English Translation

Policy Recommendations to Bolster Japan's Healthcare Startup Ecosystem

[Interim Report]

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

April 25th, 2024

Project Team on Healthcare Startup Acceleration

- This Project Team (PT) was established on February 5, 2024 to study approaches and measures for promotion and support of healthcare startups, and to publish policy proposals which are essential for bolstering the healthcare startup potential in Japan.
- This PT consists of members active at the forefront of their respective fields including physicians, incubators, entrepreneurs, investors and lawyers, as well as is strongly supported by MHLW*, METI** and MEXT.*** *See* p.34.

  *Ministry of Health, Labour and Welfare, **Ministry of Economy, Trade and Industry, ***Ministry of Education, Culture, Sports, Science and Technology
- This PT has held numerous interviews with key opinion leaders in the industry, and also has widely solicited policy proposals from the general public through the "Healthcare Startup Idea Box". *See* p.35.

Akihisa SHIOZAKI

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Parliamentary Vice-Minister of Health, Labour and Welfare

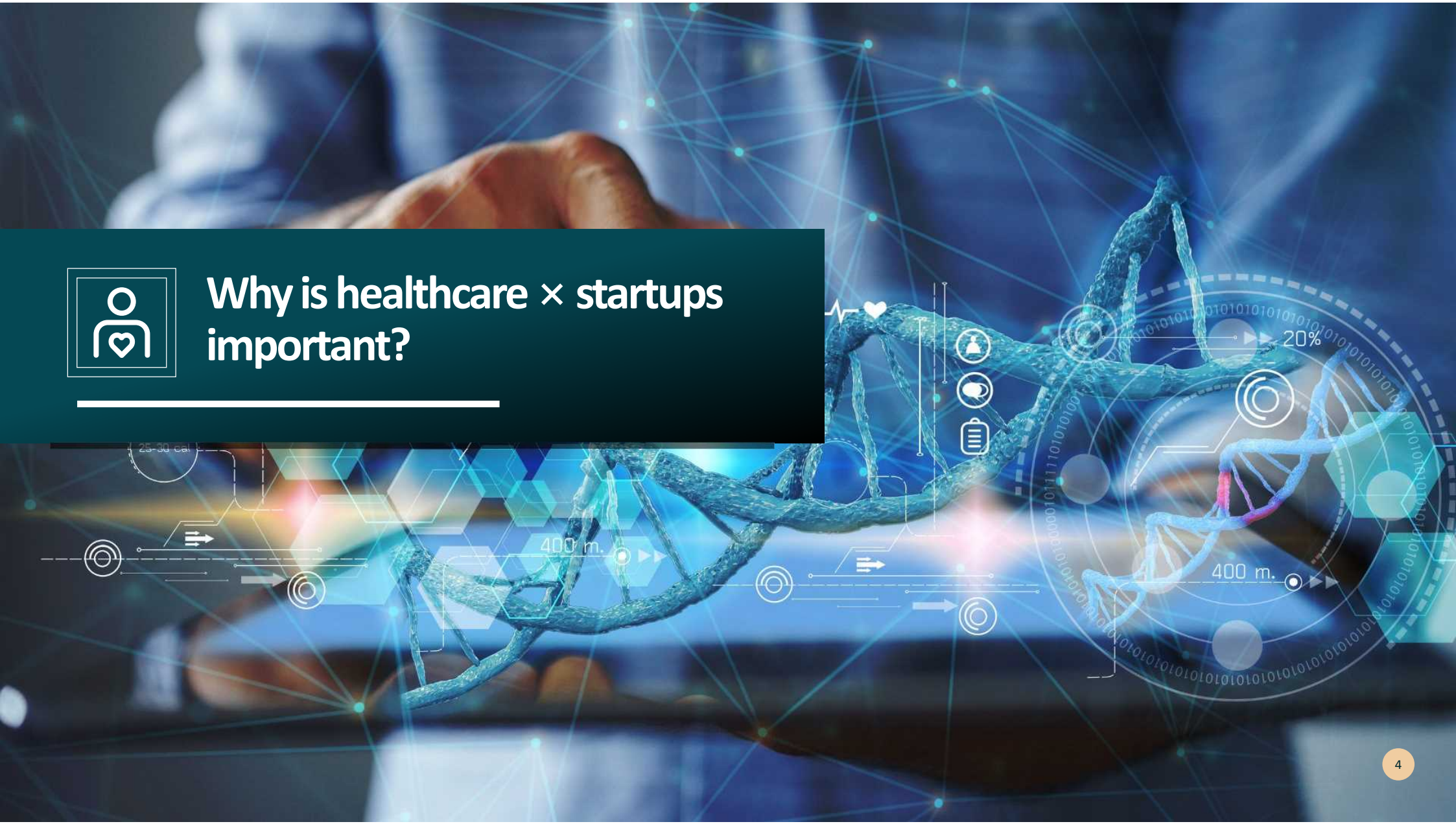
BIO

- Raised in Matsuyama City, Ehime Prefecture, Akihisa graduated from the University of Tokyo in 1999 with a B.A. in Law. He received his M.A. in International Policy from Stanford University Graduate School in 2000 and his M.A. in Business Administration at the Wharton School of the University of Pennsylvania in 2010.
- He was admitted to the bar in 2002, became Secretary to the Chief Cabinet Secretary in 2006.
- Akihisa was elected to the House of Representatives in 2021 and is currently serving his first term. He was appointed Parliamentary Vice-Minister of Health, Labour and Welfare in September 2023 (Kishida Cabinet).
- During his time as a lawyer, he was involved in many start-up support and healthcare-related compliance cases.
- Akihisa has also served as the Chief Secretary of the Liberal Democratic Party of Japan (LDP)'s PT on the Evolution and Implementation of AI.

Policy Recommendations to Bolster Japan's Healthcare Startup Ecosystem

This paper summarizes key directions required for healthcare startups in Japan (either launched from, or active in, Japan), to succeed in the four healthcare markets – 1. Biotech & Regenerative Medicine; 2. Medical Devices & Software as Medical Device (SaMD); 3. Medical Digital Transformation (DX) & AI; and 4. Nursing Care Technology

