AMED 10th Anniversary Symposium

AMED's role in the promotion of medical research and development in Japan - past and future

Hitotsubashi Hall

Review for the 2nd phase of AMED and perspective for the future

Japan Agency for Medical Research and Development (AMED)

President Dr. MISHIMA Yoshinao

March 10, 2025

Positioning of Japan Agency for Medical Research and Development (AMED)

Health and Medical Strategy Advancement Act (enacted in 2014)

Headquarters for Healthcare Policy

Health and Medical Strategy (Cabinet decision), Plan for Promotion of Medical Research and Development (Headquarters decision)

Jurisdictional ministries

Cabinet Office
(Japan Agency for Medical Research and Development Office)

MEXT **MHLW** **METI**

Related ministries

MIC, etc.

Japan Agency for Medical Research and Development

(Established in April 2015)

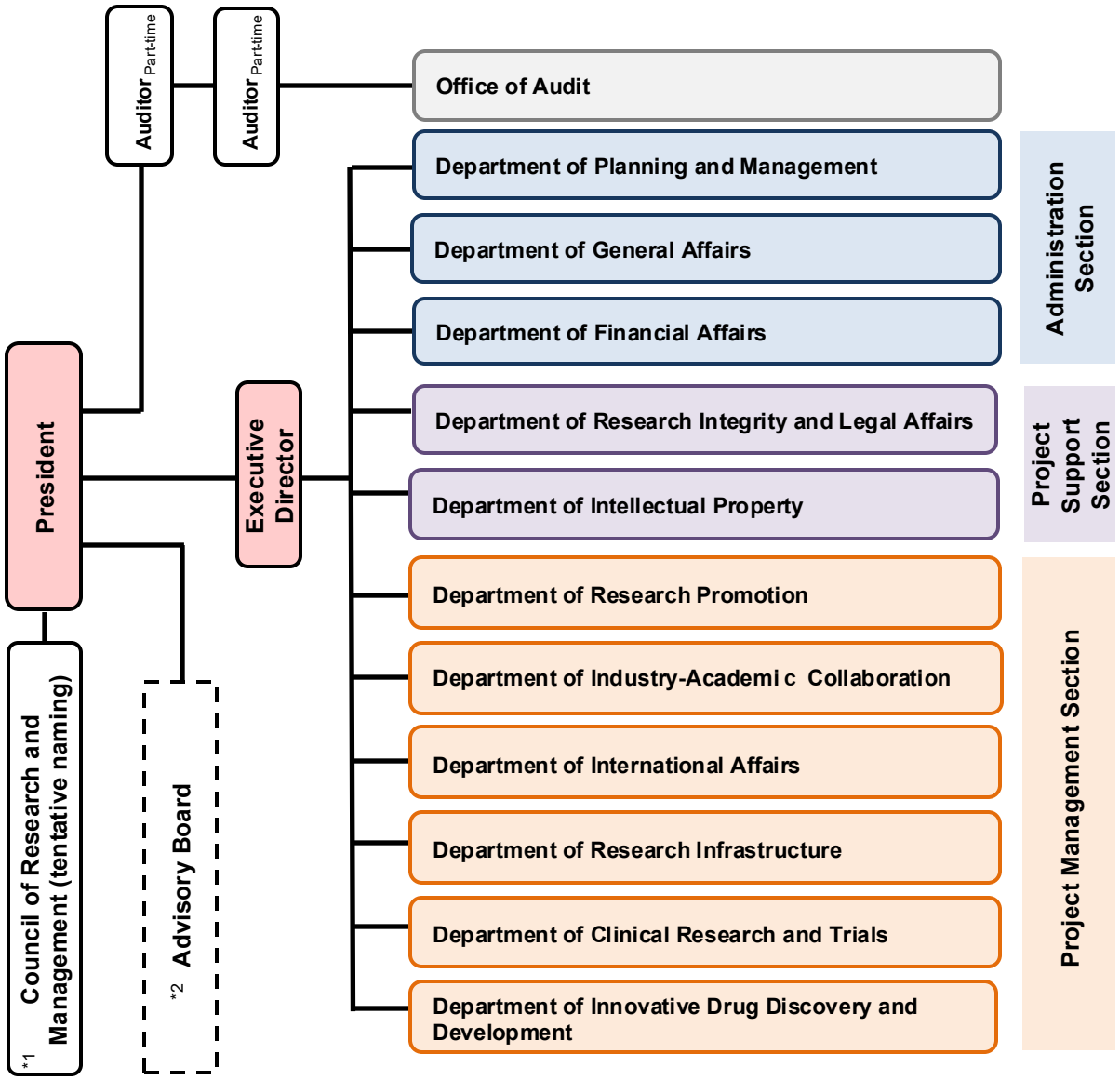
Achieving budget consolidation and integrated implementation based on the intentions of the Headquarters

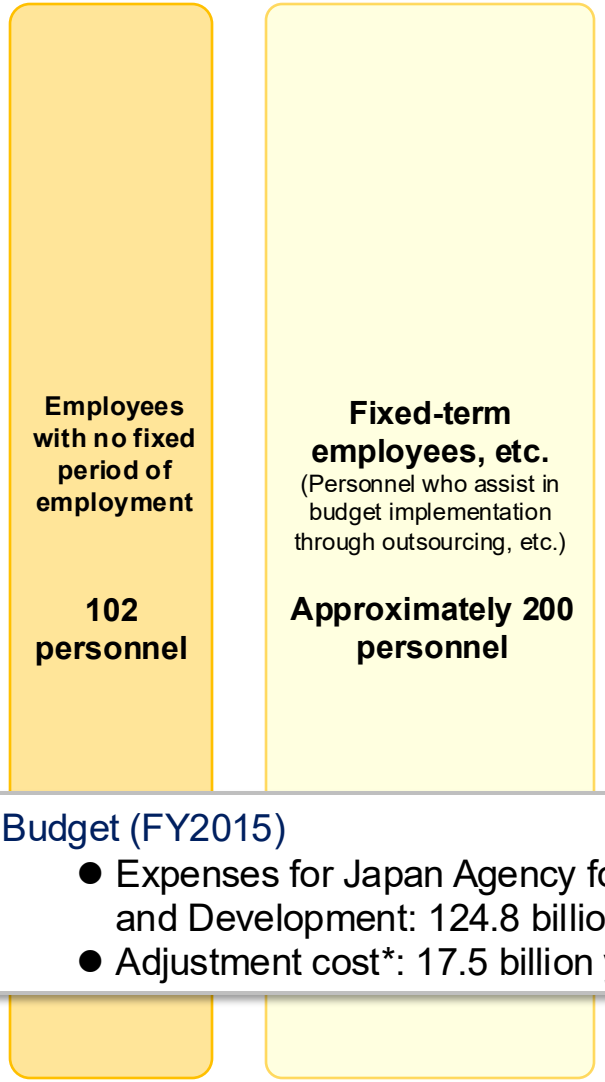
Universities Hospitals Corporations Researchers Researchers

- One-stop service for research expenses, etc.
- Uniform research management from basic research to practical application

Organizational structure of Japan Agency for Medical Research and Development in the 1st Phase

[Source] December 8, 2014 Health and Medical Strategy Council Meeting Materials
*Partly processed by AMED





Budget (FY2015)

- Expenses for Japan Agency for Medical Research and Development: 124.8 billion yen
- Adjustment cost*: 17.5 billion yen

*Additional budget allocated mid-year in accordance with the policy established by the Headquarters for Healthcare Policy

Functions required of AMED and major developments since establishment (1st Phase)

1. Implementation of medical research and development

- Management by Program Director (PD), Program Supervisors (PSs), and Program Officers (POs)
- Response to “Unification of Usage Rules, etc. for Competitive Funds”
- FY2015 1st allocation of adjustment costs related to research and development in the field of medicine; other activities

2. Infrastructure development for clinical research, etc.

- Conducting of occasional follow-up surveys to the FY2014 base survey
- Promotion of the Innovative Medical Technology Creation Centers Project

3. Support for industrialization

- Implementation of intellectual property management support for practical application
- Promotion of all-Japan drug discovery support through the Drug Discovery Support Network

4. Promotion of international strategy

- Attend the Heads of International Research Organizations (HIROs) Meeting
- Join the International Rare Disease Research Consortium (IRDiRC)

Review for the 2nd phase of AMED

Overview of Japan Agency for Medical Research and Development (AMED)

1. Purpose

In order to comprehensively and effectively promote consistent research and development from basic research to practical application in the field of medicine, achieve smooth practical application of research results, and create a suitable environment for medical research and development, we conduct various activities in the field of medicine, including research and development, improving the environment for medical research and development, and providing grants, based on the Plan for Promotion of Medical Research and Development prepared by the Headquarters for Healthcare Policy.

