

### 3. Vision 1: “Driving next-generation medicine with advanced drug discovery – Contribution to P4+1 medicine –”

#### **Strategic points for realizing the vision**

##### **Cooperation and lobbying for medical database development and application to drug discovery**

- Development and harnessing of medical “big data”
- Promotion of elucidation of disease onset mechanisms and search for biomarkers

##### **Steps taken to enable P4+1 medicine**

- Establishing the environment and providing information for the realization of “P4+1 medicine”
- Promoting post-marketing development for the realization of patient participatory medicine

##### **Commitment to the creation of personalized pharmaceuticals**

- Promoting the development of advanced medical technologies, including biopharmaceuticals, regenerative medicine, and nucleic acid pharmaceuticals

##### **Combining existing drug-discovery technology and expertise through industry and cross-industry collaboration**

- Improving productivity through increased public-private-academic collaboration
- Stepping up industry-industry collaboration to enable more advanced drug discovery
- Recommendations and support for the active formation of cross-industry collaborative research centers both at home and abroad

##### **Actions for the establishment of a world-leading clinical trial framework**

- Recommendations and support for a medical institution network with access to patient data
- Development of diagnostics for the creation of personalized pharmaceuticals and promotion of efficient clinical trials using PGx

##### **Initiatives related to systems for the realization of P4+1 medicine**

- Recommendation and establishment of the corporate framework for the implementation and expansion of the strategy of SAKIGAKE as a package
- Recommendations for the enhancement of the approval system in areas with serious unmet medical needs
- Recommendations and lobbying for a tax system that promotes research and development activities (R&D tax system)

#### **(1) Approach of the vision**

Against the backdrop of recent remarkable advances in fields such as next-generation sequencer<sup>\*1</sup> analysis, individual genome information<sup>\*2</sup> and other

biomolecular information is now being analyzed precisely and rapidly, and the cause of diseases and the onset process can be understood in more detail at a molecular level. Personalized medicine, which determines the best possible therapy for each patient based on the patient's genome information, physical condition and disease status through diagnosis using the genome information and biomarkers<sup>\*3</sup>, is becoming more widespread. It is expected to improve the therapeutic efficacy of drugs in an individual patient and to reduce side effects.

It is also expected that these advances in genome- and omics-based research<sup>\*4</sup> and diagnostic technology will contribute to enable not only the diagnosis of diseases after their onset but also the predictive and early diagnosis with a high degree of accuracy before the onset of disease. It will enable preventive medicine<sup>\*5</sup> prior to the onset of disease or during the asymptomatic stage in the early phase of disease, even for conventionally difficult-to-treat diseases, so we expect that it can prevent or delay the onset of disease.

With these next-generation medicines, there will be increasing opportunities for patient participation, namely participatory medical care in which patients think and make decisions themselves when choosing preventive treatment, providing genetic information, and participating in clinical trials.

We must therefore make efforts to increase patients' satisfaction with treatment; in other words, maximize therapeutic efficacy and minimize side effects more than ever before. To this end, we must contribute to the realization of next-generation medicine not only by providing conventional pharmaceuticals prescribed after the onset of disease, but also by providing each patient with the optimal pharmaceuticals upon obtaining the patient's understanding, including preemptive medicine at the right time. In addition, we must boldly rise to the challenge of being a driving force in advanced drug discovery.

Although JPMA and its member companies have developed many innovative drugs to address serious unmet medical needs (UMN)<sup>\*6</sup>, UMN, including intractable and rare diseases, still remain. In light of this situation, we must aim to address UMN by continuing to actively take on challenges at each stage from the elucidation of the disease mechanism to drug discovery research, clinical development and approval reviews. New drug creation has become less productive on a global scale, and the development cost per pharmaceutical item has increased year by year. Against this background, we intend to progressively promote initiatives in the technological fields in which we can be competitive by advancing and combining existing technologies, and to contribute to the establishment of a healthy long-life society by promoting the quality and efficacy of medical care and providing patients with safe and effective innovative new drugs.

## (2) Contribution to next-generation medicine “P4+1 medicine”

We coined the term “P4+1 medicine,” defining it as next-generation medicine that realizes advanced medicine and achieves improvement in the quality and efficiency of conventional medicine. P4+1 medicine is a concept in which each individual patient is provided with the early diagnosis and prediction of disease and the best possible drugs at just the right time upon obtaining the patient’s consent.

