Provisional

# Healthcare Policy

**Approved by Cabinet**
**July 22, 2014**
**Partially Revised**
**February 17, 2017**

Contents

Introduction

The whole of humanity aspires to the creation of a society with a high life expectancy; having achieved the world's highest average life expectancy, Japan has turned this into reality. This is the result of its outstanding health and medical care systems, including a universal public health insurance system, excellent public health measures, and advanced medical technology. From now on, it will be even more important to ensure that every member of the populace remains healthy from infancy to old age, and to build a society in which they can live vibrant, fulfilling lives in accordance with their preferred lifestyle, whether playing an active role in society or enjoying leisure pursuits. The desire to live a long, healthy life is shared by most of the populace. As such, while maintaining the basic principles of the medical care and welfare field, which seeks to protect the lives of the people and guarantee the livelihood of each individual, the establishment of a society in which the public can live even healthier lives and enjoy greater longevity (a society in which people enjoy long and healthy lives) is becoming a matter of urgency.

Japan's average life expectancy is growing, because the universal public health insurance system that has been in place since 1961 through to the present day allows all citizens to receive medical care. However, in 1970, the share of elderly people aged 65 or above among the population as a whole (aging rate) passed 7%, which is the threshold for being considered an aging society. Over the next 24 years, the aging of the population progressed at a rate without precedent worldwide, and in 1994 the aging rate reached the 14% threshold for being considered an aged society. As of August 1, 2016, the aging rate had risen to 27.2% and is projected to reach 39.9% by 2060.

As the aging of the population began to attract attention within Japan, the nation was faced with the challenge of how to achieve a "healthy life expectancy", a term that the World Health Organization (WHO) defined for the first time in 2000. With the highest average life expectancy and aging rate in the world, Japan now had to determine not simply how to live a long time, but also how to ensure a life that was both long and healthy.

As the aging of the population has progressed, the number of people receiving nursing care under the nursing care insurance system introduced around that time in 2000 has been increasing by the year. The main reasons for requiring nursing care are cerebrovascular disease (18.5%), dementia (15.8%), age-related weakness (13.4%), and bone fractures and falls (11.8%) (Ministry of Health, Labour and Welfare (MHLW), *Comprehensive Survey of Living Conditions (2013)*). Looking at elderly (aged 65 or above) patients by illness/injury, among those admitted to hospital, 14.7% were admitted for cerebrovascular disease, 10.1% for malignant neoplasm, and 5.6% for cardiac disease (excluding hypertensive heart disease). Among those attending as outpatients, 2.2% were seen for cerebrovascular disease, 3.3% for malignant neoplasm, and 3.1% for cardiac disease (as above) (MHLW, *Patient Survey (2014)*). Thus, in order to establish a society in which people enjoy long and healthy lives in Japan, effective medical care is required not only for these conditions but also for musculoskeletal system diseases and visual, auditory, and other sensory organ diseases related to the maintenance and improvement of living functions.

Amid this situation, under the universal public health insurance system, the Japanese market for pharmaceutical drugs (hereinafter "drugs") is worth approximately ¥9.6 trillion, while the market for medical equipment is worth about ¥2.8 trillion, and both markets are slowly growing (MHLW, *Statistics of Production by Pharmaceutical Industry (2014)*). On the other hand, the trade deficit in the drugs market amounts to around ¥2.5 trillion (Ministry of Finance (hereinafter "MOF"), *Trade Statistics (2015)*), while that in the medical equipment market has reached approximately ¥0.8 trillion (MHLW, *Statistics of Production by Pharmaceutical Industry (2014)*), and the deficits in

both areas are on the increase. Although the international competitiveness of Japanese pharmaceutical companies remains high, Japanese companies face the challenge of further enhancing their international competitiveness. For example, in 2015, Japanese companies were lagging behind in terms of the development of biopharmaceuticals such as antibody preparations, which account for eight of the ten highest-earning major drugs worldwide. Furthermore, from the perspective of company scale, Japanese manufacturers of drugs and medical equipment have fewer risk-tolerant management resources than their counterparts in the West, so while companies are investing enormous sums in drug R&D, the gap between Japan and the U.S.A. in terms of R&D expenditure per company is wide, due to the difference in company scale.

Looking at the situation worldwide, the total world population is projected to grow from 6.89589 billion in 2010 to 10.18429 billion in 2060, while the aging rate is forecast to rise from 7.6% in 2010 to 18.1% in 2060. In particular, looking at the countries of Asia, it is estimated that the aging rate in countries including China, Singapore, and South Korea will be in excess of 30% by 2060 and the aging of the population is expected to progress rapidly in future, suggesting that issues similar to Japan's will emerge as a result of the rising aging rate.

In light of such changes in the global demographic structure, it is vital for Japan, which is becoming an ultra-aging society ahead of the rest of the world, to rise to the challenge as a developed country capable of resolving problems and create the world's best medical technology and services, with the aim of establishing a society in which people enjoy long and healthy lives, as well as further extending healthy life expectancy (the length of time for which people can live without health problems restricting their daily life). In addition, Japan must contribute to improving the quality of healthcare overseas by promoting the creation of new industrial activities that assist in the establishment of a society in which people enjoy long and healthy lives, such as the Health-care New Frontier initiative focused on cutting-edge medical treatment and technologies being undertaken to this end in Kanagawa Prefecture, as well as the overseas expansion of such businesses. While doing so, it is important to cultivate these sectors as strategic industries and to use Japan's status as one of the world's leading countries for medical care and welfare, offering unparalleled safety and peace of mind, to enable these industries to spread overseas and thereby contribute to the nation's economic growth.

To respond to these challenges, the government set forth its interim policy on June 14, 2013 in the Japan Revitalization Strategy and the Healthcare Policy (hereinafter "the previous Healthcare Policy"), which was based on mutual agreement among relevant Cabinet ministers. In addition, on January 22, 2014, the government compiled the Comprehensive Policy on Medical R&D (Report by the Expert Panel on Medical R&D).

In addition, the Act to Promote Healthcare and Medical Strategy (Act No. 48 of 2014. Hereinafter "the Promotion Act") and the Japan Agency for Medical Research and Development Act (Act No. 49 of 2014. Hereinafter "the AMED Act") were enacted on May 23, 2014 during the 186th ordinary session of the Diet. As such, on July 22 that year, in accordance with the provisions of Article 17 of the Promotion Act, the government prescribed and promoted this Healthcare Policy, while also taking into account previous initiatives such as these.

According to the Status of Implementation of the Healthcare Policy and the Policy for Future Efforts 2016 determined on July 29, 2016 by the Headquarters for Healthcare Policy, because this fiscal year is the midyear of the five-year Healthcare Policy period from FY2014, an intermediate review of the Healthcare Policy was conducted as required, taking into consideration the results of inspection of the measures and changes in the social situation.

The promotion of ICT in the field of medical care and the introduction of ID for medical care are expected to enable the integration of each individual's data and the collection and use of Personal Health Record (PHR) covering the entire period from each individual's birth to death. If it is possible for healthcare professionals to use such data for taking appropriate preventive measures, healthy life expectancy will rise further. It is expected that the realization of PHR – that is, the integration of each individual's information dispersed among the fields of medical care, health and nursing care – will make it important to adopt the concept of "*mibyou*," which regards health and diseases continuously instead of separately. In this case, reform will be required in the social systems related to health and medical care and emergence of new healthcare industries can be expected during the process of reform.

(Note 1) When the Act for Establishment of Laws Related to the Enforcement of the Act to Partially Revise the Act on General Rules for Independent Administrative Agencies (Act No. 67 of 2014) came into force in April 1, 2015, the "Act on the Japan Agency for Medical Research and Development, an Independent Administrative Agency" was changed to the "Act on the Japan Agency for Medical Research and Development, a National Research and Development Agency."

(Note 2) *Mibyou* is a concept that indicates the entire process of changes between mental and physical health and illness, which are regarded as continuous instead of "dichotomous."

## 1. General outline

### (1) The Healthcare Policy

#### 1) Positioning of the Healthcare Policy

On June 14, 2013, the growth strategy that forms the third of the "Three Arrows" aimed at revitalizing the Japanese economy, entitled the "Japan Revitalization Strategy -JAPAN is BACK-", was approved by Cabinet. This set out three action plans – the Industry Revitalization Plan, the Strategic Market Creation Plan, and the Strategy of Global Outreach – as concrete initiatives aimed at achieving growth. Of these, the Strategic Market Creation Plan took "Extending the nation's 'healthy life expectancy'" as one of its themes, stipulating that the government would aim to achieve the following ideal situations in 2030:

A society where people are able to live a healthy life and get old, by enhancing effective preventive care services and health management

A society which can provide the necessary medical care at the world's most advanced level by activating medical-related industries

A society where people unable to work due to illness or injury can return to work as quickly as possible through access to better medical and nursing care

The previous Healthcare Policy, which was put together on the same day as the Cabinet approved the Japan Revitalization Strategy, was based on measures in the Five-Year Strategy for Medical Innovation compiled by the Medical Innovation Council on June 6, 2012. These measures were revised and put together based on an approach of implementing those that could be implemented without delay, and swiftly incorporating any additional measures that should be included.

More specifically, it was determined that the two should be developed in tandem to ensure consistency between them, by working closely with the team formulating the Japan Revitalization Strategy and including key items in both the Japan Revitalization Strategy and the previous Healthcare Policy. In particular, the new items included in the previous Healthcare Policy in light of the Japan Revitalization Strategy were as follows: (1) establishing control tower functions in medical R&D; (2) global expansion of the medical market; (3) creation of services to extend healthy life expectancy; and (4) promoting the use of ICT in the field of healthcare and medical care.

Regarding the establishment of control tower functions in medical R&D, the Japan Revitalization Strategy and the previous Healthcare Policy stated that the government would take such steps as:

Establishing a "Promotion Headquarters" consisting of the Prime Minister, the ministers in charge, and relevant other Cabinet ministers to serve as the headquarters of the medical R&D control tower; and

Establishing an incorporated administrative agency to ensure seamless research management, from basic research through to its practical application.

In response, the establishment of the Headquarters for Healthcare Policy was approved by Cabinet on August 2, 2013. The body was tasked with comprehensively coordinating requests for and allocation of budget funds for medical R&D, promoting the previous Healthcare Policy and serving as the headquarters for the control tower in this field.

It was decided that the incorporated administrative agency would be established on the basis of the scrap and build principle. The Council of Healthcare Policy Advisors, which provides policy advice to the Headquarters for Healthcare Policy, and the Expert Examination Committee on Medical R&D discussed the specific functions that it should have as a specialized agency optimized for the distinctive nature of medical R&D.

Following this process, during the 186th ordinary session of the Diet, the government submitted the Healthcare Policy Promotion Bill and the Japan Agency for Medical Research and Development Bill to the Diet on February 12, 2014, having obtained Cabinet approval for them the same day.

While the bills were being debated in the House of Representatives and the House of Councillors, the clause "Within three years of this Act's entry into force, the government will consider the situation concerning improvements to the clinical research environment at medical institutions playing a core role and will take the necessary measures based on the outcome of its deliberations" was added to Article 2 (1) of the supplementary provision of the Healthcare Policy Promotion Bill, in light of various circumstances surrounding medical R&D in particular. In addition, to ensure that appropriate steps are taken, supplementary resolutions were adopted concerning the accumulation of know-how regarding the prevention of fraud in research and the cultivation of specialist personnel in this area, and measures to provide citizens with a deeper understanding of the importance of R&D in the medical field. The Promotion Act and the AMED Act were subsequently enacted on May 23, 2014.

The "Japan Revitalization Strategy (Revised in 2014) -Japan's challenge for the future-" was approved by Cabinet on June 24, 2014, detailing the steady progress being made through initiatives undertaken to date with the aim of extending the nation's "healthy life expectancy," and setting forth new measures to be implemented to develop a dynamic service industry outside the public insurance system.

The Healthcare Policy was formulated on July 22, 2014 and thereafter has been promoted in accordance with the

provisions of Article 17 of the Promotion Act pursuant to the basic principles prescribed in Article 2 of the Promotion Act, in keeping with the basic measures prescribed in Articles 10 to 16 of the Promotion Act.

The "Japan Revitalization Strategy (Revised in 2015) -revolution in productivity by investment in the future-" was approved by the Cabinet on June 14, 2015, setting forth new measures to be implemented to vitalize the medical care, nursing care, and healthcare industries and improve productivity in the industries in order to continue to extend the nation's "healthy life expectancy."

The "Japan Revitalization Strategy 2016 -towards the fourth industrial revolution-" was approved by the Cabinet on June 2, 2016, setting forth measures for establishing new services in keeping with the fourth industrial revolution with the aim of making Japan the world's most advanced country in terms of health.

Based on these details so far, a necessary review has been conducted on the Healthcare Policy.

2) Basic principles of the Healthcare Policy

Article 17 (1) of the Promotion Act stipulates that "The government shall prescribe a Healthcare Policy in keeping with the basic measures prescribed in the previous Chapter, pursuant to the basic principles."

Article 2 of the Promotion Act prescribes the following matters concerning the basic principles of this policy.

[Basic principles prescribed in Article 2 of the Promotion Act]

Provide medical care using the world's best technologies

To provide people with the world's best medical care by promoting integrated medical R&D activities, from basic R&D to R&D focused on practical uses, and by facilitating the practical application of the results of these activities.

Contribute to economic growth

To contribute to Japan's economic growth while helping to improve the quality of medical care abroad by promoting the creation and overseas expansion of industries that contribute to the establishment of a society in which people enjoy long and healthy lives.

This makes it clear that building a system that steadily links Japan's advanced R&D capabilities into the practical application of drugs, medical equipment, and medical technology (technology required to provide medical care; excludes drugs (drugs as stipulated in Article 2 (1) of the Act on Ensuring the Quality, Effectiveness, and Safety of Drugs and Medical Equipment, etc. (Act No. 145 of 1960. Hereinafter referred to in this policy as the "Drugs and Medical Equipment Act".)), medical equipment (medical equipment as prescribed in paragraph 4 of said Article), and regenerative medical products, etc. (regenerative medical products, etc. as prescribed in paragraph 9 of said Article). Apart from "medical technology" in 2 (5) (b), the same shall apply hereinafter), with a view to achieving a true society in which people enjoy long and healthy lives, will enable the country to provide the world's best medical care by feeding back the outcomes of R&D to citizens. In addition, from the perspective of contributing to the international community, promoting the overseas expansion of industries that assist in establishing new societies in which people enjoy long and healthy lives will lead to improvements in the quality of medical care overseas, while also enabling markets for related industries to expand overseas, thereby contributing to the growth of the Japanese economy.

It is vital to promote the Healthcare Policy on the basis of an accurate understanding of the needs of stakeholders such as patients and other citizens.

Given that Japan is in the process of becoming an ultra-aging society ahead of the rest of the world, it is important to rise to the challenge as a developed country capable of resolving problems, and to ensure the global spread of its model for overcoming the difficulties inherent in an ultra-aging society.

(2) Period covered by the Healthcare Policy

This policy covers the period between FY2014 and FY2019, with a view toward the next ten years or so.

This policy will undergo a full review by FY2020, but may be revised as needed, based on the results of follow-up reviews.