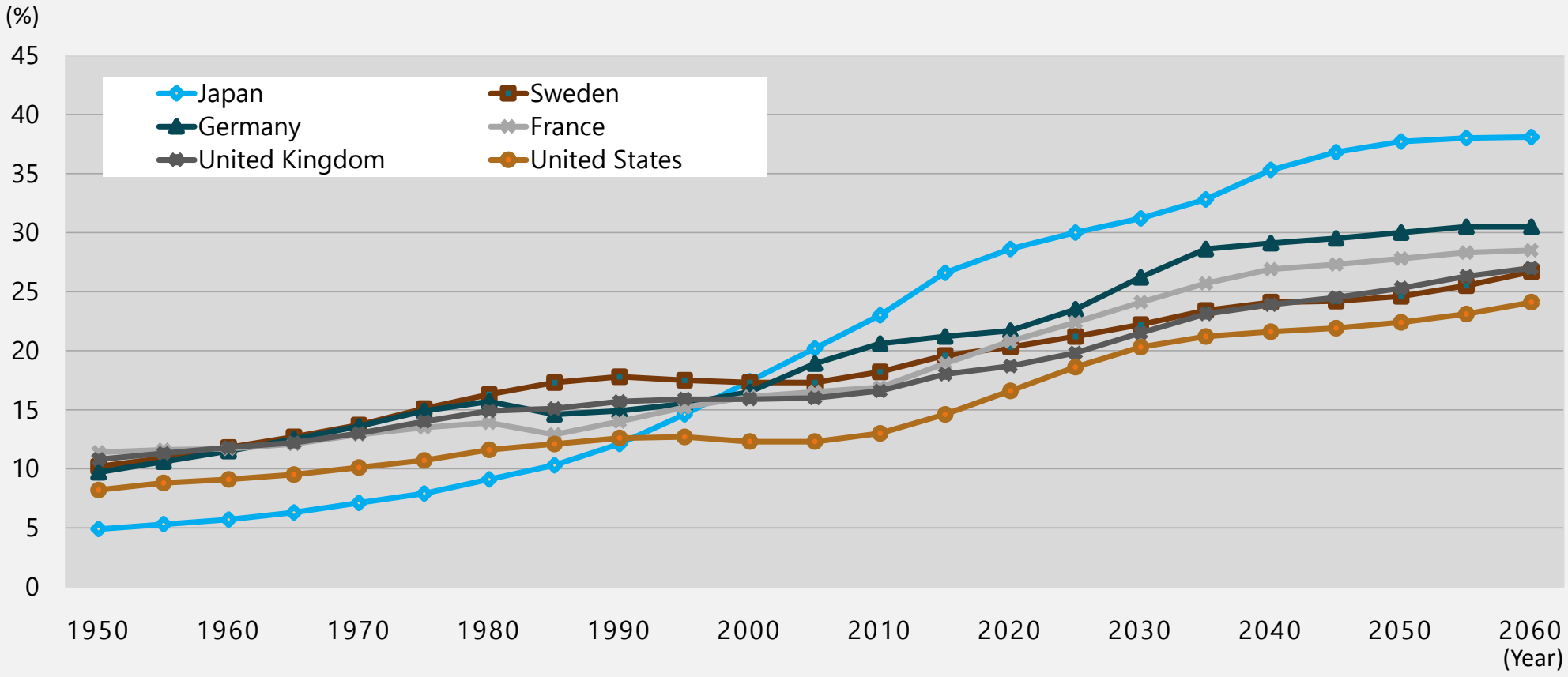
1. **Our baseline: Japan has potential to lead global innovation in healthcare; yet the healthcare startups in Japan are limited in their number and success.**
   - Japan needs to care for its **super aging population** –it is required to innovate ahead of the rest of the world.
   - Japan has been **investing heavily on healthcare research**. It also has unique advantages (e.g. accumulation of data collection through its **universal insurance system**)
   - Nevertheless, Japan's healthcare startups see limited success – it is critical for us to identify bottlenecks and reinforce our startup ecosystem.
2. **Our goals are twofold - Unlock startups' potentials to:**
   - A) **Reinforce the quality and sustainability of healthcare (medical care, wellness & nursing care) in Japan.**
   - B) **Drive development of innovative products & services, propel them to succeed globally, and then nurture them into globally competitive & growing industries.**
3. **Our strategy: Make focused investments for startup success in healthcare markets along the three following strategies, leveraging the structure and dynamics of each market domain**
   - i. **"Go global approach" for market domains with established global standards & markets (e.g. biotech in general)** - strongly support early-stage startups in Japan to acquire right talents, networks and strategies to succeed globally
   - ii. **" Two staged approach" for globally nascent or fragmented market domains (e.g. SaMD or AI)** - first support startups successfully develop & launch pioneering products and services in Japan - and in the mid~long term, propel them to expand globally.
   - iii. **" Domestic empowerment approach" for domains where the essential care services in Japan are at risk due to aging population etc.**, support healthcare startups build and deploy solutions that improve quality and sustainability of healthcare in Japan
4. **Our proposals: Across the three approaches, we identified 18 critical issues and proposals** - 6 across markets; 3 for Biotech and Regenerative Medicine; 3 in Medical Devices and SaMD; 3 in Medical DX and AI; and 3 in Nursing Care Tech. Final proposal will follow in June.



Why is healthcare × startups important?

Japan's rate of aging is ahead of the rest of the world – rich of unique innovation needs in medicine, health, and nursing care

% of Aged population: Global trends

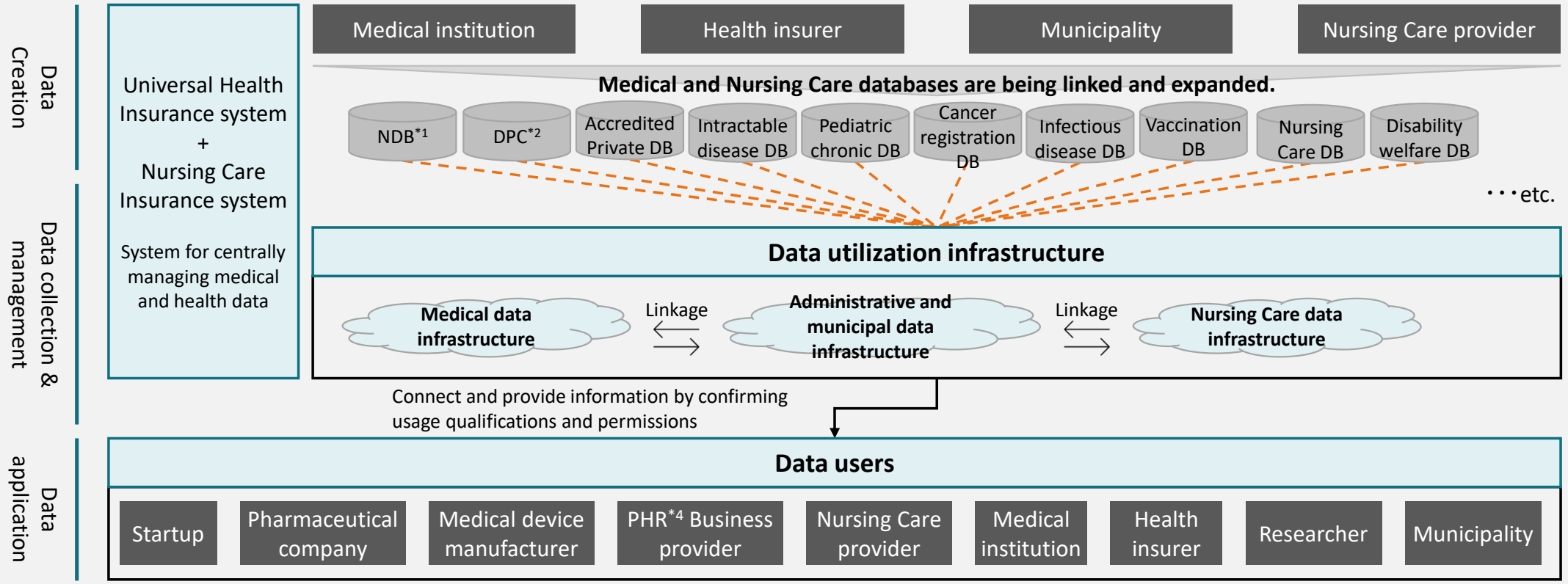


Source: United Nations "World Population Prospects 2019" (https://population.un.org/wpp/Download/Standard/Population/)

Digital transformation and data accumulation is underway under Japan's Universal Insurance system

Accumulation and utilization of medical, nursing care and health data

Japan is making a huge progress in data connectivity and usage

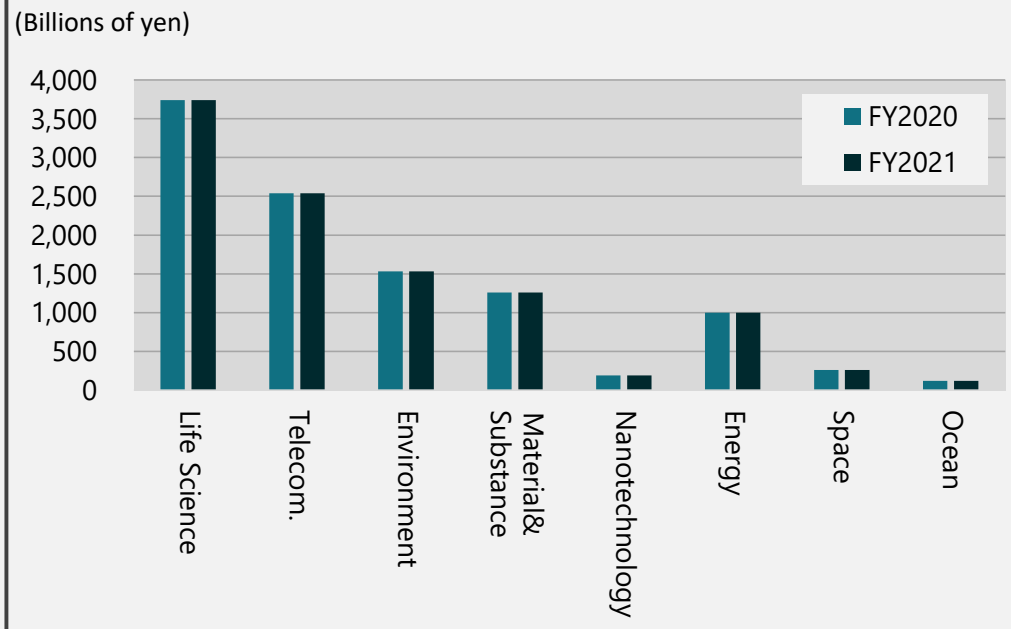


*1：NDB・・・National Database,
*2：DPC・・・Diagnosis Procedure Combination,
*3：PHR・・・Personal Health Record

Japan has strategically focused on healthcare industry - large research investments made in healthcare space

