



About AMED

November 30, 2015

Japan Agency for **Medical** Research and **Development**
(2015.4.1.~)

Today's Menu:

- New System for Medical R&D
- AMED Budget in FY2015
- Collaboration with International Research Networks

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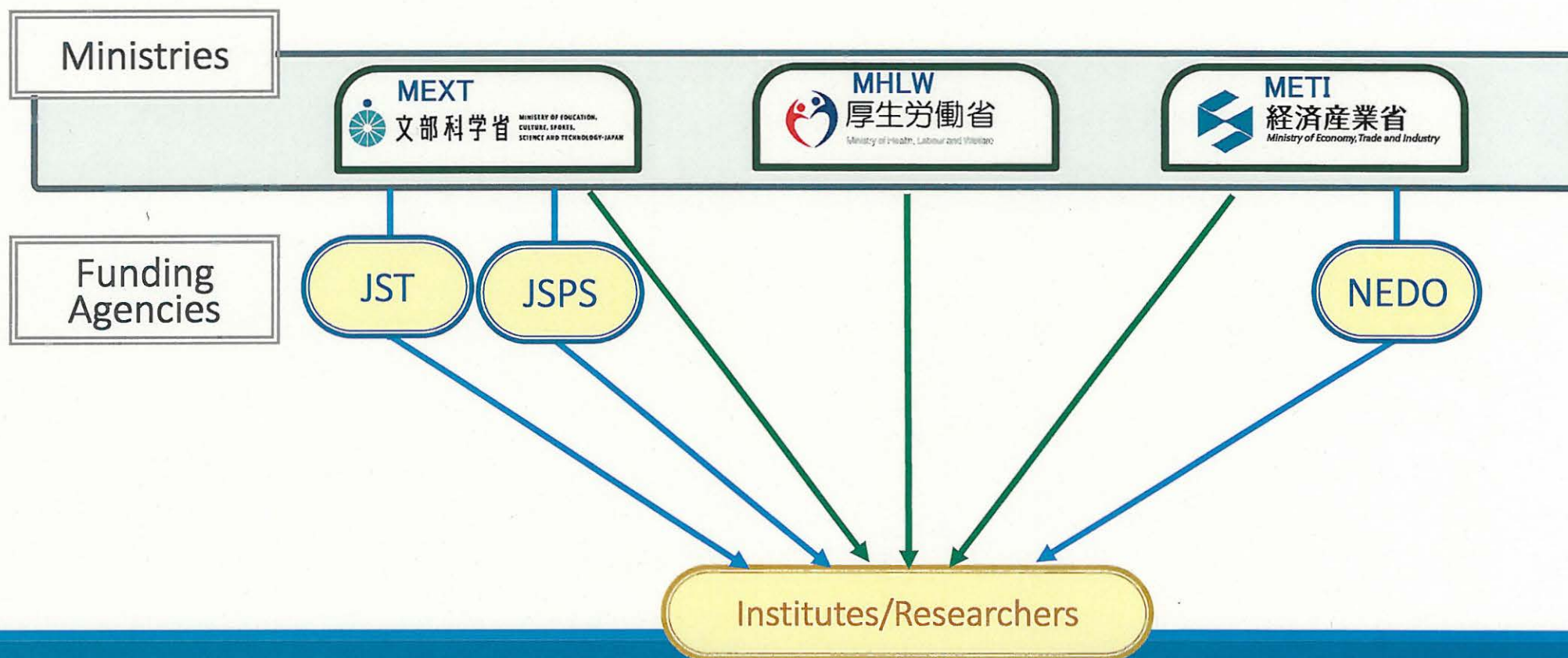
- **New System for Medical R&D**
- **AMED Budget in FY2015**
- **Collaboration with International Research Networks**

How has Japan's medical R&D changed?