2. Details

(1) Measures related to medical R&D, etc. that contribute to the provision of the world's best medical care

The government will take measures that will contribute to the provision of the world's best medical care by promoting integrated medical R&D activities, from basic R&D to R&D focused on practical uses, and by facilitating the practical application of the results of these activities. Through this, it will aim to improve industrial competitiveness in fields associated with drugs, medical equipment, etc. and medical technology, as well as promoting international medical collaboration and contributing to the international community.

Regarding medical R&D, in addition to this policy, a Plan for Promotion of Medical Research and Development (hereinafter "the Promotion Plan") will be prepared that prescribes the basic policy on measures and the measures to be implemented intensively and systematically by the government, based on Article 18 of the Promotion Act and in keeping with this policy. Medical R&D will be promoted on the basis of the Promotion Plan.

1) Governmental measures to promote medical R&D

The government will promote integrated medical R&D activities, from basic R&D to R&D focused on practical applications, through partnerships between the Japan Agency for Medical Research and Development (hereinafter "AMED"), universities, and research institutes. The objective of this will be to promote the medical R&D required to provide the world's best medical care, as well as facilitating the practical application of the results of this R&D.

○ Promoting "cyclical R&D" and achieving open innovation

・It is necessary to strengthen basic research and constantly generate groundbreaking seeds to sustain medical R&D. Accordingly, as well as promoting reverse TR, which not only channels the results of basic research into clinical settings, but also feeds the challenges identified in clinical settings back into basic research, and "cyclical R&D," which includes basic medical research and clinical research by the use of human-originated clinical specimens, the government will develop initiatives aimed at achieving open innovation while securing intellectual property. For this purpose, the government will establish a system for research institutes' transfer of R&D results, provide and manage

information on R&D results, strengthen the system for core hospitals for clinical research, national centers, and other medical institutions that have the function of supporting other hospitals' clinical research, strengthen and network research by the use of clinical information, promote industry-academia-government through the use of clinical data by core hospitals for clinical research, carry out R&D accurately in response to needs at actual medical scenes, and form foundations for radically reforming the acceleration of practical application such as drug discovery (including human resource development).

・To create innovative new drugs and medical equipment, the government will promote R&D initiated through industry-academia-government cooperation and establish an environment for such R&D.

・The government will strengthen the partnerships forged by the Pharmaceuticals and Medical Devices Agency (PMDA), which concluded a partnership agreement with AMED in August 2015, and the National Institute of Health Sciences with universities, research institutes, medical institutions, and companies. In addition, it will seek to disseminate and enhance regulatory science in R&D by augmenting the pharmaceutical affairs consultation system, developing examination guidelines, improving the specialist knowledge of examiners, and utilizing information science and technology.

○ Building new mechanisms for developing medical R&D

・To build a system for unearthing and adopting promising seeds from research institutes in Japan and link these into practical applications, the government will develop systems for promoting integrated R&D activities, from basic R&D to clinical research (medical research in which humans are the subjects, which is carried out for the purpose of improving strategies for treating illness in the context of medical care, understanding the causes of diseases, etc., and increasing the quality of life of patients; this excludes "clinical trials" as prescribed in Article 2 (17) of the Drugs and Medical Equipment Act; the same shall apply hereinafter) and trials, and on to practical applications, as well as for assisting verification in clinical settings and the identification of new challenges.

・To advance the development of innovative drugs and medical equipment in Japan, the government will seek appropriate evaluation of innovation within the prescription drug price system, etc.

・To promote research in earnest concerning the development and dissemination of technologies and systems (medical arts) for reforming medical care from the viewpoint of medical effectiveness, safety, and efficiency

○ Toward the establishment of evidence-based medicine

・To achieve medical care based on evidence such as environment or genetic background, the government will proceed with deliberations focused on developing the necessary infrastructure and information technology. Large-scale cohorts and banks not only of patients, but also healthy individuals will be networked and utilized effectively. To ensure effective use of clinical information and high-quality patient-originated diseased tissue and other samples accompanied by precise clinical information, government support will be provided in dealing with bioethical issues,

and disease specimen banks will be developed. In addition, efforts will be made to enable companies, etc. to access anonymized data and patient-originated samples.

○ Initiatives for achieving the world's best medical care

・As well as promoting initiatives aimed at regenerative medicine and genomic medicine, the government will promote the use of Japan's advanced science and technology to identify the clinical nature of diseases and the establishment of gene therapies and other new treatments based on these findings. It will also cultivate groundbreaking new seeds that offer substantial hope for future drugs, medical equipment, and medical technology, including the development of drug delivery systems (DDS) and innovative drugs and medical equipment, etc. It will seek to strengthen the development of biopharmaceuticals and middle molecule drugs, the market for which is expected to expand in the future, as well as next-generation technologies, instruments, and systems for measurement, analysis, and evaluation.

Regarding the practical use of genomic information for medical care, based on the results of examination by the Genomic Medicine Realization Promotion Council and the Taskforce for Promoting Practical Medicine by the Use of Genomic Information, the government will carry out concrete measures, such as the establishment of a system for providing medical treatment for diseases such as cancer and intractable diseases.

○ New systems for promoting medical R&D

・To promote governmental R&D in the field of medicine, the government will consolidate in the hands of AMED its strategic research expenditure allocation functions in relation to medical R&D focused on drugs, medical equipment, etc. and medical technology, ensuring the integrated allocation of funds. Regarding the medical R&D carried out by individual ministries, AMED will provide integrated research management from the basic to the applied stages, utilizing the expertise of program directors (PD), ensuring seamless support for research activities from basic research through to practical application, including intellectual property (IP) management by IP experts and cooperation with the Innovation Network Corporation of Japan (INCJ), with which a mutual cooperation agreement was concluded in March 2016.

○ Establishment of the Japan Medical R&D Grand Prize

・Establishment of the Japan Medical R&D Grand Prize for great contributions to the promotion of medical R&D

2) Governmental measures to improve the environment for R&D

The government is implementing the necessary initiatives to improve the medical R&D environment. To this end, it has enacted the Act to Partially Revise the Pharmaceutical Affairs Act, which extends the scope of the system of medical equipment certification by an accredited certification body to cover specially controlled medical devices, and establishes an approval system that takes into account the attributes of regenerative medical products, etc. that differ from ordinary drugs and medical equipment; the Act to Ensure the Safety of Regenerative Medicine, etc. (Act No. 85 of 2013), which prescribes for the first time standards for medical institutions providing regenerative medicine, etc., and standards for facilities cultivating and processing cells, to ensure the safety of regenerative medicine, etc.;

and the Act Concerning Improvement of Relevant Acts for Promoting Comprehensive Measures for Securing Regional Medical and Nursing Care (Act No. 83 of 2014), which positions hospitals playing a central role in world-class clinical research and physician-led clinical trials as core hospitals for clinical research; and the Act for the R&D and Promotion of Medical Equipment for Improvement in the Quality of the Medical Care for the Nation (Act No. 99 of 2014), which specifies basic matters concerning measures for the R&D and promotion of medical equipment, and the Basic Plan for the R&D and Promotion of Medical Equipment for Improvement in the Quality of the Medical Care for the Nation (Cabinet decision on May 31, 2016).

The government will continue to promote improvements to the environment – including systems, databases, and ICT – to facilitate the clinical research and trials required for the smooth, effective implementation of the medical R&D essential to the provision of the world's best medical care.

○ Fundamentally improving the clinical research and trials environment

・The government will make comprehensive use of the centers being developed as part of the Innovative Medical Technology Creation Center Project, namely translational research support centers and core hospitals for clinical research (hereinafter "Innovative Medical Technology Creation Centers"), as well as the national centers for advanced and specialized medicine (National Centers). In addition, it will promote clinical research and trials by building up ARO (Academic Research Organization) functions centered on these. To advance clinical research and trials, the government will create a network (Clinical Innovation Network) to seek the consolidation of cases through collaboration among the National Centers and other medical institutions and will promote further improvements in function while making effective use of these resources, thereby building a mechanism to enable high-quality world-class clinical research and trials to be conducted without fail.

・To promote the high-quality clinical research and trials required for Japan to develop innovative drugs, medical equipment, etc. and medical technology, the government will strengthen the function of core hospitals for clinical research, which are positioned in the Medical Care Act as playing a central role in conducting world-class clinical research and physician-led clinical trials, and promote core hospitals for clinical research's high-quality clinical research, physician-led clinical trials, and provision of support to other institutions. Moreover, to carry out ethical reviews of multi-institutional joint research properly and smoothly, the government will promote core hospitals for clinical research's establishment and management of central ethical review boards.

・The government will establish a system whereby researchers and medical institutions can strengthen joint possession and wide-area cooperation concerning data that can be gained through comprehensive analysis of clinical samples and data on related observations, symptoms, and progress, collaborate in collecting, collating, analyzing, and giving meaning to data, and make them reflected in the improvement of the quality of diagnosis and treatment of patients as data providers.

○ Developing the research base

・The government will aim to ensure that information and samples are shared as widely as possible, including life

science databases, nationwide databases of intractable diseases, Big Data databases, and the collection and preservation of high-quality samples. In addition, collaboration focused on the databases developed by individual ministries will be promoted. The government will develop the research base in such areas as high-quality samples from patients and will work in partnership with both existing large-scale advanced research infrastructure, such as synchrotron radiation facilities and supercomputers, and small-scale facilities with cutting-edge measurement and analysis instruments, seeking to make it easier to use common science and technology infrastructure, and to utilize it to further promote medical R&D.

By establishing the Drug Discovery Support Network and other support foundations for drug discovery, the government will cooperate with universities and the industrial world to support R&D for creation of new drugs and strengthen the foundations for support of drug discovery.

In addition, to promote the development and practical use of medical equipment with the cooperation between the medical and engineering sectors, the government will strengthen the system for several professional support organizations' provision of development support (Network for Supporting Development of Medical Devices).

Moreover, based on the Basic Guidelines for Strengthening Measures on Emerging Infectious Diseases (approved by the relevant Cabinet committee on September 11, 2015), the Basic Plan for Strengthening Measures on Emerging Infectious Diseases (approved by the relevant Cabinet committee on February 9, 2016), and the Government's Participation in the Construction of Biosafety Level 4 (BSL4) Facilities of Nagasaki University (approved by the relevant Cabinet committee on November 17, 2016), the government will provide necessary support for the formation of infectious disease research bases centering on BSL4 facilities to strengthen Japan's function of infectious disease research.

○ ICT-related initiatives

・The government will carry out legislative measures for systems for widely collecting, safely managing and anonymizing, and using technologies for increasing the number of cases accumulated, with a view to promoting efficient clinical research and trials, as well as technologies that will allow the flexible integration of citizens' medical information and various other data, taking into account the conditions for the handling of medical information. Moreover, in promoting greater application of ICT to medical information, practical database functions that meet the need for R&D will be developed to ensure its effective use in R&D. As well as promoting R&D concerning the comprehensive application of ICT in medical care, the government will undertake initiatives aimed at ensuring interoperability between systems handling various kinds of medical information.

3) Governmental measures to ensure fair and appropriate operation of R&D

The government will seek to prevent research irregularities, such as the fraudulent manipulation of data or conflict of interests in research papers, and deal with ethical issues, such as the protection of test subjects participating in clinical research. To this end, it will conduct the initiatives required to ensure the fair, appropriate implementation of medical R&D, to make sure that any research institute, medical institution, or business operator conducting medical R&D complies with legislation and administrative guidelines concerning R&D, as well as managing ethical

considerations and personal information appropriately.

○ Fair research mechanisms and improving the environment to ensure ethical, legislative, and regulatory compliance

・The system introduced in FY2014 for the accreditation of ethical review boards that meet standards prescribed by the government will continue to be used for ensuring the quality of reviews conducted by ethical review boards and making overall improvements in quality.

・On May 13, 2016, a "clinical research bill," which aims to gain the nation's trust in clinical research in Japan by specifying procedures for the implementation of clinical research, was submitted to the 190th ordinary session of the Diet. After the bill is passed, related laws and regulations will be established to facilitate smooth enforcement.

・To promote initiatives to prevent irregularities in basic and clinical research, a dedicated division will be established at AMED to ensure fair and appropriate operation of research conducted using the research funds that it allocates. In addition, through its duties, it will strive to accumulate know-how concerning responses to irregularities in medical R&D and to cultivate personnel specializing in this area.

4) Governmental measures to establish a better review system for putting the results of governmental R&D to practical use

The Act to Partially Revise the Pharmaceutical Affairs Act has been enacted to ensure that the fruits of medical R&D, namely new drugs and medical equipment, etc., are swiftly and safely put to practical use. Among other measures, the Act obliges those manufacturing and selling drugs and medical equipment, etc. to submit package inserts prepared on the basis of up-to-date knowledge. In addition, it expands the scope of medical equipment certification by accredited certification bodies (in the case of the medical equipment manufacturing / manufacturing and sale sector, the provisions are described in a separate chapter from those for drugs, etc.), and establishes a system for granting conditional approval for regenerative medical products, etc. for a limited period. A review system will be put in place to ensure the appropriate operation of this new scheme and enable the swift, accurate implementation of the procedures required for the practical application of drugs and medical equipment, etc., including reviews of approval for drugs and medical equipment, etc. The government will seek the development of the systems required for promoting science focused on swift, appropriate forecasting, evaluation, and judgment based on scientific knowledge, concerning the quality, effectiveness, and safety of practical applications for medical R&D results. In addition, it will aim to secure and nurture relevant personnel, as well as improving their capabilities.

○ Strengthening the PMDA

・The pharmaceutical affairs consultation system will be enhanced and the necessary operational improvements will be made to the priority clinical trial consultation system, to strengthen partnerships between the PMDA and universities, research institutes, medical institutions, and companies, with a view to ensuring that research results are linked efficiently to pharmaceutical approval.

・To support the development of practical applications, the government will bolster the PMDA's systems for pharmaceutical affairs consultation, etc. and AMED's business partnership and collaboration support functions, including the formulation and provision of advice concerning an exit strategy for promising seeds in partnership with the PMDA, the provision of information to companies, and business matching.

・Consideration will be given to maintaining the examination period and further expanding the scope of acceptance of English-language materials among the supporting materials submitted when applying to the PMDA for approval of a new drug.

○ Promoting regulatory science

・The government will strengthen the partnerships forged by the PMDA, which concluded a partnership agreement with AMED in August 2015 and the National Institute of Health Sciences with universities, research institutes, medical institutions, and companies. In addition, it will seek to disseminate and enhance regulatory science in R&D by augmenting the pharmaceutical affairs consultation system, developing examination guidelines, improving the specialist knowledge of examiners and utilizing information science and technology. (Described above)

・PMDA will utilize clinical test results and other big data, begin trial efforts for developing new indicators and methods for drug effective evaluation through data analysis, preparing guidelines, and promoting companies' development through it, and establish a regulatory science center that will begin full-scale efforts in 2018. In addition, PMDA will strengthen safety measures through the analysis of the medical data in the medical information database system (MID-NET) and disease information registered by National Centers and the promotion of utilization of MID-NET by companies and medical institutions.

