

U.S. Chamber of Commerce

Partnership at the Digital Health Frontier:

Accelerating Access to Healthcare
Through Public-Private Collaboration

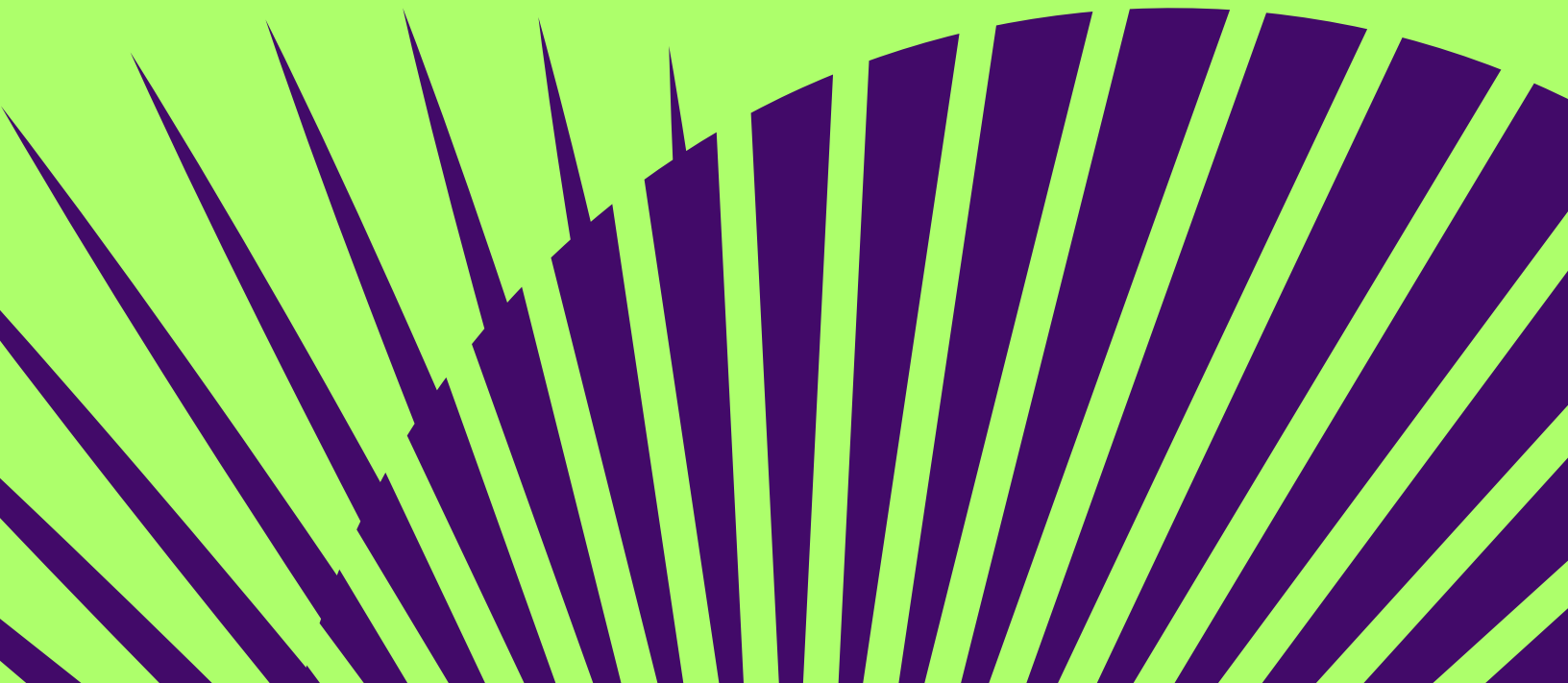


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Acronyms

AI	Artificial Intelligence
G20 HWG	G20 Health Working Group
GIDH	G20 Global Initiative on Digital Health
GSDH	WHO Global Strategy on Digital Health
HIMSS	Healthcare Information and Management Systems Society
HL-7	Health Level Seven
IP	Intellectual Property
NDHB	National Digital Health Blueprint
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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Introduction

Digital health is rapidly permeating all areas of healthcare and has the potential to transform the way medical professionals and patients interact with health services.