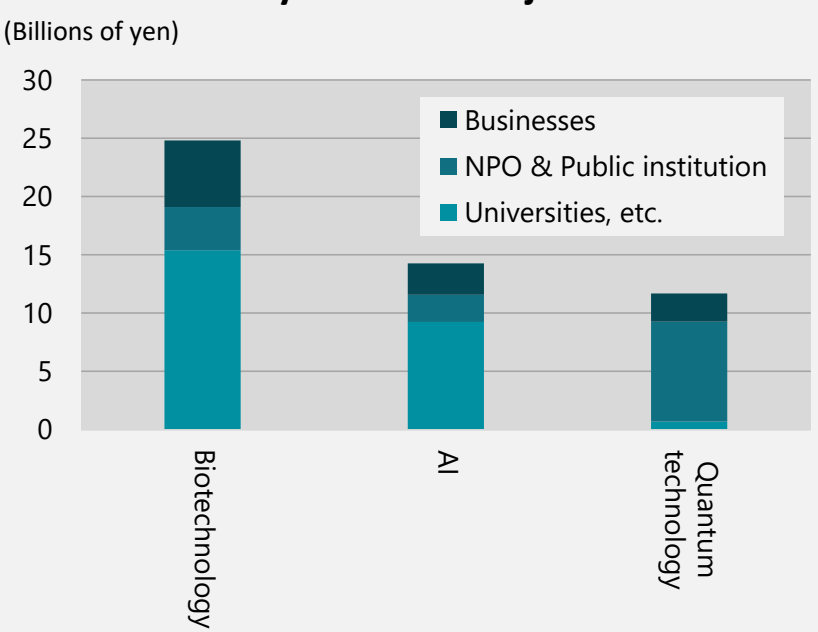
Research expenses by specific purpose

Comparison of 8 Fields



Japan invests in life sciences research more than telecom, environment and space combined

Comparison of 3 fields by research subject



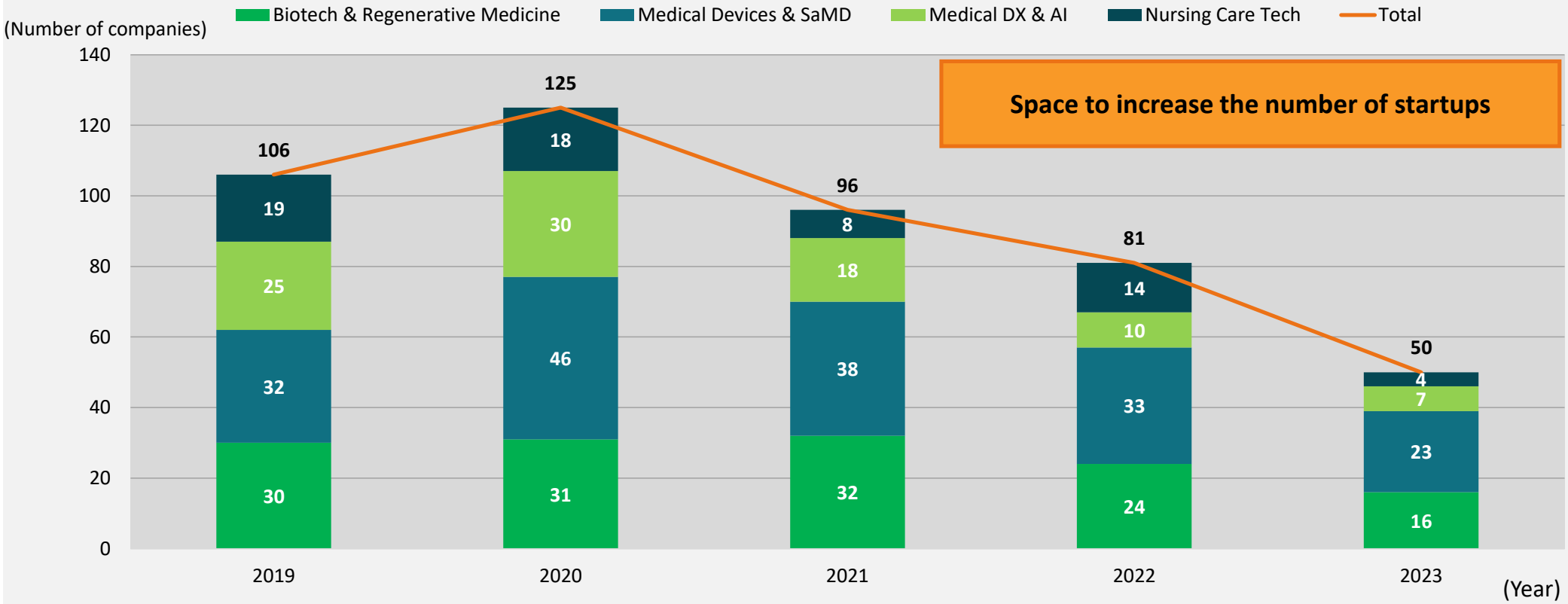
In cutting edge research, biotech receives more funds than AI

Source: "Japan's Science and Technology Research in Statistics: Results of the 2022 (R4) Science and Technology Research Survey" (Ministry of Internal Affairs and Communications) (https://www.stat.go.jp/data/kagaku/kekka/pdf/04pamphlet.pdf), processed and prepared.

However, ~100 healthcare startups are established every year – this constitutes only 10% of all startups in Japan.

Number of startups established by year in the markets relevant to our task forces

Including duplicates. For Biotech & Regenerative Medicine, Medical Devices & SaMD startups in the pre-approval stage are also included.



Source: Based on information from “INITIAL”, which is one of the established information platforms specifically featuring the startups in Japan. Extracted relevant startups founded between 2019 and 2023 with related keywords such as “health tech” and their business outline registered on “INITIAL”.

Moreover, after 2019, there has been no Unicorns; only 3 large M&As have been achieved

Unicorn companies and large M&A transactions: markets relevant to our task forces

***Number of unicorn startups*[*1,2]**

0 Company

***Large M&A（10B yen or more）transactions*[*3]**

M&A Year	Task Force Classification	Sell side	Buy side	Acquisition value
2023	Medical DX and AI	Cancer Scan	JMDC	Around 14B yen
2023	Biotech and Regeneration	OriCiro Genomics	Moderna	Around 11B yen
2022	Medical DX and AI	Allm	DeNA	Around 29B yen

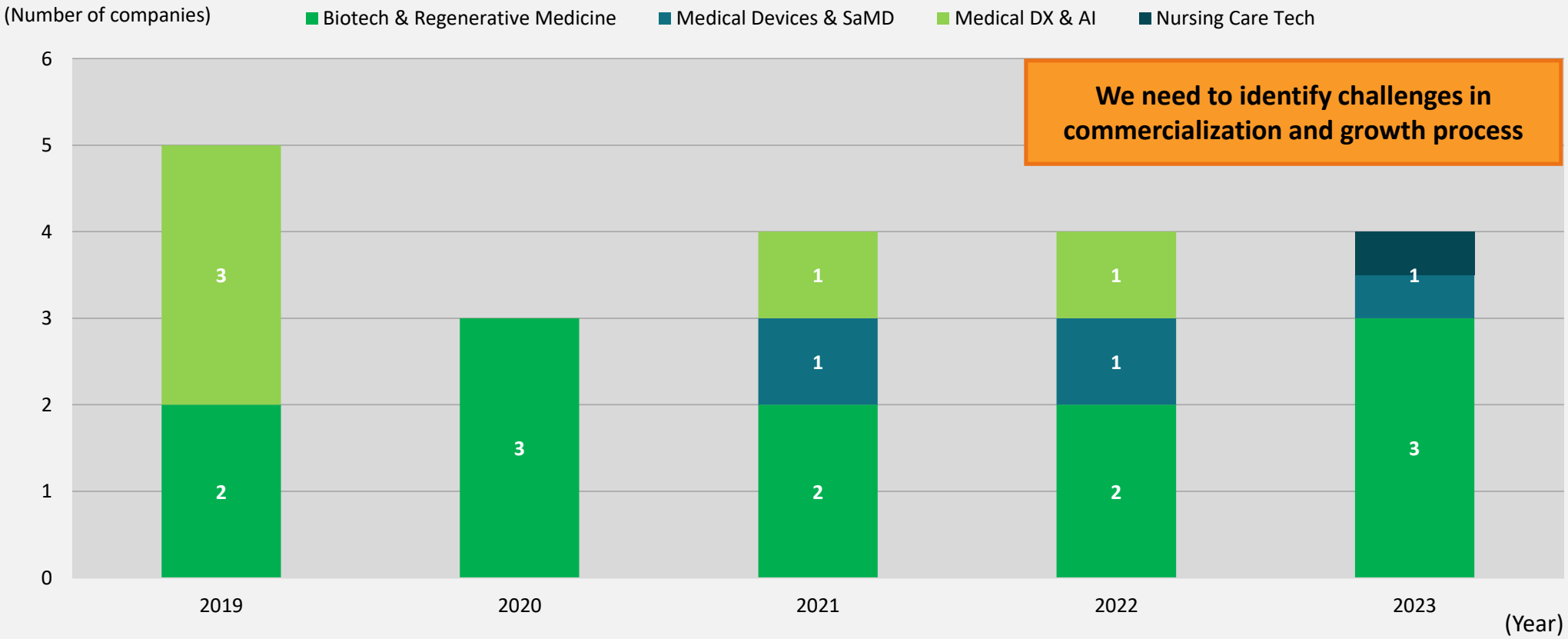
* There may be undisclosed large M&A transactions.
* 36 healthcare startup M&A transactions during the same period with a total acquisition value of less than 10 billion yen or undisclosed amount

