Provisional Translation

Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities

Interim Report

-Establish a top-level drug discovery site that contributes to the health of people worldwide-

General Remarks

(Recognition of Current Situation)

○ Japan is one of the few countries capable of drug discovery that have produced many new drugs for use globally. This was realized by the combined efforts of all concerned parties, such as academia, medical institutions conducting clinical research, and a pharmaceutical industry centering on pharmaceutical companies, and Japan can boast of it to the world.[1]

○ It is extremely important for Japan to maintain its “drug discovery capabilities” in the future to meet the wishes of patients and their families waiting for new drugs in Japan as well as to grow its economy, based on the industry that creates innovation with high added value.

○ Based on this understanding, the government established the Japan Agency for Medical Research and Development (AMED) in 2015 to provide funds for basic as well as translational research and to promote comprehensive and effective research in the medical field, and numerous achievements have been made so far.

○ In addition, the Ministry of Health, Labour and Welfare has been developing and promoting a more transparent environment for drug discovery by shortening the review period for the approval of drugs, setting and clarifying rules for the

[1] One example of a world-class new drug that has been developed by the researchers of a Japanese pharmaceutical company is a statin (brand name: Mevalotin).
In addition, the anti-PD-1 antibody drug (brand name: Opdivo) is an example of a world-class drug that a Japanese company researched and developed based on epoch-making research by Japanese academia.
Furthermore, Leqembi (brand name), a drug approved for the first time in Japan as a drug that works on the cause of Alzheimer's disease and suppresses the progression of the disease, is an example of a drug that a Japanese pharmaceutical company has succeeded in developing using foreign seed capital.

introduction of insurance, etc., and it has been effective in resolving the so-called drug lag problem, in which new drugs cannot reach the public.[2]

○ While these various efforts have been made so far, the fundamental premise of top-selling new drugs has shifted from small molecular levels to new modality drugs, such as biologics, regenerative cellular medicine, and genetic therapy. Additionally, drug discovery methods such as AI drug discovery and genomic drug discovery have been developed owing to advances in information engineering and conversion science. They combine drug discovery science with information science and humanities. Under these circumstances, opinions that suggest a decrease in the international competitiveness of Japan's pharmaceutical industry and new problems of drug lag and loss have emerged.[3]

○ To this end, it is important for Japan to develop a comprehensive vision involving industry, government, and academia, from a broad perspective, and to promote mid- and long-term measures based on this vision. It should widely consider the latest status of drug discovery around the world and include an analysis of structural issues and the direction of responses as well as of the flow of international investment funds regarding the "drug discovery capabilities" of Japan. In addition, the government should regard the overall pharmaceutical and medical industries as an important growing industry that can utilize the science and technology capabilities of Japan and strongly promote policies for it as one of the core industries responsible for the future growth of Japan.

(Strategic Goals)

○ Based on these perceptions, we set the general direction for the steps we should take to strengthen our drug discovery capabilities and the reasons for them and set it as a strategic goal. The key for these strategic goals is whether policies can be implemented and results can be achieved. Therefore, it is important to set an appropriate performance indicator (Key Performance Indicator: KPI), evaluate the achievement status continuously, and review measures accordingly.

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[2] ・Result of shortening the review period in Japan (The target review period has been clarified, resulting in approval normally being granted within one year of the application).
・The speed and predictability of the listing process for inclusion in Japan's health insurance coverage are high when compared to the other major countries (In principle, it will be listed for public insurance coverage for almost all citizens within 60 days of regulatory approval or within 90 days at the latest).
・Past performance related to shortening of drug lag (2006: 2.4 years → 2022: 0.4 years)

[3] ◎The drug discovery capabilities of Japan are decreasing, and the major cause is thought to be a delay in developing new modality drugs such as biopharmaceuticals. (Member: Mano)
◎ The decline in the competitiveness of Japan's pharmaceutical industry is similar to the critical situation in the semiconductor industry. (Member: Masato Iwasaki)

- **First, we should aim to swiftly deliver the novel drugs to meet the expectations of all patients seeking treatment, such as by shedding a light on areas such as rare diseases, which have few patients and a lack of therapeutic drugs.** Many drugs that have drug lag/drug loss issues are less profitable pediatric drugs and orphan drugs. We will promote measures to promptly deliver the novel drugs, including these, to the public.

- **Second, Japan should aim to become a global leader in drug discovery.** Improvement of drug discovery capabilities is directly related to protecting the health of the people. Therefore, it is also important from the viewpoint of Japan's health and economic security. We will build an environment/system in Japan that can continuously support academia and startup companies from the early stages of research and development to the stage of clinical application. We will work globally, gather excellent human resources and funds from Japan and overseas, and make Japan the "land of drug discovery" that can contribute to people worldwide, not just in Asia. In other words, the strategic goal is "the second opening of Japan to the world" in drug discovery, and it is a goal that we should convey to the world.

- **Third, we should aim to create a social system in which the activation of this R&D can produce results and lead to the next generation of investments, enabling the continued cycle of investments and innovations.** We should create star scientists by improving the research environment and developing human resources that include young researchers in academia. Moreover, we should achieve a virtuous cycle of concentration and re-investment of funds with them as the core by reshaping the pharmaceutical industry's structure and improving the investment environment. Moreover, we will need to simultaneously promote well-balanced measures from a mid- to long-term perspective by considering the positioning of common treatment for self-care while promoting innovation.

Specific Remarks

1. Strengthen Drug Discovery Capabilities

(What are Drug Discovery Capabilities?)

○ Drug discovery capabilities encompass a wide range of R&D capabilities in the country, ranging from basic and applied research to nonclinical studies[4] and clinical research. The manufacturing capability of candidate substances and investigational products in the R&D implementation period is also important, especially for new modality drugs. In addition to these, the impact of social systems and regulations cannot be ignored, because a new drug is difficult to use unless the country has a certain level of economic power and a well-organized public medical security system and because a highly competent review agency is required. The whole country needs human resources with multi-disciplinary specialties, and the private sector also needs a wide range of related industries that can support and implement activities from the early stages of research to the launch. In other words, the field of drug discovery capabilities is one in which the nation's comprehensive power is being tested.[5, 6]

(The Necessity to Analyze Issues in Strengthening Drug Discovery Capabilities)

○ Drug discovery capabilities need all these factors, which may be the reason drug discovery can be carried out in only a few countries worldwide. Although research is widely conducted in the world, there are few development centers worldwide. [7]In view of the current situation in which Japan's superiority is declining, it is necessary to discuss the areas in which there are issues and how to address them in order to strengthen the drug discovery capabilities in Japan by deconstructing them and rebuilding each element.

