

The Healthcare Policy  
and  
The New System of Medical R&D

# Progress and Achievements

Jun, 2013	14 <sup>th</sup>	<p><b>Japan Revitalization Strategy , Cabinet decision</b></p> <p><b>The Healthcare Policy, agreement among Ministers related</b></p>
Jul		
Aug	2 <sup>nd</sup>	<b>Establishment of Headquarters for Healthcare Policy, Cabinet decision</b>
	8 <sup>th</sup>	<p><b>Headquarters for Healthcare Policy</b>            (Decision of the basic policy for budget requests relevant to medical R&amp;D)</p>
	30 <sup>th</sup>	<p><b>Headquarters for Healthcare Policy</b>            (Compiled budget requests relevant to medical R&amp;D)</p>
Sep – Nov		
Dec	24 <sup>th</sup>	<b>Drafting of government budget FY2014, Cabinet decision</b>
Jan, 2014	22 <sup>nd</sup>	<b>Compiled the report issued by expert panel on medical R&amp;D</b>
Feb	10 <sup>th</sup>	<b>Headquarters for Healthcare Policy</b>
	12 <sup>th</sup>	<p><b>Cabinet decision regarding the relevant legislation</b></p> <ul style="list-style-type: none"> <li>- Act on Promotion of Healthcare Policy</li> <li>- Act on the Independent Administrative Agency of Japan Agency for Medical Research and Development</li> </ul>
Mar –May		<b>Deliberations in the Diet</b>
	May 23 <sup>th</sup>	<b>Enactment of the two bills</b> (promulgated on 30 <sup>th</sup> , May)
Jun	10 <sup>th</sup>	<b>Legal establishment of Headquarters for Healthcare Policy</b>

# Promoting Organization for the Healthcare Policy

Advice for Policy

## Headquarters for Healthcare Policy (HHP)

Expert Review

Headquarters Order  
Article 2.

### Advisers' Committee

Headquarters Order  
Article 1.

### Expert Panel

Director-General : Prime Minister  
 Vice Director-General : Chief Cabinet Secretary and Minister for Healthcare Policy  
 Members : Ministers of the State other than the Director-General or the Vice Director-General

< 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.

Consists of intellectual people belonging to industrial sector and medicine-related institutions, etc.

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.

- Professional advice about
- Growth strategy in the health and medical field.
  - Exit strategy for medical R&D, etc.

### Promotion Council for the Healthcare Policy

Headquarters Order  
Article 2.

Chairperson : Minister for Healthcare Policy  
 Acting Chairperson : State Minister of Cabinet Office  
 Deputy Chairperson : Parliamentary Vice-Minister of Cabinet Office and Special Advisor to the Prime Minister (Director-General of the Office of Healthcare Policy)  
 Members : Director-Generals of ministries related

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

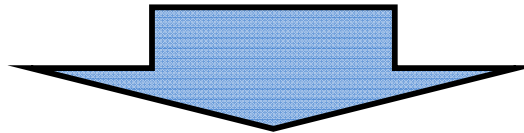
### Cabinet Secretariat The Office of Healthcare Policy

- 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).



## **Requirement for a control tower promoting medical R&D comprehensively**

(Establishment of Headquarters for Healthcare Policy and  
Japan Agency for Medical Research and Development)

- ⇒ 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.

# Functions needed for Japan Agency for Medical Research and Development

## Top-down research based on the Plan for Promotion of Medical Research and Development

### 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.

### 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

### 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.

### 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]

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

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.

### 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 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

### 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 propose a basic policy of the management of the business of the AMED based on the Plan for Promotion of Medical R&D.

Japan Agency for Medical Research and Development, independent administrative agency (AMED)

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.

General coordination across the ministries

Relevant Ministries



## Act on Promotion of Healthcare Policy (Provisional title)

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

#### **1. General Provisions**

- 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.

【Act on Promotion Art.17】 The government shall prescribe the Healthcare Policy, with regard to basic measures, in conformity with the basic principle.

## 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

【Act on Promotion Art.18】 The Headquarters shall prepare the Plan for Promotion of Medical Research and Development in line with the Healthcare Policy.

