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October 2024 (3rd Edition)

Japan Agency for Medical Research and Development



Our mission is the swift and practical application of medical research outcomes for the benefit of patients and their families.

The Japan Agency for Medical Research and Development (AMED) was established in 2015 as a funding agency to support medical research and development, and to nurture the research ecosystem in accordance with national healthcare policy. We offer various R&D management functions to maximize the impacts of AMED programs.

Currently, under the second medium- to long-term plan (2020–2024), we are striving for the rapid application of the outcomes of research in practice. We do this by promoting seamless medical research and development from basic research to practical application, centered around six " integrated projects" that focus on modalities such as drug discovery. Our goal is to advance new healthcare technologies and approaches, and to make them a reality for patients everywhere.

To achieve this mission, it is crucial that research and development projects transcend the boundaries of individal disciplines. Links must be established between research areas, and projects designed to combine research across a wide range of fields, not limited to medicine and pharmacology. While closely monitoring the latest scientific trends in research, we conduct flexible and dynamic allocation of funding, enabling AMED to serve as a catalyst for R&D progress. We will continue to create new initiatives and mechanisms that promote collaboration and transdisciplinary advancement. At the same time, we aim to further accelerate our initiatives for "co-creation with society" in medical research and development, including the participation of patients and the wider public in research projects.

Aiming to achieve the goals of the government' s "Strategy for Strengthening the Vaccine Development and Production System," we established the Strategic Center of Biomedical Advanced Vaccine Research and Development for

Preparedness and Response (SCARDA) within AMED in March 2022. This initiative aims to support the rapid development of new vaccines in line with national policy, to save lives in the event of an infectious disease emergency. SCARDA works in collaboration across related government agencies, implementing a comprehensive strategy and sharing information. Additionally, SCARDA supports R&D for new modalities that will contribute to novel vaccines and approaches to vaccine development in the future.

Internationally, we collaborate with a wide range of overseas partners to promote joint research, human exchange, and other cooperative initiatives. We also collect and disseminate relevant information to help advance projects throughout AMED. To ensure the rapid commercialization of results from AMED-funded research, we provide opportunities to connect promising research seeds with business needs through a dedicated match-making system. Furthermore, we offer guidance on the management of intellectual assets, help to develop exit strategies, and offer comprehensive support as a partner for venture capital investment in research.

Looking to the future, we will continue in our endeavors to improve healthcare by enabling world-leading new medical advances. Our work will remain fully grounded in the needs of the medical community, researchers, industries, and other stakeholders, including the patients who are central to our mission.

Japan Agency for Medical Research and Development President MISHIMA Yoshinao, PhD



Japan Agency for Medical Research and Development (AMED)

Fstablished

April 1, 2015

Ministers in charae

The Prime Minister

The Minister of Education, Culture, Sports, Science and Technology The Minister of Health, Labour and Welfare The Minister of Economy, Trade and Industry

Laws forming the basis for AMED

Act on Promotion of Healthcare Policy Act on Japan Agency for Medical Research and Development



Who we are

AMED was established in 2015 for advancement of medical discoveries that make life better for everyone.

President -

MISHIMA Yoshinao, PhD

Number of staff

689 (as of January 1, 2024)

Budget –

124.5 billion yen (FY2024)

Organization



accine Research and Development

Senior Director	Department of Planning and Management	ation
	Department of General Affairs	ninistr Sectio
	Department of Financial Affairs	Adr
	Office of Project Management	uo
	 Department of Research Integrity and Project Management 	ject Secti
	Department of Intellectual Property and Technology Transfer	Pro
	Department of International Strategy	Su
Director	Department of Innovative Drug Discovery and Development	
	Department of Medical Device and Healthcare	
	Department of Regenerative Medicine and Cell and Gene Therapies	tion
	Department of Health and Clinical Data	ect nt Sec
	Department of Basic Medical Research	Proj
Senior Director	Department of Innovation and Clinical Research Center	Mana
	Department of Cyclic Innovation	
SCARDA*	Department of Advanced Vaccine Research and Development	

Our mission

AMED plays a central role in supporting research and development in the medical field and putting in place the necessary environment for research. Our aim is to ensure that the outcomes of medical research and development are applied and delivered to patients and their families as soon as possible.

