[English Translation]

White Paper on Strengthening Japan's Healthcare Startup Ecosystem

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

June 2024

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

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1. Introduction

(1) Purpose and Significance of This White Paper

Japan is the country with the world's highest healthy life expectancy.

The potential strength of Japan's health, medical, and nursing care fields resulting in such longevity, has been attracting great attention from around the world.

Dr. Shibasaburo Kitasato, who is regarded as the "father of modern medicine" in Japan, is known not only for his great contribution to the development of infectious disease medicine, but also for his enthusiastic efforts to establish related businesses. According to Dr. Kitasato:

"Academic knowledge would not be of great value if it were not widely spread to society."

Startups are the driving force behind such innovation. In many cases, entrepreneurs' creativity and caliber of action have the key to connecting excellent academic knowledge to the real world, paving the way for solving social issues and achieving economic growth.

Based on this entrepreneurial perspective, Japan formulated a Five Year Plan for Startup Development in November 2022. Considering that startups are the "challengers" to transform social issues into the engine of growth and realize sustainable economic growth, the nation is in the midst of mobilizing all policies to increase the amount of investment in startups.

In particular, the healthcare field covering health, medical, and nursing care is an area where startups are expected to make a significant contribution. Japan has entered a super-aging society and is recognized as a country facing healthcare challenges ahead of other nations. The government established the Medical Digital Transformation Promotion Headquarters in October 2022, resulting in the development of a unique business environment, such as the accumulation of high-quality digital data under the universal health insurance system and the long-term care insurance system.

The policy-driven promotion and support of startups in Japan's healthcare field has a substantial significance in (1) making healthcare sustainable while

improving its quality, and (2) promoting new services and products originated in Japan toward overseas markets, thereby supporting the growth of industries with global competitiveness.

To explore specific policy measures to achieve this vision, the Ministry of Health, Labour and Welfare (MHLW) established a Project Team on Healthcare Startup Acceleration (the "PT") in February 2024.

Based on the results of this PT's discussions, this White Paper lists twenty-five specific measures considered to be particularly important for promoting and supporting healthcare startups, along with a timetable for their implementation (p. 77), while also developing basic guidelines for policies to promote and support startups in Japan's healthcare field.

(2) Structure of the PT and Nature of the White Paper

In preparing this White Paper, the members of the project team and the working group, consisting of Dr. Shuji Honjo (Visiting Professor at Tama Graduate School of Business) as the chairperson and members who have high expertise and are active at the forefront of their respective fields, including the founders of healthcare startups, investors, incubators, academics, doctors, and lawyers, played a central role in drafting and reviewing policy proposals and consulting with relevant ministries and agencies. The PT established task forces (each with one leader and one deputy leader) specializing in the four areas ("the target areas") of (1) Biotech and regenerative medicine, (2) Medical devices and SaMD (software as a medical device), (3) Medical DX and AI, and (4) Age tech. Regarding issues and opportunities that span multiple target areas, we also examined promotion/support measures with the active participation of members of multiple committees as part of the General Recommendations (Appendix 1).

Specifically, in addition to conducting extensive interviews with more than 70 key opinion leaders in the industries (Appendix 3), the PT set up a public online "Healthcare Startup Idea Box!", an experimental new policy-making tool, where many businesses, organizations, and experts posted approximately 120 opinions and comments, which were used as a reference for policy making.

For the preparation of this White Paper, the Pharmaceutical Industry Development and Medical Information Planning Division, and the Counselor's Office for Support for Specific Drug Development and Medical Digital Transformation,

Medical Policy Bureau of the Ministry of Health, Labour and Welfare served as the secretariat of the PT. In addition, from the viewpoints of industrial promotion and cooperation with academia, the following observers participated in all meetings: The Bio-Industry Division and the Health Care Industry Division, Commerce and Service Group of the Ministry of Economy, Trade and Industry, as well as the Life Science Division, Research Promotion Bureau of the Ministry of Education, Culture, Sports, Science and Technology (Appendix 2). The PT also received cooperation from the Financial Services Agency, the Ministry of Internal Affairs and Communications, the Digital Agency, and others.

(3) Policy Recommendations

	Recommendation details
General Recommendations	
REC 1	Enhance and strengthen the function and capabilities of MEDISO to further provide proactive and continuous support to startups.
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 and Regenerative Products	
REC 11	Expand the scope of AMEDs Project of Strengthening Program for Pharmaceutical Startup Ecosystem (a $2.2B matching fund and support program conducted in conjunction with registered VCs) to include preclinical early-stage pipelines.
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 Devices and SaMD	
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 SaMD evidence building and dissemination to medical institutions
Medical DX and AI	
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	
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.

2. The Current Status of Healthcare Startups in Japan and the Basic Perspective of Strategic Support

(1) The Current Status of Healthcare Startups in Japan

As a super-aging society facing healthcare issues ahead of time, Japan has great potential for healthcare innovation. As described above, high-quality medical and long-term care data are being accumulated under the universal health insurance system and the long-term care insurance system. Based on this fact, the development of new services and products is expected. At present, however, healthcare startups in Japan have not fully demonstrated their potential.

To begin with, Japan's healthcare field is an area where active R&D activities are being conducted and great innovation potential is expected. For example, a comparison of research expenditures by specific purpose shows that a larger amount of research funds is invested in the life sciences field than in other fields such as information and communication (Figure 1). A comparison by technology group shows that research expenditure on biotechnology exceeds that of artificial intelligence and quantum technologies[1].

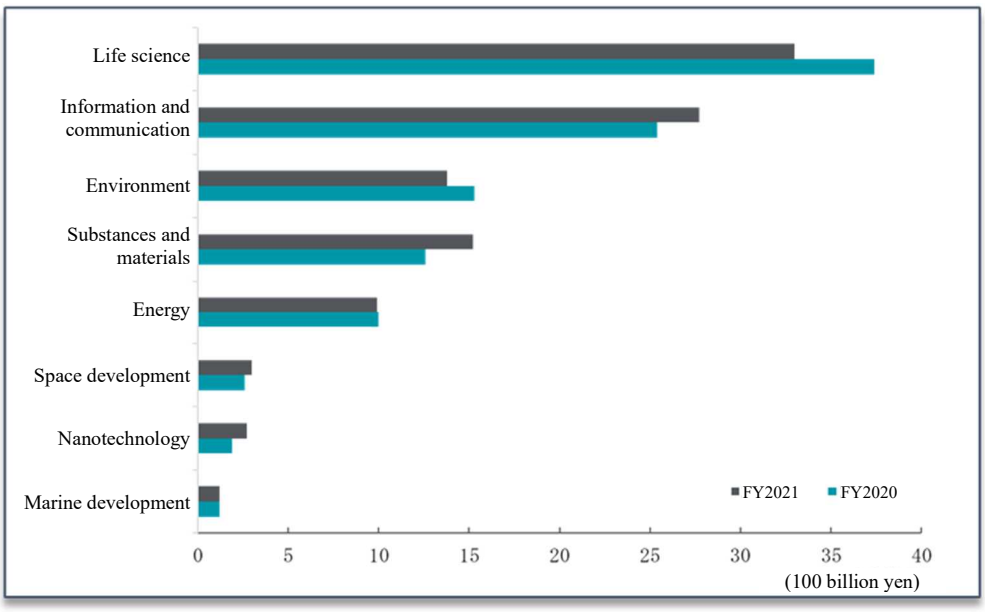

Figure 1: Comparison of Research Funds by Specific Purpose (FY2020, FY2021)[1]

[1] "Interim Recommendations" (April 25, 2024) by the Project Team on Healthcare Startup Acceleration, Ministry of Health, Labour and Welfare (https://www.mhlw.go.jp/content/10807000/001249788.pdf)

On the other hand, in terms of whether or not these studies have led to commercialization, the activities of Japanese healthcare startups are limited in both quality and quantity. For example, since 2019, approximately 1,000 to 1,500 startups have been launched in Japan each year. The number of companies established in the 4 target areas of this PT was approximately 100 in 2019, but the number has been declining since then and has fallen to about 50 companies in 2023 (Figure 2).

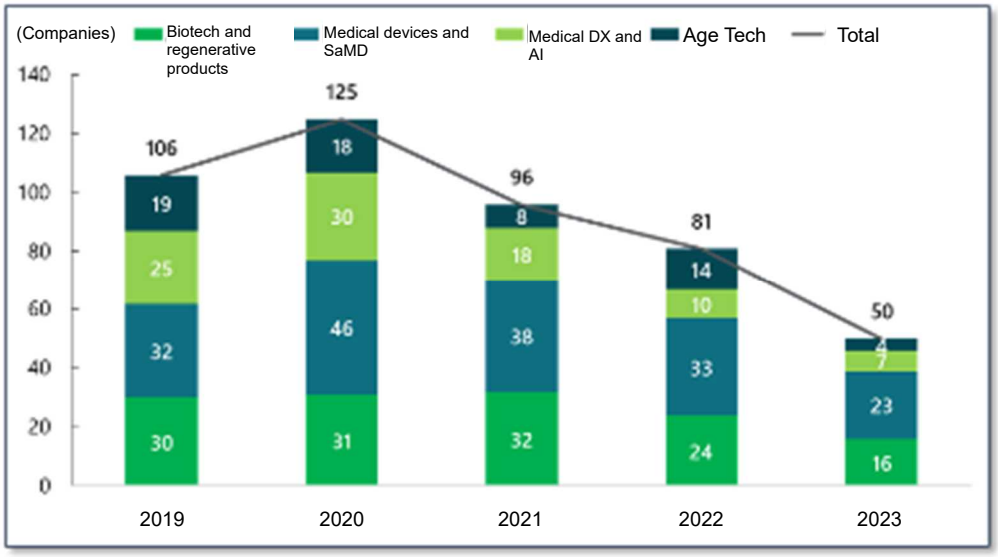

Figure 2: Number of Startups Established by Year (Target Areas)[1]

In addition, the number of unicorn companies in Japan is about 10, and about 100 companies are listed through IPOs a year, but there are no unicorn companies in the target areas of this PT, and the number of large-scale M&A (acquisition amount ≥ 10 billion yen) is 3, and only about 5 achieve IPOs a year.[1]

From a global perspective, the difference between Japan and other countries is more pronounced.

Many startups are active in the healthcare field, particularly in the areas of drug discovery and medical device development. For example, major pharmaceutical companies account for 60% of the global sales in drug discovery, while startups are believed to account for 80% of the share of development products [2](Figure 3). In the medical device field, many new products from major foreign companies handling therapeutic medical devices originated from startups. In the case of new medical devices, which account for many of the therapeutic medical devices, the

[2]Ministry of Economy, Trade and Industry "Progress of Biopolicy and Future Issues" (December 2023) (https://www.meti.go.jp/shingikai/sankoshin/shomu_ryutsu/bio/pdf/016_04_00.pdf)

number of approvals by Japanese startups is shown to be lower than that of overseas counterparts [3](Figure 4).

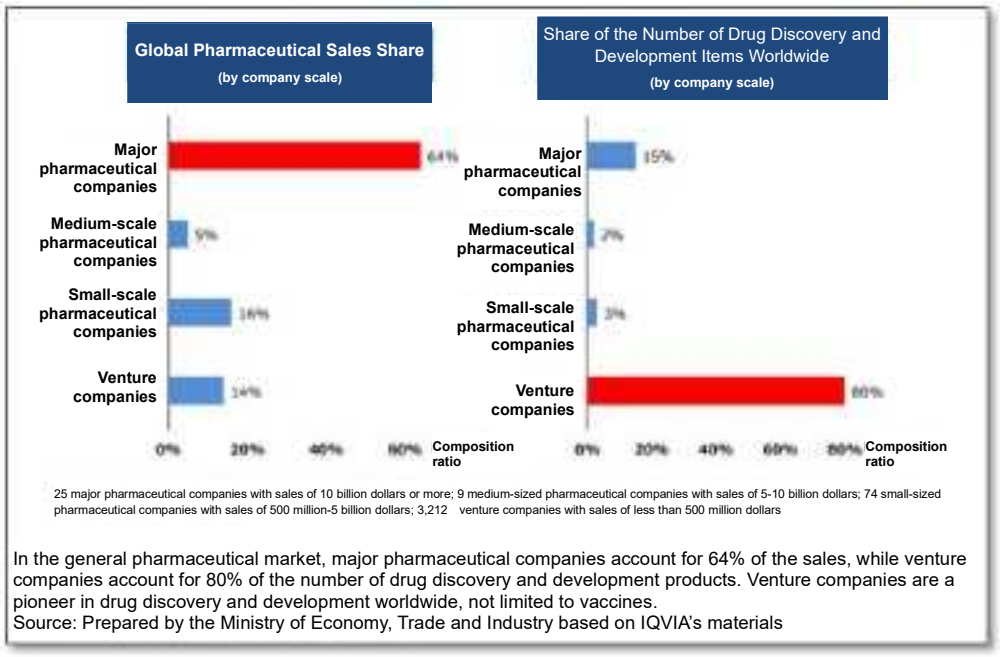

Figure 3: Global Drug Market Share by Company Size (Sales, Number of Drug Discovery and Development Items)[2]

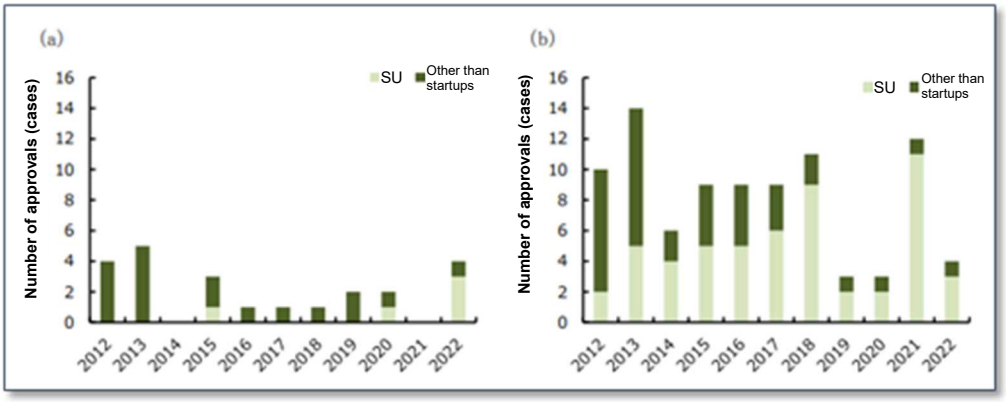

Figure 4: Number of New Medical Device Approvals in Japan Originating from (a) Japan and (b) Overseas Companies[3]

In the healthcare field, where startups play an important role, Japan has great potential in terms of human resources and science and technology. However,

[3] Ministry of Economy, Trade and Industry, Medical Device Industry Vision Study Group, "Medical Device Industry Vision 2024" (March 2024) (https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/iryoukikisangyouvision2024/iryoukikisangyouvision2024.pdf)

looking at the number of startups and their results in the target areas, it is difficult to say that they are fully demonstrating their potential, and the number of startups is on a downward trend, which together indicate a critical situation.

(2) Three Strategic Support Approaches According to Market Characteristics

As described above, healthcare is a field where more startups should be playing an active role, so there is an urgent need to support entrepreneurs who drive innovation.

The following five factors are considered to be the key for startups to succeed; science (idea), talents, funding, development environment (regulatory environment, ease of conducting clinical trials, etc.), and market. Even within the healthcare field, the structure and characteristics of the market vary greatly by target area, requiring strategic support in line with each area.

Under these circumstances, this PT examines the challenges and opportunities in the commercialization and growth of healthcare startups and proposes the following three strategic support approaches (Figure 5).

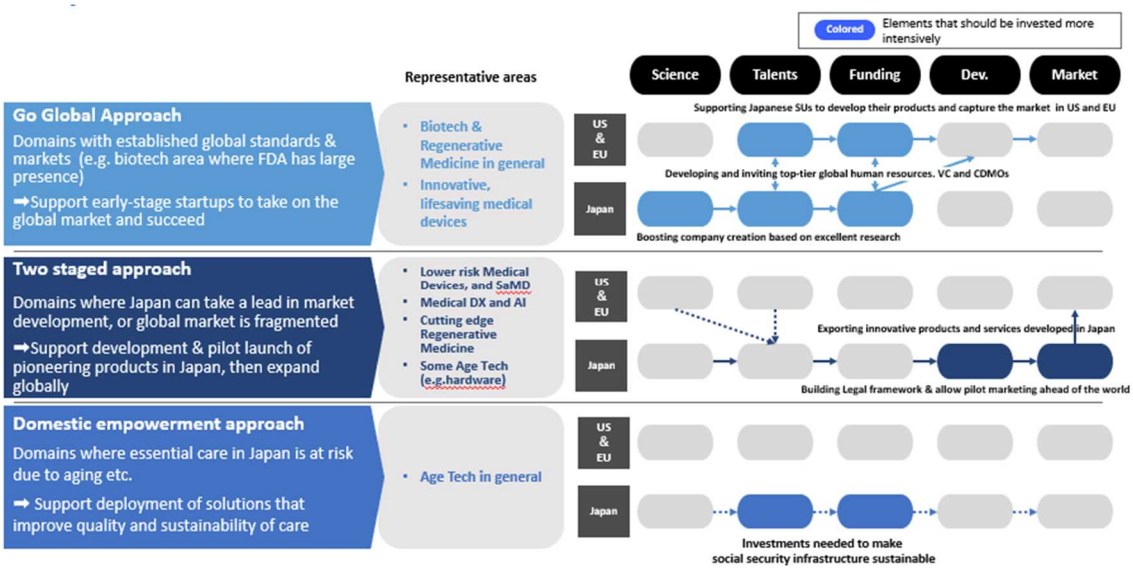

Figure 5: Three Strategic Support Approaches[4]

Strategy 1: Go Global Approach

[4] In each approach, the elements to be invested more heavily with national power are colored.

In the target areas where the structure of the Japanese and global markets is similar and the size of the overseas market is relatively large, it is reasonable to seek business strategies with a view to overseas expansion from the early stage of the business. In these areas, it is desirable to actively utilize science, talents, and funding in Japan and overseas with a view to launching and expanding into the global market from the early stages of business, such as from seed.

In this approach, overseas venture capital (VC) firms and incubators that have access to and network of information, such as the presence or absence of similar overseas studies, international intellectual property strategies, trends of competing startups, experienced management personnel, large-scale risk money, plays an important role.

Strategy 2: Two staged Approach

Some target areas have a high risk of going directly to the global market due to factors such as differences in the regulatory environment between the Japanese market and the global market and the substantial costs required for overseas expansion. In these areas, a step-by-step business strategy may be considered, in which an advanced product is first developed in Japan to a certain level of success, and then overseas expansion is attempted.

In this approach, it is essential to solve the issues of the development environment on the premise of science, talents, and funding in Japan. On top of that, it is necessary to establish a policy support system for future overseas expansion, which is often seen as a high hurdle. The development environment through international standardization of regulations and advanced legislation is also a key point in creating new Japanese markets and capturing promising overseas markets.

Strategy 3: Domestic Empowerment Approach

Some of the healthcare target areas are immature in terms of the quality and quantity of the startup ecosystem in Japan. In these areas, rather than devoting support resources to explore the possibility of future overseas expansion, there is an urgent need to first examine and address the issues of the entire ecosystem to enable sustainable innovation within Japan.

It is necessary to examine the issues in science, talents, funding, the development

environment, and the market in Japan, including the state of the insurance system, and then strengthen the entire ecosystem. In this approach, it is required to prepare effective support measures with a view to both the sustainability of Japan's social security infrastructure and the autonomous development of startups under public-private partnerships.

In the following sections, we describe specific support measures for healthcare startups based on the market structure and characteristics of each target area (Figure 6).

Figure 6: Market Structure and Characteristics of Each Target Area and Corresponding Strategic Support Approaches

3. Promotion and Support Measures

(1) General Recommendations

a. Overview of the Healthcare Startup Ecosystem

Prior to examining the issues and opportunities specific to the four target areas that are the central discussion of the PT, this section introduces the issues and opportunities that span multiple target areas as part of the general remarks.