## the Plan for Promotion of Medical Research and Development (Headquarters decision)

- The basic policy of measures that shall be taken by the government with regard to the research and development in the medical field, arrangement of a better environment, and dissemination of its outcomes (Measures for medical R&D, etc.).
- Measures for medical R&D, etc. to be taken in a focused and systematic manner.
- Any items necessary for promoting Measures for medical R&D, etc. in a focused and systematic manner.

【Act on Promotion Art.19】 The Plan for Promotion of Medical Research and Development shall be prepared so that Japan agency for medical research and development may play a role as a core institution.

## 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,**



# Act on the Independent Administrative Agency of Japan Agency for Medical Research and Development (Provisional title)

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.

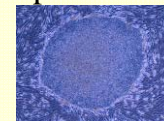
## Summary

### **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)**

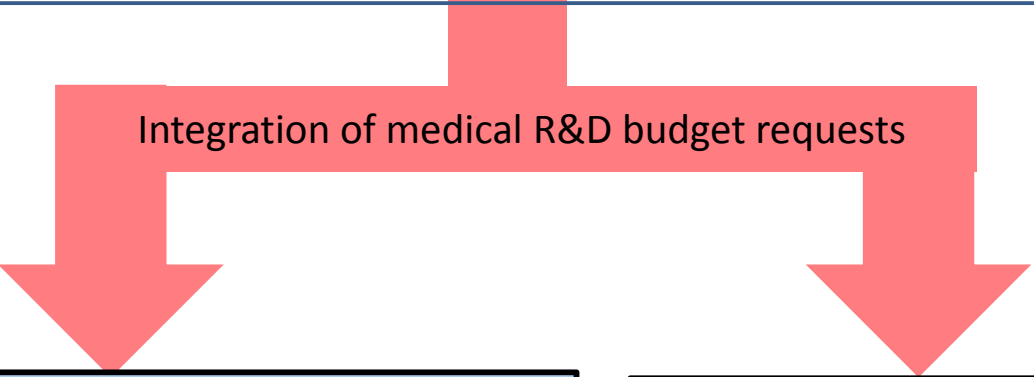
The HQ shall

- 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 .

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



**Researchers' bottom-up scientific research**  
Grant-in-Aid for Scientific Research (KAKENHI)

**Japan Agency for Medical Research and Development**  
--- Nation's top-down scientific/clinical R&D

**Intramural research**  
National Institutions

Smoothly transit discovered seeds

**Infrastructure development**

Clinical Trials Core Hospitals etc.

Steadily implement clinical research/trials based on high international standards

**Funds for individual Research**

✧ Universities, Institutions, Researchers/ Scientists

**Measure on source of revenue for Institutions**

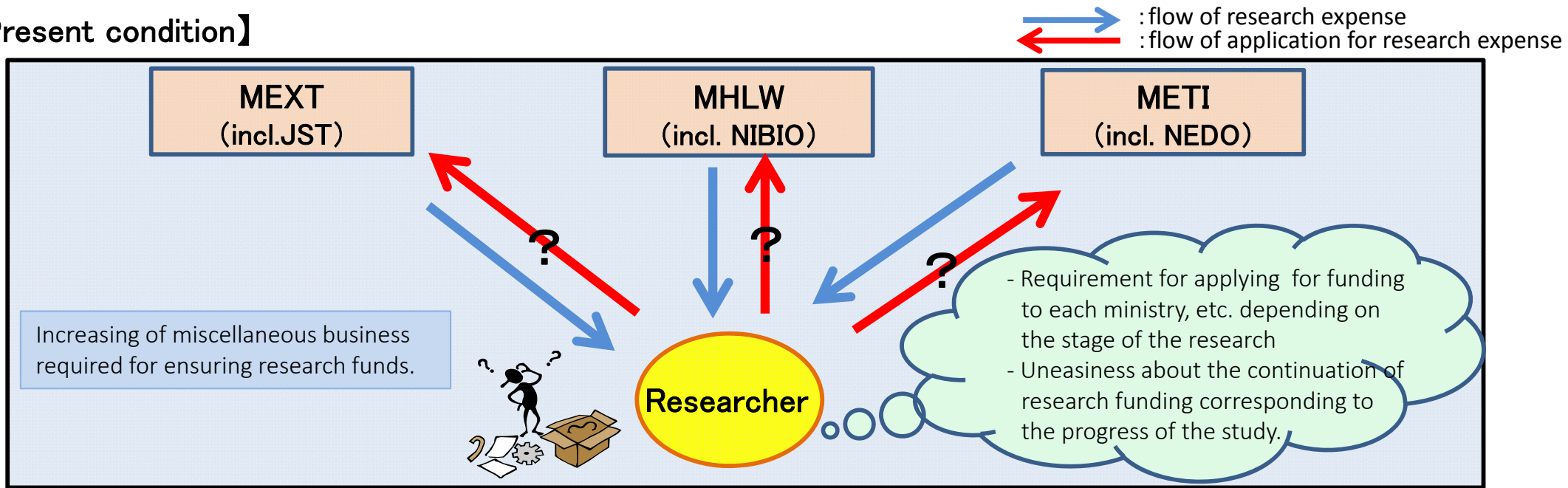
✧ National Center for Global Health and Medicine, RIKEN, National Institute of Advanced Industrial Science and Technology, National Institute of Infectious Diseases etc.