Management policy

- We promote continuous medical research and development from basic research to practical application, and we work to disseminate research outcomes and ensure their seamless application.
- We collaborate with partners globally to promote joint research based on international trends.
- We act as a catalyst to promote research and development to pave the way toward the creation of medical innovations.
- We continually improve processes for the effective management of research funding and operational efficiency.
- We support collaborations between industry and academia with the aim of practical application of research outcomes.
- We work to promote research integrity and ensure compliance with relevant regulations.

Basic Research Application Research Pre-Clinical Research Clinical Research/Trial Market/Clinical Use

Program management framework

AMED assigns highly-experienced scientific experts with outstanding records of achievement in their research fields to oversee our research programs, as Program Directors (PD), Program Supervisors (PS) and Program Officers (PO). The PD, PSs, and POs work together to achieve an in-depth understanding of each field as a whole, and they not only provide highly specialized coordination and management of research and development activities in their own fields, but also promote interdisciplinary collaboration.

They also provide consistent management to ensure

that outstanding research and development proposals are attracted and evaluated, and that the results of basic research feed into clinical research and practical implementation.

We invite submission of research and development proposals, and we select proposals that are in line with the aims of our projects and are outstanding from the perspective of scientific merit and practical feasibility. In addition, the progress of research projects that we support is reviewed by an evaluation committee comprised of external specialists. At AMED, we work carefully to ensure the participation of numerous specialists from a wide range of areas in our evaluation committees, and we are looking to improve the diversity of their membership in terms of age, gender, and institutional affiliation. We are also putting in place and promoting systems for specialists from outside of Japan to take part in our evaluation processes. At the same time, we are working to further improve both our evaluation methodology and our management of conflicts of interest.

Promotion of R&D

AMED has established six "Integrated Projects" centered on modalities, and under the Program Director (PD) these will coordinate with the projects of related ministries and agencies, and will be centrally promoted from basic research to practical application. Research in specific disease areas will be promoted across the integrated projects so that it can be managed flexibly by the coordinators of each disease area.

AMED implements a technical approach with clearly defined development objectives such as "prevention, diagnosis, treatment, prognosis, and quality of life", with a focus on extending healthy longevity.

The projects are solicited through wide-ranging calls for proposals, which are aimed at outstanding individuals working in world-class institutions. We receive approximately 4,000 proposals every year and between 800 and 900 proposals are awarded funding.

Research in specific disease areas is managed flexibly across all six integrated projects, and promoted under the coordination of experts in each respective field



Main projects

PROJECT FOR

Advanced Drug Discovery and Development

This project supports pharmaceutical R&D taking into account the characteristics and properties of different modalities in areas ranging from target identification to clinical research, in order to promote the practical application of drugs to address high medical needs. For example, essential R&D activities such as the development of new modalities, optimization of each modality's design, compound optimization, activity assessment, evaluation of efficacy/safety, and development of new manufacturing technologies are covered by this project. In addition, it aims to enable the discovery of innovative drugs for various diseases, through the utilization of new

technologies and insight about various modalities for diseases from a cross-sectional perspective. This project also focuses on establishing the infrastructure to support drug discovery, including technologies for drug design, compound libraries, and sharing of analytical tools.



PROJECT FOR

Medical Device and Healthcare

This project supports R&D of medical devices/systems and healthcare, such as integrated artificial intelligence and Internet of Things technologies, measurement technologies, and robotics technologies, in its aim to achieve improved diagnosis, more effective treatment and prevention of diseases, and better quality of life.



PROJECT FOR

Regenerative Medicine and Cell and Gene Therapies

This project supports basic research on regenerative medicine/cell therapies, non-clinical and clinical research, development of foundational manufacturing technologies, research utilizing disease-specific induced pluripotent stem cells, and establishment of necessary foundational structures for research, as well as R&D in the field of gene therapies.