5) Other necessary governmental measures

As well as developing drugs, medical equipment, etc. and medical technology originating in Japan, and promoting efforts to contribute to improving medical care not only at home, but also in other countries, the government will seek to secure and cultivate personnel in all relevant fields, in order to increase the potential for medical R&D. In seeking to increase Japan's international competitiveness in the field of medical care, the government will promote strategic IP initiatives, such as enhancing IP education, and cultivating and utilizing experts in IP. Moreover, the government will try to solve problems related to Antimicrobial Resistance (AMR), which has serious impact on public health, society, and the economy.

○ Initiatives based on international perspectives

・Adequate consideration will also be given to international perspectives when setting R&D themes. As well as experts in individual fields, personnel with an international mindset will be cultivated and utilized. When selecting topics, the government will strive to ensure an adequate hearing for the opinions of both Japanese and foreign scientists in the relevant specialist discipline. Promoting international cooperation is also essential, so the government will strengthen support systems for conducting international collaborative research, such as the development of high-

quality clinical research and trials, and the establishment of research networks. Through cooperation in the provision of medical services and development of systems suited to the circumstances and needs of the counterpart country, the government will seek to strengthen Japan's industrial competitiveness, while demonstrating an awareness of sustainable business development that truly contributes to medical care in the counterpart country. Positioning global health as a key issue in Japanese diplomacy, the government will mobilize knowledge from throughout Japan in its quest to ensure that everyone around the world can enjoy basic medical care services at an affordable price (universal health coverage (UHC)).

○ Human resource development

・The government will cultivate personnel who are well-versed in everything from basic research to clinical research and trials, have a record of world-class academic achievements, and can demonstrate strong leadership, including young and female researchers.

It will promote efforts to secure and cultivate experts in biostatistics, regulatory science, and other specialist fields.

Moreover, it will cultivate personnel capable of conducting multidisciplinary research and creating innovation, to ensure that innovative drugs, medical equipment, etc. and medical technology reach clinical practice sooner.

Efforts will also be made to raise the nation's overall understanding (literacy) concerning health and disease.

○ IP management initiatives

・A dedicated department will be utilized by AMED to support research institutes in acquiring IP (IP management and advice desk, support for the formulation of IP acquisition strategies, etc.)

○ Promotion of Antimicrobial Resistance (AMR) measures

・The government will promote necessary measures according to the National Action Plan on Antimicrobial Resistance (AMR), which was determined by the Ministerial Meeting on Measures on Emerging Infectious Diseases (approved orally by the Cabinet on September 11, 2015) on April 5, 2016.

(2) Measures related to promoting the creation of new industries and facilitating overseas expansion in the healthcare and medical care sector

Markets that can respond to specific needs at home and abroad are required for the development of drugs and medical equipment, technology, and services in Japan. On the domestic front, the government will seek to achieve the world's most advanced, highest-quality medical care, and to create new markets for healthcare services not covered by public insurance, focusing on such areas as disease prevention and chronic phase support for daily life. In addition, the government will develop overseas markets, while engaging in international medical cooperation, by seeking the overseas expansion of new drugs, medical equipment, etc. and medical technology, as well as new medical and healthcare services.

1) Creation of new industries focused on healthcare and medical care

In creating a society in which people can enjoy healthier lives as they grow old, drugs, medical equipment, etc. and medical technology are the foundation not only of the treatment of illnesses, but also of effective disease prevention, health management, and services that provide support for the daily lives of those affected by illness. As such, focusing primarily on such new healthcare services, it is essential to ensure that industrial activities contributing to the establishment of a society in which people enjoy long and healthy lives are coordinated with a variety of health promotion activities linked to the public insurance system and meet the various health-related needs of individuals and communities. This can be expected to "kill three birds with one stone": (1) improving people's health; (2) developing a new healthcare industry outside the public insurance system; and (3) as a result, optimizing expenditure on chronic medical care associated with lifestyle-related diseases, for example. Moreover, it will be important for local authorities and companies, along with insurers, to demonstrate a greater interest in the health of local citizens and employees and to make use of these industries when taking concrete actions.

At the same time, as the population declines in Japan's regions, the development of new industrial activities that contribute to the establishment of a society in which people enjoy long and healthy lives is expected to play an important role in revitalizing local economies and communities. The use of this development to achieve local economic revitalization and ensure the sustainability of the public insurance system is a pressing issue and if sufficiently positive results can be achieved, it will become the world's most advanced framework for complex healthcare.

The tasks required to achieve this include (1) rousing public awareness of health promotion and prevention; (2) visualizing the effects of disease prevention; (3) clarifying the various advantages and disadvantages of health promotion and prevention for individuals, companies, and local authorities; (4) using partnerships between medical institutions and companies to create scientifically-based services not covered by public insurance, including disease prevention and health management services; (5) utilizing local resources (collaboration between medicine, agriculture, commerce and industry) to create new industries; and (6) developing an environment in which high-quality clinical research and trials and cohort studies can be carried out smoothly at an appropriate cost, to generate scientifically-based services.

By taking on these challenges, the specific options for health promotion and disease prevention will become more diverse, making it possible to create a society in which, with reasonable effort, people can avoid contracting or aggravating diseases as far as possible. For example, in the case of diabetes and other lifestyle-related diseases, the use of health management services would enable people to routinely manage their own health, seeking a consultation at a medical institution if the possibility of a condition arose and using services to prevent disease or aggravation of a condition. Alternatively, insurers could conclude a contract with a service provider to supply the insured with a service.

To establish a proper care cycle and create industrial activities that will contribute to the establishment of a society in which people enjoy long and healthy lives, with a particular focus on services not covered by public insurance, the Next-Generation Healthcare Industry Council established under the auspices of the Headquarters for Healthcare Policy will (1) improve the environment for creating new businesses, through such efforts as eliminating gray areas where the scope of application of existing regulations is unclear; (2) encourage the purchase and use by insurers and companies, etc. of services not covered by public insurance that will contribute to health promotion and disease

prevention (hereinafter "investment in health"); and (3) promote the establishment of a mechanism for evaluating the quality of products and services. Moreover, to improve quality of life for elderly people and people with disabilities and create new manufacturing industries in Japan, the government will improve the environment to promote R&D focused on robotic care equipment and encourage its introduction.

(a) Improving the environment to create new business

○ Regional roll-out

・To develop industrial activities that will contribute to the establishment of a society in which people enjoy long and healthy lives in Japan's regions, it is vital for diverse bodies such as service providers, medical institutions, local authorities, chambers of commerce and industry, and financial institutions to work in partnership with each other. Accordingly, the government will seek to roll out regional Next-Generation Healthcare Industry Councils nationwide, to nurture industries that make use of local resources, such as collaboration between medicine, agriculture, commerce and industry.

・The government will support model demonstration projects focused on new business, to promote regional collaboration between medicine, agriculture, commerce and industry.

・In order to develop dynamic industries focused on senior lifestyles and create a society in which elderly people can live healthy lives in their communities with peace of mind, the government will enhance the diverse range of living support services offered by elderly people themselves, NPOs, volunteers, social welfare service corporations, and private sector companies, based on the concept of self-help and mutual aid, while also striving to achieve appropriate partnerships and the division of roles with the local healthcare industry.

・The government will aim for local authorities to establish new social healthcare systems that incorporate service businesses (local healthcare that takes into account the existence of private sector services not covered by public insurance), creating a forum for the exchange of information concerning community health promotion based on an appropriate combination of not only medical care covered by public insurance and services within the scope of public benefit administration, but also community prevention and health management services.

○ Supplying funds for business

・In order to provide funding and management know-how for the healthcare industry and encourage the development and widespread adoption of new business models, the Regional Economy Vitalization Corporation of Japan (REVIC) will promote the use of the Regional Healthcare Industry Support Fund to support the creation and expansion of the healthcare industry in Japan's regions.

○ Personnel

・To facilitate activities that meet various needs of the elderly, the government will give support to councils established mainly by local governments in their projects for promoting the employment of the elderly and expand

leading model communities.

・The government will support matching projects focused on the effective use of local public health nurses and active senior personnel (people aged 65 or above who are capable of working).

○ Improving ICT systems

・As well as promoting the development of systems that also share (visualize) relevant nursing and medical care information with the public, the government will promote information sharing and partnerships among diverse actors involved in integrated community care.

・The government will formulate the technical requirements and operational rules required for collaboration with patient-focused peripheral medical care services using information and communications technology, such as services in the medical cloud, and health management and monitoring. In addition, it will aim to standardize the process used for collaboration between medical institutions and private sector business operators, and verify the specific items that need to be shared.

・To promote investments in SMEs' R&D, which have already started, and participation by companies with the world's top-level technological strength as two engines of economic growth, the government will establish the Future Intelligent Medical Subcommittee (tentative name) under the Council on Foundations for Next-Generation Medical ICT and the Task Force on International Expansion of Medical Businesses to consider measures for promoting the application of Japan's internationally competitive high-definition image technology, high-level advanced ICT technology (including AI technology and big data-related technology), and sensing technology to the field of medical care.

○ Other

・To offer health examinations and guidance based on the specific attributes of elderly people, with a view to further promoting efforts to prevent the need for nursing care, the government will work in partnership with medical institutions to undertake projects focused on preventing the exacerbation of underlying conditions for those suffering from lifestyle-related diseases, taking into account the opinions of experts and insurers concerning approaches to health services for elderly people.

・The government will promote the Smart Life Stay Program, which utilizes hotels, traditional ryokan inns, and other accommodation facilities and tourism resources for people suspected of having diabetes and carry out research on verification of the effect of the program.

・In addition to services focused on meals, exercise, and mobility support for elderly people and people with disabilities, the government will encourage the development and demonstration of new technologies and services that promote the recovery of physical functions, such as improving and restoring the function of cranial nerves

(neurorehabilitation). Establishing an initial market for these new technologies and services is particularly important, so the government will actively support overseas expansion efforts in this area.

(b) Encouraging investment in health by insurers and companies

○ Utilizing data such as medical receipts and health check information

・The government will formulate and announce a “data health program”, using data such as medical receipts and health check information provided by insurers to promote health programs based on data analysis. In addition, taking into account the results of large-scale verification of health creation models using ICT, it will seek to promote individual health-consciousness in projects positioned within the data health program. A collection of case studies of health programs based on insurers and business operators working together will be compiled and published, and collaboration between insurers and business operators (collaborative health) will be promoted.

・As a means of improving the take-up rate of special health check-ups among those insured with the Japan Health Insurance Association, the government will encourage initiatives to cultivate an awareness of the problem among business operators, to promote the provision of data to insurers by business operators. For example, these initiatives include lobbying of companies by insurers that use data, and the promotion of health management declarations by the senior management of SMEs.

・As a means of improving the take-up rate of special health check-ups among dependents of those insured via employees’ insurance, the government will add items to the special health check-up that will increase motivation to undergo the check-up and will implement measures to make health check-ups more convenient. Further measures to encourage dependents to undergo these check-ups may be implemented, depending on the implementation status of the aforementioned measures. Outsourcing to the National Health Insurance (NHI) program (municipal organizations) will also be promoted.

・The government will create next-generation healthcare services to support effective health programs by insurers, while promoting the integrated use of medical and nursing care information. To this end, it will aim to ensure that municipal NHI organizations make effective use of the NHI database (KDB) held by the All-Japan Federation of National Health Insurance Organizations, which brings together data from medical receipts and special health check-ups, with a view to analyzing regional medical expenses, gaining an understanding of local health issues, and implementing finely-tuned health programs.

・As well as promoting dental health initiatives within the context of the data health program, the government will verify the effects of dental health promotion services on lifestyle-related diseases. Based on the results, it will enhance dental promotion initiatives, such as further upgrading dental health promotion services.

・Using data from medical receipts held by insurers, the government will encourage initiatives to promote mental health, by such means as supporting mental health measures undertaken by business operators.

○ Granting incentives

・With a view to granting incentives aimed at increasing the take-up rate of special health check-ups, the government will conduct demonstration projects concerning points-based healthcare incentive systems. Regarding systems for increasing or decreasing funding for older elderly people, the government will compile specific measures that take account of the opinions of relevant stakeholders and the verification of the effects of special health check-ups and special health guidance.

○ Evaluation of investment in health

・The government will select a theme-based issue (Health-Management Stocks) on the Tokyo Stock Exchange as a mechanism for evaluating companies that invest in health, and encourage companies to include details of their health management and disease prevention initiatives for employees in their corporate governance reports and CSR reports. In addition, as a program for honoring companies publicly like Health-Management Stocks, the government will establish a "program for certifying companies excellent in health management" for SMEs and medical corporations that carry out excellent health management to promote health management.

・The government will develop indicators that will allow investment in health by companies and health insurance societies to be evaluated and their health promotion initiatives to be compared. It will also encourage the use of these indicators by companies and health insurance societies in conjunction with the data health program.

○ Other

・The government will continue to support good examples of projects for preventing the exacerbation of diabetes, in order to enable the nationwide roll-out of such projects.

・To encourage investment in health, the Next-Generation Healthcare Industry Council will publish and share examples of best practice by companies and insurers.

(c) Establishing a mechanism to evaluate the quality of products and services

・Regarding "health tourism," "healthy exercise services," and other healthcare services, the government will undertake third-party certification by private sector organizations, and will encourage the use of certified services by local authorities and companies.

・The government will widely notify the nation of "healthy meals," prepare guidelines for meal delivery service, and have service providers comply with the guidelines so that elderly people using meal delivery service can appropriately manage their nutrition.

(d) Improving the environment to promote R&D focused on robotic care equipment and encourage its introduction

・To improve the quality of life of elderly people and people with disabilities and minimize the burden of nursing

care, the government will promote improvements to the environment to facilitate R&D and practical applications in the field of robot technology.

・The government will seek to support the self-reliance of elderly people and people with disabilities, reduce the burden in frontline nursing care, and create a new manufacturing industry in Japan by ensuring the rapid adoption and widespread use of cheap robotic care equipment that meets the specific needs of elderly people and people with disabilities, as well as those on the frontline of nursing care. To this end, it will promote the Five-year Plan for Developing Nursing Care Robots, which began in FY2013 and advocates using a contest format to encourage the development of cheap, convenient robotic care equipment, such as wearable transfer aids and monitoring systems. In addition, the government will establish an environment and give support for the introduction of nursing care robots, which have already reached the stage of practical use, to promote their introduction and use for clinical practice. Through this effort, it will seek to support the self-reliance of elderly people and people with disabilities, and alleviate the burden on care workers.

・ The government will promote improvements to the environment aimed at the practical application of communication robot technology, including sensor technology, to facilitate its utilization in monitoring elderly people and people with disabilities, supporting daily life and nursing care, and healthcare.

2) Supporting business expansion of startup companies, etc. in growth markets

To develop the field of healthcare and medical care, it is vital to conduct R&D with a clear awareness of the market, restructure existing businesses, and establish new business models that will aid business development both within Japan and overseas. Accordingly, it is necessary to conduct both R&D and pioneering investment as integral halves of the same whole, and to offer support for business expansion by startup companies and SMEs in the field of healthcare and medical care.

