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Business Council

Digitalization Delivers:

Japan's Digital Health Transformation and Optimizing Patient Health Outcomes through a U.S.-Japan Partnership

February 2025

Key Takeaways

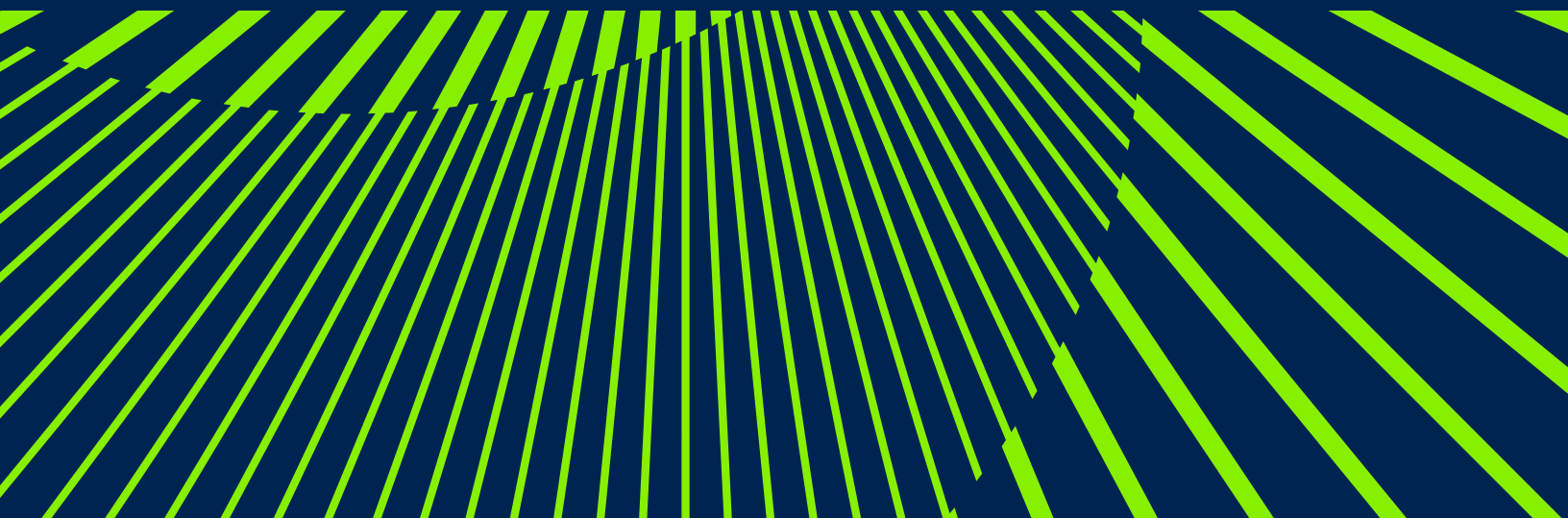
- Japan is in the midst of a digital revolution in healthcare in the areas of telemedicine, digital therapeutics, and the development of AI-based diagnostic tools. The Japanese government has advanced significant regulatory changes to embrace digitalization and strengthen Japan's global competitiveness, as well as address gaps revealed during the COVID-19 pandemic and the challenges it faces as an aging society.

- The developments have been reinforced by U.S.-Japan public and private cooperation in areas ranging from R&D to commercialization, with both governments offering significant support at the highest levels for further academic and research collaboration.

- Japan still faces significant challenges in building a globally competitive health technology development ecosystem. These challenges extend to critical areas, including the collection, storage, and transfer of electronic medical records (EMRs) and interoperability in cross-border data flows.

- To strengthen Japan's digital health infrastructure, the Japanese government should promote U.S.-Japan and other international cooperation on privacy and cybersecurity. Additionally, it should enact legislation that facilitates cross-border data exchange while protecting privacy.

    › Investment in digital health systems, particularly in underserved rural areas, should be encouraged through tax incentives, subsidies, and innovative financing models like development impact bonds. Additionally, Japan should review policies on responsible AI use in healthcare research and explore harmonizing AI ethics frameworks.



Introduction

Japan's demographic concerns and ever-straining social spending budget have long been driving forces reshaping the country's healthcare delivery system. Digital technologies can play an important role in improving the quality of healthcare services and creating efficiencies, and advance Japan's role as a leader in healthcare innovation. Demographic challenges are growing ever more acute: in 2023, one in 10 Japanese people were 80 years or older, with 29.1% of the 125 million population aged 65 or older. By 2040, those aged 65 and over are projected to account for 34.8% of the population.[1] This trend led to early research into digital health products and services, including electronic health records (EHRs) and telemedicine. However, their adoption has progressed slowly.[2] The COVID-19 pandemic further exposed severe gaps in healthcare delivery and access, especially among the older population. COVID-19 also revealed significant limitations in Japan's ability to gather necessary health data for surveillance and decision-making.

Japan's demographic decline has also contributed to a shortage of medical professionals, especially in rural areas, further limiting access to critical healthcare services and underscoring the urgent need to accelerate its digital transformation. A 2022 white paper from the Ministry of Health, Labour, and Welfare (MHLW), presented to former Prime Minister Fumio Kishida, projected a shortfall of 960,000 medical and welfare workers by 2040. This gap would leave the workforce significantly below the 10.7 million workers needed to meet the demands of an aging population. The report underscores the potential for digital health to support the existing workforce by enhancing efficiency in healthcare services.[3]

These factors, along with the experience of the COVID-19 pandemic, have renewed interest in digital health tools. The Government of Japan is actively looking at ways to provide top-of-the line healthcare and advanced medical technologies to patients and to use digital health to reduce health inequities, increase operational efficiencies, and enhance patient convenience. Reflecting its view of digital health transformation as a key priority, the MHLW allocated roughly USD 400 million (JPY 61.7 billion) for the promotion of digital health innovation in its FY2024 budget.[4] Additionally, on December 5, the Japanese

