Vision for the Medical Device Industry 2024

Vision for the Medical Device Industry Research Group

March 2024

This Document is made in Japanese and translated into English. The Japanese text is the original and the English text is for reference purposes.

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1. Background and Purpose

The Ministry of Economy, Trade and Industry (METI) formulated the "Vision for the Medical Device Industry Research Group" (chaired by Yoshiyuki Taenaka, Honorary Member of the National Cerebral and Cardiovascular Center), which brings together industry, government, and academia, to discuss the direction that Japanese companies should take amid dramatic changes in the medical device industry and what support is needed from the METI. To consider industrial support that meets the medical device industry's needs, based on the "Basic Plan for Promoting Research, Development and Dissemination of Medical Devices to Improve Medical Care Quality Available to the Public," revised on May 31, 2022, interviews were held with 45 medical device companies, including Japanese, global, and startups (hereinafter "company interviews"), and the issues in the medical device industry were summarized. The results of the company interviews are attached to this document. Based on these results and hearings with experts, the research group identified issues in the medical device industry and future goals that the industry should aim for. In addition, it discussed specific initiatives for the future, compiling the results into the Visions for the Medical Device Industry 2024.

The medical device industry market is expected to grow rapidly worldwide, but the Japanese market growth rate is expected to be slower than that of the global market. The Japanese market's share in the global market has declined from 22.1% in 1990 to 7.3% in 2018. Although the Japanese medical device industry is at a point where it needs to shift from relying on Japanese market growth to capturing the global market, it continues to depend on the Japanese market for its industrial structure.

Based on this background of the Japanese medical device industry, this research group identified the direction for the growth of this industry as a high-valued industry to be a repetition of two cycles: R&D investment to create innovation and return on investment through global expansion. Furthermore, in terms of strategic efforts to achieve this, we pointed out the importance of expanding into the the United States (US) market as a part of global expansion. We concluded that it is necessary to support companies embarking on the US expansion through subsidies for clinical trials to gain the US market shares and thereby create successful examples of the US expansion. We further suggested the need to support network building essential to global expansion. Moreover, we pointed out that, to build an R&D environment that generates innovation in Japan, it is necessary to develop and form markets for medical devices using AI and other digital technologies, and to create innovation through startups. We concluded that it is necessary to build a foundation for utilizing medical data, support the evaluation of clinical and economic effectiveness of the medical devices, and strengthen the collaboration between major companies and startups.

This vision aims to gain a shared direction not only at the METI and medical device companies but also among other stakeholders such as medical institutions, research institutes, venture capitalists, and government agencies.

The realization of this vision is expected to create a virtuous cycle of growth through innovation and international expansion, give rise to an industry that attracts more human resources and funds, and

make important contributions to medical care and human health by implementing innovation in Japan and the world.

2. Current Situation and Challenges Facing the Medical Device Industry

(1) Status of Japanese Medical Device Industry in the Global Market and the Need to Capture the US Market

(1)-1) Current Status of and Predictions for the Global and Japanese Markets

The global market for the medical device industry was worth approximately $517.6 billion in 2023, with the United States accounting for approximately 47% and Japan accounting for approximately 5%.[1] It is projected to grow to approximately $654.3 billion by 2027 due to the aging populations of developed countries, population growth and economic development in emerging and developing countries, and technological innovation, with an expected expansion at a compound annual growth rate (CAGR) of 5.9% in the 2018–2027 period. By region, the United States is expected to grow at a CAGR of 6.4%, Europe at a CAGR of 5.1%, and other regions such as Asia, excluding Japan, at a CAGR of 6.3%. While growth is expected in emerging and developing countries, in particular, it is also expected to continue in Europe and the United States, which tend to be destinations for innovative products, thus indicating growth for the industry as a whole. The Japanese medical device market is growing at a CAGR of 3.7%, and although this growth is not as large as in other regions, it is expected to be a market of approximately $38 billion by 2027 (Figure 1). Comparing the global markets of the medical device industry and other industries, the CAGR of the medical device industry is more than 5% in both 2018–2022 and 2023–2027, indicating that it is an industrial sector with sustainable growth (Figure 2).

Simultaneously, in Japanese market, where continuous growth has been observed, the value of Japanese manufacturing shipments has not changed significantly, so most of the growth has been absorbed by imports (Figure 3). Moreover, the value of Japanese production grew at a CAGR of 1.5% from 1990 to 2018, compared to the global market at a CAGR of 7.1% during the same period.[1,2] The growth rate has been low, so the share of Japanese production value in the global market fell from approximately 22.2% in 1990 to approximately 5.0% in 2018, dropping to less than one-fourth of what it used to be (Figure 4). While there's a limitation that the Japanese companies' global manufacturing for global shipments and reverse imports are not included, it is important to strengthen the international competitiveness of products manufactured by Japanese companies, particularly considering their current low competitiveness on the global stage.

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[1] Worldwide Medical Devices Market Forecasts (July 2023), Fitch Solutions
[2] Worldwide Medical Market Forecasts to 2018, ESPICOM

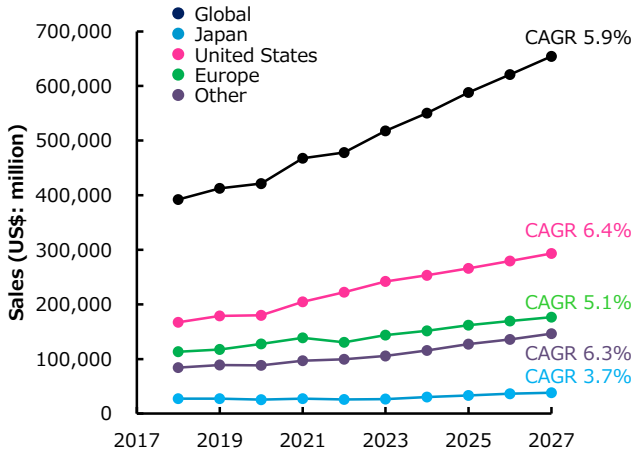

Figure 1. Medical device sales, by country.

Source: Worldwide Medical Devices Market Forecasts (July 2023), Fitch Solutions.
Created by METI.
CAGR: Calculated for the 9 years from 2018 to 2027 (predicted).

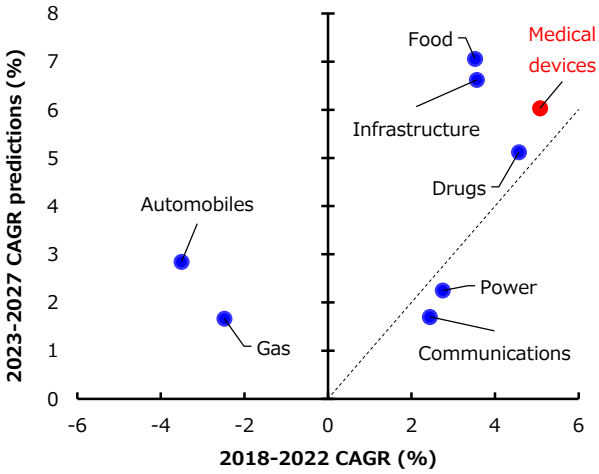

Figure 2. CAGR prediction, by industry.

Source: Global market report for each industry, published by Fitch Solutions.
Created by METI.

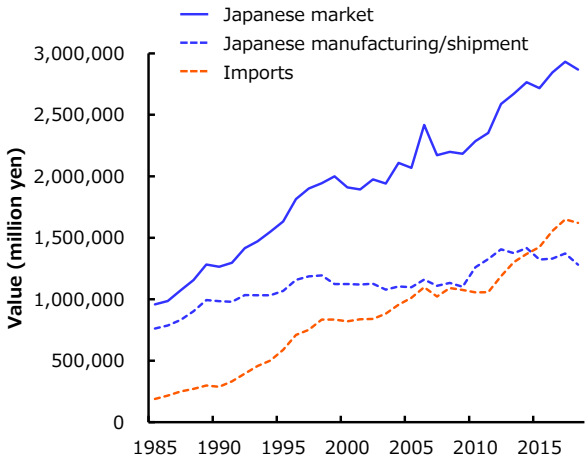

Figure 3. Japanese manufacturing/shipment and imports.