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[4] Although it has been called a preclinical study because it is conducted to ensure safety before clinical research in humans, it is generally called a nonclinical study at present. Therefore, it is hereinafter referred to as a nonclinical study in this report.

[5] The steps preceding the administration of a drug to humans comprise nonclinical studies to first confirm its safety (safety studies in animals, etc.), a first-in-human (FIH) study, and subsequent large-scale clinical studies in actual patients. The data of these studies are then reviewed by the government.

[6] Although the United States is an atypical country where the public health insurance system does not cover all citizens, it has advanced private insurance, and therefore, it provides a conducive environment for research on expensive drugs.

[7] ◎A successful drug discovery ecosystem in any country has five common denominators: 1) world-class collective academia, 2) medical institutions and systems that can support advanced clinical development, 3) abundant risks funds, 4) an exchange community to accumulate human resources and knowledge, and 5) use of overseas resources. Japan should also learn from the strategies adopted by other countries, such as specializing in the field and dispatching and inviting excellent human resources. (Person of Reference: Yanagimoto)

(Challenges Arising from the Paradigm Shift in Drug Discovery)

- The current problems are strongly influenced by the fact that, based on genome-level research, development using technologies that are completely different from those in conventional drug development (new modality drugs) has become mainstream. This includes biomedicine, regenerative and cellular medicine, gene therapy, and integrationa with other fields such as AI discovery, genomic drug discovery, and computational science. Based on this, the Council of the Concept repeatedly discussed where the long process of drug discovery is obstructed and why benefits cannot reach patients.

(Drug Discovery Model and Ecosystem in the US, etc.)

- Academia and start-ups are leading the creation of new modality drugs in the US and other countries, and the horizontal type of drug discovery model in which various stakeholders, such as pharmaceutical companies, academia, startup companies, venture capitals (VCs), and drug contract development and manufacturing organizations (CDMOs), collaborate with each other, is the mainstream.

- To support such a drug discovery model, for example, the needs of the pharmaceutical industry and knowledge of clinical application are shared among various stakeholders in the United States from the early stages of research and development, with the effect of personnel flow. Moreover, a nurturing environment has been created for academia and startup companies, with consistent support being provided like the “passing of a baton” until the clinical application. Specifically, various acceleration and incubation programs are provided by industry, academia, and the government to create startups and increase the success rate. Additionally, development programs for new concepts, such as the company creation model by VCs, are producing results. In addition, a clinical study environment has been set up in which large-scale clinical studies of innovative drug candidates can be conducted, and plenty of CDMOs are present to support the manufacturing and development of drugs including candidate substances and investigational products for the implementation of R&D. Consequently, the drug discovery ecosystem is prepared for the research, development, manufacturing, and marketing of drugs. This type of drug discovery ecosystem is attracting people and companies from around the world, leading to the further improvement of drug discovery capabilities.

(What Japan's Drug Discovery Ecosystem Lacks)

- During comparison, the following points were highlighted: In Japan specifically, parts of the value chain are currently inadequate. In particular, there is no CDMO that can support the research of new modality drugs by startups, etc. This hindrance prevents research and development from proceeding beyond the manufacturing stage of investigational products in the pre-development stage. Additionally, Japan is

significantly dependent on foreign countries for the manufacture of raw materials, intermediates, and active pharmaceutical ingredients (APIs).[8]

○ In addition, despite being in an era when startups play a significant role in drug discovery worldwide, the number of drug discovery startups in Japan is small, and their scale is much smaller than those in Europe and the US. Furthermore, it has been pointed out that the support functions to provide such startups with external support (incubation and acceleration functions) are largely behind those abroad in terms of funds, human resources, and development capacity.[9]

○ Japan needs to work strategically and effectively to realize the drug discovery ecosystem in order to solve these problems (to maintain such a cycle in which all the relevant functions work together on research, development, commercialization, and investment recovery, leading to a movement of funds and human resources toward the next investment for drug discovery and maintaining the virtuous cycle of drug discovery). This requires the development and enhancement of all personnel, related industries, clinical functions, etc., that constitute this ecosystem. Therefore, comprehensive and realistic measures that are suitable for Japan must be taken, based on the international perspective with reference to the comprehensive

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[8] ◎Parts of the drug discovery value chain are inadequate. In particular, it may be necessary to consider CDMOs as a target for national strategic investment. (Member: Masato Iwasaki)
◎ Japan lacks the technology to produce the drug substances for the drug discovery of biomodality drugs, and I do not think the solution is as simple as CDMOs being established. (Member: Masaru Iwasaki)
◎ Drugs with new modality drugs, such as regenerative cell therapy and gene therapy, account for a large proportion of the total drug loss. Currently, drug loss is high in the area of rare diseases, but it is expected to increase and spread to the area of cancer, etc., in the future. (Member: Fujiwara)

[9] ◎I think the government should take the lead in creating incubation functions, the core of the Japanese drug discovery ecosystem. For the functions lacking in Japan, such as VCs and accelerators, is it necessary to source organizations and human resources from overseas? (Member: Nagai)
◎ AMED provides support from the basic research stage to the early stage of drug discovery, but the number of human resources to provide hands-on support for drug discovery is insufficient, as is the scale of the budget. It is difficult to continue providing support from nonclinical to clinical development. (Members Masaru Iwasaki/Nagai)

strategies of other countries with developed drug discovery ecosystems, such as the US and the UK.[10]

(For the Creation of a Drug Discovery Ecosystem in Japan)

○ In terms of the cycle of drug discovery in Japan, challenges in the era of new modality drugs have arisen outside the purview of research support, pharmaceutical review, and insurance listing, which Japan has focused on to solve challenges. Therefore, the need for new measures is obvious. Specifically, there are gaps in the following stages: the function of formulation support at the stage of administration to humans, implementation of nonclinical and human clinical studies at the international levels, and preparation of data to verify the effects when providing to companies. Measures need to be taken to ensure that these are “bridged” successfully.[11]

○ The gaps can be “bridged” by enhancing, in the research by academia that is the upstream of drug discovery, the basic research that can be sources to prevent the “depletion of drug discovery outcome” and continuously nurture innovation. Moreover, funding should be pursued from a viewpoint that enables conducting R&D with the perspective of the downstream of drug discovery. In addition, an environment needs to be created that encourages investment from local/overseas