1 https://www.bbc.com/news/world-asia-66850943

2 https://www.appliedclinicaltrialsonline.com/view/is-japan-leading-a-new-digital-health-movement-

3 https://www.mhlw.go.jp/english/wp/wp-hw2022/dl/summary.pdf

4 https://pj.jiho.jp/article/250187

government released the draft of its next five-year healthcare plan, which promotes Japan's digital transformation (DX in healthcare and emphasizes the need for stronger data utilization and interdisciplinary engagement in AI and DX to advance innovation in drug discovery and medical devices. The government plans to promote and support the use of data and digital tools in research and development, including in AI drug discovery, genomic drug discovery, and software as a medical device (SaMD), as well as improve data processing and quality among other initiatives in the strategy.[5]

The U.S.-Japan Business Council's (USJBC) Healthcare Innovation Working Group previously identified digital innovation as a critical area of reform to reconfigure Japan's healthcare and regulatory frameworks to better support innovation and meet the evolving needs of its society. Since 2020, the USJBC has issued recommendations to the U.S. and Japanese governments urging greater public-private cooperation and bilateral collaboration in four key identified areas:

(1) Cross-Border Data Flows and Privacy;

(2) Telemedicine and Remote Care;

(3) Digital Therapeutics (DTx); and

(4) Data Utilization and Artificial Intelligence (AI) Diagnostic Development.

Building on these efforts, this paper analyzes the state of Japan's digital health transformation and identifies additional opportunities for collaboration between the United States and Japan—particularly within the private sector. Such cooperation can enhance patient access, improve health outcomes, lower costs, and promote innovation.

5 https://www.kantei.go.jp/jp/singi/kenkouiryou/sanyokaigou/dai24/siryou2-2.pdf

Privacy, Data Utilization & Cross-Border Data Flows

Greater cooperation among the U.S., Japan, and like-minded countries on data privacy practices and cybersecurity is needed to ensure the free flow of data with trust and data-driven innovations across borders.

–USJBC

Globally, policymakers have been assessing the formidable challenges around facilitating cross-border health data flows to enable research and deliver healthcare services and products while safeguarding patient privacy. Cross-border data flows are essential for effective disease surveillance, especially during health emergencies such as pandemics or outbreaks. Sharing timely and accurate health data across borders enables global coordination, early detection of emerging threats, and accelerates response efforts. For example, the Antimicrobial Testing Leadership and Surveillance (ATLAS) platform tracks antimicrobial resistance (AMR) globally, relying on seamless data exchange between countries to monitor trends and provide insights into resistance patterns.

Japan is a staunch advocate of its Data Free Flow with Trust (DFFT) concept, which champions more seamless exchange of data across international borders among like-minded partners. However, achieving this requires a sophisticated alignment and interoperability of privacy and data transfer frameworks between Japan and its international partners. Japan has been a leader in operationalizing DFFT through the Institutional Arrangement for Partnership (IAP), an international mechanism under the OECD.

Japan has also made significant strides in promoting cross-border data flows with trading partners through bilateral agreements. The U.S.-Japan Digital Trade Agreement, signed in 2019, includes provisions that prohibit certain data localization measures, ensure the free flow of data across borders, and protect against the forced disclosure of source code and algorithms as conditions for market access.[6] Also in 2019, Japan became the first country in Asia to obtain a declaration by the European Union (EU) recognizing its standards as adequate under the General Data Protection Regulation (GDPR). This designation allows for the free transfer of data between the EU and Japan. The EU and Japan are currently discussing the expansion of their mutual adequacy arrangement to include research institutions and government agencies

6 https://ustr.gov/countries-regions/japan-korea-apec/japan/us-japan-trade-agreement-negotiations/us-japan-digital-trade-agreement-text

beyond the scope of the original agreement. The expansion would enable the EU and Japan to collaborate more effectively and efficiently on joint research involving personal medical data, share diagnostic data during infectious disease outbreaks, and seamlessly transfer information in advanced fields such as genetic research for drug discovery and development.[7]

The Act on the Protection of Personal Information (APPI) of Japan, subject to triennial reviews and amendments, imposes stringent requirements on global healthcare companies processing or importing personal information from Japan. The bill was amended in 2021 to include several key provisions that significantly impact data handling practices, such as the need for informed consent for cross-border data transfers, mandatory reporting and notification of data breaches, and the introduction of new categories of data such as "Personally Referable Information" and "Pseudonymously Processed Information."[8] Additionally, increased criminal penalties underscore the importance of compliance. The amendments also brought government-run hospitals and universities under the same regulatory framework as the private sector, streamlining data sharing and transfer processes in compliance with APPI.

In June 2024, the Personal Information Protection Commission (PPC) released an Interim Summary outlining proposed changes to the APPI as part of its triennial review.[9] Key proposals included relaxed reporting obligations for data breaches, new rules for biometric data, the introduction of a class action system and administrative fines for data privacy violations, and updated guidelines for handling children's personal information. The proposal, however, received mixed, predominantly negative reactions, primarily with respect to the implementation of a financial penalty scheme and tightening regulations, from both the industry and the ruling Liberal Democratic Party (LDP). Both industry and LDP representatives expressed concerns that the initially proposed approach was focused more on strengthening rules than allowing open economic activity. In addition, they voiced concerns regarding the negative impact of new fines and compliance costs on business activity and data utilization.[10,11]

7 https://www.nikkei.com/article/DGXZQOUA2029E0Q4A620C2000000/

8 https://www.morganlewis.com/pubs/2022/08/how-japans-privacy-act-amendments-affect-global-healthcare-businesses

9 https://iapp.org/news/a/japan-s-dpa-publishes-interim-summary-of-amendments-to-data-protection-regulations

10 https://www.nikkei.com/article/DGXZQOUA1779V0X10C24A6000000/

11 https://storage2.jimin.jp/pdf/news/policy/208287_2.pdf

In response to the feedback urging a reevaluation of the Act's fundamental design—especially in light of new technologies like AI and the ongoing digital transformation—the PPC announced in October that it would revise its proposed amendments. The Commission will focus on three key areas:

(1) the administrative fine system and related topics to be discussed in working groups;

(2) individual issues such as biometric data; and

(3) core principles that should guide personal information protection policy moving forward.