Healthcare startups have seen limited successes

*1: For 2019 to 2022, compiled based on "STARTUPS JOURNAL" (For Startups, Inc.) (https://journal.startup-db.com/category/ranking)
*2: For 2023, based on the "NEXT Unicorn Estimated Corporate Value Ranking" (Nikkei Inc.) (https://vdata.nikkei.com/newsgraphics/next-unicorn/#/dataset/2023/list)
*3: Based on "M&A Database" (Strike Co., Ltd.) (https://www.strike.co.jp/start/madb.html) and desktop research.

Around 100 Japanese startups go public each year, while healthcare startups account for only 5%

Number of IPOs by year: markets relevant to our task forces



Source: Based on each year's IPO information from “Kabutan” (https://kabutan.jp/), taking into account each company's website and business profile.
In addition, Econavista, which was listed in 2023, is counted as a company in the two domains of Medical Devices & SaMD and Care Tech.

Our Goals

Our Goals: Unlock startups' potentials to:

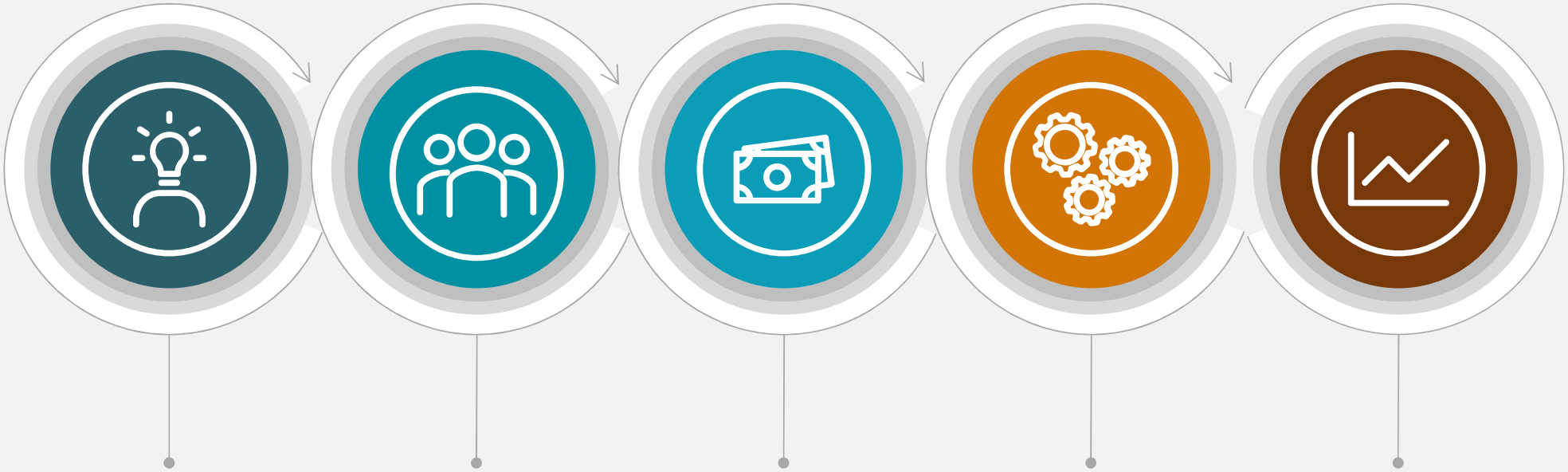
Reinforce the quality and sustainability of healthcare (medical care, wellness & nursing care) in Japan.

Drive development of innovative products & services, propel them to succeed globally, and then nurture them into globally competitive & growing industries.

Our approach

There are five key elements required for startup success - So far, Japan has directed investments across all five

5 elements of startups' success



Idea

Talents

Funding

Development Environment

(e.g., Regulations)

Market

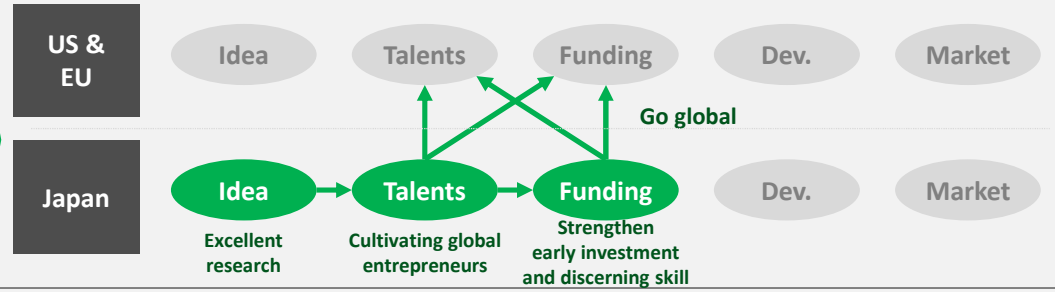
Japan needs to strategically target investment based on the structure and dynamics of each market domain

Our three approaches, and strategic focal points for investment

Colored : Elements that should be invested more intensively
Gray : Elements that require continued support

Go Global Approach

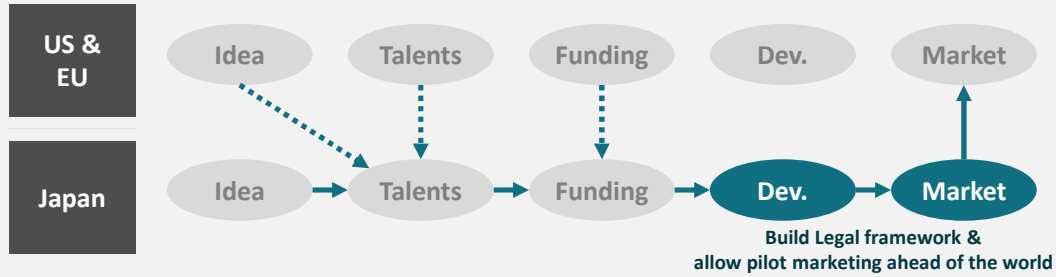
- Domains with established global standards & markets
- Support early-stage startups to take on the global market and succeed



- Biotech & Regenerative Medicine in general
- Innovative, lifesaving medical devices

Two staged approach

- Domains where global market is nascent or fragmented
- Support development & pilot launch of pioneering products in Japan, then expand globally



- Lower risk Medical Devices, and SaMD
- Medical DX and AI
- Cutting edge Regenerative Medicine
- Some Nursing Care Tech (e.g. hardware)

Domestic empowerment approach

- Domains where essential care in Japan is at risk due to aging etc.
- Support deployment of solutions that improve quality and sustainability of care

- Nursing Care Tech in general

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

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

Issues and Interim Recommendations by Major Markets

Task Force: General Recommendations Across Markets

Voices from interviewees

- Japan holds great potential for healthcare startups. Japan has a super aging population and is at the global forefront of solving associated issues. Japan has been making large investments into R&D in healthcare. It has accumulated high-quality and extensive medical and nursing care data.
- However, the number of healthcare startups is limited with not enough successful cases. This is due to "various challenges hindering their growth" and "space to improve policy measures for startup development."
- In the US, a method called "venture creation" is rapidly expanding in the field of drug discovery etc. This method involves venture capitalists (VCs) searching for, and assessing, research & seeds for products, and driving business plans, establishing companies, and securing required talents.
- Japan's startup ecosystem is more "closed to the domestic market," "lagging behind in business infrastructure" and "significantly inferior" to the best overseas ecosystems such as the ones in the US.
- Existing startup support in Japan has space for improvement; many interviewees have called for development of ecosystem and expansion of supportive measures. For example, "government's single-year budgeting system often leaves a blank period" and "the point of contact for lobbying requests on reimbursement is unclear."