[10] ◎I doubt the major obstacle in conducting multi-regional trials is the inability of Japan to lead. The main strength of the ecosystems abroad is that they have hospitals that can lead international clinical studies. Japan should also focus on clinical applications, such as the establishment of implementation systems for clinical studies, and investments should be made to attract seeds from overseas. (Member: Fujiwara)
◎ In medical education, nursing education, and science and engineering education, it is important to establish evidence to realize good medical practice both before and after graduation. Should we incorporate education/regulatory science education so that the importance of clinical studies can be recognized and the methodology of clinical studies can be learned? (Member: Fujiwara)
◎ Western countries have established national strategies for drug discovery. Isn't it necessary for Japan to have a national strategy to support biopharmaceuticals and promote activities from early development to clinical trials? (Member: Mano)
◎ The interest in research and development in the medical field has been decreasing as a result of the focus on medical care due to the change to the 6-year system in pharmacology departments and revisions to the specialist and residency systems. A comprehensive strategy including not only an industrial policy but also an educational policy is required. (Member: Minami)

[11] ◎It is important to promote the following under the leadership of the government: development of drug discovery infrastructure, such as the establishment of CMOs/CDMOs; improvement of the clinical trial environment; and establishment of utilization of health and medical data. (Person of Reference: Ueno)

venture funds, major pharmaceutical companies, etc., for startups, etc., which are at the side of taking over and nurturing this research.[12]

○ To promote research for “bridging” the gaps, collaboration is necessary with the functions that support R&D toward the aim of clinical use from the initial stage, such as acceleration and incubation programs, and with the implementation system of international-competitive clinical trials/studies in Japan. This approach is similar to that of other countries and regions with advanced drug discovery capabilities. To this end, in addition to the cultivation of human resources in healthcare, the cultivation of personnel who can lead R&D from the R&D stage with the perspective of the exit stage is essential, although such personnel are scarce in Japan. Moreover, comprehensive measures should be taken with a view to such points.[13]

○ Collaborations between academia and startups are intensifying in specific regions of the world, with innovation at their cores. In this regard, since the process from securing personnel to initiating research can be realized in a very short time, such regions of intensified collaboration boast overwhelming superiority in the current advanced competition for development speed. Additionally, it is desired that Japan will attract people, funds, and concepts from overseas and locally, will establish bases in which research and development will proceed on par with the world, and will contribute to the delivery of innovative new drugs to patients around the world as a member of the global ecosystem. Such a concentrated site cannot be created in one day. Therefore, we should pursue an approach in which the public and private sectors continue to share knowledge and abilities, considering the point that

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[12] ◎The ecosystem becomes ineffective if it is closed to countries other than Japan does not benefit any stakeholders, including overseas capitals. It is extremely important not to close the ecosystem of drug discovery in Japan to other countries in order to establish it. Based on the concept of Japan as part of the world, Japan should attract VCs and human resources from around the world or enter the global ecosystem to expand our innovation worldwide. (Members: Masato Iwasaki/Takahashi/Maki/Person of Reference: Ueno)
◎ As important parts of the drug discovery processes, such as financing and advanced manufacturing technology, are functioning in a closed network with trust, cooperation between ecosystems is essential. (Person of Reference: Anzai)

[13] The implementation system of clinical trials at the National Cancer Center achieved an international level with a total of 432 people, of whom 158 hold specialized qualifications for clinical trials (as of April 1, 2023). No other site of this level exists in Japan.
◎ We should establish a system that enables medical institutions to conduct clinical studies at an international level, and we should promote the cultivation of personnel working there from the viewpoint of fostering medical and clerical staff other than doctors. (Member: Fujiwara)
◎ We should develop the necessary facilities and human resources capable of leading the facilities in order to construct a function to support the promotion of the clinical development of new modality drugs and strengthen the function as an industry. It is important to develop personnel who can be the foundation of manufacturing, not only from the viewpoints of developing high-value-added personnel and reskilling, but also from the viewpoint of obtaining economic security. (Members: Masato Iwasaki/Nagai/Mano/Yamazaki)

investments in academia and startups by companies in Japan are small compared with those in the US, etc.

○ In particular, although some incubation functions exist in Japan, they focus on short-term education programs and pitch events. It is important to increase mentoring by experts, VCs, etc. The Ministry of Education, Culture, Sports, Science and Technology (MEXT), the Ministry of Health, Labour and Welfare (MHLW), and the Ministry of Economy, Trade and Industry (METI) should review their support systems, including their operations, to enhance their effectiveness, and they should develop and augment CDMOs that can be used by startups.[14]

○ In addition, it is important that Japan gather accelerators who provide accompanying support in cooperation with various experts and stakeholders necessary for the promotion of exit-oriented R&D. For this reason, personnel need to be brought in to Japan who have clinical application knowledge, including pharmaceutical approval, who have gained experience in the US, etc., from foreign-affiliated mega pharmaceutical companies and US-based VCs, etc., and personnel need to be cultivated in Japan by providing such knowledge. In addition, human resources for biomanufacturing in the manufacturing stage are also important, and efforts should be made to nurture and interact with “human resources (personnel).” This is the foundation of AMED funding as well. [11]

○ While improving and strengthening the R&D environment in line with new modality drugs, as described above, the possibility of drug discovery of small molecules is expected to expand with the progress of AI and information science. We must keep in mind that maintaining and developing the drug discovery capabilities of Japan is still an important issue for drug discovery capabilities of small molecules, which are the strength of Japan.[15]

To achieve these goals, the government should consider the following policies as measures to support the development of the global drug discovery ecosystem:

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[14] ◎The perspective of human resources is important as a measure to enhance incubation functions. In particular, accelerators, who support collaboration with various experts and stakeholders and provide close support, play a key role. We should aim to become a human resource hub where people gather from around the world to foster capable people throughout Japan. (Member: Yamazaki)

[15] ◎We should strengthen our basic research to facilitate the steady creation of drug discovery seeds. We should also promote cooperation with other fields, particularly those responsible for next-generation drug discovery, such as genome analysis, AI, and information science. (Member: Nagai)
◎ The possibility of drug discovery of small molecules is expected to expand along with the progress of AI and information science. We should expand to new modality drugs while maintaining our capabilities of drug discovery of small molecules, which are the strength of Japan. (Members: Masaru Iwasaki/Maki/Person of Reference: Ueno)

(Securing of Human Resources That Can Lead Exit-oriented R&D from an Early Stage)

- Accelerator personnel who can lead exit-oriented research and development in collaboration with experts and stakeholders (pharmaceutical companies, VCs, people who conduct first-in-human (FIH) trials, CDMOs, patent experts, regulatory affairs experts, etc.), including foreign ones, need to be secured to link the results of research by academics to clinical application. However, such people are scarce in Japan.

