[English Translation]

White Paper on Strengthening Japan's Healthcare Startup Ecosystem

- Making Japan a Startup Powerhouse in Health, Medical, and Nursing Care-

[Summary]

June 2024

Project Team on Healthcare Startup Acceleration,
Ministry of Health, Labour and Welfare, Japan

Overview

Circumstances

Japan has the potential to lead global innovation in healthcare, yet healthcare startups in Japan are limited in number and success

- Japan needs to care for its super aging population –it is required to innovate ahead of the rest of the world.
- Japan has been investing heavily in healthcare research. It also has unique advantages (e.g. accumulation of data collection through its universal insurance system).
- Nevertheless, Japan's healthcare startups see limited success – it is critical for us to identify bottlenecks and reinforce our startup ecosystem.

Goals

Capture the global market by bolstering Japan's healthcare SU ecosystem

Our goals are:

- To reinforce the quality and sustainability of healthcare (medical care, wellness & nursing care) in Japan.
- To drive development of innovative products & services, propel them to succeed globally, and then nurture them into globally competitive & growing industries.

Strategies

Strategically target investment based on the structure and dynamics of each market domain

1) Go Global Approach

2) Two staged Approach

3) Domestic Empowerment Approach

Tactics

25 policy recommendations in 5 fields

Total of 25 recommendations (list on p. 3)

(5 fields: "General", "Biotechnology and Regenerative Medicine", "Medical Devices and SaMD", "Medical DX and AI", and "Age Tech")

Strongly promote and support healthcare SUs in the medical and nursing care fields

Policy Recommendations

General Recommendations Across Markets

REC 1 Enhance and strengthen the function and capabilities of MEDISO* to further provide proactive and continuous support to startups.
*MEDISO: MEDical Innovation Support Office

REC 2 Introduce a new type of grant tied to development milestones ("Health-Tech Challenge"), to accelerate drug discovery for intractable diseases and development of medical devices.

REC 3 Establish a new centralized point of contact to consolidate requests from healthcare startup stakeholders regarding revision of medical fee reimbursements and related matters.

REC 4 Provide English-language services for most, if not all, of the government programs, support and application procedures for healthcare startups.

REC 5 Invite top-tier global VCs in the healthcare sector to further engage in the Japanese market.

REC 6 Highlight the importance of the healthcare sector as a key target for impact investments.

REC 7 Promote the use of Decentralized Clinical Trials (DCTs) and other digitization measures to significantly reduce the time and cost to market.

REC 8 Introduce new incentives for insurers to encourage proactive use of SUs products and services.

REC 9 Raise awareness on the types of startup activities allowed for medical doctors with executive/board positions in healthcare providers.

REC 10 Clarify the legal regulations regarding non-clinical direct-to-consumer testing services.

Biotech & Regenerative Medicine Task Force

REC 11 Expand the scope of AMED*s Project of Strengthening Program for Pharmaceutical Startup Ecosystem (a $2.2B matching fund & support program conducted in conjunction with registered VCs) to include preclinical early-stage pipelines.
*AMED: Japan Agency for Medical Research and Development

REC 12 Boost educational programs and invite world-class CDMOs to Japan, to accelerate training of R&D and manufacturing talents and build capabilities for obtaining FDA/EMA approvals.

REC 13 Clarify listing requirements for Japan Exchange Group (JPX) so as not to block the IPOs of startups in biotech and regenerative medicine space.

Medical Device & SaMD Task Force

REC 14 Accelerate the collection of clinical evidence for the development of innovative therapeutic devices equivalent to Class III/IV, by expanding financial support for medical device startups and Clinical Research Core Hospitals.

REC 15 Enhance government support for overseas expansion of Japanese healthcare startups with innovative therapeutic devices to capture the US and other global markets.

REC 16 Deregulate business license requirements and advertising regulations that are potentially restricting SaMD (Software as a Medical Device) development and commercialization.

REC 17 Support the evidence building and adoption of SaMD by medical institutions.

Medical DX & AI Task Force

REC 18 Develop continuous API connection and expand shared items between public medical databases such as Mynaportal and private service providers.

REC 19 Clarify relevant regulations regarding healthcare and AI and further support the adoption of AI products and services in the medical field.

REC 20 Establish a consultation desk and objective evaluation system, to reduce barriers for introducing startup products and services in hospitals and health insurance societies.

REC 21 Drive standardization of emergency activity records in emergency services by ambulance crew, which currently vary by municipality, and encourage digitalization.

Age Tech Task Force

REC 22 Launch a new centralized consultation desk, "CARISO (CARe Innovation Support Office)", at MHLW to support Age Tech startups.

REC 23 Increase the amount of digitization support subsidies for nursing care facilities to promote the introduction of Age Tech.

REC 24 Revise the evaluation of Age Tech products for home care providers and users under the Nursing Care Insurance to accelerate their introduction.

REC 25 Conduct overseas market research and provide network building support necessary for exporting Age Tech products and services.

Japan has the potential to lead global innovation in healthcare, yet healthcare startups in Japan are limited in number and success

Opportunities

- Japan has a super aging population ahead of the rest of the world–innovation is necessary in the healthcare sector to face this challenge.
- Japan has been investing heavily on healthcare research. It also has unique advantages (e.g. accumulation of data collection through its universal insurance system).