Through the interviews conducted by this PT, the ecosystem surrounding healthcare startups in Japan emerged with the assessment that, overall, "there are efforts to improve the healthcare SU ecosystem," but "the ecosystem is immature" and "talents are poorly connected." Specifically, there is a persistent view that even when there is excellent research and science, it is difficult to attract human and financial resources, and the foundation for commercialization or seed cultivation is fragile. Some respondents said that even when startups try to grow, rigid and ambiguous regulations, an inefficient testing environment, and a market that is unenthusiastic to startups stand in their way. It has also been pointed out that the relationship between startups and major operating companies is "weak," the community is dispersed, with few international connections, and startups tend to struggle alone.

Regardless of whether we pursue the Go Global or Domestic Empowerment approach outlined in the previous section, there is an urgent need to address these issues that underlie Japan's entire healthcare ecosystem. In the healthcare field, in particular, the government is expected to promote sound development in terms of both regulation and industrial promotion; the Ministry of Health, Labour and Welfare and other national and local governments can play an important role in this field. It is necessary to examine where in the five factors, which are science, talents, funding, the development environment, and the market, there are clogged points or coordination challenges, and to address them in parallel as a package.

The following section outlines 10 themes that emerged as issues common in multiple target areas of Japan's healthcare ecosystem and their countermeasures.

Policy Recommendations	Science	Talents	Funding	Development Environment	Market
1) Continuous and active support to healthcare SUs through MEDISO 2.0		●	●	●	
2) Introduce a new milestone based development grant ("Health-Tech Challenge")	●	●	●	●	
3) Establish a new point of contact to receive 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) New incentives for insurers to encourage promote the proactive use of healthcare SUs products and services			●		●
9) Promote business activities in SUs by medical doctors		●			
10) Clarify the legal regulations regarding nonclinical direct to consumer testing services				●	

b. Specific Promotion and Support Measures (Recommendations 1-10)

REC 1 **Enhance and strengthen the functions and capabilities of MEDISO to further provide proactive and continuous support to startups.**

a. Issue

Since 2018, MEDISO[5] has been collaborating with supporters (experts in R&D, pharmaceutical affairs, etc.) and related organizations, including the MHLW, to support startups, academia, etc., including healthcare startups and individuals aiming at the practical application of new drug discovery techniques and medical materials. As a result, its presence has steadily increased, as evidenced by an increased number of consultations and a high rate of repeaters, and other indicators.

On the other hand, regarding the existing support for startups, there are many voices calling for the improvement of the system and the expansion of measures, including "the mechanism to nurture startups is inadequate and fragmented (dispersed)" and "the single-year budget leads to a blank period of support." There are also voices pointing out gaps with the U.S. and other overseas ecosystems, including "our ecosystem is significantly inferior to those overseas" and "the business infrastructure is lagging behind."

As described above, there is a need to continuously strengthen support for startups, and it would be more effective if related organizations, such as the Ministry of Health, Labour and Welfare, collaborate in supporting startups.

b. Policy Recommendations

Fundamentally strengthen the functions and structure of MEDISO and evolve into a new organizational structure that enables continuous and active support as MEDISO 2.0.

[5] Medical Innovation Support Office

First, starting from FY 2025, extend the fiscal year of MEDISO budget to multiple years and increase the amount substantially [6] to create an organizational foundation for continuous activities.

In addition, clarify MEDISO's function as the hub of government support organizations, and provide thorough support for startups, including overseas expansion, to make them one of the core ecosystems in cooperation with other organizations, such as the Ministry of Economy, Trade and Industry. By the end of FY2024, the government should complete the structuring of coordination with the following five core support organizations: the Pharmaceuticals and Medical Devices Agency (PMDA); the Japan Agency for Medical Research and Development (AMED); the National Center for Industrial Property Information and Training (INPIT), Japan Patent Office; the Japan External Trade Organization (JETRO), Ministry of Economy, Trade and Industry; and the New Energy and Industrial Technology Development Organization (NEDO).

Preferably by the beginning of FY2025, the government should strengthen the navigation function for startups, such as providing an overview of government support programs (e.g., pioneering medical devices, in vitro diagnostics, cellular and tissue-based product designation system), information on how to use these programs and on preceding cases.

The government also should establish and implement a system to provide thorough support for startups from the early to late phases and after their listing through the following measures: introducing group mentoring (by H1 FY2025), expanding overseas supporters (by H1 FY2025), implementing integrated programs with overseas incubators (by the end of FY2026), establishing constant support functions overseas (by the beginning of FY2025), etc.

In addition, educational programs focusing on critical areas such as new modalities should be implemented, preferably by the end of FY 2026, as the core of human resource development.

[6] There was an opinion that the budget period should be 10 years and the amount should be increased 10 times, as an example.

Furthermore, the government should build a startup community centered around MEDISO users (by the beginning of FY2026), provide opportunities for startups and various stakeholders to easily communicate with each other on their views on various issues around the ecosystem (by H1 FY2025), and introduce a 24-hour, 365-day web matching system with players in Japan and overseas (by the beginning of FY2026). In addition, a mechanism for MEDISO to match startups with VCs on an individual basis should also be considered by the end of FY2024. Additionally, by holding matching events where overseas VCs are invited and Japanese academia and startups give pitching in English (by the end of FY2025), the government should strengthen exchanges and collaborations with Japanese and overseas major companies, VCs, industry organizations, overseas core organizations, etc. At the same time, an open network should be established that gathers not only startups but also top-notch human resources in the respective areas of manufacturing, non-clinical, clinical, and licensing, such as Japanese and overseas contract development and manufacturing organizations (CDMOs), VCs, pharmaceutical companies, regulatory authorities, etc. (by the end of FY2025), in order to support the promotion, growth, and success of the startups' businesses. In addition, the PDCA (Plan-Do-Check-Act) cycle, including soliciting user feedback, should be implemented every year to verify that the recommendations adequately address the ever-changing needs of healthcare startups, which starts by reviewing FY2024 results at the beginning of FY2025.

To significantly expand and strengthen support programs, a systematic strengthening plan for the next 3 years should be formulated, including strengthening the MHLW organization, by the end of FY2024. The government should enhance and strengthen the structure and human resources related to MEDISO, including flexible design of contract and compensation forms, such as upgrading and expanding the personnel of the MHLW Venture Support Strategy Office in FY2024 to have at least 2 full-time employees.

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.

a. Issue

As the issues to be addressed in the healthcare field grow in scope and complex, including the declining birthrate and aging population, there is a growing need for innovations that drive the transformation of social systems. On the other hand, amid increasing uncertainty in R&D, it is difficult to predict profitability, especially in fields with small numbers of patients, such as intractable diseases and rare diseases, and drug development will not progress if left to the market principle; there are concerns that development for high-risk themes is few and stagnant.

In order to solve these social issues (missions) with limited policy resources, it should be useful to have a mission-oriented innovation policy that uses policies focused on a particular mission as well as support measures for research and development of technologies that can contribute to solving the mission. Based on the recognition that it is difficult to identify the technology that will become the starting point of innovation at the seed stage, it should be necessary to collect a wide range of seeds of innovation, let startups work on proof-of-concept and feasibility studies with a small amount of support funding, and continue to support projects that have proven promising, and lead them to commercialization. In the United States, based on this recognition, it has been pointed out that about one-third of the annual budget (about 230 billion yen) of the SBIR (Small/Startup Business Innovation Research) system is invested in the healthcare field.

b. Policy Recommendations

As an R&D support measure that contributes to solving social issues in the healthcare field, Establish a new milestone-based support program, the Health-Tech Challenge (tentative name), by FY2025 at the latest.

Specifically, in contrast to the conventional intensive support for a small number of projects, the government should provide distributed support to a large number of projects, especially in the early phases, and promote development for themes that are difficult to start with high development risks

through step-by-step support from the early stages of development. In order to support development aiming at obtaining approval in the United States and other countries in addition to Japan, a milestone-based development support according to the theme (a framework in which additional subsidies are provided each time a milestone set in a step-by-step manner is achieved), similar to the U.S. DARPA (Defense Advanced Research Projects Agency) R&D model, should be provided. The government should also provide long-term and impactful support from a global perspective by allowing a certain degree of freedom to target startups and themes, while following the good points of the SBIR system and the AMED program and utilizing them as much as possible. In addition, the government should realize a system that provides financial and software support for the development of highly innovative drugs and medical devices in an integrated manner from academic seed to startup growth.

In preparation for the launch of the program in FY2025, the government should consider as the candidate for the program the development themes that will lead to solving social issues, such as drugs for intractable diseases, rare diseases, and medical countermeasures for infectious diseases, including antimicrobial resistance (AMR); innovative medical devices based on unmet medical needs (especially, treatment devices); and digital products, such as SaMD using AI technology. milestone-based support should be provided for up to 15 years per company, from academic seed to startup growth. It is necessary for the government to develop programs with the aim of providing support on a scale sufficient to induce development that leads to solving social issues.

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.

a. Issue

In order to ensure the continued profitability of healthcare startups' businesses in Japan, which adopts the so-called universal health insurance system, it is extremely important whether or not startups' innovative products and services are covered by health insurance and how they are handled in the medical service fee system, including their insurance points.

In fact, many of the opinions received through interviews conducted by this PT and the Healthcare Startup Idea Box! raise concerns about the scope of insurance coverage and the handling of insurance points, etc., under the medical service fee system.

On the other hand, those involved in healthcare startups have pointed out that they do not know the contact point to which they can submit their requests for insurance, etc. This means that even if they have requests for a revision of medical fees, etc., it is not clear where to submit such requests, so some people point out that the voices of those involved in the healthcare startups have not been adequately heard in the first place, and that the voices of startups are not adequately reflected in the measures because their voices are not heard.

It is also suggested that healthcare startups tend to struggle alone because they have weak connections with regulatory authorities, such as the Ministry of Health, Labor and Welfare; it is important for regulatory authorities to open their doors and listen to the voices of healthcare startups in order to support their development.

b. Policy Recommendations

Establish a new contact point to receive requests related to medical service fees at MEDISO by the end of FY2024. In addition to this MEDISO reform, a system to listen to the voices of stakeholders such as healthcare startups and investors should also be developed at the Ministry of Health, Labour and Welfare. By accepting requests for matters related to the revision of medical service fees, such as staffing standards for medical institutions, the government should aim to broadly understand the real needs of healthcare startups. After collecting requests from healthcare startups through this newly established contact point, the government should set up a system to appropriately reflect their requests in our measures as needed. This contact point will also have a function to receive consultations from healthcare startups and provide necessary advice, such as the prospects for pharmaceutical approval and insurance listing, required evidence, and a rough schedule.

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

a. Issue

In order for healthcare startups to grow and succeed in fields where the "Go Global" or "Two staged" approach is recommended, such as drug discovery and medical devices, it is pointed out that they need to be connected with overseas startup ecosystems with a large market size, especially the U.S. market. To this end, it should be necessary to actively attract excellent ideas, talents, and funding from overseas to Japan, and create an environment in which promising seeds can be selected for optimal development strategies.

At the same time, overseas investors and researchers, among others, point out that they have the impression that Japan's healthcare ecosystem is closed within Japan and has barriers to overseas countries, saying, for example, "we have not seen much information about Japan" and "Japan disseminates little information in English." Those involved in the government's support programs and related consultation desks confide the following about the current status of providing English-language services: Overseas support has not progressed sufficiently for reasons such as "Although we recognize the need, it is difficult to secure English-speaking personnel in terms of payment and other conditions."

As a first step to break through Japan's closed ecosystem, it should be necessary to have a language infrastructure that can be seen and connected from overseas.

b. Policy Recommendations

Move away from the premise that only Japanese is sufficient for communication related to healthcare startups and work on internationalization, starting with bilingual support including English.

Enhance the dissemination of startup-related information in English, such as system guidance and descriptions of related laws and regulations, such as application procedures and requirements related to pharmaceutical approval, permission, and insurance listing application in Japan on the websites and

public materials of the Ministry of Health, Labour and Welfare and other related organizations, ministries and agencies involved in the pharmaceutical affairs system and support programs. The government should provide English-language support for application documents and consultation services related to startups, such as PMDA's pharmaceutical consultation services and support programs such as subsidies, including public recruitment procedures for the AMED's Drug Discovery Venture Ecosystem Enhancement Project. Specifically, media and contact points that do not support English should be identified by the end of this calendar year and the translation of materials that can be translated into English using AI, etc., should be completed within FY2024. In addition, by the end of FY2025, the system for services that require increased personnel, such as consultations should be improved.

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

a. Issue

Many people have pointed out that one of the major weaknesses of Japan's healthcare startup ecosystem is the lack of human resources capable of working with overseas markets.

For example, when a promising seed for drug discovery is discovered in Japan, there should be many items that need to be considered along with an international network that require know-how on supporting startups overseas in order to develop optimal business strategies, such as checking whether there are any competing studies at overseas universities and research institutes, whether there are startups and other organizations that are already developing a similar drug, the prospect of obtaining FDA approval in the United States, and examining the optimal place and method of fundraising. However, it has been pointed out that there are "extremely few" experts in Japan with such knowledge at present. In drug discovery and other fields in the United States, a method called venture creation, in which VCs and others explore and evaluate promising research and seeds in terms of their potential as products, etc., and take the lead in business planning, company establishment, and securing human resources, is spreading rapidly, whereas in Japan it has been pointed out that such business infrastructure is lagging

behind, and there is a gap with the U.S. and other overseas ecosystems. Top-class overseas VCs, in particular, are said to be far superior to Japanese VCs in terms of know-how, experience, human resources, amount of funding, and other aspects.

Therefore, it is expected to develop and expand the Japanese ecosystem by connecting with overseas VCs, which are the core of overseas ecosystems.

b. Policy Recommendations

Connect top-tier overseas VCs with the Japanese ecosystem to accelerate the development and growth of seeds and human resources in Japan.

Develop a model for promoting LP investment in overseas VCs, such as METI's Global Startup Growth Investment Project, and promote personnel exchanges with top global VCs, such as making the acceptance of overseas VCs' secondments a condition for LP investment to develop venture capitalists.

With the goal of attracting Japanese branches of overseas VCs in the future, invite them to startup events in Japan and build a network to establish partnerships with Japanese VCs. Following the example of other countries, from FY2024, conduct visit programs in Japan with the participation of top-tier overseas VCs, which will include the introduction of seeds at universities and research institutes, speaking at presentations, and matching events with Japanese healthcare professionals.

In addition to implementing these measures within FY2024, formulate and implement measures to expand operations in Japan, increase investment in Japan, search for seeds in Japan, and collaborate with Japanese businesses, including promoting Japan's attractiveness to overseas VCs, inviting them to events in Japan, top sales by disseminating information on seeds in Japan, stimulating exchanges with academia, etc., in cooperation with the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT).

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

a. Issue

Despite the fact that the healthcare industry is expected to be a high-potential area in Japan, where a lot of R&D activities are being conducted. it is pointed out that there have been many cases in which healthcare startups are unable to raise sufficient funds, whether before or after their IPO, and cannot proceed with development. Especially for startups with late-stage development pipelines, it is important to raise funds after listing in Japan, but there are voices that they cannot raise funds as expected because they are not properly valued after listing.

Given the healthcare sector is a business field that contributes to solving various social issues, such as the declining birthrate and aging population, it is suitable for "impact investment," which aims to achieve social and environmental effects while ensuring a certain level of investment return as an investment. In terms of the performance of impact investment in Japan, the health and medical care field is among the top investment targets;[7] there are voices hoping that impact investment will promote investment and financing for healthcare startups, which will lead to smooth fundraising by healthcare startups. In addition, it has been pointed out that it is important to solve gender diversity issues in startups, such as gender differences in fundraising by startups;[8] impact investments should be able to flexibly and comprehensively capture and address a wide range of social issues, such as ensuring diversity. In this regard, , the percentage of female managers at or above the level of section manager in the medical and welfare sectors are significantly higher than that in other industry[9], and the healthcare field is expected to be the driving force for gender diversity in the startup sector.

While the global balance of private investment in impact investment is

[7]Document 1, Secretariat Document from the 1st meeting of the Financial Services Agency's "Study Group on Impact Investment, etc." (October 28, 2022) (https://www.fsa.go.jp/singi/impact/siryou/20221028/01.pdf)
[8]"Results of Questionnaire Survey on 'Gender Diversity in the Startup Community'" conducted by the Financial Services Agency Policy Open Lab, Startup Ecosystem Association Japan, and EY Japan Co., Ltd. (December 2023) (https://www.fsa.go.jp/common/about/kaikaku/openpolicylab/dei_startup02_1.pdf)
[9]"Summary of the Results of the FY2022 Basic Survey on Employment Equality" by the Ministry of Health, Labour and Welfare (July 31, 2023) (https://www.mhlw.go.jp/toukei/list/dl/71-r04/07.pdf)

estimated to be between $300 billion and $1 trillion, it has been pointed out that Japan's market size is estimated to be up to 5 trillion yen in 2021, which is much smaller in scale than the global market[10].

b. Policy Recommendations

Deepen and promote discussions on impact investment in the healthcare business sector that involve healthcare startups, based on the characteristics of equity and other financing across multiple stages from early stage to post-listing. With regard to impact investment in the listed market in particular, the Financial Services Agency shall, in collaboration with the MHLW and METI, consider measures to promote networking among various participants involved in the impact investment market and sharing case studies and know-how. These measures would include specifying the healthcare business sector as an investment target in the essentials of impact investment in the listed market, which is being discussed under the Market Research and Formation Working Group of Japan's Impact Consortium by the end of FY2025.

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

a. Issue

In order to promote the launch of drugs, medical devices, and SaMD that originate from healthcare startups, it is necessary to ensure that the cost and time required for clinical trials are not unnecessarily high. In Japan, however, as compared with other countries, clinical trials tend to be expensive and lengthy due to inefficient monitoring of the progress of clinical trials at each institution among a large number of participating institutions, and the time required for ethical review at each institution is long. It is criticized that such a situation is one of the reasons why Japan is not included in international

[10]The Financial Services Agency's "Study Group on Impact Investment, etc." - Toward Improving Growth and Sustainability through the Resolution of Social and Environmental Issues" (June 30, 2023)

clinical trials[11]. If clinical trials can be conducted in remote areas, for example, by using wearable devices and online collaboration between rural hospitals and hospitals that supervise clinical trials, by promoting distributed clinical trials (DCTs), thus enabling people living in remote areas to participate in clinical trials, it is expected that the time required to recruit clinical trial participants can be shortened. However, there is much room for DCTs to become more widespread. Although the centralization of the Institutional Review Board (the so-called central IRB) is permissible under the relevant regulations, it has not necessarily progressed in practice. Furthermore, it has been pointed out that the purpose of the government policy has not properly translated into practice, as evidenced, for example, by the fact that even if the Institutional Review Board is centralized, the participating cites require the approval of the head of each institution separately.

b. Policy Recommendations

Streamline clinical trials by promoting DX of various related operations. Take necessary measures, especially to promote the active use of DCTs. Specifically, expand subsidies under AMED research funds for the costs of clinical trials suitable for DCTs in FY2025, such as cancer, intractable diseases, pediatric, and infectious diseases, and consider making investment in DX for clinical trials, such as DCTs introduction, a requirement for AMED research funds. Also, 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.

In addition, standardize various operations at the time of launching clinical trials across sites. Specific examples may include centralizing the review by the Institutional Review Board at each institution and standardizing the informed consent form, etc. Also, take the necessary measures to ensure the effectiveness of these standardization efforts so that they are actually reflected in the practice of each institution.

[11] E.g., PhRMA/EFPIA Japan co-sponsored seminar "The 23rd 2023 Conference on Ideal Form of CRCs and Clinical Trials" document (https://www.phrma-jp.org/wordpress/wp-content/uploads/2023/10/phrma_efpiajapan_seminar2023-01.pdf)

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

a. Issue

Based on examples in Europe and the United States, where regulatory development has become a growth driver for the health tech market, such as Obamacare enacted the United States in 2010 and the DiGA program that enables early approval of digital health apps in Germany, intervention in insurers is considered to be important everywhere. In Japan, however, it has been pointed out that the domestic market has not played the role of a launching pad for healthcare startups because the health service budget for insurers has not been adequately secured, preventing the market for preventive solutions from growing.

