10th ANNIVERSARY BOOKLET

2015-2024

- Retrospective and Prospective -

Japan Agency for Medical Research and Development

The Japan Agency for Medical Research and Development (AMED) will mark the 10th anniversary of its foundation in April 2025.

I would like to express my sincere gratitude to the many people and organizations involved: the Cabinet Office; the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labor and Welfare; the Ministry of Economy, Trade and Industry; and all the other relevant government ministries and agencies that have consistently guided and supported the agency since its founding. Similarly, I would like to express my sincere gratitude to industry, universities and other research institutes, academic societies, and related overseas organizations. I would also like to express my sincere respect for the agency directors and personnel who are now committed to the AMED through their positions and those who have worked for the AMED in the past and made significant contributions.

Our agency was founded in line with the governmental health and medical strategy to serve as a funding agency for medical research and development in Japan. The AMED is expected to play the core function of creating and supporting an environment that enables medical research and development. Since its foundation, the AMED has consistently worked to ensure rapid practical application of research outcomes so that they become available to patients and their families as soon as possible.

If we are to steadily advance medical research and development in Japan, deploying the activities across the relevant ministries and developing coordination with the different research projects and interdisciplinary research beyond medicine and pharmaceutics are very important. To this end, the AMED has closely monitored the latest research trends and the progress in existing research projects. The agency has been flexibly and promptly allocating funds. The AMED has also been working for social co-creation to encourage patients and the general public to participate in research programs. As a recent initiative, the AMED founded the Strategic Center for Advanced Research and Development (SCARDA) in March 2022 in line with the goals of the government's Strategy for Strengthening the Vaccine Development and Production System. The AMED aims to ensure that vaccines are developed in a timely manner as a part of the national policy in the event of a viral epidemic. Currently, the agency is working on the research and development of novel modalities.

Internationally, the AMED has established several offices overseas, which are now in operation. The agency also works closely with such overseas institutions as the National Institute of Health (NIH) in the United States and the Medical Research Council (MRC) in the United Kingdom to boost joint international research and personnel exchanges and to collect and share information.

In addition, the AMED has been working to provide opportunities to match promising seeds from research institutions with corporate needs in order to put research results into practical use as soon as possible. The agency has also been operating matching mechanisms, developing intellectual property management and exit strategies, and recently started an initiative to accompany ventures and startups in its efforts to provide effective and careful support.

The third medium- to long-term plan (2025 to 2029) will begin in April 2025. The agency will continue to adhere to the AMED mission and multiply its efforts going forward. Basically, the AMED will take over the research and development system with a focus on six projects based on the modalities of the second plan. However, the agency will launch additional projects. Specifically, the Infectious Disease Project, a new project that aims to consolidate the existing infectious disease-related activities in order to increase preparedness against the potential infectious disease pandemic, will start soon. Second, the AMED will consolidate several disease research programs that should take into consideration the course of human life from the reproductive and pregnancy periods to old age into another new project, the Data Utilization and Life Course Project. The agency will set up a third project, the Innovation Ecosystem Project. Funds and other resources will be employed to guide specific research and development toward practical application using hands-on management approaches. Combining the three projects, the agency will move forward with a total of eight projects. In addition, the AMED will more aggressively push for support mechanisms that coordinate and connect existing ministerial subsidies and contract programs.

Along with the commemorative symposium, this book will provide an exceptional opportunity to look back at the initiatives that the AMED has taken since its founding and its associated experience. I hope that it will help you achieve insight into the organization. Now, the AMED has reached its 10th anniversary, an important milestone. The agency understands the expectations of its domestic and international stakeholders and has a grasp of the needs of patients, health professionals, scientists, and the business community. The AMED will further contribute to delivering healthcare enabled by the world's highest level of technology.

Japan Agency for Medical Research and Development (AMED)
President

MISHIMA Yoshinao, Ph.D.

Born in Tokyo, the individual graduated from Tokyo Institute of Technology (currently Tokyo Science University) and completed a doctoral program in Materials Science at the University of California, Berkeley. After serving as a professor and president of Tokyo Institute of Technology and as the director of the Technology Strategy Research Center at the New Energy and Industrial Technology Development Organization (NEDO), they assumed the role of president at the Japan Agency for Medical Research and Development (AMED) in April 2020.