- Personnel need to be sourced to Japan who have gained experience in the US, etc., and have clinical application knowledge, including regulatory approval, from foreign-affiliated mega pharmaceutical companies, US-based VCs, etc., and personnel in Japan need to be cultivated by providing such knowledge. To this end, for example, we will actively invite foreign-affiliated companies and foreign funds to secure accelerator personnel with proven track records overseas, on the condition that they use the Japanese clinical trial/manufacturing systems to launch their pharmaceutical products in the Japanese market. Pharmaceutical companies in Japan are expected to also work on innovative R&D of new modality drugs in collaboration with academia and startups in Japan and promote the horizontal specification-type model of drug discovery in Japan as the government takes the lead in the development of the drug discovery ecosystem through these efforts.

- With the acquisition of the above-mentioned accelerator personnel, it will become possible to continuously support exit-oriented R&D in stages, while backcasting the elements necessary for clinical application from an early stage. At that time, to foster “Star Scientists,” who will become the core of Japan’s drug discovery system, and increase their involvement in social implementation, we should seek funding methods in accordance with each stage. For example, we make evaluations from a long-term perspective at the basic research/research stages and make rapid go/no-go decisions at the development stage, considering that drug development tends to end in failure. The following measures should be taken to extend research results obtained by academia and startups to clinical application and launch by increasing the supply of risk funds to startups from an early stage: existing measures and budgetary procedure of the ministries and agencies that can be utilized by startups and entrepreneurial academia; flexible management of the AMED's Strengthening Program for Pharmaceutical Startup Ecosystem; enhancement of the Support Program for Medical Startups from Universities that was launched this year (AMED Fund); the program of the National Institute of Biomedical Innovation, Health and Nutrition (NIBIOHN) to support the development of drugs targeting rare diseases; and enhancement of RIKEN's initiative for combined technologies of drug discovery, AI and robotics (Drug Discovery and Medical Technology Infrastructure Program).

(Establishment of a Public-Private Committee toward the Attraction of Foreign-affiliated Companies and Foreign Funds)

- To attract foreign-affiliated pharmaceutical companies and VCs, the government needs to regard the pharmaceutical and medical industries as growth industries and show its continuous commitment, both locally and abroad, to policies aimed at the realization of a drug discovery ecosystem as one of the core industries of Japan. Therefore, the government should consider establishing a public-private committee that foreign-affiliated pharmaceutical companies and VCs can also be members of and discuss policies and the progress status of measures to nurture the drug discovery ecosystem, taking into account the needs of these companies. Member companies and VCs of the public-private committee need to be enticed to Japan by asking them for a commitment to activities in Japan (e.g., investment, establishment of incubation facilities, and regular dispatch of human resources).

- In addition, the use of simplified review systems needs to be promoted in Asian countries for drugs approved in Japan in order to strengthen the merits of Japan as a window for its expansion in Asia. The government needs to promote the utilization of a simplified review system in Asian countries for products approved in Japan and for their deployment in the Asian market by using Japan's Pharmaceuticals and Medical Devices Agency (PMDA) Asia Office, which will open in Thailand this summer, and by collaborating with the regulatory authorities of other countries in line with local needs, such as by strengthening of the capabilities of regulatory authorities in Asian countries and promoting regulatory harmonization.

- Seeds from academia and startups in which foreign pharmaceutical companies, etc., undertake research and development collaboratively should be considered by the government for preferential use of FIH study sites and priority advice of the PMDA.

- To attract foreign pharmaceutical companies, VCs, etc., both their Japanese affiliates and head offices need to be approached. For this reason, related ministries and agencies should cooperate to participate in global events, such as the annual BIO International Convention held in the US in June, to sell promising seeds of startups and academia in Japan and effectively inform the measures related to drug discovery in Japan (including the drug pricing system and pharmaceutical affairs system). In Japan as well, by capitalizing on opportunities such as BIO Japan and the Japan Healthcare Venture Summit, the government should invite foreign pharmaceutical companies and VCs to periodically hold matching events for promising seeds of academia and startups not only from Japan but also from Asian regions. The government should also create opportunities to exchange opinions with global stakeholders and relevant government ministries and agencies on challenges of and improvement measures for the drug discovery ecosystem of Japan.

(The PMDA's Consultation/Support for New modality drugs, etc.)

- The experiences of pharmaceutical affairs, such as efficacy and safety evaluations, are important to promote the clinical application of innovative seeds from academia and startups, and the PMDA, which has sufficient knowledge of these matters, is required to outline the various regulatory requirements and points to consider for new modality drugs from an early stage and be involved as a partner for consultation/support, not just provide a passive response.

- For this reason, in both nonclinical or clinical settings, the PMDA should aim to strengthen its organization and personnel system, for example, by establishing a section in the PMDA that provides supports such as consultation and advice, so that startups, etc., can receive active support in formulating development plans from the viewpoint of pharmaceutical affairs and undertaking R&D of new modality drugs.

(Verification and Sharing of Nonclinical Studies / Promotion of Infrastructure Development, etc.)

- The effects need to be appropriately verified to progress from nonclinical studies conducted by academia, etc., to subsequent development and nonclinical studies using animals, which, in particular, need a certain amount of funding. Therefore, the sharing and implementation of such studies needs to be promoted.

- For nonclinical studies, we will promote conducting drug efficacy studies with precision control. In addition, we will encourage the utilization of the AMED's Basis for Supporting Innovative Drug Discovery and Life Science Research (BINDS), which can provide support for pharmacokinetic and safety studies in animals. In addition, a medical start-up project (AMED Fund) that has been initiated this year will also provide support at the nonclinical stage.

(Establishment of Systems for Conducting International-level Clinical Trials/Studies)

- It is important to establish a development environment in which world-class clinical study results can be obtained as soon as possible and promising seeds can be selected from an international viewpoint. The system through which international-level clinical trials and studies can be conducted needs to be strengthened in order to improve the drug discovery capabilities of Japan. Promotion of participation in multi-regional trials and connection of Japan's sites of clinical development to a global drug discovery ecosystem will facilitate improved access to and early prevalence of cutting-edge drugs and medical technologies, leading to the mitigation of drug lag/drug loss.

- Currently, however, we cannot ensure that personnel concentrate on clinical trials/studies without being busy obtaining funds to consistently support the clinical trial/study implementation system and for regular medical operations. For this reason, we should promote the following measures:

- Establishment of an Implementation System for First-in-human (FIH) Studies
  We will promote the domestic R&D of candidate innovative new drugs including seed from foreign countries by newly developing globally competitive FIH study sites that can handle innovative modality drugs. We will nurture human resources (not limited to physicians) who can conduct clinical studies at an international level by utilizing the relevant facilities (and their personnel), and we will raise the level of clinical development capabilities through personnel exchanges (temporary staffing) with facilities in Japan and overseas , including pharmaceutical companies and regulatory authorities. We will provide an efficient drug discovery environment by setting up FIH study implementation facilities with GMP-compliant investigational product manufacturing facilities and research facilities of new modality drugs that requires FIH studies and by further utilizing, strengthening, and bridging research bases.