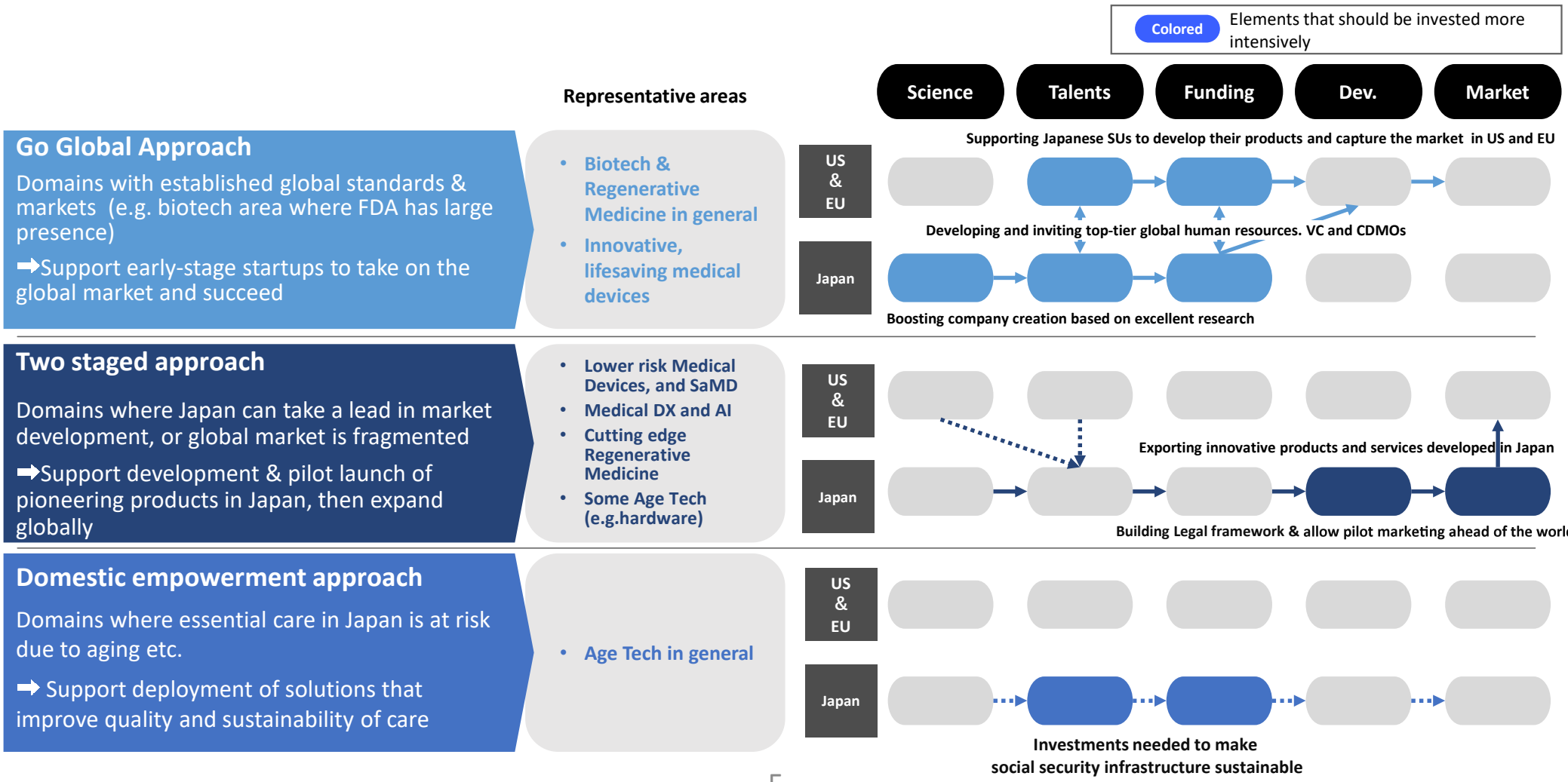
Circumstances

- While many healthcare SUs are driving innovation abroad, the number and success of healthcare SUs in Japan is limited.
- Since 2019, the number of healthcare SUs founded in Japan has dropped to about 50 per year, with no unicorn companies in the healthcare sector, and the number of large M&As and IPOs has been low.

Challenges

- Though Japan has the potential to lead the global healthcare market through its innovations, bottlenecks exist in each process of commercializing the results of academia and developing them into a new business.
- There is an urgent need for strategic support for the bearers of innovation.

Japan needs to strategically target investment based on the structure and dynamics of each market domain



The appropriate approach differs for each domain in the four markets relevant to our task forces

Four target healthcare markets for our recommendations

	Biotech and Regenerative products	Medical Devices and SaMD	Medical DX and AI	Age Tech
1) Go global approach	**General Biotech and regenerative products** • The global regulatory standard and largest markets in US & EU. • Japanese startups need to launch into US & EU to succeed globally	**Innovative life-saving medical devices** • Practices/unmet needs in critical care are universal across countries • U.S. market is large and FDA approval is the global standard		
2) Two staged approach	**Some regenerative products** • Japan has the "New Law on Regenerative Medicine" which makes it a better environment to develop regenerative medicine ahead of the rest of the world	**Medical device and SaMD with relatively low risk** • Build evidence and establish a business model in home country • Conduct market research from early stage to expand overseas	**General Medical DX and AI** • High-quality medical data is a strength of Japan, and the first step is to establish a business model in Japan before going global	**Some Age Tech(mainly hardware)** • Demographics & market structure differs from country to country, including the insurance system
3) Domestic empowerment approach				**Age Tech** • There is growing shortage of nursing care personnel in Japan; sustainability of care system is at stake unless innovative care techs are deployed

Task Force: General Recommendations

Outlook of Healthcare SU Ecosystem

- During our interviews, various experts pointed out “there are efforts to improve the healthcare SU ecosystem," but “the ecosystem is immature" and “talents are poorly connected".
- Even when there is excellent research and science, it is difficult to attract human and financial resources, and the basis for commercializing or getting the seeds off the ground is fragile. Rigid and ambiguous regulations, an inefficient testing environment, and a market that is unenthusiastic to SUs stand in their way. In addition, the community is dispersed, with few international connections, and SUs tend to be solitary.
- It is necessary to examine where in the ecosystem there are roadblocks or coordination challenges, and to address them in parallel as a package.

Policy Recommendations	Science	Talents	Funding	Dev.	Market
1) Continuous and active support to healthcare SUs through “MEDISO 2.0”		●	●	●	
2) Introduce a new milestone-type development grant (“Health-Tech Challenge”)	●	●	●	●	
3) Establish a new point of contact on requests from healthcare SU stakeholders regarding revision of medical fee reimbursement and related matters	●		●		●
4) provide English-language services for most, if not all, of the government programs, support and application procedures for healthcare SUs		●		●	
5) Invite top-tier global VCs in the healthcare sector to further engage in the Japanese market		●	●		
6) Highlight the importance of the healthcare sector as a key target for impact investments		●	●		
7) Promote the use of Decentralized Clinical Trials (DCTs) and other digitization measures to significantly reduce the time and cost to market.				●	
8) Introduce new incentives for insurers to encourage proactive use of SUs products and services.			●		●
9) Promote business activities in SU by medical doctors		●			
10) Clarify the legal regulations regarding non-clinical direct-to-consumer testing services				●	

REC 1

Enhance and strengthen the function and capabilities of MEDISO* to further provide proactive and continuous support to startups.

