The Healthcare Policy
and
The New System of Medical R&D
### Progress and Achievements

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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</thead>
<tbody>
<tr>
<td>Jun, 2013</td>
<td>14th Japan Revitalization Strategy, Cabinet decision</td>
</tr>
<tr>
<td></td>
<td>The Healthcare Policy, agreement among Ministers related</td>
</tr>
<tr>
<td>Jul</td>
<td></td>
</tr>
<tr>
<td>Aug</td>
<td>2nd Establishment of Headquarters for Healthcare Policy, Cabinet decision</td>
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<tr>
<td></td>
<td>8th Headquarters for Healthcare Policy</td>
</tr>
<tr>
<td></td>
<td>(Decision of the basic policy for budget requests relevant to medical R&amp;D)</td>
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<tr>
<td></td>
<td>30th Headquarters for Healthcare Policy</td>
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<tr>
<td></td>
<td>(Compiled budget requests relevant to medical R&amp;D)</td>
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<tr>
<td>Sep – Nov</td>
<td></td>
</tr>
<tr>
<td>Dec</td>
<td>24th Drafting of government budget FY2014, Cabinet decision</td>
</tr>
<tr>
<td>Jan, 2014</td>
<td>22nd Compiled the report issued by expert panel on medical R&amp;D</td>
</tr>
<tr>
<td>Feb</td>
<td>10th Headquarters for Healthcare Policy</td>
</tr>
<tr>
<td></td>
<td>12th Cabinet decision regarding the relevant legislation</td>
</tr>
<tr>
<td></td>
<td>- Act on Promotion of Healthcare Policy</td>
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<tr>
<td></td>
<td>- Act on the Independent Administrative Agency of Japan Agency for Medical Research and Development</td>
</tr>
<tr>
<td>Mar – May</td>
<td>Deliberations in the Diet</td>
</tr>
<tr>
<td></td>
<td>23th Enactment of the two bills (promulgated on 30th, May)</td>
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<tr>
<td>Jun</td>
<td>10th Legal establishment of Headquarters for Healthcare Policy</td>
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</table>
### Headquarters for Healthcare Policy (HHP)

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director-General</td>
<td>Prime Minister</td>
</tr>
<tr>
<td>Vice Director-General</td>
<td>Chief Cabinet Secretary and Minister for Healthcare Policy</td>
</tr>
<tr>
<td>Members</td>
<td>Ministers of the State other than the Director-General or the Vice Director-General</td>
</tr>
</tbody>
</table>

**<functions>**
- Preparing the draft and promoting implementation of the Healthcare Policy
- Role as headquarters of the control tower of medical research and development
  - Preparing and promoting the implementation of the Plan for Promotion of Medical R&D
  - Comprehensive coordination on budget requests related to medical R&D etc.

### Promotion Council for the Healthcare Policy

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairperson</td>
<td>Minister for Healthcare Policy</td>
</tr>
<tr>
<td>Acting Chairperson</td>
<td>State Minister of Cabinet Office</td>
</tr>
<tr>
<td>Deputy Chairperson</td>
<td>Parliamentary Vice-Minister of Cabinet Office and Special Advisor to the Prime Minister(Director-General of the Office of Healthcare Policy)</td>
</tr>
<tr>
<td>Members</td>
<td>Director-Generals of ministries related</td>
</tr>
</tbody>
</table>

### Advisers' Committee

Consists of intellectual people belonging to industrial sector and medicine-related institutions, etc.
- Professional advice about
  - Growth strategy in the health and medical field.
  - Exit strategy for medical R&D, etc.

### Expert Review

**Experts Panel**
- Consists of specialists in the medical R&D field.
  - Research and review with regard to preparing and promoting the implementation of the Plan for Promotion of Medical R&D.

### Committee of the Academia-Industry-Government Network for Drug Discovery Research

### Council for Research and Development of Next-Generation Medical Devices

### Task Force for Next-Generation Medical ICT

### Task Force for Fund for Healthcare Policy

### Next-Generation Healthcare Industry Council

### Task Force for Global Reach of Japanese-style Medical Technology and Services

**Cabinet Secretariat  The Office of Healthcare Policy**

**Functions of secretariat**

※The secretariat of the Next-Generation Healthcare Industry Council shall be assumed by METI.
Problems in medical R&D and Effects by Act on Japan Agency for Medical Research and Development, etc.