March 2025

In tribute to AMED's Tenth Founding Anniversary

Minoru Kiuchi

Minister in charge of the Healthcare Policy

I would like to express my heartfelt congratulations to the Japan Agency for Medical Research and Development (AMED) on its 10th anniversary.

The population of Japan is aging ahead of the rest of the world, and the average life expectancy has increased to the point that it is said to be the era of 100-year life spans. On the other hand, there are many diseases that threaten our healthy lives, and we still have a long way to go before we reach healthy longevity or a happy aging society. The global outbreak of COVID-19 highlighted the threat of unknown infectious diseases and the importance of preparedness in normal times for such threats. Many people with intractable and rare diseases are eagerly awaiting innovative medicines.Advancements in medicine bring direct benefits to the lives, safety, and security of people, and are the hope of patients and their families. At the forefront of the mission is AMED.

AMED was founded in April 2015 to centrally manage government-sponsored research and development in the medical field, from basic research to development for practical application, and to facilitate the smooth transition of research outcomes into practical use. Currently, AMED provides approximately 150 billion yen to approximately 2,600 projects per year. To date, it has steadily garnered excellent achievements, with more than 130 regulatory approvals for pharmaceuticals, medical devices, and vaccines, and nearly 800 research outcomes transferred to companies. Additionally, AMED is advancing efforts to address social issues, such as the development of novel drugs for intractable and rare diseases and research and development at the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) to prepare for new infectious disease outbreaks. Furthermore, AMED is focusing on research and development projects that are expected to bear fruit in the next 10 years, such as support for regenerative medicine and disease research using iPS cells, a technology originating in Japan, and unique basic research. The history of AMED over the past 10 years is entirely the result of the strenuous efforts of all AMED officials and staff, as well as those who have been involved in its operations so far. I would like to express our sincere respect for them.

In the third phase of the Healthcare Policy and the third phase of the Plan for Promotion of Medical Research and Development, which will begin in FY 2025, we will enhance exit-oriented research and development management and build an ecosystem for drug discovery and medical device development to further accelerate the practical application of research and development outcomes. I will dedicate myself wholeheartedly to facilitating collective effort by industry, academia and government, with AMED at the core, to swiftly deliver innovative pharmaceuticals and medical devices to the people, and to strengthen Japan's international competitiveness as one of the world's leading centers for drug discovery and medical device development.

Medical research and development activities are truly a source of national strength and security in the sense that they protect the people's lives and health and ultimately protect the entire nation. I would like to ask all those involved for their continued guidance and support.

March,2025

In tribute to AMED's Tenth Founding Anniversary

ABE Toshiko

Minister of Education, Culture, Sports, Science and Technology

I would like to extend my heartfelt congratulations to the Japan Agency for Medical Research and Development (AMED) on the 10th anniversary of its founding.

Ten years ago, the AMED was founded to serve as an engine for advancing research and development in the medical field and developing an enabling environment. Since then, the organization has provided financial and carefully developed support to many researchers and institutions.

As one of the competent ministries, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) has spent these 10 years offering its best efforts together with the AMED. Basic research is a source of knowledge and feeds the seeds of innovation. The promotion of basic research is, therefore, critically important for medical research to continue to produce results in the medium to long term. The MEXT contributes more than 50 billion yen, the largest amount in the government, each fiscal year to basic research at universities and other academic institutions together with the AMED. Specifically, it funded regeneration, cell medicine, and gene therapy research projects, such as research projects using iPS cells, as well as brain science research projects focused on dementia. We are determined to continue to lead basic research together during the third Health and Medical Strategy period.

Arguably, the biggest challenge since the AMED was established was the COVID-19 pandemic. The AMED launched the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) to ensure that vaccines are quickly developed during epidemic emergencies. In line with the move, the MEXT started the Japan Initiative for World-leading Vaccine Research and Development Centers, which was managed by SCARDA, to continue working together to prepare for future pandemics.

The Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities warned that the research capabilities of university hospitals are in critical condition. The MEXT has just included a series of budgets for the Medical Research Support Program for Schools and Faculties of Medicine in the FY 2024 supplementary budget. We will work with the AMED to support the efforts of schools and faculties of medicine of universities to build their medical research capabilities.

The AMED, which is responsible for research funding across the ministries involved, is expected to provide centralized support to medical research projects from basic research to the practical application phase and to seamlessly link them to ministerial programs. Although the tasks are challenging, the mission of the AMED, which is to pass the fruits of basic research to industry for practical application as if the results were a baton and discover novel drugs through incessant organizational reforms, is very important for the people to enjoy longer healthy lives. I look forward to making even greater progress in the future.