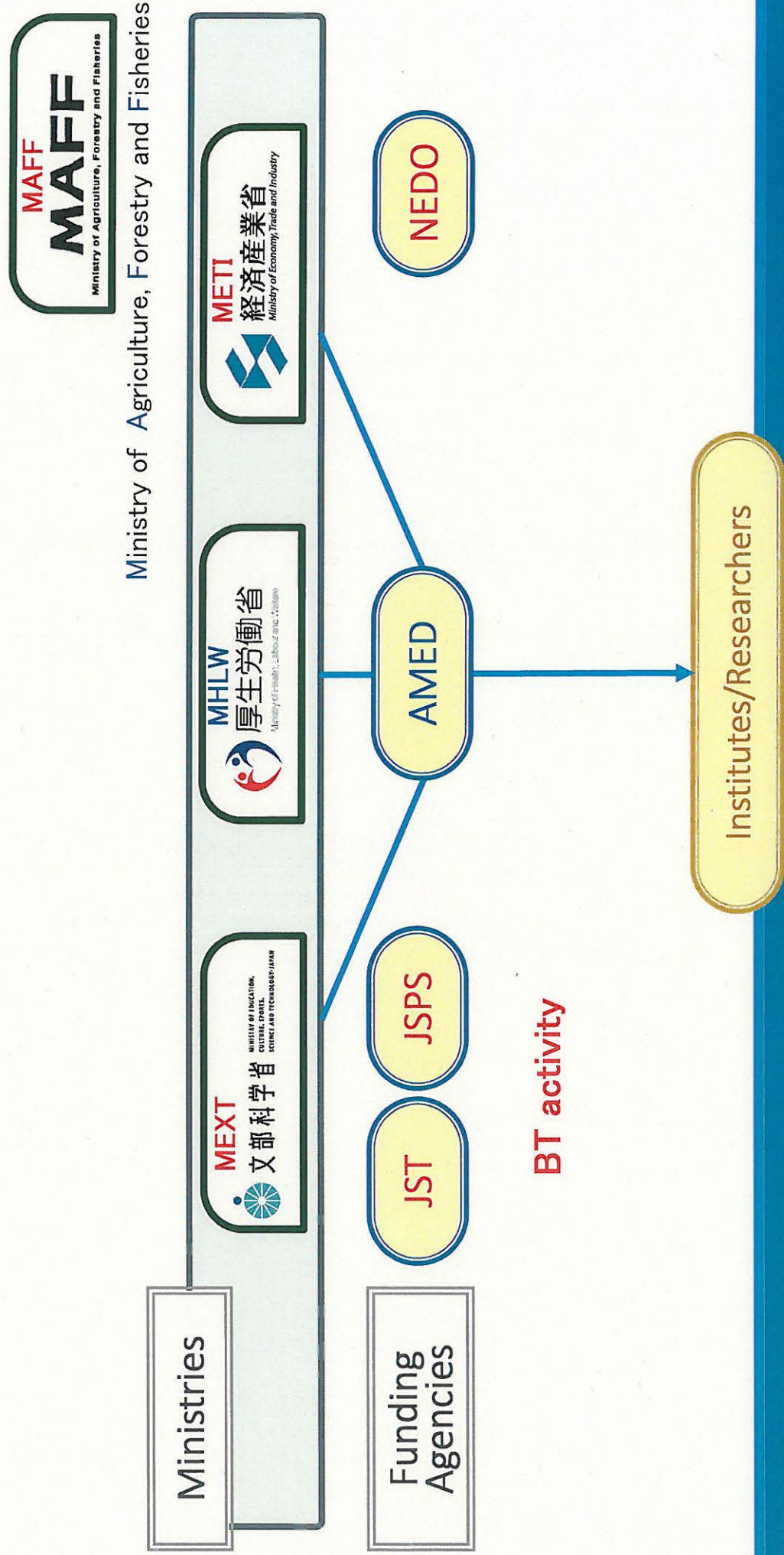
- 1 . [The Japan Revitalization Strategy](#) was approved by the Cabinet in June 2013.
⇒ To accelerate the development of practical applications of innovative medical technologies:
 - A) establish the [Headquarters for Healthcare Policy \(HHP\)](#) with core functions, headed by the Prime Minister, in the Cabinet
 - B) determine [the Healthcare Policy](#)
 - ① promote integrated medical R&D, from basic research to practical application
 - ② boost economic growth and the quality of medical care by promoting the creation and overseas expansion of new industrial activities related to healthcare and medical care
 - C) determine the [Plan for Promotion of Medical Research and Development](#)
 - ① formulate 10 basic policies
 - ② draw up 9 interrelated projects
 - D) establish the [Japan Agency for Medical Research and Development \(AMED\)](#) as a corporation that directs integrated research management

Previous Public Funding System for Medical R&D

MEXT: Ministry of Education, Culture, Sports, Science and Technology
MHLW: Ministry of Health, Labour and Welfare
METI: Ministry of Economy, Trade and Industry
JST: Japan Science and Technology Agency
JSPS: Japan Society for the Promotion of Science
NEDO: New Energy and Industrial Technology Development Organization



NEW Public Funding System for Medical R&D



New System for Medical R&D

Headquarters for Healthcare Policy (HHP)

- develop a comprehensive plan for the promotion of medical R&D
- integrate medical R&D budget requests of relevant ministries
- make strategic decisions on the allocation of promotional adjustment funds

Advise on Nomination of President and Auditor

Advise on Mid-to-Long Term Targets

Comprehensive adjustment of budget request

Ministries



Handle Nomination and Dismissal of AMED President and Auditor

Present Mid-to-Long Term Targets

Allocate Subsidy Operating Expense

budget concentration

Japan Agency for Medical Research and Development (AMED)

Funding

Institutes/Researchers

- Provides a unified point of contact for funding and for application procedures.
- Provides support from basic research to practical use.

How has Japan's medical R&D changed?

