

Revitalizing Japan's biomedical ecosystem: Policy initiatives, challenges, and future directions

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SUMMARY: Japan's international competitiveness in biomedical innovation is declining, as evidenced by its expanding trade deficit in pharmaceuticals. One reason for this is that the ecosystem connecting academic research outcomes to startups and new businesses, and promoting commercialization and industrial applications is not functioning adequately. Recently, the Japanese government has implemented policy measures to revitalize biomedical ecosystems. This study reviews the current state and characteristics of the biomedical ecosystems in Japan. Several biomedical ecosystems, both with and without geographic concentration, have been established and operated over the past 25 years, most of which are relatively small-scale and driven by governments. Recently, the Japanese government has aimed to form larger biocommunities, including biomedical innovations, to expand the bioeconomy. This study discusses these policy initiatives and their associated challenges. Furthermore, it outlines recent government initiatives to strengthen the drug discovery ecosystem, which focuses on attracting talent, companies, and new drug developers from overseas. Based on these analyses, this study addresses the challenges faced by Japan's biomedical ecosystem and discusses future directions.

Keywords: Bio-cluster, policy measure, biocommunity, Japanese government, drug discovery

1. Introduction

Japan's international competitiveness in biomedical innovation remains low. Particularly in pharmaceuticals, the trade deficit reached 4.6 trillion yen in 2022, highlighting the strong need to enhance drug discovery capabilities (1). One reason for this is the limited number of promising biomedical startups in Japan (2). Biomedical innovation relies heavily on basic academic research (3). Furthermore, this requires considerable time and costs, as evidenced by the development of new drugs (4,5). Consequently, startups, primarily university spin-offs that employ academic research achievements and investment money to support long-term risky research and development (R&D), have significantly contributed to biomedical innovations (6). However, Japan's startups are relatively inactive, which is believed to have contributed to the country's international lag in the biomedical field, particularly in pharmaceuticals (2). Recently, the number of startups involved in drug discovery has increased globally (7,8), making the maturation of the startup ecosystem and the nurturing of promising startups an urgent issue for Japan. It is well known that scientific and technological innovations often emerge from geographically

proximate clusters of stakeholders, including research institutions, startups, existing companies, manufacturing companies, and venture capitalists (9). In the U.S., biomedical clusters such as those in Boston and the Bay Area have significantly contributed to innovations in the life sciences sector (3). Therefore, enhancing the biomedical ecosystem is crucial to strengthen Japan's competitiveness in this sector. This review summarizes current examples and the status of Japan's biomedical ecosystems. Moreover, it outlines the recent government measures aimed at cluster formation to strengthen the ecosystem. Particularly regarding drug discovery, the government has recently introduced policy measures to enhance the ecosystem, which this literature also summarizes. Based on these insights, the literature aims to provide an overview of the current status and challenges of Japan's biomedical ecosystems and discuss future directions.

2. Biomedical ecosystem in Japan

In Japan, clusters of concentrated biotechnology-related institutions and companies have been established since the birth of the KOBE Biomedical Innovation Cluster in 1998. Representative Japanese bio-clusters are presented

in Table 1. The size of each cluster is smaller than those of Boston and the Bay Area. In the life science cluster in Boston, 116,000 people are employed, and over 1,700 companies and organizations are concentrated (10). In comparison, Japan's largest bio-cluster, the KOBE Biomedical Innovation Cluster, has 12,700 employees from 363 companies and organizations, whereas KING SKYFRONT employs 5,200 people from 70 companies and organizations (Table 1). Most of these clusters were created under the leadership of national and local governments, with Shonan Health Innovation Park being the only one established by private-sector initiatives. In contrast, ecosystems were autonomously formed in Boston and the Bay Area, with universities, private venture capital, and pharmaceutical companies playing

central roles (11). Even if the framework of an ecosystem is publicly established by the governments, it will not be effective unless stakeholders such as universities and research institutions, entrepreneurs and startups, incumbent companies, venture capitalists, and supporting institutions develop spontaneous incentives and motivation. In this context, market-oriented clusters, such as those in the U.S., demonstrate particular strengths when compared to government-led clusters — especially in terms of decision-making speed and clarity of profit distribution. For example, in Boston, venture capitalists with deep expertise in cutting-edge biotechnology have been investing in biotech startups from their early stages, leveraging their ability to assess technological potential (12). In some cases, they even take the lead in