**[Problems]**

- Insufficiency of the system to provide consistent support for research from basic stages to practical application, because MEXT, MHLW and METI subsidize R&D individually.
- Because the system for collecting the data of clinical research and advancing clinical trials is insufficient, it is taking a long time for the results of basic research to lead to new drugs, etc.
- Although the market related to pharmaceuticals and medical devices is growing both inside and outside of the country, the trade deficit of Japan in pharmaceuticals and medical devices is increasing (almost 2 trillion yen in 2011).

⇒ The most suitable research funds can be ensured for researchers, consistently corresponding to the progress of the research from basic stages to practical application.
⇒ Effectiveness of the research can be improved by means of avoidance of overlapping investment for equipment and instruments through enabling their optimized allocation all around Japan.
⇒ Researchers can focus on research and development more than ever because of the reduction of paperwork by unification of the contact points and the procedures for applications.
**Top-down research based on the Plan for Promotion of Medical Research and Development**

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**Implementation of medical research and development**
- Management by program director (PD) and program officer (PO), etc.
  - Implementation of research along with the Plan for Promotion of Medical Research and Development. Understanding and investigation of research trends.
  - Consistent management, such as selection of each research theme and management and advice for the progression of the theme, in order to transfer the outstanding results of basic research to clinical research and industrial use.
- Enhancement of the PDCA cycle reviewing system.
- Concentration of the medical R&D funds to one funding agency.
- Monitoring and administration for proper implementation of research and development.
  - Preventing improper use of research funding and malpractice in research.
  - Developing the environment for complying with ethics, laws and regulations and guidance. Monitoring.

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**Improvement of the infrastructure for clinical research, etc.**
- Improvement and strengthening of Clinical Trials Core Hospitals, Early/Exploratory Clinical Trials Centers and Translational Research Centers.
  - Support for allocating specialists, such as clinical research coordinators, data managers, biostatisticians, and project managers.
- Improvement of biobanks, etc. in order to develop preventive medicine and service methods based on EBM*

* EBM: evidence-based medicine

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**Support for industrialization**
- Supporting research institutes in acquiring intellectual property rights.
  - A consultation window for intellectual property rights. Support for planning an intellectual property strategy.
- Cooperation with companies and support for cooperation aiming at practical use.
  - Planning and advising for exit strategies to promising seeds, cooperation with Pharmaceuticals and Medical Devices Agency (PMDA).
  - Providing information to companies, matching with companies.

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**Promotion of international strategy**
- Supporting international joint research.
  - Promotion of joint research based on international trends.
  - Cooperation with overseas organizations that conduct medical research and development.
The main points of the Act on Promotion of Healthcare Policy

The purpose of this act is to create a society in which people enjoy long and healthy lives by promoting research and development that contributes to providing people with the top level of medical care in the world. [Article 1]

Roles of the HHP are:
1. To draft the Healthcare Policy and to promote its implementation,
2. To draft the Plan for Promotion of Medical Research and Development and to promote its implementation,
3. To make the Policies for Medical R&D Budget Allocation, and
4. To provide direction to the competent ministers when the ministers appoint the president or the auditors of the AMED and to set medium-term goals of the AMED.

Headquarters for Healthcare Policy (HHP) [Article 21 through 29]

The Healthcare Policy (Article 17)
The Prime Minister shall seek a cabinet decision on the Healthcare Policy, which consists of the following points:
- Promotion of medical R&D, preparation of R&D environment, and dissemination of the results of R&D
- Creation and vitalization of new businesses and industries including export of Japanese healthcare systems and medical equipment

The Plan for Promotion of Medical R&D [Article 18]
The HHP shall make the plan which shall include the following points:
- Decision on important fields of medical R&D in which the Government should focus its resources
- Functions of the AMED that shall play core roles in implementation and in granting of medical R&D

The HHP shall develop a concrete plan for medical R&D, etc. in conformity with the Healthcare Policy

Promotion of medical R&D, development of R&D environment and dissemination of the results

General coordination across the ministries

Relevant Ministries

General coordination regarding budget allocation etc.