2. Organization, etc.

1) Officers

- President Yoshinao Mishima (from April 2020)
- Executive Director Jiro Yashiki
- Auditors (part-time) Kayo Inaba, Shinichi Shirayama

2) Number of employees

742 personnel (including executives; as of January 1, 2025)

3. Budget (FY2024)

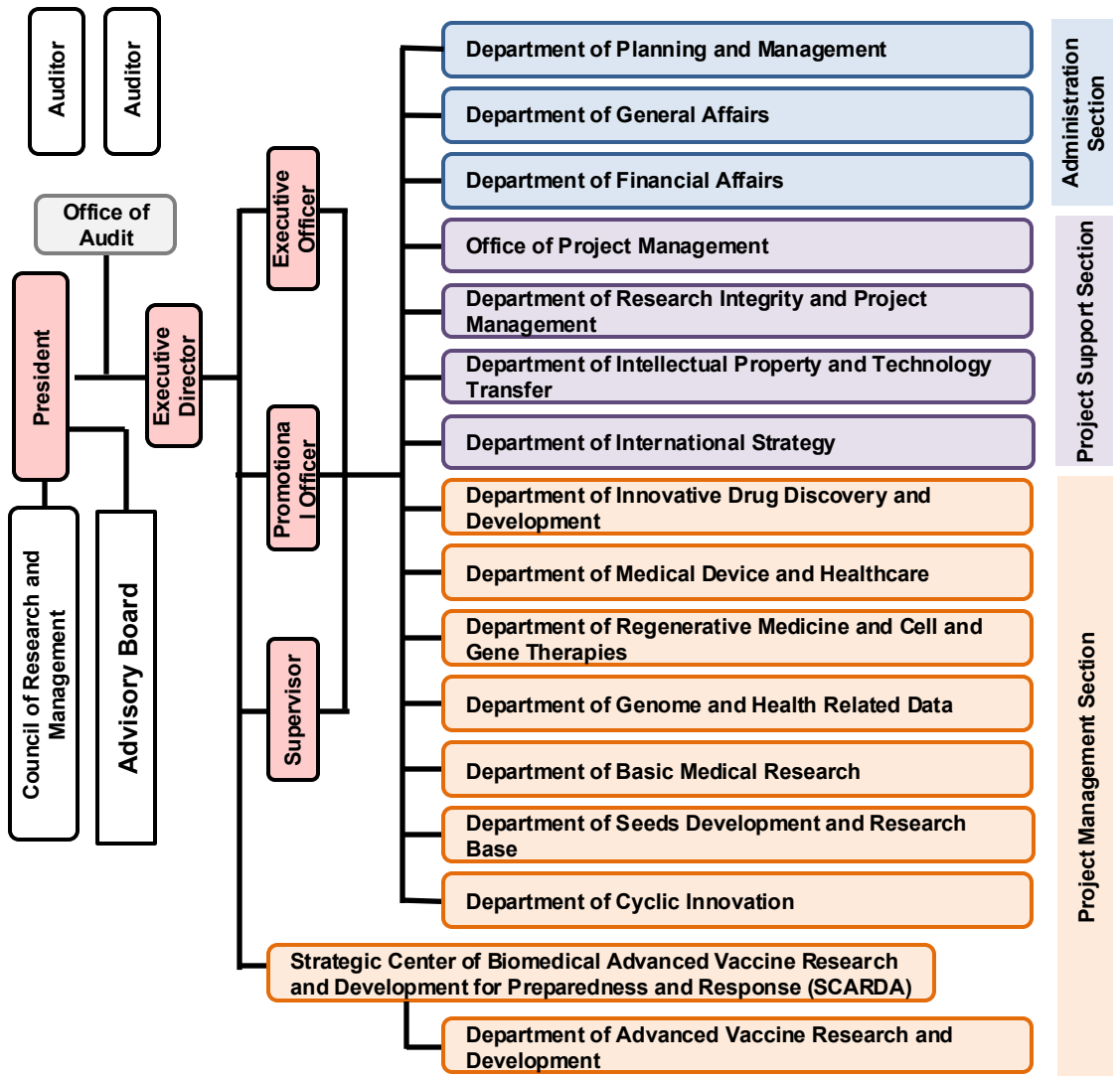
Subsidies, etc. for Japan Agency for Medical Research and Development: 124.5 billion yen
Adjustment cost 17.5 billion yen

4. Offices

Domestic offices (Headquarters, Department of Innovative Drug Discovery and Development - East Japan Office/West Japan Office)

Overseas offices, etc. (Washington D.C. Office, London Liaison)

3) Organizational chart

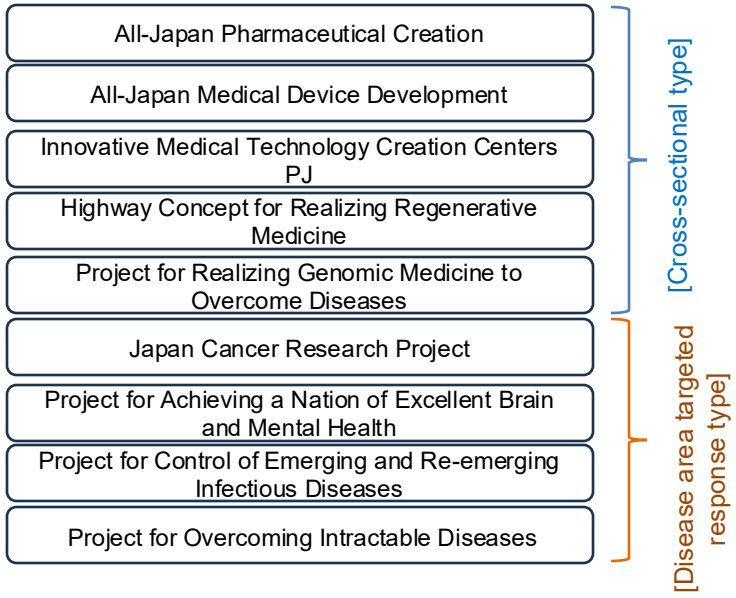


Policy changes for integrated projects from the 1st to the 2nd Phase

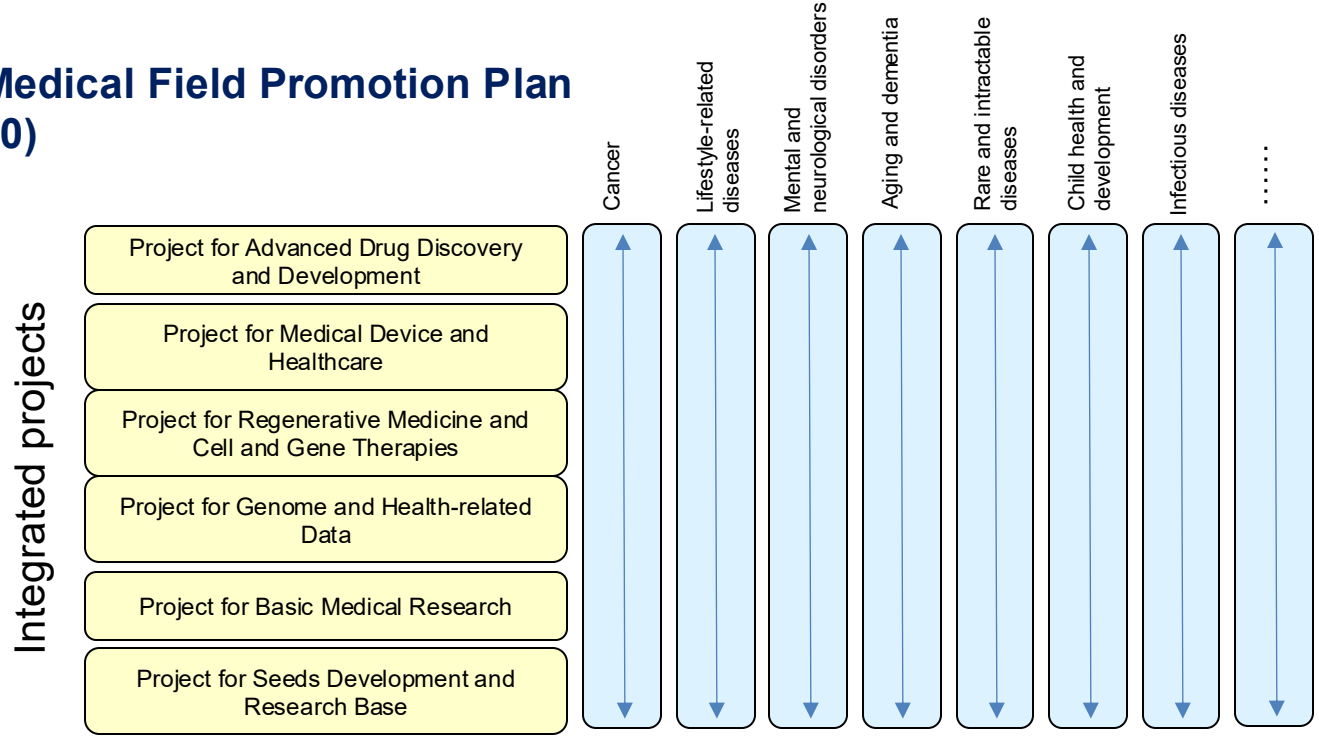
Promoting research and development for each "integrated project" that coordinates and centrally manages the projects of various ministries

- In the organization of the 1st Phase, projects for developing modalities (techniques/methods), etc. and disease-specific projects existed side-by-side, making it impossible to adequately apply the development of modalities, etc. to each disease.
- In the 2nd Phase, in accordance with the direction of considerations in the Plan for Promotion of Medical Research and Development, projects have been reorganized into six areas of modalities, etc. and research and development is promoted across disease areas.