At a December 18, 2024 meeting, the Commission also considered industry concerns regarding the business impact and decided to limit the financial penalty proposal scope to "malicious cases"; although the definition of "malicious" is unclear and will require further debate.[12] With the revised APPI set to take effect in 2027, these changes are expected to have a significant impact on the healthcare industry's data governance and compliance strategies.

Despite advancements in data flow interoperability that have enabled cross-border collaboration and research, Japan continues to face significant challenges in the collection, storage, and transfer of electronic medical records (EMRs). Japan lacks a national electronic health record (EHR) system that allows individual medical institutions to contribute to a centralized database. The United States implemented comprehensive policies in 2009 that allowed the digitalization of health records through the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act incentivized the adoption of electronic health records and strengthened the privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA). Historically, medical institutions in Japan have been hesitant to adopt EMRs due to concerns about data leakage, high IT system operating costs, and a shortage of IT personnel. To address these challenges, the Japanese government could model current approaches to EMR policy implementation on the U.S. 2009 HITECH Act.[13]

12 https://news.yahoo.co.jp/articles/b14e0a205ddb5f476d8c26baa6b7e4ba60f84e0c

13 https://www.sciencedirect.com/science/article/pii/S1386505622000661

In a meeting of the Headquarters for Medical Digital Transformation (DX) Promotion in 2023, former Prime Minister Kishida announced the development of a new system to facilitate EMR information sharing. This initiative includes the creation of a standardized cloud-based EMR system, with the goal of enabling the exchange of essential patient medical information across nearly all medical institutions by 2030.[14] Recently, the Digital Agency's My Number Portal introduced a new feature allowing individuals to access their own health and medical records. However, its scalability and adoption remain limited, suggesting that the adoption of EHRs continues to be dogged by public mistrust.

Another significant concern is the utilization of data for broader medical research and innovation. While Japan does not have a specific data protection and management framework for health information,[15] this area does fall under "special care-required personal information." In principle, medical institutions in Japan must obtain patient consent for each research or statistical project that involves extracting and sharing data from EHRs, making creating a comprehensive database difficult. According to an OECD survey conducted between 2019 and 2020, Japan, despite having a high percentage of national health datasets available, demonstrates a significantly lower rate of regular linkage of these datasets for research, statistics, and monitoring indicators—only 9%, compared to 100% in countries like Finland.[16] This presents a critical challenge to effectively leveraging health data for advancing medical research and improving patient outcomes in Japan.

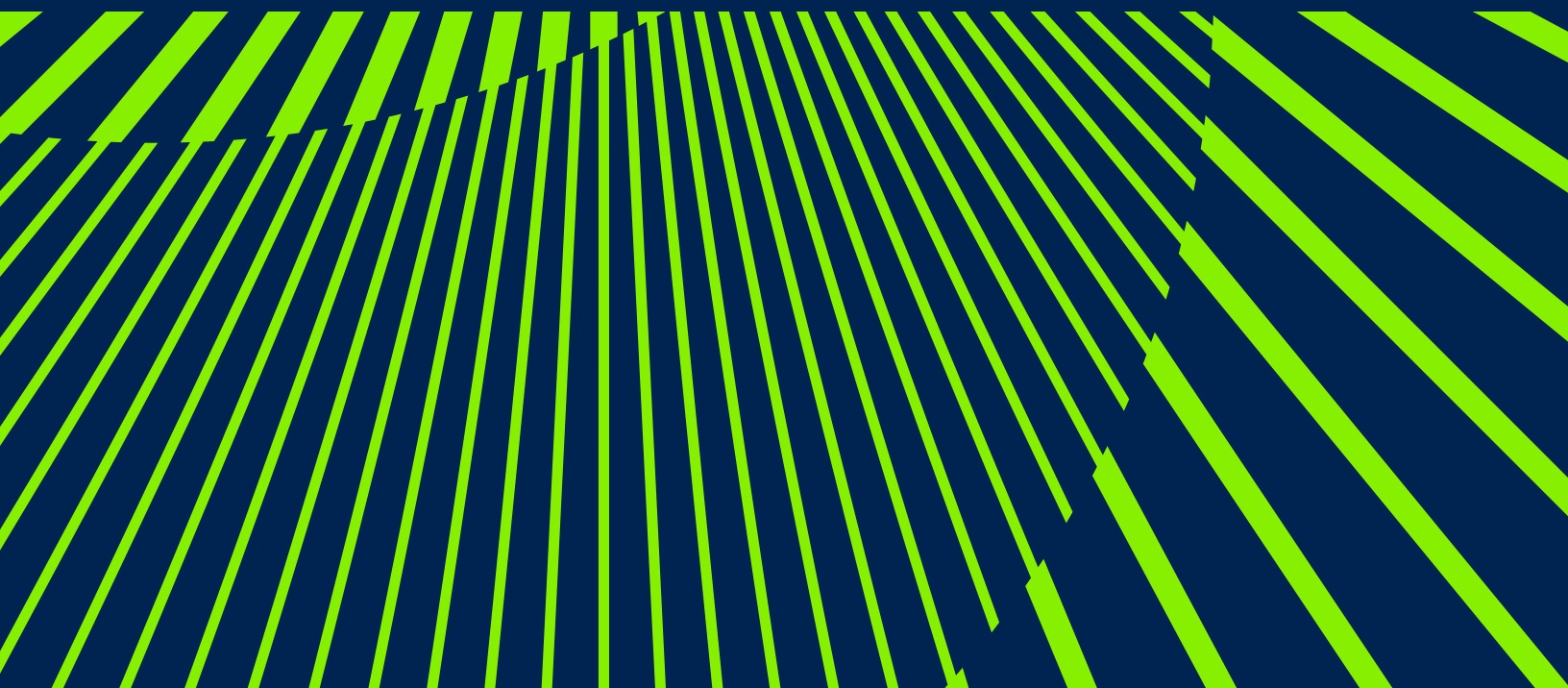
14 https://www.kantei.go.jp/jp/101_kishida/actions/202306/02iryoudx.html