Source: Statistics of Production by Pharmaceutical Industry.
Created by METI.
Japanese market is the value of "Japanese shipment" and Japanese manufacturing/shipment is calculated as "Japanese production - imports".

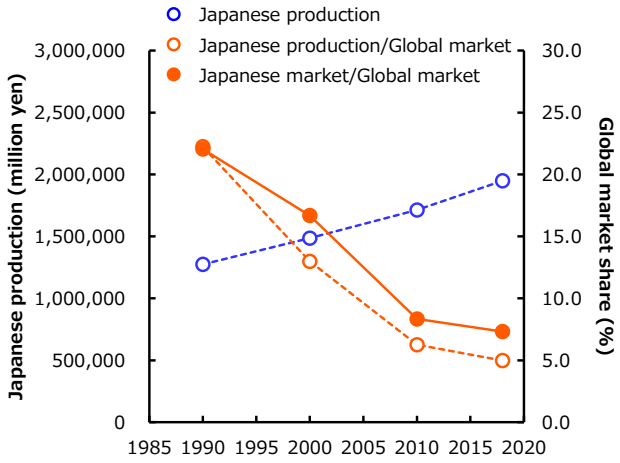

Figure 4. Japanese production in the global market.

Source: Worldwide Medical Devices Market Forecasts and Statistics of Production by Pharmaceutical Industry.
Created by METI.
Global market calculated as 1 USD = 100 yen for all decades.

(1)-2) Growth Trends by Product in the Japanese Market

Looking at the Japanese market, the product fields with a high CAGR in the decade from 2008 to 2018[3] were sterilized blood vessel tubes and catheters, artificial heart valves and related devices, surgical electrical devices and related devices, fixation/suture machinery and devices, treatment devices, and other therapeutic devices. Meanwhile, since the CAGR of diagnostic devices, such as superconducting magnetic resonance imaging systems and whole-body X-ray CT systems, tends to be low, the growth of the Japanese market to date is believed to have been largely driven by the contributions of the therapeutic device market (Figure 5). Furthermore, if we examine the future

[3] Ministry of Health, Labour and Welfare, Statistics of Production by Pharmaceutical Industry, Top 20 Areas in Terms of Japanese Shipment Value Among Medical Device Subcategories in 2018

growth predictions of the global market by product category, in addition to therapeutic devices used for treatment, software devices that directly affect disease treatment, diagnosis, and prevention of diseases (software as a medical device: SaMD) as well as robotic surgery in fields that integrate digital technology with medical devices are garnering attention (Figure 6).

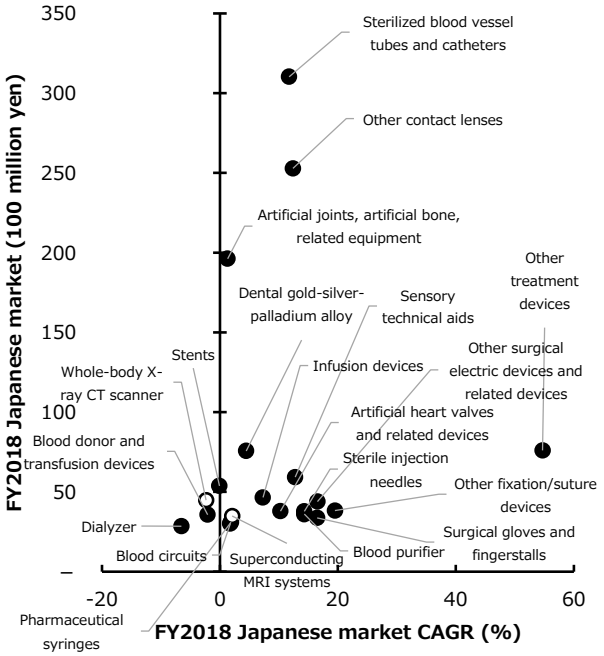

Figure 5. FY 2008-2018 Japanese market and growth rate by product.

Source: Statistics of Production by the Pharmaceutical Industry. Created by METI.

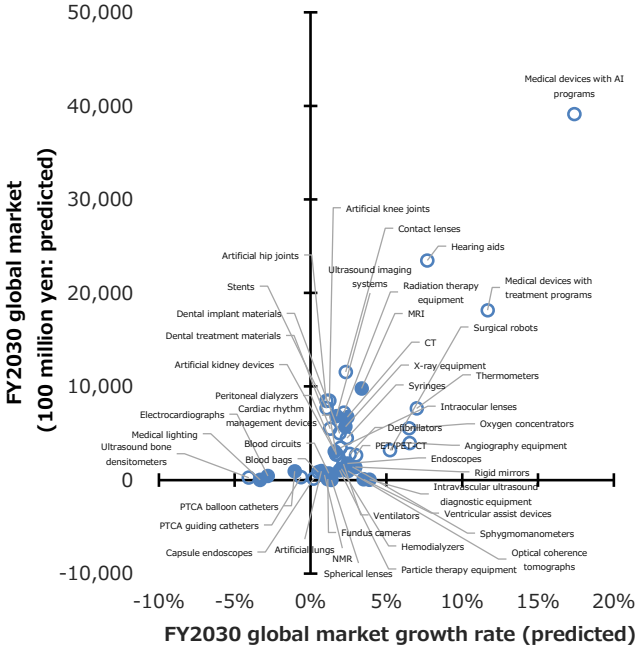

Figure 6. FY2030 global market and predicted growth rate by product.

Cited from the Japan Agency for Medical Research and Development, "Survey for Considering New Medical Device R&D Support".

(1)-3) Assessment of the Japanese Market by Japanese and Global Companies

In the company interviews, global companies, in particular, expressed both expectations for and harsh assessments of the Japanese market. The expectations for the Japanese market were as below; the largest market after those of Europe and the United States; one of the limited markets that can handle IT products and other advanced medical equipment; a good market for gathering evidence to increase the value and competitiveness of medical devices since it has one of the highest levels of medical care in the world; there's advanced manufacturing technology for realizing solutions; a developed country with issues such as population aging that are suitable for developing and demonstrating new business models and products; the latent high-quality requirements ensure that the quality that satisfies Japan is good enough for the rest of the world; etc. All of the above suggest that Japan boasts high medical standards and manufacturing technology, making it an environment with sustained potential to develop medical devices for global markets through effective data gathering and utilization. Simultaneously, in addition to limited market growth due to a declining population, it is difficult to pass on price increases because the insurance system determines prices despite increasing manufacturing costs, owing to the higher raw material and transportation costs and yen depreciation.

However, the insurance system does not particularly value innovation and contributes to considerable price declines through periodic revisions to medical fees, suggesting that investment risks in the Japanese market are a concern to global companies. In fact, even for products sold global, we found that it is unlikely that there will be any profit on the investment required to launch the product in the Japanese market, leading to delayed introductions for some products.

(1)-4) Necessity of Global Expansion

Considering these conditions of the Japanese market, there is a limit to the growth of sales of medical device companies within the Japanese market only, thereby necessitating an extension of sales through global expansion. For the top 19 companies in terms of sales among Japanese companies specializing in medical devices or with a sales ratio of 85% or more[4] (hereinafter "the 19 top-selling Japanese companies"), the average ratio of global sales is approximately 39%. These companies can be divided into two groups: those with a ratio of 50% or more and those with a smaller ratio; only 6 out of the 19 companies have expanded to 50% or more (Figure 7).

Meanwhile, a comparison of growth in the global sales ratio and sales growth of the 19 top-selling Japanese companies from FY (fiscal year) 2018 to FY 2022 shows that companies with a global sales ratio of 0–20% tended to experience lower growth rates in both the global sales ratio and the total sales. This suggests that global expansion is important for sales growth (Figure 8).