Table 1. Representative biomedical ecosystems in Japan

Name	Promoter	Year established	Summary
Geographically clustered ecosystem			
KOBE Biomedical Innovation Cluster	Kobe City	1998	Japan's largest biomedical cluster where universities, research institutes, companies, and specialized hospitals are concentrated. They pursue innovative collaboration and groundbreaking discoveries in medical, pharmaceutical, and biomedical fields, where 12700 people and 363 member and partner companies/institutions are working (24).
Tsuruoka Science Park	Yamagata Prefecture, Tsuruoka City	1999	Established through alliance between Keio University's Institute of Advanced Biosciences and cities in Yamagata prefecture. Advanced biotechnology research has been conducted, resulting in the birth of startups. Twenty-two organizations including research institutes, large companies, startups and related companies are working (25).
KING SKYFRONT	MEXT*, Kawasaki City	2011	Created as an open innovation hub that creates new industry from the world's highest standard R&D in life science and environment fields, where 5200 people and 70 institutions are working (26).
Shonan Health Innovation Park	Takeda Pharmaceutical	2018	Established by Takeda Pharmaceutical company to open its then in-house research center to outside organizations. It aims at the place where industry, government, and academia gather and accelerate health innovation. In all, 2500 people and 150 companies including pharmaceutical companies, next-generation medicine, cell agriculture, AI, government, and other fields are working (27).
Nakanoshima Qross	Osaka Prefecture, Osaka City	2019	Established by 21 private companies and Osaka prefecture as the international center for future medicine. They aim to create, practice, and share future medicines such as regenerative medicines. The main building was opened in June, 2024 (28).
Ecosystems without geographical concentration			
DSANJ**	Osaka Chamber Commerce and Industry	2005	A program that collects research seeds for drug discovery and related technologies, biomarkers, diagnostic agents and reagents from Japanese academic scholars and matches them with pharmaceutical companies (29).
LINK-J	Mitsui Fudosan	2016	Established to create platforms where people and information are exchanged and promote new life science industries (30).
The iD3 Booster	AMED***	2017	A program for accelerating the translation of promising basic research into innovative new medicines. It aims at providing drug discovery knowledge, resource for necessary experiments, and funds to basic research scientists who aim at drug discovery (31).

*MEXT: Ministry of Education, Culture, Sports, Science and Technology; **DSANJ: Drug Seeds Alliance Network Japan; ***AMED: Japan Agency for Medical Research and Development.

founding new ventures based on promising technologies (13). Established pharmaceutical companies also make substantial early investments in high-potential startups to secure future profits (14). In contrast, clusters led by governments or local authorities tend to be slower in making investment decisions. They also often lack strong intermediary functions that connect startups with private venture capital or pharmaceutical firms, and the distribution of potential profits tends to be more ambiguous. While public-sector initiatives have helped build the foundational structures of regional clusters, fostering dynamic and self-sustaining collaboration among diverse stakeholders remains a critical hurdle. Strengthening these organic linkages — particularly those that bridge academia, startups, and industry — will be essential for Japan to fully realize the potential of its biomedical innovation ecosystem.

The scope of business areas varies depending on each Japanese bio-cluster. The KOBE Biomedical Innovation Cluster targets a wide range of life science businesses, including healthcare delivery, the development of new treatments, disease prediction and prevention, and the creation of new industries in the medical and health fields. Although the Shonan Health Innovation Park primarily focuses on R&D in pharmaceuticals and advanced medical care, it also hosts companies and organizations related to research equipment, medical devices, and non-medical fields, such as agriculture, artificial intelligence (AI), Internet of Things, and robotics. KING SKYFRONT in Kawasaki covers a broad range of business areas, including health, medical care, welfare, and the environment. However, during the nine years from 2013, the Center of Open Innovation Network for Smart health (COINS) project was conducted in KING SKYFRONT and it focused on six research themes under the concept of "In-Body Hospitals" (15). This project led to the creation of nine startups and received the highest ratings of S+ in the government's post-project evaluation (16). Nakanoshima Qross focuses on regenerative medicines. A focused approach that leverages the research strengths of institutions and companies concentrated within a cluster, as observed in the example of the COINS project, appears effective. However, when exploring business opportunities, it is also necessary to pursue the potential across a wide range of fields. An approach that effectively enhances the productivity of these bio-clusters should be closely monitored.

Efforts have also been made to form ecosystems without geographic concentrations (Table 1). A pioneering initiative by DSANJ that primarily aimed to connect academia and pharmaceutical companies for drug discovery was later taken over by The Japan Agency for Medical Research and Development (AMED) and evolved into the Innovative Drug Discovery and Development (iD3) Booster program, which not only facilitates connections but also promotes practical

academia-driven drug discovery in collaboration with the private sector (17). The iD3 Booster program is a unique initiative that provides knowledge and strategies to academic scholars aiming at drug discovery and makes actual research resources available to academic scholars by linking public research institutions and private companies under the government's leadership. This program is expected to contribute to uncovering drug discovery seeds at universities and promote their applied development.