1st Phase Medical Field Promotion Plan (from FY2014)



2nd Phase Medical Field Promotion Plan (from FY2020)

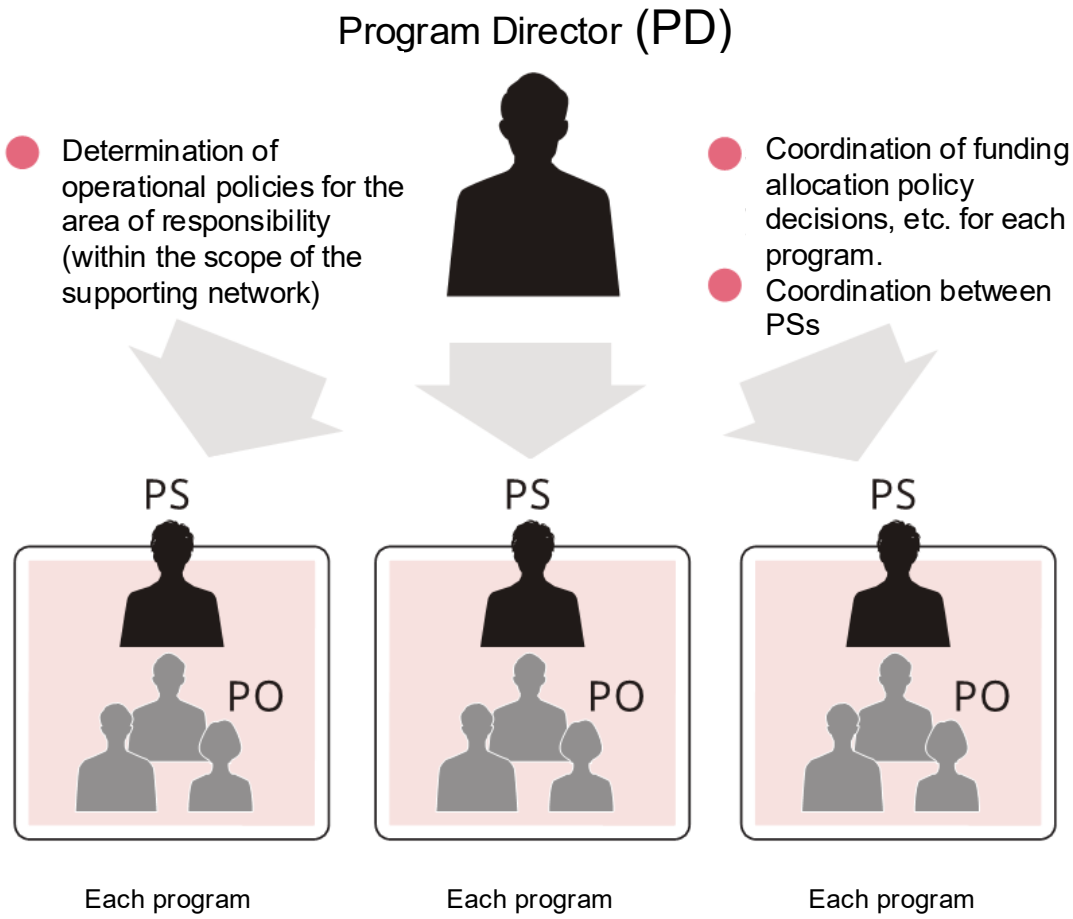


- Promoting six “integrated projects” centered on modalities, etc.
- Disease research is managed flexibly by each disease area coordinator (DC) across integrated projects.

Promotion of research and development of six integrated projects by PD/PS/PO, etc.

Uniform management of PD, PS, and PO

Program management structure for each comprehensive project



Roles of PD/PS/PO

The PD, PSs, and POs work together to understand the overall issues of the integrated projects (PJ) and carry out highly specialized coordination such as managing the integrated project they are responsible for and promoting cooperation between integrated projects, as well as conducting uniform operations to evaluate and discover excellent R&D proposals and connect the results of basic research to clinical research and practical application.

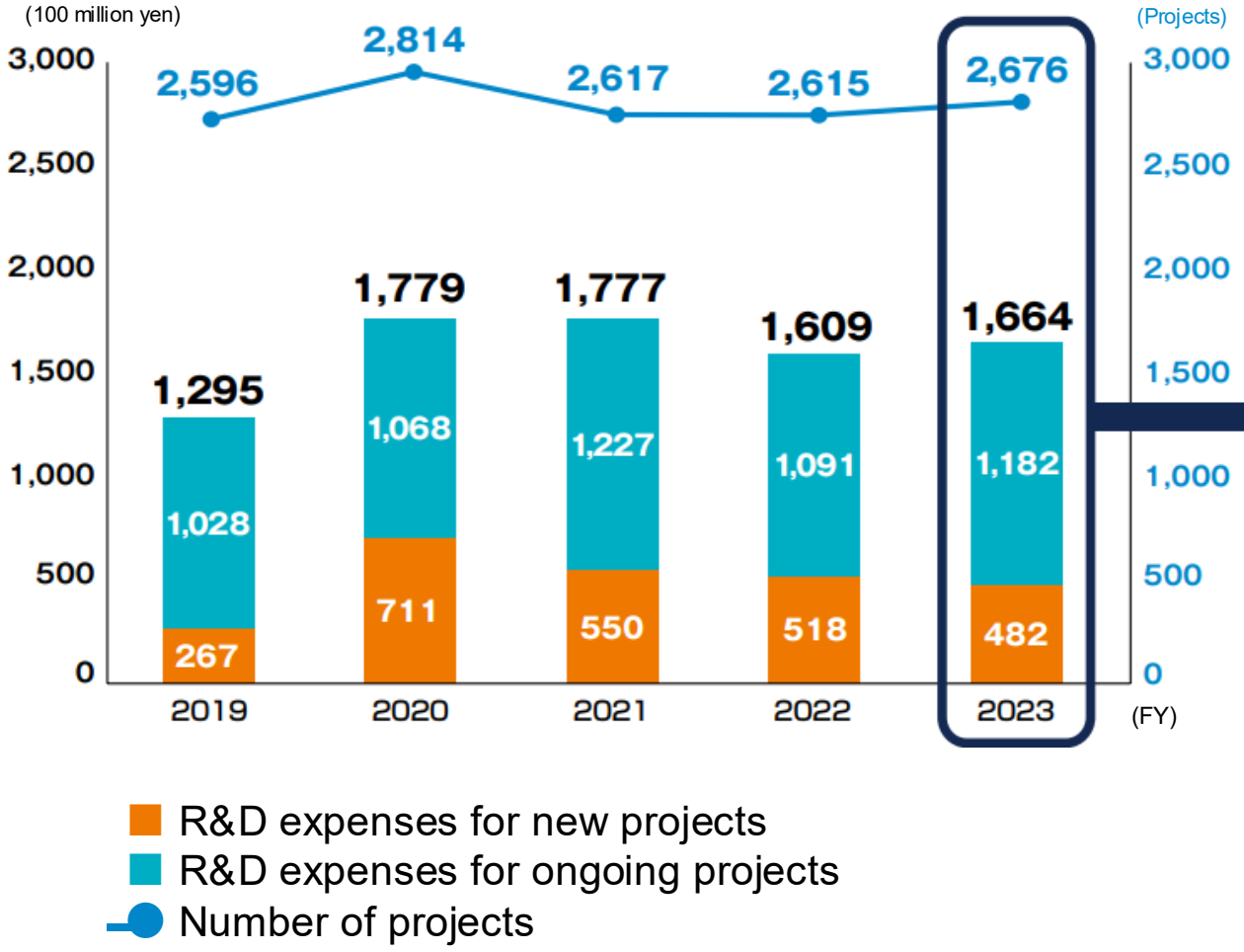
Disease area coordinators in promotion of disease research

- In order to promote response to disease areas, we have appointed disease area coordinators (DCs) with extensive experience.
- The basic mission of the DCs is to utilize their highly specialized knowledge and extensive experience in their disease field to offer proposals and advice to the Agency's President, executive officers, and each PD.