Implement research based on the comprehensive plan for promotion of medical R&D

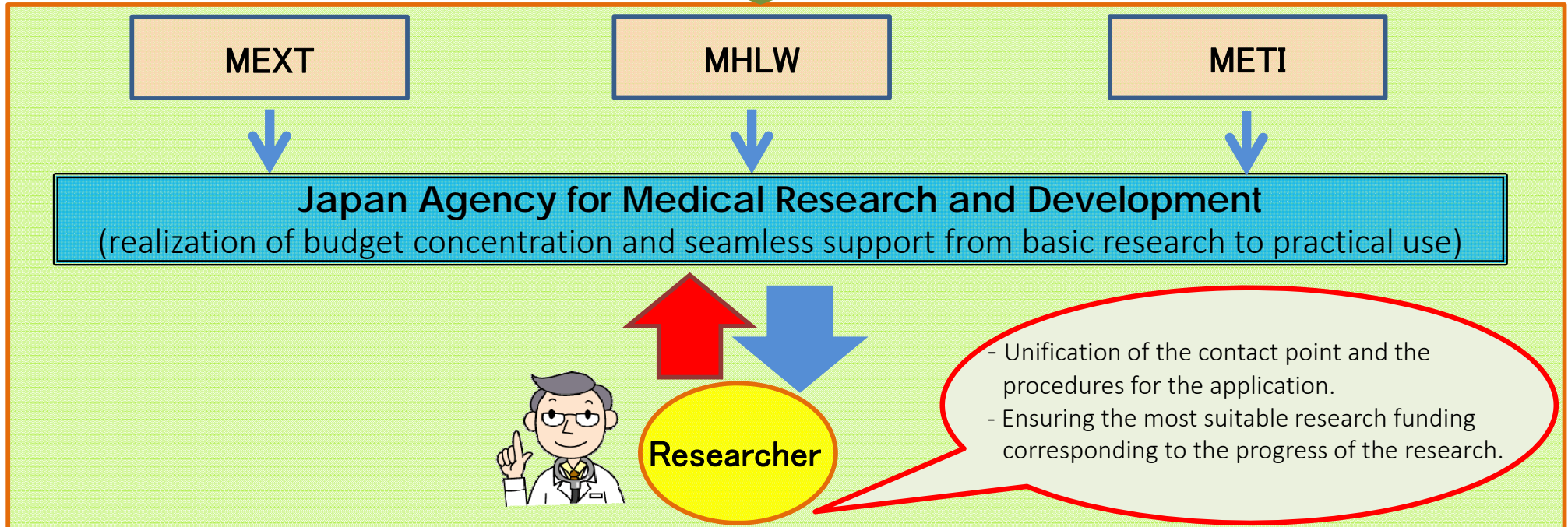


# Effects of establishing Japan Agency for Medical Research and Development

## 【Present condition】



## 【After establishing the agency】



# Budget Bill for Medical Research in FY 2014

1\$ = 100yen

	FY 2014	FY 2013
<b>New Agency</b>	<b>121.5 billion yen</b> (MEXT57.0, MHLW47.6, METI16.9)	<b>101.2 billion yen</b> (MEXT44.7, MHLW40.2, METI16.3)
<b>Related Research Institutes</b>	<b>74.0 billion yen</b> (MEXT20.0, MHLW45.5, METI8.5)	<b>71.3 billion yen</b> (MEXT15.5, MHLW47.6, METI8.1)

+20.3 billion yen  
+20.1%

+ 2.7 billion yen  
+ 3.7%

MEXT: Ministry of Education, Culture, Sports, Science and Technology  
 MHLW: Ministry of Health, Labor and Welfare  
 METI: Ministry of Economy, Trade and Industry