3. Government-certified biocommunity

Recently, the Japanese government has promoted the formation of larger-scale biocommunities. The Japanese government developed and implemented Bio-strategy in 2020, followed by the amendment as Bioeconomy Strategy in 2024 (18,19). This strategy aims to resolve environmental, food, health and other issues and achieve a circular economy and sustainable economic growth by using biotechnology and biomass, covering various biotechnology fields, including biomedical innovations such as biopharmaceuticals, regenerative medicine, cell therapy, gene therapy, and digital health (19). In this strategy, the importance of establishing bio-research and technology hubs and stakeholder networks has been discussed with reference to the examples in Boston and London, concluding with the promotion of community formation aimed at expanding the bioeconomy (20). The envisioned biocommunity in the strategy aims to function as a hub for bio-innovation, with R&D institutions, startups, incumbent companies, incubation facilities, investment funds, core hospitals, and biomanufacturing organizations concentrated and networked together (20). With this direction, a public call for biocommunity was launched in 2021. Consequently, the Cabinet Office certified two global biocommunities and six local biocommunities, and registered two incubating biocommunities for further development (Table 2). Global biocommunities are expected to function as catalysts by promoting collaboration between state-of-the-art R&D organizations and related companies and institutions, thereby enhancing access to global data, human resources, investment, and research. Their goal is to become the world's most advanced developmental base in the field of biotechnology. Local biocommunities aim to expand collaboration among local companies, business entities, and universities; lead forays into the global market; and stimulate the revitalization of the regional economy (18).

These approaches are not efforts to create entirely new biocommunities but rather initiatives to strengthen collaboration between existing organizations. Greater Tokyo Biocommunity connects eight areas around Tokyo (Tsukuba, Kashiwanoha, Hongo/Ochanomizu/Tokyo Station, Nihonbashi, Kawasaki, Yokohama, Shonan, Chiba/Kazusa) as a bio-innovation hub and

Table 2. Biocommunities certified and registered by the Cabinet Office of Japan**Global Biocommunities (certified)**

Greater Tokyo Biocommunity
Bio Community Kansai

Regional Biotech Communities (certified)

Hokkaido Prime Bio Community
Tsuruoka Bio Community
Nagaoka Bio Community
Hiroshima Bio DX Community
Fukuoka Bio Community
Okinawa Bio Community

Incubating Biocommunities (registered)

Tokai Biocommunity
Gunma Green Innovation Platform

Extracted from Reference (32).

aims at becoming the world's premier innovation center by strengthening research collaboration, startup development, investment in manufacturing facilities, infrastructure, international recognition, and foreign investment. In these eight areas, various institutions are involved in biotechnology-related research, development, manufacturing, and supporting functions. Biocommunity Kansai aims to realize a cutting-edge bioeconomy society by forming an open network among biotechnology-related companies, research institutes, banks, funds, academia, public administrations, and business associations in the Kansai area. This biocommunity leverages existing clusters, such as Doshomachi in Osaka, which thrived as a "town of medicine"; Kyoto, a world leader in induced pluripotent stem cells and cancer immunotherapy; Kobe, known for its base in advanced medical technology; and Nada and Fushimi, which have flourished through fermentation.

Enhancing communication among geographically close R&D institutions is important to generate further synergy. However, the extent of impact that can be expected from promoting collaborations through policies among institutions that have already been operating in proximity is unclear. If sufficient synergy has not yet been achieved despite geographical proximity, it is crucial to thoroughly examine the causes of the lack of collaborations and implement effective solutions to achieve meaningful results.

4. Recent policy initiative to facilitate drug discovery ecosystem

The Cabinet Secretariat decided to establish the "Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities" (hereinafter, the Council) on December 26, 2023. The Council aims to ensure access to pharmaceuticals and strengthen drug discovery capabilities (21). The Council was held five times between December 27, 2023, and May 22, 2024, resulting in an interim report. Strategic

goals and action plans were established to implement the recommendations from an interim report. The action plans included timelines and key performance indicators (KPIs). On July 30, 2024, the government hosted the Drug Discovery Ecosystem Summit, inviting approximately 20 pharmaceutical companies and related organizations from Japan and abroad to present this strategic goals and action plans (21).

The interim report decided three strategic goals, such as "Prompt delivery of novel drugs to patients," "Become one of the world's leading drug discovery sites," and "Cyclically develop investment and innovation," and measures to achieve these goals. The measures were categorized as follows; 1. Strengthen Japan's Drug Discovery Capabilities; 2. Prompt Delivery of Novel Drugs to Patients; and 3. Construction of a Social System that Allows Continued Cyclical Development of Investment and Innovation. Four, three, and three policy measures were proposed for each category, respectively, and further detailed items were included in each policy measure. Timelines and KPIs up to the year 2028 were set for each measure (22). The strategic goals, categories, and policy measures are summarized in Table 3.