Following HHS’s order based on the Policies for Medical R&D Budget Allocation for each fiscal year, MEXT, MHLW and METI make appropriate fiscal arrangements for the AMED.
In order to contribute to the formation of a society where citizens benefit from healthy lives and longevity, the State shall take the measures below:

- Formulation of the Healthcare Policy in order to comprehensively and systematically promote
  - Medical R&D that contributes to providing medical care at the highest level in the world
  - Creation of new industry activities which contribute to the formation of such a society
- Establishment of Headquarters for Healthcare Policy to promote the measures

**Summary**

   - The purpose and basic principles of the act as well as responsibilities of the State

2. Basic Measures
   - The State shall take basic measures as follows for (1) Promotion of medical R&D, improvement of the environment, and dissemination of outcomes, (2) Creation and vitalization of new industry activities as well as improvement of the environment in order to contribute to the formation of a society where citizens benefit from healthy lives and longevity.
     - Promotion of medical R&D and improvement of the environment
     - Securement of fair and appropriate operation for medical R&D
     - Enhancement of examination system of medicines for prompt and secure practical use of medical R&D results, and advancement of science with regard to the evaluation for the safety
     - Creation of new industries, facilitation of overseas development, promotion of education, and securing human resources, etc.

3. Formulation of the Healthcare Policy
   - The government shall formulate the Healthcare Policy in order to comprehensively and systematically promote the basic measures.

4. Promotion of Medical R&D
   - Headquarters for Healthcare Policy formulates the medical R&D promotion program in line with the Healthcare Policy, in order to intensively and systematically promote the measures of promotion of medical R&D as well as improvement of the environment and dissemination of outcomes with regard to medical R&D.
   - Japan Agency for Medical Research and Development, an independent administrative agency, is positioned as a core institution for operation/grants in promotion of medical R&D and in improvement of the environment of the promotion program.

5. Establishment of Headquarters for Healthcare Policy
   - In order to promote the Healthcare Policy, a Headquarters for Healthcare Policy (Director-General: Prime Minister, Members of Headquarters: Ministers of State other than Prime Minister) shall be established in the Cabinet.

**Effective Date**
- 1 and 2: The day of promulgation. 3, 4 and 5: the date specified by a Cabinet Order within three months from the day of promulgation
Function as control tower in medical research and development, etc.

**Purpose of the Act** [Act on Promotion Art.1]

The purpose of this Act is to contribute to the creation of a society where citizens benefit from healthy lives and longevity by prescribing healthcare strategy, establishing the Headquarters for Healthcare Policy to promote the strategy and taking other measures with regard to medical research and development and the creation and/or activation of healthy and active aging-related industries.

**Basic Principles** [Act on Promotion Art.2]

Measures shall be conducted in accordance with contributing to providing medical care with the world's top level of technology by promoting research and development consistently, from basic research to practical application, and bringing its results to practical use as well as contributing to the economic growth of Japan.

**the Healthcare Policy (Cabinet decision)**

- Outline of the Measures including for the medical research and development and the creation and activation of health and longevity-related industries that shall be taken by the government.
- Matters necessary for promoting measures above comprehensively and systematically.

**Basic Measures (Act on Promotion Art.10-16)**

- Promotion of R&D consistent from basic research to practical use
- Arrangement of better environment for clinical research, etc.
- Fair and proper implementation of R&D
- Establishment of better examination systems, etc. for practical use of the results
- Creation of new industries and promotion of international deployment
- Promotion of Education -Securing human resources

**Roles of Japan Agency for Medical Research and Development**

1) Implementation of R&D and arrangement of better environment in medical field (commissioned projects).
2) Dissemination and promotion for practical use of the outcomes originated from 1).
3) Subsidization for R&D and arrangement of better environment in medical field.
4) Supplemental operations for 1)-3).