Challenges and Opportunities

- **Startups have weak ties to the Ministry of Health, Labour and Welfare (MHLW) and other regulators,** and tend to be lone players, so it is important to open the door to have **their voices heard.**
- It is essential to **strengthen continuous support to startups**, and effectiveness will be enhanced if the MHLW and other **related organizations collaborate in startup support.**
- We need to accelerate the **challenge in innovative or difficult-to-focus topics** with phased support from early development stages
- **A language infrastructure open to overseas** is necessary, and it is essential to **connect with** overseas ecosystems, among others **with VCs,** who are the core of the ecosystem, and to work on **raising the level of the ecosystem.**
- Compared to other countries, **clinical trials are expensive and time-consuming** due to inefficient monitoring of clinical trial implementation at each site and time-consuming ethical review.

Task Force: General Recommendations Across Markets

Recommendation 1

Approach 2: Development Environment

Establish a new centralized point of contact to receive and review requests for revision of medical service fees and related matters from healthcare startup stakeholders.

- Establish a new contact point to receive requests for revision of medical service fee reimbursed from Universal Health Insuranceand related staffing standards.
- Develop a system to adequately listen to healthcare startups, investors, and other stakeholders.
- Establish a system to collect requests and reflect them in appropriate measures.

Recommendation 2

Approach 1: Talents

Approach 2: Development Environment and Market

Enhance and develop robust structure and human resources around MEDISO* to expand toward further continuous and active startup support.

*MEDISO・・・MEDical Innovation Support Office

- Clarify MEDISO's function as a hub for government support organizations, provide support for startup, including overseas expansion, and collaborate with other organizations such as METI to evolve MEDISO into one of the core components of the ecosystem.
- Create an organizational foundation for continued MEDISO activities by significantly increasing the MEDISO budget for multiple fiscal years.
- Upgrade and expand the Office of Venture Support Strategy at MHLW, and improve its structure and human resources.

Recommendation 3

Approach 2: Development Environment

Introduce a new milestone-type development grant to accelerate drug discovery and medical device development on themes that have been difficult to initiate due to lack of marketability.

- To support development that aims to obtain approval in the U.S in addition to in Japan, implement milestone-type development support (a framework where additional subsidies are provided each time the targets set in stages are met) tailored to the theme, similar to the DARPA subsidies (R&D by the Defense Advanced Research Projects Agency in the U.S.).
- The subject of the support should include development themes that lead to solutions to social issues, such as drugs for intractable diseases, rare diseases, and infectious disease crises including drug resistance (AMR), and innovative medical devices based on unmet needs.

Task Force: General Recommendations Across Markets

Recommendation 4

Approach 1: Talents

Approach 2: Development Environment

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

- Expand offering of startup-related information in English (websites and public documents of MHLW and other related organizations involved in the pharmaceutical affairs system and relevant support programs).
- Enable English-language support for application documents and consultation services related to startup, including consultation services for pharmaceutical affairs by PMDA*1 and support programs such as grants.

*1: PMDA: Pharmaceuticals and Medical Devices Agency

Recommendation 5

Approach 1: Talents and Funding

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

- Expand personnel exchange with top global VCs to train and nurture venture capitalists, leveraging LP investment programs in overseas VCs conducted by the Ministry of Economy, Trade and Industry (METI).
- MHLW and METI shall cooperate in designing and implementing measures to invite global healthcare VCs to better identify academic seeds and investment opportunities in Japan, such as further advocacy efforts on Japanese investment environment, and invitation to participate in domestic events.

Recommendation 6

Approach 2: Development Environment

Proactively utilize clinical trial DX such as Decentralized Clinical Trials (DCT) to drastically reduce time and cost to market.

- Promote DCT through AMED's*2 research funding to clinical trials suitable for DCT such as cancer, intractable diseases, pediatric, and infectious diseases.
- Add maintenance of a system capable of performing DCT as a requirement for approval as Clinical Research Core Hospital.
- Standardize various tasks related to clinical trials (including central Institutional Review Board, Informed Consent Form) across sites, and implement such standardization among hospitals effectively.

*2: AMED: Japan Agency for Medical Research and Development

Task Force: Biotech & Regenerative Medicine

Voices from interviewees

Approach 1 Approach 2

- Obtaining US & EU approval and capturing their markets are essential for startups in Japan. This is due to US & EU regulations being at the core of global harmonization, and their markets being the largest (~60% of the world*1).
- Startups in Japan need to develop early stage in Japan and then bring them into US and EU. However, lack of talents, advisors and funding at early stage often makes this challenging.
- In many cases the bottleneck leads startups to be requested to redo clinical trials or resubmit data in terms of R&D strategy, GMP*2, or licensing, down the road. Similarly, Japanese CRDMOs*3 , while having invested in latest hardware, see shortage of GMP talents & advisors.
- On a separate note, the Japanese stock market listing criteria is too stringent, making it difficult for later stage companies to obtain adequate financing for final stages of development.

Challenges and Opportunities

- Currently, there is a lack of **talent, advice and funding for early stage development in Japan (the stage of finding pre-clinical and final development candidates).** In order to successfully connect to development in the U.S., the support system for early development in Japan needs to be strengthened in anticipation of FDA review.
- As a result of the **overwhelming lack of world-class human resources in manufacturing, non-clinical, clinical, and licensing strategies**, development strategy planning is weak and Japan is unable to compete globally in the manufacturing field, where it should be strong.
- **IPO requirements need to be changed** so that the company can maintain a proper growth trajectory before and after listing.

*1: "Global Use of Medicines 2023" (IQVIA INSTITUTE) (https://www.iqvia.com/-/media/iqvia/pdfs/library/presentations/presentation_global_ meds_2023_webinar.pdf)
*2: GMP: Good Manufacturing Practice of Pharmaceuticals in Japan
*3: CRDMO: Contract Research, Development and Manufacturing Organization for pharmaceuticals

Task Force: Biotech & Regenerative Medicine

Recommendation 1

Approach 1: Talents and Funding

Ease the requirements for investment capital for AMED*'s Drug Discovery Venture Ecosystem Enhancement Project (startup's companion support program by accredited VCs) and expand its scope to include preclinical early-stage pipelines.

*AMED: Japan Agency for Medical Research and Development

- Since it is difficult for accredited VC to commit to a large investment in the early development stage, the current AMED application requirement of a minimum investment from the lead accredited VC (1 billion yen) should be revised so that it can be interpreted more flexibly.

Recommendation 2

Approach 1: Talents

Establish a public-private cooperative educational program to develop human resources capable of dealing with new modalities from a global perspective in the areas of manufacturing, non-clinical, clinical, and licensing.

- Establish industry-wide practitioner training programs for new modalities with the cooperation of related business associations.
- Establish an open network of top-notch talent in manufacturing, non-clinical, clinical, and licensing from domestic and international CRDMOs, VCs, pharmaceutical companies, startups, regulatory authorities.

Recommendation 3

Approach 2: Market

Clarify listing requirements for Japan Exchange Group (JPX), which may be an obstacle to IPOs of biotech and regenerative medical product startups.

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

Task Force: Medical Devices & SaMD

Voices from interviewees

Approach 1 Approach 2

- “Access to appropriate physicians is difficult”, and “clinical trial environments such as first-in-human (FIH) are not well-developed and too expensive”, while a deep understanding of the needs of patients and the medical community and robust evidence are necessary to develop therapeutic devices, which has contributed significantly to the Japanese medical devices market.
- However, “there is a lack of human resources and support personnel who can develop business overseas”. Compared to the Japanese medical device market (CAGR 3.7%[*1]), the global market is expected to grow 5.9%[*1] , especially 6.4%[*1] in the US, and overseas expansion is considered important for the growth of healthcare startups.
- Aside from the foregoing, for Software as Medical Device (SaMD), "the staffing requirements for the medical device marketing license is a huge hurdle for startups to recruit human resources”. Also, in connection with home-use therapeutic applications, it is important to promote understanding of patients through direct communication to patients so that they are used voluntarily.

Challenges and Opportunities

- **Healthcare startups are expected to play a particularly important role in the development of high-risk, high-return innovative therapeutic devices** because large companies are often reluctant to take risks and get their hands on such development. However, the high risk makes it difficult for startups to raise funds, and there are challenges in accessibility to physicians and medical institutions, as well as in the environment and cost of clinical trials, including FIH.
- In overseas expansion, it is important to verify local needs and business feasibility from an early stage. However, there is a lack of **human resources** and **relationships with key opinion leaders and key persons familiar with overseas business development, pharmaceutical affairs, insurance reimbursement.**
- Since **the personnel requirements for the medical device manufacturing and sales business** are based on hardware medical devices, it is necessary to establish the proper business license regulations that also take SaMD into consideration. Despite the ongoing deregulation of advertisement of therapeutic applications, a type of SaMD, it is **still prohibited providing reliable evidence such as clinical trial data to the general public for home-use therapeutic applications**. There is a regulatory imbalance in that for general health care apps it is not allowed to advocate efficacy, but allowed to advertise evidence whose reliability is not guaranteed.