Since the finances of health insurance societies, in particular, are considered to be strongly affected by the premium system for the Late-stage Support Payment, it is expected that the system will provide an incentive to encourage the use of startups' products and services by incorporating evaluations related to the use of digital technology, in which startups have strengths.

b. Policy Recommendations

Revise the formula of the premium system for the Late-stage Support Payment payable by insurers so that those working on advanced businesses by utilizing digital technology, including startup solutions, can be favorably evaluated. Specifically, revise the formula of the premium system, which has emphasized the conventional specified medical examinations and specified health guidance, to add new evaluation items for digitization and indirectly shift the emphasis to advanced fields that are easier for startups to enter, preferably in the 4th period (FY2024 to FY2028) or the 5th period at the latest.

In addition, by FY2025, promote pioneering efforts by insurers, including the use of startups, by incorporating evaluations related to the use of digital technology when adopting subsidy programs for their health insurance societies, and also consider how the subsidy program as a whole should be designed from this perspective. Based on the effectiveness of the use of startup solutions by health insurance societies through these initiatives, also

consider how to handle the incentive system of the National Health Insurance Association and the insurer effort support grant system of the National Health Insurance.

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

a. Issue

Healthcare professionals with clinical expertise and experience are expected to make good candidates for personnel for healthcare startups, but if the healthcare professionals are officers of medical corporations [12], the administrative notice by the Ministry of Health, Labour and Welfare specifying the non-profit nature of medical institutions requires that the healthcare professionals, in principle, may not serve concurrently as officers or employees of for-profit corporations that have an interest in the establishment or management of medical institutions operated by the medical corporation. For example, if a physician who is an officer of a medical corporation intends to introduce to the medical corporation a service or product that the physician has been involved in developing as an officer or employee of a startup, even if the medical corporation and the startup company are managed independently, if a business relationship arising from the above introduction falls under an interest in the establishment or management of a medical institution operated by the medical corporation, the physician may not concurrently serve as an officer of the medical corporation and as an officer or employee of the startup company, unless the transaction amount is small, and must resign from one of the positions. Thus, it has been pointed out that it is not clear under what circumstances healthcare professionals may or may not concurrently serve as officers of medical corporations and as officers of startups whose business activities the healthcare professionals are involved in, which is a factor preventing them from becoming employees of startups.

[12] "Confirmation of the founder of a medical institution and its non-profitable nature" (joint notification No. 5 and No. 9 dated February 3, 1993 from the Director of the General Affairs Division and the Director of the Guidance Division, Health Policy Bureau, Ministry of Health and Welfare) No. 1, 1 (2) (4)

b. Policy Recommendations

The Ministry of Health, Labour and Welfare should notify the prefectural governments that direct and supervise medical corporations by the end of FY2024 that, if a physician affiliated as an officer or employee of a startup company at its establishment intends to introduce a service or product in the development of which the physician was involved to a medical institution operated by a medical corporation in which the physician concurrently serves as an officer, the startup company and the medical corporation may be allowed to do business to the extent that the transaction does not affect the non-profit nature of the medical institution, so that the regulations concerning officers of medical corporations would not unduly interfere with their activities at startup companies.

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

a. Issue

Various non-clinical direct-to-consumer services, such as genetic testing, blood testing, and urinalysis, are spreading in Japan and overseas, driven mainly by startups. The Japanese market from 2020 onward is estimated to be worth 10 billion yen, which is expected to be an attractive growth market for healthcare startups as well.

On the other hand, as the use of testing services by general consumers expands, there are voices calling for the establishment of a governance system for the quality and credibility of these services. In this regard, it has been pointed out that while the United States and Europe already have specific legal regulations for non-clinical direct-to-consumer testing services, Japan does not have specific laws and regulations for such non-clinical consumer testing services; as a result, it is difficult for the government to get involved even if a problem arises with the credibility of a test.

In order to ensure the healthy growth of healthcare startups that provide non-clinical direct-to-consumer services, it is important to dispel the impression that this is an unregulated, chaotic industry and to create a properly competitive environment where consumers can use the services with greater

peace of mind. It is necessary to promote the sound growth and development of the testing business through the establishment of an appropriate governance framework.

b. Policy Recommendations

From the standpoint of jurisdiction over the Medical Practitioners' Act, etc., the Ministry of Health, Labour and Welfare should promote the 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 consumer testing services.

Specifically, consider and implement the following measures by the end of FY2024.

1) In order to correct inappropriate notification of test results, clarify how to interpret the concept of Article 17 of the Medical Practitioners' Act, which states that "notifications must be limited to the facts of test (measurement) results and general reference values of test (measurement) parameters," as indicated in the Guidelines for New Business Activities in the Healthy Life Extension Industry Field (2014 joint notification of the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry) by issuing related Q&As and administrative notifications.
2) Clarify the interpretation for cases where there is a risk of violation of the Medical Practitioners' Act, such as when test results to be notified to consumers lack publicly known scientific evidence, or when unqualified persons make their own medical judgments.

(2) Measures for Promoting and Supporting the Biotech and Regenerative Medicine Market

a. Biotech and Regenerative Medicine Market

a. Characteristics of Market Structure

The need for better drugs is growing, and intense competition continues in development around the world. As the United States and Europe have formed a huge market for biotech and regenerative products (see below), the integration of international regulatory rules (Global Harmonization) has been driven, primarily by the U.S. FDA and the European EMA, which have a strong influence on regulatory reviews. In the development of many biotech and regenerative products, it can be said that the acquisition of FDA and EMA approvals is inevitable (NB: the Chinese FDA has also emerged as a third pole in recent years).

On the other hand, the Japanese market has potential in that it has created an environment that allows for world-first approvals in some areas, such as the conditional approval of regenerative medicine products under the regulatory framework for cellular and tissue-based products.

In addition, the role of CDMOs has become particularly important in the development and manufacturing process of drugs leading up to their approval. In recent years, there has been a shift from small-molecule drugs and antibody drugs to a variety of new modalities (e.g., RNA vaccines, CAR-T, gene and cell therapies) (Fig. 7), requiring not only advanced know-how, such as special synthesis technology specific to each modality, but also a large initial investment, such as in culture vessels. For this reason, biotech startups and pharmaceutical companies are increasingly partnering with proven CDMOs carefully selected from around the world, but Japan is lagging behind with a low market share of less than 10% worldwide (Figure 8).

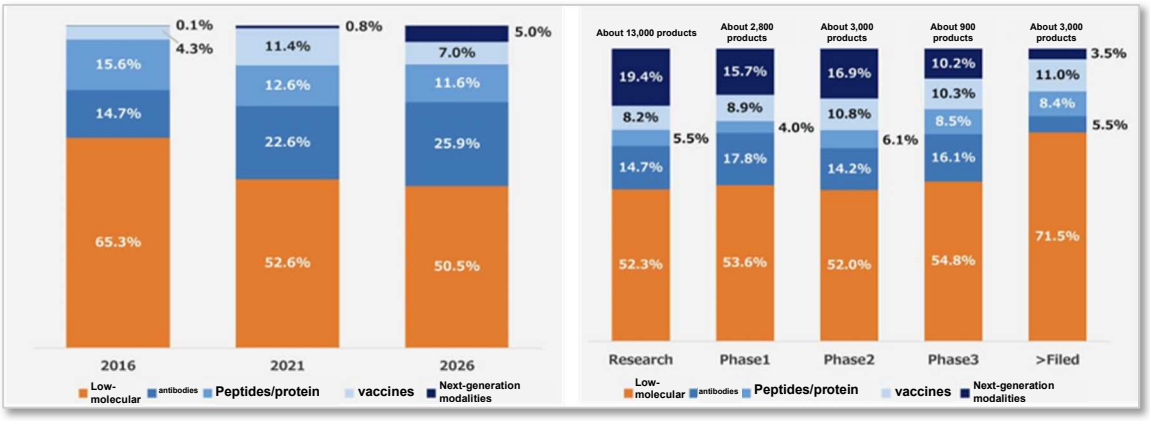

Figure 7: Global Sales by Modality in 2016, 2021, and 2026 (left) and Global Sales in 2022 by Modality and Phase (right)[13]

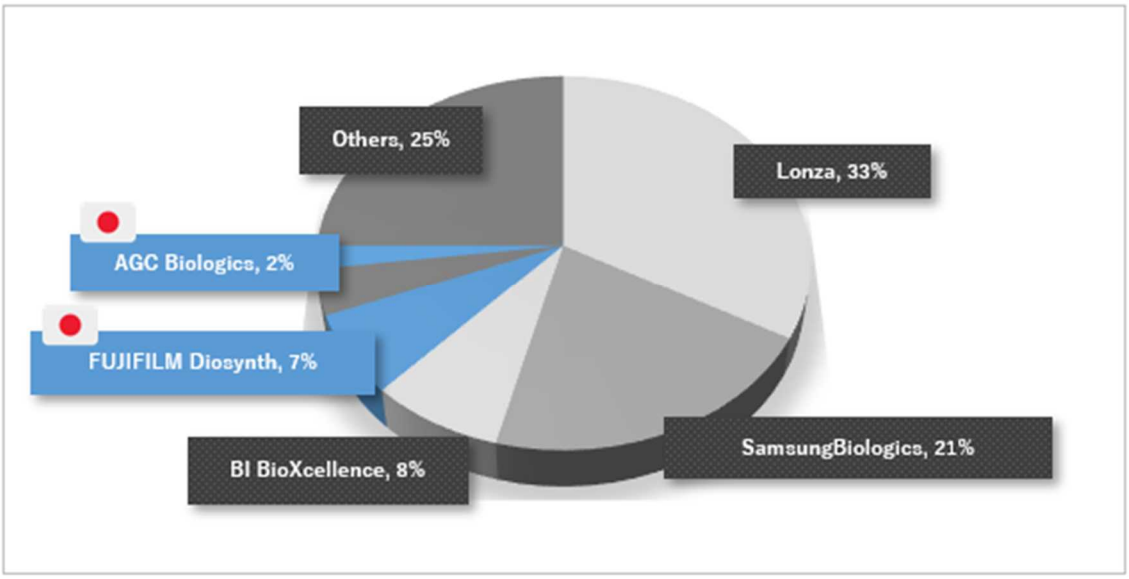

Figure 8: Manufacturing Capabilities of the Top 90 Global Biotech Contract Manufacturing Organizations[14]

[13]Prepared by Answer News based on data from Evaluate (https://answers.ten-navi.com/pharmanews/22657/)

[14] "Biotechnology Part 1: Aimed at by Major Companies in Different Industries" (Mizuho Securities Co., Ltd.)(12/2019)

b. Market Size

The global pharmaceutical market is estimated to be about 200 trillion yen in 2022, [15]with the United States accounting for approximately 40% of the market. Positive growth is expected in the overall market, with prominent growth rates in the United States and Europe. On the other hand, the Japanese market, which accounts for about 4.5% of the global market (about 10 trillion yen), is expected to continue to grow at -1%-2% until 2028 due to price pressure on existing drugs, etc. (Figure 9).

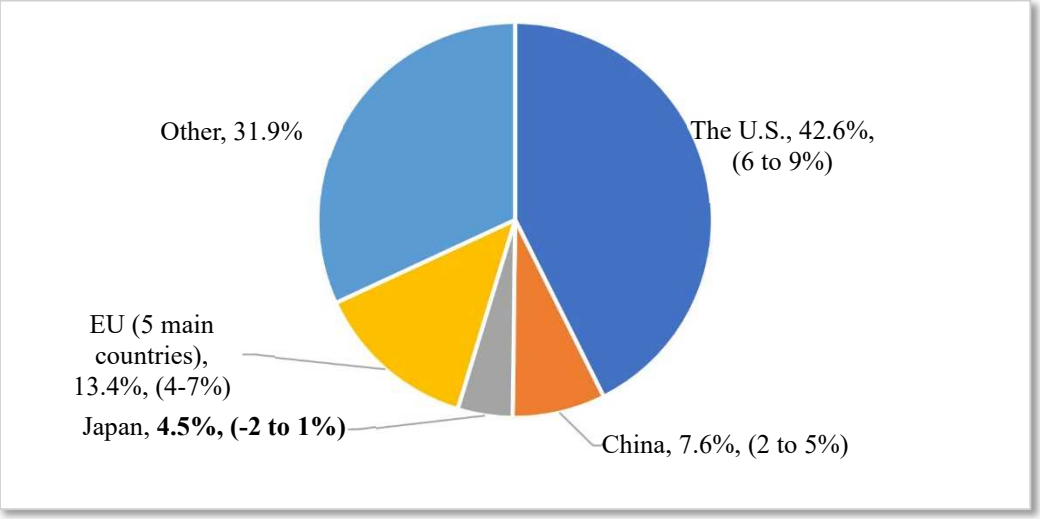

Figure 9: Percentage and Growth Rate of Major Pharmaceutical Markets
(Country name, projected annual growth (2024-2028))[1617]

c. Startup Performance

In the United States, startups play a central role in the development of new drugs. There are more than 9000 unlisted drug discovery startups, about 80% of the seeds technology comes from the startup, and about half of the approved products come from the startup application. From 2016 to 2022, an annual average of more than 20 drug discovery startups made it to IPOs, indicating a certain level of success for the companies. On the other hand, the number of unlisted drug discovery startups in Japan is only about 600, and an annual average of only about 2 of them made IPOs during the same

[15] IQVIA Global Pharmaceutical Market Data 2022
[16]"The Global Use of Medicines 2024" (Statista 2024, IQVIA)
[17] Note that for the EU, the market share is on a country-by-country basis and the growth rate is the average for Western Europe as a whole.

period, showing that both the number and success cases are limited compared to those in the United States. In particular, the number of unlisted drug discovery ventures is 1/15th of the U.S. level, the annual investment is 0.4% of the U.S. level, and the annual number of investments is 7.2% of the U.S. level, showing a stark difference (Figure 10).

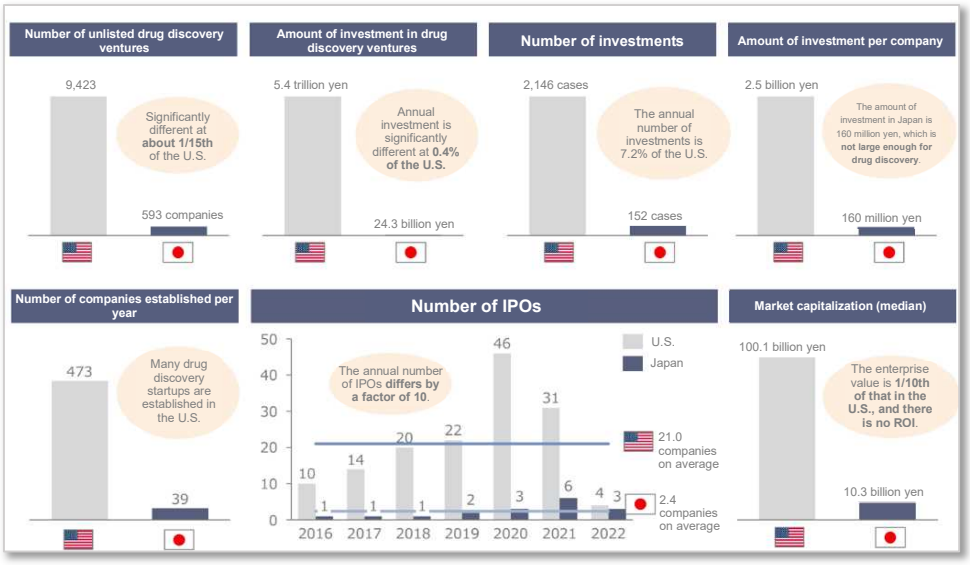

Figure 10: Comparison of the United States and Japan in Terms of the Number of Unlisted Drug Discovery Ventures, Investment Amount in Drug Discovery Ventures, the Number of Investments, the Amount Invested per Company, the Annual Number of Founders, the Number of IPOs, and Market Capitalization (Median)[18]

Japan's drug discovery capabilities in the world are also declining. In the creation of basic patents for globally approved products, the United States accounted for the majority of the total number of products in the global market throughout the period from 2013 to 2021, while Japan created 18 products in 2013 to 2015, but only 7.5 products, less than half, in 2019 to 2021. In terms of the percentage, Japan accounted for 15% from 2013 to 2015, but this fell to 7% from 2019 to 2021 (Figure 11).

[18]Prepared by Eight Roads based on the Initial, Crunchbase, Venture White Paper, NVCA 2023 Yearbook, and "Science and Technology Indicators 2022" by the Ministry of Education, Culture, Sports, Science and Technology

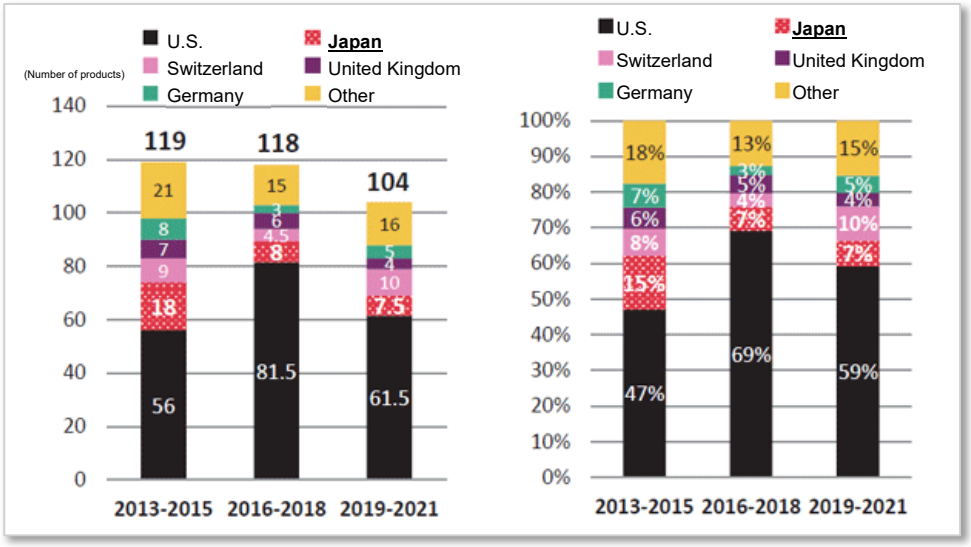

Figure 11: Basic Patent Creation and Annual Changes in Globally Approved Products by Country[19]

b. Basic Strategies for Startup Support

Fortunately, Japan has focused on basic research in the field of life sciences and is considered to have relatively abundant scientific expertise. The key to success for Japanese drug discovery startups is rapid entry into the United States and Europe, which account for the majority of the global market. In light of the foregoing, it is necessary to provide advice and funding on strategies and practical operations targeting the global market before a startup is launched or from the early stages of development in Japan. Not a few startup stakeholders claim, "Drug development depends on whether or not the (US) FDA approval can be obtained." (Strategy 1: Go Global Approach)

However, it is not easy to succeed in the highly competitive global market. We need to monitor competing research at top universities, pharmaceutical companies and other research institutions in foreign countries timely and continue to challenge ourselves for various options, such as in-house development, licensing, and M&A. It is also important to pay attention to the

[19] "Nationality of Patent Creation Organizations for NME-Approved Products in Japan, the United States, and Europe - Comparison of Approved Drugs Containing New Active Ingredients in Japan, the United States, and Europe" The Office of Pharmaceutical Industry Research (OPIR News No. 70, November 2023) (https://www.jpma.or.jp/opir/news/070/03.html)
(Clarivate-based analysis of products approved for the first time since 2013 in two or more regions of Japan, the United States, and Europe)

evolution of commercialization approaches, as the "venture creation" method, in which VCs with deep knowledge of development and management in the drug discovery field take the lead in discovering and refining seeds present in academia and combining them with professional management, is attracting attention, in the United States and other countries.