To capture global markets, it is necessary to clarify the target markets and strategy, with the US market regarded as particularly important for global expansion and economic returns. The US market accounts for approximately 47% of the global market, where leading technologies and medical devices are created and developed. In the US and other markets that can handle leading technology, medical devices must incorporate technologies that solve high unmet medical needs. These devices must demonstrate efficacy and safety backed by evidence and possess high usability. If a technology or product satisfying these requirements is recognized in the US market and appreciated as a standard treatment method by relevant medical societies (e.g., in their guidelines), it will be considered a global standard treatment and disseminated worldwide, including to developed and developing countries other than the United States.

An example of global growth triggered by gaining recognition in the US market is Asahi Intecc Co., Ltd. The company's percutaneous coronary intervention (PCI) guidewire for the treatment of chronic total occlusion (CTO) ,developed in 1995, enables guidewire endovascular treatment that applies ultra-fine stainless steel wire rope technology cultivated in the industrial equipment field to CTO lesions in coronary arteries. These lesions could previously only be treated by thoracotomy, which puts a huge burden on the patient. The developed product attracted attention in the United States through Japanese doctors' academic reports on clinical results. By accumulating clinical results in the United States together with Japanese doctors, it came to be recognized as a general treatment method for CTO,

[4] Company IR materials

including in Asia and Europe where it had already been marketed. This recognition also established the company's product brand globally. Since FY 2004, when the company began full-scale sales in the United States and Europe, Asahi Intecc has increased its global sales ratio by approximately 50 percentage points, increasing sales by 12 times and ranking of 19th in sales among all Japanese medical device companies, excepting foreign-affiliated companies.[4]

Meanwhile, the following issues were raised regarding global expansion in the company interviews:

- The importance of expanding global through partnership strategies with global local companies
- The necessity of building an environment where it is possible to grasp needs and regulations from the early stages of development in anticipation of global expansion
- The importance of expanding structures for exempting products from applications in other countries when marketing approval has been obtained in Japan
- The necessity of negotiating with a large number of insurance companies especially in the case of global expansion of innovative technologies. This presents a significant challenge for companies without the expertise
- The necessity of establishing a continuous follow-up base after sales, which requires a large investment, in the case of medical devices
- Although Asia is a market that cannot be skipped in the future, challenges such as the tapering off of sales when countries put themselves first and the difficulties of maintaining supply chains persist

The METI is currently providing support for developing medical devices and improving the healthcare environment mainly in Asian countries and Africa through projects for international healthcare development and promotion; it is also providing support for international development systems. In the future, we will be able to grasp local needs from the early stages of development by supporting the development of medical devices aimed at global expansion to the United States and through communication and partnerships with various stakeholders. The scope of such support has been insufficient in previous projects. Moreover, there is a need to discuss the enhancement of opportunities for building networks to develop systems for not only development but also market dissemination.

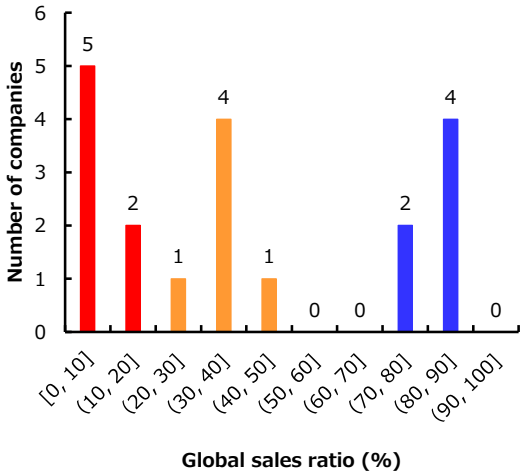

Figure 7. Japanese companies' FY2022 global sales ratio.

Source: FY2022 company IR materials from the 19 top-selling companies among companies specializing in medical devices or related businesses with 85% or more sales.
Created by METI.
Companies whose Japanese sales exceeded 90% and without global sales in their IR materials were approximated to 5%.

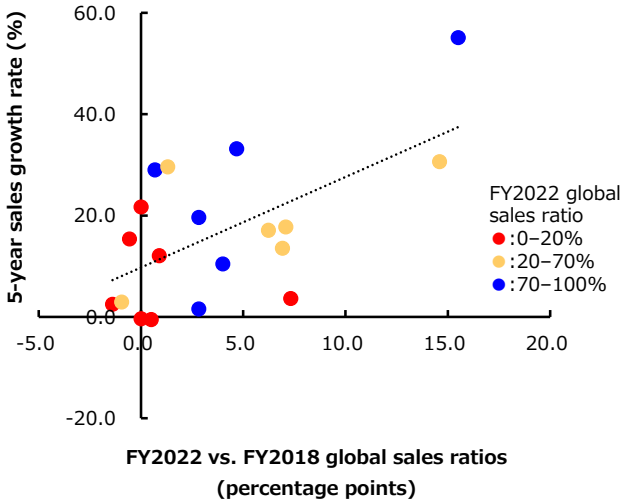

Figure 8. Correlation between overseas sales ratio growth and sales growth rate (FY2018–2022),

Source: FY2018 and FY2022 company IR materials from the 19 top-selling companies among companies specializing in medical devices or related businesses with 85% or more sales.
Created by METI.
Companies whose Japanese sales exceeded 90% and without global sales in their IR materials were approximated to 5%.

(2) Importance of Strategies for "Fostering and Evolution" of Medical Devices to Capture the Global Market

(2)-1) R&D Investments

The average R&D investment ratio of the 19 top-selling Japanese companies has been 5–6%, a difference of approximately 2% from that of the five top-selling global companies (Figure 9). The ratio of R&D expenditures to sales among the 19 top-selling Japanese companies has shown a polarization, with approximately half allocating 5% or more and the other half allocating less. Moreover, companies with a ratio of R&D expenditures to sales of 5% or more in FY2013 improved their global sales ratio by approximately 14.4 percentage points in the decade from FY2013 to FY2022. Contrarily, companies with a ratio of less than 5% had an increase of only approximately 7.3 percentage points in the same decade (Figure 10). As shown in Figure 8, given that the growth of the global sales ratio correlates with the sales growth rate, companies that invest more than a certain amount in R&D are believed to increase their ratio of global sales, which in turn leads to future sales growth. Medical device R&D differs depending on the class of medical device developed, but it is generally considered to take more than 5–10 years from the discovery of a need and conceptualization of the product to its market launch. Figure 10 shows that the ratio of R&D expenditure to sales in FY2013 affected the ratio of global sales 10 years later in FY2022, suggesting that long-term, rather than short-term, R&D investment with an eye on the future is important in this field.

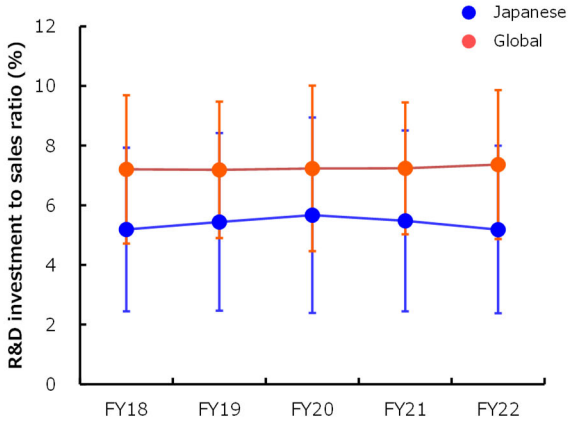

Figure 9. Japanese and global companies' R&D investment to sales ratio.

Source: FY2018-2022 company IR materials from the 19 top-selling domestic companies among companies specializing in medical devices or related businesses with 85% or more sales and the five top-selling global companies whose medical device-related business details are available.
Created by METI.