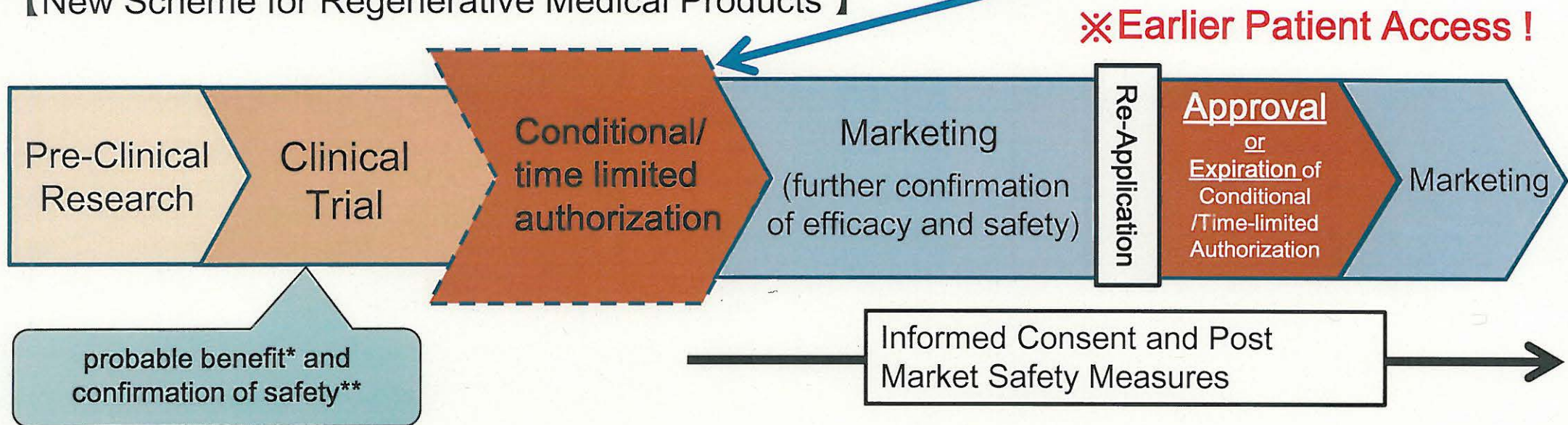
- 1 . The Japan Revitalization Strategy was approved by the Cabinet in June 2013.
- 2 . **The Pharmaceutical Affairs Act** was partly revised.
 - ⇒ Enhancing safety measures for drugs and medical devices and establishing regulations for **medical devices** based on their characteristics separately from those for **drugs**
 - ⇒ Establishing a new definition of **regenerative medical products** and their regulations

New Scheme for Regenerative Medical Products

【Traditional Approval Process】



【New Scheme for Regenerative Medical Products】



* Probable benefit: Confirmation of efficacy with small patient population.

** Safety: Evaluation of acute adverse events etc.

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Japan Agency for Medical Research and Development (AMED)



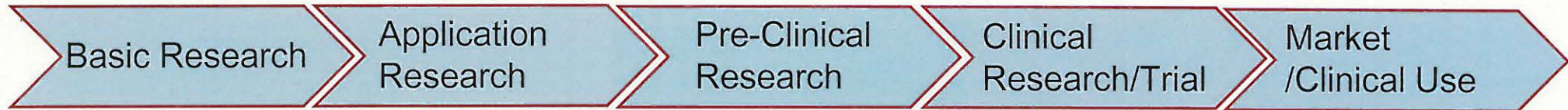
There are still people all over the world with diseases that lack treatment because causes have yet to be elucidated and or who are suffering from illnesses that still do not even have a diagnosis, and this fact has become more widely recognized as information technology has advanced.

*Our goal is to fast-track medical R&D that directly benefits people not only by extending lifespans but also by improving quality of life: supporting “**life**” as biological existence, daily living, and lifespans.*



*Makoto Suematsu, MD, Ph.D.
President, Japan Agency for Medical Research and Development (AMED)*

From basic research to clinical research/trial



Promote and support medical R&D consecutively from basic research to clinical research/trial by funding

- ◆ Strong management of R&D program by PD, PO and etc.
- ◆ Improvement of the infrastructure for clinical research/trial
- ◆ Support for industrialization; bridging academia and industry
- ◆ Promotion of International strategy

9 interrelated Projects supported by 3 Ministries;

- | | |
|---|---|
| ① Drug discovery | ⑥ Cancer |
| ② Medical devices | ⑦ Psychiatric and Neurological Disorders (Brain research) |
| ③ Infrastructure of clinical research and trial | ⑧ Emerging and re-emerging infectious diseases |
| ④ Regenerative medicine | ⑨ Intractable diseases |
| ⑤ Genomic Medicine | |

Nine interrelated projects and project directors (PD)



1. Project for Drug Discovery and Development

Toichi Takenaka, Chairman, Japan Health Sciences Foundations

Supports R&D on developing new drugs and reinforcing the basis for new drug development, in cooperation with universities and industry, by establishing a support network for new drug development. Also promotes research related to the identification of drug targets, technology development as a basis for new drug development, and practical application of medical technologies to help develop innovative drugs and orphan drugs.