*1: "Medical Device Industry Vision 2024" (Ministry of Economy, Trade and Industry) (https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/ iryoukikisangyouvision2024/iryoukikisangyouvision2024.pdf)

Task Force: Medical Devices & SaMD

Recommendation 1

Approach 1: Ideas

Approach 2: Development Environment

Expand financial support for the collection of clinical evidence for the development of high-risk, high-return innovative therapeutic devices, and subsidies for Clinical Research Core Hospitals that cooperate with such evidence collection.

- Implement Base Projects with a view to needs exploration/identification and concept validation and collaboration with related academic societies to enhance accessibility to physicians and medical institutions.
- Provide financial support for clinical trials related to high-risk, high-return innovative therapeutic devices to assist in obtaining clinical evidence.
- Expand subsidies for Clinical Research Core Hospitals that cooperate in FIH trials of innovative therapeutic devices to establish implementation flow of such trials.

Recommendation 2

Approach 1: Talents

Approach 2: Market

Support overseas expansion by healthcare startups, including the development of expert personnel and strengthening international coordination of pharmaceutical regulations.

- In collaboration with JETRO and other organizations, support early verification of local needs and business potential, build relationships with local experts (pharmaceutical, reimbursement, business), KOL, and key persons, and develop specialized human resources, through overseas dispatch programs and R&D support for companies, entrepreneurs, investors, and regulatory authorities.
- Strengthen international coordination of pharmaceutical regulations and lowering the hurdles for building evidence and dealing with foreign pharmaceutical regulations.

Recommendation 3

Approach 2: Development Environment

Promptly deregulate business license requirements and advertising regulations that may restrict SaMD development and commercialization.

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

Task Force: Medical DX & AI

Voices from interviewees

Approach 2

- Japan has the potential to become an attractive market in terms of medical digital transformation and AI, given high-quality medical and nursing care data is being accumulated through the government's medical DX initiative. It is necessary to create systems and markets for data utilization.
- The Japanese healthcare IT market is expected to remain at around ¥400B by 2025 with a low growth rate while the global market is expected to exceed $80B by 2025 with a high growth rate.
- “Currently, data sharing and connection of electronic medical records and related research activities are sparse, and the medical data infrastructure is not sufficiently established." A specialist also pointed out that it is important that the cycle from data input to the return of value through the utilization of data be repeated smoothly to promote the collection and utilization of medical data.
- In addition, “the infrastructure for returning the value generated by data sharing to relevant parties and the guidelines for the development and use of medical AI are not well organized.”
- On another note, in introducing healthcare startup’s digital services for appointments, medical interviews, medical information and other operational matters, "medical institutions' decisions vary and take a lot of time.”

Challenges and Opportunities

- To establish **API connections between private services including PHR services and public medical data system** including Mynaportal and Online Health Insurance Verification, **users must be authenticated each time**, and **information items shared through API are limited,** which hinders service quality improvement (for example, for the Mynaportal API, prescription information cannot be sequentially updated to alert users to prevent them from forgetting to take their medication). Also, **API connections to private medical data system** such as electronic medical records at hospitals and health insurance companies’ core systems **have not progressed sufficiently**.
- When healthcare startups try to develop **new products that utilize AI**, the **application of regulations is unclear**, which tends to stifle development discussions. In addition, there is a need for further clarification of indicators that are important for healthcare startups to consider in their business planning and profitability, such as what **kind of performance should be clinically evaluated.**
- When introducing healthcare startup’s digital services for appointments, medical interviews, and medical information and other operational matters, the security division of each hospital have **different interpretations of relevant information security guidelines**, and **established certification of security of private digital services has not progressed**, which tends to make hospitals less positive on introduction of such digital services

Task Force: Medical DX & AI

Recommendation 1

Approach 2: Development Environment

Achieve sustained API connection between medical database such as Mynaportal and private service providers, and expand shared items.

- For APIs connection between private services including PHR services and Mynaportal and Online Health Insurance Verification, instead of requiring users to authenticate each time, modify operations so that once a user authenticates, automatic connection can be maintained for a certain period of time.
- Expand information items shared through Mynaportal API, such as medical treatment records as well.

Recommendation 2

Approach 2: Development Environment

To promote AI development in the medical field, clarify relevant regulations by the end of FY 2024, and consider measures to improve predictability of business.

- In cooperation with experts, identify regulations that are particularly relevant for medical AI development and clarify the applications of the regulations by the end of FY 2024 (e.g., potential legal issues on medical image data and LLM* derived from medical data).
- To enhance the predictability of economic returns for businesses developing medical AI products and to encourage the development and proliferation of such products, we aim to improve business predictability without limiting the ways in which economic returns can be obtained.

*:LLM: Large-scale language model AI

Recommendation 3

Approach 2: Development Environment

Approach 2: Market

Establish a consultation desk and objective evaluation system to eliminate various obstacles (e.g. vendor lock-in, security) on the active introduction of startup‘s products and services in hospitals and health insurance societies.

- Facilitate understanding of the issues faced by healthcare startups in relation to data sharing with and API connections to electronic medical records and health insurance societies’ core systems, by, for example, establishing a cross-ministry consultation desk for startups.
- Facilitate a certification program of private digital services related to medical information systems of medical institutions by the public or academic societies on their conformity to the technical requirements of the guidelines on medical data security issued by the government.

Task Force: Nursing Care Tech

Voices from interviewees

Approach 2 Approach 3

- The size of the nursing care market is mainly defined by the expenditures by Nursing Care Insurance (around 10 trillion yen per year), while the market is expanding year by year with the aging of the population, with some exceptions, such as fee-based nursing care facilities.
- In such market environment, nursing care service facilities have limited capacity for investment in ICT, as personnel costs account for 60-70% of the expenditures, and the average income/expense difference is as low as 2.4%*1.
- Nursing care technology are expected to reduce the burden on nursing care workers and maintain and improve the quality of care. Demand from nursing care facilities is increasing year by year (actual amount of subsidy to support the introduction of nursing care robots and ICT increased 227% from 5.39 billion yen to 12.24 billion yen*2 from FY 2021 to FY 2023.)
- However, nursing care tech startups “do not have access to consulting services for business strategies including exit strategies, and have little track record of being listed," so the ecosystem is underdeveloped.

Challenges and Opportunities

- Nursing care tech startups have a **very weak ecosystem**, with only one company finally listed in the facility sector in 2023, but none listed in the home sector
- The promotion of nursing care tech startups is **expected** to **create a market environment that can provide care tech options that meet the diverse needs of the nursing care field**, where it is essential to promote productivity improvement initiatives.
- **While the introduction rate of nursing care tech in nursing care facilities is about 30%**, the adoption rate of DX support subsidies for nursing care facilities is only 40%*3 , and the subsidy amount per population is uneven among prefectures. In particular, there is **much room for the use of care tech at home care facilities** *4, which account for more than 50% of the Nursing Care Insurance expenditures (about 11 trillion yen) in FY2021.
- The current **Nursing Care Insurance system provides limited incentives for the use of technology**, and especially **Nursing care tech in the home care field has not yet been fully implemented in society.**

*1: FY2023 survey of nursing care business management
*2: For FY2023, the actual amount of the introduction support program based on the supplementary budget.
*3: "FY2022 Report on a set of practical application support for welfare equipment and nursing care robots" (Ministry of Health, Labour and Welfare), p. 49 (https:・・・www.mhlw.go.jp・content・12300000・001137824.pdf)
*4: This section refers to Home-Visit Nursing Care, Home-Visit Bathing Nursing Care, Home-Visit Nursing, Home-Visit Rehabilitation, Outpatient Day Nursing Care, Outpatient Rehabilitation, Rental Service of Equipment for Nursing Care Covered by Public Aid, Short-Term Admission for Daily Life Nursing Care, Short-Term Admission for Recuperation, Guidance for Management of In-Home Medical Nursing Care, In-Home Nursing Care Support, Regular Patrol and On-Demand Home-Visit Nursing Care and Nursing Care, Home-Visit at Night for Nursing Care, Community-Based Outpatient Day Nursing Care, Outpatient Nursing Care for a Dementia Patient, Small-Scale Multifunctional Home Nursing Care, and Nursing Small-Scale Multifunctional Home Nursing Care.

Task Force: Nursing Care Tech

Recommendation 1

Approach 2: Development Environment

Approach 3: Talents

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

- Establish a consultation service for nursing care tech startups at the MHLW through a constructive reorganization of the ongoing Platform Project to collectively accept consultations and requests from nursing care tech startups and provide them with necessary support.
- Expand support programs with reference to programs by MEDISO, including nursing care tech promotion events, networking events with investors, awards.
- Provide ICT literacy education in nursing care facilities.