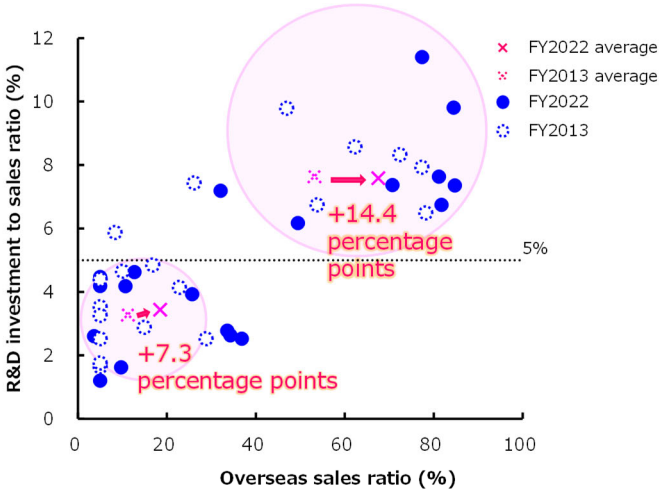

Figure 10. R&D investment to sales ratio and overseas sales ratio.

Source: FY2013 and 2022 company IR materials from the 19 top-selling Japanese companies among companies specializing in medical devices or related businesses with 85% or more sales.
Created by METI.
Companies whose Japanese sales exceeded 90% and without overseas sales in their IR materials were approximated to 5%.

(2)-2) Importance of "Fostering and Evolution" of Medical Devices and the Current State of Clinical Trials

The manufacture and sale of medical devices require marketing approval from national regulatory authorities, and regulatory strategies occupy an important position in the development of medical devices. However, for a new medical device to be accepted and widely disseminated in the market, it is important not only to obtain marketing approval but also to demonstrate its efficacy through clinical trials and other means. In other words, it is important to demonstrate the efficacy of this device in meeting medical needs such as improving patients' lives and the quality of life (QOL). An example of global success is a thrombectomy stent developed by a US company for the treatment of cerebral infarctions. This medical device is inserted into the cerebral blood vessels of patients with a cerebral infarction to collect and treat blood clots.[5] By 2012, it had been approved in the United States, and although it was groundbreaking, its efficacy and safety had not yet been established, so the technology was not widely used. However, from 2014 to 2015, treatment efficacy was established through multiple clinical trials,[6] some funded by companies, and the medical societies of Japan and the United States identified this technology as a recommended treatment. Since then, it has become a widely used technology worldwide, forming a large market with a global market size of 300 billion yen in 2026.[7] In the company interviews, it was expressed that in addition to medical device development, making big investments over the long term is necessary to get evidence for market acquisition after

[5] Medtronic website
[6] Tomotaka Oshima, "Evidence and Therapeutic Indications for Acute Thrombectomy," Jpn J Neurosurg, Vol. 30 No. 11, 11.2021
[7] Terumo Corporation, "Terumo Report 2022"

commercialization. In this way, for a technology or product to capture a market, it is important to have a strategy of "fostering and evolution" of medical device development evaluated through clinical trials and so on, both in Japan and global, even after marketing approval or commercialization.

In global markets and especially in the United States, which is the main market for medical devices as shown in (1), the clinical trials required to obtain marketing approval from the US Food and Drug Administration (FDA) for innovative medical devices are said to take 3–4 years and cost approximately 50 million dollars.[8] Moreover, clinical trials may not show efficacy or they may affect the lives of patients, so companies run the risk of reputational damage and large losses, which poses significant hurdles to implementation. In fact, when comparing the number of clinical trials conducted by the 19 top-selling Japanese companies and the five top-selling global companies, the number of clinical trials by global companies is approximately seven times higher than that of Japanese companies (Figure 11(a)). Moreover, the number of government-funded clinical trials of medical devices in Japan is less than one-sixth that of the United States, so government support is thought to be relatively small (Figure 11(b)). This suggests that many Japanese companies have not been able to engage in the R&D necessary for introducing innovative medical devices in the United States.

Moreover, the following issues were raised in company interviews:

- Especially in the United States, the risk of medical litigation is high, so the more evidence is needed for an innovative product to be used widely. This means that the accumulation of evidence through post-commercialization clinical trials is essential for capturing the global market, which requires huge investments and a large company size.
- For Japanese companies, having a revenue base in the Japanese market, it needs to recover their investments in Japan as a source of funds for global expansion. However, in the Japanese environment, development costs cannot be passed on to sales prices, which means investment recovery prospects are poor, as is government support for clinical trials.

For Japanese companies to capture the US market, they need to enhance their product competitiveness based on evidence such as clinical trials, so providing support to promote such market acquisition strategies is extremely important.

Moreover, among the companies specializing in medical devices and with a sales ratio of 85% or more, there was a correlation between the cash (simplified cash flow: operating income + depreciation and amortization) obtained from the business and their clinical trial track record. This suggests that the difference in the number of clinical trials between global and Japanese companies affects the companies' financial strength (Figure 12). Moreover, medical device companies' net sales and earnings before interest, taxes, depreciation, and amortization (EBITDA) margins (EBITDA/sales) are positively correlated for companies with net sales of 30.0 billion yen[9] or more, suggesting that

[8] FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION, November 2010.

[9] Equivalent to the sales of businesses that rank around the 30th largest in sales among Japanese medical device companies (according to company IR materials)

profitability is high for big companies (Figure 13). As such, company size seems to be an important factor in the R&D investment and growth of medical device companies.

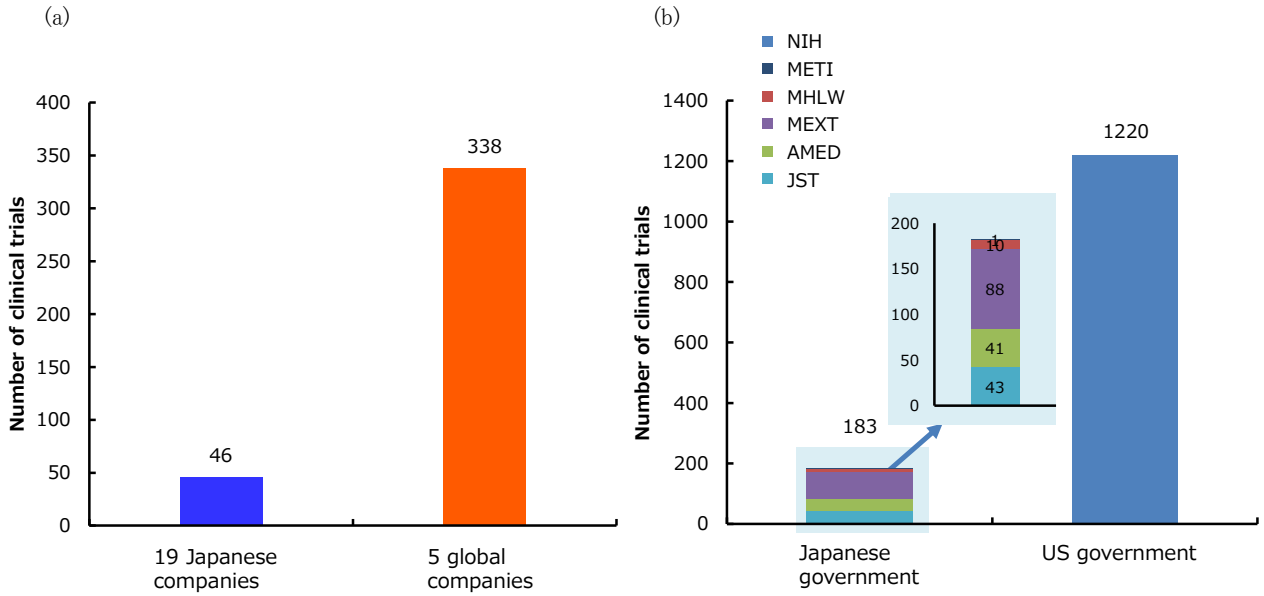

Figure 11. Number of clinical trials by (a) Japanese/global companies and (b) funding government.