As this diffusion and uptake continue to evolve, policymakers are faced with a crucial decision: they can either opt for a coordinated, equitable, and systematic implementation of digital health solutions or risk a chaotic, fragmented, and inequitable rollout. By choosing the former, policymakers can ensure that digital health innovations are accessible to all, bridge gaps in healthcare access, and create a more resilient and efficient healthcare system. In contrast, the latter scenario may lead to increased disparities, uneven access to quality care, and, ultimately, missed opportunities to harness the full potential of digital health technologies for the betterment of global health.

Setting policy and regulation in a complex, technically diverse, and rapidly evolving area, such as digital health, presents unique challenges.

Decision-makers must address a wide range of factors, such as patient safety, data privacy, and interoperability, all while minimizing the unintended consequences of poorly designed policy and regulation, like unintentionally stifling innovation and delaying access. By working in partnership with industry, patients, and other stakeholders, policymakers can develop comprehensive, adaptable, and supportive policies and regulations that foster innovation and promote equitable access to cutting-edge healthcare solutions.

What do we mean by 'digital health'?

For the purposes of this white paper, we use the World Health Organization (WHO) definition of digital health as “the field of knowledge and practice associated with the development and use of digital technologies to improve health”. Digital technologies in this context include but are not limited to: mhealth, telemedicine, wearable smart devices, digitally enabled implantable devices, therapies and diagnostics, artificial intelligence (AI), and tools that enable data exchange and storage across the health ecosystem, including for research & development (R&D), manufacturing, safety monitoring, and supply chain optimization.



Digital health solutions have the potential to reduce healthcare costs¹, improve care quality^{2,3} and outcomes⁴, and, in so doing, accelerate access toward Universal Health Coverage.

For example, AI, which is just one component of the digital health landscape, can support clinicians to identify high-risk individuals earlier in the disease process, thereby improving patient outcomes and simultaneously optimizing the allocation of limited healthcare resources. AI enables providers to rapidly identify babies at risk of pre-term birth using routine ultrasound scans⁵, predict disease severity in children with malaria without complex laboratory equipment 6000 deaths from severe malaria (SM), and identify cases of breast cancer on x-rays that might otherwise be missed.⁷

Expanded access to digital health solutions can also have significant economic implications, including increased economic growth through improved productivity and a healthier workforce.

Although the economic impacts of improved digital health adoption can be challenging to quantify due to their diverse applications and complexities, economic projections indicate that the widespread adoption of digital health innovations could generate a global health impact valued between US\$250 billion and US\$420 billion by 2030.⁸

In 2020, the WHO launched the Global Strategy on Digital Health (GSDH) to support countries to accelerate the development and adoption of digital health solutions under the technical stewardship of the newly created Department for Digital Health and Innovation.⁹ The GSDH was launched in the context of increasing recognition of the importance of digital health. Many multilateral organizations are now supporting national governments and the private sector to scale digital health solutions, including the G20 Health Working Group, United Nations agencies, such as UNICEF¹⁰ and the United Nations Development Programme,¹¹ multilateral financing institutions, like the World Bank¹² and the Asian Development Bank,¹³ and regional organizations like the African Union,¹⁴ the Asia-Pacific Economic Cooperation¹⁵, and the Organisation for Economic Cooperation and Development.¹⁶ Further, a growing ecosystem of international organizations, including the Global Digital Health Partnership¹⁷ and Digital Square,¹⁸ are working collaboratively with country governments and industry to advance digital health initiatives, enhance coordination, and provide valuable technical support.

Objectives and Approach

The U.S. Chamber of Commerce ('the Chamber') commissioned Enlumen to work with industry leaders, standard-setting organizations, and multilateral agencies with experience in digital health to better understand their perspectives on how the private sector might best be engaged to accelerate the development and equitable adoption of digital health solutions globally. Specifically, Enlumen set out to:

Identify opportunities for the private sector to support governments, regulators and policymakers to advance digital health objectives.

Identify policy and regulatory enablers of, and barriers to, implementation of digital health solutions.