It should also be effective to support the development and deployment of pioneering products and services in Japan by developing and expanding the regulatory environment for new modalities, such as the regulatory framework for cellular and tissue-based products, and then expanding to overseas markets. (Strategy 2: Two staged Approach)

In all cases, it is necessary to support startups and create an ecosystem. Some expect that further support in the early stages of development will lead to the discovery of more promising seeds. It is also important to prepare lecture and practical training programs to develop manufacturing and development personnel with a track record of obtaining approval in the United States and Europe as well as a financial environment that allows startups to grow smoothly.

c. Specific Promotion and Support Measures (Recommendations 11-13)

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

a. Issue

It is often pointed out that there is a lack of advice and funding in the early stages of development in Japan, especially at the stage of finding preclinical and final development candidates, before Japanese drug discovery startups will challenge the U.S. and European markets.

On the other hand, there are high expectations for the registered VC system for the AMED's Project of Strengthening Program for Pharmaceutical Startup Ecosystem. Especially in the global market, the importance of registered VCs is increasing, coupled with a trend of VCs taking the lead from an earlier stage in the aforementioned venture creation.

At present, the registered VC system is mainly targeted at the clinical development stage rather than the early development stage, and the minimum investment requirement is set as high as $6.6M.

b. Policy Recommendations

Strengthen the support system for early-stage development in Japan through the AMED's Project of Strengthening Program for Pharmaceutical Startup Ecosystem.

The Ministry of Economy, Trade and Industry and the AMED should discuss and revise the requirements for AMED's Drug Discovery Venture Ecosystem Enhancement Project, including lowering the current minimum investment requirement ($6.6M) from lead-registered VCs, to expand its scope to include early-stage pipelines (especially in the stage of finding pre-clinical and final development candidates).

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.

a. Issue

In order for Japanese biotech startups to challenge the world, it is necessary to formulate development and manufacturing strategies from the early stages of development in anticipation of future FDA submissions. At present, however, many people in Japan say that they are "lack" human resources who can formulate such strategies based on past successful experiences.

According to interviews with people familiar with VCs and the biotech startup industry in the United States, many of them say that the development of such human resources requires both university education programs, etc. (classroom lectures) and successful experience (practical training) at CDMOs, etc.

As for "classroom lectures," there are existing programs in Japan, such as the Fukushima Institute for Research, Education and Innovation (F-REI) and

those at Kobe University, but there are voices that these have not been able to serve as a sufficient bridge to practical experience due to the size of the budget and the lack of faculty members with a track record of FDA approval.

In addition, as for "practical training," there is a lack of "CDMOs with a track record of FDA approval," which is a prerequisite. In the U.S. ecosystem, many people who have experience in development, manufacturing, and regulatory processes at CDMOs move to biotech startups and VCs, which is a major factor in increasing the development success rate. In Japan, on the other hand, although capital investment in Japanese CDMOs has progressed in the past several years, there are few Japanese CDMOs with a proven track record, except in some areas such as small molecules and peptides. If the government continues to invest AMED or milestone-based funding, Japanese biotech startups are expected to spend the funding on either (1) contracting Japanese CDMOs with insufficient FDA approval experience and track record, resulting in low success rates and results in the ecosystem, or (2) contracting overseas CDMOs with proven track records across national borders. There are voices that, in either case of (1) and (2) above, the lack of practical training in which human resources in Japan accumulate experience and track record leading up to FDA approval will persist, resulting in the "negative spiral" continuing in the ecosystem.

b. Policy Recommendations

To get rid of the negative spiral, it is necessary to prepare both classroom lectures and practical training programs in Japan.

As for "classroom lectures," the government should reorganize the existing educational bases as described above, while paving the way for increasing the number of faculty members with practical experience by collaborating with the above CDMOs and industry organizations with a view to considering the necessary budget and drawing up a direction within FY2025.

As for "practical training," the government should continue to support CDMOs in Japan, as well as consider, among other things, inviting global top-class CDMOs capable of handling FDA and EMA regulatory affairs to Japan to provide a place for trainees to gain successful experience in development and manufacturing as a transitional measure until human resources are developed, it will be desirable.

Currently, the U.S. Biosecure Act[20]is causing many projects to seek CDMOs with proven track records. It is expected that, coupled with the strengthened development of CDMOs in Japan, invited overseas CDMOs will expand development and manufacturing in Japan, and excellent human resources who graduate from them will move to biotech startups in Japan and Japanese-affiliated CDMOs and VCs, thereby strengthening human resources for ventures, CDMOs and VCs in Japan.

In addition to the strengthened development of CDMOs in Japan, the government should consider the tax incentives offered by local governments and their regions interested in attracting overseas CDMOs, cooperation with educational institutions, access to distribution hubs, etc. Based on these perspectives, the government also should examine what strategies are realistic within FY2025 under the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry.

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.

a. Issue

While initial public offerings (IPOs) are important as an exit strategy for financing healthcare startups, for biotech startups, certain clinical trial phases or alliances with major pharmaceutical companies in terms of drug discovery pipeline are virtual requirements for IPOs among business practitioners at VCs, etc. Although the Tokyo Stock Exchange's guidebook for initial listings has been revised to clarify that the above practices are not essential requirements for listing, there are many voices that there is still a discrepancy in perception among business practitioners. As a result, there is criticism that IPOs are not yet a realistic option for individual drug pipelines at early stages where pharmacological effects have not yet been confirmed in Phase IIa clinical studies. In addition, there are many concerns that entering into

[20] A bill submitted to the U.S. Congress in January 2024, passed by the Congress's Senate Expert Committee, and is expected to become law next year. Four Chinese companies, including major genomic analysis firms and contract development and manufacturing organizations (CDMOs), are named and banned from government procurement projects due to national security concerns.

alliance agreements with major pharmaceutical companies in order to meet listing requirements could damage the corporate value of biotech startups, as alliance agreements at an early stage of development may be disadvantageous to startups. As a result, IPOs are not functioning sufficiently as a realistic option for biotech startups, and the virtuous cycle of Japan's healthcare startup ecosystem is not turning.

b. Policy Recommendations

Further review the Tokyo Stock Exchange's guidebook for initial listings and related Q&As and other statements to make it clear that certain clinical trial phases or alliances with major pharmaceutical companies in terms of drug discovery pipeline are not requirements for an IPO by the end of 2024. Specifically, it is necessary to revise descriptions that give the impression that, for individual drug pipelines, common viable cases include a pharmacological effect confirmed in clinical trial phase IIa and the conclusion of an alliance as described above, with other limited cases permitted as exceptions. It is also required to revise the descriptions to clarify that it is acceptable for an applicant company to plan to outsource the business structure ranging from research and development to manufacturing and marketing to an alliance partner, rather than preparing it in-house, but has not yet concluded an alliance agreement. At the same time, it is important to promote the understanding of market participants, including lead managing underwriters, of these listing requirements (including the fact that deficit listings are permitted) and the business environment in the healthcare field in order to ensure a smooth IPO of healthcare startups.

In addition, dialogue with investors is important for healthcare startups to continue to grow, including raising growth capital; the Tokyo Stock Exchange is expected to promote the effective dissemination of information to investors, such as encouraging companies listed in growth markets to share their growth stories.

(3) Measures for Promoting and Supporting the Medical Device/SaMD Market

a. Medical Device/SaMD Market

a. Characteristics of Market Structure

Medical devices are broadly divided into two types: "diagnostic," used to detect and evaluate a specific disease or condition based on phenomena observed in patients, and "therapeutic," used by doctors to cure or alleviate a patient's disease or symptoms.

Japan has international competitiveness in diagnostic medical devices, especially diagnostic imaging devices, but its international competitiveness in therapeutic medical devices is relatively low. From the perspective of international competitiveness, it would be ideal for Japanese companies to have a large market share, but it has been reported that this is not the case (Figure 12). From a product-specific perspective, Japanese companies have strengths in diagnostic imaging devices, such as endoscopes, CT scanners, and ultrasound diagnostic devices, and in endoscopes in particular, Japanese companies account for nearly 100% of the world market share. On the other hand, in therapeutic medical devices, such as stents used to treat aneurysms and radiotherapy devices used to treat cancer, Japanese companies have only about 1% of the global market share[2122]. This is also reflected in a substantial import surplus of therapeutic medical devices, with about 87% of the medical device trade deficit of about 950 billion yen in 2018 coming from therapeutic medical devices.[23]

[21] "Information Collection on International Competitive Position of Goods, Services and Software of Japanese Companies in FY2008". (New Energy and Industrial Technology Development Organization (NEDO)) (Fuji Chimera Research Institute, Inc.)
[22] "Report on Competitiveness Survey in Japan's Medical Devices and Healthcare Industries" (2nd Medical Device and Healthcare Development Council (May 25, 2021) material) (NTT Data Institute of Management Consulting, Inc.)
[23] "Materials submitted by the METI at the 2nd Medical Device and Healthcare Development Council) (Ministry of Economy, Trade and Industry) (2nd Medical Device and Healthcare Development Council (May 25, 2021) material)

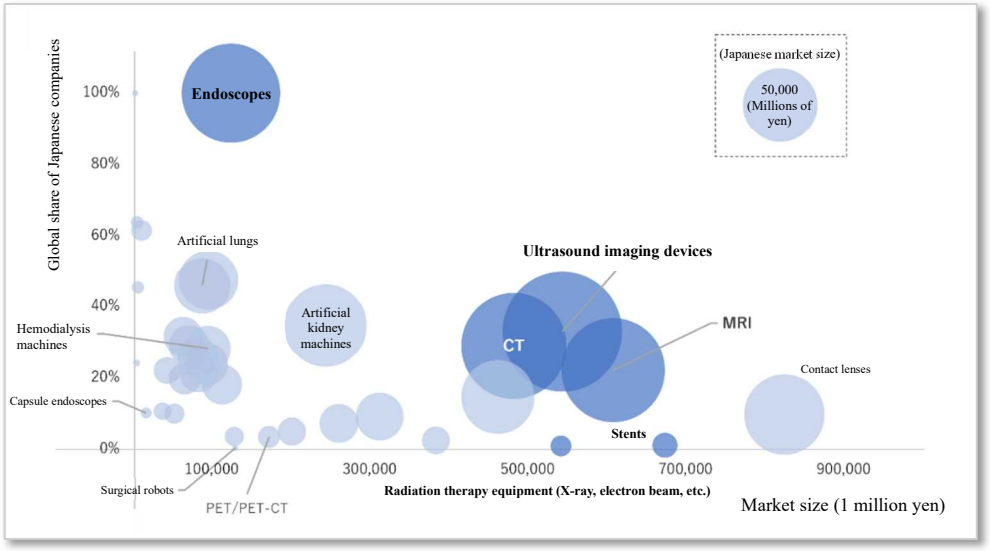

Figure 12: Global Market Size by Device and Share and Sales of Japan Companies[22]

Rather than relying solely on overseas products, it is necessary to strengthen the development of therapeutic medical devices in Japan. To improve international competitiveness, it is necessary to acquire overseas markets, especially the United States.

Through technological innovation such as AI, SaMD, which has the ability to develop into direct prevention, diagnosis, and treatment of diseases, is attracting attention as a new growth area. Due to its technological characteristics, SaMD is also expected to be a new solution to social issues such as uneven distribution of specialists, overwork of healthcare professionals, and increased healthcare costs.

b. Market Size

The global medical device market exceeded 70 trillion yen[24] in 2023. Due to global population growth and other factors, the population is expected to grow at an annual growth rate of 5.9% by 2027.

The United States has the world's largest market share of about 47% and has one of the pharmaceutical regulatory systems that drive international standards.

[24] Converted at the 2023 average dollar/yen exchange rate (central rate) announced by the Bank of Japan

On the other hand, the Japanese medical device market is expected to be approximately 3.7 trillion yen in 2023[24] with a CAGR of 3.7% through 2027; although our medical device market is expected to grow, its growth rate is lower than that of the global market.[3]

In addition, SaMD is attracting attention as an area with a particularly high growth rate. For instance, for SaMD using AI, a growth forecast expects that the global market size in 2030 is at approximately 4 trillion yen and the market growth rate is at approximately 18%[25].

c. Startup Performance

In Japan, about 30 startups involving medical devices or SaMD ("medical device startups") are established annually. Given around 300 medical device startups are established in the United States annually, this number is still small in terms of GDP ratio (Japan:U.S. =1:6).

In terms of fundraising, the focus is on SaMD. For example, a startup that provides a treatment app, which is a type of SaMD, and a startup that has put AI-based diagnostic support into practical use have each raised realized a total of more than 5 billion yen.

In the global trend, the main exit strategy for medical device startups is M&A. This is because, as a strategy for entering the medical device market, it is extremely important to have sales and dissemination strategies before and after the market launch, such as acquiring and expanding sales channels and providing guidance to doctors, all of which require a large amount of money. For this reason, startups are more likely to be able to efficiently deliver their products to patients by leveraging the abundant assets of large medical device manufacturers, making M&A a viable option. A well-known example of a large M&A in Japan is the acquisition of a startup that developed and provided a SaMD service, which was covered by insurance for the first time in Japan, for about 29.2 billion yen.

It is likely that medical device startups in Japan are difficult to appear as attractive acquisition targets for major companies. Of a total of 149 M&A

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[25] "Final Report on Investigation on How to Support New Medical Device Research and Development" (Deloitte Touche Tohmatsu LLC) (Japan Agency for Medical Research and Development, March 29, 2023) (https://www.amed.go.jp/content/000112289.pdf)

cases in which the top 5 companies in terms of sales from both Japanese and overseas companies acquired medical device startups between 2018 and 2022, only 2 cases involved Japanese medical device startups (both acquired by major Japanese companies).[3] The reason for this is that while major medical device manufacturers are mainly interested in products that can compete in the North American market, which is the largest market, it has been pointed out that "there are few medical device startups in Japan that have systems in place to develop novel products, build patents, and perform quality control with the North American market in mind."

b. Basic Strategies for Startup Support

For medical devices, it is necessary to determine whether the "Go Global" or the "Two staged" approach is appropriate for each product type.

The Go Global approach is appropriate for medical devices for which there is an urgent need in clinical sites. There are two types of such medical devices. The first is therapeutic medical devices that overcome the situation of extremely low patient satisfaction with existing therapeutic technologies (unmet medical needs). The second is diagnostic medical devices for diseases that have conventionally been difficult to diagnose despite the availability of treatment methods due to their high invasiveness, etc.. Since these medical devices are highly urgent in terms of their needs, they are less likely to be affected by differences in the medical environment in each country's market. For this reason, it is desirable to proceed in anticipation of acquiring approval and commercialization in the United States, the largest market for medical devices, and to provide intensive support for the funds and other resources necessary for this purpose. (Strategy 1: Go Global Approach)

On the other hand, the Two staged approach is appropriate for medical devices for which consistency with the medical environment and sales efforts are more important in the decision to introduce them than the urgency of the need. SaMD with relatively low risk to the human body is included in this category. In anticipation of Two staged, it will be feasible for us to first make use of relationships with doctors and medical institutions in Japan, as well as our deep understanding of the Japanese medical environment, to establish a business foundation in Japan. For this reason, it is desirable to create opportunities to collect information and built relationships with a view to

overseas expansion, while also improving the development environment that makes it easier to build evidence in Japan. (Strategy 2: Two staged Approach)

There are various types of medical devices, which are greatly affected by the evolution of AI and other technologies. Therefore, it is necessary to support medical device startups based on the characteristics of each product and trends in related technologies.

c. Specific Promotion and Support Measures (Recommendations 14-17)

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.**

a. Issue

Innovative medical devices that address unmet medical needs, such as those that save lives, involve greater technology development risk than ordinary medical devices, which risk can be such large that major companies can tolerate. Therefore, product development based on the innovative ideas and technologies of medical device startups is one of the promising areas, but it has been pointed out that, especially in Japan "the supply of venture capital to such areas is particularly low due to the difficulty of determining feasibility."

In addition, in the development of such medical devices, the study environment to build clinical evidence, such as the registry and cadaver studies, including FIH (First in Human) studies, which are clinical studies at the stage of first application to humans, and real-world data/real-world evidence ("RWD/RWE"). However, due to development risks such as high invasiveness, the FIH studies have only been accepted in some medical institutions such as Clinical Research Core Hospitals in Japan. Registries such as RWD/RWE are not adequately developed in Japan. For example, in the United States, there is a NEST initiative that seeks to build big data on medical devices, where the FDA awarded a grant of approximately 3.3 billion yen to an organization called MDIC to develop a framework that incorporates RWE/RWD into regulatory decision-making. Japan has not participated in the international joint standard called the UDI system, which

is designed to collect data such as information on medical devices, adverse reactions, and indications in order to streamline the development and commercialization of new medical devices, and is referred to only in administrative notices from the Ministry of Health, Labour and Welfare. Although the environment for cadaver studies is being developed in Japan, there are issues such as a lack of diversity in terms of the number of participants and target diseases, as well as difficulties in using the results of overseas studies in Japan.

b. Policy Recommendations

From FY2025, expand the support for Clinical Research Core Hospitals, etc. that cooperate in clinical studies, including FIH studies conducted by medical device startups and other organizations engaged in the development of innovative therapeutic medical devices, etc. (medical devices equivalent to Class III or IV in the classification of medical devices). This includes innovative diagnostic medical devices that may lead directly to highly effective treatments for diseases that have previously been difficult to diagnose.

At the same time, further enhance and strengthen our bases from FY2025 onward to create an environment that makes it easier for medical device startups to collaborate with doctors and medical institutions and to promote the development of such medical devices. This includes improving access to hospitals and related facilities, providing opportunities to explore needs and verify concepts, developing human resources on the host side, and supporting collaboration with related academic societies for projects with high clinical needs and high clinical outcomes.

In addition, provide milestone-based support (Recommendation 2) to medical device startups working on the development of such medical devices to fund clinical studies, etc.

Consider initiatives to identify new needs and streamline the collection of clinical evidence to accelerate the development of next-generation medical devices. Utilize the world's first data obtained from innovative medical devices and post-marketing data, for example, by further promoting the activities of the Clinical Innovation Network (CIN) in order to promote the creation and renovation of registries in a form that is easier for third parties

to use. In this way, support related initiatives in academic societies and other organizations and promote the utilization of data for the development of next-generation medical devices.

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

a. Issue

Given the situation in the Japanese market and from the perspective of the growth potential of medical device startups, it is necessary to make efforts for overseas expansion, focusing on the United States.

In the case of medical devices with clear global needs of patients and doctors, it is important to reach out to stakeholders such as local academic societies, regulatory authorities, and insurance companies, to ensure that the process to market launch is as streamlined as possible. Even if the needs are not clear, it is desirable to examine the target market and market launch strategy from the early stages of development, and it is necessary to conduct a needs survey with a view to overseas expansion and to deepen the understanding of institutional systems such as regulations.

In both cases, it is necessary to have human resources with a high level of expertise, an international perspective, and a strong local network, but it has been pointed out that "there is a lack of human resources capable of developing business overseas and supporting human resources, including regulatory compliance, etc."

In addition, although the overseas compatibility of the acquired evidence is important for overseas expansion, it has been pointed out that "the clinical study environment in Japan is not consistent with international standards in some respects." For this reason, there are cases where clinical studies, etc. need to be reworked while interacting with local regulatory authorities, which requires more time and cost than necessary.

b. Policy Recommendations

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. This includes connecting with local inner circles and key persons, introducing trial programs to local medical institutions, and overseas dispatch programs for healthcare startups, including medical device startups.

In addition, in order to acquire markets other than the United States, strategically promote international conversion of medical device regulations for emerging countries, especially those in Asia. Furthermore, support product development based on the local needs of developing countries and emerging countries such as those in Asia, Africa, etc., as well as work with local regulatory authorities, form a community in cooperation with key persons from local industry, government, academia, and medicine, and support medical device startups that are expanding into the region.

In addition, in order to bring the way of clinical studies and regulations on medical devices closer to international standards, in FY2025, conduct a survey on the medical device field in the United States, a leader in international standards of pharmaceutical regulations. Based on the results of this survey, starting from FY2026, gradually implement efforts to close the gap with international standards. This includes making innovative medical devices from medical device startups a target of Harmonization By Doing (HBD; activities to harmonize medical device regulations in Japan and the United States through the practice of clinical studies and regulatory reviews).