In closing, I would like to offer the AMED my sincere congratulations and best wishes for its continued success.

March,2025

In tribute to AMED's Tenth Founding Anniversary

FUKUOKA Takamaro

Minister of Health, Labour and Welfare

I would like to extend my congratulations to the Japan Agency for Medical Research and Development (AMED) on its 10th anniversary.

AMED was established in April 2015 to command and guide medical research and development in Japan. In this context, the Ministry of Health, Labor and Welfare merged the National Institute of Biomedical Innovation (NIBIO) and the National Institute of Health and Nutrition (NIHN) in order to support AMED's mission of the centralized coordination of medical research and development. For the past 10 years, AMED has coordinated research and clinical activities to move forward with quick and efficient interactions. The organization has also constructed a research and development infrastructure that reliably enabled clinical research and studies that exceed international standards on study quality. Through these approaches, AMED has provided support for many innovative projects and made a significant contribution to medical research and development.

During the first phase of the Medical Research and Development Promotion Plan, Japan's first anticancer virus drug was discovered. A nationwide diagnostic system was also established to find patients whose diseases were difficult for local medical institutions to diagnose. AMED shared the information with those patients and made research and development efforts to characterize the diseases.

During the second phase, AMED voluntarily supported the development of the COVID-19 vaccine and coordinated with the relevant institutions to commercialize it. The initiative led to the development of a monovalent mRNA vaccine, which was the first domestic COVID-19 vaccine to receive marketing approval. Many people benefited from the vaccine. In addition, AMED linked the businesses focusing on basic research to businesses focusing on product development and then provided all-inclusive support from basic research to the commercialization stage. In effect, AMED garnered substantial achievements: a blood biomarker for pancreatic cancer was developed and later covered as an in vitro diagnostic drug for diagnosis of the cancer by health insurance reimbursement system.

Advances in medical technology shape the future of healthcare and constitute a great asset not only for Japan but for the world. I sincerely hope that AMED will continue its commitment to the mission "Put research results to practical use as quickly as possible and deliver them into the hands of patients and their families" and vigorously drive research and development in the medical field. I also hope that AMED will make further leaps forward toward a society where the world's highest level of medical care is available to the public.

Finally, I offer my heartfelt congratulations to AMED on the 10th anniversary of its founding and wish the agency continued success in the future.

March,2025

In tribute to AMED's Tenth Founding Anniversary

MUTO Yoji

Minister of Economy, Trade and Industry

The Japan Agency for Medical Research and Development (AMED) reached its 10th anniversary this fiscal year. I would like to offer our heartfelt congratulations to AMED on the marking of this milestone.

I would also like to express my respect for the commitments made to medical research and development in our country by Dr. Mishima, President, Dr. Yashiki, Executive Director, and the senior directors, who have tirelessly demonstrated their efforts along with all those involved in AMED.

AMED has achieved substantial success in the past 10 years. In line with the guiding principles of "Leverage the world's highest level of technologies to contribute to the medical services" and "Contribute to economic growth" set forth in the 2020 Second Phase of Japan's Healthcare and Medical Strategy, AMED made progress especially in its efforts to accelerate the incubation of the promising seeds identified through basic research.

In the pharmaceutical field, AMED launched programs with a combined budget of approximately 350 billion yen and provided research and development support to drug discovery venture firms in cooperation with domestic and international venture capitalists. The aim of the initiative was to build a drug discovery venture ecosystem in the hope that it would be the engine for innovation. The ecosystem has developed connections with global counterparts. The connections function as the base for enabling drug discovery venture firms, incubators of seeds, to develop businesses partnerships. In the fields of regeneration, cell medicine, and gene therapy, iPS cell products are now close to receiving marketing approval. The ventures have made major advances in the industrialization of the associated culture and quality evaluation technologies, which were previously challenging tasks.

In the medical device field, AMED has focused on increasing the international competitiveness of the Japanese medical device industry. The organization has pushed forward the development of advanced medical devices that heavily utilize state-of-the-art technologies and partnership between excellent manufacturing companies and frontline health professionals to boost innovation and industrialization. The agency has also focused on its substantial efforts to increase productivity in nursing care activities. AMED has been working to support development and dissemination of technological solutions to the challenges that first-line nursing care workers now face.