(a) Source: Search results from ClinicalTrials.gov (as of February 2024) and UMIN with the following search conditions about the 19 top-selling domestic companies among companies specializing in medical devices or related businesses with 85% or more sales and the five top-selling global companies whose medical device-related business details are available.
Created by METI.
ClinicalTrials.gov: Study Type→Interventional Studies (Clinical Trials), Intervention / Treamtment→Device
Study Start→From 1/1/2018 to 12/31/2022,Sponsor/Collaborator→"company's name", Founder Type→Industry
UMIN: 試験の種類→介入/Interventional, 介入の種類→医療器具・機器/Device equipment, 研究費提供組織機関名→each company's name
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(b) Search results from ClinicalTrials.gov (as of February 2024) and UMIN with the following search conditions.
Created by METI.
ClinicalTrials.gov: Study Type→Interventional Studies (Clinical Trials), Intervention / Treamtment→Device
Study Start: From 1/1/2018 to 12/31/2022, Funder Type→NIH, Other U.S. Federal agency
UMIN: 試験の種類→介入/Interventional, 介入の種類→医療器具・機器/Device equipment, 研究費提供組織機関名→each funding government's name
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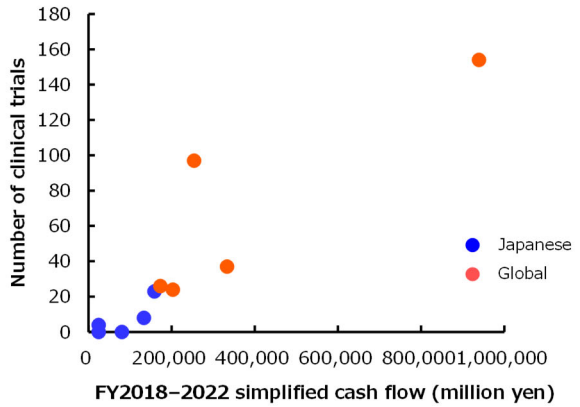

Figure 12. Average simplified cash flow and number of clinical trials for Japanese and global companies in FY2018–2022.

Source: FY2018–2022 company IR materials and search results from ClinicalTrials.gov. (as of February 2024) and UMIN with the following search conditions about the 19 top-selling Japanese companies among companies specializing in medical devices or related businesses with 85% or more sales and the five top-selling global companies whose medical device-related business details are available.
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Intervention / Treamtment→Device
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Sponsor/Collaborator→"company's name"
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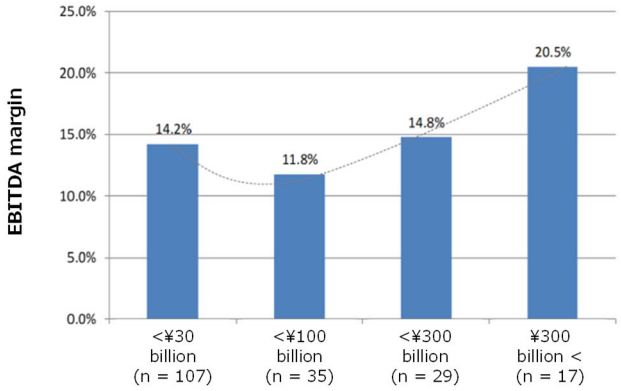

Figure 13. Company sales size and EBITDA margin.

Cited and partially edited by METI from Materials 1 of the Vision for the Medical Device Industry Research Group.
Created by the Nomura Research Institute after analysis of 2014 and 2019 financial data for medical device makers (registered in S&P Capital IQ) listed in Japan, the United States, and Europe.

(2)-3) Japanese and Global R&D Trends

In the company interviews, many companies, both Japanese and global, regardless of their main medical departments, expressed that they are emphasizing not only conventional product sales but also a sales strategy of increasing competitive advantage through digitalization and data utilization.

As a representative example, recent advances in IT/AI technology have led to the emergence of software devices that directly affect disease treatment, diagnosis, and prevention of diseases (SaMD), the development race accelerating globally as a new modality for medical and social issues such as unmet medical needs, overwork of medical professionals, and increasing medical costs. Regarding the status of practical applications of SaMD, the SaMD product groups approved in Japan and those produced in the United States do not differ significantly. Furthermore, Japan has put some products into practical use ahead of the rest of the world, so this can be considered an area of competitiveness for Japanese companies in terms of their development. On the other hand, in terms of the number of clinical trial registrations, which is an indicator of the number of SaMD under development,[10] there are 1,006 clinical trials in the United States, 57 in China, and 23 in Japan for mobile apps and 188 in the United States, 204 in China, and 75 in Japan for medical devices using AI technology. This suggests that Japan is lagging when it comes to exploratory technology development for future applications, thereby highlighting the importance of supporting evidence building, including demonstration tests, for the sake of market formation.

[10] ClinicalTrials.gov., UMIN search results (as of July 2023).

To promote exploratory technology development that sows the seeds for medical devices utilizing digital technologies, which are rapidly diversifying, it is important to accelerate the development process from new product conceptualization to proof-of-concept. For example, in the development of medical devices and solutions using AI technology, since medical data is very important, it is necessary to establish data utilization platforms that allow companies to access medical data in a way that satisfies both “various medical data” and “ease of access.” However, in Japan, no such data utilization platform provided by medical data holders exists as a business at this time. Japanese companies and researchers must utilize medical data obtained from Japan’s high healthcare standards as a way to boost the technological development of advanced medical devices and enhance competitiveness.

(3) Creation of Innovation through Collaboration between Japanese Startups and Major Companies

It is often difficult for major companies to conduct speedy R&D of innovative medical devices that are not an extension of their existing products because of the huge risks involved. In fact, especially in Europe and the United States, the development of innovative medical devices often originates from startups (SUs), with the role and presence of SUs in revitalizing the medical device industry increasing significantly. Regarding new medical devices approved in Japan from 2012 to 2022, SUs accounted for 60% of the 90 products originating global, their presence increasing year by year, while approximately 78% of the 23 products originating in Japan were developed by non-SU companies, and the proportion of products developed by SUs was approximately 22%. Meaning the presence of medical device SUs in Japan is limited (Figure 14).

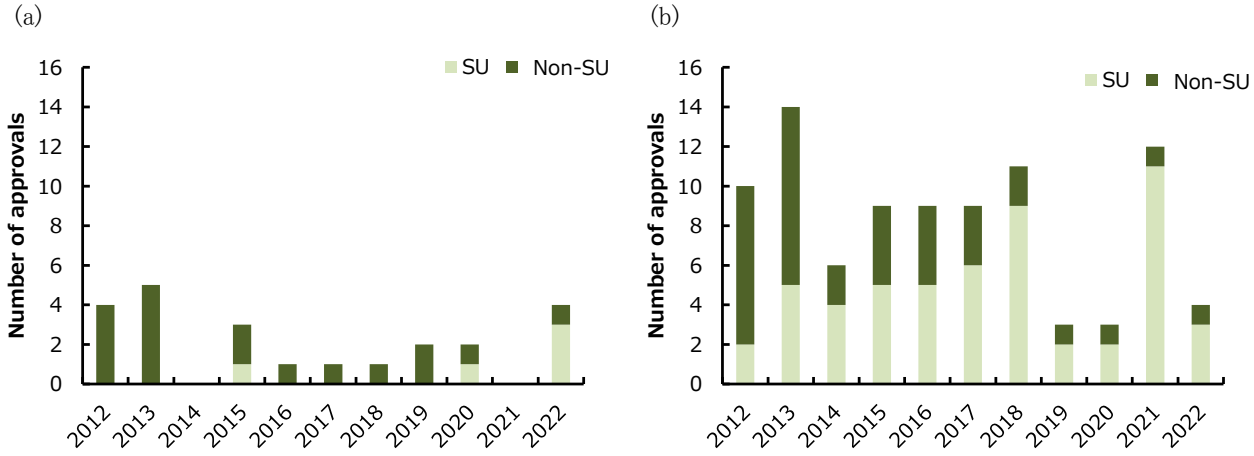

Figure 14. Number of Japanese approvals of new medical devices from (a) Japanese and (b) global companies.