15 https://www.lexology.com/library/detail.aspx?g=80355ecc-4c42-4c5e-9488-3cd533b26b2c

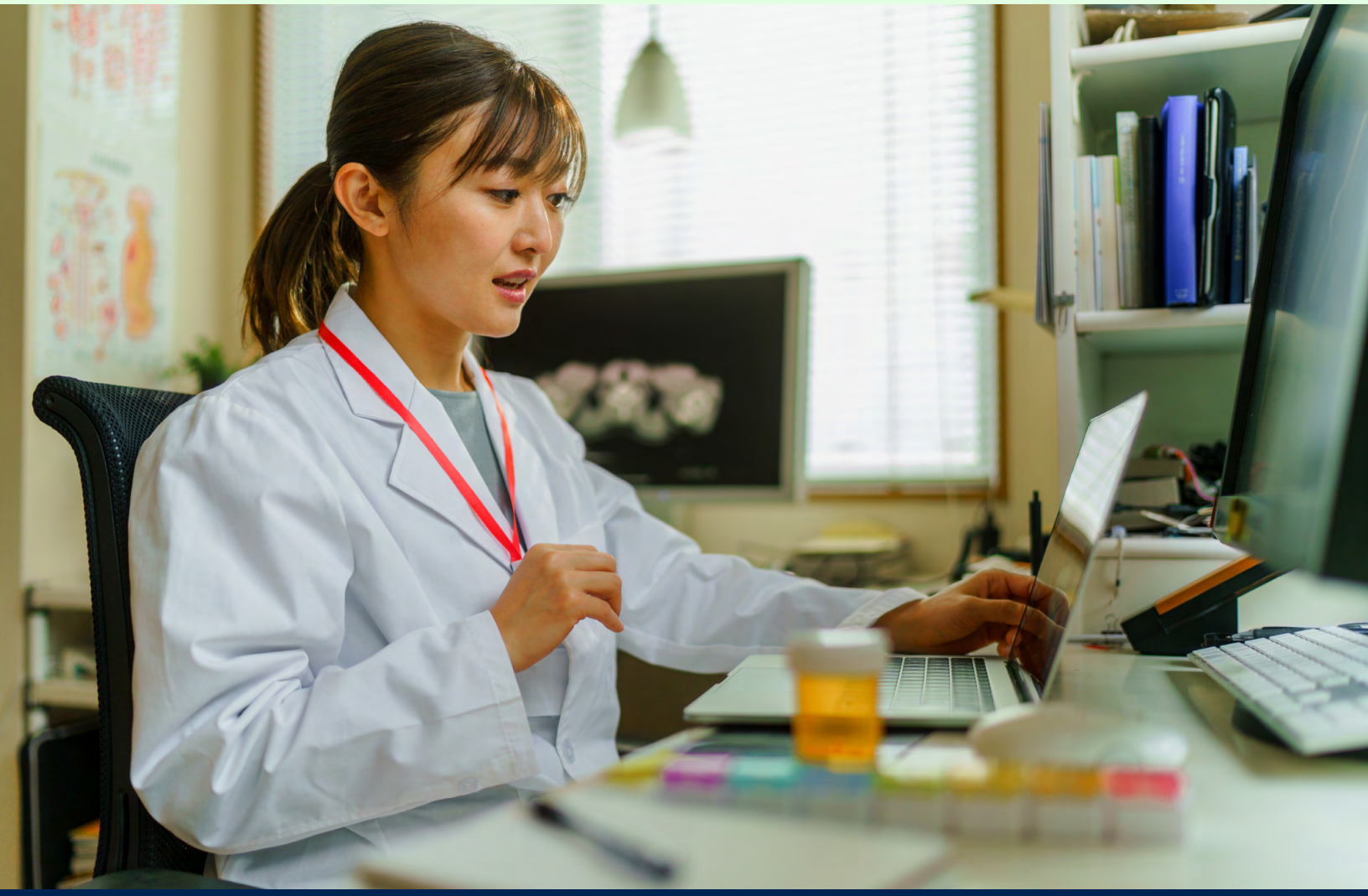
16 https://www.oecd-ilibrary.org/docserver/55d24b5d-en.pdf?expires=1721309713&id=id&accname=guest&checksum= 574AE73C2EEDC2DEC9A1674B5EF6CC04

Recommendations

- Exchange best practices on responsible data collection, enhancing interoperability, cybersecurity, and leveraging private sector technologies and capacity.
- Promote trust and understanding with the public about the value of collecting, storing, and using data to evaluate and/or create new medicines/technologies, and support pandemic detection and response.
- 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.
- Support U.S.-Japan and multilateral cooperation on privacy and cybersecurity efforts by ensuring that: privacy and cybersecurity policies are risk-based and globally aligned; privacy regimes are proportionate, balanced, and developed in partnership with industry; and cybersecurity is strengthened by enabling cross-border data flows and investing in cloud computing storage services, as opposed to forced data localization, which would only undermine the security of health data.