AMED has also made great efforts to implement evidence-based and scientifically proven healthcare services. In order to socially implement high-quality healthcare services, the organization has been consolidating the evidence provided by academic societies in related disease fields and developing relevant guidelines. AMED also developed background conditions that enable the guidelines to be widely used by stakeholders.

I would like to express my sincere gratitude to the people involved with AMED for their efforts to date, and I hope that the third phase of the Healthcare and Medical Strategy, which will start during the next fiscal year, will strengthen the organizational base and facilitate further collaboration between businesses to implement research and development and garner further achievements in the real world. The Ministry of Economy, Trade and Industry will also continue to be committed to even greater contributions.

I sincerely hope that as the leading policy implementation organization in Japan AMED will continue to drive scientific research that enables economic growth and develop solutions to social issues.

March,2025

Commemorating AMED's 10th Anniversary

Professor Patrick Chinnery, FMedSci, FRS

Medical Research Council (MRC) Executive Chair

Japan and UK are both powerhouses in science and innovation and the UK ranks second among Japan's international partners for research collaboration in the life sciences. The Medical Research Council was delighted when in 2015 Japan announced the formation of a new agency specifically dedicated to the support of biomedical research. We feel that by working in partnership, the MRC and AMED have strengthened collaborative efforts in our shared area of interest. We were particularly pleased that AMED decided to base its European office in London and, at the launch of the AMED London office in 2017, MRC and AMED signed a joint Memorandum of Co-operation. The MOC identified the desire to strengthen links in regenerative medicine, dementia research, antimicrobial resistance and infections research in a global context. The agreement was renewed in 2022 and has resulted in numerous workshops and site visits resulting in joint calls on infectious diseases, neuroscience, regenerative medicine and engineering biology. In the neurosciences we were delighted to be able to initiate a joint annual UK-Japan symposium series which encourages early-stage researchers to participate in events that alternate between the two countries each year and which is now in its sixth year. We have also participated in alignment calls of AMED's ASPIRE programme. We hope that the numerous meetings, joint calls and other activities, such as our joint participation in the international Human Frontiers Science Program, will lead to stronger and even more productive research collaborations between the two countries.

MRC would like to congratulate AMED on its 10th anniversary. We have been impressed by the impact that AMED has made to advancing medical research and innovation in such a short time and look forward to working together in the future to contribute to the health and well-being of people everywhere.

March,2025

Commemorating AMED's 10th Anniversary

Jeanne M. Marrazzo, M.D., M.P.H.

Director
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health
United States Department of Health and Human Services

On behalf of the National Institute of Allergy and Infectious Diseases (NIAID) , I extend my heartfelt congratulations to the Japan Agency for Medical Research and Development (AMED) on the momentous occasion of your 10th anniversary. This milestone is a testament to your unwavering commitment to advancing medical research and development, and to fostering collaborations that transcend borders.

Over the past decade, AMED has emerged as a beacon of innovation and excellence in the global medical research community. Your achievements in pioneering new treatments, enhancing healthcare technologies, and addressing pressing public health challenges have had a profound impact not only in Japan but around the world. The collaborative spirit that AMED embodies has been instrumental in driving forward the frontiers of medical science.

NIAID is proud to be co-leading the U.S.-Japan Cooperative Medical Sciences Program with AMED, a partnership that has flourished over the years. Our joint efforts have yielded significant advancements in understanding and combating infectious diseases, improving public health, and training the next generation of scientists. This collaboration stands as a model of international cooperation, demonstrating how shared knowledge and resources can lead to groundbreaking discoveries and improved health outcomes.

As we look to the future, the challenges in medical research and development are both daunting and exhilarating. The emergence of new infectious diseases, the need for innovative treatments for chronic conditions related to infectious and immunological diseases, and the quest for personalized medicine require our continued dedication and collaboration. I am confident that AMED will continue to lead with vision and determination, and that together, we will rise to meet these challenges.

Once again, congratulations on this remarkable milestone. NIAID looks forward to many more years of fruitful collaboration with AMED as we work together to advance medical science and improve health for all.

March,2025

In tribute to AMED's Tenth Founding Anniversary

FUJIWARA Yasuhiro, MD, PhD

Chief Executive,
the Pharmaceuticals and Medical Devices Agency (PMDA)

I would like to express my heartfelt congratulations to the Japan Agency for Medical Research and Development (AMED) on the 10th anniversary of its founding. I wish to express my sincere respect for the efforts of all those who contributed to its functions as the command center for research and development in the medical field in Japan.