3. Project for Japan Translational and Clinical Research Core Centers

Takao Saruta, Adviser at the Foundation for Promotion of Medical Training, Emeritus Professor at Keio University

Promotes integration between research support centers, which work as a bridge, and core clinical research hospitals, in order to establish a system for the consistent, practical application of basic research outcomes at universities. Also works to strengthen the function of core centers, including securing and developing human resources, and to promote their networking and expansion of promising technologies. Is involved in conducting high-quality clinical research and trials in compliance with the ICH-GCP Guidelines, and improving a system to support multicenter studies by using an ARO function.



5. Japan Genomic Medicine Project

Masato Kasuga, President, National Center for Global Health and Medicine

Is engaged in the BioBank project for people with diseases and healthy people. Analyzes data including genome analysis information and clinical information to enhance the identification and validation of disease- and drug-related genes and identification of the standard genome sequence of Japanese people. Also promotes an integrated search for genes responsible for intractable or rare diseases through joint research, research contributing to the formulation of guidelines for diagnosis and treatment using genomic information, improvement of the research base for genomic medicine, and experimental and empirical clinical research.



7. Project for Psychiatric and Neurological Disorders

Tadaharu Tsumoto, Senior Team Leader, RIKEN Brain Science Institute

Promotes R&D and improvement of the basis for clarifying the structure and function of the entire neural network in the brain and for developing bio-markers. Aims to clarify the mechanism of the development of psychiatric disorders, such as dementia and depression, and to establish diagnostic methods and appropriate treatments.



2. Project for Medical Device Development

Makoto Kikuchi, President, Japan Association for the Advancement of Medical Equipment

To promote the development of medical devices through collaboration between medicine and engineering, is working to establish a system to support the development of medical devices (a medical device development support network) consisting of several specialized support institutions. Also engages in R&D to create new promising technologies and to achieve the practical use of medical devices and systems, making use of Japan's sophisticated technologies. Is also working to speed up the approval process for medical devices and to develop human resources for R&D.



4. Japan Regenerative Medicine Project

Hidehiko Saito, Honorary Director, National Hospital Organization Nagoya Medical Center

Provides consistent support for basic research through clinical trials, and promotes the improvement of the basis for regenerative medicine-related projects and support for the utilization of iPS cells as a drug development tool to raise the efficiency of new drug development.



6. Japan Cancer Research Project

Tomomitsu Hotta, President, National Cancer Center

Strictly selects promising outcomes from basic research and promotes further research to develop practical drugs and medical devices, in order to link research outcomes to clinical research. Also feeds back clinical data obtained from clinical research to basic research to accelerate the practical application of cancer treatments, including the development of drugs and medical devices, based on the Comprehensive 10-year Strategy for Cancer Control.



8. Emerging /Re-emerging Infectious Disease Project of Japan

Tatsuo Miyamura, Honorary Member, National Institute of Infectious Diseases

Promotes domestic and overseas research related to infectious diseases to protect Japanese people as well as people around the world from infectious diseases, such as new types of influenza. Also strengthens measures against infectious diseases by linking research outcomes to the more efficient and effective development of therapeutic agents, diagnostic agents, and vaccines.



9. Rare/Intractable Disease Project of Japan

Shigeki Kuzuhara, Dean, Graduate School of Health Science, Suzuka University of Medical Science

Aiming to overcome rare or intractable diseases, promotes research to clarify the causes and clinical conditions of new diseases, leading to the development of new therapeutic methods, and research to develop breakthrough diagnostic, therapeutic and preventive methods for the practical application of drugs and medical devices. Also aims to promptly feed back research outcomes using iPS cells to society by promoting analysis of the pathogenic mechanisms of diseases, drug discovery research, and development of preventive and therapeutic methods, which are conducted using disease-specific iPS cells.

Budget Bill for Medical Research in FY 2015



	FY 2015	FY 2014	I / D
Budget Bill [promotional adjustment funds]	124.8 billion Yen (MEXT : 59.8、MHLW : 47.4、METI : 17.7) [17.5 B Yen]	121.5 Billion Yen (MEXT : 57.0、MHLW : 47.6、METI : 16.9) [17.5 B Yen]	+3.3 B Yen [0 B Yen]