(a) Improving the environment for the supply of funds in the field of healthcare and medical care

・Compared with other fields, healthcare and medical care requires the investment of large sums of money and there is a tendency for the risks to be comparatively high as well. Accordingly, to ensure that investment and funding in this field is implemented and managed effectively, the Task Force on Healthcare Policy Funds established under the auspices of the Headquarters for Healthcare Policy will seek to ensure appropriate management in accordance with the attributes of the field in question, while exchanging and sharing information concerning such matters as the investment policies of public-private investment funds in this field, examples of investment, and the implementation status of relevant government policies. In doing so, consideration will be given to such guidelines as the Guidelines on the Management of Public-Private Investment Funds (approved on September 27, 2013 by the relevant Cabinet committee on promoting the use of public-private investment funds).

・To establish a virtuous circle in which public-private investment funds serve as pump-priming measures, with the

startup companies thus cultivated then investing in new private sector startups, the government will compile examples of success in joint investment with the private sector from the initial stages of investment, and will seek ongoing revitalization throughout the healthcare and medical care industry, while ensuring cooperation between the public and private sectors. In addition, to enhance the investment environment, the government will continue to develop and strengthen business support systems in the healthcare and medical care sector, such as the establishment of teams focused on healthcare and medical care at public-private investment funds and other businesses and the development of systems for this, with a view also to human resource development and the cultivation of private sector funds.

・Creating innovative drugs and medical equipment, etc. while dealing with the diversification of medical needs and new technologies requires an environment in which private sector companies can actively engage in such endeavors as selection and concentration in areas of strength, and the promotion of open innovation that blends the company's own R&D and human resources with external seeds, technologies, and money. Accordingly, the government will continue to implement measures to encourage efforts to strengthen the R&D capabilities of private sector companies and develop drugs and medical equipment, etc. that will contribute to increased international competitiveness.

(b) Support for industry development by startup companies and SMEs

○ Collaboration between industry, academia and government

・Through collaboration between industry, academia and government, the government will utilize subsidies to realize innovations to support R&D that creates innovations by linking excellent seeds to practical applications.

・To promote business partnerships with startup companies and SMEs, the government will offer support for business matching forums with large corporations from both within Japan and overseas, as well as supporting overseas expansion. In conjunction with this, it will make effective use of gatherings, seminars, and exhibitions, etc. attended by companies, universities and other R&D organizations from across the globe, and will encourage startup companies and SMEs to form alliances with domestic and overseas pharmaceutical companies and medical equipment manufacturers. In addition, the government will provide support for the development and commercialization of drugs and medical equipment in which manufacturing SMEs, medical institutions, universities, etc. cooperate, and give continuous support at the stages between early development and commercialization with the cooperation of related organizations.

・Starting from the pre-launch stage, the government will utilize the commercialization know-how of private sector venture capital companies and other private sector bodies to support the creation of university startups focusing on markets and outlets in their quest to commercialize high-risk seeds with a high potential for developing new markets.

○ Regulation

・The PMDA's pharmaceutical affairs consultation program (including on-site consultation) will be enhanced, with the aim of offering advice concerning the development process (roadmap) for innovative drugs, medical equipment, etc. and medical technology, and ensuring that they are put to practical use without delay. The primary focus of this

advice will be universities, research institutes, business companies and SMEs.

・To promote the practical application of innovative medical equipment created by startup companies or SMEs, the government will continue to provide support for consultation and carry out measures for reducing the burden of paying examination fees.

3) Facilitation of overseas expansion in the healthcare and medical care sector

Boasting a universal public health insurance system and some of the world's best drugs, medical equipment, etc. and medical technology, Japan's medical and nursing care system is one of the world's foremost, ranking among the top countries in the WHO's assessment of health care systems. On the other hand, in many emerging countries, there are growing expectations that economic growth will be accompanied by efforts to meet medical and nursing care needs and build sustainable systems. However, such countries have little experience of constructing insurance systems or medical and nursing care systems, as well as suffering from both a lack of sophisticated technology and personnel shortages.

Accordingly, giving adequate consideration to the situation in each country, Japan will provide specific drugs, medical equipment, etc., medical technology, and medical services to emerging and developing countries, as well as providing cooperation in the construction of medical and nursing care systems, thereby building mutually-beneficial relationships in the field of medical and nursing care. Through this, Japan will ensure diversity in its methods of building diplomatic and economic relationships, thereby creating an environment that allows Japanese citizens to play an active role overseas with peace of mind. Furthermore, the government will aim to create a virtuous circle for both Japan and emerging and developing countries by using its efforts to encourage overseas expansion as a catalyst for creating cutting-edge medical and nursing care services in Japan as well.

(a) Appropriate operation of frameworks for international medical cooperation

・In forums such as the Task Force on International Expansion of Medical Businesses, which has been established under the auspices of the Headquarters for Healthcare Policy, relevant organizations (including Medical Excellence JAPAN (MEJ, a general incorporated association), the Japan International Cooperation Agency (JICA, an incorporated administrative agency), the Japan Bank for International Cooperation (JBIC, a joint-stock corporation), the Japan External Trade Organization (JETRO, an incorporated administrative agency), and the PMDA) and ministries will join forces to plan the overseas expansion of Japanese drugs, medical equipment, etc., medical and nursing care technology, and medical and nursing care services in a manner tailored to the needs of emerging and developing countries, sharing information and operating the PDCA cycle.

・In the process of operating frameworks for international medical cooperation, diplomatic missions overseas will work in partnership with JICA and other relevant government institutions to ascertain the health and medical care situation in emerging and developing countries and identify their needs. In addition, they will promote specific overseas expansion initiatives, such as collaboration and coordination with health authorities in the counterpart

country.

(b) Building healthcare infrastructure in emerging countries

○ Improving the environment in relation to health and medical care systems, technical standards, and regulatory requirements

・The government will seek the overseas expansion of medical and nursing care services based on an approach focused on both specific countries within each region and regions as a whole. To this end, it will provide emerging and developing countries in the ASEAN region and beyond with support for the establishment of health and welfare policies concerning measures to deal with the aging of the population, as well as sharing Japan's experience and knowledge concerning public medical insurance systems, and helping to improve the environment by offering personnel education systems. In addition, it will undertake cooperation with developed countries in the realm of dementia measures.

・Based on cooperation between Japanese companies with overseas offices and relevant ministries and agencies, the government will promote exchanges that bring together the public and private sectors. More specifically, with a view to furthering the overseas expansion of high-quality drugs and medical equipment, etc. originating in Japan, the government will strengthen dialogue with regulatory authorities in various countries and regions, focusing primarily on emerging and developing countries, in order to increase understanding of Japan's regulations, standards, and approval systems, thereby building and reinforcing relationships of trust at the national level.

・Japan will work in partnership with the countries of the West and Asia to improve understanding of Japan's regulations and standards around clinical trials and applications for approval of pharmaceuticals, as well as seeking to ensure international consistency in this area.

・The government will enhance research aimed at developing guidelines on evaluating the quality, effectiveness, and safety of drugs, medical equipment, etc. and medical technology that utilizes cutting-edge technology. In addition, ahead of other countries, it will propose the formulation of international standards and criteria concerning methods of evaluating state-of-the-art drugs, medical equipment, etc. and medical technology, and promote international standardization as a benchmark that can be used in regulation. At the same time, it will strengthen its efforts to disseminate information about Japanese drugs, medical equipment, etc. and medical technology to the rest of the world.

・The appropriate use of relevant international standards will be pursued to facilitate international distribution of Japanese drugs and medical equipment, etc.

・In facilitating the overseas expansion of drugs, medical equipment, etc., medical technology, and medical services, the government will promote the active use, etc. of telemedicine and other ICT.

・The government will establish practical model cases by the use of 8K and other high-definition image technologies as well as mobile technology and other ICTs in the field of medical care, verify and establish communications standards for networks tailored to such equipment, and will promote the overseas expansion of these models and communications standards.

・In pursuing the overseas expansion of drugs, medical equipment, etc., medical technology, and medical services originating in Japan, the government will work with relevant countries to promote the establishment of an international environment for protecting IP rights so that the IP rights in these products can be protected appropriately.

・To pursue the overseas expansion of Japan's medical technologies, the government will solve health and medical problems in rising and developing countries and promote the development of medical technologies, drugs, and equipment that fully meet developing countries' needs and the construction of evidence contributing to the expansion of Japan's medical technologies, etc. to rising and developing countries. Concretely, R&D will be carried out to improve the specifications of existing medical equipment according to the conditions in the countries so that the medical equipment can be suitable for the medical level, the condition of power supply, the climate, and other conditions in each country. After the equipment is improved, efforts will be made to put it to practical use. In addition, the government will change the medical technologies, drugs, and equipment recognized as effective in Japan into those suitable for local standards for use and confirm whether they are suitable for genetic characteristics and local environments. Moreover, regarding lifestyle-related and other diseases spreading in rising and developing countries, the government will develop a health guidance method, taking into consideration local culture.

○ Human resource development

・In terms of infrastructure for undertaking international medical projects, such as the overseas expansion of drugs, medical equipment, etc., medical technology, and medical services, the government will introduce foreign medical personnel to high-quality Japanese diagnostic and therapeutic techniques, providing them with ongoing opportunities to actually come into contact with them and strengthening educational functions in this area.

・The government will contribute to social stability in the Western Pacific Region in particular, by improving the standard of public health via the WHO's support programs. Maternal and child health and measures against infectious disease remain a high priority in emerging and developing countries, and they face a double disease burden in the form of lifestyle-related diseases and other non-communicable diseases (NCDs), so tackling these is a major challenge. However, the increase in the financial burden on the individual is also becoming a problem, so in order to achieve UHC that contributes to strengthening response to public health crises and preventing and preparing for crises, the government will strengthen support for human resource development in the field of health policy by sharing Japan's own experience and knowledge. By increasing the number of human resources developed in this way, the government will make environmental improvements for facilitating Japanese companies' advance into rising and developing countries.

(c) Overseas expansion through international medical projects

・Positioning MEJ as the core organization for promoting international medical projects, the government will support research, feasibility studies, demonstration projects, and finance focused on healthcare-related markets in each country, as well as conducting human resource development and accepting foreign patients, with a view to aiding the overseas expansion of drugs, medical equipment, etc., medical technology, and medical services into markets in emerging and developing countries. Through this, it will support Japanese medical institutions and companies in establishing bases for offering medical services and undertaking related business initiatives overseas in a self-reliant, sustainable manner. At the same time, it will strengthen its efforts to disseminate information about Japanese drugs, medical equipment, etc. and medical technology to the rest of the world.

・Having gained an adequate understanding of the living and social environment in emerging and developing countries, particularly those in Asia, the government will encourage the deployment of drugs, medical equipment, etc., medical technology, and medical services suited to the circumstances of each country and region, while improving the environment for the supply of funds for integrated overseas expansion that unites these elements.

(d) Support via public-private partnerships focused on neglected tropical diseases (NTD) and malnutrition

・ Via public-private partnership, the government will use the outstanding R&D capabilities of Japan's pharmaceutical industry to promote support for the provision of drugs to developing countries to fight diseases such as NTDs. In addition, it will continue to seek progress in partnership with the Global Health Innovative Technology Fund (GHIT Fund).

・The government will aim to ensure that Japan can demonstrate leadership in collaborative international clinical research and trials, so that high-quality evidence about the creation and use in clinical settings of innovative drugs, medical equipment, etc. and medical technology originating in Japan can be disseminated. To this end, it will develop systems for global clinical research led by Japan that will facilitate the construction of international networks and support the systems of Japanese institutions participating in collaborative international clinical research and trials.

・To promote collaboration aimed at the discovery of innovative drugs, the government will support the Asia Partnership Conference of Pharmaceutical Associations (APAC) initiative, which aims to develop a platform for open innovation in the field of drug discovery involving industry, academia, and government throughout Asia.

・To contribute to the overseas expansion of drugs, medical equipment, etc. and medical technology originating in Japan, the government will promote greater efficiency by such means as the digitalization of import and export procedures for such items using the Nippon Automated Cargo and Port Consolidated System (NACCS).

・In light of the fact that Japan and the UK affirmed in a joint statement their intention to strengthen worldwide initiatives to improve nutrition in the lead-up to the 2020 Tokyo Olympics and Paralympics, the government will make use of Japan's outstanding R&D capabilities in the field of fortified foods and promote the overseas expansion

of inclusive business and other business initiatives via public-private partnerships focused on improving nutrition across the globe, including in emerging and developing countries. In addition, it will use the Sport for Tomorrow program and other opportunities to disseminate information about such initiatives.

(e) Use of Official Development Assistance (ODA) (support that utilizes drugs, medical equipment, etc., medical technology, and medical services in which Japan has a comparative advantage, effective implementation of bilateral aid, and collaboration with global initiatives, based on the Strategy for Global Health Diplomacy, which positions initiatives in the field of international health as a key topic in Japan's diplomatic relations)

・In light of the Basic Design for Peace and Health (determined by the Headquarters for Healthcare Policy on September 11, 2015), the government will position international health as a key topic in Japan's diplomatic relations and promote widespread adoption of UHC that contributes to strengthening response to public health crises and preventing and preparing for crises. Concretely, it will strengthen the efforts for the Sustainable Development Goals (SDGs) through collaboration with global initiatives and effective implementation of bilateral aid, mobilizing Japan's knowledge concerning health and medical care systems and measures to deal with the aging of the population. Measures will be carried out especially with consideration for the results of international meetings related to Japan's health policy, such as the G7 Ise-Shima Vision for Global Health (May 2016), the TICAD VI Nairobi Declaration and Implementation Plan (August 2016), and the Kobe Communiqué G7 Health Ministers' Meeting (September 2016).

・While making effective use of ODA and other public funds, the government will support efforts to facilitate human resource development and the construction of medical insurance systems in emerging and developing countries, integrating these endeavors with initiatives focused on expanding exports of Japanese drugs, medical equipment, etc., medical technology, and medical services.

・The government will promote proactive use of Special Terms for Economic Partnership (STEP) in Japanese ODA loans and overseas investment and lending by JICA.

(f) Promotion of the Asia Health and Human Well-Being Initiative

In Japan, with a sharp decline in the number of children and a rapid aging population, all the so-called "baby boomers" will become 75 years old by 2025, when Japan will become an ultra-aging society. Because of this, it is imminently necessary to make Japan a society where each person's healthy life expectancy will rise and the elderly can live cheerfully.

To cope with this "2025 problem," at the second meeting in November 2016, the Council on Investments for the Future decided that new medical and nursing care systems should be operated in earnest, centering on "prevention and health management" and "support for self-reliance," to assist the elderly in their development of self-reliance ability, and a paradigm shift in nursing care should be made to recover the elderly to a condition that does not require nursing care as long as they wish.

Meanwhile, at the 14th meeting of the Headquarters for Healthcare Policy in July 2016, given that Asian countries

where the population will be rapidly aging has been increasing their interest in elderly-related industries in Japan, the Headquarters determined the "Basic Policy for Asia Health and Human Well-Being Initiative" and, to promote the "Asia Health and Human Well-Being Initiative," decided to promote the extension of Japanese-style nursing care all over Asia, the development of high-level human resources for nursing care in Asia, and the reverse flow of them into Japan.

Because nursing care insurance and other programs related to the elderly have not been established or funds are insufficient in some Asian countries, it can be thought that there are latent demands for "nursing care for what elderly people cannot do" and "nursing care in support of self-reliance." Moreover, the promotion of the Asia Health and Human Well-Being Initiative can be expected to improve education in the nursing care in support of elderly people's self-reliance and promote the penetration of Asian markets with the next-generation nursing care technology that will improve the productivity of nursing care in support of self-reliance and reduces the burden of providing such nursing care. By promoting the Asian Health and Human Well-Being Initiative, the government will aim to contribute to the paradigm shift from nursing care for what elderly people cannot do to nursing care in support of self-reliance.