Explore successful public-private partnership models in digital health that can inform future initiatives in this space.

Enlumen undertook a global desk review of digital health strategies, policies, technical guidance, and case studies to support these objectives. Additionally, Enlumen conducted semi-structured key informant interviews (n=15) with representatives from industry, the public sector, and professional associations involved in digital health.

Where can public-private collaboration deliver impact in digital health?

On analysis, three key domains emerged that play a pivotal role in shaping digital health outcomes: Policy & Regulation; Finance, Infrastructure & Operations; and Innovation & Collaboration. In each domain, we highlight specific areas that warrant attention and collaborative action from policymakers and the private sector.

Domain 1.

Policy & Regulation

In the rapidly evolving digital health landscape, effective policy and regulation are crucial to ensure that innovative solutions are safe, effective, efficient, and universally accessible. By ensuring that regulations and policies are comprehensive, adaptable, and supportive, policymakers and regulators can help to foster innovation and promote equitable access to cutting-edge healthcare solutions. Specific areas of consideration in the domain of policy and regulation include:

Governance

A robust governance and policy framework is essential to implement and scale digital health initiatives effectively. Our respondents stressed the need for clear and consistent policies, strategic planning, and alignment between digital health goals and broader health system priorities. The private sector can contribute by sharing best practices, collaborating with public stakeholders to inform policy development, and highlighting existing standards, guidance, and policies that support convergence, innovation, and digital health growth. Governments and policymakers can support by appropriately resourcing and training teams involved in policymaking and regulation, implementing existing international best practices for digital health oversight, facilitating private sector consultations for policy harmonization, and promoting transparent benchmarking of digital health outcomes.

Regulatory Standards

Adopting established, internationally accepted, and industry-supported regulation and standards for digital health products and services is crucial because they ensure patient safety, foster innovation, and facilitate international interoperability, creating a globally consistent environment for their development and adoption. Policymakers should carefully calibrate their approach to standard-setting with industry and the private sector, ensuring that regulations are aligned to the internationally accepted best practice, are not overly rigid (which could unintentionally suppress innovation and delay the delivery of health solutions), and avoid technical barriers to trade. Key challenges identified by our respondents in this area include the need for clear, comprehensive, and flexible regulations that can adapt to the rapidly changing digital health landscape. Multilateral fora should rely on industry and sector-based standards organizations (including, for instance, through participation in standards-developing organizations like Health Level Seven International [HL7] and GS1) as the most effective way to promote the adoption of best practices that are technically sound to deliver on technology solutions and policy objectives. Governments and policymakers can aid regulators in achieving their goals by providing resources and training to enhance their capacity and expertise in reviewing digital health products and conducting post-market surveillance. Participating in regulatory sandboxes or pilots to test new products and services and creating multidisciplinary expert panels for regulatory oversight to ensure fair and balanced application of the rules may also be advantageous.

Example: In the United States, the Food and Drug Administration has established the Digital Health Center of Excellence to promote innovation and support the development of regulatory approaches

for digital health technologies.²⁰ The Digital Health Center of Excellence actively engages with private sector stakeholders, including digital health companies, medical device manufacturers, and software developers, to track the evolving digital health landscape and develop appropriate regulatory guidelines and standards that protect patient safety and foster innovation.

Privacy & Cybersecurity

Handling sensitive personal health information carries significant risks and requires a commitment to protecting customers' and patients' right to privacy. Industry experts highlight the importance of transparent, risk-based, and harmonized privacy protections for securing sensitive data in a way that supports innovation, safety monitoring, and evidence-based decision-making. Key informants acknowledged the challenge policymakers and regulators face in maintaining stringent cybersecurity measures without hindering timely access to information for clinical care or decision-making. The private sector should continue investing in secure data storage and transmission technologies, including zero trust networking which leverages strong encryption, collaborating with public stakeholders to develop privacy-preserving solutions, and sharing best practices in cybersecurity. Policymakers can support international cooperation and collaboration of privacy and cybersecurity efforts by ensuring that: (i) privacy and cybersecurity policies are risk-based and globally harmonized, (ii) privacy regimes are proportionate, balanced, and developed in partnership with industry, (iii) cybersecurity is strengthened by enabling cross border data flows and investing in cloud computing storage services vs. forced data localization, which would only undermine the security of health data, and (iv) GIDH guidance complements, supports and does not duplicate existing agreements developed by industry experts (for instance, the Cybersecurity Tech Accord²¹).