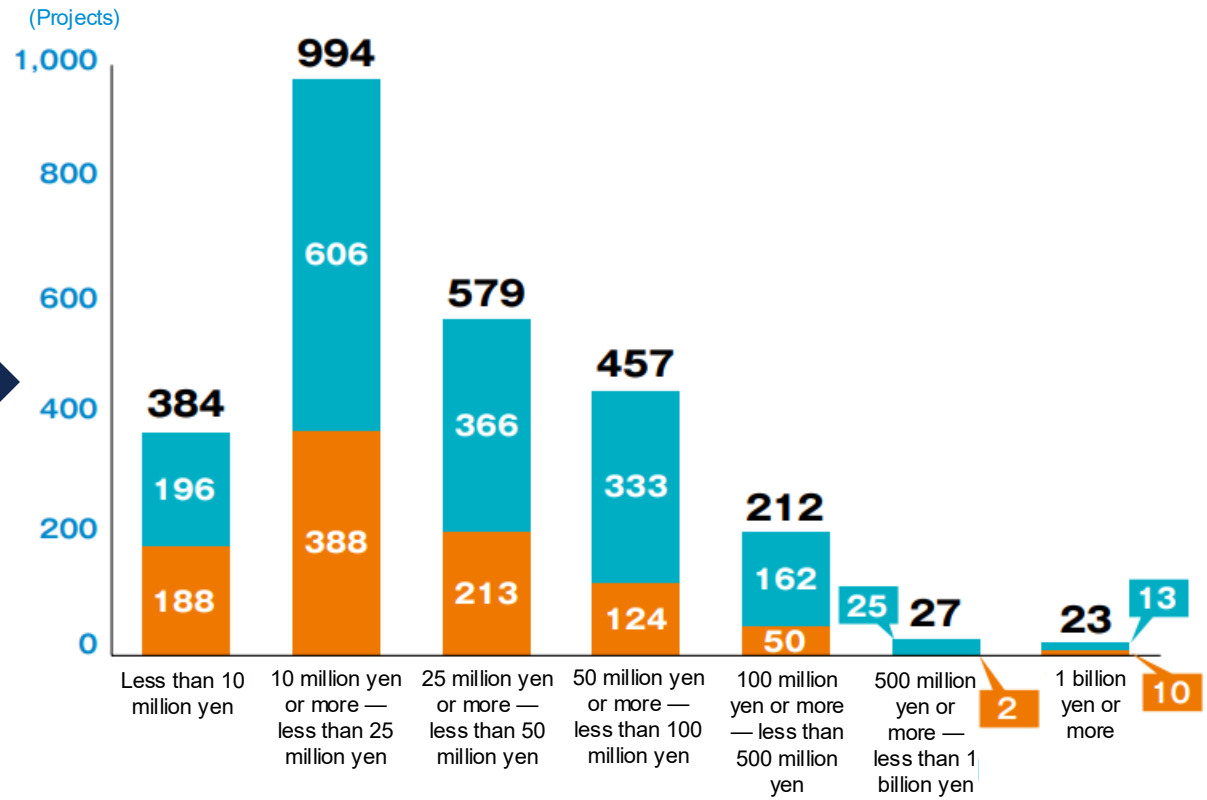
Status of AMED R&D promotion (1)

[Source] AMED Data Book 2023 (excerpt)

Trends in number of projects and R&D expenses



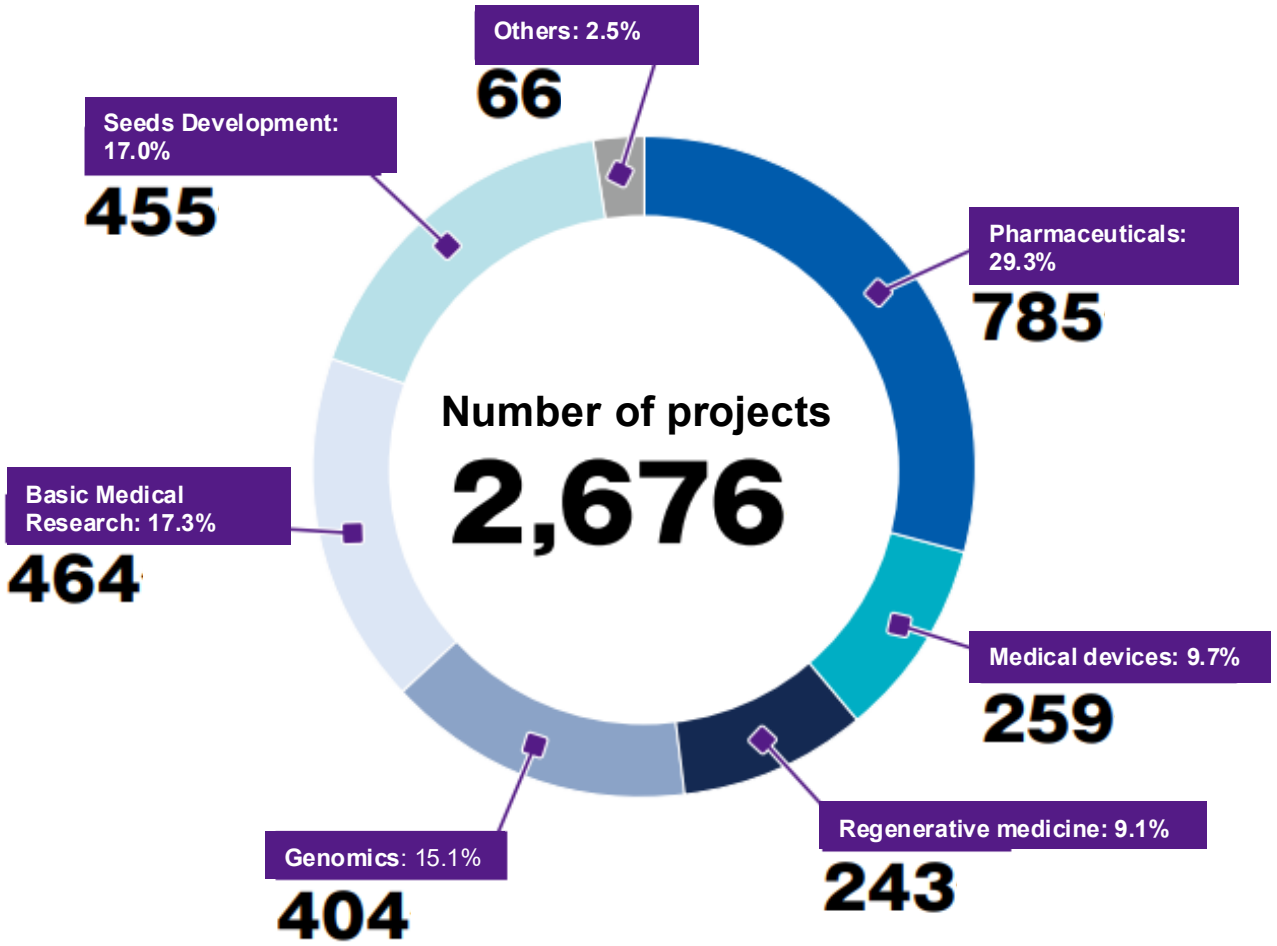
FY2023 projects and distribution of R&D expenses



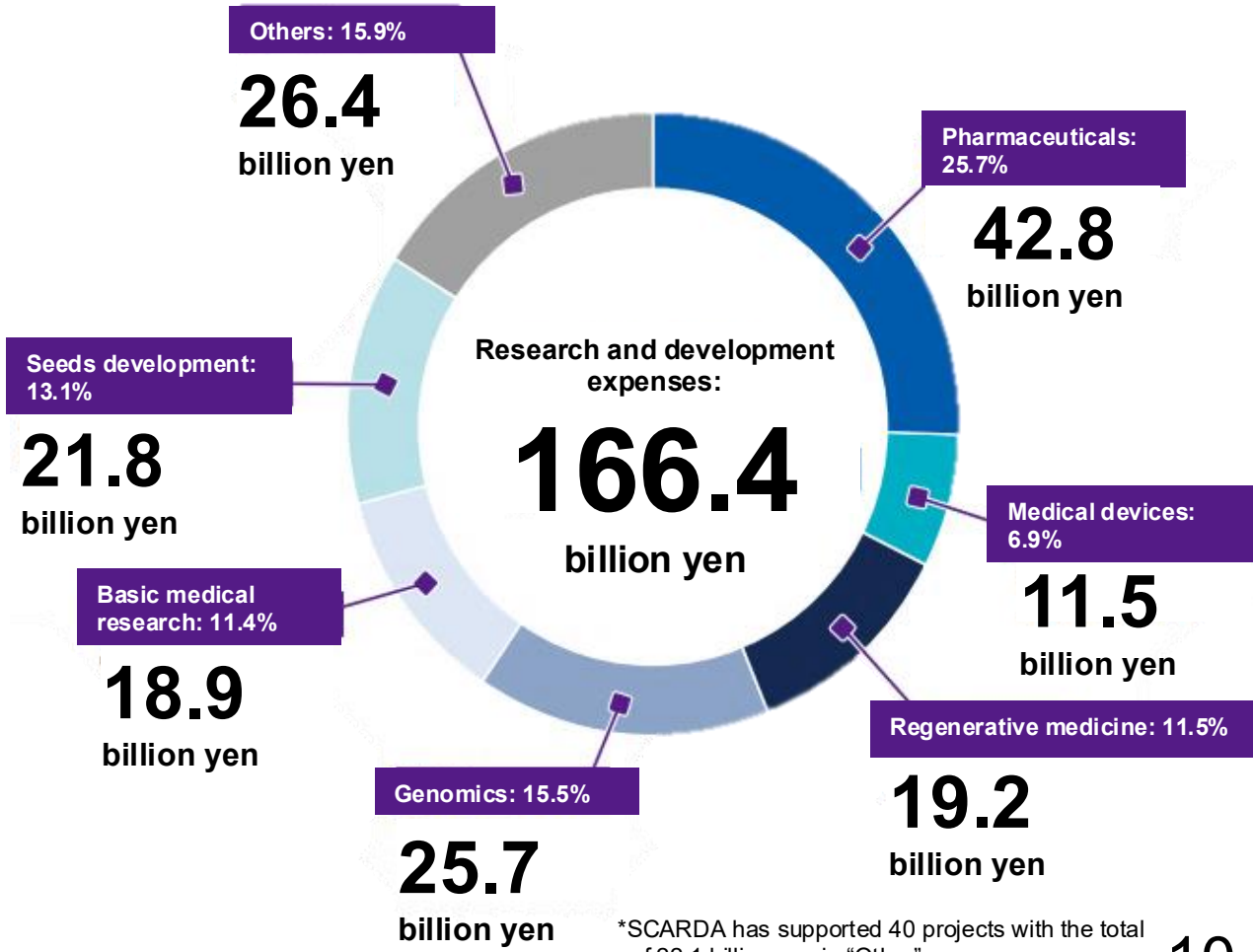
Status of AMED R&D promotion (2)