- Review of Approval Requirements for a Clinical Research Core Hospital
  Regarding the approval and renewal requirements for clinical research core hospitals, their degree of contribution to drug discovery will be evaluated more stringently than it currently is. For example, the degree of contribution to the approval of drugs, etc., and the results of supporting/implementing multi-regional trials and large-scale clinical trials including company clinical trials will be newly evaluated. We will create evaluation axes covering multiple years as well. In addition, we will consider establishing a new category for clinical research core hospitals that have high international competitiveness and excellent (disease-specific) clinical development capabilities.

○ Promotion of multi-regional clinical trials

We will support contracts/coordination with pharmaceutical companies and other study sites, etc., toward the implementation of clinical trials/studies in English and the development and allocation of human resources capable of managing the entire clinical trial/study (including personnel other than doctors, such as medical and clerical staff). We will increase personnel dispatch to medical institutions, etc., conducting cutting-edge clinical trials/studies in Western countries, etc. We will also build strong relationships with overseas regulatory authorities and pharmaceutical companies, etc., improve negotiation power, and strengthen the cultivation of human resources who can lead multi-regional trials in Japan.

In addition, we will set up a one-stop service counter to receive consultation about the implementation of clinical trials/studies in Japan from foreign startups and pharmaceutical companies that do not have a development base in Japan and to provide them with support. The organization responsible for one-stop services should coordinate the implementation of clinical trials/studies in Japan by clinical research core hospitals and the National Center for Global Health and Medicine (National Center), etc. It also has functions to introduce to overseas pharmaceutical companies and leading startups centered in Europe and the United States the contents of various supports toward the implementation of clinical trials/studies in Japan and to invite clinical trials, etc., to Japan.

○ Support for the Development of Human Resources Engaged in Clinical Trial/Study Operations and Maintenance of Their Career Track

We will enhance the cultivation of personnel, including project managers, study managers, clinical research coordinators (CRCs), biostatisticians, data managers, clinical laboratory technicians, persons in charge of ethical review/clinical trial offices, etc., as well as physicians, nurses (research nurses), pharmacists, etc., who are engaged in clinical trial/study operations, in order to improve the quality of clinical trials/studies, further attract multi-regional trials, and manage the increase in the number of trials conducted. In addition, we will provide these research support personnel with appropriate treatment and aid in the establishment of their career path according to their capabilities and roles. Furthermore, continuous development of clinical trial/study experts requires the nurturing of “clinical research and development literacy” from an early stage. Therefore, we will improve educational programs on the knowledge of related laws and regulations, significance of the implementation of clinical trials/studies, methodology of clinical development, etc., for students and young medical professionals seeking healthcare professionals such as physicians, dentists, nurses, pharmacists, and clinical laboratory technicians.

○ Standardizing Reviews by a Single Institutional Review Board (Single IRB) in Multicenter Clinical Trials

The EU Clinical Trial Directive in the European Union and the US Common Rule require a review by a single Institutional Review Board (IRB), which is generally

carried out in the US and Europe. In order to promote multi-regional trials in Japan and improve the quality of reviews, we will standardize reviews by a single IRB for clinical trials in Japan as well, and we will try to solve regulatory and procedural issues for that purpose. In addition, we will nurture IRBs and Certified Review Boards (CRBs) that can review a protocol, an investigator's brochure (IB), informed consent form (ICF), etc., in English to promote multi-regional clinical trials.

○ Strengthening of Clinical Study Networks in Japan and Overseas
We will strengthen clinical trial/study networks centered on Asia to promote multi-regional trials. Moreover, we will strengthen cooperation through the sharing of knowledge, personnel exchange, and the implementation of joint clinical trials/studies among clinical research core hospitals, the National Center, the National Hospital Organization (NHO), etc., to strengthen the network of clinical trials/studies, including FIH studies in Japan .

○ Promotion of a Decentralized Clinical Trial (DCT)
By utilizing remote medical care and visiting nursing services, we will spread DCTs, namely, clinical trials not based on hospital visits, and we will secure opportunities for patients living far from the study site and for those with rare diseases, infections, etc., to participate in clinical trials/studies. The usage of DCTs has been increasing in clinical trials/studies in Europe and the US as digitization progresses. Hence, we will make efforts to disseminate DCTs in order to attract multi-regional trials to Japan.

○ Strengthening of the Pharmacovigilance System in Post-marketing Monitoring
Monitoring post-marketing safety and providing prompt analysis, judgment, and response are indispensable in responding to the Conditional Early Approval System. Hence, we will make efforts to strengthen the pharmacovigilance system and develop human resources in academia capable of understanding the QCD (Quality, Cost, Delivery) business model.

○ Disclosure of Information on Clinical Trials/Studies and Promotion of Public Understanding
Information on clinical trials/studies is registered and disclosed in the jRCT (Japan Registry of Clinical Trials), but it has been pointed out that the function of registration and search is difficult to use. Necessary modifications will be made based on the opinions of researchers, pharmaceutical companies, patient groups, etc., and efforts will be made to educate the public about knowledge on clinical trials/studies and how to investigate information on clinical trials/studies. In addition, we will request that the jRCT number be included in the information on the main clinical trial/Japan compassionate use program published on the PMDA website. At the same time, we need to make efforts to enhance the public's understanding of the significance of clinical studies, i.e., the promotion of safe and secure drug discovery.

(Improvement of the Manufacturing System for New Modality Drugs)

- We will promote clinical application research in Japan and realize the early prevalence of innovative drugs to the public by strongly improving the manufacturing system for new modality drugs including investigational products, radiopharmaceuticals, and biosimilars. Specifically, the following measures should be promoted:
  - Assuring GMP-compliant Investigational Product Manufacturing Facilities
  - Enhancement of support for CDMOs (support for mechanization/automation and manufacturing process development in addition to utilization of dual-use subsidies)
  - Integration of international-level CDMOs with core sites conducting FIH studies and promotion of collaboration with overseas core sites
  - Continuous cultivation of people to manufacture biopharmaceuticals (including biosimilars) and become the foundation for their manufacturing in Japan and sourcing of such people from overseas

(Constant Creation and Growth of Seeds in Academia and Startups)

- Japan needs to maintain and improve its sustainable drug discovery capabilities in order to continuously create drug discovery seeds. Therefore, we should further promote basic research on medicine, pharmacology, physiology, etc., that will become the seeds of innovation; and new modality drugs, such as combinations of AI and robotics with drug discovery, through the cooperation of different fields and incorporation of the results of conversion science. Furthermore, we should utilize the strengths of Japan, such as nonclinical studies without experimental animals and regenerative medicine that uses the research basis of iPS cells. These are the strengths of Japan for drug discovery seeds. In addition, appropriate funding that contributes to the development and utilization of star scientists who create a virtuous cycle of science and business should be sought.