## 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

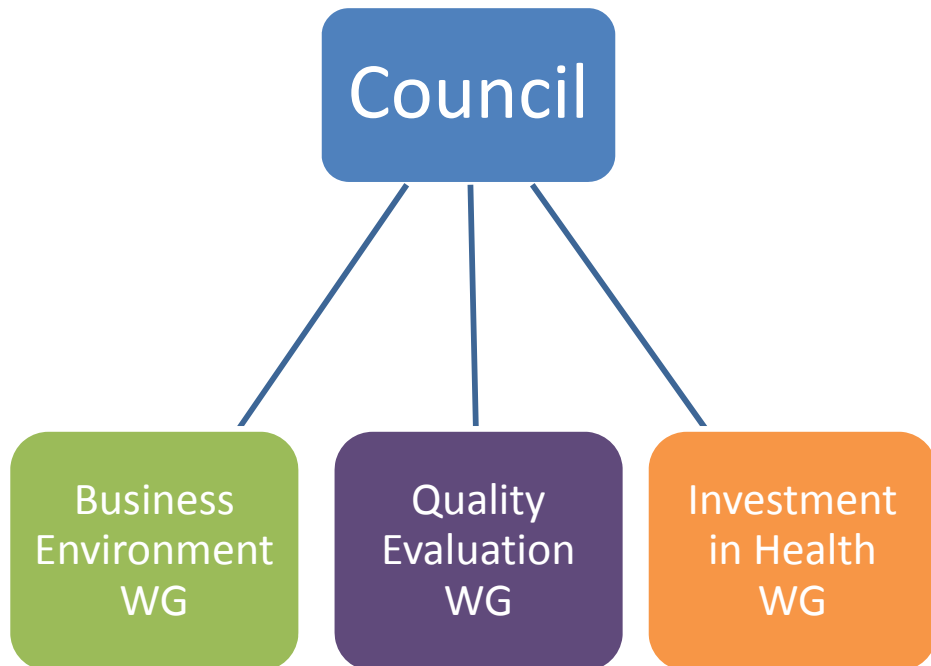


# Next-Generation Healthcare Industry Council

## 