Recommendation 2

Approach 3: Funding

Increase the amount of DX support subsidy for nursing care facilities to encourage the introduction of care tech and help alleviate the worsening shortage of nursing care workers.

- In light of the current situation where 60% of nursing care facilities do not receive DX support subsidies, expand the scale of support, including expanding the scope of the budget related to DX support subsidies, centered on the Nursing Care Technology Introduction Support Project, in order to respond to the potential needs of nursing care facilities.
- Establish one-stop consultation offices in all prefectures to provide one-stop advice and other support (concierge) for various subsidies

Recommendation 3

Approach 2: Market

Review the evaluation of nursing care tech products for home care providers and users in terms of Nursing Care Insurance and clarify incentives for their introduction.

- Promote the collection of evidence related to the use of technology, including at home, through projects such as Health Promotion Program For the Elderly, in order to review the services covered by the Additional Payment for Productivity Enhancement Promotion System.
- Consider increasing the frequency of the Nursing Care Insurance Welfare Equipment and Home Improvement Evaluation Study Group and adding a constituent in the area of nursing care tech.

Each of the recommendations corresponds to our three approaches on which element to intensively invest in

List of Task Force Recommendations *At the time of the interim recommendations

General Recommendations Across Markets

① Establish a new central contact point to receive and review requests from healthcare startup stakeholders for insurance compensation revisions, etc.
[**Approach 2**: **Development Environment**]

② Fundamentally strengthen MEDISO functions and structure, and expand and shift to more continuous and active startup support.
[**Approach 1: Talents**, **Approach 2: Development Environment and Market**]

③ Accelerate drug discovery and medical device development on themes that have been difficult to initiate by utilizing milestone-type development grants [**Approach 2: Development Environment**].

④ Enable English-language support in principle for consultations on government support and application procedures related to healthcare startups.
[**Approach 1: Talents resources**, **Approach 2: Development Environment**]

⑤ Attracting top-tier global VC in the healthcare sector to Japan [**Approach 1: Talents & Funding**]

⑥ Proactively utilize clinical trial DX such as Decentralized Clinical Trials (DCT) to significantly reduce the time and cost to market.
[**Approach 2**: **Development Environment**]

Biotech & Regenerative Medicine Task Force

① AMED's Drug Discovery Venture Ecosystem Enhancement Project (startup's companion support program by certified VC) will relax the requirements for the amount of investment capital and expand the scope to include early-stage pipelines [**Approach 1: Talents and Funding**].

② Establish public-private cooperative educational programs to develop human resources capable of dealing with new modalities from a global perspective in the areas of manufacturing, non-clinical, clinical, and licensing [**Approach 1: Talents**].

③ Clarify listing requirements for the JSE Group, which may be an obstacle to IPOs in the early stages of biotech and regenerative startup [**Approach 2: Market**].

Medical DX & AI Task Force

① Achieve sustained API connection between medical database such as Mynaportal and service providers, and expand shared items.
[**Approach 2: Development Environment**]

② To promote AI development in the medical field, clarify relevant regulations by the end of FY 2024, and consider measures to improve predictability of business.
[**Approach 2: Development Environment**]

③ Establish a consultation service and objective evaluation system to eliminate various restrictions (vendor lock-in, security) on the active introduction of startup's products and services in hospitals and health insurance societies.
[**Approach 2: Development Environment and Market**]

Medical Device & SaMD Task Force

① Expand financial support for the collection of clinical evidence for the development of high-risk, high-return innovative therapeutic devices, and subsidies for Clinical Research Core Hospitals that cooperate with such evidence collection.
[**Approach 1: Ideas**, **Approach 2: Development Environment**]

② Support overseas expansion by healthcare startups, including the development of expert personnel and strengthening international coordination of pharmaceutical regulations.
[**Approach 1: Talents**, **Approach 2: Markets**]

③ Promptly deregulate business license requirements and advertising regulations that may restrict SaMD development and commercialization.
[**Approach 2: Development Environment**]

Nursing Care Tech Task Force

① Early launch of "CARISO (tentative name: CARe Innovation Support Office)" (nursing care version of MEDISO) as a centralized consultation service to support care tech startups
[**Approach 2: Development Environment**]

② Increase the amount of DX support subsidy for nursing care facilities to encourage the introduction of nursing care tech and help alleviate the worsening shortage of nursing care workers.
[**Approach 3: Funding**]

③ Review the evaluation of nursing care tech products for home care providers and users in terms of Nursing Care Insurance and clarify incentives for their introduction.
[**Approach 2: Market**]

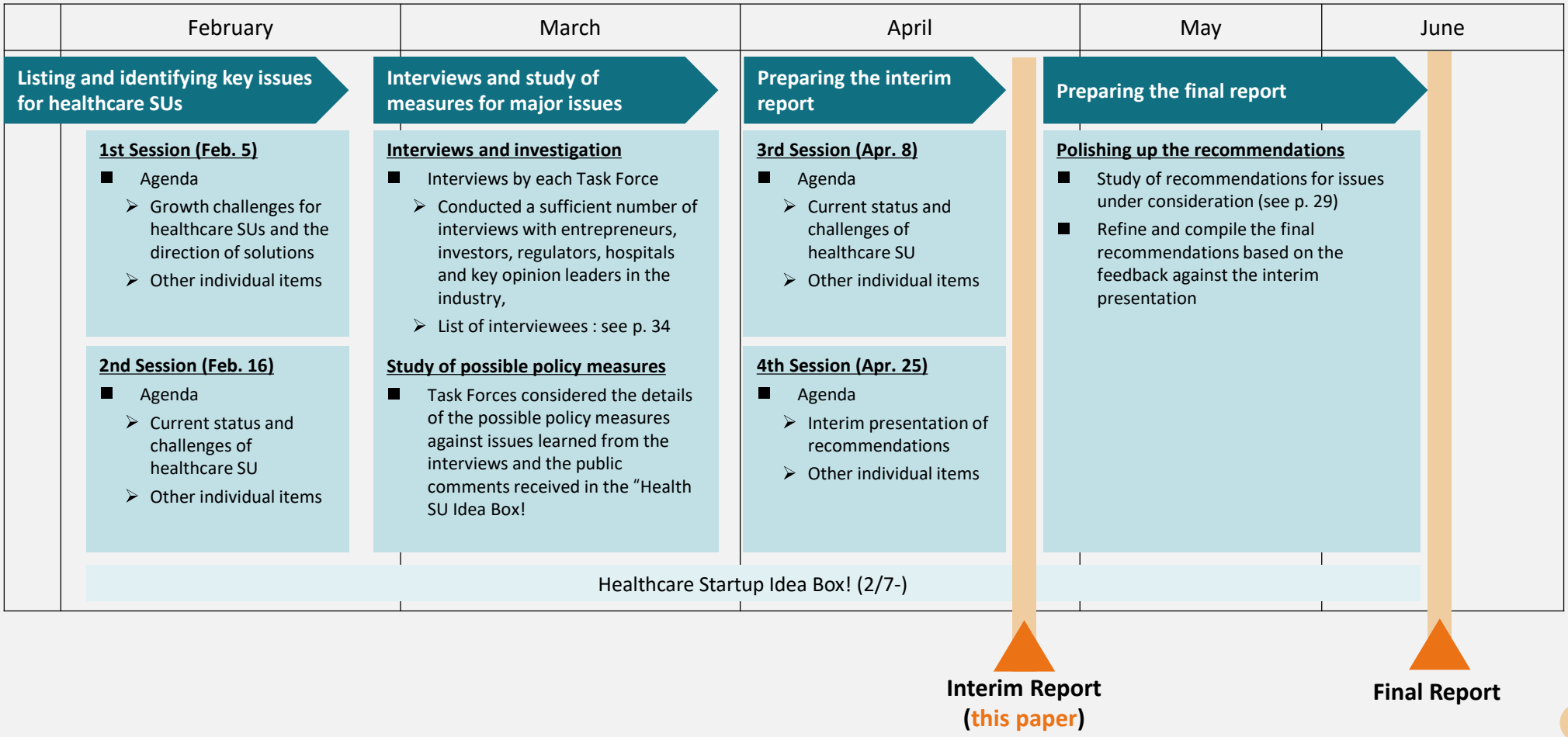
Other issues are also under consideration for the final recommendations

Examples of issues under consideration *At the time of the interim recommendations. Additional items will be added in the final recommendations.