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

a. Issue

The requirement for obtaining a medical device marketing business license include the establishment of manufacturing control, quality control, and post-marketing safety management systems from the stage before starting the

product approval process, which are regulations against companies unique to Japan. It is necessary to assign a manager with a certain level of work experience, but it has been pointed out that, in the field of SaMD, in which many startups participate, “the personnel requirements of medical device manufacturing and marketing make it difficult for startups with weak capital to recruit human resources.”

In addition, the regulations on advertising to general consumers for government-approved products of medical therapeutic apps, which are a type of SaMD, are being relaxed, but for therapeutic apps for home use, it is not possible to advertise reliable evidence such as clinical trial data to general consumers. However, while general healthcare apps cannot claim efficacy, they can advertise evidence whose reliability has not been verified. Thus, there is a problem with balance between the two types of healthcare app in terms of the content that can be advertised.

b. Policy Recommendations

Promote deregulation of “licensing for medical device marketing authorization holders” in the SaMD area. Relax the personnel requirements from FY2025 and make it possible to obtain a medical device marketing business license in prefectures by the time the pharmaceutical approval of the product is obtained. Also strive to correct the heterogeneity in the investigations for marketing business licenses conducted by prefectures.

In addition, from the perspective of ensuring the quality of medical devices, consider and gradually provide education and training for medical device startups in accordance with international standards from FY 2025.

In FY2024, investigate the medical device field other than SaMD, and if deregulation of personnel requirements is deemed appropriate, expand the scope of deregulation after conducting necessary investigations in FY 2025.

Regarding the advertising regulations for SaMD, in 2025, consider launching a working group in which marketing authorization holders, healthcare professionals, patient groups, etc. participate to allow advertising of clinical data whose objectivity is assured, such as data attached to the application for approval of therapeutic apps for home use.

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

a. Issue

Amid the shortage of healthcare resources associated with Japan's declining birthrate and aging population, we have high expectations for SaMD as a means of reducing the burden on healthcare professionals, but its development and adoption have not progressed. Although SaMD may contribute to the equalization of healthcare and operational efficiency, it is often difficult to directly verify clinical and medical-economic outcomes at an early stage, and under the current system, even if reimbursed by insurance, it is not evaluated as a premium. Under these circumstances, adoption to medical institutions is also limited.

For example, Germany has in place a regulatory approval and insurance reimbursement system called "DiGA," dedicated to SaMD, which clearly demonstrates the national intent to develop SaMD as an industry.

Japan is designing some regulatory systems according to the characteristics of SaMD, such as the "Notification of Rebalance for SaMD," but the mechanism to verify the outcomes and promote its dissemination to their medical environment is still insufficient.

b. Policy Recommendations

Establish a demonstration environment to conduct comprehensive evaluations based on the characteristics of SaMD in addition to clinical and medical-economic outcomes at the National Center for Advanced Medical Research and other institutions from FY2025 onward. Also implement the development environment such as the establishment of the DCTs system (Recommendation 7). In addition, advance medical DX initiatives because the flexible use of medical data is important for the development of SaMD.

In addition, continue to consider measures for the dissemination of high-quality medical devices, including SaMD, by utilizing the Fund for securing comprehensive medical and long-term care in local communities, which is aimed at promoting physicians' work style reform and building an efficient

and high-quality medical care delivery system, and with reference to examples where appropriate incentives are given such as the HITECH Act and the MACRA Act in the United States.

(4) Measures for Promoting and Supporting the Medical DX/AI Market

a. Medical DX/AI Market

a. Characteristics of Market Structure

In Japan, a distinctive social security system has been established in which most citizens enjoy high-level medical and nursing care services through a universal health insurance system and a nursing care insurance system; therefore, high-quality medical and nursing care data are entered and accumulated on a daily basis.

In addition, the government has compiled the Timetable for Promoting Medical DX, and efforts are underway to promote data entry and accumulation to further utilize the data. The timetable describes a plan to build a "national medical information platform" by expanding the online health insurance verification systems. It also describes the government's plans, including an "electronic medical record information sharing service" for sharing such information with medical institutions and pharmacies, to be gradually started by medical institutions that have achieved the standardization of such information by the end of FY 2024, and the development of a standard electronic medical record to promote the dissemination of electronic medical records.

However, at present, the potential of Japan's medical and nursing care data has not been fully exploited. In order to promote the collection and use of medical data, it is important to ensure that the cycle from data entry to returning value through data use runs smoothly (Figure 13). However, it has been pointed out that data sharing, including electronic medical records and other data, how to link them, and research activities based on these have not been fully implemented; in addition, the mechanism for returning to related parties the value generated by data sharing and use and the basic understanding in terms of the development and use of medical AI has not been sufficiently organized, resulting in "clogging at many points in the above cycle."

For example, regarding the medical information network in the local medical care zone, although the system has been established, the actual use is slow in some cases. This evinces the fact that the cycle to return the value of medical

data is not running sufficiently[26].

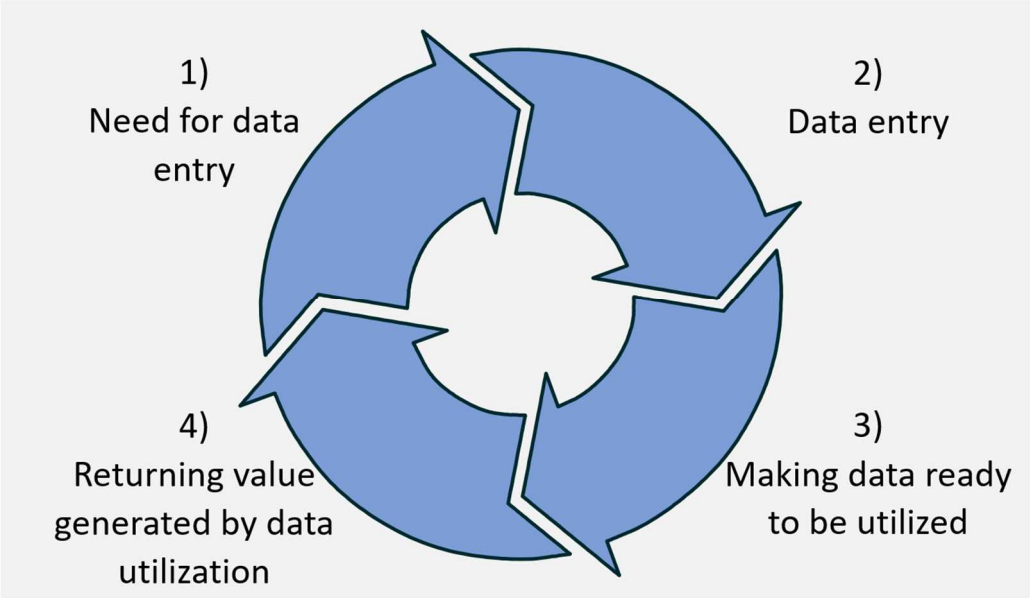

Figure 13: Cycle for Generating Value from Medical Data

b. Market Size

The global healthcare IT business market[27] is projected to exceed $80 billion by 2025 under high growth rates. On the other hand, the Japanese healthcare IT business market[28] is estimated to reach only about 400 billion yen in 2025 under a low growth rate (Figure 14).

In addition, the electronic medical record market size in Japan is estimated to be around 300 billion yen in 2025.[29]Thus, the market size of healthcare IT business other than electronic medical records, including PHR, is relatively small, and there is room for further growth.

[26]"Report on Account Settlement Audit 2018" (Board of Audit) (November 8, 2019)_ (https://report.jbaudit.go.jp/org/h30/2018-h30-0271-0.htm)

[27] Include PHM (services for health improvement and reduction of medical expenses by integrating and analyzing patient data) and EMR (services for electronic records composed of standard medical and clinical data of individuals collected within one medical institution).

[28] Includes medical big data analysis for healthcare-related industries, DPC data warehouse for hospitals and hospital management analysis service, receipt analysis and planning for data health plants, systems to utilize the results of specified health checkups and regular checkups, and the electronic medical record system.

[29]"2023 Current Status and Future Prospects of Markets Related to Medical/Healthcare DX" (Fuji Keizai) (March 20, 2023)

Furthermore, the market for medical-related products and services using artificial intelligence (AI) is expected to explode in both quality and quantity in the future due to the emergence of rapidly evolving generative AI.

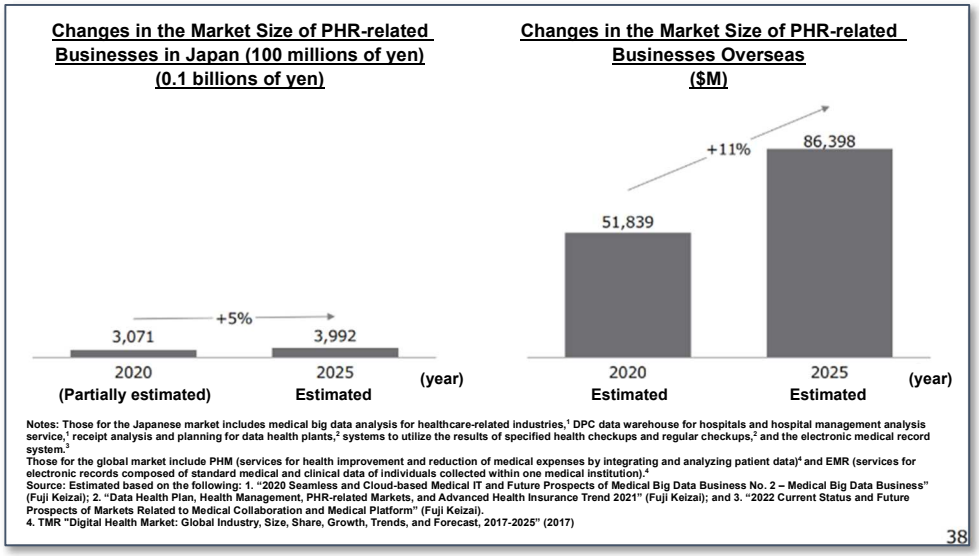

Figure 14: Market Size of PHR-related Businesses in Japan and Overseas*[30]

(c) Startup Performance

In the medical DX/AI market where technological innovation and changes in the business environment occur on a daily basis, flexible and agile development and innovation by healthcare startups play an important role. For example, healthcare startups are working on research topics related to medical data under the Cabinet Office's Strategic Innovation Promotion Program (Building an Integrated Healthcare System), and healthcare startups are also promoting medical data collaboration across local governments under the Vision for a Digital Garden City Nation using the National Strategic Special Zone System. Thus, it has been pointed out that "the participation and cooperation of startups, in addition to academia and existing companies, makes it easier to conduct research and development that is closer to practical application." On the other hand, there are also voices that "startups are facing systemic problems that cannot be solved by their

[30] "Final Report of Fiscal Year 2021 Health Care Service Social Implementation Project (Survey on Improvement of Business Environment for Health Care Industry)" (The Japan Research Institute, Limited) (Ministry of Economy, Trade and Industry, March 25, 2022) (https://www.meti.go.jp/meti_lib/report/2021FY/000656.pdf)

own efforts," such as the disparate format of data entry and the fact that existing public data is not open to the private sector.

In addition, AI is growing remarkably fast in the healthcare field. For example, an AI product shows an acceptable level of performance in the national examination for doctors under certain conditions[31], and healthcare startups are launching products and services to support medical interviews and diagnoses.

However, although AI startups have a big role to play, they have not attracted enough investment. While AI-related investment is accelerating in various countries, it has been pointed out that Japan "absolutely lacks the fuel" to spur innovation[32]; for instance, while the United States made more than $67 billion in private investment in AI-related startups in 2023, Japan made only about $700 million (12th in the world). In order for more startups to enter the healthcare field and drive innovation, it is important to improve the business environment by, for example, clarifying regulations.

b. Basic Strategies for Startup Support

Products and services in the DX/AI market are greatly affected by the uniqueness of each country's healthcare system and data privacy regulations, so a common global market has not been established. In addition, the possession of high-quality medical and nursing care data is one of Japan's strengths, and in order to take advantage of this, it is important to first establish a business model in Japan. On this basis, we should aim for global expansion in the future by overcoming differences in data infrastructure and markets (Strategy 2: Two staged Approach).

Specifically, it is necessary to establish infrastructure for "data entry" and "data utilization" and to provide support for the development environment of products and services. In particular, it is necessary to standardize the format of data entry and expand the possibilities of utilizing existing data

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[31] Kung TH, Cheatham M, Medenilla A, Sillos C, De Leon L, Elepaño C, et al. (2023) *Performance of ChatGPT on USMLE: Potential for AI-assisted medical education using large language models.* PLOS Digit Health 2(2): e0000198.
Tanaka Y, Nakata T, Aiga K, Etani T, Muramatsu R, Katagiri S, et al. (2024) *Performance of Generative Pretrained Transformer on the National Medical Licensing Examination in Japan.* PLOS Digit Health 3(1): e0000433.

[32] Artificial Intelligence Index (2024) *Artificial Intelligence Index Report 2024.* Stanford Institute for Human-Centered Artificial Intelligence.

promptly, starting with areas with high feasibility. In addition, there is an urgent need to support the use of products and services created by the use of data to "return value," thereby shaping and developing a healthy market. In particular, it is necessary to carefully remove barriers to the dissemination of products and services created by the use of data.

c. Specific Promotion and Support Measures (Recommendations 18-21)

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

a. Issue

The personal health record (PHR) service, which handles personal health and medical information through smartphones, etc., is a growing market where many healthcare startups are expected to be active in the future[33]. Currently, various types of public medical information and health information are being accumulated through the promotion of medical DX by the government, and in public systems such as Mynaportal and online health insurance verification, it can be used by PHR apps of private business providers through API (application programming interface) connection with the consent of the principal.

However, at present, in order to obtain public data, it is necessary for users to authenticate with the My Number Card each time, and the information that can be obtained is limited. As a result, it has been pointed out that the service content of private business providers is limited and the improvement of service quality is hindered. For example, regarding Mynaportal APIs, it is not possible to provide push-type services by continuously updating prescription and dispensing information to provide alerts to prevent forgetting to take medication. In addition, it has been pointed out that "since the items of medical information to be shared are not sufficient, their use in AI drug discovery, etc. is not progressing sufficiently." It has also been pointed out that, regarding APIs for web services for online health insurance

[33] According to page 167 of the Ministry of Economy, Trade and Industry's "2020 Supplementary Remote Health Consultation Business System Enhancement Project (Survey Project on Promotion of Remote Health Consultation, etc.)," the PHR service market size in Japan is estimated to be approximately 26 billion yen as of 2024.
(https://www.meti.go.jp/policy/mono_info_service/healthcare/reiwa2houkokusyo.pdf)

verification, the improvement of user convenience is hindered in services that integrate the entire process of medical appointments, interviews, online medical consultations, medication guidance, etc.

b. Policy Recommendations

From the perspective of improving the convenience of the PHR service, take the necessary measures to ensure that the automatic connection can be maintained for a certain period of time once the user is authenticated, rather than the API associated with Mynaportal requiring authentication by the user each time the data is shared. Specifically, regarding electronic prescriptions, which are being introduced among medical institutions and pharmacies, given data on prescription and dispensing information is provided in real time, modify the medical insurance information acquisition API associated with the Mynaportal by the end of FY 2024, and also revise the usage guidelines and other related documents to clearly indicate that automatic linkage is possible. Regarding the security risks associated with enabling automatic linkage, encourage necessary and reasonable levels of security measures so as not to inhibit the sound use of data by healthcare startups. In addition, regarding APIs provided by web services for online health insurance verification, taking into account the above measures, consider measures to prevent situations where personal authentication is required more than necessary in a single visit process from the viewpoint of improving the convenience of online medical services.

Also expand the items of information sharing between the Mynaportal and private PHR service providers, etc. and in addition to the existing items of information linkage such as prescription and dispensing information and medical examination information, make medical information such as the name of the medical institution visited, date of medical care, and name of medical care available for API linkage, thereby promoting the development of PHR services through the ingenuity of healthcare startups.

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

a. Issue

With the widespread use of rapidly evolving generative AI, many new businesses are emerging. One of the markets where AI is expected to be used the most is the healthcare field, and healthcare startups are expected to play a major role[34].

However, it has been pointed out that, when healthcare startups try to develop new products or services using AI, conflicts with the existing medical and pharmaceutical regulations or regulations on personal information protection may become an issue, but it is not clear how the regulations will be applied, such as "how to involve patients when trying to develop an AI model using medical image data as training data, and therefore the healthcare startups have to act in an excessively atrophic manner. In addition, new products and services using AI from healthcare startups are expected to improve medical outcomes and efficiency. While people praise the fact that the technical arguments regarding the evaluation system for medical service fees for SaMD[35] have been put in perspective to some extent, it has also been pointed out that "it is still difficult to clearly predict how new products and services using AI from healthcare startups will be evaluated in terms of medical service fees." In addition, some say that "it is important not to focus solely on evaluation based on medical service fees, but to open up ways to obtain economic returns in forms other than medical service fees, including involvement in healthcare services ."

[34] "Progress of Generative AI and Its Applicability in Healthcare" (Yutaka Matsuo) (https://www.mhlw.go.jp/content/10601000/001194484.pdf)
[35] Meeting materials of the 127th meeting of the Medical Materials Subcommittee of the Central Social Insurance Medical Council (https://www.mhlw.go.jp/content/12404000/001191811.pdf)

b. Policy Recommendations

In order to promote the innovation of new products and services using AI in the healthcare field, it is important to clarify various arguments that may hinder business development at an early stage.

Specifically, in order to identify regulations and arguments that are particularly problematic in AI development and clarify how regulations should be applied, the Ministry of Health, Labour and Welfare should put these issues in perspective to some extent by the end of FY2024, while taking care not to unnecessarily hinder innovation by healthcare startups. The regulations and arguments that become particularly problematic in the development of healthcare AI include: (1) how to address regulations on the LLM derived from medical data containing personal information and the protection of personal information in medical image data; (2) the application of regulations on the location of servers used to store medical information with respect to model applications running in the cloud; and (3) ambiguities regarding whether various regulatory concepts related to AI should target individual services developed using AI or the infrastructure AI.

In addition, from the perspective of enhancing the options for healthcare startups to obtain economic returns through the dissemination of new products and services using AI, promote the dissemination of technology through the use of contact points for receiving requests for revision of medical service fees, as described in Recommendation 2, the use of milestone-based development support, as described in Recommendation 3, and involvement in insurance operations by insurers , as described in Recommendation 8.

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.

a. Issue

As the management systems of various medical institutions incorporate DX and cloud-based processes, many healthcare startups are providing services

that improve the operational efficiency of medical institutions and the quality of medical care.

In this regard, when each medical institution introduces private digital services related to appointments, interviews, medical care information, the medical information department of each medical institution examines whether such introduction will lead to security problems. It has been pointed out that healthcare startups engaged in the development of digital services will be subjected to essentially the same type of review in each medical institution in parallel, which is burdensome for them and leaves room for efficiency improvement. In addition, there is criticism that the interpretation of information security guidelines provided by the government varies from medical institution to medical institution, and public certification, for the security of private digital services has not progressed. As a result, medical institutions tend to be conservative in terms of the risk of introducing new private digital services, and the introduction of digital services has not progressed.

In addition, it has been pointed out that while the information sharing of the public medical data systems with private service providers' services using APIs is progressing, the information sharing with private service providers' services using APIs for systems related to private medical data, such as electronic medical records and health insurance core systems, has not progressed sufficiently, and therefore the entry of healthcare startups has not progressed. It has been pointed out that the background of this situation is that the operators of the existing core systems do not yet have advanced understanding of APIs, and that "there is a situation like vendor lock-in," which require high costs for data sharing.

b. Policy Recommendations

Publicize existing initiatives by the end of FY2024, such as the operation of a certification system, by public organizations or academic societies of private digital services related to medical information systems of medical institutions for their conformity with technical requirements, as described in the so-called "2 guidelines of 3 ministries"[36] to ensure adequate protection

[36] "Guidelines for the Safe Management of Medical Information Systems" (Ministry of Health, Labour and Welfare) and "Guidelines for the Safe Management of Information Systems and Service Providers

of information. At the same time, by examining the necessity of additional measures from FY2025 onward, aim to standardize and improve the efficiency of security reviews by each medical institution, and to promote the sound dissemination of the services and products of healthcare startups.