*MEDISO・・・MEDical Innovation Support Office

- Fundamentally strengthen MEDISO's function and capabilities into "MEDISO 2.0," clarify the hub function of government support organizations, and provide thorough support for SUs, including overseas expansion.
- Establish a system and human resources related to MEDISO and formulate a plan to strengthen the system by upgrading and expanding the personnel of the MHLW Venture Support Strategy Office during FY2024.
- Create an organizational foundation for continued MEDISO activities by significantly increasing the MEDISO budget for multiple fiscal years from FY2025.

REC 2

Introduce a new type of grant tied to development milestones ("Health-Tech Challenge"), to accelerate drug discovery for intractable diseases and development of medical devices.

- Introduce a milestone-type development support program (a framework in which additional subsidies are provided each time a step-by-step target is met) in FY2025.
- While also utilizing the SBIR system, the program shall target development themes that lead to solutions to social issues such as drugs for intractable diseases and rare diseases, and medical countermeasures for infectious disease including antimicrobial resistance(AMR), innovative medical devices based on unmet medical needs, and SaMD using AI technology.

REC 3

Establish a new centralized point of contact to consolidate requests from healthcare startup stakeholders regarding revision of medical fee reimbursements and related matters.

- Establish a new contact point to consolidate requests for revision of medical service fee reimbursed from Universal Health Insurance and related staffing standards in FY2024.
- Develop a system to adequately listen to healthcare SUs, investors, and other stakeholders, and to provide prospects and advice on the realization of their requests as appropriate, and establish a mechanism to appropriately reflect them in measures as necessary.

REC 4

Provide English-language services for most, if not all, of the government programs, support and application procedures for healthcare startups.

- Identify media and contact points of related organizations related to healthcare SUs that do not yet have English-language support by the end of FY2024, and complete the translation of those that can be translated using generative AI by the end of FY2024.
- Increase the number of staff for consultation during FY2025 to enable English-language support for SU-related application documents and consultation services, including consultation services for pharmaceutical affairs through PMDA* and support programs such as subsidies.

*: Pharmaceuticals and Medical Devices Agency

REC 5

Invite top-tier global VCs in the healthcare sector to further engage in the Japanese market.

- Implement a visit program to Japan in FY2024 with the participation of top overseas VC firms, including introduction of domestic seeds, events, etc.
- Develop METI's model for promoting LP investment in overseas VCs and promote personnel exchange with top global VCs to foster venture capitalists.
- Formulate and implement measures to expand overseas VC operations in Japan, increase investment in Japan, and search for domestic seeds, in cooperation with MHLW, METI and MEXT.

REC 6

Highlight the importance of the healthcare sector as a key target for impact investments.

- Promote impact investment in FY2025, by measures including explicitly designating the healthcare business domain as an investment target in the "Essentials of Impact investment in Listed Markets," which is being discussed under the Impact Consortium.
- The FSA shall, in collaboration with the MHLW and METI, consider measures to promote networking and the sharing of case studies and know-how among participants in the market for impact creation.

REC 7

Promote the use of Decentralized Clinical Trials (DCTs) and other digitization measures to significantly reduce the time and cost to market.

- Expand subsidies under AMED research funds for the costs of clinical trials suitable for DCTs, such as cancer, intractable diseases, pediatric, and infectious diseases, and consider whether making investment in DX for clinical trials, such as DCTs introduction, should be a requirement for AMED research funds in FY2025.
- Add the requirement for approval of Clinical Research Core Hospitals that they have a system that enables them to conduct DCTs by the end of FY2025 at the latest.
- Promote standardization of various tasks related clinical trials (including central Institutional Review Board, Informed Consent Form) across sites, and implement such standardization among hospitals effectively.

REC 8

Introduce new incentives for insurers to encourage proactive use of SUs products and services.

- Evaluate the active use of digital technology in the future subsidy projects for health insurance societies so as to encourage pioneering efforts by insurers, including proactive use of SUs products and services by the end of FY2025.
- Revise the formula of the Late-stage Support Payment payable by insurers so that insurers who are working on the use of digital technology, including SU solutions, can be highly evaluated by the 5th term (starting in FY2027) at the latest.

REC 9

Raise awareness on the types of startup activities allowed for medical doctors with executive/board positions in healthcare providers.

- Clarify that it is permissible for healthcare SU and medical corporations to conduct transactions as long as such transactions do not affect the non-profit nature of medical institutions by the end of FY2024 so as to ensure that startup activities by medical doctors in SUs are not unduly hindered by the eligibility requirement of the officers of medical institutions under the “Not-For-Profit” rule.

REC 10

Clarify the legal regulations regarding non-clinical direct-to-consumer testing services.

- Promote examination of legal issues related to medical practice and non-clinical direct-to-consumer testing services, and work to clarify the outer boundaries of non-clinical direct-to-consumer testing services by the end of FY2024.
- In order to regulate improper notification of test results, clarify the interpretation of Article 17 of the Medical Practitioners' Act, which states that "the notification of test results must not go beyond notifying the fact of test results and the general standard values of test items" in related Q&As and administrative communications. In addition, clarify the interpretation for cases where there is a risk of violation of the Medical Practitioners' Act, such as when test results lack publicly known scientific evidence, or when unqualified persons make their own medical judgments.