PROJECT FOR

Seeds Development and Research Base

This project combines with clinical research and the other integrated projects in supporting basic research and international research collaboration with the potential to provide seeds for creating ground-breaking new research and modalities, while also cultivating a research system that transcends the boundaries of academic disciplines. It promotes the development of a seamless research system and infrastructure that supports research from basic through to clinical phases, while also supporting reverse translational research (rTR). This project also aims to develop systems and mechanisms for discovery and the translation of research seeds, as well as for the implementation of high-quality clinical research in Centers for Advancing Translational Research and clinical research core hospitals.

PROJECT FOR

Genome and Health-Related Data

Towards the realization of genomic and personalized medicines, this project promotes the creation of infrastructures for and utilization of genomic and related data. It also supports medical R&D that contributes to improved understanding of the onset of various diseases, prevention of serious illnesses, and improved diagnostics and therapies, through investigation of associations between genetic polymorphisms and various diseases across life-stages. Moreover, this project will support

various studies for the implementation of new diagnostics and interventions that utilize medical data (e.g. medical registries), and studies for the collection of intangible assets, such as knowledge and experience.AMED will progress its data-sharing objectives based on this project.



Basic Medical Research PROJECT FOR

This project supports basic R&D to better understand various functional aspects of life phenomena such as brain functionality, immunity, and aging, as well as R&D to elucidate various disease mechanisms. Results will be linked with clinical R&D and other integrated projects, while R&D that incorporates clinical aspects will also be supported.





Other projects

Moonshot Research and Development Program

Moonshot Goal 7: Realization of sustainable care systems to overcome major diseases by 2040, for enjoying one's life with relief and release from health concerns until 100 vears old

The "Moonshot Research and Development Program" is a large-scale national research program that aims to create disruptive innovations originating from Japan, and promotes challenging R&D (Moonshots) based on revolutionary concepts that are not simply the extension of existing technologies. The program promotes R&D in view of our future society, targeting complex social issues, the resolution of which will have profound impact. Under the direction of Moonshot Program Director, Dr. HIRANO Toshio, and with "Control of chronic inflammation" as the key objective, eight project managers are working on eight projects.



Alliance program for Innovative Medical/healthcare research by Government-Academia-Industry collaboration

Realization of research and development of pharmaceuticals, medical devices, healthcare, etc. under the new framework of Government-Academia-Industry collaboration

The promotion of research and development through Industry-Academia collaboration has become more important in recent years due to increasing expectations for the implementation of research results in society. In the "Alliance program for Innovative Medical/healthcare research by Government-Academia-Industry collaboration

(AIMGAIN)", multiple academic and industrial partners collaborate to conduct multi-year (up to 5 vears) research and development activities. supported by government funds and company resources.

This program aims to conduct a wide range of industry academia collaborations over multiple

years, in non-competitive areas that are difficult for a single academic or industrial partner to tackle alone, and to conduct research and development of innovative pharmaceuticals, medical devices, healthcare, etc. that are impossible to create through conventional schemes.

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

Based on the national strategy, the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) was established at AMED in March 2022 to strengthen strategic research funding and to promote the formation of world-class research and development centers. SCARDA will prepare for future infectious disease emergencies very well and respond to more virulent mutant strains and infectious diseases that could be a threat in the future.

The three core functions of SCARDA: 1. Extensive information collection and analysis 2. Strategic decision-making 3. Flexible funding

Japan Agency for Medical Research and Development Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response

Programs related to the Strategy for Strengthening the Vaccine Development and the Production System

Strengthening Program for Pharmaceutical Startup Ecosystem

Most new drugs in recent years have been developed by pharmaceutical startup companies, and it is startups that were the first to successfully develop vaccines during the COVID-19 pandemic. The development of new drugs requires a large amount of funding, but it is more difficult to secure the necessary funds in the pharmaceutical startup ecosystem in Japan, compared with those in Europe or the United States. To solve the shortage of large-scale development funds, this program supports the





Program on R&D of new generation vaccine including new modality application

With regard to prioritized infectious diseases stipulated by the government, AMED aims to provide safe and effective vaccines that can make domestic and international contributions in the event of an infectious disease emergency at the earliest possible juncture. Accordingly, in anticipation of an infectious disease emergency, support is provided for (i) vaccine development against the prioritized pathogens and

(ii) research and development into new modalities contributing to vaccine development through integrated and flexible allocation of budgets.