Note that the considerations and administrative burdens of introducing new systems and services from healthcare startups at each medical institution are on a case-by-case basis depending on the content of the introduced service and compatibility with the core system, and it is not easy to determine generally whether the introduction conditions are appropriate. First of all, by the end of FY2024, grasp the actual situation and consider measures as necessary, by, for example, establishing a cross-ministry consultation desk for startups in the event that healthcare startups face issues in terms of conditions when introducing products and services involving data sharing and API connectivity with information systems such as those of medical institutions.

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

a. Issue

The Emergency Activity Record Form prepared by ambulance crew plays a certain practical role in coordinating patient information between the fire department and the medical institution in emergency transportation. It is stipulated that the Emergency Activity Record Form should be prepared by each member of the ambulance crew to include the minimum items of information to be documented as specified in Article 24 of the Emergency Operation Practice Code, which is subject to Article 37 of the Fire Service Organization Act, and the form is prepared by filling in the required items in a form specified by each local government. It has been pointed out that the format of the Emergency Activity Record Form varies from municipality to municipality, which leads to a sharp increase in the cost of implementing systems for DX related to the form, and at the same time, this is a factor that

Handling Medical Information" (Ministry of Economy, Trade and Industry and the Ministry of Internal Affairs and Communications)

hinders large-scale information coordination among municipalities[37]. It is expected that the digitization of the field activities of ambulance crew and the proliferation of useful products and services from healthcare startups will lead to improved matching with the medical institutions to which emergency patients are transported and improve the quality of emergency medical care.

b. Policy Recommendations

Drive standardization of emergency activity records in emergency services by ambulance crew, which currently vary by municipality, and encourage digitalization. The Ministry of Health, Labour and Welfare 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[38]. 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.

[37] In general, issues such as that region-specific forms/formats may hinder DX and that the rationale for establishing regional differences should be carefully considered, See, for example, "Basic Approach to the Review of Local Rules" (Regulatory Reform Promotion Council) (June 1, 2023) (https://www8.cao.go.jp/kisei-kaikaku/kisei/publication/opinion/230601_general16_01.pdf)

[38] The Fire and Disaster Management Agency is working on the standardization of firefighting operation systems and the use of cloud computing and plans to publish the standard specifications of firefighting operation systems, including reference forms for the Emergency Activity Record Form around October 2024.

(5) Measures for Promoting and Supporting the Age Tech Market

a. Age Tech Market

a. Characteristics of Market Structure

While the demand for nursing care services is increasing with the aging of the population, the working-age population is steadily decreasing due to the declining birthrate, and many care providers in the nursing care industry are suffering from a chronic shortage of human resources. With a projected need for approximately 690,000 new nursing care workers in FY2040, the use of Age Tech (including products that utilize advanced digital technologies such as ICT in addition to nursing care robots and sensors used in nursing care sites) to reduce the burden on nursing care staff and maintain and improve the quality of care is considered to be an urgent policy issue.

On the other hand, it has been pointed out that "the capacity of nursing care providers to invest in Age Tech is limited." The majority of the income of nursing care providers providing nursing care insurance services comes from nursing care benefits, of which 60-70% is personnel costs; there is a lot of room for improving operations through efforts to increase productivity[39]. The importance of DX is being recognized in the nursing care sites, and there are growing expectations for the development of the devices based on diverse needs of the nursing care sites, but at the same time, many nursing care providers are hesitant to introduce Age Tech due to lack of funding and staff ICT literacy. In order to promote capital investment and social implementation in Japan, it is required to establish a cycle of effective use of Age Tech and management improvement in nursing care providers.

[39] The FY2023 Survey on the Nursing Care Business Management Survey points out that the average rate of the balance between income and expenses is 2.4%, which is lower than the profit margin of other industries.

b. Market Size

The benefit costs of nursing care insurance are steadily increasing in Japan. In particular, home care service providers[40] account for 50% or more of the total nursing care insurance expenditure in FY2022 (about 11 trillion yen), and in terms of the number of providers, they account for 225,000 or more out of a total of about 260,000 providers. The structure in which home care services account for about half of the nursing care insurance benefit costs has not changed over the past 20 years (Figure 15). This area, in particular, has a lot of room for the use of Age Tech, which contributes to reducing the burden on care managers and family members.

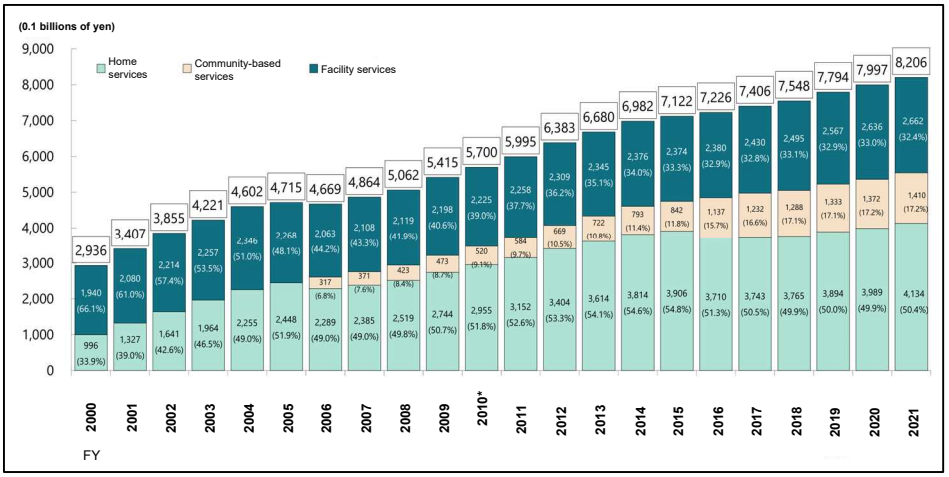


Figure 15: Changes in Benefit Costs by Fiscal Year (by In-home, Community-based, and Facility) (Monthly Average)[41]

Under these circumstances, the Ministry of Health, Labour and Welfare has been evaluating Age Tech through the successive revision of nursing care benefits since FY2018, and the amount of subsidies for introducing Age Tech for nursing care providers has been increasing year by year (Figure 16).

[40] This term refers to home-visit care, home-visit bathing care, home-visit nursing, home-visit rehabilitation, day care, day rehabilitation, welfare equipment rental, short-term residential care, short-term medical care, in-home medical care management guidance, in-home care support, home-visit care nursing for regular patrol and as needed, nighttime home-visit care, community-based day care, dementia support day-care services, small-scale multifunctional in-home care, an small-scale multifunctional in-home care for nursing.

[41] "FY2021 Nursing Care Insurance Business Status Report (Annual Report)" (Ministry of Health, Labour and Welfare) (https://www.mhlw.go.jp/topics/kaigo/osirase/jigyo/21/index.html)

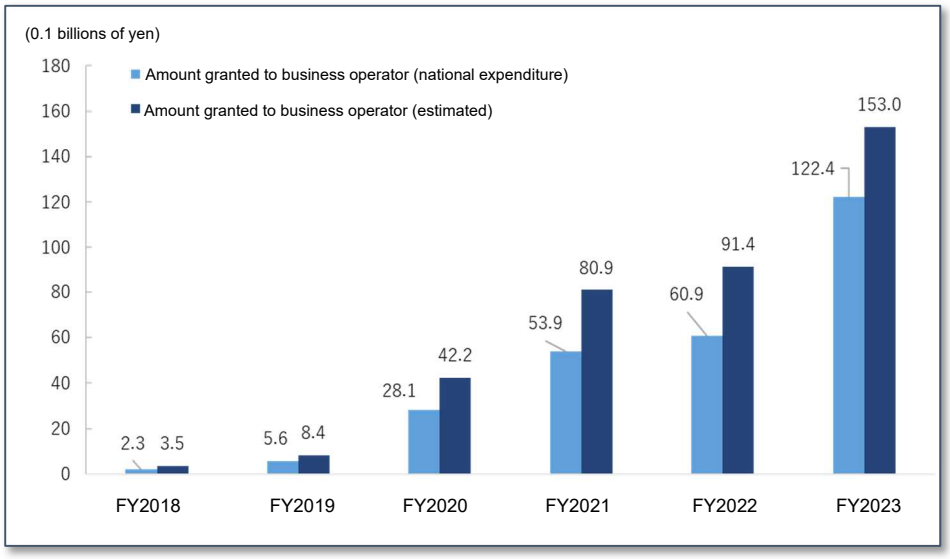


Figure 16: Results of the Support Programs for Introducing Nursing Care Robots and ICT[42]

On the other hand, from a global perspective, Age Tech is an area in which Japan, a country facing advanced challenges, has strengths. It is an effective measure to address the global issue of the shortage of human resources for nursing care, [43]and at the same time, it can serve as a basis for improving the quality of care in the future. Since 2005, Japan has the highest aging rate in the world, but it is expected that in some countries, such as emerging Asian countries, will have a higher aging rate than Japan in the future.

However, when it comes to nursing care, the fact that the current needs vary greatly from country to country makes it difficult to capture overseas markets. Due to the difference in the concept of care, barriers in each country include language, culture, and various laws and regulations,[44] the number of Japanese age tech companies actively operating overseas is currently very small, not limited to startups. For example, South Korea has a nursing care environment and nursing care system similar to Japan's and shares a common national challenge of a shortage of human resources due to a declining

[42] Note that this is an estimate because the subsidy rate varies from prefecture to prefecture.
[43] The proportion of the global population aged 65 years or older (aging rate) was 9.3% in 2020, but is expected to rise to 17.8% by 2060, about 40 years from now "FY2021 State of Aging and Implementation of Measures for Aging Society (FY2023 White Paper on the Aging Society)" (Cabinet Office) (https://www8.cao.go.jp/kourei/whitepaper/w-2022/html/zenbun/s1_1_2.html)
[44] For the current state of the nursing care market and an overview of laws and regulations in other countries, see AMED's survey report ("Preliminary Survey Report on Support for Overseas Expansion of Robotic Nursing Care Equipment for Home Use" (Japan Economic Research Institute Inc)) (March 20, 2023) (https://www.amed.go.jp/content/000110860.pdf)).

birthrate and an aging population. On the other hand, in Southeast Asian countries such as Vietnam and Thailand, it is common to hire live-in housekeepers, and the problem of labor shortage has not become apparent; they are in the stage of building a nursing care environment and nursing care system for the aging population in the future. The nursing care environment in China is complex, and the construction of a unified nursing care system has not been realized due to the income gap in the country, and each province or region is independently exploring the ways to develop a nursing care system.

(c) Startup Performance

As mentioned above, the demand for nursing care services is expanding both in Japan and overseas, and the expectations for Age Tech are also increasing, but Age Tech startups in Japan have not been able to reap the fruits of this trend at present. As evidenced by the fact that few Age Tech startups have been listed, there is not enough ecosystem in place to support their growth and lead them to success. In 2023, one Age Tech startup focusing on facility-based care was finally been listed, but there are still no listed startups in the home-based care.

Investors have pointed out that "it is difficult to predict the profitability of the business and the return on investment in the Age Tech field due to the lack of successful cases;" it is an industry sector with high barriers to new entry for both entrepreneurs and investors. In addition to supporting the construction of businesses that meet the needs of society, there is a need for measures to improve investors' expectations of the Age Tech market through such support.

b. Basic Strategies for Startup Support

Unlike the health and medical care fields mentioned above, in the nursing care field, it is necessary to first take measures to address the growing shortage of caregivers in Japan, which has the highest aging rate in the world, before expanding overseas. To this end, there is an urgent need to take measures for the speedy social implementation of Age Tech, which is required in the nursing care sites. In general, it is extremely difficult for tech startups with poor management strength to carry out a series of processes to launch their products and services overseas on their own, by identifying

countries where there is demand for their products and services, investigating the relevant legal systems and local operations of each country, finding a local office where they can perform demonstrative experiments, and collecting effective evidence. As a result, the number of entrepreneurs who make the decision to expand overseas is very limited, and the same is true for age tech startups.

For this reason, at present, it is realistic to use the "domestic empowerment" approach as the basic route for considering support measures for age tech startups. In order to increase the introduction rate of Age Tech, which contributes to improving the productivity of nursing care sites in Japan, it is necessary to further strengthen human support for Age Tech startups to develop products that meet the needs of these sites, as well as financial support for nursing care providers. (Strategy 3: Domestic Empowerment Approach)

On the other hand, some Age Tech, mainly hardware nursing care robots and sensors, have been relatively well implemented in Japan. Although it is difficult to say that Age Tech for home users has become widespread in Japan, there are some products that fall under the category of welfare equipment that are eligible for benefits under the nursing care insurance system. In these areas, it is considered possible to aim to make Age Tech an overseas export industry in parallel with promoting its introduction in Japan by revising the evaluation of nursing care insurance with the support under the Two staged approach. If the Age Tech market expands in Japan and overseas, it is expected that the number of new entrepreneurs and investors entering the market will increase, and nursing care innovation will be promoted. Through these initiatives, it is not a dream to transform the nursing care field, which has been regarded as a social security cost, into the position of a profit center for Japan to earn foreign currency in the future. (Strategy 2: Two staged Approach)

c. Specific Promotion and Support Measures (Recommendations 22-25)

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

a. Issue

In order to maintain and improve the quality of nursing care services even in the midst of a labor shortage, it is important to implement initiatives[45] to improve productivity, including the use of "robots, sensors, and ICT" in nursing care sites. It is necessary to support the creation of innovations in the Age Tech field by promoting Age Tech startups to ensure that technical options are provided to improve the productivity of different care providers according to their needs.

There are already measures in place to support Age Tech companies that are not limited to startups, such as supporting demonstrations in the Living Lab and matching the needs of care providers with seeds in development companies. However, some managers of Age Tech startups have told us that "since there is no public consultation desk for Age Tech startups, entrepreneurs who intend to enter the Age Tech field for the first time may give up at the preparation stage before taking advantage of existing support measures, unless they have mentors who have the experience of such managers" and "there was no advice service on fundraising and monetization strategies; this made us struggle in the seed and early stages before getting the business off the ground."

b. Policy Recommendations

The Ministry of Health, Labour and Welfare shall establish a CARe Innovation Support Office (tentatively named CARISO)," modeled on MEDISO, as a consultation service for Age Tech startups by reorganizing and upgrading the existing platform project in FY2025, and will start operations within the same year. CARISO shall act as a central service desk for consultations and requests from Age Tech startups. The consultation desk shall be equipped with a system that enables consultation services throughout the entire process from the development stage of highly innovative Age Tech to the consideration of exit strategies for market launch. To support exit strategies, it shall also publish information that can be used as a reference for development companies on priority development areas related to Age Tech, as specified by the Ministry of Health, Labour and Welfare and the Ministry

[45] "Basic Policy of the Council for the Innovation in Nursing Care Sites – "Nursing Care Field Innovation Plan" for Nursing Care Staff and Nursing Care Service Users" (Ministry of Health, Labour and Welfare) (https://www.mhlw.go.jp/content/12301000/000494186.pdf)

of Economy, Trade and Industry, within FY2024. These efforts shall be carried out in cooperation with, among others, the Small and Medium Enterprise Agency, which provides comprehensive support for startups.

In addition, with reference to venture promotion events such as the Japan Healthcare Venture Summit conducted by MEDISO, the Ministry of Health, Labour and Welfare shall hold the Age Tech Summit (tentative name), a networking event in the Age Tech field, in cooperation with the Ministry of Economy, Trade and Industry. Specifically, the government should hold exhibitions to create opportunities for matching Age Tech companies with nursing care providers, large companies, and investors, and from the perspective of raising the challenge spirit of development companies, the government should sponsor the "Age Tech Awards (tentative name)" to recognize Age Tech that many nursing care providers actually want to use.

In addition, it is important to develop core human resources with knowledge and skills for in the use of digital technology in order to promote initiatives to improve productivity in nursing care sites. Therefore, the government should aim to improve the ICT literacy of nursing care staff by holding training sessions and Age Tech introduction consultation meetings, etc., in cooperation with the public and private sectors.

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

a. Issue

The number of Age Tech introduction cases is increasing due to initiatives such as the progressive expansion of the Age Tech introduction subsidy for nursing care providers, such as the Age Tech Introduction Support Program. However, of all nursing care providers, about 30% have already introduced Age Tech products using technology, while the majority of them have not yet introduced it. In addition, the adoption rate of the Age Tech introduction subsidy (the number of applications approved for the introduction support program ÷ the number of total applications for the program) remains at

40%,[46] and the remaining 60% of nursing care providers have not received the subsidy even though they applied for it.[47]

When implementing the budget for the Age Tech introduction subsidy, some prefectures set conditions different from the subsidy conditions indicated by the national government, such as the subsidy rate for the Age Tech introduction subsidy, the scope of equipment to be subsidized, and the maximum amount, based on the situation of each prefecture. For nursing care providers operating in multiple prefectures, this situation is a high hurdle to understand the subsidy system of each prefecture and formulate an Age Tech introduction plan for each office.

b. Policy Recommendations

While working to improve the user interface (UI) of Age Tech products based on the voices of nursing care sites, the Ministry of Health, Labour and Welfare should expand its support and aim to solve the severe shortage of caregivers from FY2025 by, for example, expanding the scope of the related budget to meet the needs of nursing care providers trying to introduce Age Tech. For example, review the 13 key areas of the 6 fields to be subsidized and add new fields to the scope of the subsidy that have recently been needed in nursing care sites and are expected to be effective.

At the same time, when the prefectural governments implement the budget for the subsidy for the introduction of Age Tech, the national government should request the prefectural governments to clearly explain to the business operator the difference from the national subsidy conditions so that each prefectural government can set reasonable subsidy conditions. Establish one-stop consultation desks for nursing care providers in all prefectures to provide comprehensive advice and other support (concierge)[48] regarding the scope and conditions of various subsidies by FY2026.

[46] "A Set of Reports on FY2022 Support Programs the Practical Application of Welfare Equipment and Nursing Care Robot for" (Association for Technical Aids, Inc.) (March 2024) (https://www.mhlw.go.jp/content/12300000/001137824.pdf)

[47] There were circumstances in which the fund was used to prevent the spread of infection caused by the new coronavirus, making it difficult to take budgetary measures to subsidize Age Tech.

[48]: 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.

a. Issue

The current nursing care benefits provide limited incentives for the introduction of Age Tech. For example, the productivity improvement promotion system premium was newly established in the 2024 revision of nursing care benefits to promote the introduction of ICT by facility-based nursing care providers, such as special nursing homes, but the home care service providers are not eligible for this premium. In addition, among Age Tech products for home users, 4 out of the 19 welfare equipment items are covered by nursing care insurance benefits, etc., but the adoption of Age Tech in the home care sector has not progressed because many users may not be sufficiently convinced of the effects of Age Tech. VCs have pointed out that "the corporate value of Age Tech startups cannot be highly evaluated unless their Age Tech products are regularly evaluated in terms of nursing care benefits as devices or welfare equipment subject to the premium."

b. Policy Recommendations

In order to examine the promotion of initiatives to improve the productivity of home care service providers, facilitate the understanding of the status of implementation of the Additional Productivity Enhancement Promotion System, and promote the collection of evidence on the use of technology through projects such as the Health Promotion Program for the Elderly from FY2024.

In addition, promote the introduction of Age Tech that can be used effectively and safely as a welfare equipment as defined by nursing care insurance. Specifically, in order to ensure that Age Tech products using cutting-edge technologies such as AI, IoT, and ICT are evaluated and reviewed promptly in line with the pace of technological innovation, consider increasing the frequency of meetings of the Nursing Care Insurance Welfare Equipment and Home Remodeling Evaluation Study Group, which is held once a year for new proposals, for new proposals, from FY2024, based on the status of proposals, and also consider adding experts familiar with the Age Tech field to its membership.