○ Standardization of nursing care in support of self-reliance and establishment of foundations in Asia

・The government will promote the systematization and standardization of nursing care in support of self-reliance so that education in nursing care can be effectively provided to Asian human resources, clarify what nursing care is effective for what condition and what kind of nursing care contributes to support for self-reliance, and promote the support for self-reliance provided with the cooperation of various types of jobs, such as nursing care staff and professionals in medical care and rehabilitation. At the same time, the integrated community care system will be exported to Asia.

・To clarify nursing care in support of self-reliance, the government will collect data on conditions of users, concrete details of care, etc. for analysis.

○ Promotion of reverse flow of human resources who studied support for self-reliance

・Because the Act on Adjustment of Technical Training of Foreigners and Foreign Technical Trainees' Protection (Act No. 89 of 2016) was approved in November 2016, nursing care will be added to the types of jobs covered by skill training subjects when the new skill training system starts so that opportunities for studying Japanese-style nursing care can be given to more Asian human resources. Moreover, the government will consider facilitating foreign students' on-the-job training at companies that give nursing care in support of self-reliance so that after human resources who learned skills in Japan return to their home countries, they can become core human resources in the local nursing care industry, including Japanese nursing care providers that have advanced into the country.

○ Promotion of the next-generation nursing care technology that will improve the productivity of nursing care in support of self-reliance and reduce the burden of providing such nursing care

・The government will promote the development and introduction of watching sensors and robots and the use of ICT to improve the productivity of nursing care in support of self-reliance and reduce the burden of providing such nursing

care.

・To clarify nursing care in support of self-reliance, the government will collect data on conditions of users, concrete details of care, etc. for analysis.

4) Other measures that contribute to the establishment of a society in which people enjoy long and healthy lives

The government will promote the following measures to assist in the creation of new industrial activities that will contribute to the establishment of a society in which people enjoy long and healthy lives, as well as encouraging overseas expansion.

○ Responding to the escalation in the aging of the population and growing health-consciousness

・The government will support initiatives at every stage from food production to consumption, to encourage consumers to maintain a healthy diet. In addition, it will support activities aimed at providing a deeper understanding of food and the agriculture, forestry and fishery industry, developing food education as a national movement.

・Japanese cuisine is attracting growing attention not only from within Japan, but also from various other countries. However, although it is deemed to be highly effective in maintaining and promoting health, there is little scientific evidence to support this. The government will evaluate its functions in maintaining and promoting health, as well as its effects on stress resistance and motor function, arrange the information systematically, and publicize it at home and overseas.

・The government will appropriately use the systems for displaying the functions of food, such as the food function labeling system established in FY2015, and improve the education of consumers to increase their understanding.

・The government will create a new industry focused on so-called health foods and other functional foods that will contribute to efforts to promote health. To this end, it will promote the sharing of information with nutritional guidance and meal delivery services that hope to use such foods, as well as encouraging interaction among business operators in this realm.

・The government will promote the discovery of local agricultural, forestry, and fishery products and foods said to be related to health and longevity and the development of new functional foods and establish information bases for eating design focusing on not only nutritional ingredients but also functional ingredients, such as the publication of information through the “database on agricultural, forestry, and fishery products contributing to health,” in order to improve the eating habits of citizens, thereby contributing to efforts to build a rich, healthy diet.

・The government will promote the establishment of new markets by the private sector by promoting initiatives based on partnerships between the medical, welfare, food, and agriculture sectors. Examples of these include

initiatives focused on improving awareness of nursing care food, support for initiatives aimed at establishing systems for the provision of new nursing care food developed using local agricultural, forestry, and fisheries produce, and development of industrial infrastructure to support new market development based on foods and services that promote a healthy life expectancy.

・As an initiative aimed at creating new demand for agricultural and livestock products through the use of such products in drugs and medical equipment, the government is promoting the development of such products as rice containing cedar pollen protein, blood vessel prostheses made from silk yarn, and dressings made from collagen. In due course, the government will share the results of this initiative with private sector business operators and undertake trials of their safety and effectiveness in humans, with a view to their practical application.

・The government will undertake R&D focused on next-generation functional agricultural, forestry, and fisheries produce and foods aimed at maintaining and improving brain function and physical and motor function. In addition, as well as verifying their synergistic effect with sport and exercise, it will develop systems that make it simple to measure their effects in humans.

○ Encouraging sports activities that contribute to health promotion

・Taking the opportunity offered by the decision to hold the 2020 Olympics and Paralympics in Tokyo, the government will aim to cultivate a nationwide awareness of health promotion through sport. To this end, based on collaboration between industry, academia and government, it will improve the environment with a view to enabling everyone – including women and people with disabilities – to enjoy sport from infancy through to old age, and will promote effective use of the results of research in the fields of sports medicine and science. Sports tourism in Japan's regions will also be promoted in conjunction with this.

○ Improving the environment so that foreign residents can receive medical services in Japan with peace of mind

・The government will steadily promote various measures aimed at improving the environment so that foreign residents can receive medical services in Japan with peace of mind.

○ Creating homes, towns, and transport systems that allow elderly people to live a comfortable and healthy life

・To enable people to live independently and comfortably at home for as long as possible into old age, the government will strive to build an advanced model based on using ICT, making homes more energy-efficient, and promoting greater use of wood. In addition, it will use PPP/PFI to turn particularly old and dilapidated public rental housing estates (public housing and UR rental housing) in Japan's regions into welfare centers and develop serviced housing for elderly people. Moreover, the creation of multi-generational housing and communities adapted to people's life cycles (Smart Wellness Housing and Cities) will be promoted.

・To encourage elderly people to either renovate their home with a view to continuing to live there or to move to a home better suited to their needs in old age, the government will encourage efforts to revitalize the market for used

houses and renovation. To this end, it will promote such measures as the dissemination and firm establishment of an appropriate method for appraising existing houses on the market, the effective use of the assets of elderly people and other citizens, including via reverse mortgages, and the upgrading of existing housing to create houses that remain in excellent condition in the long term.

・With a view to the utilization of healthcare REITs to promote effective use of private sector funds, the government will develop guidelines and raise awareness concerning the acquisition and use of hospitals and housing for the elderly (including municipal hospitals).

・Through the framework of the "compact city formation support team," which was established for comprehensive support to local governments formulating site rationalization plans in accordance with the Act on Special Measures concerning Urban Reconstruction and local public transport restructuring plans in accordance with the Act on Revitalization and Rehabilitation of Local Public Transportation Systems and consists of related government offices, the government will promote the development of compact communities of a walkable size based on consolidation of urban functions such as medical care and welfare, and residence along public transport routes, and will seek to expand opportunities for relocation through the enhancement of public transport. In conjunction with this, the government will further promote the introduction of barrier-free design in passenger facilities and vehicles, and will ensure thorough implementation of barrier-free measures along whole lines and throughout entire districts, rather than adopting a piecemeal approach focused on individual sites. Moreover, in promoting local industries focused on extending healthy life expectancy and constructing new regional social healthcare systems, the government will implement pioneering initiatives aimed at ensuring widespread adoption of super-compact mobility devices to complement public transport.

○ Development of communities friendly to demented elderly people

・To realize a society where demented people's intentions are respected and they can continue to live their own lives in familiar communities as long as possible, the government will promote necessary measures according to the Comprehensive Strategy to Accelerate Dementia Measures (New Orange Plan) (January 27, 2015).

○ Development of measures contributing to national resilience

・Based on the Fundamental Plan for National Resilience (Cabinet decision on June 3, 2014), the government will promote the coordination among health, medical, and nursing care in ordinary times to proceed with the construction of the community-based integrated care system and promote necessary measures, such as the establishment of an environment where the elderly can participate in community activities, and the strengthening of communities' power to cope with disasters.

(3) Measures for promotion of education and securing of personnel associated with cutting-edge healthcare and medical R&D and the creation of new industries

In promoting advanced R&D in the field of healthcare and medical care and the creation of new industries, the

government will implement the necessary measures to secure and cultivate personnel with expertise, and to further enhance their skills. In addition, it will promote education and learning aimed at deepening people's interest and understanding, and will also enhance PR activities in this area.

1) Securing and cultivating the personnel required to promote cutting-edge healthcare and medical R&D

The government will promote the necessary initiatives to secure personnel with the expertise required to promote advanced R&D in the field of healthcare and medical care, as well as cultivating their abilities and enhancing their skills.

○ Securing and cultivating the personnel required for efficient, effective promotion of clinical research and trials

・The government will secure and cultivate the personnel required for efficient, effective promotion of clinical research and trials. Moreover, in doing so, it will seek to secure and expand the educational opportunities related to clinical research and trials that are offered to staff involved in associated duties, including further development of education, training, and e-learning.

i. Specialist physicians, etc. who can play a leading role in clinical research and trials

ii. Personnel who can carry out or support duties associated with clinical research and trials (clinical research coordinators (CRD), data managers, biostatisticians, project managers, etc.)

○ Utilizing personnel in the field of bioinformatics to respond to new needs

・Medical data and information is growing exponentially and personnel working in the field of bioinformatics are indispensable to efforts to ensure its effective use, as well as to the future development of R&D in the life sciences. As such, the government will nurture personnel working in the field of bioinformatics.

○ Promoting exchange and cultivation of personnel well-versed in innovative technologies and evaluation techniques for encouraging the practical application of innovative drugs, medical equipment, and regenerative medical products, etc.

・The government will support research that contributes to the establishment of techniques for evaluating the safety and effectiveness of innovative drugs, medical equipment, and regenerative medical products, etc. In addition, it will promote the exchange and cultivation of personnel with a view to encouraging the practical application of innovative drugs, medical equipment, and regenerative medical products, etc. Universities will also cultivate such personnel.

○ Cultivating personnel with specialist skills in the specific handling methods required for regenerative medical products, etc.

・The government will promote human resource development, developing training facilities where personnel can learn techniques essential to researchers investigating the clinical application of regenerative medicine, such as cell culture and processing.

2) Securing and cultivating the specialist personnel required to promote the creation of new industries

The government will promote efforts to secure and cultivate specialist personnel, such as innovative personnel who can provide integrated management of everything from the practical application of the drugs, medical equipment, etc. and medical technology required to promote the creation of new industries, close collaboration and matching between industry, academia, and government, and the identification and planning of medical care needs, to the formulation of business plans.

○ Cultivating personnel who can match medical and nursing care needs and seeds as a viable business

・Vision and knowledge concerning interdisciplinary medicine and engineering are required to develop medical equipment. Accordingly, the government will upgrade the medical equipment technology development environment by utilizing the results of research focused on development and appraisal methods, and encouraging partnerships between universities, the industrial sector, and medical institutions. Moreover, it will promote the cultivation of personnel who can formulate and commercialize plans and designs for medical equipment originating in Japan, response to regulations, intellectual property and standardization strategy, and business plans, as well as personnel who can demonstrate leadership in managing all of these elements in an integrated manner. In addition, the government will strive to encourage universities to offer education in interdisciplinary medicine and engineering and expand education in intellectual property and standardization.

・To cultivate innovative personnel in the field of medical care, the government will actively promote the introduction of advanced programs and people-to-people exchange.

○ Cultivating personnel to support entrepreneurship

・To encourage venture capital funds, financial institutions, tax and other accountants, other entrepreneurship-supporting human resources, venture enterprises, business companies, etc. to strengthen cooperation and create new industries, the government will promote the development of human resources able to create new businesses acceptable all over the world through the holding of exchange events, the overseas development of medical ventures, the support of global cooperation, etc.

・The government will register domestic and foreign human resources (supporting human resources) familiar with intellectual property, pharmaceutical affairs, insurance, management, etc., such as persons retired from drug or medical equipment manufacturers, hospital or university researchers, et al. and provide comprehensive support to venture manufacturers of drugs and medical equipment, including the provision of consultations about intellectual property, pharmaceutical approval applications, management, cooperation with drug manufacturers, etc. to solve the issues, etc. arisen at each stage of development. In addition, the government will give training to supporting human resources from time to time to improve their knowledge and ability.

・The government will encourage exchange and cultivation of the personnel who are essential to the provision of peripheral medical and nursing care services and the internationalization of medical care.

・To enable Japan to respond to the simultaneous worldwide development of innovative drugs, medical equipment, and regenerative medical products, etc., the government will promote the strengthening of systems and efforts to secure and educate personnel at medical institutions actively involved in collaborative international clinical research and trials, to ensure that they are capable of dealing with linguistic and regulatory differences between countries.

3) Advancing education and learning, and enhancing PR activities concerning cutting-edge R&D and the creation of new industries

The government will promote PR activities and other initiatives to deepen public interest in and understanding of the importance of medical R&D and ensure wide-ranging cooperation in this area.

○ Disseminating information to promote understanding of the significance, benefits, and risks of clinical research and trials

・To enhance websites providing information concerning clinical research and trials, including those already underway, the government will actively endeavor to disseminate information that is easier for patients and the public as a whole to understand, in order to promote understanding of the significance, benefits, and risks of clinical research and trials. It will also promote more widespread awareness of these websites, with a view to deepening interest and understanding among the public concerning the importance of clinical research and trials and other medical R&D. Furthermore, it will conduct active PR campaigns to raise awareness of the significance of clinical research and trials.

(4) Measures related to the establishment of infrastructure for data use and the promotion of ICT use in the fields of medical and other care by an "all-Japan" system

In the fields of health, medical, and nursing care, efforts for ICT have so far been made without connecting related data. As a result, ICT cannot be used integrally and it is impossible to draw power from actual workplaces and industrial, academic, and governmental personnel or have patients and people actually feel advantages.

The nation's healthy life requires various social systems and services that support the prevention of diseases and frailty, and recovery from diseases and conditions requiring nursing care. In addition, it is desirable to construct systems for providing support to medical institutions based on the latest anonymous data. Recently developing AI technologies and big data based on medical ICT foundations should be combined for use, and efforts should be made according to the needs at domestic and foreign clinical practice sites. Moreover, on behalf of other industrial, academic, and governmental entities and researchers, it is necessary to create an environment where anonymous big data can be used easily for R&D.

It is important to make these efforts to minimize demands for medical and nursing care and thoroughly improve necessary medical and nursing services. Regarding the use of ICT in the fields of health, medical, and nursing care, under this basic direction, it is necessary to construct ICT infrastructure that will enable clinical practice sites and industrial, academic, and governmental personnel to display their power and enable patients and people to feel

advantages so that the infrastructure can be used in earnest by 2020.

When ICT infrastructure is constructed, it is necessary to carry out the following three paradigm shifts: 1) from the stage of data collection, create outcome-oriented data that will improve the quality of medical and nursing care through data collection and analysis; 2) integrate chronological data on health, medical, and nursing care for individuals between the time when they were healthy and the stage of illness and nursing care, make the data available among medical and nursing care staff, and enable the individuals to check and use their own medical and health information; and 3) enable various industrial, academic, and governmental entities to access and use data on medical and nursing care.