Japan Initiative for World-leading Vaccine Research and Development Centers

Aiming for the achievement of Japanese-made vaccines, world-leading research and development centers (a flagship center, synergetic centers, support institutions) have been is strengthened and promoted, with the aim of achieving practical results during normal period.



development and commercialization activities of pharmaceutical startup companies, especially those engaged in non-clinical studies. Phase 1 clinical studies. Phase 2 clinical studies or exploratory clinical studies. The startup companies must also receive funding from venture capital firms registered with AMED. These registered firms specialize in drug development and provide hands-on business management and commercialization support.



Adopting Sustainable Partnerships for Innovative Research Ecosystem (ASPIRE)

ASPIRE (Adopting Sustainable Partnerships for Innovative Research Ecosystem) based on sufficient funds supports large-scale collaborative joint research projects in cutting-edge fields, to be conducted at the initiative of the Japanese government in collaboration with advanced countries with high standards of science and technology.

Through international research collaboration supported by this program, Japanese researchers will participate in the worldwide scientific top tier. The exchange of excellent

researchers between Japan and partner countries will also be strengthened. These researchers are expected to be leaders in the next generation. This will promote international talent mobility and circulation, and contribute to long-term collaborative networks.



WEB site —

The AMED website provides basic information on AMED along with details of medical research and development programs, calls for proposals, events, press releases, and achievements. Feel free to visit the website if you are interested in AMED projects or wish to learn the latest information on medical research.

YouTube

of our operations.

X (GL)

announcements from AMED.

Information sharing

https://www.amed.go.jp/en



The AMED YouTube channel offers recordings of symposiums and conferences, as well as briefings on project applications and procedures, and explanatory videos on other aspects

https://www.youtube.com/@amed



Our X feed provides up-to-date information on AMED and its activities, such as the launch of calls for proposals and selection outcomes, information on events, and other

https://x.com/amed_officialql











Official Twitter account of the Japan Agency for Medical Research and Development (AMED). Japanese:@AMED officialJP

International strategy of AMED

In light of the challenges facing our super-aged society, as well as global emergencies such as pandemics, AMED continues to drive forward collaboration with partner countries worldwide that are leading R&D advances in various medical fields. For the most cutting-edge R&D, we focus on the research fields of infectious disease, genome medicine, cancer, and dementia. We are committed to international collaborations in genomic research, actively utilizing and contributing to frameworks that enable international sharing of genomic and clinical data. We are working to strengthen Japan's industrial

competitiveness, with a focus on sustainable operations that contribute to the improvement of healthcare globally and on international joint research with a view to practical implementation. We also aim to foster the development of human resources capable of engaging in these international activities.

Human Frontier

Science Program

HFS

In order to enhance international joint research and development, AMED has built cooperative frameworks with 13 institutions in 11 countries /regions based on memorandums of cooperation and participates in 10 international alliances. Eight

Collaborative research



Fostering and utilizing internationally competent research personnel ~Interdisciplinary and International Cooperation~

CASE STUDY

Human Frontier Science Program

The Human Frontier Science Program (HFSP) is an international program that promotes international collaboration in basic research focused on the elucidation of the sophisticated and complex mechanisms of living organisms. HFSP supports a broad range of biological fields, from studies of the molecular basis of biological complexity to research into brain functions and biological systems through its two research grants and two postdoctoral fellowships.

Together with the other member countries, Japan makes financial contributions to the HFSP, provided via AMED from the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Economy, Trade and Industry (METI). President Mishima of AMED serves as a Trustee member representing Japan.

International collaboration

ioint research programs, involving partners from 28 countries, are currently in progress (as of July 2024). We are making use of our overseas office and liaison to build international research networks and develop the research environments,

to promote international joint research, to contribute to global health, and to nurture young researchers who are expected to flourish internationally.