P4	Personalized	: Personalization based on genetic and environmental factors
	Predictive	: Precise prediction through the use of genetic information and biomarkers
	Preventive	: Preventive intervention based on precise predictions
	Participatory	: Patients’ understanding of information and participation in medical care
+1	Progressive	: Improvement in the quality and efficiency of medical treatment through advancement and combination of existing technologies

“P4 medicine” means personalized, predictive, preventive and participatory medicine. It is an advanced concept developed in the US, which represents preventive medical care using predictions based on personalized genetic data and biomarkers, and patient understanding and participation in the medical care. No one would deny the importance of the progressive development and advancement of existing technologies for improving the quality and efficiency of conventional medicine that has significantly helped address UMN. JPMA aims to realize drug discovery innovation that contributes to both P4 medicine and progressive medicine, and consequently adopted the vision of contributing to P4+1 medicine, which combines P4 medicine with progressive medicine, and driving next-generation medicine with advanced drug discovery.

## (3) Specific details of the vision in the future

- Effectively using medical “big data” for drug discovery in order to contribute to the establishment of medical care, whereby individual patients are provided with the best possible drugs at just the right time
- Bringing in drug discovery resources and knowledge from all over the world in order to establish world-leading drug discovery capabilities in advanced and growth sectors, such as personalized medicine, preemptive medicine, and regenerative medicine
- Creating innovative drugs for patients with intractable diseases and serious unmet needs (UMN)

JPMA has made active efforts and provided support to establish the systems required to achieve the above three objectives as well as to develop and gather human resources.

Consequently, Japan has shown a strong presence in the world; more specifically, the number of Japanese-origin innovative drugs accounts for more than 13% of the global market and more than 20% of those drugs are intended for personalized and preemptive medicine<sup>\*7</sup>. Moreover, the number of new drugs for treating intractable and rare diseases approved in Japan has doubled compared to five years ago<sup>\*8</sup>.

#### **(4) Current situation of R&D in the pharmaceutical industry**

##### **1) The US is ahead of Japan in terms of database development and medical information**

Tremendous efforts have been made on a global scale in genome and cohort research<sup>\*9</sup>, and the medical “big data”<sup>\*10</sup> integrating such research results is attracting attention. The “big data” is expected to be harnessed for personalized and preemptive medicine. In Japan, a committee for the advancement of genomic medicine was established in January 2015, and efforts have been made for the realization of genomic medicine. However, we fall behind the Western nations, in particular the US, in terms of the development of the environment for the actual use of genomic medicine in disease-oriented research and clinical practice.

##### **2) The share of the number of Japanese origin pharmaceuticals has increased slightly, and Japan is attempting to catch up with the West, which is more advanced in the biopharmaceutical field**

The sales share of Japanese origin pharmaceuticals with global sales of \$300 million or more is trending downward. On the other hand, the share in terms of their numbers increased from 9.6% in 2008 to 10.9% in 2014<sup>\*11</sup>.

Above all, the sales ratio of Japanese products among the world’s top 50 ranked biopharmaceuticals has risen from 21% in 2006 to 45% in 2013<sup>\*12</sup>, which shows that our presence in biopharmaceuticals has been increasing rapidly. In the R&D of biopharmaceuticals, Europe and the US have been more advanced. However, the number of newly initiated clinical trials of biopharmaceuticals developed by JPMA member companies has increased over the past 10 years, from 15 products (2000-2004) to 30 products (2010-2014)<sup>\*13</sup> and the number of developers has also increased from 9 (2000-2004) to 24 (2010-2014), suggesting that initiatives in this area have been somewhat more active.

##### **3) R&D focus has shifted towards conditions with serious UMN**

R&D for serious unmet medical needs, including rare diseases affecting fewer

patients and intractable diseases, is becoming more widespread. The number of approved treatments for rare diseases has increased continuously in Japan, specifically from 29 products (2000-2004) to 52 products (2005-2009) to 79 products (2010-2014)<sup>\*14</sup>. JPMA member companies are currently developing more drugs than before in areas with serious UMN, such as cancers and diseases of the central nervous system (CNS)<sup>\*15</sup>.