① Drug Discovery 21.1 B Yen

② Medical Devices 14.5 B Yen

③ Infrastructure of clinical research and trial 10.6 B Yen

④ Regenerative Medicine 14.3 B Yen

⑤ Genomic Medicine 5.9 B Yen

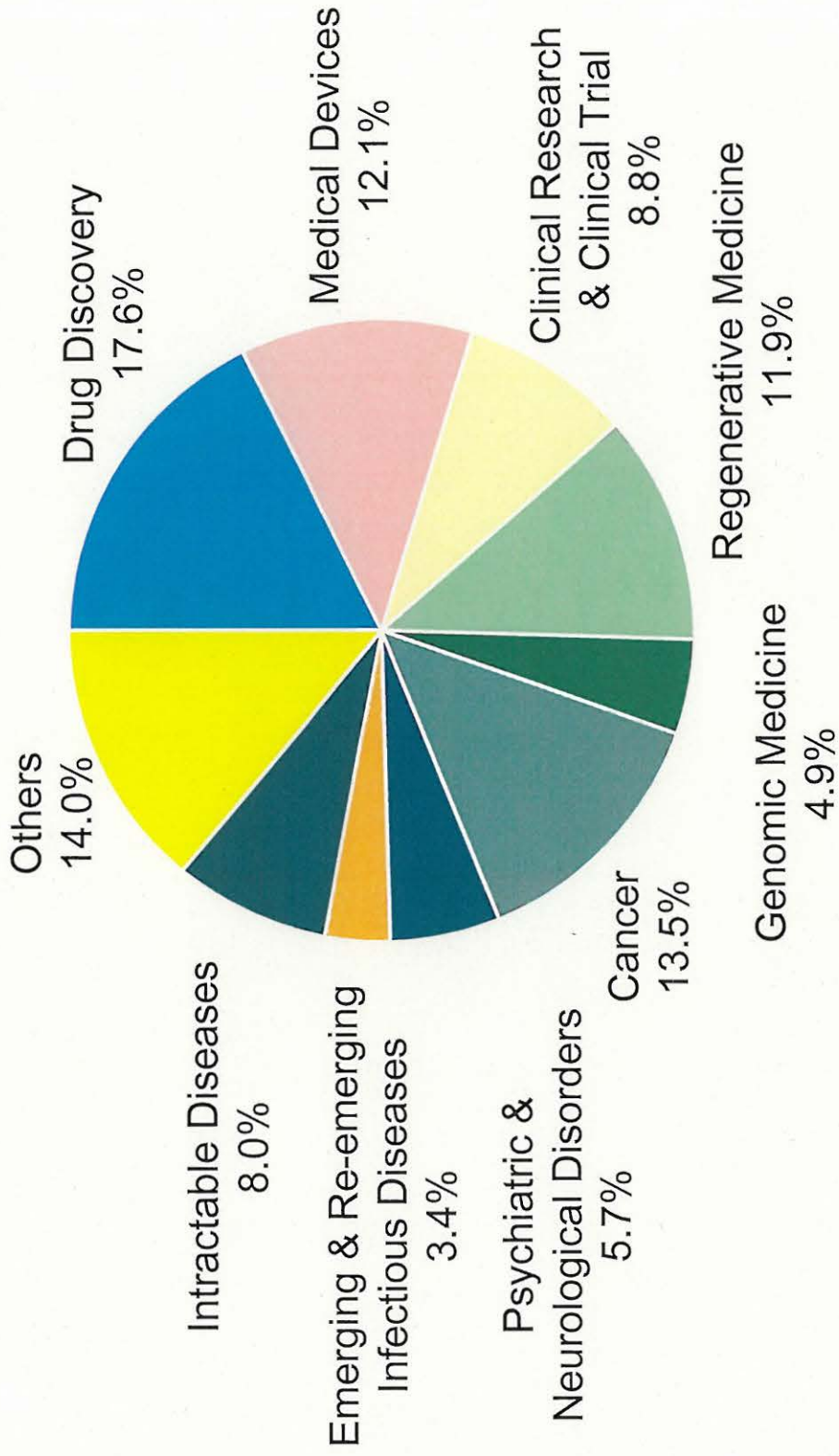
⑥ Cancer 16.2 B Yen

⑦ Psychiatric and Neurological Disorders 6.8 B Yen

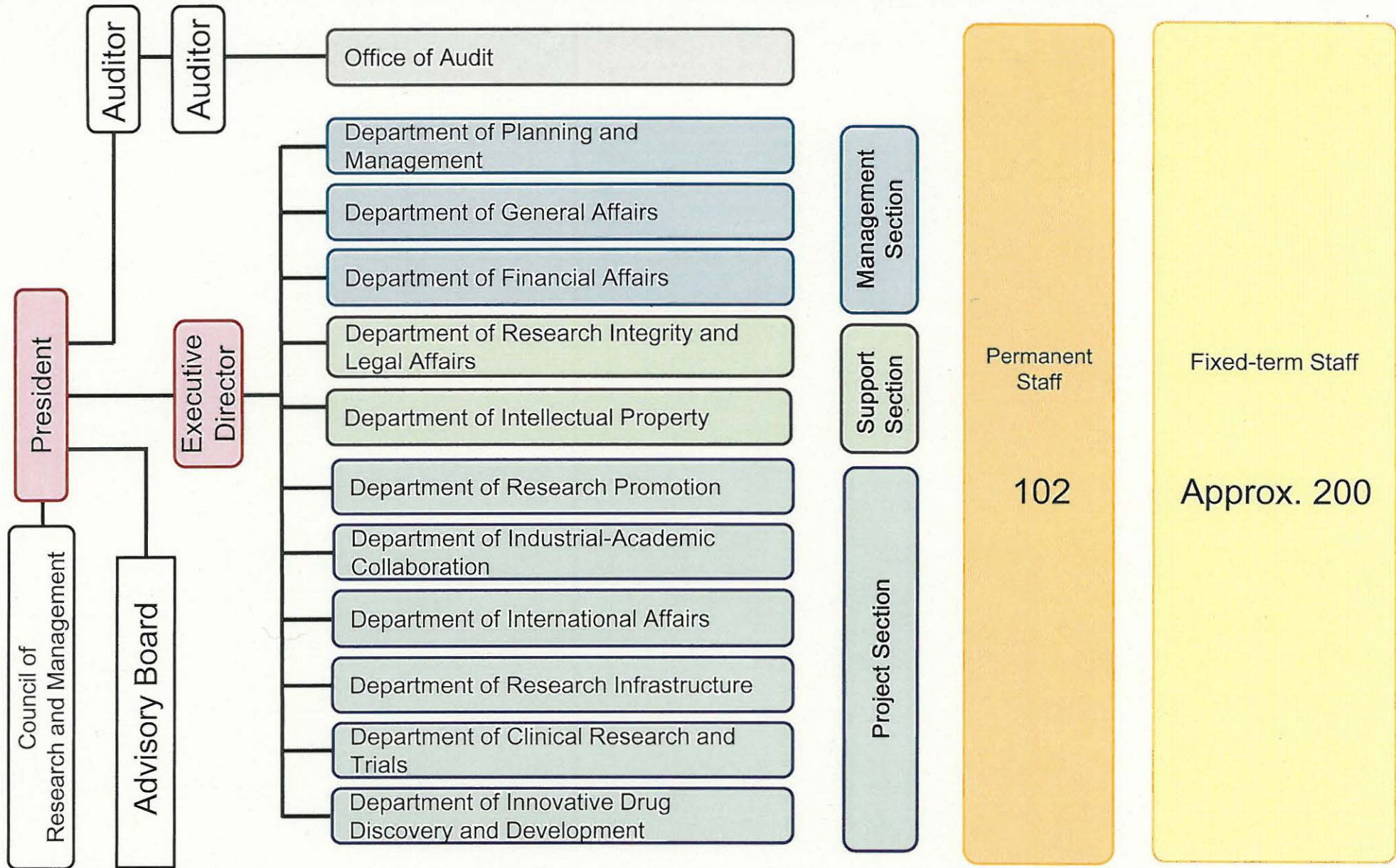
⑧ Emerging and Re-emerging Infectious Diseases 4.1 B Yen

