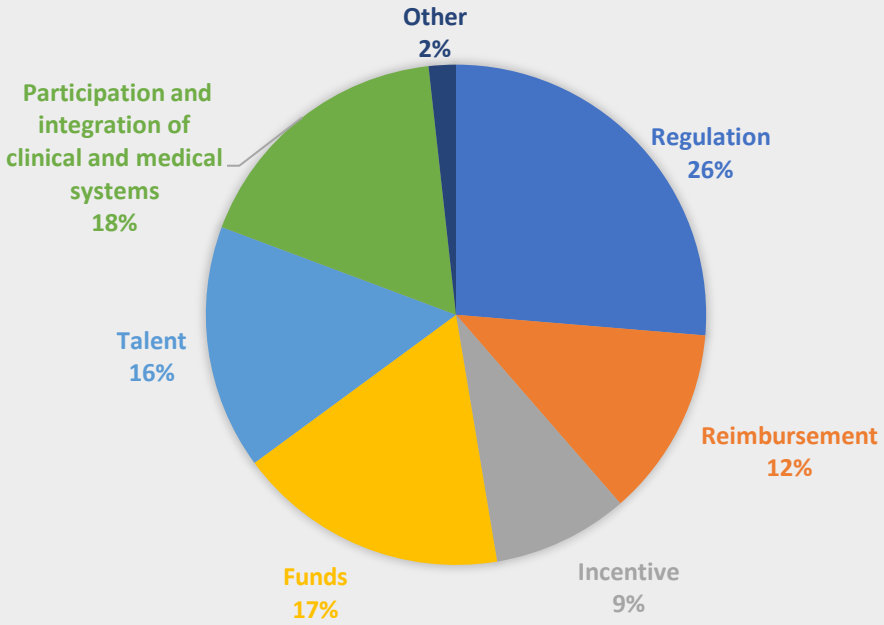

Figure 12: Immediate digital health innovation bottlenecks compared to the most advanced markets (e.g., the US)

Finally, survey participants converged on three main recommendations to the Taiwan government:

- Regulatory relaxation
- Integrated platform for digital health developers from approval to reimbursement
- Harmonization with international standards and regulations for medical data

The following reiterates main requests articulated by industry with additional proposed actions pertaining to each segment:

#1 Organizational structure

- Create a multi-stakeholder digital health taskforce across the public and private sectors, including a mechanism for sharing international best practices
- Define a specific budget and publish a clear roadmap, milestones to be achieved, with articulation of how digital health reimbursement delivers socio-economic returns
- Promote a more connected ecosystem facilitating public-private partnerships and including patient participation through real world data and harmonized regulations [19]

#2 Reimbursement

- Formally incorporate digital health into national planning cycles, with an aim to adopt a bespoke approach to fit-for-purpose funding and reimbursement including evidence generation requirements
- Rapidly launch a pilot program to reimburse digital health solutions by 2022, leveraging and learning from systems like Germany's DiGA
- Create a Health Technology Assessment (HTA) group specific to digital health solutions

#3 Regulatory platform

- Put in place a digital health-specific government agency centralizing all actions and responsibilities needed to effectively accelerate the adoption of digital health in Taiwan (comparable to France's G_NIUS and Agence du Numérique en Santé (ANS))
- Clear pathways for digital health registration with short review timelines (e.g., German DiGA) with clear guidance on evidence generation (e.g., the UK DHT functional classification) and the creation of evidence tiers to guide manufacturers
  Work with manufacturers and end users to establish a Pre-Cert like pilot program (See Table 4).

	End User	**Business**	**FDA**	**Payor**	**Investor**
	Patient, Providers, Caregivers	SaMD Developer	Agency Reviewer	Insurance Provider	Venture Capitalist
Enhanced confidence in organizations developing SaMD products	+		+	+	+
Improved quality/safety/proactivity to address known and emerging risks	+	+	+	+	
Timely availability of the solutions to patients	+	+	+	+	+
Enhanced regulatory simplicity and experience		+	+	+	+
Business simplicity-faster/timely market access	+	+	+		+

Table 4 : Expected benefits of the US FDA Pre-Cert program[17]

[17] Source: FDA, developing a software precertification program-a working model

CONCLUSION

With arguably one of the best healthcare systems in the world and over 99% of the population covered through the NHIA scheme, Taiwan has a unique role to play in the digital health transformation. The following recapitulates key considerations for a striving ecosystem.

Evidence-base decision making

For digital health to be successful it needs to achieve scale across the continuum of care from diagnosis to post-procedure. Digital health must be integrated from end to end in a way that benefits the system and the patient. It requires a change in mindset while considering the intersection of everything to reduce the need for critical care and unburden expenditure. It is, therefore, important to think carefully about what is needed to achieve that including socio-economic and environmental determinants of health.

Digital health specific regulation

Currently, bringing a digital solution to market can become a logistical nightmare, from generating clinical evidence required for a device to ongoing patient data management. Taiwan's manufacturing capabilities and TFDA's maturity level allow for the implementation of a system similar to the US FDA Pre-Cert program. A combination with the DiGA model would enable innovators to secure immediate reimbursement and doctor prescription, facilitating the collection of real-world data supporting NHIA reimbursement and TFDA clearance.

Pro-Innovation Reimbursement Schemes

Taiwan's government took various deregulation measures to help advance the healthcare sector. With the creation of pandemic-specific telemedicine codes, NHIA and TFDA have good justifications and precedents to support a change in the direction of digital health. In June 2021, the National Development Council approved the scope of the total medical expenses for 2022 with telemedicine being one of the three policy goals for the year [20]. However, it has been delaying discussion of improving the overall reimbursement structure and policy amendments remain isolated steps with limited tangible benefits for patients or innovators. Such fragmentation could be addressed through the creation of cross-agency advocate for digital health and an e-Health platform where all ecosystem stakeholders exchange and collaborate. Finally, this will not only unburden healthcare expenditure, fuel Biomedical innovation and support patients, it is in line with Taiwan's "5+2 Industrial Innovation Plan" and the "Six Core Strategic Industries promotion" goals.

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