#### **4) Shortening of clinical development period and initiatives to further activate and improve the quality of clinical trials**

In the decade since 2005, the duration of clinical development (from initial clinical trial notification until application filing) of all the domestically approved drugs with new active ingredients (new molecular entities; NMEs) has been shortened by 21 months (from 69.2 months in 2005 to 48.2 months in 2014). A comparison shows that in 2014, the number of NME applications filed in Japan was almost double that in the US (60 items in Japan and 31 items in the US)<sup>\*14</sup>.

To activate clinical research and studies and improve the quality, it is essential to increase the number of specialists with high levels of knowledge in the field of regulatory science<sup>\*16</sup> and biostatisticians. In particular, in order to foster biostatisticians, who are increasingly in demand, JPMA has repeatedly consulted with the MHLW and AMED and cooperated in setting up training courses and endowed courses at universities and hospitals.

#### **5) Establishment of AMED and major advances in pharmaceutical legislation and systems**

In April 2015, AMED was established. Now that we have a research management system covering the entire process from basic research to product development and practical application, we expect that public-private-academic collaboration will be further strengthened. In terms of pharmaceutical legislation and systems, the review period for new drug approval has shortened significantly over the last decade, and has reached a level comparable to that in Europe and the US<sup>\*14</sup>. Moreover, a system for accelerating the practical use of innovative drugs, such as the strategy of SAKIGAKE as a package, has been introduced.

### **(5) Issues and strategies for realizing the vision**

#### **1) Cooperation and lobbying for medical database development and application to drug discovery**

Thanks to the universal health insurance system, which has more than 50 years'

history, health and medical data on almost all the people of Japan has been acquired and accumulated in the form of medical insurance claims<sup>\*17</sup>, medical records, and medical examination data.

The digitalization and standardization of these valuable resources make it possible to build a world-class medical health database of the entire population, however there are a host of issues regarding the preparation of the environment for its actual use in medical practice. In terms of the collection of genome- and omics-based information and database development as well, Japan is behind Europe and the U.S., where research has been promoted for the realization of advanced medicine as national projects.

The important key for realizing P4+1 medicine is to actually harness medical “big data” for drug discovery at the stage such as searching for new disease targets and biomarkers. The medical databases in Japan, however, have not yet been fully established so that they can actually be used for drug discovery.

#### **(i) Development and harnessing of medical “big data”**

To address the challenges involved in the build-up of medical “big data,” including the appropriate accumulation, digitalization and standardization of medical information, such as clinical test data, medical insurance claims and cohort research data, as well as new forms of medical data, such as genome and omics data, and to handle the issue of making such information available to the industry, close collaboration will be required not only within the pharmaceutical industry but also among related parties, such as healthcare professionals, IT vendors, insurers, patient groups, regulatory authorities and the National Institute of Research and Development. JPMA will actively cooperate and lobby the government by unifying opinions within the industry and making recommendations regarding the establishment of medical “big data” for drug discovery.

#### **(ii) Promotion of elucidation of disease onset mechanisms and search for biomarkers**

We will facilitate the use of medical “big data” for drug discovery and encourage the elucidation of disease onset mechanisms and the search for biomarkers through joint initiatives with multiples companies led by JPMA in non-competitive fields. Through the reinforcement of collaboration with academic and medical institutions, including other industries and ventures with original technologies, and various other industries, we will introduce image analysis technologies and advanced diagnostic technologies using DNA or blood samples and contribute to the early discovery of disease factors.

### **2) Steps taken to enable P4+1 medicine**

P4+1 medicine, namely personalized and preemptive medicine based on diagnosis

and predictions using each patient's personalized data, means that a shift occurs from conventional collective medicine to personalized medicine. Under these circumstances, we face a number of issues to be resolved, such as technical issues regarding the prediction accuracy of disease risk and preparations to increase public awareness of P4+1 medicine. With P4+1 medicine, there are likely to be more situations in which patients think and make decisions for themselves when choosing preventive medicine, providing genetic information, or participating in studies.

Although more medical knowledge has been accumulated through interactive communication, including the promotion of self-medication, the initiation of pharmaceutical education, the expansion of support materials, improvement in the knowledge level of the general public thanks to the penetration of the internet, and the common usage of informed consent, healthcare professionals and patients cannot yet sufficiently exchange opinions about the treatment.

**(i) Establishing the environment and providing information for the realization of P4+1 medicine**

When it comes to medical information database development, we will establish a framework which also enables feedback to patients and share information on international trends, discuss and formulate opinions, and provide information to promote P4+1 medicine via JPMA expert committees with the aim of establishing the environment necessary for the realization of personalized and preemptive medicine based on diagnosis and predictions using each patient's personalized data.