⑨ Intractable Diseases 9.6 B Yen

Allocation of FY2015 Budget for Medical Research



Organization of AMED

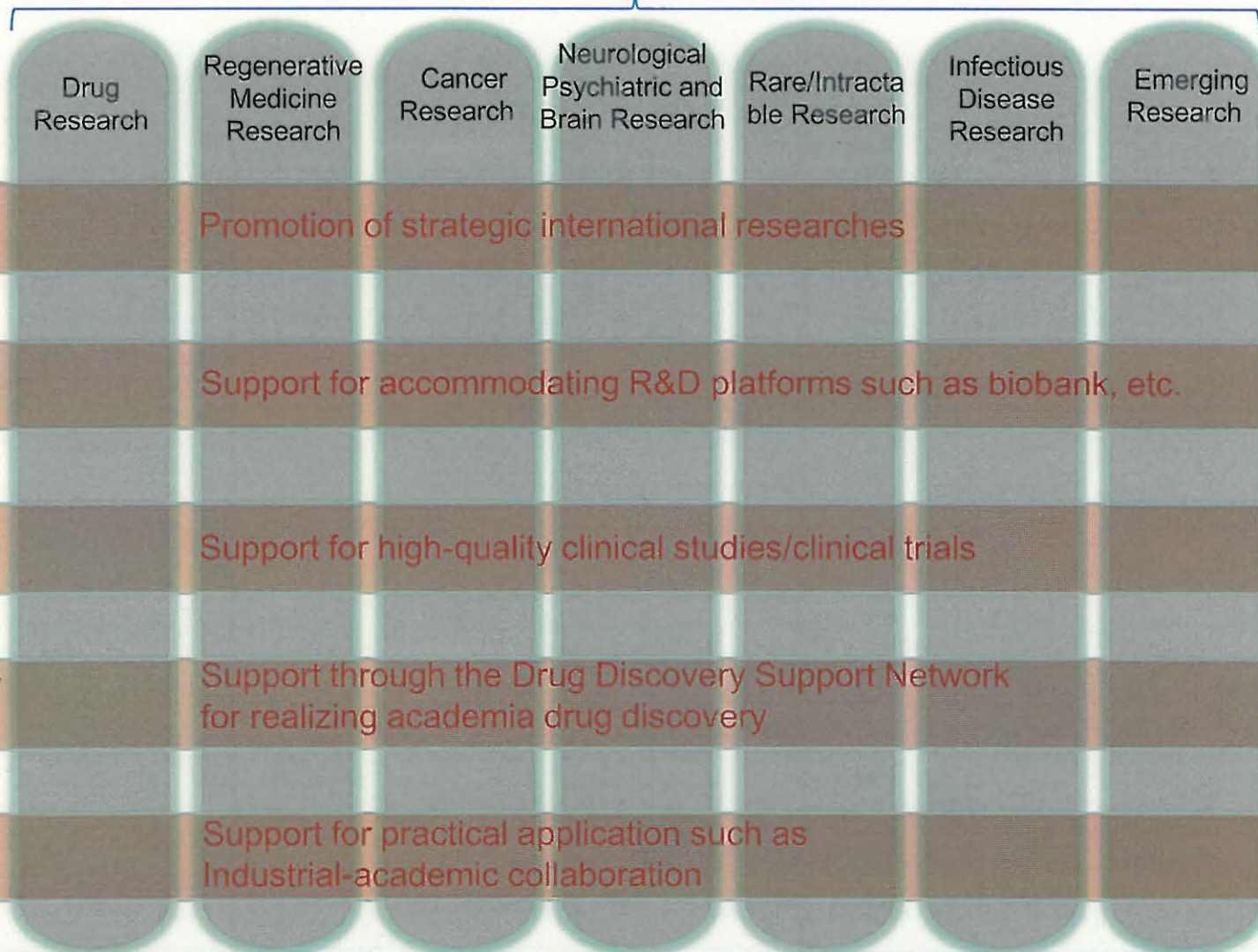


Longitudinal/cross-sectional cooperation between Department of Research Promotion, which is in charge of 7 projects, and 5 other departments for total optimization of Medical R & D



Department of Research Promotion

7 Research Projects



5 Other Departments

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AMED Department of International Affairs; International cooperative research



1. Bilateral and multilateral cooperation



U.S.-Japan Cooperative Medical Sciences Program

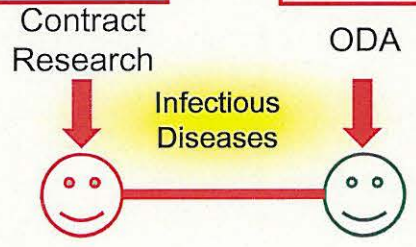
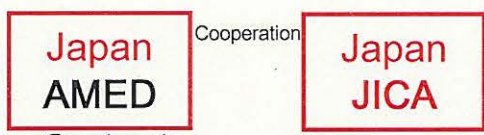


- Studying diseases prevalent in Asia through cooperation between Japan and the U.S.

- Viral diseases
- Hepatitis
- AIDS
- Acute respiratory tract infection
- Tuberculosis/Hansen's disease
- Parasitic diseases
- Cholera/Bacterial enteric infection
- Environmental genomics/diseases
- Nutrition/Metabolism
- Immunity

SATREPS ODA utilization-type

Agreement with the governments of partner countries



- Partner countries are ODA target countries.
- Addressing global health issues based on the needs of partner countries

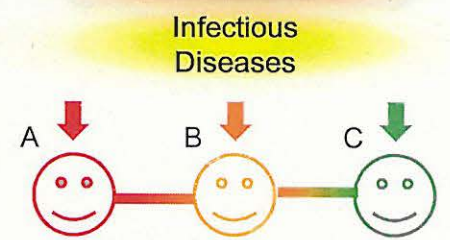
SICP/SICORP Bilateral agreement-type



- Publicly soliciting research themes, setting research fields that leverage the strengths of both countries
- Examined by both Japan and partner countries

e-ASIA Multilateral agreement-type

Agreeing to and publicly soliciting joint research themes in the framework of ASEAN+8



- Joint research conducted by three or more countries
- Examined by individual countries

Examples of International Collaboration of AMED



Prime minister's Leadership on Healthcare Research

Leaders' Declaration G7 Summit 7-8 June 2015

Neglected Tropical Diseases

We commit ourselves to the fight against neglected tropical diseases (NTDs).

We are convinced that research plays a vital role in the development and implementation of new means of tackling NTDs. We will work collaboratively with key partners, including the WHO Global Observatory on Health Research and Development.



International Collaborative Research Program(2015) International Joint Research Program to Address Neglected Tropical Diseases (NTDs) in Africa

This program will be implemented at universities and other research institutes both in Japan and African countries to achieve the goal of controlling NTDs. The program covers research and development in the medical and public hygiene fields, including from basic research to the establishment of methods for diagnosis, surveillance, prevention, drug discovery and treatment. It also includes research on proposing policies and operations, such as a public-hygiene system to control NTDs, based on the results of the aforementioned research and development.