Telemedicine and Remote Care



Telemedicine could provide long-term, irrevocable benefits and convenience for Japanese society beyond COVID-19, not just to address the rising demands of a rapidly aging population but as a beneficial medical service for patients during public health crises.

–USJBC

During the COVID-19 pandemic, telemedicine was quickly identified as an area of critical importance for the transformation of healthcare services in both Japan and the United States. In June 2020, then-U.S. Embassy Tokyo Chargé d'Affaires ad interim Joseph Young spoke about the "rapid adoption of digital solutions" amid the disruption of COVID-19 and pointed to healthcare—specifically telemedicine—as an important area of "leveraging innovative technology in patient care, contact tracing and the development of treatments."[17] Young, at the time, was encouraged by the increased use and popularity of telemedicine and progress in related regulatory review in both countries.

In Japan, telemedicine services had a very slow uptake in clinics and medical institutions prior to the COVID-19 pandemic. Regulations still required in-person first contact for reimbursement; platforms for virtual engagements were still limited; and trust in new methods of healthcare delivery was low. In 2018, only 970 clinics were registered as offering telemedicine services. By July 2020, this number had increased exponentially to 16,100 as regulations were temporarily eased during the COVID-19 pandemic, allowing first visits to happen virtually and be reimbursed. By 2021 (the most recent year for which data is available), the number of registered clinics with telemedicine services increased to 17,000[18] (15%). In 2022, the top diseases treated via telemedicine were COVID-19 (56.5%), acute upper respiratory tract infection (19.8%), and acute bronchitis (16.4%).[19] Although the United States' market and regulatory environment differs from Japan's, it saw a similar growth in telemedicine services during the pandemic: according to a 2023 American Medical Association survey, 74.4% of physicians reported that telehealth was used in their medical practices—up from 25.1% in 2018.[20] However, in Japan, the

17 https://asia.nikkei.com/Opinion/US-Japan-digital-cooperation-is-world-leading

18 https://www.reuters.com/article/idUSKBN24A01P/

19 https://www.mhlw.go.jp/content/12404000/001165066.pdf

20 https://www.ama-assn.org/system/files/2022-prp-telehealth.pdf

percentage of medical institutions that have actually implemented telephone or online medical care from the first visit is currently less than 1% of the total.[21] This may be due to gaps in IT literacy among GPs (78% of whom are over 50 years old) and the fact that the elderly are particularly comfortable with face-to-face consultations.

While the sector was at first slow to pick up telemedicine services, COVID-19 provided the catalyst for rapid adoption and expansion. The Japanese telehealth market is expected to grow to USD 15 billion by 2030[22], supported by ongoing government deregulation and updated reimbursement policies. These efforts have made it possible for the industry to drive development and innovation in the market, with major players and startups both playing key roles. Limited but expanding reimbursement for telemedicine services and incentives for expanded access are further driving uptake, as local governments provide medical institutions with subsidies and reimbursements to adopt new service formats and insurance companies start to cover these services.

Furthermore, research and development to advance telemedicine technologies to create better access, especially for rural and isolated areas, and reduce health disparities is advancing at the university level – a prime area for U.S.-Japan collaboration, and one highlighted by both countries' leaders during the historic April 2024 U.S.-Japan Leaders' Summit. An example of this is research at Nagoya University investigating how 5G connectivity can enable telemedicine to contribute to medical care in remote communities. The Japanese government is also taking a direct part in this transformation, recently completing a three-month demonstration project establishing telemedicine services at "community centers" like post offices.[23]