**(ii) Promoting post-marketing development for the realization of patient participatory medicine**

We collaborate with patient groups, AMED, and others to establish systems that effectively reflect patient needs in drug discovery R&D. We also proactively provide appropriate information so that patients are more accurately informed, as well as support patients so they can participate actively in their own medical care.

**3) Commitment to the creation of personalized pharmaceuticals**

There are still many diseases with high unmet medical needs, such as intractable and rare diseases, and it is an urgent need to understand the mechanism that underlies these diseases and to search for biomarkers. At the same time, another challenge is strengthening global competitiveness in the creation of biopharmaceuticals, regenerative medicine, and nucleic acid pharmaceuticals, which are important modalities<sup>\*18</sup> in advanced drug discovery. In the biopharmaceuticals field, in particular, only a limited

number of companies have the human resources and manufacturing facilities required to produce products, and consequently Japan is lagging behind internationally.

**(i) Promoting the development of advanced medical technologies, including biopharmaceuticals, regenerative medicine, and nucleic acid pharmaceuticals**

It is expected that needs for biopharmaceuticals will increase further in the future. To ensure that domestic companies are internationally competitive with regard to the development of biopharmaceuticals, it is necessary to develop the framework for public-private-academic industry collaboration that is required to commercialize the seeds from academia and others, to upgrade and expand manufacturing facilities that can domestically produce biopharmaceuticals (including investigational drugs), and to secure sufficient human resources with expertise and experience in biology and biotechnology. JPMA therefore works to promote the R&D of biopharmaceuticals, and provides support and reinforces the collaboration with the government for the promotion and expansion of human resource development programs related to the manufacturing technology of biopharmaceuticals.

To enable its member companies to show a global presence and become world leaders in advanced technical fields, such as regenerative medicine and nucleic acid pharmaceuticals, JPMA will promote public-private-academic cooperation and cooperate proactively in the resolution of issues related to regulatory affairs, activities for international cooperation, and the development of an environment for the practical application of advanced technologies.

**4) Combining existing drug-discovery technology and expertise through industry and cross-industry collaboration**

Against the background of a lack of R&D pipelines and the spiraling costs of R&D, commitment to open innovation by pharmaceutical companies is increasing. While public-private partnerships, such as the foundation of AMED, and relationships between academia and industry are developing, stronger government-academia cooperation and inter-industry collaboration with a wide range of partners is required to develop world-class innovative drugs. In terms of industry-industry cooperation between companies, there have been some unconventional initiatives —such as the sharing of compound libraries<sup>\*19</sup> — although still on a limited scale.

**(i) Improving productivity through increased public-private-academic collaboration**

We aim to further improve drug discovery productivity by increasingly promoting R&D models whereby companies make effective use of other resources besides their

own. We are promoting public-private-academic collaboration, including AMED, and combining the standalone technologies of pharmaceutical companies, the seeds of academic institutions and drug discovery venture companies, and advanced technologies through multiple companies' joint projects led by JPMA in non-competitive fields.

**(ii) Promoting industry-industry collaboration to enable more advanced drug discovery**

Industry-industry collaboration, including the unprecedented initiative to share knowhow through the mutual use of compound libraries, is advancing. To further strengthen the drug discovery capabilities and international competitiveness of pharmaceutical companies, we are supporting the flexible industry-industry collaboration among JPMA member companies in the following ways: the establishment of JPMA-centered facilities for collaboration, the promotion of exchanges between the senior management of the R&D divisions of member companies, the proactive exchange of information more than the sharing of compound libraries, and the proactive exchange of items for the purpose of drug repositioning<sup>\*20</sup>.

**(iii) Recommendations and support for the active formation of cross-industry collaborative research centers both at home and abroad**

To further strengthen international competitiveness, we seek to attract foreign drug discovery resources and expertise, and activate the domestic drug discovery innovation environment. We therefore make recommendations and provide support for industrial agglomeration, including special medical zones and clusters, as bases for corporate and institutional collaboration between various industries and drug discovery ventures both at home and abroad. JPMA also works on fostering drug discovery ventures in an increasingly proactive manner and considers what appropriate platforms should be like. Furthermore, with the establishment of AMED, we make recommendations and provide support from the industry side to ensure that public support for ventures and the development of an environment for matching needs and seeds in the medical area can be promoted effectively and efficiently across government offices and agencies.