Task Force: Biotechnology and Regenerative Medicine

Characteristics of Market Structure

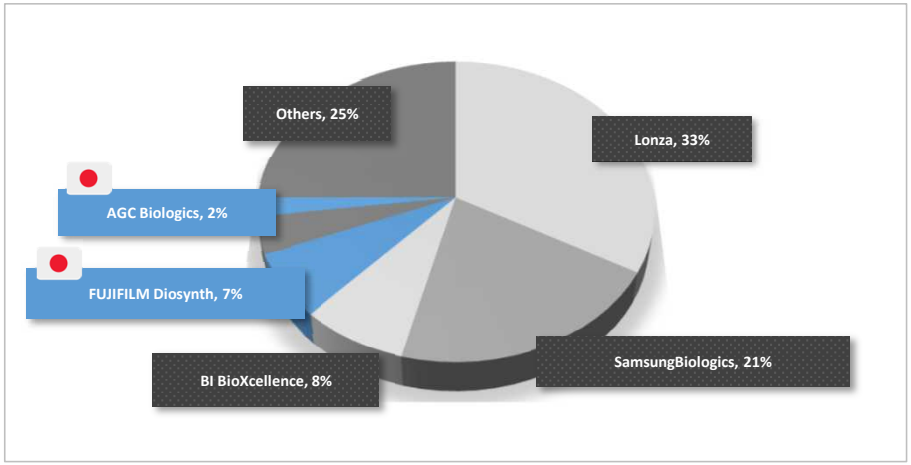
- **As competition in drug development around the world intensifies and regulatory standardization continues, the approval of the FDA and EMA, which hold huge markets, is especially important and essential.**
- **On the other hand, the Japanese market is facing challenges in the development environment, such as the low market share of CDMOs (Contract Development and Manufacturing Organizations), although the new Acts on Regenerative Medicine has created a partially advanced developing environment (Figure 1).**
- **In addition, the number of basic patents created for globally approved products in Japan decreased from 18 in 2013-2015 to 7.5 in 2019-2021, and the percentage also decreased from 15% to 7%.**

Market Size

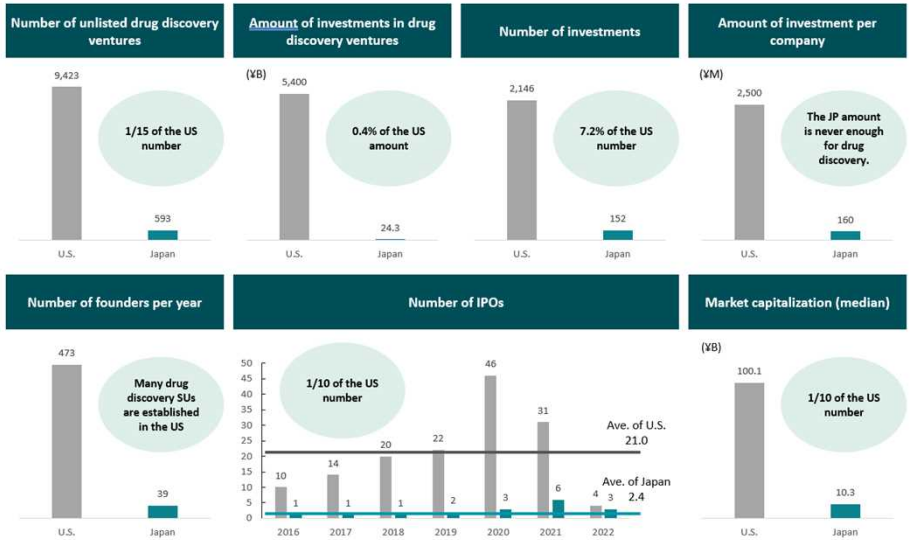
- The global pharmaceutical market in 2022 is expected to be approximately 200 trillion yen, with the U.S. accounting for about 40% of the market, and overall positive growth is expected.
- The Japanese market in 2022, on the other hand, is expected to be about 10 trillion yen and grow negatively.

SU Achievements

- There are more than 9,000 unlisted drug discovery SUs in the U.S., with about 80% of new drugs originating from SUs and a large number of IPOs.
- Japan, on the other hand, lags far behind in terms of the number of SUs and the amount of investment (Figure 2).



(Figure 1) Manufacturing Capabilities of Top 90 CDMOs the global biotech sector*
(Representative Japanese companies are highlighted in blue)



(Figure 2) Comparison of the number of drug discovery ventures, the amount/number of investment, the number of IPOs, the market capitalization, etc. in the U.S. and Japan**

*: Compiled by Answers News based on data from Evaluate
**: "Biotechnology Part 1: Aimed at by Major Companies in Different Industries" (Mizuho Securities Co., Ltd.)

REC 11

Expand the scope of AMEDs Project of Strengthening Program for Pharmaceutical Startup Ecosystem (a $2.2B matching fund & support program conducted in conjunction with registered VCs) to include preclinical early-stage pipelines.

- Revise the requirements for AMEDs Project of Strengthening Program for Pharmaceutical Startup Ecosystem (a $2.2B matching fund & support program conducted in conjunction with registered VCs) to expand its scope to include early-stage pipelines (especially in the stage of finding pre-clinical and final development candidates) including lowering the current minimum investment requirement ($6.6M) from lead-registered VCs.
- In addition, strengthen the support system for early-stage development in Japan through the AMED's Project of Strengthening Program for Pharmaceutical Startup Ecosystem.

REC 12

Boost educational programs and invite world-class CDMOs to Japan, to accelerate training of R&D and manufacturing talents and build capabilities for obtaining FDA/EMA approvals.

- Compile the direction of policy measures on development of domestic human resources related to drug discovery within FY2025 by organizing the existing educational bases in manufacturing and development and enhancing the number of faculty members with practical experience.
- In order to provide opportunities for domestic personnel to gain experience and achievements up to FDA/EMA approval, continue to strengthen the development of domestic CDMOs, as well as consider attracting global top-class CDMOs with abundant experience and projects.

REC 13

Clarify listing requirements for Japan Exchange Group (JPX) so as not to block the IPOs of startups in biotech and regenerative medicine space.

- Review Q&As and other statements on the Exchange to make it clear that certain clinical trial phases and alliances with large pharmaceutical companies regarding drug discovery pipelines are not a requirement for an IPO by the end of 2024.
- Promote understanding that an IPO may be a realistic option for biotech startups, even if a pharmacological effect has not been confirmed in Phase IIa clinical trials or an alliance has been formed.