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

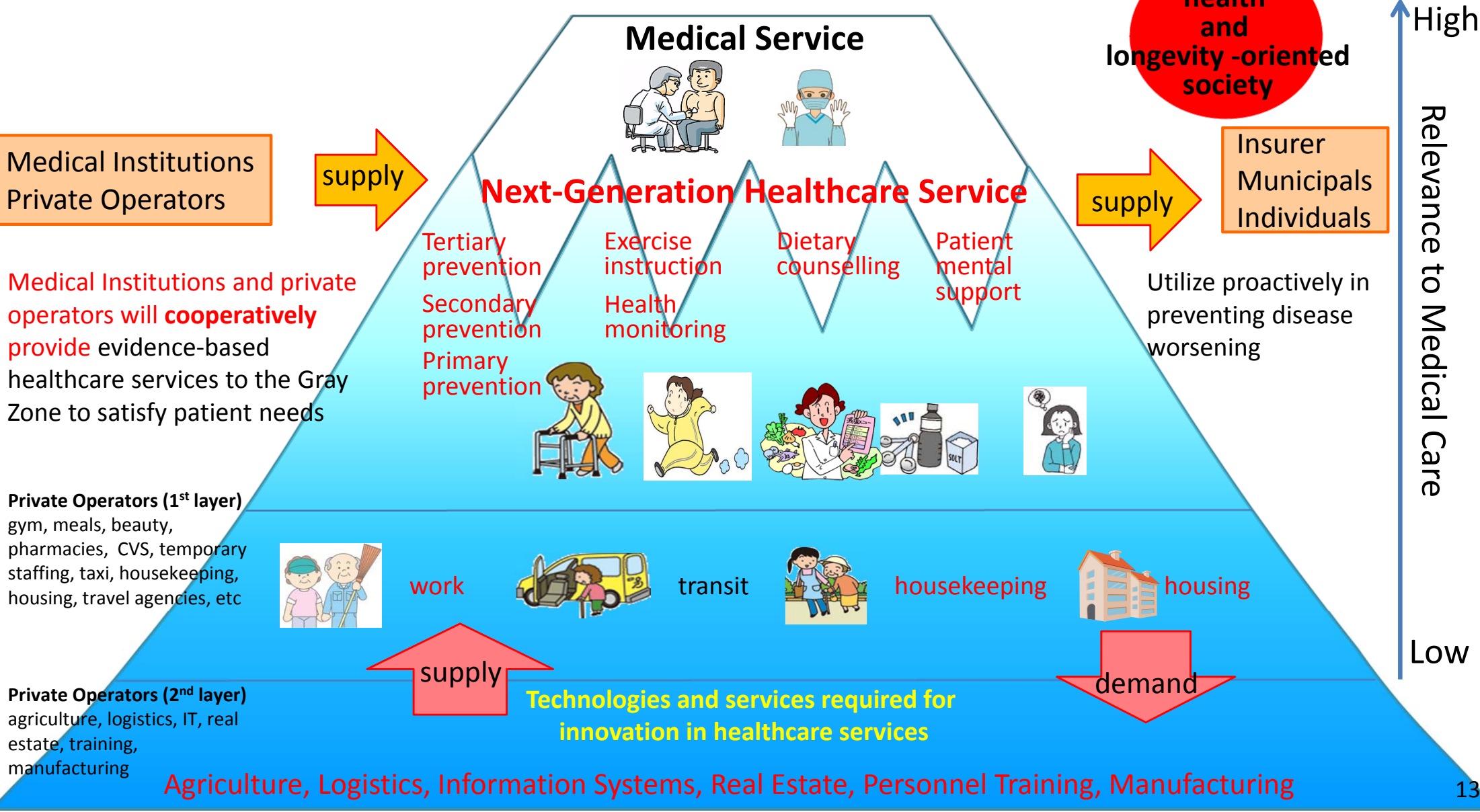
Examine quality evaluation for healthcare-related services and products.