Initiatives of the Japanese government have focused on ecosystem development. As reported in Section 2, regional cluster development and network formation for biomedical innovation have been conducted over the past 25 years in Japan. Nevertheless, biomedical startups have not been sufficiently nurtured and international competitiveness in pharmaceuticals has decreased in Japan (2). Considering this, the government's efforts to strengthen the drug discovery ecosystem through specific measures are commendable. Not only creating clusters and forming networks, but also effectively functioning the ecosystem has become important. This initiative is expected to have a positive impact. In Boston and San Francisco Bay Area, several factors contribute to the success of their biomedical clusters. One key element is the robust framework for industry-academia collaboration. For example, institutions like Massachusetts Institute of Technology and Stanford University have dedicated offices and funding programs to support technology transfer and commercialization (23). Furthermore, the presence of a mature venture capital ecosystem, with well-established exit channels through initial public offerings and merger & acquisition, creates strong incentives for innovation and entrepreneurship. The flexibility of the U.S. patent system, particularly under the Bayh-Dole Act, also enables universities to retain intellectual property rights and license them effectively, facilitating knowledge spillover and commercialization (23). These insights highlight the importance for Japan to pursue a more holistic strategy, fostering dynamic interactions between universities, startups, investors, and public agencies to ensure its ecosystems function effectively.

Table 3. Three strategic goals and policy measures proposed by the Council**Strategic goals**

Prompt delivery of novel drugs to patients
 Become one of the world's leading drug discovery sites
 Cyclically develop investment and innovation

Policy measures*1. Strengthen Japan's Drug Discovery Capabilities*

Proactively recruit and utilize human resources with foreign experience and commercialization know-how, together with funding, chiefly through the public-private council

System for conducting international-level clinical trials and studies

Domestic manufacturing system for new modality drugs

Continuous generation and development of drug discovery seeds in academia and startups

2. Prompt Delivery of Novel Drugs to Patients

Review of pharmaceutical regulations, etc.

Promotion of the development of drugs for children, intractable diseases, and rare diseases

PMDA's consultation/review system

3. Construction of a Social System that Allows Continued Cyclical Development of Investment and Innovation

Appropriate evaluation of the value of innovative drugs, departure from dependence on long-listed products, etc.

Promotion of self-care and self-medication by supporting the switch to over-the-counter (OTC) drugs, etc.

Promote the use of biosimilars and utilize private insurance in addition to public insurance for new technologies

Extracted from Reference (22).

In this initiative, not only are the strategic goals clearly outlined, but concrete action plans have also been presented with timelines and KPIs to achieve these goals. This bold proposal demonstrates a serious commitment toward realizing it. A future challenge will be to determine the effectiveness of this method. The timeline of the action plans spans five years, ending in 2028; however, it is essential to monitor KPI achievements along the way and adjust the plan as required. Careful and responsive action is crucial to ensure success.

The unique aspect of this initiative is its ambitious focus on attracting accelerator talent, companies, and new drug development projects from overseas. The challenge in this proposal is to secure talent from abroad. It would be difficult for someone with limited Japanese proficiency to make efforts to understand Japanese pharmaceutical regulations and interact with the authorities. Moreover, understanding and practicing Japan's unique business customs, such as an emphasis on teamwork and high-context communication, are essential. Considering the language, compensation, and cultural barriers, it is questionable how many overseas professionals are willing to relocate to Japan to serve as accelerators. Instead, the development of domestic talent should be emphasized. Japan has traditionally relied on large pharmaceutical companies to lead drug discovery and development, and it is likely that many individuals with extensive R&D experience in these companies possess the potential to serve as accelerator talent in startups. In addition, enhancing the attractiveness of the Japanese pharmaceutical market and increasing incentives for foreign companies to develop new drugs in Japan are crucial. Thus, efforts to attract foreign talent should be considered alongside measures such as fair drug pricing systems and the simplification and acceleration of approval processes.

5. Conclusions

In Japan, the establishment of bio-clusters has been driven primarily by the government over the past 25 years. Efforts have also been made to form networks without geographic concentration and support academic drug discovery. However, it is difficult to ascertain whether these ecosystems have successfully nurtured startups and generated significant bio-innovations. Recently, the Japanese government has aimed to form larger-scale biocommunities by connecting existing research, development, and manufacturing institutions. Specific policies have been introduced to build drug discovery ecosystems that focus on attracting foreign talent and capital. Building an ecosystem requires time and an alignment with the interests of all stakeholders, necessitating long-term efforts. For the Japanese biomedical ecosystem to generate sufficient achievements, a self-sustaining and positive cycle within the ecosystem must be established. The steady achievement of the action plans set by the government and ongoing efforts to strengthen the ecosystem are highly anticipated.

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