Task Force: Medical Devices and SaMD

Characteristics of Market Structure

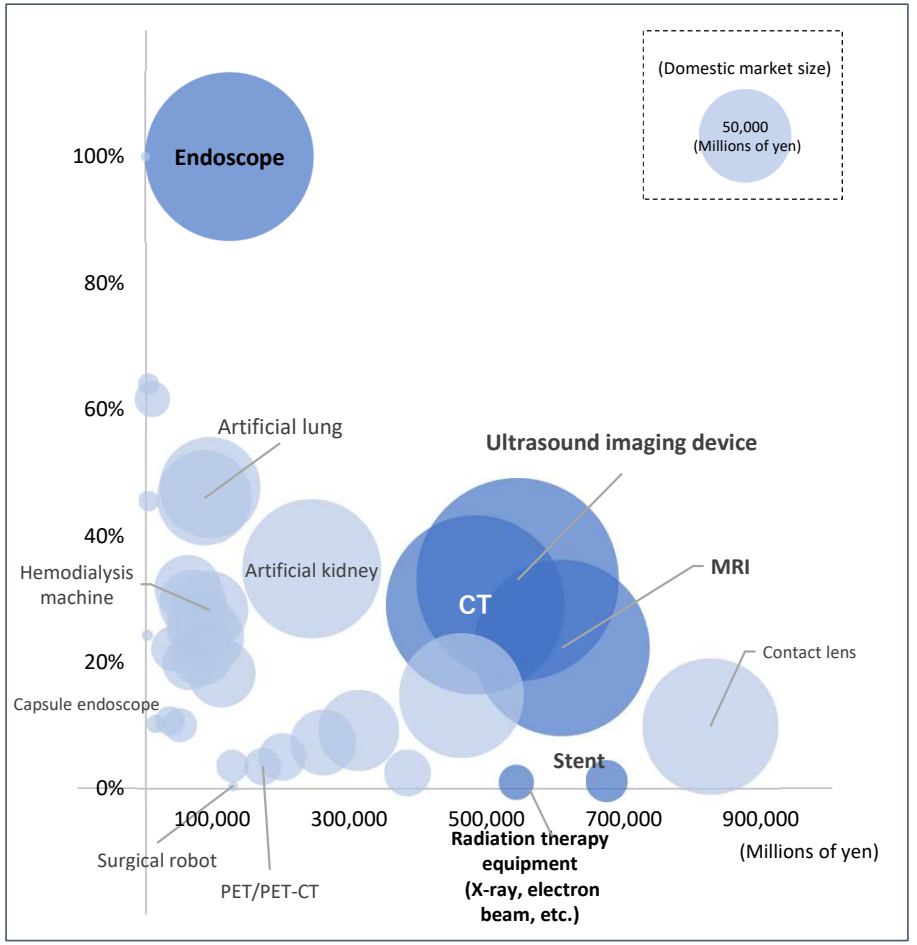
- **Medical devices are roughly classified into "diagnostic" and "therapeutic" devices. Japan is strong in diagnostic imaging equipment, while its international competitiveness in "therapeutic" medical equipment is low (Figure 1).**
- **Medical device SUs play a particularly important role in developing innovative medical devices that support or sustain human life or is of substantial importance in preventing impairment of human health etc, as the risk of technological development may exceed the tolerance of major companies, and there is a high need for such devices in overseas markets. On the other hand, for devices that require a great deal of labor and cost when introduced to the medical field, it is considered important to first form a business foundation in Japan before expanding overseas.**
- **In addition, SaMD is attracting attention as an area with growth potential due to innovative technologies such as AI, but there are challenges in development and business implementation (e.g., obtaining clinical evidence and advertising).**

Market Size

- The global medical device market will exceed 70 trillion yen in 2023 (CAGR* is 5.9% through 2027), of which the U.S. accounts for about 47%.
- The Japanese market, on the other hand, is expected to be approximately 3.7 trillion yen in 2023, with a CAGR of 3.7% through 2027.

SU Achievements

- Since 2019, about 30 Japanese medical device SUs have been established annually, but only about 1/10 the number in the US.
- Exit strategies are dominated by M&A internationally, but large acquisition deals for Japanese medical device SUs are extremely limited.



(Figure 1) Global market size by equipment (horizontal axis) and share of Japanese firms (vertical axis) and sales (size of bubble)**

*: Compound Annual Growth Rate
**: "Information Collection on International Competitive Position of Goods, Services and Software of Japanese Companies in FY 2008". (New Energy and Industrial Technology Development Organization (NEDO)) (Fuji Chimera Research Institute, Inc.)

REC 14

Accelerate the collection of clinical evidence for the development of innovative therapeutic devices equivalent to Class III/IV, by expanding financial support for medical device startups and Clinical Research Core Hospitals.

- Expand subsidies for Clinical Research Core Hospitals that cooperate in FIH studies of innovative therapeutic medical devices from FY2025.
- Enhance and strengthen the relevant projects for SUs on searching for and identifying needs, verifying concepts, and providing access to physicians and medical institutions with a view to collaborating with physicians and related academic societies from FY2025 onward.
- Promote the utilization of data for the development of next-generation medical devices by stablishing a comprehensive registry such as enhancing the initiatives of CIN* *

**: Clinical Innovation Network

REC 15

Enhance government support for overseas expansion of Japanese healthcare startups with innovative therapeutic devices to capture the US and other global markets.

- In order to capture US market, which is the most important factor in acquiring the global market, the government should enhance government support for overseas expansion strategy building and clinical trials and strengthen cooperation between medical device SUs and major companies in collaboration with JETRO and other organizations from FY2025.
- Strategically promote international coordination of pharmaceutical regulations for emerging countries in Asia, and support product development and community building with key players based on the needs of those countries.
- Conduct a survey on the international standardization of medical device regulations in FY 2025, and promote efforts for such standardization from FY2026.

REC 16

Deregulate business license requirements and advertising regulations that are potentially restricting SaMD (Software as a Medical Device) development and commercialization.

- Relax the requirements for obtaining a medical device manufacturing and sales license in a manner that both promotes business development and ensures product quality from FY 2025.
- Consider allowing the use of clinical data that guarantees objectivity, such as data attached to the application for marketing approval, for advertising of SaMD products for home use by establishing a working group in FY 2025.

REC 17

Support the evidence building and adoption of SaMD by medical institutions.

- Establish a demonstration environment to conduct comprehensive evaluations based on the characteristics of SaMD in addition to clinical outcomes at the National Center for Advanced Medical Research and other institutions in FY2025 and beyond.
- Consider measures to promote high-quality medical equipment, including SaMD, by utilizing the funds for securing comprehensive medical and long-term care in local communities, which is to promote physicians' Work Style Reform and to build an efficient and high-quality medical care delivery system, as well as with reference to examples of incentives in other countries.