Source: Application overview published on the PMDA website and information from Crunchbase, Pitchbook, and the relevant company websites. Created by METI.
Identifying companies listed as having developed new medical devices approved in 2012-2022 according to the application overview published on the PMDA website.
Identified companies were regarded as SUs if Crunchbase, Pitchbook, or company website reported VC capital procurement.

Moreover, in general, medical device SUs undergo mergers and acquisitions (M&A) in the phase around the time of launch, such as between clinical trials and marketing approval/insurance coverage,

such that major companies are often responsible for sales and post-sales.[11] However, in Japan, there are issues regarding the financing and M&A environments related to development, with few cases going all the way to market development. Regarding the funding environment, while the development of highly novel medical devices requires billions of yen, only a few venture capital companies (VCs) with the required expertise exist, so conducting the evaluations necessary for evidence building is financially difficult. Moreover, the company interviews suggest many cases where major Japanese companies are targeting global SUs for M&A, meaning that their investment in SUs in Japan and activities to develop SUs are limited. A survey of M&A trends among the five top-selling Japanese and global companies showed that Japanese companies engage in few M&A, reaching only approximately 1/5 of the global companies. However, the ratio of SUs to M&A (from the establishment to M&A within 10 years) was 35% and 43% for Japanese and global companies, respectively, meaning that Japanese companies are also engaging in some M&A with SUs (Figure 15). Meanwhile, only two M&As by Japanese companies took place in Japan as most happen global (Figure 16), so cooperation between SUs and existing companies in Japan is limited. The company interviews further revealed that acceleration by existing companies is not happening so much in Japan when compared to global. They also revealed that SUs are seldom used to form strategies for alliances with existing companies and investments from VCs and that Japanese SUs have weak systems of horizontal divisions of labor. Moreover, SUs find it challenging to consider production and costs from the initial stages, with many expressing difficulty in developing an ecosystem that involves contract development and manufacturing organizations (CDMOs), as well as evaluation agencies. Collaboration between Japanese SUs and major companies is regarded as a major issue, through mechanisms such as CDMOs shaping SU technologies in Japan as a whole and mechanisms for brushing up business and intellectual property strategies together with major companies.

Incubation and acceleration are actively carried out by major companies in global. Additionally, in Japan, Johnson & Johnson Innovation co-hosted incubation projects for early seeds, including medical devices, in 2020 and 2022 together with Janssen Research & Development, LLC (from the same Group), Shonan Health Innovation Park, and Takeda Pharmaceutical Company Limited. Moreover, in 2023, for example, in cooperation with the Ministry of Health, Labour and Welfare's Medical Innovation Support Office (MEDISO) project, experts from major companies teamed up with applicants in the selection process to brush up the contents of the proposals from a major company perspective, thus making efforts to promote innovation by SUs, including human resource education.[12] Moreover, in 2023, a business contest aimed at incubating healthcare innovation was held in collaboration with the Johnson & Johnson Japan group. Collaboration between SUs and major companies, not only in the medical device industry but also in other industries, is gradually progressing,

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[11] Japan Agency for Medical Research and Development, Ministry of Economy, Trade and Industry, "Capital Policy Guidance for Medical Device Startups," https://www.med-device.jp/pdf/2022/20220527-2.pdf, March 2022

[12] Japan External Trade Organization, "Success Stories: Johnson & Johnson Innovation," https://www.jetro.go.jp/invest/investment_environment/success_stories/jji.html

but such collaboration is limited especially in the medical device industry, so we deem that countermeasures will be necessary.

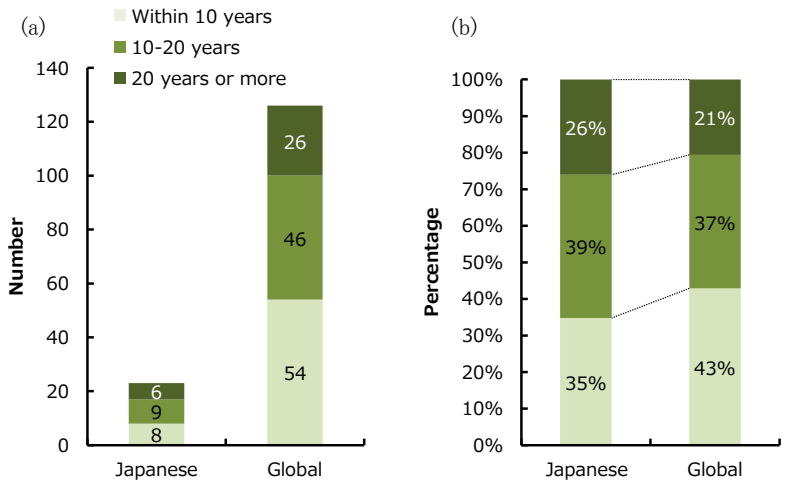

Figure 15. M&A by Japanese and global major companies by years from company founding to M&A: (a) number and (b) percentage.

Source: FY 2018-2022 Crunchbase data on the 5 top-selling among companies specializing in medical devices or related businesses with 85% or more sales.
Created by METI.

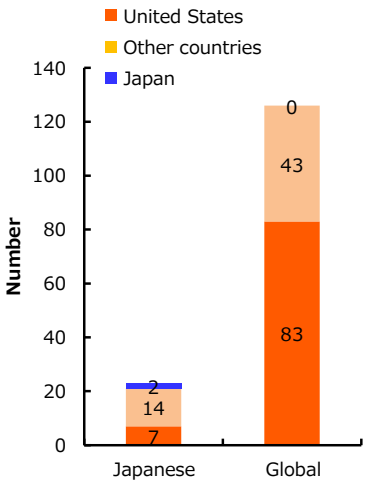

Figure 16. Nationality of companies subject to M&A by Japanese and global major companies.

Source: FY 2018-2022 Crunchbase data on the 5 top-selling among companies specializing in medical devices or related businesses with 85% or more sales.
Created by METI.

3. Vision for the Medical Device Industry

(1) Capturing the Global Market to Support the Growth of the Medical Device Industry

Considering the current circumstances of the medical device industry and changes in the environment, the direction that the medical device industry in Japan should aim for and the direction of necessary industrial support are as follows:

- ✓ Since the growth of the medical device industry in Japan is limited by an industrial structure that is dependent on the Japanese market, which has limited growth, it is necessary to aim for growth by capturing the global market.
- ✓ The US market being the largest in the world is the most important market, so gaining recognition as a standard medical technology in that market will allow us to capture the global market.
- ✓ Until now, the government's support for medical device development has focused on generating innovation and support for practical applications in Japan, but almost no support has been aimed at capturing the global market. The aim is to strategically and intensively invest industrial support resources in the activities necessary for Japanese companies to expand into the United States, creating a cycle of R&D investment to create innovation and returns on investment through global expansion.
- ✓ By creating a positive growth cycle through innovation in medical technology and international expansion, we expect to create an industry that attracts more human resources and funds, as well as makes important contributions to medical care and human health by implementing innovations in Japan and worldwide.

(2) Strategic Initiatives toward Realizing this Vision

[Creating companies that embark on global expansion, including the United States]

(2)-1) Strengthening Competitiveness by Generating Evidence and Supporting Network Building for US Expansion

To break away from the current industrial structure that is dependent on the Japanese market and to aim for growth by capturing the global market, it is important to capture the US market. To this end, we aim to strengthen our product competitiveness by building evidence through clinical trials and such, which is necessary for capturing the US market, and to establish product value globally through our expansion into the US market. Moreover, at each step of medical device research and development, clinical trials, licensing, insurance coverage, and distribution, we will develop products that conform to the unique systems and business practices of the United States through communication and partnerships with appropriate stakeholders, such as local businesses in charge of distribution, clinical

experts, government agencies, insurance companies, relevant academic societies, and standardization organizations. We aim to create an environment where we can formulate a US expansion strategy.