- In order to secure and develop human resources who can also contribute to the R&D of new modality drugs, the acceptance of global human resources in academia should be promoted. Moreover, a review of the contents of education should be considered to include the viewpoints of human resource development that quickly responds to changes in medical and pharmaceutical sciences, such as new clinical studies, and the appropriate method of drug discovery from the stage of education in medical and pharmaceutical departments. This includes the ideal form of pharmaceutical education, the development and strengthening of human resources for data science, and the recruitment of such human resources from other countries, which are essential for the future enhancement of drug discovery capabilities.

- Intellectual property and business strategies need to be established so that the application of the results of basic research in academia can create profits from

businesses in industry and researchers can create new innovation based on the circulation[16] of funds, which becomes the source of the next basic research.

○ In hospitals conducting clinical research, such as university hospitals, it is also important for healthcare professionals who know the endpoint of clinical sites to promote the research and development of drug discovery seeds in cooperation with clinical trial hub sites. However, it has been pointed out that such research systems for seeds in such medical workplaces are in a critical situation. As the background of this situation, it has been pointed out that physicians working at university hospitals, etc., are exhausted from the increased work burdens related to medical care and education, the contribution to regional medical care, etc. Moreover, sufficient resources are not allocated to research and development, and these factors cause a deterioration of the drug discovery capabilities as a whole. As the work style reform for the entire medical field is being promoted, it is important to actively work on improving operational efficiency by using medical DX and AI and to promote the improvement of the research and development capabilities of university hospitals that conduct advanced medical care and clinical studies.[17]

○ In the AMED's support for R&D, we sincerely accept the indication of a barrier between policies and projects linked to respective ministries and agencies. We should consider the allocation of funds, usage of funds, mechanism of funding, etc., to promote projects focusing on the purpose of drug discovery from the basic/applied research stages. In addition, the Cabinet Secretariat and the Cabinet Office should fully demonstrate their function as a control tower for R&D, independent of the AMED's support. Additionally, the government as a whole should promote measures and businesses to improve the drug discovery capabilities of Japan.

(Promotion of Secondary Use of Real-world Data)

○ It has been pointed out that the use of real-world data, etc., for research in Japan is difficult when compared to western countries. Although the use of anonymized information has been promoted to date, the use of pseudonymized information (information that has been anonymized by deleting the name, etc.) with high expectations for research use has not been promoted. In addition, it has been pointed out that user burdens may be great because in Japan, various databases (DBs) and registries concerning medical data are scattered rather than combined, the procedures for their utilization by researchers and companies are complex, and a strict environment is required for their use.

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[16] ◎To ensure the cycle of science, basic researchers should understand where the research funds manifest and understand that their intellectual property becomes an industry, generating profits and research funds. The intellectual property strategy of academia is very important. (Member: Takahashi)

[17] The Ministry of Education, Culture, Sports, Science and Technology's "Study Group on the Ideal Form of Future Medical Education" issued an Interim Report in September 2023. It is important to continue the discussion based on the summary of this Concept Council.

To promote the use of medical and other data for research, it is important to promote the use and application of pseudonymized information and promote the construction of information linkage infrastructure that will enable researchers, companies, etc., to use the various DB data in an integrated, safe, and efficient manner, by ensuring the quality of the data for example.

2. Measures to Promptly Deliver the Novel Drugs to the People

We should consider the goal of strengthening our drug discovery capabilities, as early prevalence of the novel drugs to the public and resolution of the current drug lag/drug loss are urgent issues.

In order to prevent future drug lag/drug loss and meet the expectations of patients and their families who are waiting for the development of therapeutic drugs, the government needs to establish an efficient drug discovery environment, understand the areas of difficulty in the development of new drugs and their causes, and take proactive measures, which include reviewing pharmaceutical regulations, improving their operation, and approaching global pharma.[18]

Drugs for children, intractable diseases, and orphan diseases are often put on hold by companies because of the small number of patients. Therefore, strong national involvement is required. For this reason, we should take measures such as strengthening the operation of the system and strengthening approaches to companies after verifying the adequate functioning of the conventional incentive measures.

Currently, the hurdle of pharmaceutical regulations is very high for startups and academia developing drugs. It is desirable for the PMDA to consider a framework for proactively providing consultation support, etc., for overseas startups, etc., and increase the number of reviewers so that it can support companies, etc., from an early stage in terms of pharmaceutical regulations.

(Review of Pharmaceutical Regulations)

○ Pharmaceutical regulations need to be reviewed based on international harmonization in order to incorporate Japan into the international flow of simultaneous development. To this end, the reviews that their policies were presented at the “Review Committee on Regulatory Affairs to Strengthen Drug Discovery Capabilities/Ensure Stable Supply”, such as the concept of phase I study in Japanese subjects when Japanese sites participate in multi-regional trials and the clarification of Japanese data in confirmatory studies, etc. when such data are not necessary, should be surely carried out and applied. At the same time, the contents should be proactively dispatched to foreign countries in English, etc.

(Improvement of Clinical Study and Clinical Trial Environments)

○ Drug lag/drug loss has occurred partly because Japan has not participated in multi-regional trials. In order to introduce innovative drugs swiftly to Japan, a development environment needs to be fostered in which world-class clinical study results can be

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[18] ◎Support for the creation of clinical evidence with a view to expand academia seeds to the global level is required for R&D cases that are difficult for companies to enter, such as rare diseases, intractable diseases, pediatric diseases, and AMR. The enhancement of support from the viewpoints of enhancement of consultation support as a partner, clarification of approval requirements, and internationalization of pharmaceutical reviews at the PMDA will help resolve the drug lag/drug loss issue. (Member: Masaru Iwasaki)

obtained as soon as possible and promising seeds can be selected from an international viewpoint. Therefore, the system for the implementation of world-class clinical trials/studies should be strengthened.

○ Specifically, we should make efforts for the following: [1] improvement of the system for conducting first-in-human (FIH) studies; [2] review of approval requirements for clinical research core hospitals; [3] promotion of multi-regional clinical trials; [4] development of personnel who are involved in clinical trial/study operations and establishment of their career track; [5] standardization of the principles of review at a single institutional review board (single IRB) in a multicenter clinical trial; [6] strengthening of clinical trial networks in Japan and overseas; [7] promotion of dispersive clinical trials (DCTs); [8] strengthening of the pharmacovigilance system in post-marketing monitoring; and [9] disclosure of clinical trial/study information and promotion of public understanding. (For details, see pages 11–13.)