[Source] AMED Data Book 2023 (excerpt)

FY2023 Number of projects by integrated project area



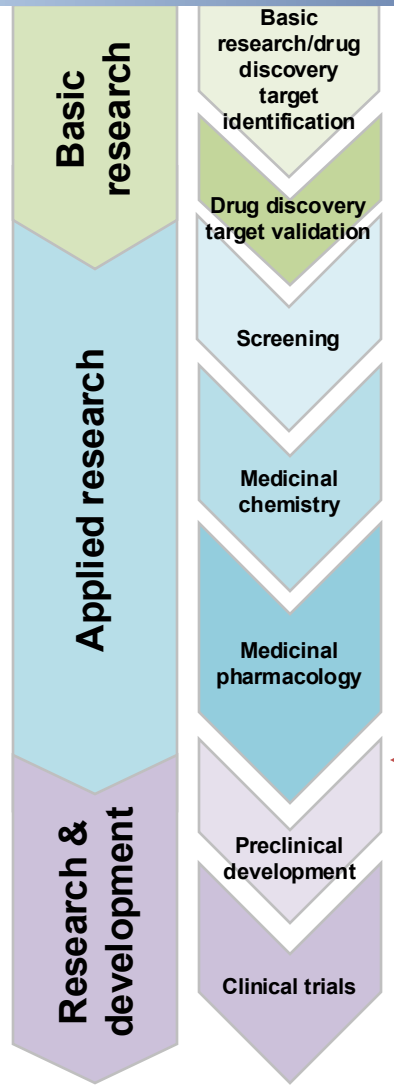
FY2023 R&D expenses by integrated project area



*SCARDA has supported 40 projects with the total of 22.1 billion yen in “Other”.

Examples of promoting R&D through inter-program collaboration (Part 1: Adjustment cost measures)

Promotion of R&D through disease management and adjustment cost measures



2016

Next generation cancer programs

Development of blood biomarkers for early cancer and risk disease diagnosis through protein/peptide modification analysis

Acceleration and enhancement with adjustment costs

Accelerated research and development in next-generation cancer programs by collecting samples and establishing models to identify biomarker candidates.

- FY2017: Quantification and validation of identified biomarkers through sample collection and targeted proteomics
- FY2019: Omics analysis using pancreatic cancer organoid generating technology and orthotopic transplantation models
- FY2021: Simultaneous trace blood analyses using over 1,000 types of antibodies

2021

2021

Innovative cancer programs

Clinical development of diagnostic methods for pancreatic cancer risk diseases and early pancreatic cancer detection using blood biomarkers to assess pancreatic exocrine function

2023

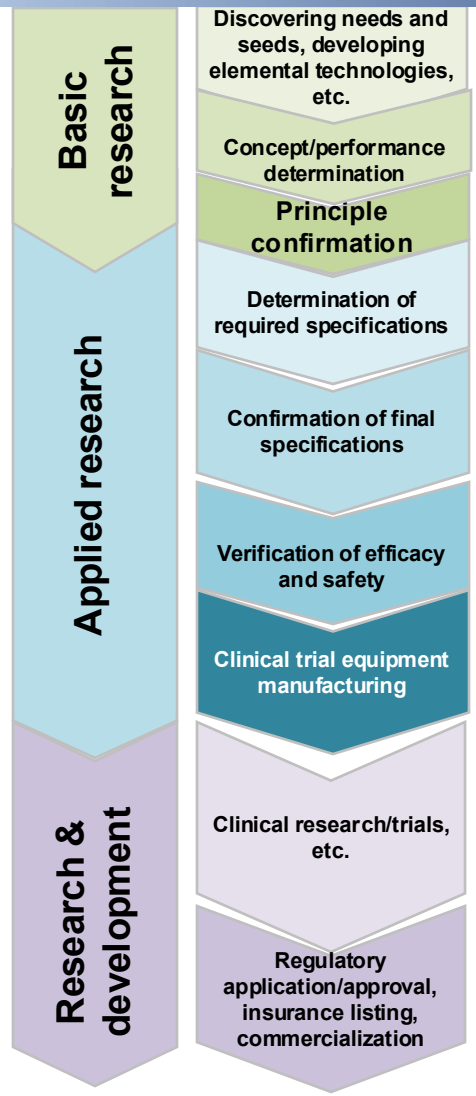
Out-licensing

Pancreatic cancer in vitro diagnostic drugs

- 2022 MHLW regulatory application
- June 2023 Regulatory approval
- February 2024 Entered into the national health insurance system

Examples of promoting R&D through collaboration among programs (Part 2: Inter-program collaboration)

Promoting R&D and practical application through seamless “inter-program collaboration”



2016

Medical research results development program

Development of vagal nerve stimulation catheter device to prevent heart failure after myocardial infarction

Experimentally proved that vagal nerve stimulation using an existing pacing catheter has a significant effect on reducing infarction and suppressing heart failure, and clarified the development process

2018

2019

Medical-engineering collaborative innovation promotion program

Development and commercialization of an intravenous vagal nerve stimulation catheter that protects the heart through bradycardia

- Completion of mass production prototype of catheter, sterilization test, and biological safety test
- Completion of clinical trial protocol creation for QMS system construction and regulatory affairs response

2021

2022

Research on development of new medical devices

World's first investigator-initiated clinical trial and practical application of a vagal nerve stimulation myocardial protection catheter (JOHAKU)

Planning and implementation of exploratory trials and confirmatory trials using non-clinical trials and investigator-initiated trials within this program

2024

Main results of AMED's medium- to long-term targets for the 2nd Phase
Results up to the end of 2023

Basic research → Applied research → Clinical trials → Practical application

AMED → Industry

Publication of papers in top journals
6,090 items

Non-clinical PoC acquisition
357 items

Out-licensing of seeds
434 items

Regulatory approval
40 items

Examples of regulatory approval

Pharma-ceuticals [New drugs]
Ezharmia
Approved in September 2022

A treatment drug for a rare cancer—relapsed or refractory adult T-cell leukemia-lymphoma—that reduces patient burden through a new approach

Pharma-ceuticals [New drugs]
Daichirona intramuscular injection
Approved in August 2023Partial changes approved in November 2023

Domestic mRNA vaccine for COVID-19

In regard to novel coronavirus infection, we achieved approval for **4 vaccines, 23 medical test drugs, and 2 medical devices**.

Pharma-ceuticals [Expansion of indications]
Rapalimus
Approved in September 2021, additional indications and dosage forms approved in January 2024

Providing drug therapy for intractable lymphatic anomalies, intractable pediatric diseases previously handled primarily with surgical treatment and symptomatic treatment

Pharma-ceuticals [New drugs]
Unituxin
Approved in June 2021

Introducing a domestically unapproved pediatric cancer drug as a treatment that can be procured domestically

In vitro diagnostic drugs
APOA2-iTQ
Approved in February 2024

Providing a new test that is expected to enable early detection of pancreatic cancer

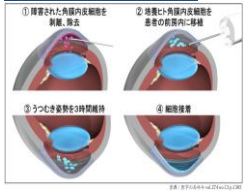
Medical devices
Synfolium
Approved in July 2023

Cardiovascular patch that improves postoperative QOL in children

Regenerative/cellular medicine and gene therapies
Delytact Injection
Approved in June 2021 (with conditions and limited period)

Japan's first virotherapy that can eradicate cancer stem cells for which existing treatments are ineffective

Regenerative medicine products
Vyznova
Approved in March 2023



Providing an innovative new treatment alternative to corneal transplantation

Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA)

1. Purpose

In order to swiftly promote vaccine development as a national strategy in the event of an infectious disease emergency, the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response was established within AMED to manage and coordinate the overall process of promoting vaccine development both before and after the outbreak of an infectious disease.

Three core functions of SCARDA

① **Extensive information collection and analysis functions**
② **Strategic decision making**
③ **Flexible funding**

2. Date of establishment

March 22, 2022

3. Organization, etc.

- Director General: **Michinari Hamaguchi**

- Provost: **Masayuki Yabuta**

- Center staff (Approx. 40 personnel)

4. Vaccine strategy related budget (FY2021 adjustment)

Japan Initiative for World-leading Vaccine Research and Development Centers

51.5 billion yen (5 years for the time being)

Establishing world-class R&D centers (a flagship center and centers where synergistic effects can be expected)

Program on R&D of New Generation Vaccine Including New Modality Applications

150.4 billion yen

- Research and development of infectious disease vaccines
- Research and development of new modalities that contribute to vaccine development

Strengthening Program for Pharmaceutical Startup Ecosystem

*As related budget

50 billion yen

Supporting practical development of drug discovery ventures with investment from certified VCs

[Department in charge: AMED Department of Intellectual Property and Technology Transfer]

Project of Developing Biopharmaceutical Manufacturing Sites to Strengthen Vaccine Production

(METI) 227.4 billion yen

Establishment of centers, etc. with dual-use equipment that can be switched to vaccine production in case of an emergency.

International collaboration

Collaboration with the U.S. (NIH)

- U.S. - Japan Cooperative Medical Sciences Program (1965-)
- Memorandum of Cooperation (MOC) between AMED and NIH (2016)
- U.S. - Japan Competitiveness and Resilience (CoRe) Partnership (2021)
- Others: Participation in ASPIRE calls (alignment type), etc.