Domain 2.

Finance, Infrastructure & Operations

Countries worldwide face various cross-cutting challenges as they strive to build equitable and sustainable digital health ecosystems. Several respondents expressed concern about the digital divide, which underpins many other challenges in this domain. Ensuring adequate funding, capacity building, and infrastructure development are crucial to achieving health equity and reaching underserved populations. Potential areas of public-private collaboration within this domain include:

Funding & Investment Equitable access to digital health solutions depends on the availability of robust digital health infrastructure, including widespread internet access. The International Telecommunications Union estimates that \$428 billion in investment will be necessary by 2030 to provide internet access to currently unconnected populations worldwide.²² Our key informants emphasized that attracting innovative sources of financing and fostering public-private partnerships are some of the most significant policy challenges in this area. Given the scale of funding required, policymakers will need to mobilize public and private investment. Additionally, policymakers can establish dedicated funding for digital health infrastructure, offer tax incentives for private sector investment in digital health assets, and foster international collaboration to mobilize resources for equitable access to digital health solutions.

Capacity Building Building required capacity among the healthcare workforce and other stakeholders is essential for successfully implementing and adopting digital health technologies. Key informants highlighted several critical challenges in this area, including training healthcare professionals in digital tool use and fostering digital literacy among the general population. The private sector can contribute by providing training and education programs for

healthcare providers, developing user-friendly and accessible digital health tools, and collaborating with governments and educational institutions to promote digital literacy. Governments can support private sector efforts by incorporating digital health education into healthcare curricula, establishing national digital health literacy campaigns, and creating targeted upskilling programs for healthcare workers.

Supply Chain Supply chain digitization offers end-to-end tracking capabilities to safeguard health product safety and quality, improve logistics efficiency, and reduce delivery costs. Interviewees identified several challenges, including harmonizing data standards across diverse stakeholders, ensuring robust data security and privacy measures, and managing organizational change while building capacity for new technologies and processes. The private sector can contribute by sharing best practices and technical expertise on innovative digital supply chain management solutions and collaborating with public stakeholders to agree on and implement supply chain standards. Policymakers can foster advancement in this domain by investing in digital infrastructure to support supply chain digitization and establishing public sector procurement policies that emphasize compliance with digital supply chain standards. Additionally, policymakers can encourage public sector providers to adopt innovative supply chain management solutions through attractive incentives and comprehensive capacity-building programs.

Example: The Global Health Supply Chain Program—Procurement and Supply Management Project, funded by the United States Agency for International Development, involves partnerships with various private sector firms, including multiple pharmaceutical and logistics companies.²³ The program aims to strengthen and digitize supply chains for essential health commodities in low- and middle-income countries. The collaboration has resulted in improved procurement, increased visibility of supply chain data, and more efficient delivery of vital health products.

Domain 3.

Innovation & Collaboration

Innovation is crucial for expanding access to digital health solutions because it drives improvements in the outcomes and quality of care and increases efficiency, cost-effectiveness, and scalability. Specific opportunity areas for public-private collaboration within this domain include:

Research & Development

A robust global R&D ecosystem is crucial for equitable access to digital health solutions. Key informants underscored the need for increased investment in R&D, the importance of North-South knowledge exchange, and the critical function of intellectual property (IP) protection in incentivizing industry to commit to long-term investment to enable breakthroughs. The private sector can substantially contribute by investing in R&D, forming partnerships with diverse stakeholders such as academic institutions and government agencies, and engaging in collaborative research projects. Governments and policymakers can support these efforts by establishing a pro-innovation policy environment that protects IP rights, increasing public funding for digital health R&D, incentivizing private sector investment through grants and tax breaks, and fostering international collaboration on research projects.