(Promotion of Development of Drugs for Children, Intractable Diseases, and Rare Diseases)

○ Regarding drugs for children (hereafter referred to as “pediatric drugs”), their medical needs are high, but it is difficult to advance the clinical development of these drugs compared with drugs for adults, partly because the market size is small. However, the aim is to develop them without delay from drugs for adults. In addition, regarding drugs other than pediatric drugs, the development of drugs for small patient groups has been increasing in the US, etc., and many of the current drugs with drug loss in Japan are unprofitable drugs for intractable and orphan diseases.[19]

○ For this reason, companies should be encouraged to develop a pediatric drug development plan collaboratively and receive confirmation from the PMDA when applying for approval of drugs for adults. In addition, the Pharmaceutical Affairs Consultation Center for Pediatric Drugs and Orphan Drugs, which will be established at the PMDA this fiscal year, should promote the development of pediatric drugs based on the development plan by offering incentives to companies through reduced consultation expenses.

○ In addition, the PMDA has decided to review the designation of orphan drugs so that designation can be made as soon as possible without waiting for the results of clinical studies. Thus, the PMDA should ensure the implementation of the review.

[19] Of the 86 products with drug loss, 40 are drugs for intractable and orphan diseases. (As of the end of March 2023)

- For drugs that currently have drug lag/drug loss issues, the PMDA needs to accelerate the evaluation, development request, etc., at the “The Evaluation Committee on Unapproved or Off-label Drugs with High Medical Needs.”

- The government should aim to strengthen the PMDA’s organization and its personnel system that deals with the following actions, which have been described above: confirmation of the development plan for pediatric drugs, priority reviews related to early designation associated with the product expansion of orphan drugs, and acceleration of evaluation by the Review Committee on Unapproved and Off-label Drugs.

(From Passive-mode Regulations to Proactive-mode Regulations)

- The excessive burden of the Japanese translation of application documents may be a factor that prevents the entry of overseas startups into Japan and international expansion of the development of new drugs originating in Japan. In addition, while the framework for cooperation in international reviews is expanding, it is possible for the government to show that the pharmaceutical regulations are internationally open by delivering English messages of Japan’s actions and by showing the presence of Japan.

- Additionally, the government should promote globalization, such as through the promotion of various English-language services and active participation in the framework of international review collaborations. Furthermore, considering the establishment of the PMDA’s new Washington DC office, the PMDA should make efforts to inform overseas startups, etc., of the pharmaceutical regulations in Japan. For example, it is important to promote the domestic development of new modality drugs by startups by publicizing that pharmaceutical regulatory systems have been established according to the characteristics of products. These systems include the pioneering drug designation system that can receive prompt approval reviews and preferential treatment on drug prices and the conditional approval system that enables early access for cases in which it is difficult to conduct confirmatory clinical studies.

3. Social System with Continuable Virtuous Cycle of Investment and Innovation

Drug discovery is innovation in itself, because it constantly produces innovative technologies and generates new growth by overwriting old technologies. In order to deliver the novel drugs to patients, the viewpoint that the entire system will become sustainable; be able to deal with the diversification of patient needs, the introduction of new treatments, etc.; and activate the entire medical market; while maintaining harmony between the pharmaceutical market, economies, and finances; is important.

An opinion suggested that it would be necessary to discuss the social system with a continuable virtuous cycle of investment and innovation. These issues need to be discussed continuously from a mid- to long-term perspective.[20]

(Discussion about Evaluation Methods according to the Value of Innovative Drugs)

- The circular development of the drug discovery ecosystem requires continued investments from Japan and foreign countries. Private investments are made[21] based on economic rationality, and it is important to evaluate the predictability of returns and innovation after drug launch.

- In the drug pricing system reform that was carried out in FY 2024, drug pricing measures were implemented to promote the appropriate evaluation of innovative new drugs in order to resolve the drug lag/drug loss issue as well as strengthening the drug discovery capabilities of Japan.

- Additionally, it has been decided that the validity of the drug pricing system reform in FY 2024 for new drugs will be verified, and the ideal drug prices for innovative new drugs will then be continuously discussed at the Central Social Insurance Medical Council. During the validity verification process, companies will most likely be required to provide sufficient data and explanations.

(Departure from Dependence on Long-listed Products)

- In order to ensure a stable supply of generic drugs, the government needs to take measures such as promoting the transformation of the industrial structure of generics and promote policies to support the development of the global drug discovery ecosystem. In addition, the industry will inevitably need to respond to

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[20] ◎Considering the medical industry as a growing industry, we should aim to obtain the recognition that innovation is properly evaluated at the pharmaceutical market in Japan and that the market is highly productive. From a mid- and long-term perspective, it is important that the medical industry in Japan has clear policies that are easy to understand abroad. (Member: Masato Iwasaki)

[21] ◎We should consider the economic rationality of all stakeholders for the circulation of the ecosystem. In order to increase the rationality for a pharmaceutical company to acquire a drug discovery startup, the profit needs to be clarified by creating new drugs and drug prices and predictability should be sufficiently high. (Member: Maki)

changes in government policies, the drug discovery environment, and the market environment. If a global drug discovery ecosystem is established and innovative drugs are evaluated more highly, research and development competition will be further promoted among new drug makers. For this reason, if companies aim to conduct the research and development of innovative new drugs for global distribution[22], transformation of business models will be demanded more than ever before.

○ In addition, while the “promotion of innovation” and “sustainability of universal health insurance” are required, it is also necessary to proactively promote self-care/self-medication from the viewpoint of improving health literacy, in which people proactively care for their own health, by promoting switch OTC and providing information in accordance with individual needs regarding health, based on the progress of the information society.

○ In this Council, a suggestion was made that private insurance should be used in addition to public insurance for new treatments, in consideration of the purpose of delivering drugs to patients, when the effective use of the non-public insurance market, specifically, [23]and innovation is evaluated from the viewpoint of the whole pharmaceutical market.

(Promotion of Use of Biosimilars)

○ We believe that the promotion of the use of national generic drugs accelerated, to a certain degree, the shift from a business model dependent on long-listed drugs to the R&D-type business model. The drug pricing system reform in FY 2024 aimed to review the ideal way insurance benefits should be provided for long-listed products and to introduce a system for selective treatment.

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[22] Some pharmaceutical companies may choose a strategy/business model to obtain a license for R&D and sales in Japan for new drugs that are created in overseas bio startups, etc.