Consistent research management on the top-down R&D from basic research to practical application under consideration to practical use.
The purpose of the act is to establish the Japan Agency for Medical Research and Development, an independent administrative agency, aiming to make the Agency carry out the operations of implementation/grants in promotion of medical R&D and in improvement of the environment, and is to prescribe the name of Agency, the purpose of its foundation, and the scope of its operations, etc.

### Summary

1. **Establishment of Japan Agency for Medical Research and Development, an Independent Administrative Agency**

   - In order to promote coherent R&D from basic research to practical realization, to smoothly put research outcomes to practical use in medical R&D, and to comprehensively and effectively implement medical R&D as well as improvement of the environment, the purpose of the act is to establish the Japan Agency for Medical Research and Development, an independent administrative agency, aiming to make the Agency carry out the operations of implementation/grant in promotion of medical R&D and in improvement of the environment, under the medical R&D promotion program that the Headquarters for Healthcare Policy formulates, and is to prescribe the name of Agency, the purpose of its foundation, and the scope of its operations …etc.

2. **The duties of Japan Agency for Medical Research and Development, Independent Administrative Agency**

   1) Medical R&D and environmental arrangement
      - (e.g. In a contracted project, research regenerative medicine using iPS cells and prepare necessary research instruments for the research at Kyoto University)

   2) Dissemination and promotion of effective use of the outcomes from the medical R&D and from environment arrangement
      - (e.g. Introduce the outcomes of the drug discovery rudimentary research to pharmaceutical companies and facilitate practical use development)

   3) Subsidization for promotion of medical R&D and improvement of the R&D environment
      - (e.g. Subsidize processing technology of biotechnology-based drugs or improvement of clinical research system)

   4) Related operations of 1), 2) and 3)
      - (e.g. Survey of R&D or of technology development (domestic and international), public relation of research outcome, and global cooperation through research)

3. **Involvement of Headquarters for Healthcare Policy**

   - When appointing a president and auditors and formulating medium-term goals of the Agency, competent ministers shall hear the opinions of Headquarters for Healthcare Policy.

### Effective Date

- The day of promulgation (excluding some provisions). The founding of the Agency is scheduled for April 1, 2015.
The New System of Implementation of the Medical Strategy

**Headquarters for Healthcare Policy (HHP)**

The HQ shall

- develop a comprehensive plan for promotion of medical R&D.
- integrate medical R&D budget requests of relevant ministries.
- strategically and intensively decide allocation of promotional adjustment funds.

**Integration of medical R&D budget requests**

- Adopt agenda based on the comprehensive plan for promotion of medical R&D
- Manage and integrate both allocated grants to researchers/scientists and institutions, and funding
- Integrate the budget for infrastructure development into a new agency

**Japan Agency for Medical Research and Development**

- Nation’s top-down scientific/clinical R&D

**Intramural research**

- National Institutions
  - Measure on source of revenue for institutions
  - Universities, Institutions, Researchers/Scientists

**Funds for individual research**

- Universities, Institutions, Researchers/Scientists
- Clinical Trials Core Hospitals etc.

**Infrastructure development**

- Smoothly transit discovered seeds
- Steadily implement clinical research/trials based on high international standards

**Researchers’ bottom-up scientific research**

- Grant-in-Aid for Scientific Research (KAKENHI)

- National Center for Global Health and Medicine, RIKEN, National Institute of Advanced Industrial Science and Technology, National Institute of Infectious Diseases etc.
Effects of establishing Japan Agency for Medical Research and Development

【Present condition】
MEXT (incl. JST) -> MHLW (incl. NIBIO) -> METI (incl. NEDO)

- Requirement for applying for funding to each ministry, etc. depending on the stage of the research
- Uneasiness about the continuation of research funding corresponding to the progress of the study.

Increasing of miscellaneous business required for ensuring research funds.