Collaboration with the EU

- Research exchange in cooperation with the European Research Council (ERC-IA)
- Signing of a working arrangement with HERA (2023)
- Signing of a memorandum of cooperation by AMED's SCARDA and CEPI (2023)

International joint calls and MOC

- International joint calls, MOC and MOC
  Singapore, Spain, UK, Germany, Canada, Lithuania, NordForsk (Finland, Norway, Sweden), Australia, South Africa, Israel, Korea
- Multilateral Joint Research Support Program for East Asia Summit participating countries (e-ASIA)

e-ASIA member countries

Collaboration with the UK (MRC)

2017 Memorandum of Cooperation (MOC → **2022 MOC Update**

Infectious diseases	2019	AMED-MRC SICORP
Regenerative medicine	2019	AMED-MRC Joint call
Dementia/Neuroscience	2022	AMED-MRC SICORP

ASPIRE (Alignment)	**2023 AMED ASPIRE** Participation in alignment calls (MRC, NIHR, etc.)
ASPIRE (Joint call)	**2023 AMED ASPIRE JOINT CALL**
ASPIRE (Alignment)	**2024 AMED ASPIRE** Participation in alignment calls (MRC, NIHR, etc.)

Collaborations in African countries

- Science and Technology Research Partnership for Sustainable Development (SATREPS)
- International Collaborative Research Program for Tackling the NTDs (Neglected Tropical Diseases) Challenges in African Countries

Others

Human Frontier Science Program (HFSP)

Japan's international position in science and technology

- Japan faces high expectations from Europe, the U.S., and other developed nations as a partner country in international joint research. These expectations are increasing in response to recent geopolitical changes.
- On the other hand, with the number of internationally co-authored papers being relatively low compared to other countries, and stagnation of researcher exchanges, Japan is not currently part of the international brain circulation network.

All areas	2000 - 2002 (PY) (Average)		
	Adjusted top 10% of papers		
Country/Region	Integer count		
	Number of papers	Share	Rank
U.S.	35,734	47.5	1
United Kingdom	8,529	11.3	2
Germany	7,381	9.8	3
Japan	5,470	7.3	4
France	5,292	7	5
Canada	4,082	5.4	6
Italy	3,281	4.4	7
Netherlands	2,717	3.6	8
Australia	2,476	3.3	9
China	2,380	3.2	10
Spain	2,201	2.9	11
Switzerland	2,167	2.9	12
Sweden	1,898	2.5	13
Belgium	1,214	1.6	14
South Korea	1,171	1.6	15

All areas	2010 - 2012 (PY) (Average)		
	Adjusted top 10% of papers		
Country/Region	Integer count		
	Number of papers	Share	Rank
U.S.	48,987	41.2	1
China	15,986	13.4	2
United Kingdom	13,651	11.5	3
Germany	12,287	10.3	4
France	8,464	7.1	5
Canada	7,393	6.2	6
Italy	6,508	5.5	7
Japan	6,179	5.2	8
Australia	5,882	4.9	9
Spain	5,626	4.7	10
Netherlands	5,427	4.6	11
Switzerland	4,233	3.6	12
South Korea	3,418	2.9	13
India	3,086	2.6	14
Sweden	2,976	2.5	15

All areas	2020 - 2022 (PY) (Average)		
	Adjusted top 10% of papers		
Country/Region	Integer count		
	Number of papers	Share	Rank
China	78,155	38.8	1
U.S.	54,534	27.1	2
United Kingdom	21,070	10.5	3
Germany	16,071	8	4
Italy	13,175	6.5	5
Australia	12,161	6	6
India	11,136	5.5	7
Canada	11,038	5.5	8
France	10,171	5	9
Spain	8,926	4.4	10
Netherlands	7,615	3.8	11
South Korea	7,338	3.6	12
Japan	7,302	3.6	13
Switzerland	6,226	3.1	14
Iran	5,990	3	15

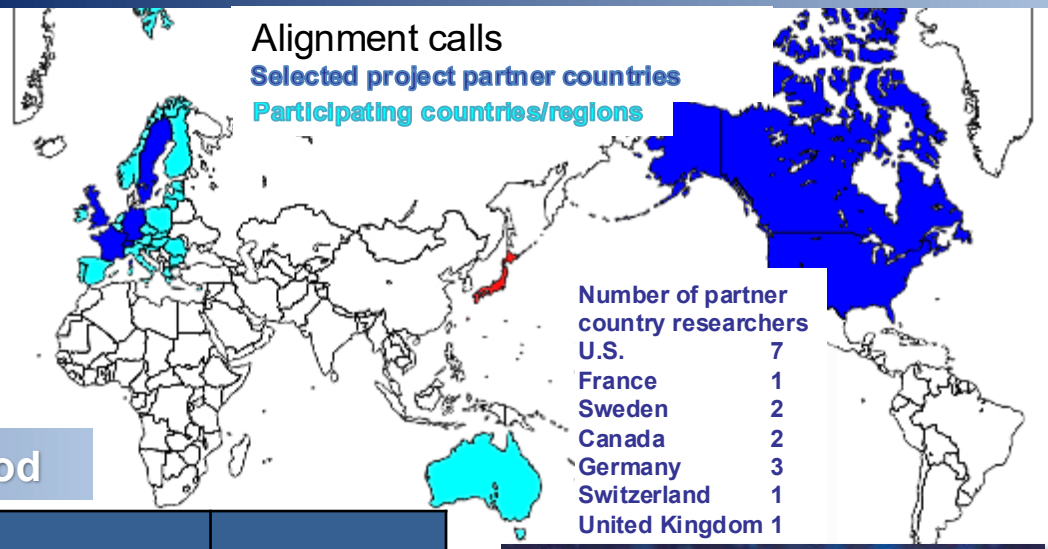
[Source] Science and Technology Indicators 2024 *Processed by AMED
NISTEP RESEARCH MATERIAL No.341 DOI: https://doi.org/10.15108/rm341National Institute for Science and Technology Policy: Japanese Science and Technology Indicators [Figure 4-1-6] Number of papers by country/region, adjusted top 10% of papers: Top 25 countries/regions

Advanced International Collaborative Research Program (ASPIRE)

Adopting Sustainable Partnerships for Innovative Research Ecosystem

Scale and flexibility of international joint research support

- The scale and support period of our existing international joint research frameworks are insufficient (it is regarded as “too little, too late”), and we are unable to support international joint research on the scale carried out by Europe, the U.S., and other developed nations.
- Japanese researchers are dropping out of top international scientific circles, and opportunities to foster young talent are being lost.



Selected projects for alignment calls (1st round): 5-year research period

Type	Total amount for research period (direct expenses only)	Research representative	Affiliated institution	Research and development topics	Partner country
A	380 million yen	Masahito Ikawa	Osaka University	International collaborative research pioneering next-generation assisted reproductive medicine	U.S.
		Kei Sato	The University of Tokyo	The pandemic 5W1H investigation	U.S. France
		Katsuhiko Shirahige	The University of Tokyo	Chromatin molecular pathology for precision medicine	Sweden
		Hiroaki Wake	National Institutes of Natural Sciences	International collaboration to understand physiological mechanisms of glial cells and their pathological transitions	Canada, Germany Switzerland, U.S.
B	115 million yen	Shigeharu Fujieda	University of Fukui	Exploration of novel therapeutic targets and construction of a foundation for personalized medical strategies based on the onset and refractory mechanisms of chronic rhinosinusitis in Japanese and U.S. patients	U.S.
		Yoshio Yamaoka	Oita University	Understanding the immune response to the carcinogenic pathogen Helicobacter pylori and its application to immunotherapy	Sweden

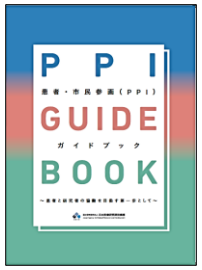
AMED Social Co-creation for R&D

In October 2021, we created the concept of “Social Co-Creation,” established a specialized department, and are promoting initiatives across the organization with the aim of pursuing medical research results that meet the true needs of society and achieving their practical application and delivery to patients and their families as soon as possible, while gaining the safety, security, understanding, and trust of the public.

2017-2019 (1st Phase)

Patient and Public Involvement

“Patient/Public Involvement in Research” (PPI) basic survey



April 2020 (2nd Phase)

Planning and implementation of infectious disease research and development ELSI program

Implementation of four projects as an emergency response to COVID-19

October 2021 (2nd Phase)

Concept creation/department establishment for AMED Social Co-creation

February 2023 (2nd Phase)

Launch of the AMED Social Co-Creation EXPO

Established as a place for dialogue where various stakeholders such as researchers, patients and their families, pharmaceutical companies, and citizens can gather together.

December 2024 (2nd Phase) *R&D starting from 2025

Establishment of the AMED Research Ethics and Social Co-creation Promotion Program

R&D recruitment call program for ELSI, research ethics, and social co-creation related to medical R&D

April 2025 (3rd Phase)

Establishment of the Social Co-Creation Promotion Division as an independent division (planned)

AMED Social Co-creation

Working with society to build up medical care and building the next society together

Responding to ethical, legal and social issues (ELSI)

Patient/citizen involvement, diversity promotion, etc.