Data Sharing & Integration

Data sharing and integration are essential for creating a more connected and effective digital health ecosystem; these two actions facilitate better-informed decision-making, promote research and innovation, and enhance patient care. For example, seamless data sharing between electronic health records and telemedicine platforms can improve the accuracy of diagnoses

and the efficiency of treatments. Similarly, facilitating secure cross-border data flows is paramount, as these support the delivery of global clinical trials, real-time disease and pandemic surveillance, and enhanced pharmacovigilance and safety monitoring. Interview respondents called attention to several challenges in this area, including ensuring data privacy, maintaining security, establishing standardized data formats, and addressing disparities in digital infrastructure. The private sector can support public sector efforts by investing in and implementing interoperable data systems, promoting global data standards adoption, and developing secure and user-friendly data-sharing platforms that adhere to privacy regulations. Governments and policymakers can advance data sharing and integration by enacting legislation that facilitates cross-border data exchange and safeguards privacy, endorsing the development and adoption of international data standards, and providing targeted funding or incentives to public providers for the implementation of interoperable data systems that adhere to stringent security and privacy regulations.

Example: The African Alliance of Digital Health Networks (African Alliance) is a regional network of digital health experts and organizations, including governments, private companies, and development partners.²⁴ The network aims to strengthen health systems in Africa by promoting the adoption of digital health solutions and fostering cross-border collaboration. One example of their work is the development of the Africa Health Data Collaborative, which aims to improve health data sharing and integration across the continent. Key private sector partners include companies like Philips, Merck, and Novartis.

Equitable Access

Achieving equitable access to digital health solutions is essential for addressing health inequalities, enhancing care for underserved populations, and fostering universal health coverage. For instance, telemedicine can provide healthcare services to remote communities that previously lacked access. The private sector can continue to support equitable access to life-saving digital health solutions by engaging in collaborative research efforts and continuing their long-standing engagement in public-private financing mechanisms that support equitable access. Governments and policymakers can promote equitable access by investing in digital infrastructure, fostering public-private partnerships, and supporting public providers in adopting innovative digital health solutions.

Example: GAVI, the Vaccine Alliance, is a public-private global health partnership committed to ensuring equitable access to vaccines for people in low- and middle-income countries. The private sector plays a significant leadership role within GAVI, holding board seats and contributing to decision-making processes. GAVI's innovative financing mechanisms and collaborative approach foster cooperation among pharmaceutical companies, governments, and non-profit organizations. By harmonizing various stakeholders' interests, GAVI enables sharing expertise while addressing equity concerns. Through the collective efforts of GAVI and its partners, vaccine development and distribution have been accelerated, promoting health equity and improving immunization coverage worldwide.

Digital Health Case Studies

Case Study 1:

Public-Private Collaboration for Strengthened and Streamlined Regulation

Indonesia is a lower-middle-income country in South-East Asia with a growing economy and the world's fourth-largest population.

The Government has taken an increasingly assertive role in healthcare planning and financing in recent years, including through the introduction of a national health insurance scheme that now covers over 80% of the population.²⁵ However, geographical barriers to healthcare remain, with 94.1% of the population living more than 5km from a healthcare facility.²⁶

In the first months of the COVID-19 outbreak in Indonesia, the dynamics of demand for healthcare shifted dramatically.

Client demand for in-person consultations for routine health services fell substantially, with the utilization of pregnancy care services, for example, declining by up to 44% in some districts.²⁷ In parallel, the number of people admitted to healthcare facilities for COVID-19 treatment put increasing pressure on the healthcare system.²⁸

Before the pandemic, telemedicine providers in Indonesia faced unclear regulations and guidance.

The prevailing rules lacked clarity on: (i) which healthcare workers were eligible to provide telemedicine services, (ii) which treatments and

services could be administered remotely, and (iii) how patient data should be shared among telemedicine providers, patients, and the Ministry of Health. This ambiguity made it difficult for providers and operators to know if they complied with regulations and guidance. In so doing, the uncertainty increased operational risks and created an atmosphere of uncertainty that hindered providers from expanding their services effectively.

In response to the pandemic, the Ministry of Health worked with industry and professional bodies to test and implement clear guidelines and regulations for telemedicine providers.