Concretely, it is necessary to promote effective health and prevention activities through the creation of a network on medical and nursing care data and the use of everyday data, AI, IoT, etc., carry out prompt and accurate medical treatment all over Japan according to individuals' symptoms and constitutional characteristics, materialize remote monitoring of patients and elderly people, and reduce their financial and other burdens by the efficient use of medical and nursing resources. In addition, it is necessary to establish a platform that enables industrial, academic, and governmental personnel to use big data on health, medical, and nursing care and efficiently and effectively proceed with the development of innovative drugs and medical equipment. Moreover, even before the establishment of an environment where data on results of medical diagnosis and treatment (outcome data) can be collected and used, examination and payment organizations and insurers each should realize high-quality medical care through the reform of the organizations under public medical insurance programs and the promotion of health improvement by big data analysis (data health) based on medical fee claim data (receipt data).

Moreover, it is necessary for the related government offices to establish an "all-Japan" system to examine problems in systems for putting the ICT infrastructure into practice and managing it sustainably, including incentive design and the burden of paying the cost, while coordinating with related councils, such as the Council on Investments for the Future.

In addition to the above, because computers are generally used for individual fields and purposes, such as medical examination, pharmacy, administrative affairs, corporate management, insurance claims, academic research, and R&D, to develop the situation into a stage of multidisciplinary understanding – that is, a stage where systems are connected into a network – the government will enact rules on how to treat data, including technological standardization. Moreover, discussions should be held also about efforts for facilitate individuals' prevention and health management by the use of data.

What is described above is the "future vision." It will be most effective to divide the specific ICT promotion measures into three levels and adopt a phased approach to their implementation.

Level 1 is the digitization of frontline medical, nursing, and health care

Level 2 is digitization throughout medical, nursing, and health care (digital infrastructure)

Level 3 is the effective use of medical, nursing, and health information

More specifically, it will be important to ensure that the diverse data collected from frontline digitized medical settings are coordinated and put together to consolidate them into an overall digital infrastructure that can be shared safely among relevant parties and that this digital infrastructure is utilized to (1) improve the level and efficiency of medical administration, service, etc.; (2) stimulate research through greater efficiency in clinical research and trials;

and (3) create new medical technologies and health care services.

The information expected to be used via the digital infrastructure includes everything from data available from medical receipts, which has comparatively simple content (patient data, data concerning the name of the illness or injury, etc.) through to more complex data, including data from prescriptions, examinations, questionnaires, operative notes, lifestyle records, reports, and death certificates.

Currently, the digitization of some data from clinical practice (Level 1), such as data from medical receipts, has been more or less completed; the MHLW has built the digital infrastructure (Level 2) and has used it for health administration (Level 3).

On the other hand, regarding output data essential for discovering ill effects and measuring the effect of drugs, although the number of medical institutions is limited, the stage has moved from digitalization (Level 1) to infrastructure building (Level 2) and the use of the infrastructure has begun (Level 3). Generally, however, the grasp of mid- and long-term trends toward improvement across medical institutions has not been realized.

To realize digital infrastructure, it is necessary to collect medical information widely, manage and make it anonymous safely, and take legislative measures to create a system for using it. In addition, it is necessary to create a system for making the digitalization economically sustainable, including the following: technical integration, such as the standardization and structuralization of data collection and analysis; provision of incentives to supply data to the digital infrastructure; and establishment of rules on digital infrastructure users' payment of costs necessary for maintaining the infrastructure.

Moreover, regarding the introduction of the system for online confirmation of qualifications for medical insurance and the ID system for medical and other care, the government will make preparations for systems development to begin to use them gradually from FY2018 and use them fully from 2020 so that the systems can be used for sharing information on patients among hospitals and clinics, managing data for medical research, and carrying out individuals' and insurers' health and prevention activities.

The construction of digital infrastructure is not the purpose itself. It is important to produce the following good circulation in the whole society: the results of the use of information are returned to the places where medical and nursing care are actually provided; the improvement of the level and efficiency of medical and nursing care is facilitated through on-site digitalization and on-site introduction of ICT; and the construction of digital infrastructure (Level 2) and the use of information (Level 3) are further accelerated and improved.

1) Establishing digital infrastructure in the fields of medical, nursing, and health care

In the fields of medical, nursing, and health care, to give regional medical cooperation (the so-called hospital-clinic cooperation) and community-based integrated care, medical information has been shared and a system for sending and receiving letters of introduction by electronic media has been used in a limited number of cases. However, there is no nationwide digital infrastructure for measuring the effect of medical care and using anonymous data.

However, as described above, to realize the world's most advanced intelligent infrastructure that produces new medical technologies and services, it is necessary to establish digital infrastructure for collecting medical information widely, managing it safely, making it anonymous, and using it. Because of this, the government decided to examine how to treat personal information in the field of medical care.

On this occasion, the government will build mechanisms that facilitate the integrated collection and analysis of data gathered from different systems (including databases). More specifically, it will build a framework for a comprehensive package capable of (1) implementing technical collaboration and coordination; (2) implementing cross-sectoral coordination between system operators; and (3) continuously securing funds to cover the cost of maintaining the digital infrastructure (for example, mechanisms and rules to ensure that those benefiting from the analysis bear the cost of maintenance) (digital infrastructure in the fields of medical, nursing, and health care).

From this viewpoint, a meeting of the Working Group on Coordination of Medical Information Management Systems (WG-B) was held to consider establishing new infrastructure that should be established urgently for promoting the use of medical and other information.

A bill based on the results of the meeting will be submitted to the Diet to realize the use of medical and other information based on a new system.

○ Framework for deliberations

・The Council on Foundations for Next-Generation Medical ICT will continue deliberations. The composition of the Council and each of the working groups established under the Council will be reviewed if needed for concrete use of systems.

○ Technical collaboration and coordination

・The government will conduct cross-sectoral coordination with a view to the efficient, effective use of ICT in existing programs focused on data collection and analysis. More specifically, the government will group together databases, etc. (consolidating purpose-specific databases and information concerning their data structure into a single catalog, which will also encompass local information-sharing infrastructure) and integrate them as far as necessary and possible (improving the environment to facilitate data exchange using common data structure rules and analysis of data from several different databases).

・With a view to building digital infrastructure, the government will seek appropriate ICT enhancement of projects including the Medical Information Database Infrastructure Development Project, medical information system backup projects undertaken by national university hospitals to assist with disaster countermeasures, cancer registration database projects, demonstration projects focused on standardization of dental care information, and database projects being undertaken by academic societies.

・Based on the results of the consolidation, integration, and expansion specified in the preceding two paragraphs, the program for using data in medical and other fields will be reviewed at some intervals.

・The MHLW has established the Healthcare Information Specifications and Standards (MHLW Specifications and Standards), and will instruct project implementing bodies planning to collect and analyze data to input and output data according to standard specifications. In addition, standard specifications will be formulated in areas where these have not yet been prescribed.

・When dealing with information from several different databases, the government will solve issues regarding the standardization of methods of testing different from technological issues in the field of medical care (for example, the use of different reagents in blood tests leads to different interpretations of the figures in the results) and the lack of homogeneity in the structuring of expressions used in findings from history taking.

・While conducting data collection and analysis, the government will improve the environment to facilitate greater interoperability and portability of databases.

・Making use of the outcomes of the Tohoku Medical Megabank program, which is conducting regional medical collaboration and cohort studies, the government will roll out its digital infrastructure in each region, as part of its efforts to implement the standardization required for sharing the medical and lifestyle data that will form the digital infrastructure for regional medical collaboration.

・To ensure integrated community care (collaboration between home medical care and nursing care), the necessary standardization will be carried out to facilitate the sharing of medical and nursing care data. In addition, the government will collect and analyze data on nursing care service, including the use of ICT, use them as evidence, and proceed with necessary measures for improving nursing care service and identifying services contributing to the achievement of support for self-reliance.

2) Using digital infrastructure in the fields of medical, nursing and health care

Data from medical receipts are already being analyzed and the results are beginning to be used. In addition to enhancing projects in this area, the government will promote the creation of projects focused on the large-scale collection, analysis, and use of currently-unused test data to promote the creation of high-quality, efficient medical services and healthcare services not covered by public insurance that are based on the utilization of ICT and the digital infrastructure.

○ Comprehensive efforts aimed at ensuring reasonable medical expenses and health promotion among the public

・The MHLW has completed the standardization of data from medical receipts, so it has begun collating and analyzing it, and using the results. The government will promote efforts to facilitate the use, such as the establishment of on-site research centers (facilities having a set of environments for using security and others) and the publication of open data of the National Database on Receipts and Specific Health Checkup (NDB).

・In addition to the information contained in medical receipts, the MHLW is gathering and analyzing Diagnosis Procedure Combination (DPC) data to which information has been added concerning the name of the illness or injury to which the largest amount of medical resources were devoted, along with certain information about the treatment received, focusing primarily on acute care hospitals. However, this information is not currently submitted to the

MHLW online, so consideration will be given to the online submission to the MHLW of DPC data via the examination and payment organizations at the same time as details of medical receipts are submitted, with the aim of alleviating the burden on medical institutions. Moreover, MHLW will attempt to use DPC data to collect and analyze data regarding chronic care hospitals in addition to acute care hospitals.

・The government will promote the analysis of regional medical expenses, the understanding of local health issues, and the implementation of finely-tuned health programs through municipal NHI organizations' use of the KDB system operated by the All-Japan Federation of National Health Insurance Organizations, which brings together data from medical receipts and special health check-ups, etc.

・The government will promote the construction of a system that enables patients to grasp their medical and other information chronologically (PHR: Personal Health Record).

○ Preventing the exacerbation of lifestyle-related diseases

・The government will create projects focused on large-scale collection and analysis of test data, gathering the minimum amount of information necessary to obtain useful results. More specifically, with the aim of preventing the exacerbation of lifestyle-related diseases, the government will clearly stipulate such matters as targets for preventing the exacerbation of conditions, as well as the scale of the anticipated reduction in medical expenses. At the same time, it will collect and analyze the relevant test data from various databases, consider the potential for its secondary use in clinical research and trials and cohort studies, and generate concrete results while enhancing the digital infrastructure.

○ Providing high-quality medical services at a low cost

・The government will promote the provision of sustainable medical services, such as telemedicine by the use of ICT (such as cloud technology, AI technology, IoT, and smart devices) and critical care by the use of information on emergency medical care.

○ Providing healthcare services not covered by public insurance

・The use of ICT in next-generation healthcare services and other industries outside the public insurance framework will be promoted.

・The government will aim to establish models that enable insurers, local authorities, and companies to use data and systems for the purpose of health promotion.

○ Overseas expansion of efficient, high-quality medical care

・In facilitating the overseas expansion of drugs, medical equipment, etc., medical technology, and medical services, the government will promote the active use of telemedicine and other ICT. (Described above)

・The government will establish practical model cases by the use of 8K and other high-definition image technologies as well as mobile technology and other ICTs in the field of medical care, verify and establish communications standards for networks tailored to such medical equipment, and promote the overseas expansion of these model cases and communications standards. (Described above)

3) Advanced digitization of frontline medical, nursing and health care

The government will promote R&D focused on the application of ICT and the establishment of the requisite environment (for example, building mechanisms for evaluating and demonstrating new technologies and systems).

○ R&D and practical applications focused on next-generation medical ICT

・As well as promoting R&D aimed at further digitization of clinical practice and seeking the practical application of the results, the government will consider approaches to interoperability, portability, and extensibility, with a view to the overseas expansion of these new systems.

・The government will promote R&D aimed at creating integrated systems capable of simultaneously analyzing a variety of medical information, including the development of a platform incorporating a diagnostic aid system capable of associating and organizing information from various systems, such as electronic medical records and other hospital information systems (HIS) as well as picture archiving and communication systems (PACS) for CT and other images, and capable of assisting physicians, et al.

・The government will develop operating theaters that offer highly efficient treatment. To this end, it will network various information about the patient undergoing surgery and the operating status of the diagnostic and therapeutic apparatus to be used in surgery, with the aim of building a surgical environment that dramatically increases the efficiency of treatment by facilitating the exchange of information both within the operating theater and outside it.

・To strengthen infrastructure for using supercomputer-based simulation techniques to make medical care and drug discovery processes more sophisticated and to encourage their use by pharmaceutical companies, the government will develop cutting-edge supercomputers that will assist in promoting efficient drug discovery.

・The government will begin to arrange issues for promotion of telemedicine and consider measures for solving the issues.

○ The government will conduct R&D on AI technologies and put them to practical use in the fields of medical, nursing, and health care.

・The government will proceed with R&D contributing to medical treatment support and the creation of new drugs and medical technologies by proceeding with the construction of foundations for using digital data on medical, nursing, and other care and by constructing innovative basic AI technology and utilizing the AI technology based on collected big data.

○ Demonstrating next-generation medical care systems

・It is hoped that next-generation medical care systems will actually support efforts to ensure greater operational efficiency in medical care, rather than being medical care systems that have evolved from medical accounting systems solely for the purpose of the digitization, storage, and sharing of information. In medical institutions that have introduced such next-generation medical care systems, teams will be established to (1) verify the performance of these systems; (2) establish techniques for their evaluation; (3) consider approaches to the necessary standards and common rules; and (4) examine measures for encouraging their practical application as medical software systems, thereby substantiating improvements in the quality of medical care.

4) Systems associated with the use of medical and personal information

The government will formulate rules for the introduction of the ID system and the handling of medical information.

○ Considering systems

・In medical-related fields, to develop the use of medical information that includes personal information, the government will design sustainable data usage systems that utilize the dynamism of the private sector, introducing the ID systems for medical and other care by the use of the infrastructure of the My Number system and clarifying the social rules for the use of medical and other information.

(5) Key Performance Indicators (KPIs)

The Key Performance Indicators (KPIs) for the measures set out in this policy in sections (1) to (4) of "2. Details" are as follows. These will be subject to further examination and verification as the measures in this policy are implemented, and will be revised if necessary.

a) Measures related to medical R&D, etc. that contribute to the provision of the world's best medical care

○ Drug discovery

[KPIs to be achieved by 2020]

・Consulting and evaluation of seeds: 1,500 cases

・Drug discovery support for promising seeds: 200 cases

・Licensing-out to companies: 5 cases

・Identification of drug discovery targets: 10 cases

○ Development of medical equipment

[KPIs to be achieved by 2020]

・Double the value of medical equipment exports (from approx. ¥500 billion in 2011 to approx. ¥1 trillion)

・Put at least 5 types of innovative medical equipment to practical use

・Expand the scale of the domestic market for medical equipment to ¥3.2 trillion

○ Innovative Medical Technology Creation Centers

[KPIs to be achieved by 2020]

・Number of physician-led clinical trials notified: 40 per year

・First in Human (FIH) studies (including company-initiated clinical trials): 40 per year

○ Regenerative medicine

[KPIs to be achieved by 2020]

・Develop clinical applications for new therapeutic drugs manufactured using iPS cell technology (beginning of clinical research or trials)

・Increase the number of pharmaceutical approvals granted for regenerative medical products, etc.