Task Force: Medical DX & AI

Characteristics of Market Structure

- **The healthcare data industry is expected to grow rapidly worldwide, but is greatly affected by healthcare systems and privacy regulations in each country.**
- **In Japan, the government's medical DX measures under the universal health insurance and nursing care insurance systems are rapidly accumulating high-quality healthcare data, and there is potential to become an attractive market for businesses related to healthcare data.**
- **At present, however, the actual use of medical data sharing services remains sluggish, and there is stagnation in various parts of the cycle from data input to the return of value through data utilization (Figure 1).**

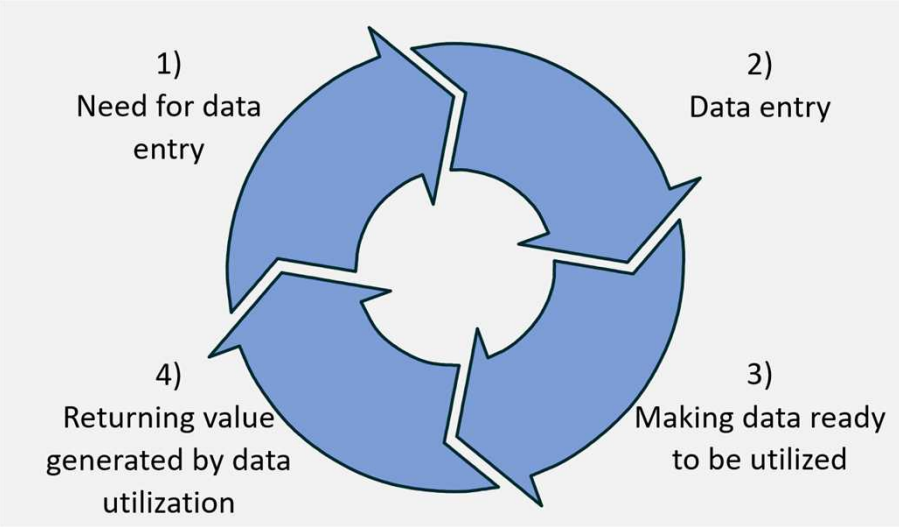
Market Size

- The global healthcare IT business market* is projected to exceed $80 billion by 2025 under high growth rates.
- On the other hand, the Japanese healthcare IT business market* is estimated to reach only about 400 billion yen in 2025 under a low growth rate (Figure 2).

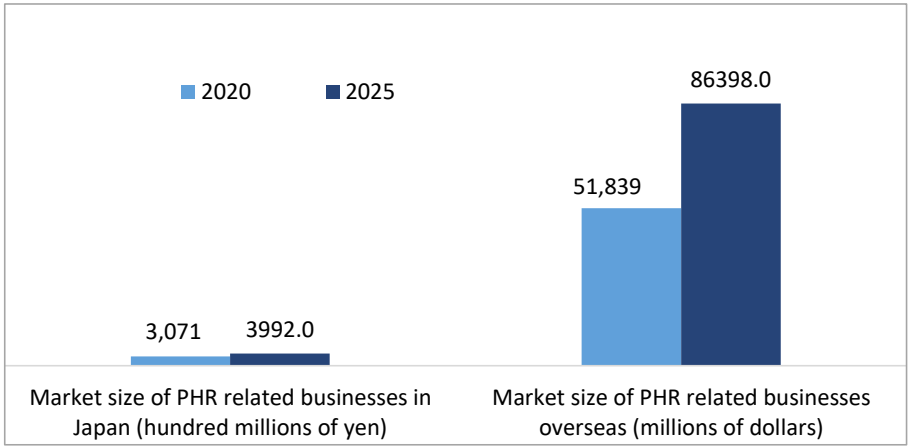
SU Achievements

- In the U.S., investment in AI-related SUs is accelerating rapidly, not only in the healthcare sector.
- Medical DX and AI-related businesses are increasing in Japan as well, but a lack of absolute investment and institutional and regulatory challenges are preventing further performance growth.

*For detailed definitions of each market, please refer to the "FY2021 Healthcare Service Social Implementation Project (Survey on Business Environment Development of Healthcare Industry) Final Report" (Ministry of Economy, Trade and Industry).



(Figure 1) Cycle for generating value from medical data



(Figure 2) Market size of PHR-related businesses in Japan and overseas*

REC 18

Develop continuous API connection and expand shared items between public medical databases such as Mynaportal and private service providers.

- For APIs connection between private PHR services and Mynaportal, instead of requiring users to authenticate each time, modify operations so that once a user authenticates, automatic connection can be maintained for a certain period of time.
- Similarly, for APIs connection between private services and Online Health Insurance Verification, ensure that no redundant authentication is required when seeing a doctor and getting prescribed pharmaceuticals.
- Expand information items shared through Mynaportal API, such as medical treatment records including the name of the medical institution where the patient was consulted, the date of consultation, and the name of the medical procedure as well.

REC 19

Clarify relevant regulations regarding healthcare and AI and further support the adoption of AI products and services in the medical field.

- Identify regulations that are particularly relevant for medical AI development and clarify the applications of the regulations by the end of FY 2024.
- Encourage milestone-type development support (REC 2), the use of a request contact point for medical fee reimbursement (REC 3), and involvement in insurance operations by insurers (REC 8) in order to enhance options for SUs to obtain economic returns through the spread of new products and services using AI by SUs.

REC 20

Establish a consultation desk and objective evaluation system, to reduce barriers for hospitals and health insurance societies.

- Promote awareness of the existing certification program of private digital services on their conformity to the technical requirements of the guidelines on medical data security in FY2024 and consider the need for additional measures in FY2025 and beyond.
- Facilitate understanding of the issues faced by healthcare startups in relation to data sharing with and API connections to electronic medical records and health insurance societies' core systems and consider how to deal with such issues, by, for example, establishing a cross-ministry consultation desk for SUs during FY2024.

REC 21

Drive standardization of emergency activity records in emergency services by ambulance crew, which currently vary by municipality, and encourage digitalization.

- MHLW and the Ministry of Internal Affairs and Communications (MIC) shall work together to standardize the different emergency activity records for each municipality by presenting a reference format for “Emergency Activity Record Form” that incorporates the opinions of both fire departments and medical institutions that receive emergency patients during FY2024, .
- Promote awareness of the benefits of emergency medical care brought about by digitalization of emergency activity, which realize smooth and wide-area data sharing between ambulance crews and medical institutions, in order to encourage the standardization of emergency activity records and digitalization.