Indonesia's telemedicine providers benefited from expanded market opportunities, accelerated innovation, and strengthened collaboration due to regulatory clarity and streamlining. As a result, patients experienced improved healthcare access, faster treatment, and more personalized care.

As a result of regulatory strengthening and streamlining, telemedicine providers in Indonesia were able to rapidly scale services to meet demand. The number of telemedicine users jumped from 4 million in 2019 to 15 million in 2020.²⁹

Case Study 2:

Global Standards for Pharmaceutical Product Traceability

Healthcare supply chains have become increasingly complex, and pharmaceuticals and medical products pass through many hands as they move from the point of manufacture to the patient.

The complexity of health supply chains challenges manufacturers and national regulatory authorities to track and monitor the quality of medical products. As a result, substandard and falsified health commodities can enter the market: WHO reported a 10.5% failure rate among medicines sampled for quality testing.³⁰ This statistic highlights that patients are at risk of exposure to substandard or falsified medical products, especially in emerging market contexts. Governments and commercial pharmaceutical actors can leverage digital traceability technologies to address these vulnerabilities and optimize business outcomes.

GS1 is a not-for-profit and neutral organization that brings together private sector stakeholders to test, develop, and implement standards, including for the healthcare industry.

GS1 member organizations invest significant time and resources in the development of standards, including through participation in working groups and technical committees, sharing of best practices and case studies, and engagement in pilot projects to test new standards and technologies. Through their active participation in GS1, private sector stakeholders play an instrumental role in developing and implementing healthcare standards that improve patient safety, streamline supply chain management, and reduce costs.

By shaping and promoting the adoption of GS1 standards, private companies directly support public sector stakeholders to make better-informed decisions, increase patient safety and reduce waste.

For instance, the GS1 standards adoption can give regulators greater visibility and control over the supply chain, enabling them to monitor and enforce compliance with safety and quality standards more effectively. Similarly, by enabling more efficient tracking and management of medical products throughout the supply chain, GS1 standards can help reduce waste, minimize stockouts and overstocking, and lower the overall cost of healthcare delivery. Further, using standardized data exchange and traceability provided by GS1 standards can help prevent medication errors, reduce the risk of counterfeit or substandard medical products, and facilitate more accurate identification of patients and their medical records.

Global pharmaceutical traceability standards are becoming mainstream, and as of 2019, more than 45 countries had signed some form of traceability into law.³¹

To continue this momentum, the public and private sectors must continue working collaboratively to set standards, create reasonable implementation plans and timelines, and define policy and regulations to carry implementation forward.

Traceability Applications in Ireland During COVID-19

Traceability standards supported the diverse public-private consortium that converged to develop and roll out vaccines against COVID-19. In Ireland, the Health Service Executive implemented a GS1 standards-based approach to efficiently and effectively track and report vaccinations across vaccination clinics using two software applications. In addition to the substantial health benefits associated with vaccination scale-up, traceability standards provided useful data on vial yields and stock expiry dates to assist in keeping wastage to a minimum: an estimated 75,000 doses were saved based on early detection of vial yield discrepancy and reduced staff needs.³²

Recommendations for Global, Regional, and Multilateral Policymakers

In light of the significant potential for digital health solutions to transform global healthcare, and the essential role of public-private collaboration in unlocking this potential, the Chamber proposes the following recommendations for global, regional, and multilateral policymakers in the digital health space:

Recommendation 1:

Ensure representation of the private sector in decision-making bodies related to digital health.

The private sector offers invaluable expertise in technology development, financing, global standards, and market access, which are vital for catalyzing the adoption and scaling of digital health innovations. Effectively harnessing the strengths, resources, and innovative capabilities of the private sector is crucial for the success of the digital transformation of the health sector. Policymakers should ensure the establishment of well-defined mechanisms and platforms that facilitate ongoing dialogue and cooperation between the public and private sectors. A clear framework should be put in place for private sector engagement in digital health activities broadly,

including the allocation of seats for private sector representatives on pertinent decision-making bodies. Such representation would mirror the private sector's engagement in the governance of global initiatives to advance equitable access to healthcare technologies like, the Global Fund, and GAVI and would encourage sharing of insights, experiences, and best practices, fostering a collaborative and innovative approach to digital health. In addition to formal representation on governance bodies for digital health, policymakers could organize regular roundtables, webinars, or workshops involving key public and private stakeholders to facilitate the continuous engagement of industry in advancing digital health initiatives.