21 https://www.soumu.go.jp/johotsusintokei/whitepaper/ja/r03/html/nd122320.html

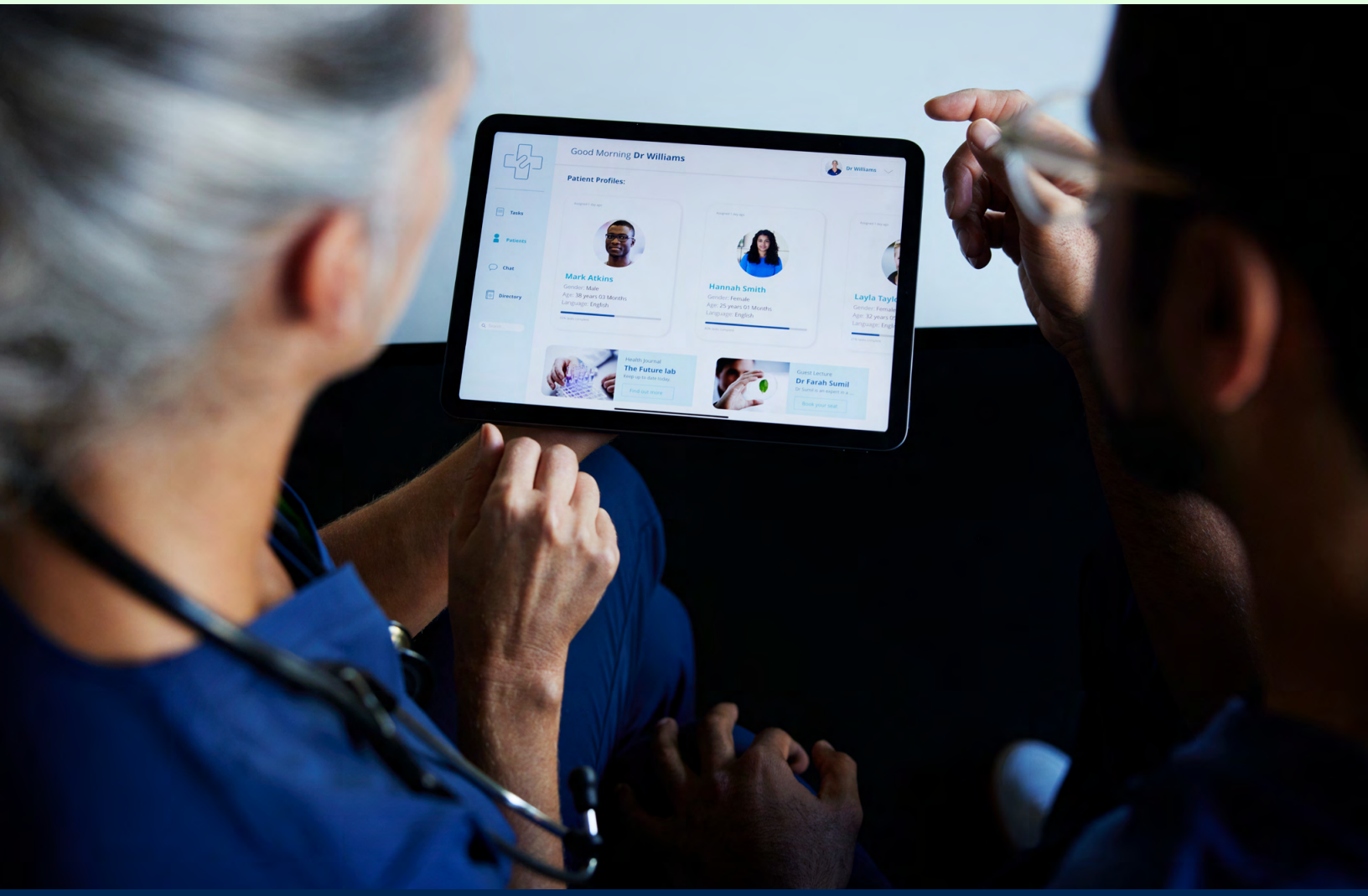
22 https://www.insights10.com/report/japan-telemedicine-market-analysis/

23 https://pj.jiho.jp/article/250830

Recommendations

- Promote equitable access by investing in digital infrastructure, including widespread internet access, and by fostering public-private partnerships.
- Support healthcare providers in adopting innovative digital health solutions through education campaigns and adoption incentives like expanding reimbursement scope for telemedicine services.
- Mobilize investment for digital health infrastructure, particularly in remote, rural, and underserved areas, through traditional financing mechanisms like tax incentives, subsidies and fund-matching schemes, as well as through innovative financing mechanisms like development impact bonds and blended financing instruments.
- Promote digital health literacy to ensure that all individuals are equipped to effectively use digital health technologies, including by collaborating with educational institutions to incorporate digital health education into healthcare curricula and conducting outreach campaigns to groups that may face additional barriers to digital health literacy, such as the elderly.
- Develop best practices to promote paperless operations for healthcare, including by removing the requirement to create/submit physical documents and amending the regulations under the Electronic Signature Act to clarify the legal status of cloud-based digital signatures.

Digital Therapeutics (DTx)



Develop policies and a regulatory environment conducive to the monetization and reimbursement of digital solutions to accelerate the development of digital therapeutics (DTx).

–USJBC

The development and implementation of Digital Therapeutics, also known as DTx, is making further headway in Japan, given the growing need for alternative and innovative ways to deliver and monitor health. Software for mobile devices, software as a medical device (SaMD), and other software tools are being developed with the same vigor as innovative medical devices and pharmaceuticals, with clinical trials verifying their safety and efficacy to support or implement medical practices and advance disease prevention, diagnosis, treatment, and health management. Such technologies include everyday items like health and fitness apps on smartphones, clinically approved apps to manage chronic conditions, and new technologies like head-mounted displays.

Companies are pushing ahead with innovative digital health products, supported by the Japanese government's efforts to streamline regulations for the adoption and implementation of DTx as part of its initiatives to upgrade its healthcare system. The 2014 revision of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices and the release of the Japanese government's Action Plan of Growth Strategy called for initiatives to set the foundation for Japan's digitalization of medicine, nursing care, and healthcare, like the establishment and utilization of a digital infrastructure in medical care and the creation of a system for utilizing medical and personal information. The government subsequently promoted the early adoption of SaMD products through the Digital Transformation Action Strategies in Healthcare (DASH) for SaMD in 2020 and unveiled an updated DASH strategy package (dubbed DASH 2) to enable clearer approval processes in 2023.

Despite early support and changes toward development and implementation of DTx, adoption remained sluggish until 2020, when startup CureApp received Japan's first DTx regulatory approval for its "CureApp SC," a nicotine addiction treatment app. This was followed by the world's first regulatory approval for its "CureApp HT"– a hypertension management app – in 2022.

Japanese companies are also contributing to the development of DTx in the United States, with Otsuka Pharmaceutical and Click Therapeutics recently announcing U.S. FDA approval for Rejoyn, the first prescription digital therapeutic authorized for the treatment of major depressive disorder symptoms.[24]

However, Japan still lags behind its counterparts in the United States and Europe, approving or reviewing only three SaMD therapeutic apps as of April 2024, compared to 32 in Germany and 27 in the United States. Additionally, a total of 141 apps in the United States and 48 in Europe were in development at that time, while just 12 were being developed in Japan.[25] So while there has been movement in this space, there is clearly room for improvement and opportunities for further industry engagement and collaboration. Clearer criteria for reimbursement for SaMDs would provide a more predictable environment for developers. Chronic regulatory challenges around language requirements also hinder expansion of SaMDs in the Japanese market, given the Japanese language requirement for application documents.[26] The Japan Digital Health Alliance (JaDHA), established in 2022, is leading the charge in Japan for further regulatory and reimbursement reform, as well as to grow familiarity with digital health among consumers and healthcare providers. The group also aims to expand its international collaboration, exploring opportunities to cooperate with the U.S. Digital Therapeutics Alliance.[27]