To realize the above, creating many successful examples of US expansion is crucial. Regardless of the company size, we will support companies that have already developed and marketed products in Japan and that have some level of reputation for solving high unmet medical needs and are considering expanding into the United States. We will provide package support aimed at expansion into the US market, utilizing subsidies and other policy tools to support clinical trials and other activities for US expansion that capture that market. Moreover, to support the establishment of networks with appropriate stakeholders, we will promote participation in international conferences and exhibitions, which are important opportunities for collaboration between clinical experts and local businesses. We will also support the building of networks and rules necessary for companies to expand into the United States through collaboration among the Ministry of Health, Labour and Welfare, Japanese embassies in various countries, the Japan External Trade Organization (JETRO), the Japan Agency for Medical Research and Development (AMED, the Pharmaceuticals and Medical Devices Agency (PMDA), and other support organizations with offices in Japan and global.

(2)-2) Improving the Environment and Support for Building Networks That Facilitate Global Expansion

Since capturing the global market further from US expansion is important for the growth of Japanese companies, we aim to strategically develop competitive products and launch them in the global market from the beginning. Moreover, we aim to build human resources and a supportive environment that can lead global clinical research to build evidence for improving product competitiveness. Furthermore, we aim to simplify the acquisition of marketing approval in the destination country, which may be one of the barriers in the process of global expansion, on the premise that it will mutually benefit Japan and the destination country, such as improving medical care in the country concerned.

To realize the above, in addition to governmental support for medical device development, which mainly targets the creation of innovation and practical applications in Japan, development support will be established for the global expansion phase, regardless of the company size. Furthermore, an environment will be created to facilitate access to information on the needs and regulations of global markets from the beginning of development. Moreover, to accumulate and spread experience in the US and to secure human resources to support global expansion, we will train human resources in Japan who can handle competitive evidence building through support for overseas clinical trials, including international joint clinical trials. In addition, to harmonize the regulatory systems of each country, we will work with organizations in these countries in cooperation with the Ministry of Health, Labour and Welfare, Japanese embassies, AMED, JETRO, Medical Excellence Japan (MEJ), and so on, including the use of Official Development Assistance (ODA).

[Establishing an R&D Environment That Fosters Innovation]

(2)-3) Promoting the development of medical devices using AI and other digital technologies

The medical device industry is undergoing a shift from selling physical products to selling services and systems, so securing a competitive advantage using digital technology has become an important strategy worldwide. For this reason, realizing a society that utilizes medical devices with AI and other digital technologies ahead of the rest of the world is necessary. In addition to actively utilizing medical data obtained from the high level of medical care that exists in Japan for the technological development and strengthening of competitiveness of advanced medical devices, we aim to implement them in society and form markets through the demonstration of the medical device value in terms of medical utility and economic efficiency using AI and other digital technologies.

To realize the above, we will promote the development of medical devices using digital technology by building a data utilization platform available to companies for medical device development in a way that satisfies both "various medical data" and "ease of access." Moreover, for products in new fields such as AI-based medical devices and other SaMD, which are expected to grow, we will support demonstration tests to establish value of the product, since establishing value related to therapeutic efficacy and economic efficiency is important for social implementation and market formation.

(2)-4) Strengthening Collaboration with and Acceleration of Startups by Major Companies

SUs play an important role globally as players that create highly novel medical devices and facilitate dramatic industrial growth. The aim is for major companies, VCs, medical institutions, research institutes, and countries to participate as we build a model in which Japanese SUs commercialize innovative ideas from Japan, which has one of the world's highest levels of medical care, with major companies launching them globally.

To realize the above, given that the collaboration between major companies and SUs is currently limited, we will build a place for networking between SUs and major companies. We will also build a place for acceleration by major companies through the Medical Device InCubation platform (MEDIC), the Healthcare Innovation Hub (InnoHub), and other R&D support projects, to supplement medical device SUs' lack of experience in manufacturing, marketing, global expansion, and such, to strengthen their exit strategies, and to promote investments, sales alliances, and M&A with major companies. Moreover, to encourage the supply of risk money in the private sector, we will prioritize support for SUs, where major companies are deeply involved in supporting the development of medical devices in the country.

(Appendix)

Results of Company Interviews on Issues Pertaining to the Medical Device Industry

1. Summary

Interviews were conducted with Japanese medical device companies to survey their initiatives and awareness of issues, as well as to consider support in line with social needs.

Date: September to October 2023

Participants: 45 medical device companies

[Diagnosis, treatment, and technology areas (some overlap)]

Circulatory and thoracic	10	Obsterics and gynecology	1
Respiratory	4	Radiology	8
Neurology and Neurosurgical	5	Homecare medicine	2
Ophthalmological	4	Laboratory medicine	7
Nephrology	6	Consumables	1
Orthopedic	5	Robotics	3
Urology	1	Particle beams, etc.	4
Gastroenterology	8	Digital	4
Psychiatry	1	Other	1
Dental/oral	2		

[By capital]

Japanese: 37 companies Foreign: 8 companies

[By the time of founding]

Major and Small and medium enterprises 40 companies Startups* 5 companies

*Founded within 10 years

2. Interview Results

(1) Assessment of the Japanese market
• The Japanese market is important as the largest market after those in Europe and the United States. The core markets for handling advanced medical devices are the United States, Europe, Japan, and Australia. • Japan is an attractive market for IT products. • Japan **has high-quality medical care. It is also a good market in terms of creating evidence for products and increasing their value and competitiveness.** • Since it is a developed country with issues such as population aging, it is assessed to be suitable for developing and demonstrating new business models and products with a global perspective.

- Japanese quality requirements are high, so **quality that satisfies Japan is good enough for the rest of the world.**
- In addition to the declining population, higher raw material and transportation costs, and yen depreciation, the medical device industry makes it difficult to pass on price increases, which makes **global business growth relatively poor and reduces attractiveness**.
- Compared to global businesses, product prices are evaluated to be low, with subsequent decline as well. There are concerns regarding the risk of investment in the Japanese market, which might decrease investment in the future.
- Despite the growth in volume, sales will decline due to falling prices. The Japanese business is tough and unprofitable, but some products are supplied as a social responsibility.
- Even if the products are sold global, there are no prospects of making a profit in the Japanese market. Consequently, **there are already products that cannot be introduced in Japan**.

(2) Challenges for investment in innovation development

[R&D investment]

- Medical devices take time to develop and **require long-term development investment**.
  * Examples: Endovascular treatment Company A: 7–8 years, Implantation device Company B: 30 years or more
- Since many shareholders are adamant about short-term results, R&D expenses may be subject to cuts depending on sales and other market conditions.
- In the case of innovative medical devices, **clinical trials alone exceed 2–3 billion yen**. One investment criterion is whether the development cost can be recovered within five years* after launch, but the price of medical devices has fallen so much that the **prospect of recovery is poor, making it difficult to invest in the development of new technologies**.
  *Average of businesses that responded
- Even if the product is developed in Japan, the price of a new product will be based on the price of existing products whose prices have decreased, but the cost structure of the new and the existing products is completely different. **We would like to see a system that values innovation.**
- Investment in large-scale clinical trials is difficult, and **financial support for clinical trials is also scarce**.
- It is difficult for businesses based in Japan to **invest in global expansion if they cannot recover a certain amount of investment in Japan**.
- Resources are allocated to stable supply and other legal and regulatory matters, so they are not allocated to new development.