**5) Actions for the establishment of a world-leading clinical trial framework**

Towards the realization of P4+1 medicine, it is important both to domestically develop innovative drugs and to improve access to new drugs developed in other countries, and a world-leading clinical trial framework is expected to be built. Thinking from an international perspective, however, the clinical trial framework of Japan has room for improvement, such as the limited number of case series and the high per subject costs. Regarding the development of drugs for intractable and rare diseases,

there is a problem with the evaluation of the effectiveness of a therapeutic agent in only small numbers of patients.

**(i) Recommendations and support for a medical institution network with access to patient data**

JPMA actively supports the concept of the Clinical Innovation Network (CIN) being promoted by the government, makes recommendations and cooperates for the establishment of the clinical development environment—including clinical research and clinical studies—and seeks to improve the efficiency of clinical trials through the following means: using registration information on diseases, expediting the selection process of trial sites, accelerating the subject enrollment process, and increasing the number of case series. We also recommend the use of CIN to create and expand a registry<sup>\*21</sup> that aggregates patient information, including their treatment history, for the development of drugs to treat intractable and rare diseases that affect only small numbers of patients.

We also consult and cooperate with related stakeholders for the realization of a one-stop service that enables the completion of the necessary procedures for clinical trials at multiple medical institutions (such as requests, agreements, and screenings) via a single point of contact.

**(ii) Development of diagnostics for the creation of personalized pharmaceuticals and promotion of efficient clinical trials using PGx**

In order to develop personalized pharmaceuticals, the challenges associated with the development of companion diagnostics<sup>\*22</sup> must be addressed, and there is also a need to advance research that uses pharmacogenomics<sup>\*23</sup> (PGx) as markers for patient stratification<sup>\*24</sup>. JPMA promotes the development of diagnostics and the use of biomarkers in trials, strengthens cooperation with related industries and government bodies, and holds consultations and makes recommendations on regulatory affairs.

**6) Initiatives related to systems for the realization of P4+1 medicine**

In terms of drug legislation, therapies for serious unmet needs, non-communicable diseases (NCDs)<sup>\*25</sup>, intractable and rare diseases are not accessible enough compared to the situations in various countries (such as Breakthrough Therapy in the U.S., the Early Access to Medicines Scheme of the UK's Medicines and Healthcare products Regulatory Agency, and the Adaptive Pathways Scheme of the European Medicines Agency), and the pharmaceutical jurisprudence for preemptive medicine is still being established. To increase access to foreign pharmaceuticals in Japan, there is room for

improvement such as corrections of inconsistencies in regulatory systems between countries and the preparation of application documents written in Japanese.

From the perspective of tax system, Japan's tax credit for experimental and research expenses (R&D tax credit) plays an important role as a measure to support research and development investments in a private-sector and it should be maintained and expanded in the future as well. This R&D tax credit should not be discussed in a way as if cuts in the tax credit for experimental and research expenses were needed to compensate deficiency from the reduction in corporate income tax rate because the R&D tax credit was introduced for the unique purposes not just to reduce tax burdens in a private sector broadly. It should rather be discussed by reference to the UK which pursues both the reduction in corporate income tax rate and the enhancement of the tax system to promote research and development activities.

**(i) Recommendations for the implementation and expansion of the strategy of SAKIGAKE as a package and establishment of a corporate framework**

To effectively implement the strategy of SAKIGAKE as a package, JPMA will recommend that the authorities ensure that the personnel necessary for shortening the period of priority consultations and priority review are in place, and further enhance the education system for application reviewers. Moreover, in order to facilitate and increase the efficiency of the application and review procedures, we will summarize each company's opinion and make recommendations for improvements on issues such as increasing the level of acceptance of English for the regulatory dossier, unifying the submission packages of various countries, and accepting more data of Asian subjects who are enrolled in the global phase 3 studies in order to make up for Japanese subjects. JPMA member companies should establish internal systems for the future international standardization of local regulations by, for example, preparing an application supported by the review report in foreign countries, and securing/training in-house human resources to cope with the speedy approval and review system, such as Sakigake review.