【After establishing the agency】
MEXT -> MHLW -> METI

Japan Agency for Medical Research and Development
(realization of budget concentration and seamless support from basic research to practical use)

- Unification of the contact point and the procedures for the application.
- Ensuring the most suitable research funding corresponding to the progress of the research.
## Budget Bill for Medical Research in FY 2014

<table>
<thead>
<tr>
<th>Project Area</th>
<th>FY 2014</th>
<th>FY 2013</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Agency</strong></td>
<td>121.5 billion yen</td>
<td>101.2 billion yen</td>
<td>+20.3 billion yen (+20.1%)</td>
</tr>
<tr>
<td></td>
<td>(MEXT57.0, MHLW47.6, METI16.9)</td>
<td>(MEXT44.7, MHLW40.2, METI16.3)</td>
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</tr>
<tr>
<td><strong>Related Research Institutes</strong></td>
<td>74.0 billion yen</td>
<td>71.3 billion yen</td>
<td>+ 2.7 billion yen (+3.7%)</td>
</tr>
<tr>
<td></td>
<td>(MEXT20.0, MHLW45.5, METI8.5)</td>
<td>(MEXT15.5, MHLW47.6, METI8.1)</td>
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</tbody>
</table>

### Cooperation Project among Related Ministries

**For Drug Discovery and Medical Devices**
- Drug Discovery: 25.4 billion yen
- Medical Devices: 11.2 billion yen

**For the Most Advanced Medical Care**
- Regenerative Medicine (iPS cells, ES cells etc..): 15.1 billion yen
- Genomic Medicine: 7.0 billion yen

**For Clinical Research and Clinical Trial**
- 12.1 billion yen

**For Specific Diseases/Disorders**
- Cancer: 17.2 billion yen
- Psychiatric and Neurological Disorders: 7.1 billion yen
- Emerging and Re-emerging Infectious Diseases: 5.3 billion yen
- Intractable Diseases: 9.3 billion yen

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1$ = 100 yen

MEXT: Ministry of Education, Culture, Sports, Science and Technology
MHLW: Ministry of Health, Labor and Welfare
METI: Ministry of Economy, Trade and Industry
Next-Generation Healthcare Industry Council

Aim of the Council

○ Creating and developing an industry to increase healthy life expectancy will contribute to improving quality life of the people, preventing excessive rise in medical expenses, creating jobs and promoting economic growth.

○ The council will endeavor to understand the situation of various products and services in health and longevity that the private sector provides, and analyze the issues and countermeasures from both demand and supply sides.

Initial issues to work on

○ Business Environment Working Group
  Investigate measures to improve business environment (e.g. system to remove gray zone areas) to create new healthcare-related services and products.

○ Quality Evaluation Working Group
  Examine quality evaluation for healthcare-related services and products.

○ Investment in Health Working Group
  Investigate ways to promote investment in health by companies and individuals.
Examples of services that Next-Generation Healthcare Council aims to create

Objective of Healthcare Council is to foster creation of diversified evidence-based healthcare service (outside public insurance), such as effective disease prevention, health monitoring, and life support service related to illness. Through such initiatives, the Council will contribute to realizing a society where people can live in better health (health and longevity-oriented society).

Medical Institutions and private operators will cooperatively provide evidence-based healthcare services to the Gray Zone to satisfy patient needs.

Private Operators (1st layer)
gym, meals, beauty, pharmacies, CVS, temporary staffing, taxi, housekeeping, housing, travel agencies, etc

Private Operators (2nd layer)
agriculture, logistics, IT, real estate, training, manufacturing

Medical Service
Tertiary prevention
Secondary prevention
Primary prevention
Exercise instruction
Health monitoring
Dietary counselling
Patient mental support

Next-Generation Healthcare Service

Law
Health and longevity-oriented society

High
Relevance to Medical Care

Low

Insurer
Municipals
Individuals

Utilize proactively in preventing disease worsening

Supply

13

Technologies and services required for innovation in healthcare services

Agriculture, Logistics, Information Systems, Real Estate, Personnel Training, Manufacturing
Utilization of ICT for Healthcare