[Development for market acquisition after market launch]

- Especially in the United States, the risk of medical litigation is high, so the more scarce the evidence for an innovative product, the less it will be used. **Accumulation of evidence through**

post-commercialization clinical trials is essential for capturing the global market, but **this requires huge investments** and a large company size.

- **In other countries, there is a lot of government funding for clinical trials**, but in Japan, it is scarce.
- Global companies have marvelous strategies for collaborating with relevant academic societies to create indicators that evaluate the usefulness of their technologies. There are strong strategies to demonstrate efficacy by establishing evidence and increasing competitiveness and value.

[DX strategy]

- There is a limit to the growth of sales of "physical products" such as devices and disposable products. **We need a strategic shift to the sale of "services and systems" through digital technology and solutions**.
- Technological advances are rapid in the digital field, including AI. It is necessary to increase the speed of development through collaboration with SUs, which have technical capabilities and expertise, and through M&A of SUs.
- **To secure competitiveness in the digital domain, it is necessary to secure large volumes of diverse medical data**. Tens of thousands of image data are used during development in the United States, but they cannot be used for development in Japan due to a lack of regulations and platforms.
- **SaMD is important not only for its diagnostic and therapeutic efficacy but also for its medical economic efficacy, yet the evaluation environment is poor**.
- It is necessary to create an environment and support that enable evaluations of the medical economic value.
- Compared to other countries, SaMD regulations in Japan facilitate development and are being developed.
- The inheritance of manufacturing techniques of Japanese artisans who are dexterous with their hands has become a problem, so the challenge lies in improving versatility through the digitalization of manufacturing technology.

(3) Challenges for collaboration with other organizations and strategies after market launch

- Proposals from clinical settings and academia often exhibit a high level of clinical needs/seeds, and although they understand the medical needs, **they are difficult to realize from a business perspective**.
- **In the United States, many researchers have MBAs, and they are actively engaged in joint research because of the environment that facilitates business-focused research. In Japan, we rely on basic research, and business-focused research is not actively conducted because the goals of business operators differ from those of researchers.**
- University medical–engineering collaboration often stops at the point of creating the base of the concept design. **It is necessary to create a place where universities can commercialize their**

results and present them to the world through industry involvement.

- We are actively collaborating with universities both in Japan and global. Medical devices that have been used since school days are often selected global, so it is necessary to consider collaborating with global universities to gain experience in using them at an early stage.

(4) Issues for collaboration with startups

- There is no difference between SUs in Japan and global in terms of SU ideas, so if it fits the development strategy, we would like to collaborate with SUs both in Japan and global.
- It seems that foreign-owned companies have a high demand for new things. It is necessary to create an environment where major Japanese companies can adopt challenging development strategies, including collaboration with new technologies from Japanese SUs.
- In many cases, they do no more than explain their technologies to major operators and VCs, so it seems that **many SUs in Japan are unfamiliar with marketing**. It is important to have a strategy that effectively communicates the information necessary for major operators and VCs to make decisions.
- **Global, major companies may provide accompaniment support and acceleration programs such as business contests to SUs. The challenge lies in creating a similar environment in Japan.**
- In anticipation of global expansion, we **would like to collaborate with SUs that have made some progress in addressing global regulations, but there are few such SUs in Japan.**
- There is an increasing division of labor in global SUs, and environments to outsource manufacturing have been developed. There are environments where proceeding with discussions about prototype production, production location, manufacturing cost, etc., is easy. **Japanese SUs have a weak system of horizontal division of labor, making it difficult to evaluate production and costs. The challenge lies in forming an ecosystem involving CDMOs and evaluation organizations**.

(5) Challenges for logistics and commercial distribution

- It is necessary to transport the products and surgical instruments required for each surgery to the medical institution, which is costly. It is necessary to implement measures that address logistics costs and efficiency.
- To provide SaMD to medical institutions, it is necessary to build a platform that can be used in collaboration with other companies.
- For digital devices, the system on the medical device side should be connected to electronic medical records as a way to improve workflow efficiency, etc., but ensuring such a connection is difficult.

(6) Challenges for global expansion

- Due to differences in the medical environment, culture, race, etc., **Japanese and global needs differ in many cases.**
- **The required evaluations and needed control groups may differ between Japan and global, thus necessitating renewed trials during global expansion.**
- **From the early stages of development, it is necessary to build an environment where needs and regulations can be checked in anticipation of global expansion.**
- Resources are allocated to meet the detailed regulatory requirements of Europe, China, the United States, ASEAN, and other countries. **We would like to see expanded mechanisms for exempting products from applications in other countries when marketing approval has been obtained in Japan.**
- Having to comply with the regulations of each country, some regions have introduced outdated products instead of the latest ones.
- In the case of global introduction of technologies that do not already exist, negotiations with a large number of insurance companies are necessary in countries where private insurance is the mainstream, so there are significant hurdles for those who lack the expertise.
- The medical device industry is not new, and each country has its own established sales channels for medical institutions. **It takes time and cost for Japanese companies to develop new sales channels. Partnership strategies with local businesses are also important.**
- It is necessary to establish a base for the continuous follow-up of medical equipment global (repair and maintenance, information sharing with doctors, and feedback on development), training in the medical field, rental of auxiliary equipment, etc., which requires a large investment.
- Although Asia is a market that cannot be skipped in the future, challenges such as the tapering off of sales when countries put themselves first and the difficulties of maintaining supply chains persist.

(8) Challenges for Japanese regulations and systems

[Insurance system]

- **There is an upper limit to the funds that medical institutions can spend on medical equipment, depending on the number of insurance points. The prices of parts and materials are soaring, but generating profits is difficult because those costs cannot be passed on.**
- The reimbursement price of a new product will be the same as that of an existing similar product, but the cost of development and other costs will be highly different. **For the insurance system, we would like to request that innovation be appreciated.**
- In the United States, value-based care can be used to commercialize the digital field. If Japan does not change its insurance system, there will be no digital development.

[Regulations of medical devices]

- Japanese marketing approval standards differ from global standards. When trying to develop a product from Japan in the United States, the FDA's standards were stricter than those in Japan, so it had to be re-evaluated from scratch. **Harmonization of global standards is necessary**.
- Since test data that can be used global are not accepted in Japan, and data that are not required global are required in Japan, few applications make it to Japan.
- **The cost of introducing something to the Japanese market, including regulatory approval, is too high, thus making it a low priority**. Selling it in Europe appears to be a better option.

(9) Challenges for government support projects

- Challenging research and development of medical devices takes a long time, but **government support requires short-term results. Support with a long-term perspective is required**.
- To increase R&D investment by businesses, **we would like the government to support early development for the sake of risk sharing since prospects for commercialization are uncertain at that point**.
- **Even large companies doing business in various industries often have small divisions that handle medical devices**, but they are treated as large companies and cannot receive government support. It is necessary to provide support that can be used based on the actual circumstances of the department that handles medical devices, not the whole company's capital.
- Medical SUs begin in the red ahead, so business is tough even after listing, and continuous development is necessary to capture the market. Global, you can receive support from the government even after listing in many cases, but **in Japan, often pre-listing support is provided, so providing support after listing is important as well**.

(10) Challenges for securing human resources

- **There is a shortage of human resources in regulatory affairs and engineering**, and the current situation is such that "there are many things that we want to do, but there is no one who can do them." The development of human resources is a challenge.
- **Regulatory science personnel are important**. Networks can also be built by creating an environment where students can learn and where employees from other companies and universities are also present. Such efforts are necessary for company systems. We would be grateful if there was support for human resource development.
- For researchers in academia to start a company, gathering the necessary human resources is essential to ensuring company management, including accounting and sales. **Networking with the right entrepreneurs is a challenge**.
- There are few IT personnel in medical institutions, so they rely on companies for product maintenance and inspection. Vendor locks, high costs, and obstructed standardization are contributing factors. **Is it not necessary to have a system for letting IT take root, such as**

allocating human resources to promote DX in the management of medical institutions?