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

a. Issue

In the future, the declining birthrate and aging population are expected to progress rapidly worldwide, especially in emerging Asian countries, and many countries and regions are interested in Age Tech in Japan, a country facing healthcare issues ahead of time. In fact, the Living Lab, which is installed in 8 locations throughout Japan as a support organization for the demonstration of Age Tech companies, receives more than 100 visits to Japan annually from Asian, especially China, and European countries.

Despite the fact that Japan is a super-aging society and has high IT technical capabilities, the domestic development of Age Tech is still limited, and only a limited number of such products that have been exported overseas. On top of that, there are differences in the way of thinking about nursing care and the barriers of language and culture, so it is not easy for Age Tech startups to reach a point where they can independently investigate differences in overseas systems and local operations, and then conduct demonstrations at local facilities.

In order for Japanese Age Tech startups to expand overseas and demonstrate the potential of nursing care innovation ahead of the rest of the world, it is necessary to establish connections with investors who have a proven track record of investing in the healthcare field in each country, nursing care providers and caregivers in each country, and business operators who may become business partners, etc. In addition, since Age Tech is effective in the operation of nursing care services, the key to success is to expand overseas by combining the operation of nursing care services in Japan with Age Tech.

b. Policy Recommendations

The Ministry of Economy, Trade and Industry should support the activities of Japanese Age Tech companies aiming to expand overseas, such as improving devices/equipment, developing sales channels, and obtaining certification in accordance with the needs of overseas nursing care sites and

relevant regulations. Specifically, conduct research on nursing care-related systems and market research on products and services in high demand from nursing care sites, giving priority to countries and regions where there is a high level of interest in Age Tech in Japan or where the population is rapidly aging, and publish the report of the first research by the end of FY2025.

In addition, the Ministry of Economy, Trade and Industry, in collaboration with JETRO, the Ministry of Health, Labour and Welfare, and CARISO, should support Age Tech in Japan in building networks with overseas VCs, CVCs, business companies, government agencies, nursing care-related industry organizations, and domestic healthcare companies that are willing to expand overseas. For example, the Age Tech Summit (tentative name) sponsored by the Ministry of Health, Labour and Welfare in cooperation with the Ministry of Economy, Trade and Industry should promote personnel exchanges in the Age Tech field, including consideration of holding pitching events and nursing care-related networking events with various industries and inviting overseas stakeholders. In addition, in cooperation with the aforementioned Living Lab, implement a program for overseas nursing care providers, government officials, startup accelerators, and incubators to visit nursing care sites in Japan where Age Tech is being used.

Taking advantage of the fact that Japan's Age Tech is attracting international attention in this way, Japan should take the initiative to attract people involved in Age Tech from overseas and make the country the "World champion of Age Tech."

4. Conclusion

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 startups is essential as the bearers of innovation.

The recommendations in this White Paper present a concrete action plan for the promotion and support of startups in the Japanese healthcare ecosystem. The solid implementation of these measures by the entire country will accelerate innovation in the health, medical and nursing care fields in Japan and will be a powerful driving force for the evolution of healthcare in the people's lives to be of higher quality and more sustainable. At the same time, these measures will serve as an engine for Japan to create internationally competitive growth industries as a "startup powerhouse" in the healthcare field. While maintaining the excellent universal health insurance system for medical and nursing care, we aim to nurture the seeds of new industries. Boldly and persistently challenging towards this highly difficult mission is the key to unlocking the future of Japan.

The efforts noted in this White Paper should not be considered a one time stunt.

The true value of these recommendations are only realized through solid implementation and continuous improvement. It is imperative that each and every measure be steadily put into practice with the concerted efforts of related ministries and agencies in accordance with the timetable shown below. It is also essential that their effectiveness be regularly reviewed and course corrected as necessary by implementing the Plan-Do-Check-Act (PDCA) cycle. Each measure included in the recommendation is designed to have a synergistic impact as a policy package, rather than a bundle of independent policy proposal. To ensure that the recommendations in this document do not end up as a desk plan, but continue to have a lasting impact, we will hold follow-up meetings led by members of this PT at least once a year and establish a mechanism for continuous progress management and improvement.

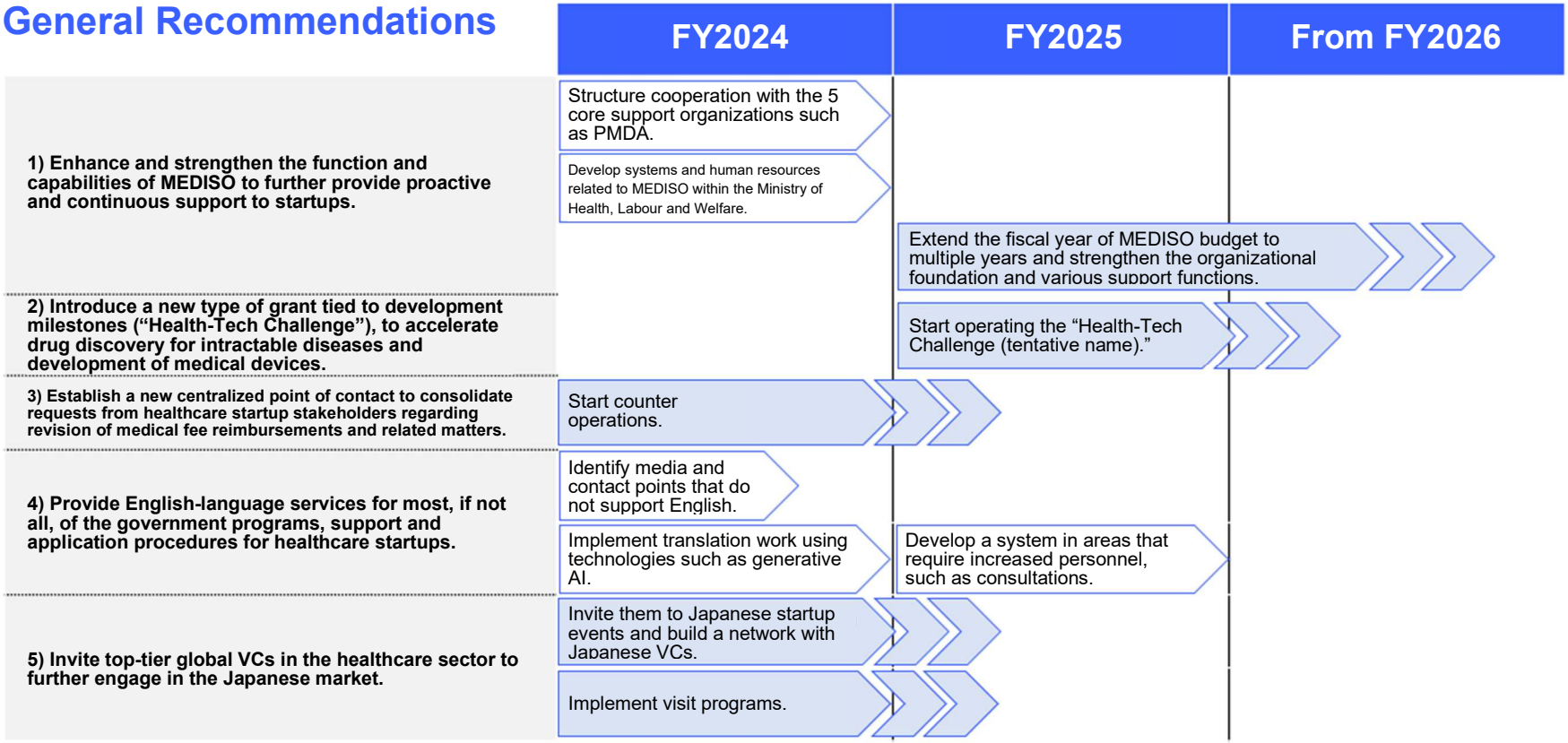
This White Paper is the compilation of the voices of many people who have actually been involved in the growth of healthcare startups as entrepreneurs and investors, and who have experienced both hardships and achievements. We hope that this White Paper will be actively read and used not only by policymakers but also by Japanese and overseas researchers, entrepreneurs, investors, and business

companies involved in healthcare startups as they work on future R&D and business plans.

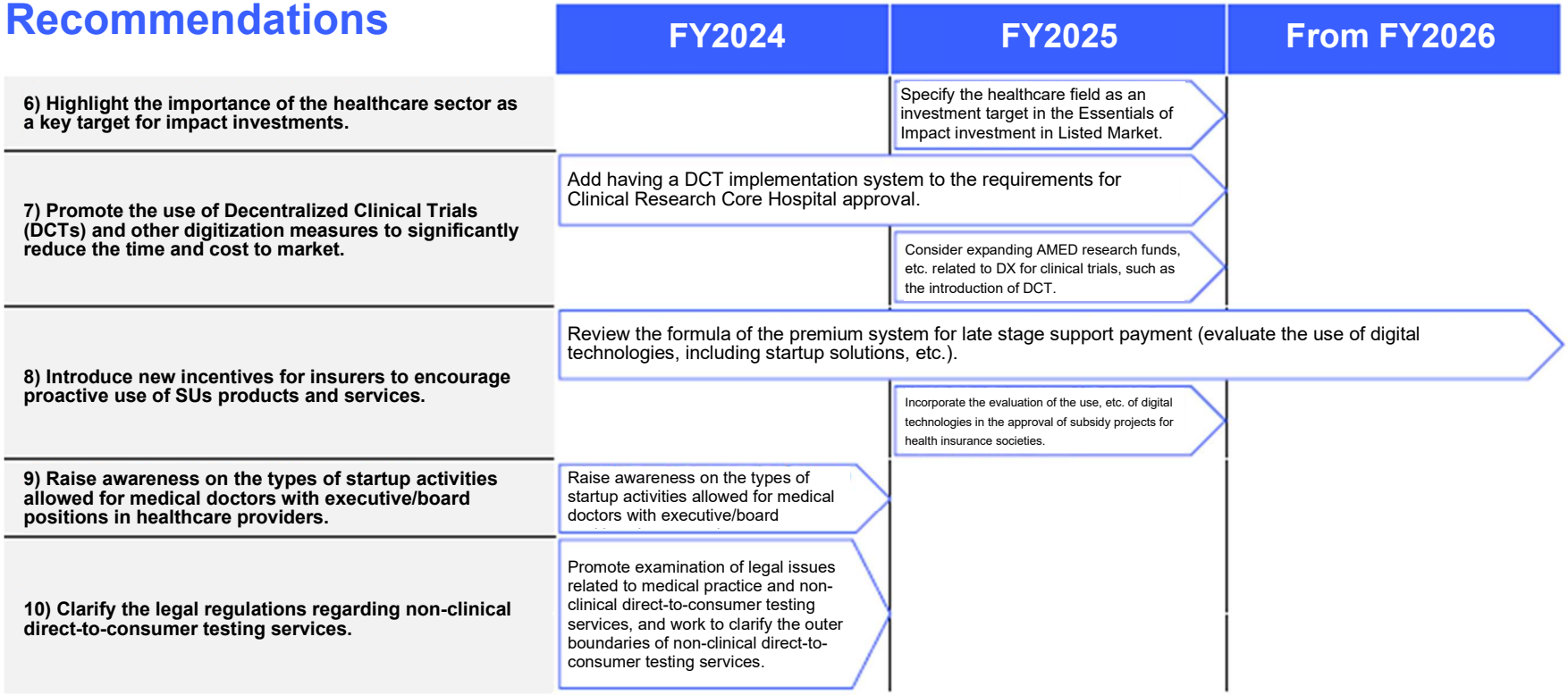
Finally, we would like to express our sincere gratitude to the many people involved in the preparation of this White Paper. We conclude this White Paper with the hope that the government, the business community, academia, and other stakeholders will work together to sincerely respond to the voices of expectations in Japan and overseas to ensure that the future of healthcare in Japan will be brighter.