Task Force: Age Tech

Characteristics of Market Structure

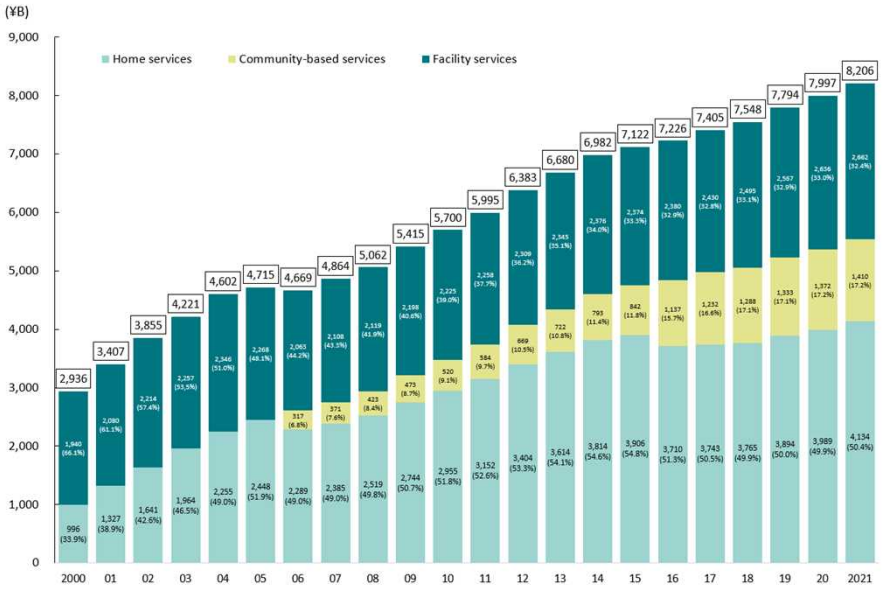
- **Against the backdrop of a declining birthrate and aging population in Japan, the nursing care industry is facing a chronic shortage of human resources, and there are high expectations for the use of age tech to reduce the workload of nursing care workers and maintain and improve the quality of nursing care.**
- **However, the majority of the income of nursing care facilities comes from nursing care fees, most of which is spent on labor costs, and the industry's overall profit level is low compared to other industries, which limits "the capacity for investment in age tech by nursing care facilities.**
- **Some Asian countries are also expected to experience rapid aging in the future, but the assumptions underlying the systems and cultural backgrounds of each country differ greatly, and this has been a high barrier to overseas expansion.**

Market Size

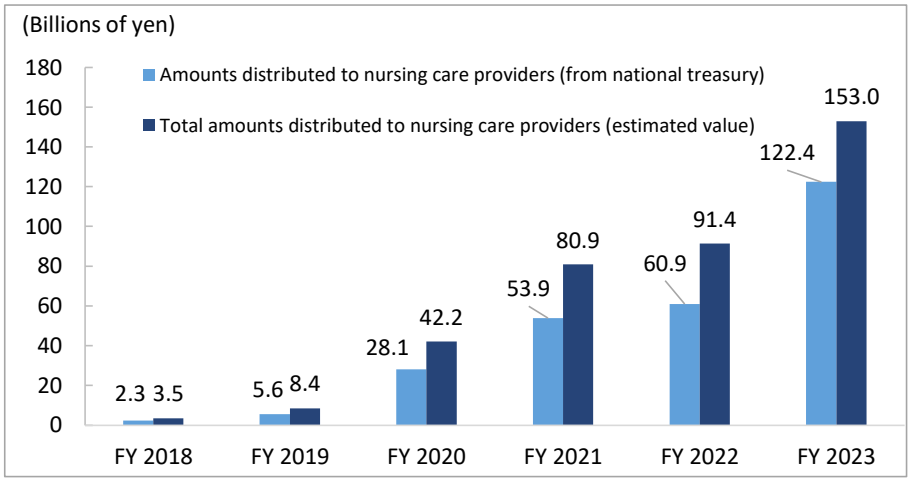
- The total cost of nursing care insurance benefits is steadily increasing to 11 trillion yen (in FY2022), of which approximately half is accounted for by in-home services (Figure 1).
- MHLW has also been increasing the amount of subsidies to nursing care facilities for the introduction of age care tech every year (Figure 2).
- On the other hand, information on the size and reality of overseas markets is limited, and the different systems make comparisons difficult.

SU Achievements

- Listed cases and large M&A deals for age tech SUs are extremely limited.
- In the institutional nursing care sector, one company was finally listed in 2023, but none have been listed in the in-home nursing care sector.



(Figure 1) Trends in benefit costs by fiscal year (by in-home, community-based, and facility) (monthly average)*



(Figure 2) Achievements of the Support Program for Introduction of Nursing-care Robots and ICT

* "FY2022 Report on a set of practical application support for welfare equipment and nursing care robots" (Ministry of Health, Labour and Welfare)

REC 22

Launch a new centralized consultation desk, "CARISO (CARe Innovation Support Office)", at MHLW to support Age Tech startups.

- Publish information on priority development fields related to Age Tech to serve as a reference for Age Tech SUs to consider their exit strategy during FY2024.
- Establish a consultation service for Age Tech SUs ("CARISO") through a constructive reorganization of the ongoing Platform Project to collectively accept consultations and requests from Age Tech SUs and provide them with necessary support from FY 2025.
- Expand support programs with reference to programs by MEDISO, including networking events with the nursing care providers, major care device companies, and investors ("Age Tech Summit") and awards.
- Implement ICT literacy education for nursing care providers through public-private partnerships.

REC 23

Increase the amount of digitization support subsidies for nursing care facilities to promote the introduction of Age Tech.

- Expand the scale of support, including expanding the scope of the budget related to Digitalization support subsidies, centered on the Nursing Care Technology Introduction Support Project, in order to respond to the potential needs of nursing care facilities from FY2025
- Establish one-stop consultation offices in all prefectures* to provide one-stop advice and other support (concierge) for various subsidies by FY2026.