### ○ Investment in Health Working Group

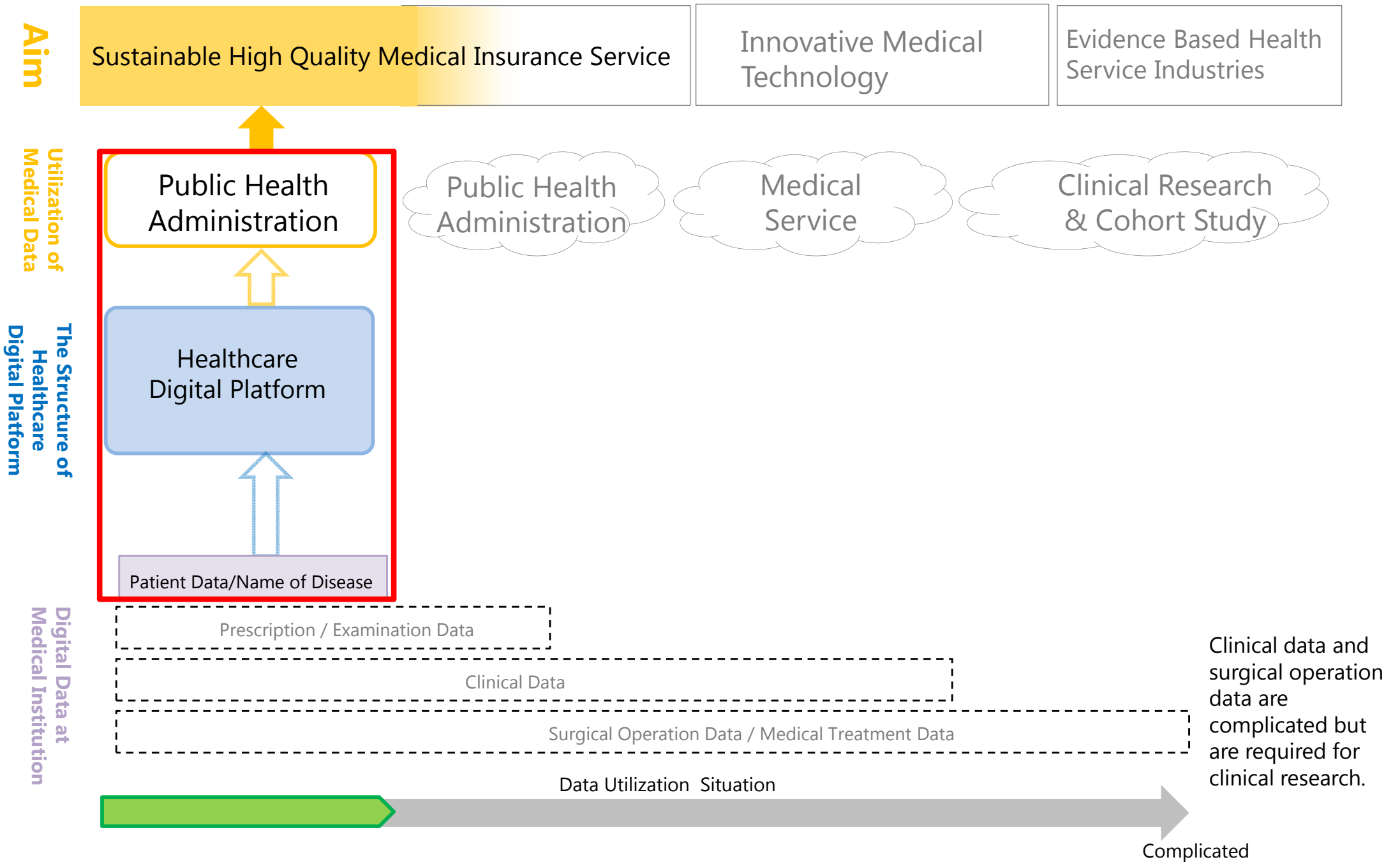
Investigate ways to promote investment in health by companies and individuals.

# 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).



# Utilization of ICT for Healthcare



# Future Vision for ICT Utilization for Healthcare

**Aim**

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

**Utilization of Medical Data**

Public Health Administration      Medical Service      Clinical Research & Cohort Study