24 https://www.otsuka-us.com/news/rejoyn-fda-authorized

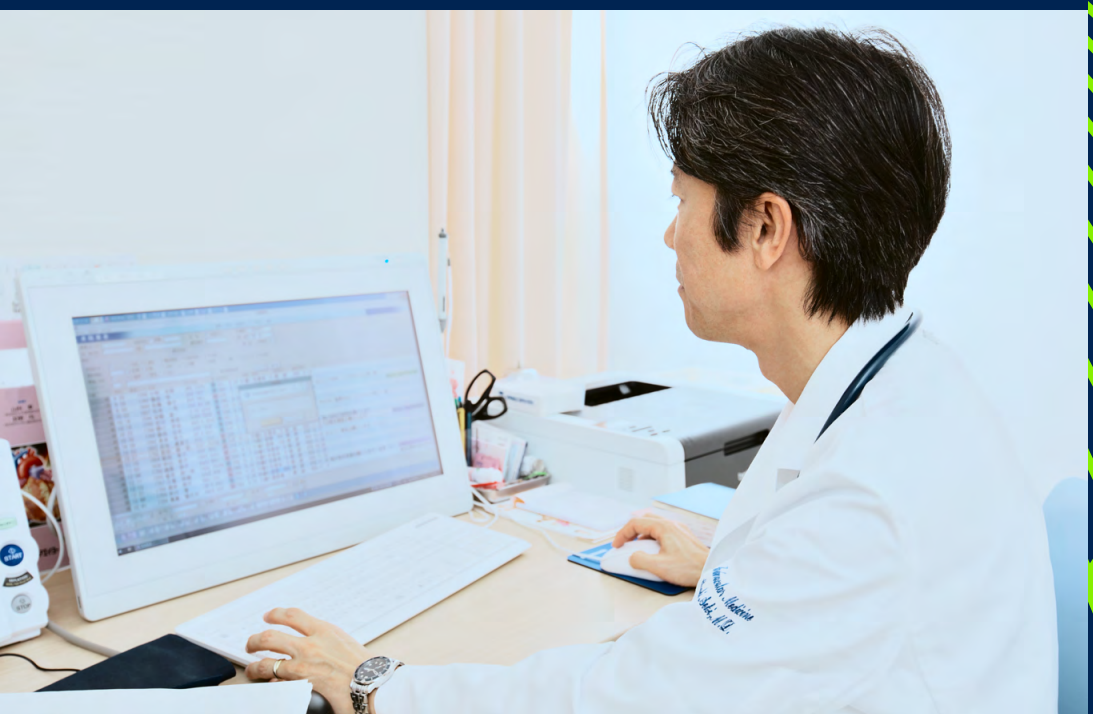
25 https://pj.jiho.jp/article/249676

26 https://www.pmda.go.jp/english/about-pmda/0004.html

27 https://pj.jiho.jp/article/251210

Recommendations

- Review existing reimbursement methods with the potential for identifying new options for payment policies that could promote the alternative delivery of treatments including via digital therapeutics and telemedicine.
- Engage with domestic and international partners from the public and private sectors to share best practices and discuss ways to improve the DTx development process, resolve delays in regulatory reviews and approvals, and enhance patient access to innovative digital therapeutics.
- Develop a clear criteria for reimbursement for SaMDs, in close collaboration with the private sector, to allow for a predictable regulatory environment.
- Address regulatory challenges around language requirements by extending PMDA's pilot English-language application initiative for pharmaceutical applications to medical devices and SaMD. The September 2024 initiative allows foreign companies to submit an application in English if they do not have a branch office in Japan on a case by case basis. The program could be extended to include foreign medical device companies as well to accelerate SaMD development and innovative product launches.



AI in Diagnostics and Drug Discovery

Research in healthcare AI has been growing rapidly, but launching real-world applications remains challenging given concerns about generalizability and bias, as well as compliance with data privacy laws.

–USJBC

Patient access to critical care and the efficient development of drugs and medical devices have driven much of the digital transformation in healthcare and research and development. Developers and providers are also driving change to address the accelerating shortage of medical workers and researchers. A growing number of startups are exploring alternative resources, including AI-enabled or enhanced medical technologies, to make processes faster and more efficient for developers, medical institutions, providers, and patients. Japan's market for diagnostic and therapeutic healthcare tools enabled by AI is expected to be worth around USD 114 million by 2027[28], with startups founded by medical professionals driving much of this momentum.

AI for healthcare, as currently conceived, involves the ability to process and learn from massive amounts of data, and includes machine and deep learning, expert systems, natural language processing and large language model (LLM) technologies, healthcare informatics, and cloud computing, as well as applications in robotics. Japan has focused on the use of AI in health and medical care since as early as 2015, when the government established an expert panel on the promotion of the use of information and communications technology (ICT) in the fields of health and medical care.[29] It then launched a consortium for accelerating the development of AI in the fields of health and medical care in 2018, which developed a road map to address challenges in the use of AI, such as informed consent, anonymization of data, and regulatory reviews.