*: Scheduled to be established in a total of 31 prefectures by the end of FY2024

REC 24

Revise the evaluation of Age Tech products for home care providers and users under the Nursing Care Insurance to accelerate their introduction.

- Facilitate the understanding of the status of implementation of the Additional Productivity Enhancement Promotion System, and promote the collection of evidence related to the use of technology through projects such as Health Promotion Program For the Elderly from FY2024.
- Consider increasing the frequency of the Nursing Care Insurance Welfare Equipment and Home Improvement Evaluation Study Group and adding a constituent in the area of Age Tech from FY2024.

REC 25

Conduct overseas market research and provide network building support necessary for exporting Age Tech products and services.

- METI shall conduct a survey of nursing care-related systems in other countries and market research on products and services in great demand from nursing care providers, and shall release the first research report during FY2025.
- Consider holding pitch events and networking events with different industries related to nursing care, including those from overseas at the “Age Tech Summit".
- Implement a program for overseas nursing care providers, government officials, SU accelerators and incubators to visit nursing care sites in Japan where Age Tech is being utilized.

Conclusion

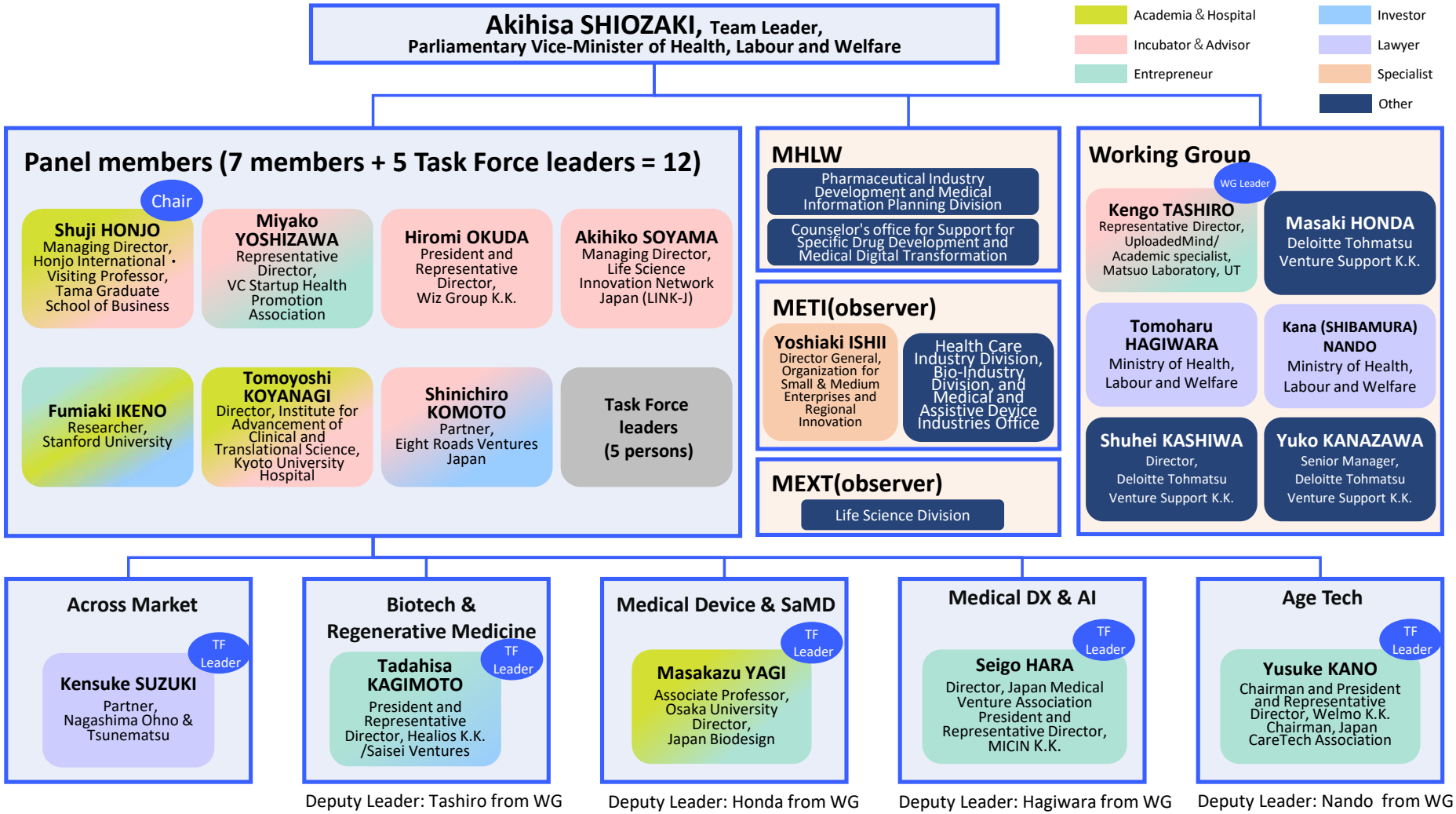
We hope domestic and international researchers, entrepreneurs, investors, and business companies who are involved in healthcare SUs will make active use of this White Paper in working on future R&D and business plans.

- Japan's social infrastructure for health, medical, and nursing care has been attracting worldwide attention. In order to materialize its strengths and achieve further evolution, the power of SUs is essential as the bearers of innovation.
- The recommendations in this White Paper present the concrete action plan for the promotion and support of SUs in the Japanese healthcare ecosystem. It is also a compilation of the voices of many people who have actually been involved in healthcare SUs as entrepreneurs and investors, and who have experienced both hardships and achievements.
- In order to ensure that the recommendations remain effective and continue to generate impact, a follow-up meeting led by the members of this PT will be held at least once a year to implement the PDCA (Plan-Do-Check-Act) cycle, making course corrections as necessary.

This project team consists of members active at the forefront of their respective fields, as well as MHLW*, METI** and MEXT***

* Ministry of Health, Labour and Welfare
** Ministry of Economy, Trade and Industry
*** Ministry of Education, Culture, Sports, Science and Technology

Academia & Hospital / Incubator & Advisor / Entrepreneur / Investor / Lawyer / Specialist / Other



Deputy Leader: Tashiro from WG

Deputy Leader: Honda from WG

Deputy Leader: Hagiwara from WG

Deputy Leader: Nando from WG