Responding to Sustainable Development Goals (SDGs)

89% Percentage of projects in which AMED hears about “Patient/Public Involvement in Research” (PPI) initiatives during recruitment calls (FY2024)

77 items The number of lectures, training sessions, manuscript creations, etc. conducted by social co-creation personnel based on external requests to AMED during the 2nd Phase.

Promotion of social co-creation initiatives in research and development is included as an item in both the **3rd Phase of the Health and Medical Strategy (Cabinet decision on February 18, 2025)** and the 3rd Phase of the Plan for Promotion of Medical Research and Development (decision by the Headquarters for Healthcare Policy on February 18, 2025).

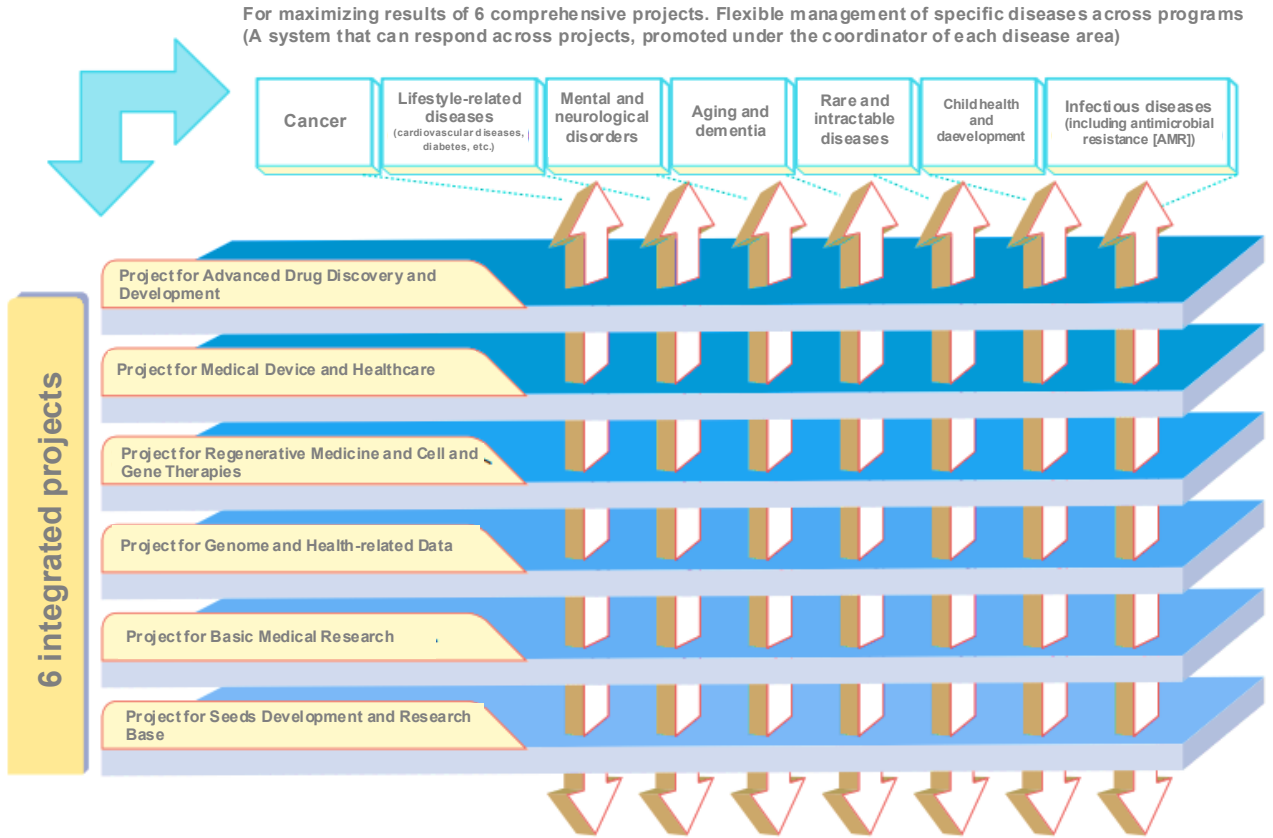
Perspective for the 3rd Phase

Reviews on 6 integrated projects in the 2nd phase

Since last fiscal year, through holding integrated project collaboration promotion meetings, etc., with the participation of PDs and others of each project, we have continually reviewed activities in the 2nd Phase and discussed issues for the 3rd Phase.

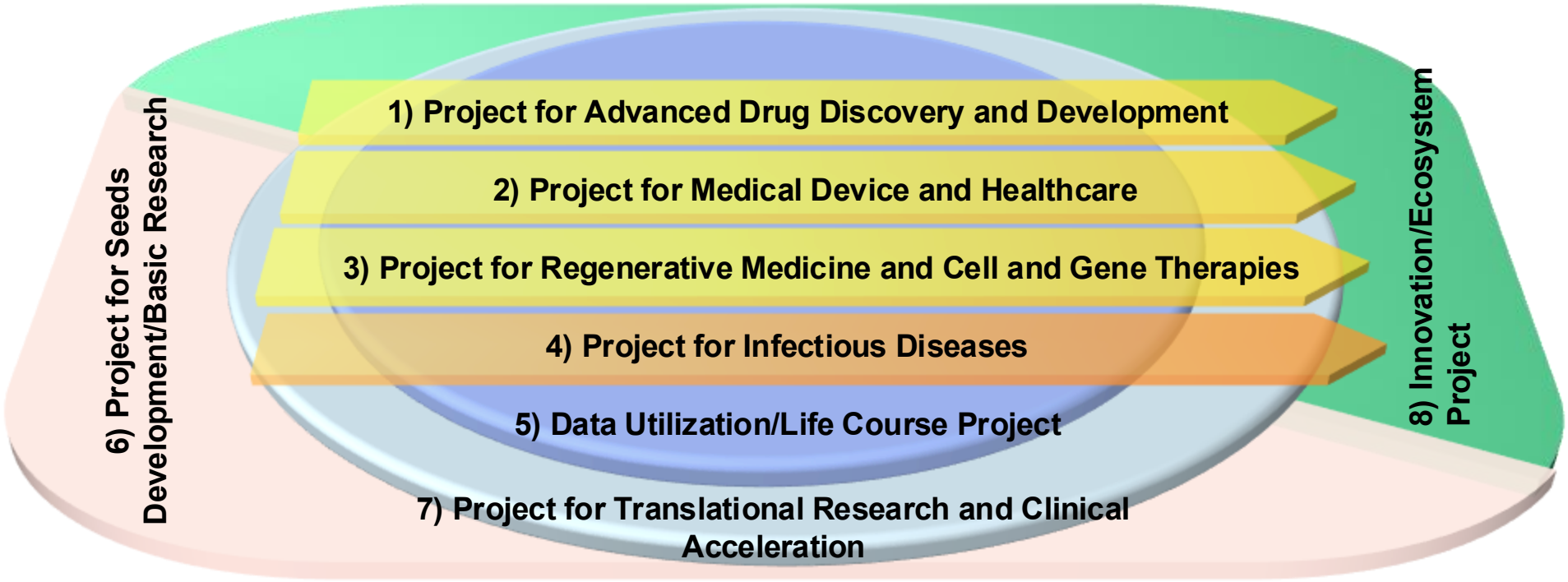
2nd Phase initiatives

- By reorganizing projects into six integrated projects centered on modalities, etc., development objectives such as pharmaceuticals, medical device development, and regenerative medicine became clear, and researchers' awareness of practical application changed.
- In the 1st Phase, the projects were separated into cross-sectional projects and disease-specific projects, but in the 2nd Phase, they were consolidated into projects with common research and development modalities, making it possible to develop new medical technologies that can be used cross-sectionally, such as drug delivery systems (DDS), for various diseases.
- Through AMED-FluX for pharmaceutical projects, the practical application program for medical device projects, and the network program for the Project for Regenerative Medicine and Cell and Gene Therapies, we have promoted initiatives such as escort support that leads from basic research to practical application from a variety of perspectives, including strategy building for technology development, regulatory requirements, corporate collaborations, etc.



The integrated project structure centered on modalities in the 2nd Phase is basically functioning effectively.

Image of 3rd Phase integrated project/area structure



R&D related to disease areas

The following areas are set across the above integrated projects.

Cancer / Intractable and rare diseases / Life course

Working toward social implementation of research and development supported by AMED

Direction towards practical application of AMED basic research

How to incorporate it into drug discovery process of pharmaceutical companies

Material from Hiroaki Ueno, President of Japan Pharmaceutical Manufacturers Association

Basic research	Applied research	Non-clinical study	Clinical Trial			Approval
Target, modality / Indications			Ph1	Ph2	Ph3	

Drug discovery process

Basic Research Supported by AMED

A huge gap

Lead → Non-clinical POM → Optimization → Candidate selection → IND → POC → Application → Approval

License-out to startups and pharma at an appropriate stage

Academia (AMED) and pharma need to work together in order to bridge this gap

- **To link basic research to drug discovery, it is necessary to create "drug discovery research project" using appropriate combination of targets, modalities, and indications.**
  → Add ideas and combine with other researches from the perspective of experts with corporate experience
- **In this way, it is necessary to create "drug discovery research project" and incorporate it into "drug discovery process".**

Strengthening the AMED system (inter-program collaboration functions, etc.)