Japan's push to incorporate AI into its healthcare ecosystem is largely meant to address the difficult intersection of a declining healthcare workforce, growing aging population, and unmet needs in drug discovery and medical devices. The government has recognized the strain on human resources—researchers, doctors, and medical professionals—to maintain quality care for patients and contribute to drug discovery and development. An interim

28 https://www.weforum.org/agenda/2023/12/three-ai-tools-setting-the-stage-for-a-tech-revolution-by-japans-entrepreneurial-doctors/

29 https://www.jstage.jst.go.jp/article/jniph/72/1/72_2/_pdf

report released in May 2024 by Japan's "council for the rapid delivery of the latest medicines to public through the improvement of drug discovery and development capabilities" details the human resource constraints at university hospitals, where doctors face an increased workload and lack the resources to contribute to drug discovery. The report recommends that resources are allocated to improve work efficiencies through the use of digital health transformation and the use of AI in development and clinical trials, as well as medical treatments and diagnostics.[30]

AI is already enabling more efficient, rapid innovation in drug discovery and medical devices and enhances the ability of existing diagnostic modalities to identify diseases. Such use of AI in disease categorization and identification reduces misclassification and increases quality of care, while opening up the market to other telemedicine solutions. Japan has established programs to integrate data derived from industry and academia into AI databases to better support research and development. One such program had 18 participating firms as of 2021. Another program launched in 2021, called the Healthcare AI Platform Collaborative Innovation Partnership, has supported efforts to integrate AI into R&D and helped find effective ways to utilize AI in healthcare.[31] Universities are also working to establish hubs and institutions in support of AI utliziation in research and development. Tohoku University Graduate School of Medicine created The Medicinal Hub to connect doctors, AI experts, and health technology companies to develop AI-based medical solutions.[32]

As the government looks to support providers and developers, the startup community has been active in enhancing Japan's established strengths in areas like diagnostics with AI technologies. For example, one area of focus has been endoscopes for early cancer detection. Japanese companies hold 98% of the global market, and entrepreneurial AI companies like AI Medical Services (AIM) are leveraging their resources and expertise to develop AI tools to enhance cancer detection.[33] Other diagnostic areas that startup companies have focused on include influenza and heart disease.

30 https://pj.jiho.jp/sites/default/files/pj/document/2024/05/Interim%20Report%20%28May%2022%2C%20Japanese%20only%29.pdf

31 https://www.jstage.jst.go.jp/article/jniph/72/1/72_2/_pdf

32 https://www.nature.com/articles/d42473-023-00376-2

33 https://www.weforum.org/agenda/2023/12/three-ai-tools-setting-the-stage-for-a-tech-revolution-by-japans-entrepreneurial-doctors/

The United States and Japan are also collaborating on AI diagnostic development. In June 2024, SoftBank announced a joint venture with Chicago-based health tech company Tempus, worth USD 200 million, to develop AI medical technology starting in oncology. The joint venture will enable the Chicago-based company to "build clinical sequencing capabilities, organize patient data and build a real-world data business in Japan," with SoftBank providing "genomic testing, medical data aggregation and analysis (genomic, clinical, pathology and imaging data), as well as AI insights for personalized treatments and therapies."[34]

Despite the accelerating development of innovative diagnostic and research tools using AI, and Japan's focus on supporting medical care professionals by making their work more efficient, companies still face regulatory hurdles in Japan. With regulatory approval for AI medical tools taking up to a year, only about 30 AI medical devices have been approved and certified in Japan as of February 2023, and any upgrades are required to undergo additional scrutiny post-approval. Integrating the devices into everyday medical use also continues to be a challenge as not all new innovative AI tools are covered by the national health insurance system and healthcare providers do not receive reimbursements for the service.

The Japanese government clearly recognizes the challenges and opportunities presented by AI technologies in healthcare. In addition to the government's interim report, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) is already implementing policies that address the evolving nature of medical devices that incorporate software and machine learning (ML) technologies. As part of the government's support, MHLW also earmarked JPY 61.7 billion of its JPY 33.8 trillion FY2024 budget toward "promoting the establishment of a platform for innovation" and supporting AI-driven drug discovery research that is oriented toward patients and clinical settings. A separate report from the MHLW's Project Team on Healthcare Startup Acceleration, led by former MHLW Parliamentary Vice-Minister Akihisa Shiozaki, urged further government support of startups in this area. The project team pledged to unlock Japan's startup potential and address challenges through strategic investments in areas like AI data utilization and increased communication and government engagement with startups.[35]

34 https://techcrunch.com/2024/06/27/softbank-forms-ai-healthcare-jv-in-japan-with-tempus/

35 https://www.mhlw.go.jp/content/10807000/001257559.pdf

Recommendations

- Review policies on responsible AI use in healthcare R&D and explore consensus-based definitions and frameworks for responsible AI.
- Incorporate education on AI tools for healthcare workers.
- Improve the regulatory approval system for AI-based technologies in the health sector.
- Push for legislation that covers more AI tools within the national health insurance scheme.
- Support the more extensive utilization of EMRs or EHRs for medical research and drug development and the use of AI tools, including LLM, by healthcare workers in research using these records.
- Promote public-private dialogue to encourage Japan to embrace data-driven solutions to healthcare challenges through evidence-based policy that supports data utilization.

Conclusion

Japan is making strides in its digital health transformation, especially in the post-COVID-19 era, but there are ample areas for further leadership and improvements to ensure reliable, accessible health systems. Foremost among these are hurdles to sharing health data among medical institutions and companies to improve patient care and support research efforts. However, even this area has been trending toward eased regulations due to the need to improve efficiency in medical research and development and provide transparency in clinical trials.[36]

As it works to create an innovative, efficient, and resilient healthcare ecosystem, the Japanese government has been engaging the private and academic sector for their perspectives now more than ever. U.S. companies can further build on this momentum and engage with the Japanese government, partners in the private sector, and research institutions to advance the country's digital health transformation.

Cooperation between the U.S. and Japan on digital health presents a unique opportunity to revitalize bilateral engagement and secure some near-term wins for both countries that can advance the health and well-being of their populations.

36 https://www.jpma.or.jp/english/reports/drug_evaluation_committee/eki4g60000001d6n-att/ctds_nl_2019.pdf

U.S. Chamber of Commerce
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