International Collaborative Research Program for Tackling the NTDs (Neglected Tropical Diseases) Challenges in African countries

This research conducted by Japan alone in overseas

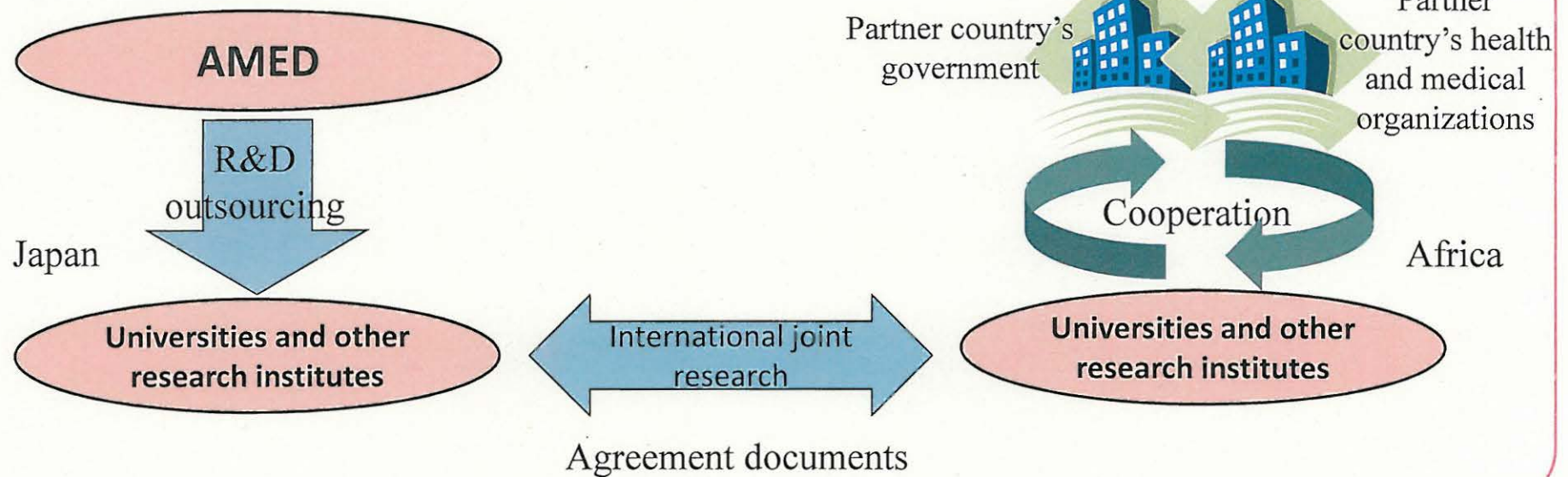
Objective

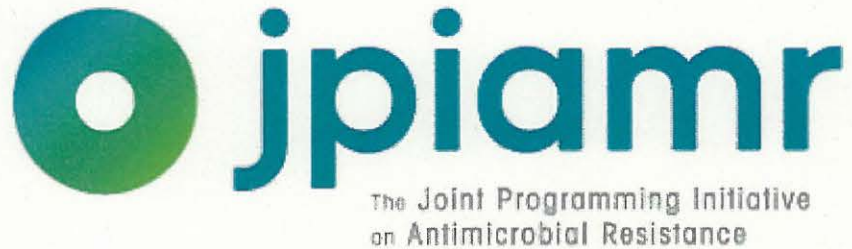
The objective of this program is to enhance the contribution of Japan, using its science and technology capabilities, to addressing NTDs, which are serious impediments to the development of African countries that need to be addressed urgently, through strengthening the development of science and technology and human resources both in Japan and African emerging and developing nations.

Program period : The period is five years.

R&D expenses : The expenses per project must not exceed 75 million yen annually.

Implementation Structure





International priorities surrounding antimicrobial resistance / antibiotic development

GloPID-R

GLOBAL RESEARCH COLLABORATION FOR INFECTIOUS DISEASE PREPAREDNESS

New member joins the fight against global epidemics
August 4, 2015 - Lyon, France

The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) welcomes [the Japan Agency for Medical Research and Development \(AMED\)](#) as a member into the initiative. AMED is the 13th research funding organization to join the GloPID-R members in their commitment to collaborate in research for infectious disease preparedness.

International Rare Diseases Research Consortium (IRDIRC)

The International Rare Diseases Research Consortium (IRDIRC) was initiated by the European Commission and the US National Institutes for Health Research and launched in April 2011 to foster international collaboration in the rare diseases field. IRDiRC will team up researchers and organizations investing in rare diseases research in order to achieve two main objectives, namely to deliver 200 new therapies for rare diseases and means to diagnose most rare diseases by the year 2020.

Thank you for your attention!

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