The PMDA and AMED concluded a partnership agreement in August 2015 to create innovative pharmaceuticals, medical devices and regenerative medical products originating from Japan. The AMED's mission consists of driving medical research and development, while the PMDA's offers the review and consultation on medical products. Our partnership has the objective of building a system that would allow the mutual use of their respective functions, expertise, and experience. Accordingly, we have closely worked together.

In addition, the PMDA and the AMED have also collaborated in terms of personnel; some PMDA staffs have participated in the research supported by the AMED. The PMDA dispatches its staffs to the AMED to develop the medical field in Japan.

During my time at the National Cancer Center, I worked as a program officer for the Project for Promoting Clinical Trials for Development of New Drugs and the incubation-type, Leading Advanced Projects for medical innovation (LEAP). I also headed the Patient and Public Involvement (PPI) Project in Medical Research and Development. Eventually, I was involved in the publication of the Patient and Public Involvement (PPI) Guidebook. Now, I am supporting the AMED in some small way as the chair of its advisory board.

Recently emerging biotech companies have become mainstream in pharmaceutical development. However, they have no business locations in Japan. Their preferred business model has changed from working toward an initial public offering (IPO) to exploring M&A opportunities and prioritizing approval for marketing in the US. Therefore, what is known as "drug loss" has been exacerbated in Japan. They will not try to commercialize their products in Japan nor even apply for marketing approval (i.e., they do not conduct preclinical or clinical trials in Japan) while those products have been launched in the EU and the US. We should enhance Japan's drug development capabilities in order to quickly deliver innovative pharmaceuticals and medical devices to patients in Japan to keep up with the EU and the US.

Under these circumstances, the PMDA and AMED should fulfill their respective functions and work "together" to address the challenges before the necessary medical care can be swiftly delivered to the public.

The PMDA has established its own Purpose as the 20th anniversary initiative; "Making everyone' s lives brighter together." The PMDA is keeping to take on new challenging tasks together with the AMED to deliver innovative medical care to the public as quickly as possible.

In closing, I congratulate the AMED and wish its continued success in the future.

March,2025

In tribute to AMED's Tenth Founding Anniversary

UENO Hiroaki, Ph.D.

Japan Pharmaceutical Manufacturers Association (JPMA)
President

Japan Agency for Medical Research and Development (AMED) has significantly contributed to the practical application of medical technologies in Japan through many research and development projects since its establishment. We would like to extend our heartfelt congratulations on its 10th anniversary.

In recent years, drug discovery originated from academic research has been increasing. Japanese pharmaceutical companies have been in urgent need of strengthening and collaborating with academia. AMED has supported the development of innovative pharmaceuticals and medical technologies by serving as a bridge to promote basic research in academia and link the results to practical applications.

One significant achievement by AMED is increased opportunities for developing partnerships between academia and the pharmaceutical industry. AMED has coordinated many industry-academia collaboration projects. A industry-academia-government program, known as GAPFREE, aligned the needs of the pharmaceutical companies into its designs and helped a collaboration research that would attract pharmaceutical companies. Indeed, many companies participated in the programs. AMED also created a forum for incubating academia's seeds and catalyzing novel drug discovery, known as AMED-FLuX where researchers from pharmaceutical companies provide advice on academia's research with a view to drug development. As of November 2024, 35 advisors from 15 companies are participating. The initiative has provided an opportunity to introduce industrial viewpoints into academia's research in the early stages. Academic researchers who participated in AMED-FLuX said that the advice helped them redefine their research approaches and find a path to practical application. As demonstrated by these initiatives, AMED introduced many-to-many industry-academia collaborations, not only traditional one-to-one collaboration. Additionally, new challenges have also been implemented to diversify and deepen industry-academia collaborations and encourage interactions and consultations between individual researchers.

Through these efforts, AMED has achieved many outcomes. Pharmaceutical projects resulted in a total of 28 regulatory approvals (new drugs and added indications) during the period from fiscal year 2020 to the end of fiscal year 2023. Additionally, more non-clinical and clinical Proof of Concept (POC) programs have been proceeding successfully. The third phase of the Health and Medical Strategy will begin in the next fiscal year. AMED must continuously reform and update its strategies to ensure that more innovative and globally competitive new drugs are continually created. We would like the government to continue to improve the system so that both the basic and practical application research support by AMED will be strengthened and AMED can operate autonomously. JPMA will also enhance cooperation and coordination with AMED as an important drug discovery partner.