Aim

Sustainable High Quality Medical Insurance Service

Innovative Medical Technology

Evidence Based Health Service Industries

The Structure of Healthcare Digital Platform

Public Health Administration

Healthcare Digital Platform

Patient Data/Name of Disease

Prescription / Examination Data

Clinical Data

Surgical Operation Data / Medical Treatment Data

Data Utilization Situation

Clinical data and surgical operation data are complicated but are required for clinical research.
Future Vision for ICT Utilization for Healthcare

- Sustainable High Quality Medical Insurance Service
- Innovative Medical Technology
- Evidence Based Health Service Industries

**Aim**

Utilization of Medical Data

**The Structure of e-Healthcare Digital Platform**

- Public Health Administration
- Medical Service
- Clinical Research & Cohort Study

**Healthcare Digital Platform**

- Patient Data/Name of Disease
- Prescription / Examination Data
- Clinical Data
- Surgical Operation Data / Medical Treatment Data

Most advanced infrastructure in the world
Promoting global deployment of Japanese medical services

- Business development that contributes locally
  - Exporting medical services as a business

- Universal Health Coverage
  - Emphasis on ensuring access to health services for all people at a price they can afford, utilizing ODA funding

- Improve health situation and create economically expanding market locally
- Enhance Japanese credibility and contribute to Japanese economy
## Projects to promote global expansion of medical services

<table>
<thead>
<tr>
<th>Area</th>
<th>Country</th>
<th>Projects</th>
<th>Status</th>
<th>Project MOU/Agreement</th>
<th>G to G MOU*</th>
<th>Factors planned</th>
</tr>
</thead>
</table>
| Russian Far East      | Russia    | • Hokuto Image Diagnosis Center (Vladivostok)                            | operation begun | signed                | negotiating | Overseas base for medical service
|                       |           |                                                                         |                 |                       |            | Train personnel
|                       |           |                                                                         |                 |                       |            | Health system/standards
|                       |           |                                                                         |                 |                       |            | ICT remote medicine
|                       |           |                                                                         |                 |                       |            | Area infra.
| Southeast Asia        | Bangladesh| • Image Diagnosis Training Center (Dacca)                                 | operation begun | signed                |            | ○
|                       |           |                                                                         |                 |                       |            | ○
| India                 | India     | • SAKRA World Hospital (Bangalore)                                      | operation begun | signed                | negotiating | ○
| West                  | Russia    | • Advanced Medicine Center (Moscow)                                     | forming consortium | signed                | negotiating | ○
| Russia                |           |                                                                         |                 |                       |            | ○
| Southeast Asia        | Cambodia  | • Emergency and Critical Care Center                                    | forming consortium | signed                | signed     | ○
|                       |           |                                                                         |                 |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○
| Central Asia          | Kazakhstan| • Cancer Diagnosis Center                                               | forming consortium | signed                |            | ○
|                       |           |                                                                         |                 |                       |            | ○
| Southeast Asia        | Laos      | • Emergency Care and Training Center (Vientiane)                        | forming consortium | signed                |            | ○
|                       |           |                                                                         |                 |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○
| Middle East           | Qatar     | • Reproductive Medicine and Cell Sheet Center                            | investigating   |                       | negotiating | ○
|                       |           |                                                                         |                 |                       |            | ○
| Middle East           | Kuwait    | • General Hospital and Training Center                                  | investigating   |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○
| Southeast Asia        | Myanmar   | • Emergency Care and Training Center                                    | investigating   |                       | signed     | ○
|                       |           |                                                                         |                 |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○
| Southeast Asia        | Bhutan    | • Medical University                                                   | investigating   |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○
|                       |           |                                                                         |                 |                       |            | ○

* Government to Government MOU with MOH has also been signed with Vietnam, Turkmenistan, Bahrain and Turkey and is under negotiation with Brazil and Malaysia.
What global expansion of medical services means to Japan

Positive cycle for developing innovative technology (e.g. regenerative medicine)
- Population will decrease in Japan, and there may not be enough treatment cases to conduct clinical trials or to improve technology

Progress in securing pharmaceutical products for children
- Birthrate is declining and it may be difficult to develop products for children as cases are decreasing