- Ge-ASIA JRP (East Asia Science and Innovation Area Joint Research Program)
- **2**NTDs (International Collaborative Research Program for Tackling the NTDs (Neglected Tropical Diseases) Challenges in African countries)
- SATREPS (Science and Technology Research Partnership for Sustainable Development)
- **O**SICORP (Strategic International Collaborative Research Program)
- **G**Research Program on the challenges of Global Health issues
- **G**U.S.-Japan Cooperative Medical Sciences Program (USJCMSP)
- OU.S.-Japan Cooperative Medical Sciences Program Collaborative Awards for early-stage and female scientists
- ③ASPIRE (Adopting Sustainable Partnerships for Innovative Research Ecosystem)

International alliances and partners

cdisc	Clinical Data Interchange Standards Consortium
Global Alliance for Genomics & Health Collaborate, Imports, Accelerate,	The Global Alliance for Genomics and Health
GACD	The Global Alliance for Chronic Diseases
GL PID-R	Global Research Collaboration for Infectious Disease Preparedness
HFSP Human Frontier Science Program	Human Frontier Science Program
HIROs	Heads of International Research Organizations
CRP	International Cancer Research Partnership
	International Rare Diseases Research Consortium
🗿 jpiamr	Joint Programming Initiative on Antimicrobial Resistance
T translation together	Translation Together
	Health Emergency Preparedness and Response Authority
CEPI	Coalition for Epidemic Preparedness Innovation

AMED at a glance!

AMED's medical research and development work is wide-ranging. Here are some data that will help you understand at a glance who we are and what we do.



R&D projects



* The number of R&D projects is the number of projects in FY2023, including new and continuing projects. * Based on AMED data (as of June 2024). It excludes projects from the Cyclic Innovation for

Clinical Empowerment (CiCLE). * "Others" includes basic R&D projects that do not target specific diseases, and R&D projects

for research infrastructure and drug discovery infrastructure development, etc Figures with fractions less than one unit are rounded to the nearest unit.

> Empowerment (CiCLE). * R&D expenditures are the total expenditure amounts for grants Foundations. awarded and contracted by the Incorporated associations, etc. end of EV2023 for all supported Others 100 8.2 billion yen (5.0%) commissioned or subsidized million yen (0.1%) projects, including indirect costs Local government and amounts assigned or subcontracted to other research organizations, etc. institutions by the Principle 2.7 billion yen (1.7%) Investigators. * Figures with fractions less than Private companies, etc. one unit are rounded to the FY2023 nearest unit. 18.9 billion yen (11.5%) Universities, Research institutes, etc. Oliversities, etc. 133.9 billion ven 105.3 billion yen (64.3%) Private companies, etc. Incorporated Over 70 **18.9** billion ven administrative 18 (1.9%) agencies, AMED supported a wide range 60-69 National research of projects from basic medical 149 (15.8%) research to practical institutes applications 28.7 billion yen (17.5%) **50-59** 287 * All Principle Investigators whose (30.4%) projects started during FY2023. * Ages are taken at the beginning of the fiscal year when the research started. * Data submitted to e-Rad (as of June 2024) was used to calculate the age of the investigators (excluding any for whom date of birth was not available).

Intellectual Property In FY2023,

2,756

IP Forms (reports on the creation, filing, and acquisition of rights to inventions, etc.) were submitted by grantees.

FY2023 AMED supported 2,629 R&D projects

from basic research to practical applications.

Applications, Awards, and Success Rates



Competing Applications Awards - Success Rates

* This is compiled for each fiscal year based on public information AMED's calls for proposals (as of August 2024).

* Success rate is the ratio of the number of awards to the number of all applications received for each fiscal year.

* Based on AMED data (as of June

2024). It excludes projects from

the Cyclic Innovation for Clinical

FY2023

Institutional Classification: **R&D** expenditure by institution type

Competing **4,110** Applications Awards **948** Success Rates 23.1%

Ages of Principle Investigators of newly awarded grants