・Expand the scope of target diseases that transition into the clinical research or trial stage: 35 cases

・Put peripheral equipment and apparatus related to regenerative medicine into practical use

・Present a proposal for international standardization of a method for evaluating drug cardiotoxicity using iPS cell technology

○ Genomic personalized medicine

[KPIs to be achieved by 2020]

・Create evidence related to risk prediction, prevention, diagnosis (stratification), medical treatment, selection and optimization of drugs, etc. concerning diabetes and other diseases

・Start clinical research concerning predictive diagnosis of cancer incidence, and of reactions to and adverse side-effects from anticancer drugs

・Start clinical research concerning genome therapy in the fields of dementia and sensory organs

・Start clinical research concerning development of innovative methods of diagnosing and treating incurable neuromuscular diseases

○ Disease-specific research <Cancer>

[KPIs to be achieved by 2020]

・License out at least 10 types of drug for clinical trial, with a view to developing innovative anticancer drugs based on Japanese technology

・License out at least 12 types of drug for clinical trial, with a view to establishing practical applications for therapeutic drugs to treat pediatric, refractory, and rare cancers, including unapproved and off-label drugs

・Obtain approval or additional indications for at least 1 type of drug to treat pediatric and rare cancers, etc.

・Eliminate the so-called drug lag and device lag

・Establish standards of care for cancers that affect pediatric and elderly patients, and for rare cancers (formulate at least 3 sets of guidelines)

○ Disease-specific research <Neuropsychiatric disorders>

[KPIs to be achieved by 2020]

・Establish biomarkers contributing to the effects of the diagnosis and treatment of dementia (1 or more cases of acquisition of clinical POC)

・Start clinical trials of disease-modifying drug candidates for dementia originating in Japan

・Establish objective diagnostic techniques for psychiatric disorders (4 or more cases of acquisition of clinical POC, 5 or more cases of establishment of diagnosis guidelines)

・Establish appropriate therapies for psychiatric disorders (3 or more cases of acquisition of clinical POC, 5 or more cases of establishment of diagnosis guidelines)

・Complete maps of the structure and activity of all neural circuits in the brain

○ Disease-specific research <Emerging and re-emerging infectious diseases>

[KPIs to be achieved by 2020]

・Identify drug target sites based on whole-genome databases obtained for pathogens (influenza, dengue fever, infectious diarrhea, drug-resistant bacteria); develop and put new rapid diagnosis methods into practical use

・Conduct clinical research and trials of a norovirus vaccine and a nasal influenza vaccine, and apply for pharmaceutical approval for these

*KPI to be achieved by 2030

・Develop new vaccines

(E.g. versatile influenza vaccines)

・Develop new antibiotics and antivirals, etc.

・Eradicate/eliminate infectious diseases such as polio and measles, working in partnership with the WHO and various other countries

(KPI to be achieved by 2050 in the case of tuberculosis)

○ Disease-specific research <Intractable diseases>

[KPIs to be achieved by 2020]

・Approve new drugs and additional indications for existing drugs in at least 11 cases

(amyotrophic lateral sclerosis (ALS), distal myopathy, etc.)

・Start collaborative international clinical research and trials in partnership with U.S. and European databases

・Achievement of 5 or more cases of discovery of new diseases or new causative genes for undiagnosed or rare diseases

b) Measures related to promoting the creation of new industries and facilitating overseas expansion in the healthcare and medical care sector

[KPIs to be achieved by 2020]

・Expand market scale in industries related to health promotion and prevention and living support (from ¥4 trillion

to ¥10 trillion)

・Raise the proportion of projects in receipt of joint investment from public-private investment funds and private sector companies in the field of healthcare and medical care to 100%

[KPI to be achieved by 2020]

・Establish Japanese medical centers overseas (increase from 3 to around 20 centers)

*KPI to be achieved by 2030

・Expand the scale of overseas markets captured by Japanese medical technologies and services to ¥5 trillion

c) Measures for promotion of education and securing of personnel associated with cutting-edge healthcare and medical R&D and the creation of new industries

[KPI to be achieved by 2020]

・Extend the nation's healthy life expectancy by at least one year

[KPI to be achieved by 2020]

・Reduce the number of citizens with metabolic syndrome by 25% from the figure for FY2008

[KPI to be achieved by 2020]

・Increase the health check-up take-up rate (in the 40-74 age range) to 80% (including special health check-ups)

d) Measures related to the establishment of infrastructure for data use and the promotion of ICT use in the fields of medical and other care by an "all-Japan" system

[KPI to be achieved by 2020]

・Create a digital infrastructure in the fields of medical, nursing, and health care that includes both hitherto-unused test data and data from medical receipts, and utilize medical information (that is not currently available for use) in clinical research and trials, cohort studies, etc.

3. Implementing measures

(1) System for implementing the Healthcare Policy

The Headquarters for Healthcare Policy and AMED will work together to promote the Healthcare Policy in a comprehensive and systematic manner.

The measures described in the Healthcare Policy will be promoted on the basis of the following five perspectives.

● Prioritization of measures

In implementing policy measures, the government will clearly identify the key fields to which the allocation of

resources should be prioritized, and will set targets for the outcomes to be achieved from the input of these resources.

● Adoption of effective, efficient policy instruments

To achieve these outcome targets, the government will adopt the most effective, efficient policy instruments, using everything from regulatory and institutional reforms to budgets, the tax system, and policy-based finance.

● Thorough operation of the PDCA review cycle

The government will ensure thorough operation of the PDCA review cycle. As well as using evidence to verify the effects and efficiency of policies, the government will ensure that the results of this verification are used to revise policy measures.

● Utilization of private sector dynamism

The measures implemented will be based on the approach of utilizing the creativity and ingenuity of the private sector to generate new dynamism. From this perspective, the government will seek an appropriate division of roles between the public and private sectors. In addition, where there is public sector involvement, the government will clarify the grounds for this.

● Executive ability

The tasks involved in promoting the Healthcare Policy are clearly defined. Industry, academia, and government will work together to promote the various policy measures, as well as swiftly implementing the policy measures that should be implemented without delay.

1) Establishment of the Headquarters for Healthcare Policy

June 10, 2014 marked the full-scale entry into force of the Promotion Act, resulting in the abolition of the Headquarters for Healthcare and Medical Strategy Promotion, which had been established by Cabinet decision on August 2, 2013. In its place, the Headquarters for Healthcare Policy (hereinafter "the Headquarters") was established in law within the Cabinet, to serve as a control tower for medical R&D and efforts to create and revitalize industrial activities that contribute to the establishment of a society in which people enjoy long and healthy lives, with a view to establishing such a society in accordance with the Promotion Act. The Headquarters has been established within the Cabinet, with all Cabinet ministers serving as members. The Prime Minister is the Director-General, while the Chief Cabinet Secretary and Minister for Healthcare Policy serve as Vice Directors-General. The Headquarters will formulate plans for the following and will promote measures based on these plans.

(i) The Healthcare Policy

The new Headquarters will stipulate the basic principles concerning advanced R&D and the creation of new industries in the field of healthcare and medical care, as well as prescribing the duties of the government and others, the basic measures to be implemented to promote these activities, and other fundamental matters. In addition, it will draft a plan – the Healthcare Policy – for the comprehensive and systematic promotion of the measures that the government should implement concerning advanced R&D and the creation of new industries in the field of healthcare and medical care, and will seek approval for the Healthcare Policy from the Cabinet.

(ii) The Plan for Promotion of Medical Research and Development

To intensively and systematically promote the measures that the government should implement concerning medical R&D, the improvement of the environment for this, and the widespread adoption of the outcomes thereof, the new

Headquarters will formulate a Promotion Plan concerning the promotion of measures focused on medical R&D, in accordance with the Healthcare Policy. This plan will specify the areas to be promoted strategically as a priority, such as regenerative medicine and cancer therapy.

(iii) Policy on budget allocation

In accordance with the Healthcare Policy and the Promotion Plan, the new Headquarters will draw up a policy on the allocation of budget funds for medical R&D and efforts to improve the environment for this. Relevant ministries and agencies will submit budgetary requests based on this policy. In addition, the government will make mobile and efficient budget allocation based on the adjustment expenses for medical R&D by partial use of the "expenses for the creation and promotion of scientific and technological innovations" allocated to the Cabinet Office.

(iv) Basic policy on business operations

The Cabinet Office will be positioned as the ministry with supervisory authority over AMED. As such, it will prepare a basic policy on operational management, covering such matters as the setting of AMED's medium- to long-term goals and efforts to clarify the division of roles between competent ministers in the evaluation of A-MED's performance of its duties.

2) The Japan Agency for Medical Research and Development

Medical R&D has peculiarities not found in other research fields, such as the fact that it requires clinical research on human subjects that could have an adverse impact on their health, as well as the need for applications for approval under the Drugs and Medical Equipment Act.

Accordingly, research support by people with expert knowledge and integrated research management functions that take into account the goal of obtaining approval in accordance with the Drugs and Medical Equipment Act are essential in order to ensure effective, efficient R&D with a view to practical application.

As such, the government has decided to consolidate medical R&D programs into a specialized agency optimized for the specific characteristics of medical R&D by establishing a new national research and development agency that can offer seamless support from the basic research stage through to practical application.

In the Promotion Plan, AMED is positioned as an institution playing a core role in medical R&D and efforts to implement and support improvements to the environment for this. The consolidation of budgets relating to medical R&D (research funds allocated to researchers and research institutes for conducting top-down research based on national government policy) will facilitate the integrated provision of seamless research support from the stage of basic medical R&D through to its practical application. To this end, A-MED will undertake the following in relation to the medical R&D that has hitherto been undertaken by individual ministries:

(i) integrated research management from the basic research stage through to practical application, crossing the boundaries between individual ministries and making effective use of the Program Directors (PD), the Program Supervisors (PS), and Program Officers (PO) allocated to each integrated project;

(ii) IP management by IP experts, support for the formulation of strategies for the acquisition of IP, and research support by expert personnel such as staff specializing in supporting clinical research and trials; and

(iii) provision of a one-stop service for research funds, etc. through the integration of points of contact and procedures

for applying for research funds.

To guarantee the steady implementation of the Promotion Plan by AMED, the Headquarters will be involved in the appointment of AMED's president and/or auditors by the competent minister in accordance with the law, and in the setting of AMED's medium- to long-term goals.

(2) Roles of relevant parties, and partnership and cooperation among them

To promote the Healthcare Policy in a comprehensive and systematic manner, it is vital for the government, local governments, universities and other research institutes, medical institutions, and business operators to cooperate on the basis of mutual partnership, actively implementing measures in accordance with their respective roles.

1) Partnership and cooperation among relevant national government administrative organs

In promoting the Healthcare Policy, the Headquarters will pursue adequate partnership and cooperation with the control towers for other policy realms, including the IT Strategic Headquarters, the Intellectual Property Strategy Headquarters, the Council for Science, Technology and Innovation, and the Regulatory Reform Promotion Council, as well as relevant ministries and agencies. Thus, the whole government will work together to promote the measures described in the Healthcare Policy, while striving to ensure consistency.

2) The role of local governments and partnership and cooperation involving them

It is important for local governments to plan, formulate, and implement the measures required in their regions to establish a society in which people enjoy long and healthy lives, tailoring these efforts to the characteristics and circumstances of the local economy, society, and industry, based on the division of roles between national and local government. Local governments are beginning to undertake various pioneering initiatives tailored to specific local circumstances.

(i) Pioneering initiatives in Kanagawa Prefecture

The following pioneering initiatives are being undertaken in Kanagawa Prefecture to establish the next-generation social systems.

○ Cutting-edge life sciences research

・Promotion of cutting-edge research focused on personalized medicine, preventive medicine, regenerative medicine, and other next-generation medical care, as well as research focused on next-generation regulatory science; improvement of the quality of clinical research and trials

i. Public-private establishment of the Life Innovation Center, an industrial base, to put regenerative and cellular medicine to practical use early; the medicine is expected to grow highly as next-generation medicine (to be opened in April 2016)

ii. Management of the Kanagawa Medical Device Regulatory Science Center, which conducts research and field trials

in medical equipment by the use of state-of-the-art technologies, and the Kanagawa Center for Clinical Research and Strategy, which conducts research and field trials in regenerative medical products and innovative drugs, in order to create new regulatory science for the facilitation of swift market development for medical equipment and innovative drugs by the use of state-of-the-art technologies

○ Field trials, development, and introduction of personal care robots and healthcare robots

・Initiatives undertaken in partnership with the Sagami Robot Industry Special Zone, aimed at field trials of nursing care robots, medical care robots and other personal care robots, as well as their development and introduction, with a view to their use in monitoring elderly people, supporting their self-reliance, alleviating the burden in frontline nursing care, and improving QOL

・Use of state-of-the-art healthcare robots to make efforts to carry out demonstrative projects for health tourism models and *mibyou* curing models (improvement of the walking function) and research and examination concerning new social systems

○ Cultivating international medical and innovative personnel for the next generation

・Consideration for the establishment of medical innovation schools that will reform social systems and technologies and train international medical human resources who can lead next-generation healthcare

○ Promotion of the Research Complex Promotion Program by the Japan Science and Technology Agency (JST)

・An area surrounding the Tonomachi district (King Sky Front) in Kawasaki City, which had been offered jointly by Keio University, Kawasaki City, etc., was officially adopted as the base for promoting this program.

In the future, this program will be used to make efforts for R&D and human resource development by cross-sectoral fusion and accelerate the creation of innovations.

○ Deploying global strategies

・Initiatives to support overseas expansion by research institutes and companies and promote collaboration with government institutions and universities, etc. in various countries, with which the Prefecture and prefecture-related organizations have concluded memorandums of understanding (MOU) concerning cooperation in the field of the life sciences

○ Cooperation with the World Health Organization (WHO)

・Initiatives to strengthen cooperation with WHO, such as sharing of knowledge about measures for aging society

○ Promoting ICT in healthcare

・Initiatives to improve *mibyou* through the construction and expansion of My ME-BYO Karte, application software for visualizing personal health information as a list in coordination with various kinds of healthcare application software, by utilizing ICT technology.

・Initiatives to solve regional and social issues by the use of My ME-BYO Karte, such as the popularization of

electronic mother-child health records, disaster measures, companies' health management (CHO plan), etc.

・Initiatives to utilize big data accumulated through My ME-BYO Karte

○ Creating an industry focused on "*mibyou*" (presymptomatic states)

・Initiatives to designate the Prefecture as secretariat and promote the creation of an industry focused on *mibyou*, including the creation of new goods and services through the facilitation of cooperation among the member companies of the Association for ME-BYO Industry Creation, the establishment of scientific grounds for *mibyou* in cooperation with academia, and branding of *mibyou* by the use of a certification system

○ Promotion of CHO plan

・Initiatives to facilitate and expand the CHO plan (health management) so that companies and associations will appoint a Chief Health Officer (CHO) and promote the employees and their families' health as a part of management

○ Dissemination and popularization of the concept of *mibyou*

・Initiatives to disseminate the concept of *mibyou*, such as the holding of ME-BYO Japan, an exhibition for disseminating state-of-the-art technologies related to *mibyou*, and ME-BYO Summit Kanagawa, an international symposium for discussing *mibyou* from various angles and disseminating it within Japan and overseas to establish the next-generation social systems.

○ Initiatives in National Strategic Special Zones

・Various kinds of deregulation were promoted to encourage medical institutions in the Prefecture to provide the world's highest-level medical care early by the use of exceptions to medical expenses combined with treatment outside insurance coverage and the regulated number of beds and facilitate the market expansion of healthcare robots and individuals' health activities for the creation of an industry focused on *mibyou*.