We expect that AMED will continue to contribute to research and development in the medical field in Japan.

March,2025

In tribute to AMED's Tenth Founding Anniversary

YAMAMOTO Akio

Chairman
The Japan Federation of Medical Devices Associations (JFMDA)

I extend my congratulations to the Japan Agency for Medical Research and Development (AMED) on its 10th anniversary. Congratulations on your success.

Since its founding, AMED has demonstrated leadership as the driver of medical research and development in Japan. I would like to express my gratitude for AMED' s contributions to numerous medical research programs and use in clinical settings. In parallel, the research and development projects separately conducted by the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labor and Welfare; and the Ministry of Economy, Trade and Industry have been consolidated and reorganized to allow medical research and product development to be fulfilled in a one-stop, strategic manner so that those activities can be more efficiently carried out. AMED has been giving advice to the industry in a variety of different contexts. Indeed, the organization has become an integrated part of the medical device development community.

As a member of the advisory board representing the medical device industry, I am in a position to advise AMED on its internal operations. AMED is an excellent organization because it has decisively implemented several reforms for better organizational governance and continues to evolve.

Looking at our society, we are experiencing the rapid changes of a declining birthrate and aging population, accelerated technological innovation, intensified global competition, and a shift from deflation to inflation. The medical industry, however, is among the growth industries in the national policy, and it is now in a phase that requires critical innovations and global deployment. AMED is at the heart of those developments. We hope that AMED will lead innovations and social implementation and make the medical industry sustainable. To this end, we hope that AMED will further deepen its current efforts and provide more guidance to the medical device industry from the research and development stage and later, which will also contribute to making the medical device industry a sustainable business. We also hope that AMED will work hard to achieve further internal reforms.

We sincerely hope that AMED will continue to lead the way in medical research and research and development programs in Japan and achieve further success. Once again, we would like to express our heartfelt congratulations to AMED on this important milestone, its 10th anniversary, and wish you continued success in the future.

March,2025

In tribute to AMED's Tenth Founding Anniversary

SHITAKA Yoshitsugu

Chairperson of
the Forum for Innovative Regenerative Medicine (FIRM)

We would like to offer our heartfelt congratulations to the Japan Agency for Medical Research and Development (AMED) on its 10th founding anniversary. We are convinced that this exceptional milestone is a testament to the tireless efforts and passion of all AMED personnel. We wish to express our sincere respect for your dedication so far.

Since its founding in 2015, AMED has played an important role as the command center for overseeing medical research and development in Japan. Its significant support was extended to various regenerative medicine-related projects, such as Programs for accelerating the realization of regenerative medicine and cell and gene therapies, Research Project for Practical Applications of Regenerative Medicine, Project to Build Foundation for Promoting Clinical Research of Regenerative Medicine, Project to Promote the Foundation for Practical Application of Regenerative Medicine, Projects for developing fundamental technology for the industrialization of regenerative medicine and gene therapies. AMED' s comprehensive involvement from research and development to the practical application phase has driven advancements in a wide range of cutting-edge technologies, including cell and gene therapy and tissue engineering, and paved the way to challenge innovative therapeutics. Even after Professor Shinya Yamanaka of Kyoto University won the Nobel Prize in 2012, AMED has continued to support the development of treatments using iPS cells, thus Japan has become a world leader in the research and clinical development of iPS cells. The foundation for the practical application of regenerative medicine, which has the potential to be a game changer, is the fruit of the continuous support provided by AMED to date.

AMED has organized numerous symposiums and networking events in the field of regenerative medicine, fostering knowledge sharing and collaboration across academic and industrial communities. Moreover, educational outreach for citizens and patients, including public lectures, is extremely crucial in cultivating a future where regenerative medicine is widely recognized as a viable and available treatment option. Such educational efforts over the years have greatly enhanced public awareness and understanding of the importance of citizen and patient participation. We are deeply grateful to AMED for all these contributions as well.

We sincerely hope that AMED will continue to demonstrate leadership in order for Japan's regenerative medicine technology to continue leading the world. We believe that AMED and FIRM are indispensable partners for the industrialization of regenerative medicine. We look forward to deepening our collaboration and working together to unlock a promising future of regenerative medicine. Once again, we extend our warmest congratulations to AMED on its 10th anniversary.