**(ii) Recommendations for the enhancement of the approval system in areas with serious unmet medical needs**

As a measure to promote the development of drugs for rare diseases, there is an existing system where therapies can be approved based on clinical trials with a small number of subjects provided that additional clinical trials will be conducted or the medical institutions being applied will be limited. Given that there is likely to be increasing demand for the development of pharmaceuticals to treat serious diseases with high unmet medical needs in the future, we recommend expanding the scope of

application of the system and including designated intractable diseases and serious infections as those covered by the system. We will secure the appropriate human resources to ensure safety and efficacy and provide them with high quality training, and additionally, request that the authorities responsible for reviews secure and train human resources for approval reviews.

**(iii) Recommendations and lobbying for a tax system that promotes research and development activities (R&D tax system)**

JPMA will make recommendations and take lobbying actions for establishment of a R&D tax system that is more attractive than that of any other country and the introduction of a tax system for enhancement of intellectual properties in order to accelerate development of innovative drugs aiming to provide patients with better drugs more quickly and to sharpen the competitive edge of the Japanese pharmaceutical industry.

[Notes]

- \*1 Sequencer: Device used to analyze DNA base sequences
- \*2 Genome information: All genetic information stored in DNA
- \*3 Biomarkers: A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a therapeutic intervention. An even broader definition includes vital signs used in routine medical care, measurements obtained in various clinical tests such as biochemical tests, blood tests and tumor markers, and image diagnosis data.
- \*4 Genome- and omics-based research: Researching genetic information and biological molecules such as gene transcripts, proteins and metabolites
- \*5 Preemptive medicine: Using the genetic information and biomarkers of individuals to accurately predict the onset of disease, performing therapeutic interventions at the right time before the occurrence of symptoms or serious tissue damage, and preventing or delaying the onset
- \*6 Unmet medical needs: Medical needs in the areas where there is still no effective treatment or medicine
- \*7 Japanese origin pharmaceuticals account for a 13% share in terms of number (1.2 times compared to 2014) among all the pharmaceuticals with global sales of \$300 million or more.
- \*8 Twice as many drugs to treat intractable and rare diseases are expected to be approved in the period from 2020 to 2024 as those approved in the period from 2009 to 2014 (79 items).
- \*9 Cohort research: Research method for epidemiology by which a specific group is followed up and the incidence of disease and other factors (severity, use of medication, age, etc.) that might affect

- the outcome (death, etc.) are analyzed
- \*10 Medical big data : Vast quantities of medical data including medical insurance claims, electronic medical records, clinical testing and other medical examination data, and genome and omics data. It is a term used to refer collectively to various types of large data sets that are being produced on a daily basis.
  - \*11 Utobrain. The May 2015 issue of *Pharma Future*
  - \*12 Office of Pharmaceutical Industry Research. Industry Report No. 5 “Current Situation and Issues Surrounding the Pharmaceutical Industry – Delivering Better Pharmaceuticals to the World – Part 1: Innovation and New Drug Discovery” (December 2014) (produced based on Utobrain. The May 2015 issue of *Pharma Future*)
  - \*13 Pharmaprojects, EvaluatePharma
  - \*14 Office of Pharmaceutical Industry Research. Research Paper Series No. 68 “Clinical Development of New Drugs and Approval Reviews in Japan: Approved Items during 2000-2014” (November 2015)
  - \*15 Materials published by each company
  - \*16 Regulatory science: Science that brings the fruits of science and technology into the most desirable form for harmony between people and society by means of making accurate predictions, evaluations and decisions based on evidence
  - \*17 Medical insurance claims: Medical service fee statements
  - \*18 Modality: The class or physical classification of drug substances; for example, low molecular compound, biological pharmaceutical or nucleic acid pharmaceutical
  - \*19 Compound libraries: Library consisting of compounds for use in drug discovery research
  - \*20 Drug repositioning: Identifying unknown actions or indications for existing drugs or drugs whose development was discontinued
  - \*21 Registry: Registry of patient information to facilitate clinical research and clinical studies
  - \*22 Companion diagnostics: Extracorporeal diagnostic agents used to optimize medication use by predicting drug efficacy and individual differences in adverse drug reactions at the time of the drug use.
  - \*23 Pharmacogenomics (PGx): Approach that uses the analysis of patients’ genome information to search for and develop safe and effective pharmaceuticals for specific patient groups
  - \*24 Markers for patient stratification: Biomarkers used to screen patients with specific drug-related genes
  - \*25 Non-communicable diseases (NCDs): Lifestyle diseases and chronic diseases such as circulatory diseases, cancers, diabetes and chronic respiratory diseases