*What is "*mibyou*"?

Rather than regarding health and illness as being mutually exclusive, the concept of *mibyou* views a person's mental and physical condition as continuously changing along a spectrum between health and illness, expressing the process of all of those changes. Bringing the whole body closer to a healthy condition in addition to the prevention and treatment of a specific disease in the process of this series of changes are called improvement of *mibyou*.

(ii) Pioneering initiatives in the Kansai region

In the Kansai region, the following pioneering initiatives are being undertaken:

○Promotion of R&D of innovative drugs

・In the fields of the treatment of cancer, cardiovascular diseases, cranial nerve diseases, and sensory organ diseases and regenerative medicine, the government will mainly encourage core hospitals for clinical research to conduct R&D focused on innovative drugs, medical equipment, regenerative medical products, etc. originating in Japan.

○ Translating innovative clinical research into reality

・Initiatives to promote innovative clinical research by establishing medical centers promoting the practical application of cutting-edge medical technology such as retinal regeneration therapy, which is the world's first clinical research project using iPS cells

○Formation of a medical cluster by open innovation

・The government will promote the formation of a medical cluster (Northern Osaka Health and Biomedical Innovation Town) where community development is combined with state-of-the-art R&D and industrial revitalization by open innovation under the concept of "health and medical care."

○ Future initiatives

・Promotion of global people-to-people exchange in team-based medicine in Japan through the establishment of a center for medical research into BNCT (boron neutron capture therapy), which will be soon put in practical medical use for the first time in the world, and through the export of particle beam therapy instruments and endoscopes, such as the heavy ion radiotherapy that Japan pioneered ahead of the rest of the world.

・Because many research institutes that lead research in the field of regenerative medicine are located in the Kansai region, to make use of this advantage, the government will promote the establishment of centers that will promote industrialization based on the results of clinical research on regenerative medicine.

○ Initiatives in National Strategic Special Zones

・Various kinds of deregulation were proposed to promote R&D and commercialization of advanced drugs and medical equipment, such as regenerative medicine, through the formation of international innovation centers in the fields of health and medical care by the use of National Strategic Special Zones.

In addition, initiatives utilizing the National Strategic Special Zones are being promoted through partnerships between the national government, local governments, and the private sector. Specific projects were detailed in the Zone Plans formulated by the Zone Council established in each Zone, and have been implemented with the approval of the Prime Minister.

In planning and formulating the Healthcare Policy and promoting the measures therein, the government will encourage such initiatives by local governments by maintaining close partnerships and cooperation with pioneering initiatives by the local governments in question, striving to reflect in measures at the national level those initiatives that are achieving outstanding results.

3) The role of research institutes at universities, etc. and partnership and cooperation involving them

Wide-ranging basic research based on innovative thinking by researchers is crucial to the promotion of the Healthcare Policy. It is anticipated that the Innovative Medical Technology Creation Center and National Centers

will be involved in partnership and cooperation, to ensure that the results of this lead smoothly into clinical research and trials.

In planning and formulating the Healthcare Policy and promoting the measures described therein, the government will strive to encourage partnership and cooperation between these institutions.

Measures to prevent fraud in both basic and clinical research must be actively implemented not only by the government, but also by universities and other research institutes. Accordingly, it is necessary for universities and other research institutes to develop an environment that prevents fraud and to strengthen ethics education for researchers, while complying with the government's guidelines on research fraud.

In addition, universities and other research institutes are expected to endeavor to contribute to the creation of new industries and human resource development in the field of healthcare and medical care through the construction and effective use of frameworks for collaboration between industry, academia and government. Accordingly, the government will strive to encourage such initiatives.

4) Partnership and cooperation with medical institutions and business operators

It is vital for medical institutions and business operators involved in advanced R&D and the creation of new industries in the field of healthcare and medical care to cooperate with measures implemented by the national government and local governments to promote the Healthcare Policy.

It is anticipated that medical institutions – above all, the core hospitals for clinical research and centers for early and exploratory clinical trials that will play a central role in clinical research at the international level and physician-led clinical trials – will promote high-quality clinical research and trials aimed at the development of innovative drugs, medical equipment, etc. and medical technology. Accordingly, the government will strive to encourage such initiatives.

Moreover, it is expected that business operators involved in advanced R&D and the creation of new industries in the field of healthcare and medical care will actively undertake R&D and establish pioneering practical applications for innovative drugs, medical equipment, etc. and medical technology ahead of the rest of the world. As such, the government will endeavor to encourage such initiatives.

(3) Implementation of measures based on the Healthcare Policy

The government will implement the following measures to comprehensively and systematically promote the measures described in the Healthcare Policy.

1) Implementing measures based on the Healthcare Policy

As well as efficiently and effectively implementing the measures described in the Healthcare Policy, in accordance with the provisions of Article 9 of the Promotion Act, the government will make use of legislation, fiscal measures, and the tax system, and take any other steps deemed necessary to encourage the private sector to engage in the

activities required for the steady promotion of these measures.

Based on the estimated budgets for each fiscal year, the Headquarters will draw up a policy on the allocation of budget funds for medical R&D and efforts to improve the environment for this, and will present these to the relevant ministries and agencies. Having undertaken the necessary coordination with the Cabinet Secretariat to ensure the steady implementation of the Promotion Plan in accordance with this policy, the relevant ministries and agencies will submit a joint budgetary request with the Cabinet Secretariat for budgetary funds for medical R&D. Thus, the Headquarters will strive to secure the necessary budget each fiscal year on the basis of comprehensive coordination of the allocation of budgetary funds, taking into account the country's fiscal situation.

2) Implementing measures that take account of the needs of all segments of Japanese society

Pursuing partnership and cooperation at all levels of society, the Headquarters will promote the measures described in the Healthcare Policy and the Promotion Plan, based on an accurate understanding of the needs of stakeholders, including people with relevant knowledge and experience, industry, medical institutions, and patients and other citizens, while also taking into account the opinions of the Council of Healthcare Policy Advisors and the Expert Panel on Promotion of the Healthcare Policy.

3) Promoting PR activities at home and abroad

The Headquarters will use appropriate methods to publish information via the Internet, etc. concerning the background, necessity, and content of the Healthcare Policy and the measures described therein, and will promote understanding of and cooperation with these measures at all levels of society.

In conjunction with this, the Headquarters will disseminate information in English to ensure a proper understanding of these measures overseas.

4) Promoting activities to strengthen collaboration between implementing agencies

In steadily implementing medical R&D in accordance with the Healthcare Policy, it will be vital to ensure that the results of basic research carried out at universities and other research institutes lead smoothly into practical applications. Accordingly, the new Headquarters will seek to build partnerships and cooperative relationships between universities, research and development corporations, other research institutes, medical institutions, and companies, etc., as well as encouraging the acquisition and use of IP and the matching of seeds with company needs. In addition, it will promote clinical research and trials using funding provided by private sector companies and organizations.

5) Monitoring and disclosing the progress status of measures

Under the supervision of the Headquarters, the Cabinet Secretariat will follow up on the implementation status of

the measures described in the Healthcare Policy (conducting surveys regarding the implementation status of measures) and will use appropriate methods to publish the results of the follow-up and the policy via the Internet, etc.

6) Implementation of the PDCA cycle for the Healthcare Policy by the Headquarters

Under the supervision of the Headquarters, the Cabinet Secretariat will conduct progress management of the Healthcare Policy based on the PDCA review cycle. In follow-up activities focused on the measures described in the Healthcare Policy, evidence will be used to verify the effects and efficiency of the measures. Where necessary, the results of this verification will be used as the basis for revising the content of the measures.

7) Reviewing the organization, budget, etc. in light of the PDCA results

The PDCA review cycle will be thoroughly implemented in regard to the Healthcare Policy and, in order to facilitate more comprehensive, systematic promotion of the measures described in the Healthcare Policy in light of the results of such reviews, consideration will be given to relationships between the Headquarters, AMED, relevant ministries and agencies, and relevant incorporated administrative agencies, as well as to approaches to budgets and organization, with the necessary steps being taken in light of the results of these deliberations.

Glossary

・AMED: Japan Agency for Medical Research and Development, which was founded in April 2015

・ARO: Academic Research Organization
An organization equipped with functions that universities, etc. with research institutes and medical institutions can use to support drug development.

・CSR Report
A voluntary report concerning a company's corporate social responsibility (CSR). Based on an approach aimed at gaining the trust of the various stakeholders surrounding a company, CSR refers to the behavior of companies that take responsibility for the effects of their activities, with the aim of enabling the company to coexist with society and the environment, and achieve sustainable growth.

・ICT: Information and Communication Technology

・KPI: Key Performance Indicator, a target to be achieved

・PD: Program Director
AMED's PD is appointed for each integrated project from among external experts and manages the project and cooperates with the other PDs in coordinating the integrated projects.

・PFI: Private Finance Initiative
A technique for providing public services more efficiently and effectively than direct provision by the national government or local governments, via the introduction of private sector money, managerial skills, and technical capabilities to public services (construction, maintenance and management, and operation, etc. of public facilities).

・PMDA: Pharmaceuticals and Medical Devices Agency
With the aim of helping to improve the health of the public, the PMDA offers rapid redress for health hazards due to side-effects from drugs; reviews the quality, effectiveness, and safety of drugs and medical equipment, etc.; and gathers, analyzes, and disseminates information concerning safety once these items become commercially available.

・PO: Program Officer
AMED's PO is appointed for each project from among external experts and cooperates with the PS in managing and carrying out the project.

・POC: Proof of Concept
Proving through simple trials with a small number of subjects that a cure or the concept, theory, or principle of drug

development is feasible

・PPP: Public Private Partnership

An approach aimed at achieving greater efficiency in public services by introducing market mechanisms to such services, by such means as outsourcing to the private sector, the creation of incorporated administrative agencies, or privatization, depending on the nature of the service concerned.

・PS: Program Supervisor

AMED's PS is appointed for each project from among external experts and manages the project and cooperates with the other PSs in coordinating the projects.

・Medical Information Database Infrastructure Development Project

Implemented in 10 medical institutions nationwide, the Medical Information Database Infrastructure Development Project is a project currently focused on using SS-MIX2 to build up a store of both data from electronic medical records (data concerning illness/injury, prescriptions and injections, and laboratory tests, radiological examinations, and physical examinations, etc.) and medical receipt and Diagnosis Procedure Combination (DPC) data (data concerning illness/injury, admission and discharge, treatment, etc.) This data will be used to compile a database at each medical institution, which will then be used to analyze such matters as the frequency of adverse events, in order to develop safety measures for drugs, medical equipment, etc.

*SS-MIX2: Standardized Structured Medical record Information eXchange 2

The generic term for a system aimed primarily at standardized storage, developed via an MHLW project to promote the storage of standardized medical information.

・Open innovation

The resolution of problems through the use of external development capabilities and ideas, creating entirely new value.

・NTD: Neglected Tropical Diseases

A group of parasitic and bacterial diseases that are especially endemic in low-income populations in tropical regions and affect more than 1 billion people worldwide. These infectious diseases not only trap individuals in a cycle of poverty and disease, but also exacerbate and prolong the poverty of their local communities.

・Genome

A word created from a combination of the words gene and chromosome, meaning all genetic information in DNA.

・Investment in health

The purchase and use by companies or individuals, etc. of services not covered by public insurance that contribute to health promotion and disease prevention, for the purpose of extending healthy life expectancy, improving productivity,

and curbing increases in medical expenses.

・Corporate Governance Report

A report compiled in order to provide investors with a clear understanding of a company's corporate governance situation, which a securities exchange requires all companies listed on that exchange to prepare.

・Strategy for Global Health Diplomacy

Positioning initiatives in the field of international health as a key topic in Japan's diplomatic relations, this was approved by relevant Cabinet ministers as a means of increasing the international community's trust in Japan through efforts that bring relevant ministries and the public and private sectors together in an effort to resolve global health challenges. It positions health as a field that is essential in order to achieve human security and seeks to realize a world in which every person can receive basic healthcare services, making use of Japan's comparative advantage as a society in which people enjoy the longest and healthiest lives in the world.

・Cohort (study)

A follow-up study concerning the state of health or disease over the long term among a certain group of the population.

・Disease-modifying drug

Drug that intervenes in the cause of a disease and stops or hinders the progress of disease

・DPC: Diagnosis Procedure Combination

A classification system used in the fixed payment system for medical expenses.

・SFT: Sport for Tomorrow

An initiative designed to promote the value of sport and promote the Olympic and Paralympic Movement to people of all ages – especially the young people who will be the leaders of tomorrow – to achieve a better future worldwide, targeting more than 10 million people in more than 100 countries, including developing countries, over the seven years from 2014 to 2020

・Clinical trial

Clinical trials are implemented with the aim of gathering data that can be submitted as test results, along with other materials that must be submitted when applying for approval to manufacture or sell a drug, an item of medical equipment, etc.

・Data health program

A business plan formulated by insurers to implement efficient, effective health programs via the PDCA review cycle, based on the analysis of data from medical receipts and health check-ups.

・DDS: Drug Delivery System

A system that controls the delivery of drugs within the body in terms of quantity, space, and time

・PHR: Personal Health Record

System for individuals' collecting and using information on health, medical, and nursing care efficiently; or such information

・Biopharmaceuticals

Drugs in which the active ingredient has been created from biological agents, such as proteins derived from cells, viruses, bacteria, or other organisms (e.g. growth hormones, insulin, antibodies, etc.)

・Bioinformatics

A field of study focused on using techniques from computer science to analyze biological data, and the technologies used for this analysis.

・Bank (biobank)

A collection of biological specimens and related information.

・Frailty

State in which mental and physical power (such as muscular strength and cognitive function) decline with age and this increases the risk of damaging vital functions, so that the sufferer becomes in need of nursing care or dies

・Healthcare REIT

Real estate investment trusts in which healthcare facilities are the target of investment.

・Inclusive business

A business model promoted by the United Nations and the World Bank Group, which seeks to achieve compatibility between development objectives and company profits by including the poor in the business process.

・UHC: Universal Health Coverage

A situation in which all people can access the appropriate healthcare and medical services – including prevention, treatment, and rehabilitation – at a reasonable cost in times of need.

・Reverse TR

Research in which knowledge and information gained through clinical medicine or research are fed back to basic research

・CRC: Clinical Research Coordinator

A person who assists with tasks associated with clinical research and trials, such as dealing with test subjects and coordination with those in other occupations, to ensure that clinical research and trials are carried out smoothly at medical institutions.

・Regulatory science

A branch of science that aims to make accurate, evidence-based projections, appraisals, and judgments, in order to ensure that the fruits of science and technology take the most desirable form from the perspective of their harmonization with people and society, with the objective of ensuring that the results of R&D in this area benefit people and society as a whole. (Fourth Science and Technology Basic Plan) In particular, in the fields of drugs and medical equipment, etc., science focused on swift, appropriate forecasting, evaluation, and judgment based on scientific knowledge, concerning the quality, effectiveness, and safety of practical applications for medical R&D results. (Article 13 (2) of the Act on Promotion of Healthcare Industries and Advancement of Healthcare Technologies)