5. Timetable for Achieving the Recommendations

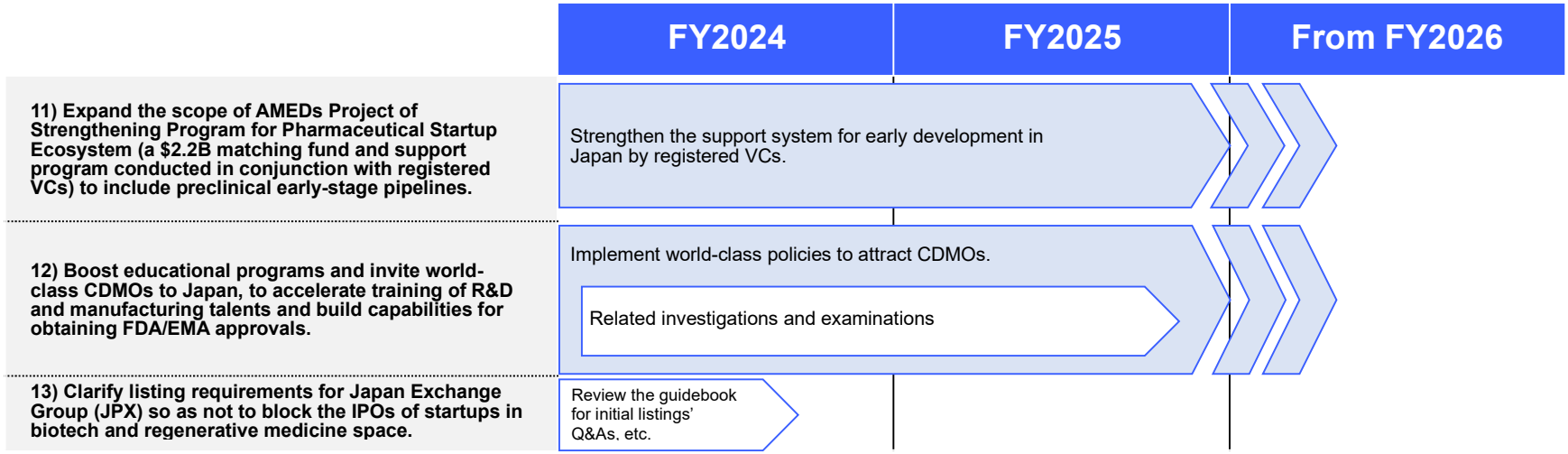
General Recommendations



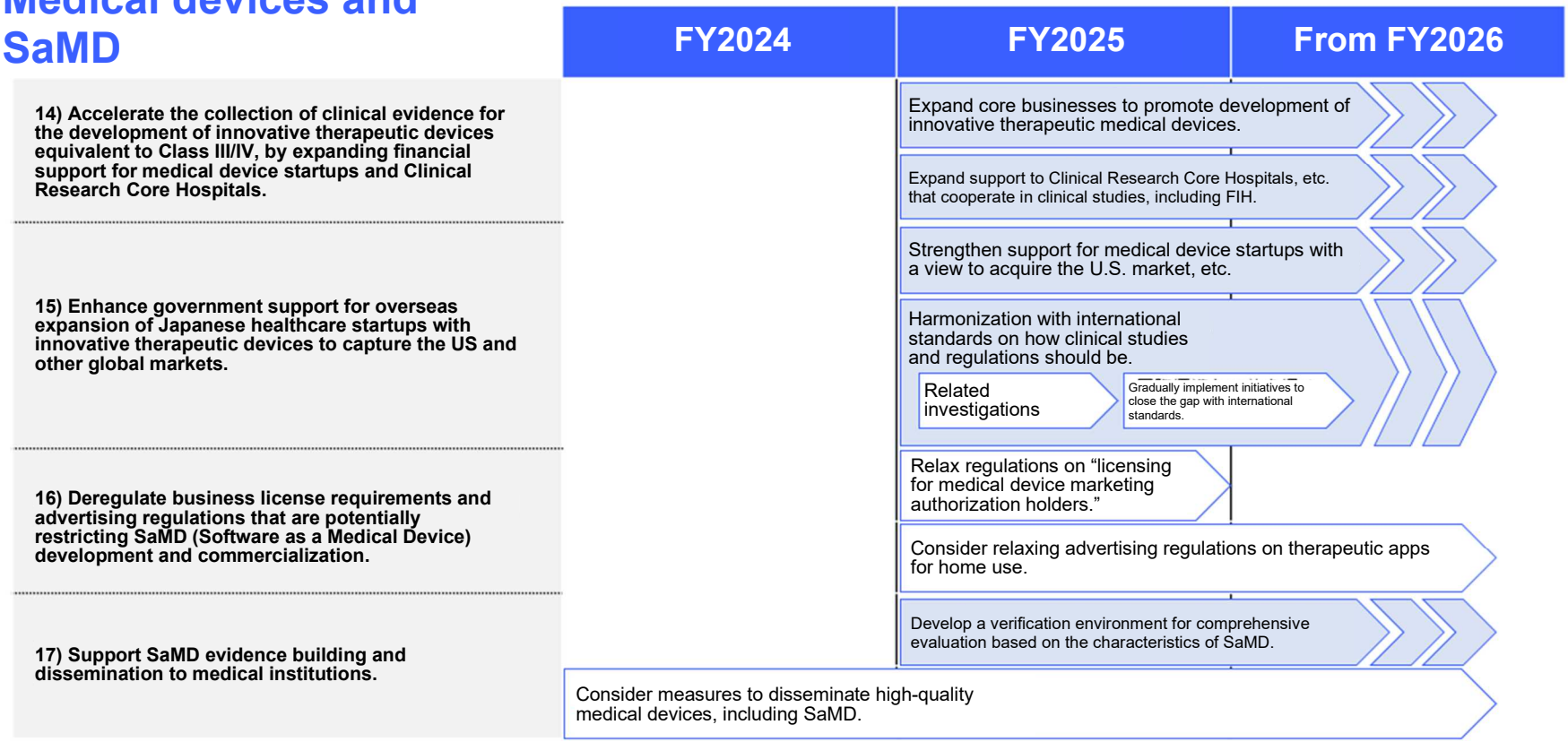
General Recommendations



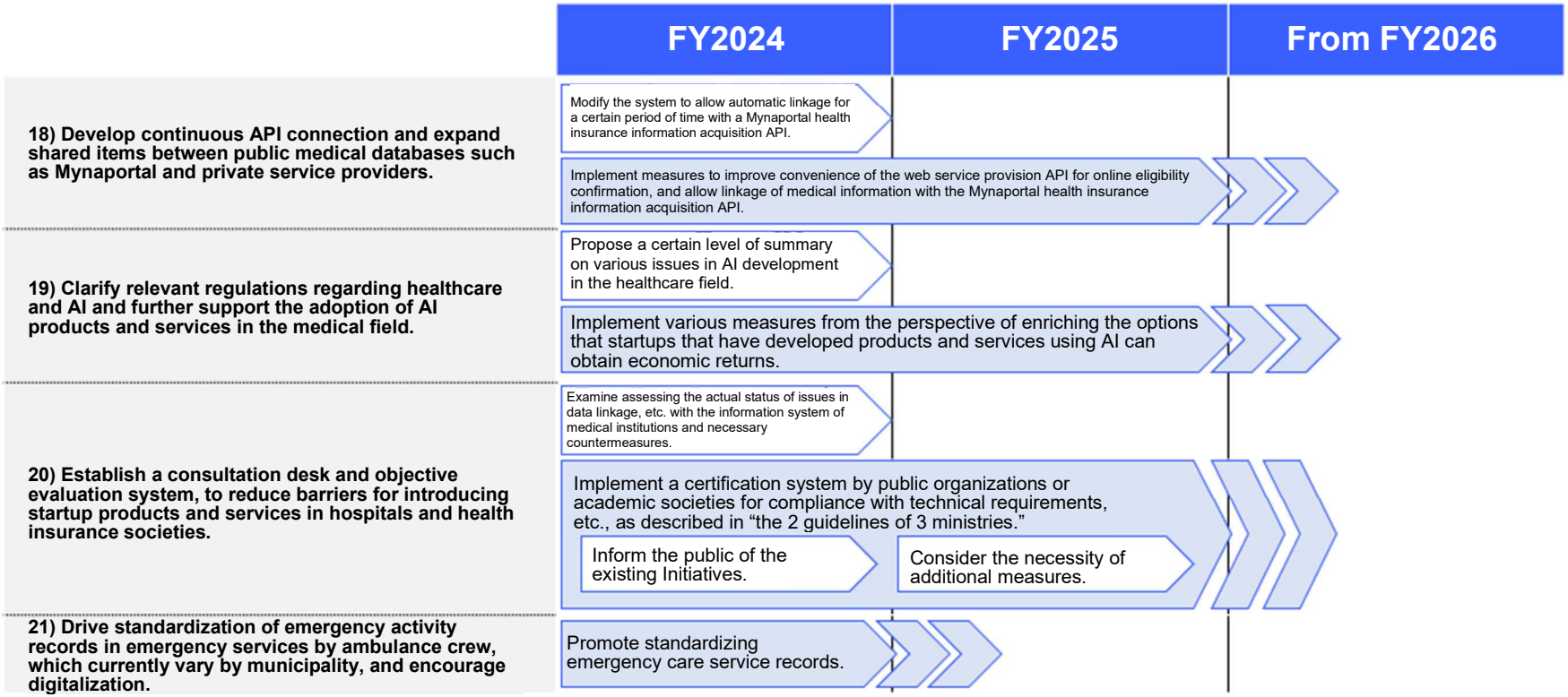
Biotech and regenerative products



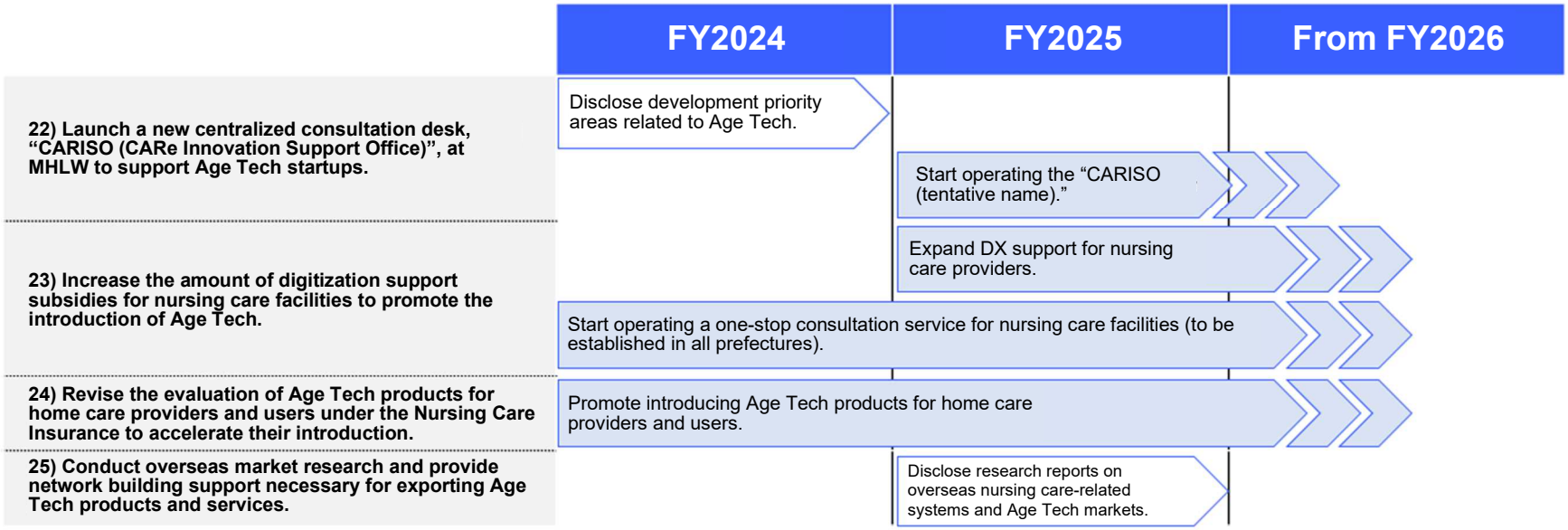
Medical devices and SaMD



Medical DX and AI



Age Tech


FY2024
FY2025
From FY2026
22) Launch a new centralized consultation desk, “CARISO (CARe Innovation Support Office)”, at MHLW to support Age Tech startups.
Disclose development priority areas related to Age Tech.
Start operating the “CARISO (tentative name).”
23) Increase the amount of digitization support subsidies for nursing care facilities to promote the introduction of Age Tech.
Expand DX support for nursing care providers.
Start operating a one-stop consultation service for nursing care facilities (to be established in all prefectures).
24) Revise the evaluation of Age Tech products for home care providers and users under the Nursing Care Insurance to accelerate their introduction.
Promote introducing Age Tech products for home care providers and users.
25) Conduct overseas market research and provide network building support necessary for exporting Age Tech products and services.
Disclose research reports on overseas nursing care-related systems and Age Tech markets.

Appendix 1

Project Team on Healthcare Startup Acceleration (Team Leader: Akihisa Shiozaki, Parliamentary Vice-Minister of Health, Labour and Welfare)

	Name	Affiliation
	Fumiaki Ikeno	Stanford University Researcher/ MedVenture Partners, Inc Chief Medical Officer
	Hiromi Okuda	Representative Director, With Group Inc./Representative Director, Health and Wellbeing Alliance
TF Leader	Tadahisa Kagimoto	Director, President and CEO, HEALIOS K.K. CEO,/Saisei Ventures
TF Leader	Yusuke Kano	President, Japan CareTech Association/Chairman and President, Wermo Inc.
	Shinichiro Komoto	Eight Roads Ventures Japan Partner
	Tomoyoshi Koyanagi	Specified Professor and Director, Business Development Office, Institute for Advancement of Clinical and Translational Science (iACT), Kyoto University Hospital
TF Leader	Kensuke Suzuki	Partner, Nagashima Ohno & Tsunematsu
	Akihiko Soyama	Managing Director, Life Science Innovation Network Japan
TF Leader	Seigo Hara	Director, Japan Medical Venture Association/CEO, MICIN Inc.
Chairperson	Shuji Honjo	Representative, Honjo Office/Visiting Professor, Tama Graduate School of Business
TF Leader	Masakazu Yagi	Associate Professor, Endowed Chair, Department of Health Sciences, Osaka University Graduate School of Medicine
	Miyako Yoshizawa	VC Startup Health Promotion Association

(In the order of Japanese syllabary, honorifics omitted)

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Life Science Division, Research Promotion Bureau, Ministry of Education, Culture, Sports, Science and Technology		
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	Shuhei Kashiwa	Director, Startup Business Division, Deloitte Tohmatsu Venture Support Co., Ltd.
	Yuko Kanazawa	Unit Manager, Senior Manager, Healthcare Business Unit, Industry & Function Business Division, Deloitte Tohmatsu Venture Support Co., Ltd.
	Kana Nando (Shibamura)	Litigation Specialist, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare/lawyer
Group Leader	Kengo Tashiro	Representative Director, UploadedMind Co., Ltd./Academic Specialist, Matsuo Laboratory, University of Tokyo
	Tomoharu Hagiwara	Legal Officer, General Affairs Division, Minister's Secretariat, Ministry of Health, Labour and Welfare/lawyer
	Masaki Honda	Consultant, Innovation Solutions Division, Deloitte Tohmatsu Venture Support Co., Ltd.

(In the order of Japanese syllabary, honorifics omitted)

Task Force Chief/Assistant Chief List

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TF Leader	Kensuke Suzuki	Partner, Nagashima Ohno & Tsunematsu

Biotech & Regenerative Medicine Task Force		
TF Leader	Tadahisa Kagimoto	Director, President and CEO, HEALIOS K.K. CEO,/Saisei Ventures
Deputy Leader	Kengo Tashiro	Representative Director, UploadedMind Co., Ltd./Academic Specialist, Matsuo Laboratory, University of Tokyo

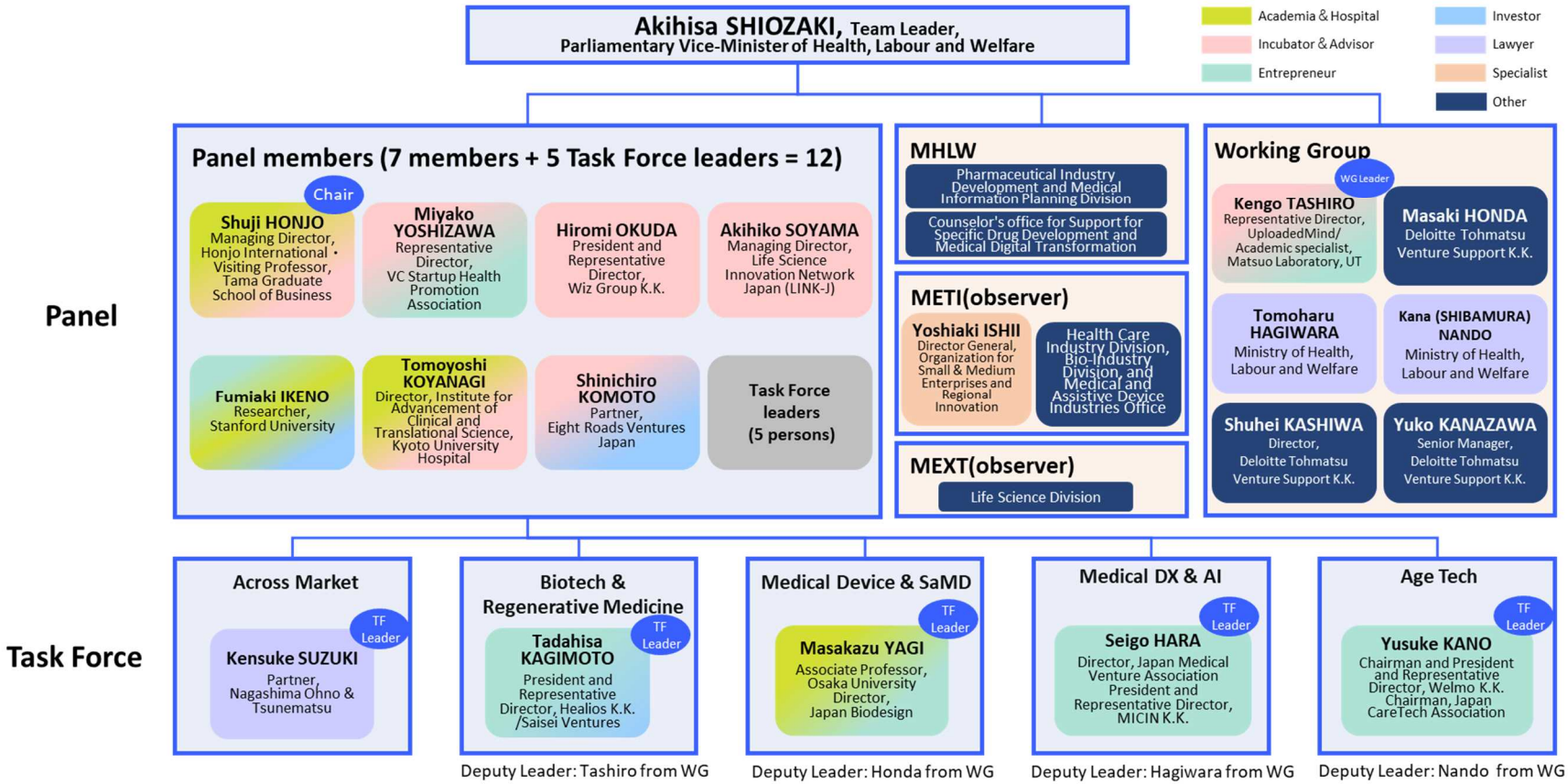
Medical Device & SaMD Task Force		
TF Leader	Masakazu Yagi	Associate Professor, Endowed Chair, Department of Health Sciences, Osaka University Graduate School of Medicine
Deputy Leader	Masaki Honda	Consultant, Innovation Solutions Division, Deloitte Tohmatsu Venture Support Co., Ltd.

Medical DX & AI Task Force		
TF Leader	Seigo Hara	Director, Japan Medical Venture Association/CEO, MICIN Inc.
Deputy Leader	Tomoharu Hagiwara	Legal Guidance Officer, General Affairs Division, Minister's Secretariat, Ministry of Health, Labour and Welfare/lawyer

Age Tech Task Force		
TF Leader	Yusuke Kano	President, Japan CareTech Association/Chairman and President, Wermo Inc.
Deputy Leader	Kana Nando (Shibamura)	Litigation Specialist, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare/lawyer

(In the order of Japanese syllabary, honorifics omitted)

Project Team Structure for Healthcare Startup Acceleration



Appendix 3

Main interviewees (*honorifics omitted, in the order of alphabets or Japanese syllabary)

Name	Affiliation (at the time of interview)	Task Force in charge
James Buxton	New Enterprise Associates Principal	General Recommendations
John Hammit	HITLAB Executive Director	General Recommendations
Stan Kachnowski	HITLAB PhD MPA CIBE	General Recommendations
Walter Olesiak	Remiges Ventures Operating Partner	General Recommendations
Kevin Outterson	CARB-X Executive Director	General Recommendations
Avi Rosenbaum	Peak B Chief Operating Officer	General Recommendations
John Stanford	Incubate Coalition Executive Director	General Recommendations
Francis deSouza	Illumina President and CEO	General Recommendations
Bill Taranto	Merck Global Health Innovation Fund Founder, President & General Partner	General Recommendations
Robert Weisskoff	F-Prime Capital Senior Partner	General Recommendations
Kiyohiko Igarashi	Professor, Graduate School of Agricultural and Life Sciences, The University of Tokyo/Special Assistant to the President (promotion of industry-academia collaboration)	General Recommendations
Yoshinori Ikeura	President and Representative Director, Axcelead, Inc.	General Recommendations
Akihiko Kawakami	Chief Researcher, Healthcare Industry Strategy Group, Healthcare Business Division, Mitsubishi Research Institute, Inc.	General Recommendations
Yasuhiro Kuda	Representative Director, ELEMENTS, Inc.	General Recommendations

Tomotaka Goji	The University of Tokyo Edge Capital Partners President and CEO	General Recommendations
Fumio Takada	Professor, Clinical Genetics Lecture, Kitasato University Graduate School of Medicine	General Recommendations
Kohei Tsumoto	Deputy Director, Graduate School of Engineering, The University of Tokyo	General Recommendations
Takashi Nakagawa	Representative Director and CEO, Kakehashii Co., Ltd.	General Recommendations
Yoshimitsu Fukushima	Specially Appointed Professor, Shinshu University School of Medicine	General Recommendations
Yasuhiro Fujiwara	President, Pharmaceuticals and Medical Devices Agency (PMDA)	General Recommendations
Takashi Futami	AN Venture Partners	General Recommendations
Satoshi Miura	Director, JETRO NY Office	General Recommendations
Yoshinao Mishima	President, Japan Agency for Medical Research and Development (AMED)	General Recommendations
Hiroki Yamada	Representative Director and Physician, Medii, Inc./Visiting Associate Professor, Tokyo Medical and Dental University	General Recommendations
Nao Yoshizawa	Director Attorney-at-law, GRiT Partners Law Office	General Recommendations
-	Astellas Pharma Inc.	General Recommendations
-	Takeda Pharmaceutical Company Limited	General Recommendations
Behnam Baghbaderani	Global Head of Commercial and Program Management, Lonza Cell and Gene Technologies Vice President	Biotech and Regenerative Products
Stephen Barker	Jefferies Japan Limited	Biotech and Regenerative Products
Daniel Camardo	Athersys Inc. Chief Executive Officer	Biotech and Regenerative Products
Jorge Conde	Andreessen Horowitz General Partner	Biotech and Regenerative Products

Serkan Eroglu	Senior Director, Global HRBP, Cell and Gene Technology, Lonza	Biotech and Regenerative Products
Shinichiro (Shin) Fuse	TPG Life Sciences Innovation	Biotech and Regenerative Products
Michael Langer	T.Rx Capital Managing Partner	Biotech and Regenerative Products
Janice Pai	Egon Zehnder, Core Member of the Technology, Healthcare, and Supply Chain Practices	Biotech and Regenerative Products
Atsushi Yasumoto	President and Representative Director, Nexredge Inc.	Biotech and Regenerative Products
Miyabi Yamakita	Jefferies Japan Limited	Biotech and Regenerative Products
Todd Brinton	Edwards Lifesciences Chief Scientific Officer & Corporate Vice President	Medical Devices and SaMD
Yuki Aoyama	Representative Director, Splink, Inc.	Medical Devices and SaMD
Hiroki Ishida	Chief Technical Officer, Epsilon Medical Inc.	Medical Devices and SaMD
Masaaki Ito	Director of Department of Colorectal Surgery, National Cancer Center Hospital East (concurrently serving as Vice President, Director of the Medical Device Development Promotion Department, and Director of the Surgical Device Development Department, Centre for Advanced Medical Development)	Medical Devices and SaMD
Chie Iwaishi	Edwards Lifesciences	Medical Devices and SaMD
Hajime Ohshita	President, MedVenture Partners, Inc.	Medical Devices and SaMD
Hiroaki Kato	Specially Appointed Professor, Digital Hollywood University Graduate School; Clinical Professor, Tokyo Medical and Dental University; Co-Founder, Executive Vice President and CSO, Aillis, Inc.	Medical Devices and SaMD
Masashi Kiyomine	Kicker Ventures Founder & Managing Partner	Medical Devices and SaMD

Jun Kusunoki	Senior Director, Japan Country Lead, Early Innovation Partnering, Johnson & Johnson Innovation	Medical Devices and SaMD
Kazuya Shobayashi	N.B. Medical Co., Ltd., Representative Director	Medical Devices and SaMD
Masakatsu Noguchi	Policy Makers Lab Managing partner	Medical Devices and SaMD
Yuji Matsumaru	Professor, Department of Neurosurgery, Faculty of Medicine, University of Tsukuba	Medical Devices and SaMD
Motohiro Asonuma	Visiting Professor, Juntendo University	Medical DX and AI
Taro Ueno	President and Representative Director, SUSMED, Inc.	Medical DX and AI
Teppei Sakano	Representative Director and President, Alm Inc.	Medical DX and AI
Tomohiro Sono	TXP Medical Co. Ltd.	Medical DX and AI
Kenichi Nakamura	Director, International Development Division, National Cancer Center Hospital	Medical DX and AI
Ryozo Nagai	President, Jichi Medical University	Medical DX and AI
Yutaka Matsuo	Professor, Department of Technology Management Strategy, Artificial Engineering Research Center, Graduate School of Engineering, The University of Tokyo	Medical DX and AI
Moe Miura	Policy Liaison Counselor, Ubie, Inc. (Japan Digital Health Alliance)	Medical DX and AI
Eiichi Yamaguchi	Representative Director & CEO, OlBio Inc. Professor Emeritus, Kyoto University	Medical DX and AI
Yuji Yamamoto	MinaCare Co., Ltd., President & CEO	Medical DX and AI
Yoshimi Ui	Representative Director, aba Inc.	Age Tech
Ryo Okubo	Representative Director, Rehab for JAPAN Co., Ltd.	Age Tech
Yumiko Kawamura	Representative, Rehanowa Communicator, Capital Medica Ventures Co., Ltd.	Age Tech
Ryosuke Kimura	Representative Partner, Life Time Ventures	Age Tech

Fumito Shimizu	Founder, 3Sunny Inc. (the company was sold to Teijin Limited.)/entrepreneur	Age Tech
Shuhei Fujimoto	Shizuoka Graduate School of Public Health	Age Tech
Tetsuro Honma	Representative Director, Executive Vice President, Panasonic Holdings Corporation; General Representative of China and Northeast Asia	Age Tech
Takashi Miyamoto	Director, Social Welfare Service Corporation Zenkokai and Representative Director, Zenko Laboratory Co., Ltd.	Age Tech
Isao Yano	Director, Future Care Lab in Japan	Age Tech
Kimihito Watanabe	President and Representative Director, Econavista Inc.	Age Tech
Toshiaki Watanabe	President, Social Welfare Service Corporation Daishokai	Age Tech
-	Nichii Holdings Co., Ltd., Nichiigakkan Co., Ltd., NichiCare Palace Co., Ltd.	Age Tech