Recommendation 2:

Leverage private sector expertise to ensure that policy, regulation, and standards are robust, agile and fit-for-purpose.

The private sector brings unique expertise in the rapidly evolving digital health landscape and has first-hand experience in navigating the regulatory, infrastructural, and market-related challenges that typically accompany such innovation. Policymakers should actively involve the private sector in shaping and adopting regulations and standards for digital health that are robust, agile, and that minimize the potential for unintended consequences. This collaboration should focus on promoting innovation, patient safety, and global interoperability, while avoiding overly rigid regulations that could hinder progress. Specifically, policymakers should encourage the adoption of established healthcare standards which have been developed in partnership with industry, including, for instance, the GS1 Healthcare³³ and HL7 FHIR standards³⁴. The GS1 Healthcare standard focuses on improving patient safety and supply chain efficiency through the use of globally unique identification numbers for products and assets, enabling seamless traceability and information sharing. The HL7 FHIR standard, on the other hand, enables the exchange of electronic health records and other healthcare data across different systems through the use of standardized data formats. Other areas of digital health practice where policymakers could work

to advance the adoption of common standards include, for instance, the DICOM standards for medical imaging data sharing³⁵, the ISO/IEEE 11073 standards for interoperability of medical devices³⁶, and the LOINC standards for standardized laboratory and clinical test results³⁷.

To capitalize on these benefits and foster a conducive environment for private sector engagement, there are several key opportunities to engage and leverage private sector expertise in this area. These include, for instance: (i) establishing dedicated working groups that bring together representatives from government agencies, private sector companies, academia, and civil society and which focus on identifying challenges and proposing solutions for regulation and policy, (ii) creating 'regulatory sandboxes', where new digital health solutions can be tested in a controlled environment under regulatory supervision, and (iii) promoting public-private partnerships to accelerate the implementation and scalability of digital health solutions. These partnerships can provide the necessary resources and guidance for digital health innovations, thus driving more effective and efficient health systems.

Recommendation 3:

Address the digital health divide, including through increased investment in foundational infrastructure and efforts to improve digital literacy.

Equitable access to digital health solutions depends on the availability of robust digital health infrastructure, including widespread internet access, and on service users having the requisite level of digital literacy to use and engage with the solutions provided. Policymakers should mobilize investment for digital health infrastructure, particularly in remote, rural and underserved locations, including through traditional financing mechanisms like tax breaks, subsidies and fund-matching schemes as well as through innovative financing mechanisms like development impact bonds (DIB) and blended financing instruments. In parallel, policymakers should prioritize the promotion of digital health literacy to ensure that all individuals are equipped to effectively use digital health technologies, including, for instance, by collaborating with educational institutions to ensure digital literacy is included in educational curricula, and by engaging with community-based organizations to conduct outreach campaigns for older adults, low-income individuals, or non-English speakers, who may face additional barriers to digital health literacy.



Conclusion

Broad-based and equitable access to digital health solutions has the potential to significantly advance global access to universal healthcare coverage. Public-private partnership will be critical to ensure that these digital health solutions are accessible to all, bridge gaps in healthcare access, and create a more resilient and efficient global healthcare system.

Policymakers have a crucial role to play in mobilizing the private sector's capabilities, expertise, and resources towards the broader goal of equitable access to digital health solutions. To do so, policymakers are encouraged to focus on implementing policies, regulations and standards that are agile and responsive to the needs of industry; ensure that adequate financing, investment and infrastructure are in place to support the adoption of digital health solutions; and foster collaboration and innovation, both domestically and across borders.

The private sector stands ready to support policymakers in advancing access to digital health solutions and in realising the potential of these tools to improve access to life-saving health services, increase the efficiency of health service delivery and reduce health disparities globally.

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