[23] ◎ Japan has continued to reduce expenditures on healthcare, which is a growth industry, until now. As a result, reduction in the quality of healthcare, namely, drug lag/drug loss, has occurred. Efforts should be made to effectively utilize private insurance in addition to public medical care for innovative medical care. (Member: Takahashi)

◎ We should make efforts to review the ideal methods of intervention in the pre-event and post-event areas, such as prevention and nursing care, public insurance coverage, private insurance in advanced medical care, and free medical care, and we should activate the medical industry of Japan. (Members: Masato Iwasaki/Uehara/Takahashi)

◎ People widely recognize that their health is protected by universal health insurance and that there is no literacy education system for health problems. Therefore, they are generally unaware that they should protect their own health. Enhancement of public awareness about the reality, the universal health insurance system, and health is essential. Self-care and self-medication should be promoted to maintain and promote the health of the public and to enhance the sustainability of the social security system. (Members: Uehara/Minami)

○ While the number of biopharmaceuticals whose patents, etc., will expire is expected to increase in the future, promotion of the use of biosimilars is important not only from the viewpoint of the optimization of healthcare insurance finance but also from the viewpoint of promotion of conversion to the R&D-type business model.

○ As for biosimilars, the government policy in 2023 set a target to promote their use; specifically, “the number of ingredients that will be replaced by biosimilars by at least 80% will be at least 60% of the total number of ingredients by the end of FY 2029.”

○ In order to ensure the achievement of this goal, it is necessary to increase acceptance of biosimilars and promote the use of biosimilars through workshops for physicians and insurers, etc., in cooperation with related medical societies. In addition, it is important to investigate the actual use status of each ingredient and take measures while continuously conducting analysis. For example, investigation should be conducted of the cause in cases when a replacement is not progressing.

(Strengthening of Support for Startups in the Healthcare Field)

○ Innovation by Japanese startups needs to be promoted in the healthcare field, where advanced healthcare needs and abundant data on healthcare, etc., are accumulating. For this reason, we should[24] also promote startup support measures based on the characteristics of the healthcare market, such as the use of milestone-type development support.

[24] Regarding measures to promote and support healthcare startups, an interim report executive summary was issued on April 25 by the “Project Team on Healthcare Startup Acceleration and Support” of the MHLW.

Conclusion

○ In order to strengthen our drug discovery capabilities, we should seriously consider the indication that medical care and research sites, such as university hospitals and medical faculties, which support advanced medical care and R&D as their foundation, are in crisis. We should also address various challenges facing medical care in Japan by analyzing medical education/research, the health delivery system, and the medical security system. Furthermore, we should work on consistent reform, including the further effective utilization of private insurance.

○ The strengthening of our drug discovery capabilities is necessary for patients and their families who are waiting for the novel drugs as well as for the economic growth of Japan. Drug discovery is a comprehensive strategy in academia, clinical practice, and related industries, and it is necessary to reflect opinions from various fields so that it leads to overall development. [25]In addition, one opinion suggested that it was important to widely convey to the public and healthcare professionals about the balance between patient-centered medical care and medical care as a growth industry.

○ In the discussion of this Concept Council, one opinion suggested that the construction of the ecosystem is a long-term battle and we should realize a mechanism through which policies for the organizational system and budget can be implemented. Another opinion suggested the importance of taking more effective actions to detect changes in the status of the latest research and development in Japan and foreign countries by sharing information on such changes between public and private sectors on a daily basis.[26]

○ With these discussions taken into account, it is important to establish appropriate KPI(s) with the aim of achieving the goal of this Council for strengthening drug discovery capabilities. Furthermore, it is important to evaluate the achievement status continuously while constantly obtaining the latest information and firmly

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[25] ◎Different perspectives are required at the basic/applied stages and the clinical application. For example, in basic research, a wide range of support is provided from diverse perspectives, while in clinical research, support is provided based on the perspective of the industry. The public and private sectors should share these concepts. (Person of Reference: Ueno)

[26] ◎We should have a long-term perspective to build an ecosystem. We should realize the ideal methods to continuous secure organizational structures and budgets and sustainably implement policies. (Member: Maki)

◎ It is important that Japan is attractive from the three viewpoints of producing, fostering, and selling drugs. In order to effectively allocate resources, execute policies in the country from a long-term perspective, and understand changes in the situation, I believe it is necessary to have a place to conduct continuous discussions among the public and private sectors, i.e., the committee for public-private cooperation. (Member: Masato Iwasaki)

maintaining the overall strategy. This will aid in the promotion and appropriate review of measures.

- If these actions proceed steadily, the expectation is that:
  - Patients suffering from pediatric diseases, intractable diseases, or rare diseases will be able to use the novel drugs from Japan and overseas that have been difficult to obtain so far and treatment for them will be advanced;
  - For pharmaceutical companies, organic cooperation in various phases will progress, and drug discovery utilizing a wide range of seeds from Japan and overseas will be activated, leading to the development of new markets and growth of the companies;
  - For drug discovery startups, these actions will attract investments from Japan and overseas, leading to the activation of corporate activities, clinical use of seeds, and corporate growth;
  - For healthcare sites, treatment using the novel drugs will be possible, and differentiation and collaboration of the functions of medical care delivery systems will be promoted;
  - The research activities of prominent researchers will expand and their research outcomes will appear in a visible form, such as in treatment development;
  - Above all, for everybody in this country, rapid delivery of the novel drugs from Japan and overseas will prolong healthy life expectancy and activate society.

- Based on this proposal, we request the government to promptly take the necessary measures and continue to follow the progress status of the measures to be taken in the mid to long term.

Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities

Members

Chairperson	Hideki Murai	Deputy Chief Cabinet Secretary
Acting Chairperson	Ichiro Kamoshita	Special Advisor to the Cabinet
Members	Masato Iwasaki	Former Representative Director, Takeda Pharmaceutical Company Limited.
	Masaru Iwasaki	Vice-president of the University of Yamanashi /Director of the Center for Advanced Clinical Research
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	Hiroyuki Mano	Director, National Cancer Center Research Institute
	Masago Minami	Managing Director at the Yomiuri Shimbun Tokyo Headquarters and Chief Officer at the Yomiuri Research Institute
	Shiro Yamazaki	Chief Executive Officer, Headquarters for Social Security System Oriented to All Generations, Cabinet Secretariat

Persons of Reference

Tomohiro Anzai	COO and Managing Partner, Fast Track Initiative, Inc.
Hiroaki Ueno	President, Japan Pharmaceutical Manufacturers Association
Takeshi Yanagimoto	Managing Director and Partner, Boston Consulting Group

Meeting Schedule

1st	December 27, 2023
2nd	February 8, 2024
3rd	March 7, 2024
4th	April 17, 2024
5th	May 22, 2024