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

Healthcare Digital Platform

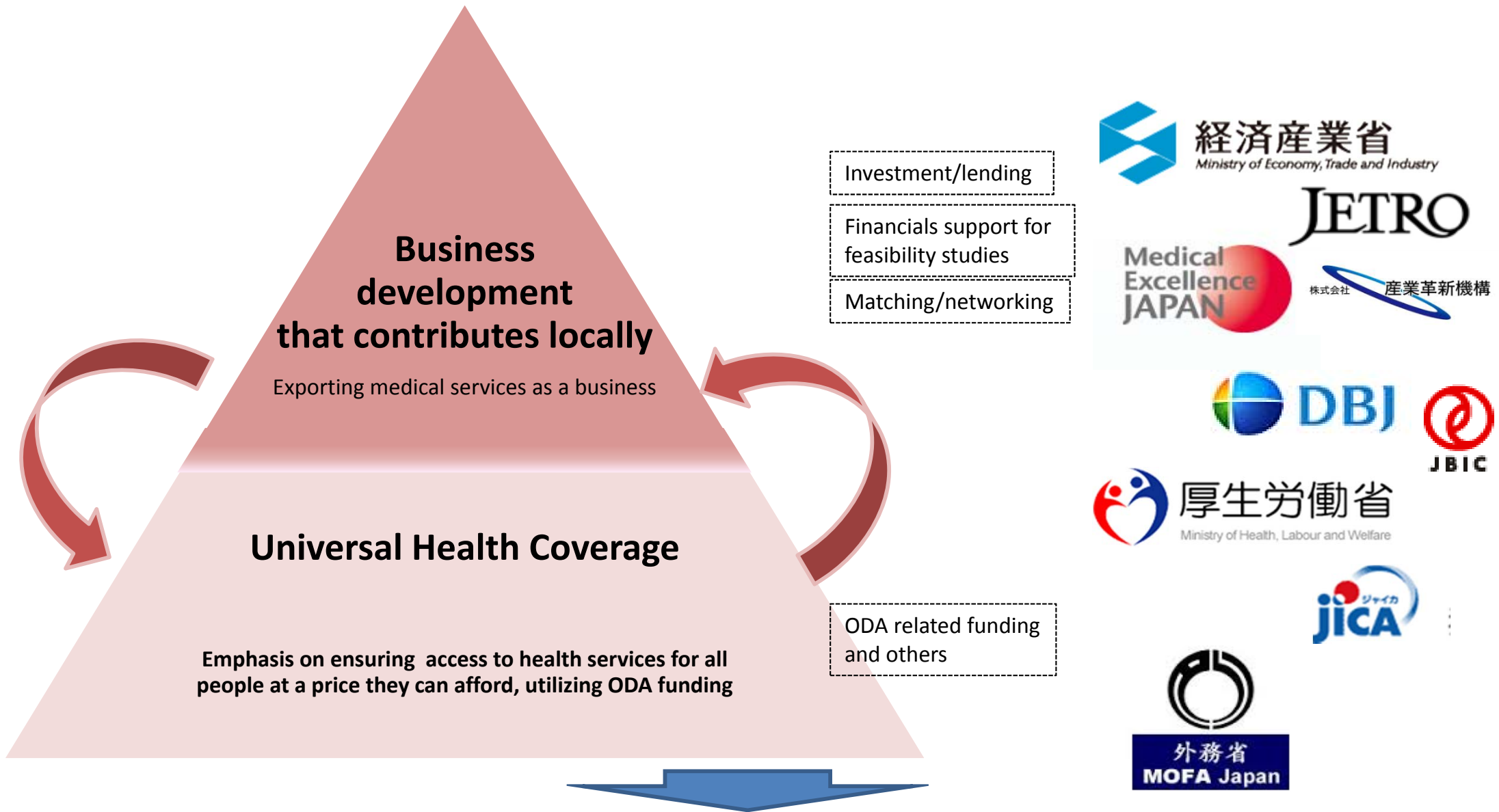
**Digital Data at Medical Institution**

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



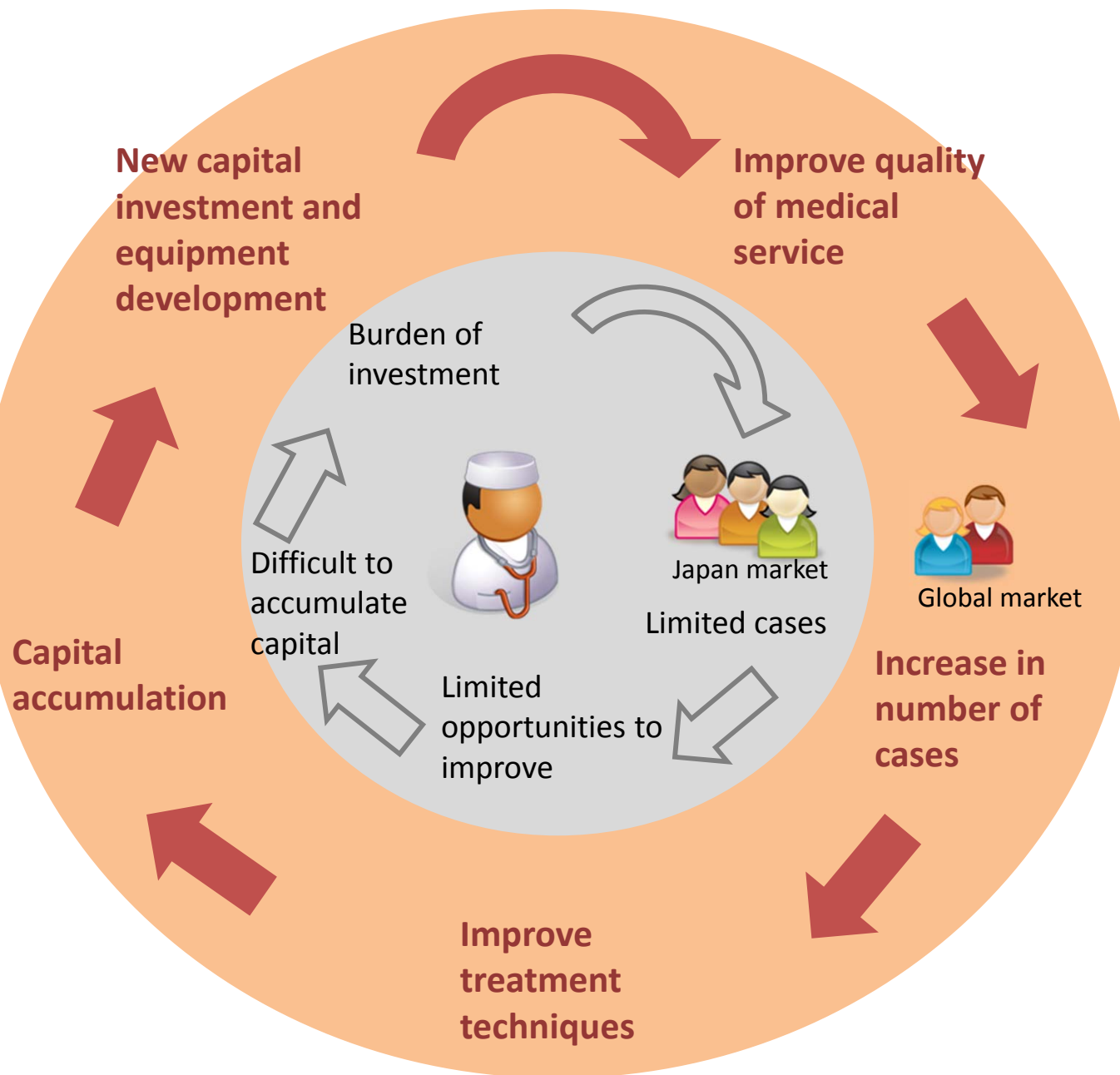
- Improve health situation and create economically expanding market locally
- Enhance Japanese credibility and contribute to Japanese economy

# Projects to promote global expansion of medical services

Area	Country	Projects	Status	Project MOU/ Agreement	G to G MOU*	Factors planned				
						Overseas base for medical service	Train personnel	Health system/ standards	ICT remote medicine	Area infra.
●operation begun   ●forming consortium   ●investigating										
Russian Far East	Russia	●Hokuto Image Diagnosis Center (Vladivostok)	operation begun	signed	negotiating	○	○		○	
Southeast Asia	Bangladesh	●Image Diagnosis Training Center (Dacca)	operation begun	signed			○			
India	India	●SAKRA World Hospital (Bangalore)	operation begun	signed	negotiating	○	○			
West Russia	Russia	●Advanced Medicine Center (Moscow)	forming consortium	signed	negotiating	○	○			
Southeast Asia	Cambodia	●Emergency and Critical Care Center	forming consortium	signed	signed	○	○	○ Private insurance	○	○
Central Asia	Kazakhstan	●Cancer Diagnosis Center	forming consortium	signed		○	○		○	
Southeast Asia	Laos	●Emergency Care and Training Center (Vientiane)	forming consortium		signed	○	○	○ Private insurance		
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	○	○	○ Private insurance		
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