Information aggregation/analysis (expert assessment)

- Analysis and investigations using trends in the medical community, information from patients and their families, international research trends, databases, etc.
- Participating in communities and building networks to gather information, etc.
- Creating a short list of important technologies, performing impact analysis

Target assets
Approx. 2,600 projects/year
(including approx. 1,000 new projects)

Exit strategy planning

- Milestone setting for commercialization
- Exploration of related research and technology necessary for social implementation, intermediation between researchers, engineers, medical personnel, companies, etc.
- Cross-sectional management that goes beyond the boundaries of business and departments

Proposal adjustment

- Flexible operation of new adoption process to promote continuous support (pairing/matching)
- Hearing opinions from PDs, PSs, POs, DCs, evaluation committee, etc.; holding joint meetings and symposiums with PSs and POs

Continuous support → Effect

- **Accelerating the out-licensing of excellent seeds**
- **Maintaining and strengthening competitive advantage**
- **Exit-oriented R&D management**
- **Practical application of research results that have not been utilized until now**

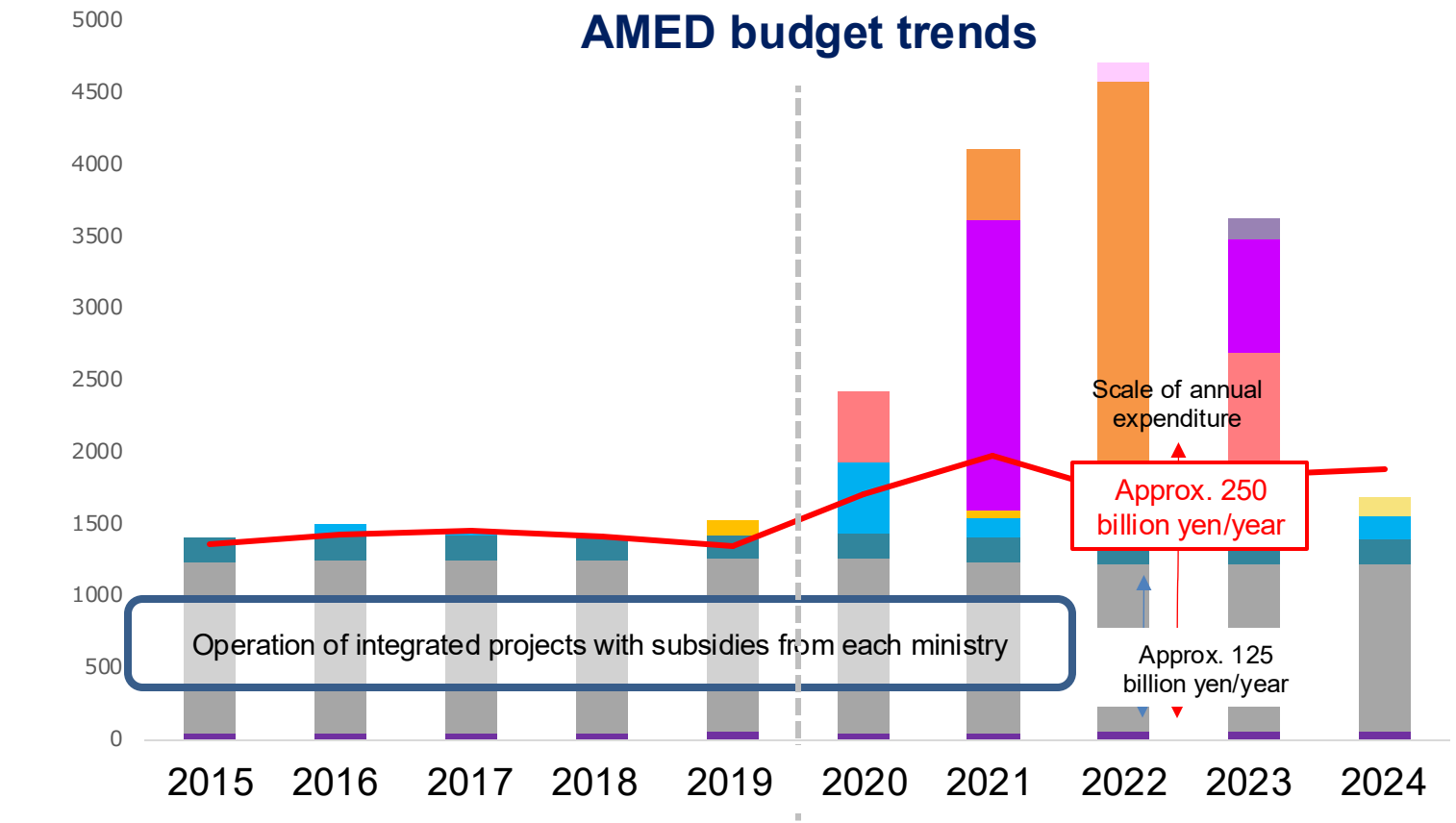
Issues to be Considered for the 3rd Phase Plan for Promotion of Medical Research and Development

1st Phase
President, 1 Executive Director, 2 auditors
567 employees
(including 386 full-time employees)

As of Jan 1, 2019

2nd Phase
President, 1 Executive Director, 2 auditors
697 employees
(including 464 full-time employees)

As of Dec 1, 2023



(Program periods are tentative.)

Advanced International Collaborative Research Promotion Program
*From FY2023: 6.1 billion yen
Alliance program for Innovative Medical/healthcare research by Government-Academia-Industry Collaboration
*FY2022 to 2027: 8 billion yen

Strengthening Program for Pharmaceutical Startup Ecosystem
*FY2022 to 2031 (10 years): 350 billion yen

(SCARDA related) Japan Initiative for World-leading Vaccine Research and Development Centers *FY2022 to 2026 (5 years): 51.5 billion yen
Program on R&D of New Generation Vaccine Including New Modality Applications
*FY2022 to 2026 (5 years): 150.4 billion yen

Vaccine Development Promotion Program (related to COVID-19 countermeasures)
*FY2020 to 2024 (5 years): 50 billion yen

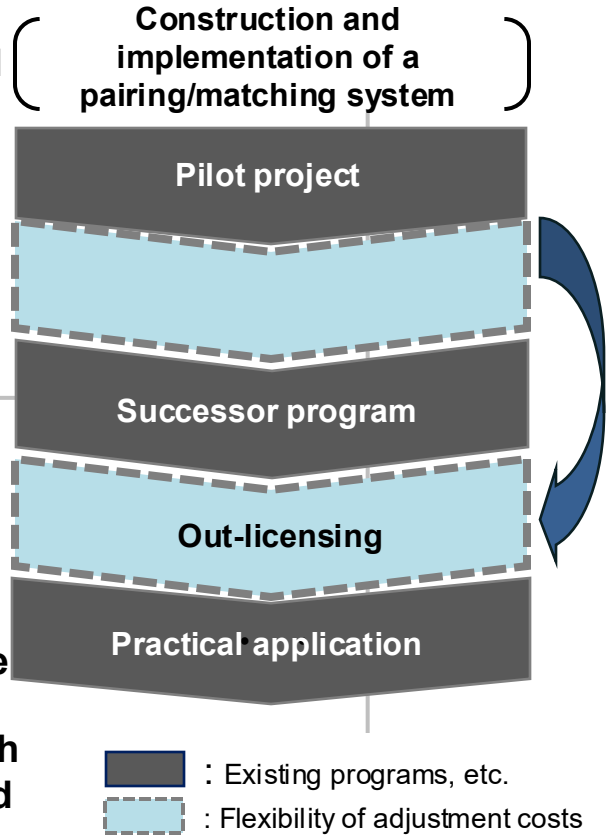
Moonshot Research and Development Program
*FY2020 to 2027 (8 years): 51.5 billion yen

Support Program for University-originated Medical Startups
*FY2023 to 2029 (6 years 15.2) billion yen

Medical Research Support Program
*FY2024 to 2027 (4 years): 13.4 billion yen

Review of AMED's research and development support

Means / Effect	Flexibility of adjustment costs	Strengthening the system
Elimination of gaps between programs	◆ **Flexible measures not limited by the framework or scope of programs** ◆ **Measures aimed at promoting practical application** ◆ **Reducing of fiscal year constraints** ◆ Continuous support of promising seeds through President's discretionary expenses	◆ **Re-examination of review committee, industry participation** ◆ **Strengthening of R&D management functions** • Multi-faceted judgment and expert assessment of seeds • Development know-how/intellectual property guidance • Exploring and incorporating related research and technology for strengthening and creating seeds • Exit strategy planning, stage gate setting • Proposal adjustment • Process management, cross-sectional management ◆ **Strengthening of operational functions** • Multifaceted evaluation of inter-program collaboration measures, PDCA implementation • Management of drug discovery research (portfolio management, go/no-go decision-making, budget management) • Proposals for reviewing fast-pass designs and program designs based on on-site experience
Early out-licensing of seeds	◆ **Establishment of conditions required for out-licensing** • Efficacy/safety/reproducibility data sufficient for risk-taking decisions • Data/intellectual property strategies, etc. ◆ **International advantage of cutting-edge technology trends** ◆ **Market trends and competition research** ◆ **From pilot projects to out-licensing and commercialization** ◆ **Support for direct cases (fast pass)**	



Scenes from Boston branch offices (October 2024)

Koch Institute
Professor Robert Langer, MIT

Broad Institute

Lab Central

10th AMED

Towards the next 10 years — Thank you for your attention.