General Recommendations Across Markets	Medical DX & AI Task Force	Nursing Care Tech Task Force
① Insurers' budget constraints have made it difficult for startups to sell solutions (including for prevention) in the healthcare market. [Approach 2: Market] ② Not enough healthcare professionals with clinical expertise and experience are available to take on healthcare startups. [Approach 3: Talents]	① The emergency rescue-related forms (including activity records) differ from municipality to municipality and are not standardized, which is an obstacle to digital transformation. [Approach 2: Development Environment]	① It is not easy for individual care tech startups to research differences in overseas systems and on-site operations and conduct demonstrations at local facilities, and only a limited number of companies have decided to expand overseas. [Approach 2: Development Environment]

Next Steps

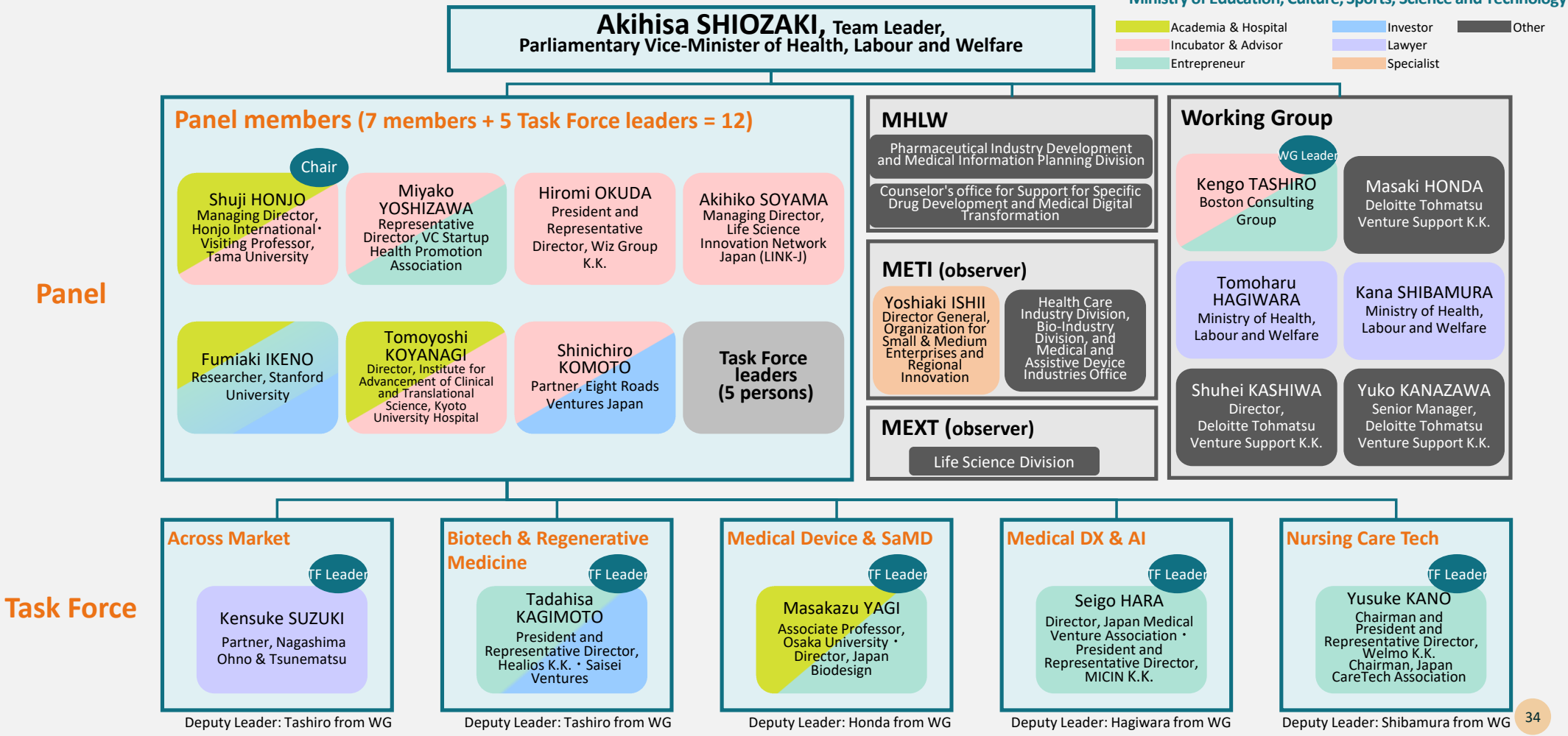
This paper presents our interim recommendations. Final proposal will follow in early June



NEXT STEPS

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

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



Conducted numerous interviews with key opinion leaders in the industry

No.	Name	Affiliation (at time of interview)	Task Force in Charge
1	Stephen Barker Miyabi YAMAKITA	Jefferies Securities, Inc.	Bio/Regen.
2	Dr. Shinichiro (Shin) FUSE	TPG Life Sciences Innovation	Bio/Regen.
3	Atsushi YASUMOTO	President and Representative Director, Nexredge K.K.	Bio/Regen.
4	Daniel Camardo	Chief Executive Officer, Athersys Inc.	Bio/Regen.
5	Michael Langer	Managing Partner, T.Rx Capital	Bio/Regen.
6	Janice Pai	Core Member of the Technology, Healthcare, and Supply Chain Practices, Egon Zehnder	Bio/Regen.
7	Hirokazu SHIMODA	Director, Bio-Industry Division, Ministry of Economy, Trade and Industry	Bio/Regen.
8	Yuki AOYAMA	Representative Director, Splink K.K.	MD and SaMD
9	Masaaki ITO	Chief, Division of Colorectal Surgery, National Cancer Center Hospital East (concurrently Deputy Director, Chief, Division of Medical Device Development and Promotion, and Chief, Division of Surgical Device Development, Center for Advanced Medical Care and Development)	MD and SaMD
10	Chie IWAISHI	Edwards Lifesciences	MD and SaMD
11	Hajime OSHITA	President and Representative Director, MedVenture Partners K.K.	MD and SaMD
12	Hiroaki KATO	Specially Appointed Professor, Graduate School of Digital Hollywood University, Clinical Professor, Tokyo Medical and Dental University, Co-Founder, Executive Vice President and CSO, Aillis K.K.	MD and SaMD
13	Masashi KIYOMINE	Founder & Managing Partner, Kicker Ventures	MD and SaMD
14	Kazuya SHOBAYASHI	Representative Director, N.B. Medical K.K.	MD and SaMD
15	Jun KUSUNOKI	Senior Director, Johnson & Johnson Innovation, Japan Country Lead, Early Innovation Partnering	MD and SaMD
16	Shinichi TAKAE	Research Planning Officer, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare	MD and SaMD
17	Masakatsu NOGUCHI	Managing Partner, Policy Makers Lab	MD and SaMD

No.	Name	Affiliation (at time of interview)	Task Force in Charge
18	Dr. Todd Brinton	Chief Scientific Officer & Corporate Vice President, Edwards Lifesciences	MD and SaMD
19	Motohiro ASONUMA	Visiting Professor, Juntendo University	Medical DX & AI
20	Taro UENO	President and Representative Director, Susmed K.K.	Medical DX & AI
21	Teppei SAKANO	President and Representative Director, Allm K.K.	Medical DX & AI
22	Kenichi NAKAMURA	Director, Division of International Development, National Cancer Center Hospital	Medical DX & AI
23	Ryozo NAGAI	President, Jichi Medical University	Medical DX & AI
24	Yutaka MATSUO	Professor, Research into Artifacts, Center for Engineering, Department of Technology Management for Innovation, and Program for Social Innovation, School of Engineering, The University of Tokyo	Medical DX & AI
25	Moe MIURA	Japan Digital Health Alliance	Medical DX & AI
26	Yuji YAMAMOTO	President and Representative Director, MinaCare K.K.	Medical DX & sAI
27	Yumiko KAWAMURA	Representative of Rehanowa, Communicator for Capital Medica Ventures K.K.	Nursing Care Tech
28	Ryosuke KIMURA	Managing Partner, Lifetime Ventures	Nursing Care Tech
29	Fumito SHIMIZU	Founder of 3Sunny K.K. (the company has been sold to Teijin K.K.), Entrepreneur	Nursing Care Tech
30	Shuhei FUJIMOTO	Shizuoka Graduate University of Social and Health Medicine	Nursing Care Tech
31	Tetsuro HOMMA	Representative Director, Executive Vice President, General Manager of China and Northeast Asia, Panasonic Holdings K.K.	Nursing Care Tech
32	Isao YANO	Director, Future Care Lab in Japan	Nursing Care Tech
33	(Individual names withheld)	Nichii Holdings K.K., Nichii Gakkan K.K., Nichii Care Palace K.K.	Nursing Care Tech

* Many additional interviews were conducted (not listed above)