March,2025

Congratulations on AMED's 10th anniversary

SUEMATSU Makoto, M.D., Ph.D.

Director, Central Institute for
Experimental Medicine and Life Science (CIEM)
Professor Emeritus, Keio University
The First President of
Japan Agency for Medical Research and Development (AMED)

I served as the first president of the AMED for five years from April 2015 to the end of March 2020. Earlier, from November 2014 to the end of March 2015, I also helped with the preparatory activities for founding the agency during my deanship at my alma mater. I was involved in it, therefore, for a combined five years and five months.

I remember the people from the MEXT, MHLW, and METI who worked for the fledgling agency, the people who worked hard on secondment from the School of Medicine, the Faculty of Nursing & Medical Care, and the Faculty of Science and Technology for many universities, and the people who assumed administrative operations. They were all exceptional. With their support, I believe that I did the best job possible. I set forth an overarching vision on the mission of the AMED in driving research and development: support life in three meanings: life as life science, life as livelihood, and life as healthy longevity. Under an agreement with colleagues, I made countless decisions during my term, but I retained all the projects that met the philosophy even if they were not feasible. I rejected all the projects that deviated from it.

Soon after the AMED was founded, Dr. Francis Collins, director of the NIH, welcomed it to the HiRO Conference and thanks to him, the AMED hosted the HiRO Conference in Tokyo for the first time. Thanks to Dr. Jeremy Farrar (currently chief scientist of the WHO), who led the Wellcome Trust at the time, we successfully brought the data sharing principle (no share, no budget) into the agenda for a HiRO Symposium. Another important event was the publication of a paper (Cell Genomics, 1, 100029, 2021) in collaboration not only with the AMED but also with overseas research institutions and researchers at the GA4GH initiative. The article advocated the promotion of genomic medicine-based healthcare through data sharing, and it has already been cited widely as a scientific paper. The achievement was made possible only after the AMED obtained international confidence by joining the International Rare Diseases Research Consortium (IRDiRC), participating in rare and undiagnosed diseases projects, and achieved substantial scientific accomplishments in infectious diseases. Together. the AMED staff thought about how it could most effectively appeal to the international community, and we joined the GA4GH Plenary Meeting in Miami with the staff from the Division of Biobank (at the time) as a last-ditch attempt to convince the audience. Of course, you cannot talk about the AMED's achievements without referring to the achievements made by individual research institutions and scientists. At the same time, however, they were the result of all the AMED staff members who tried to implement creative and effective measures. Some people who stepped into the AMED at a crossroads in their careers helped us.

I believe that the dissemination and creation of mechanisms, which are beyond the ability of individual researchers, will be developed by current AMED staff members and all the people who are now active in new positions at universities or research institutes across the country after working with me at the AMED. I hope that you will all work hard every day with pride and confidence in your AMED. Please receive my words as my sincere message for congratulating AMED's 10th anniversary.

March,2025

The Japan Agency for Medical Research and Development (AMED) will mark the 10th anniversary of its foundation in April 2025. 2

Japan Agency for Medical Research and Development (AMED)
President — MISHIMA Yoshinao, Ph.D.

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Minister in charge of the Healthcare Policy — Minoru Kiuchi

Minister of Education, Culture, Sports, Science and Technology — ABE Toshiko

Minister of Health, Labour and Welfare — FUKUOKA Takamaro

Minister of Economy, Trade and Industry — MUTO Yoji

Medical Research Council (MRC) Executive Chair — Professor Patrick Chinnery, FMedSci, FRS

Director
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health
United States Department of Health and Human Services — Jeanne M. Marrazzo, M.D., M.P.H.

Chief Executive,
the Pharmaceuticals and Medical Devices Agency (PMDA) — FUJIWARA Yasuhiro, MD, PhD

Japan Pharmaceutical Manufacturers Association (JPMA)
President — UENO Hiroaki, Ph.D.

Chairman
The Japan Federation of Medical Devices Associations (JFMDA) — YAMAMOTO Akio

Chairperson of
the Forum for Innovative Regenerative Medicine (FIRM) — SHITAKA Yoshitsugu

Director, Central Institute for Experimental Medicine and
Life Science (CIEM) Professor Emeritus, Keio University
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Japan Science and Technology Agency (JST)
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Function of AMED

AMED's research and development

AMED at a glance!

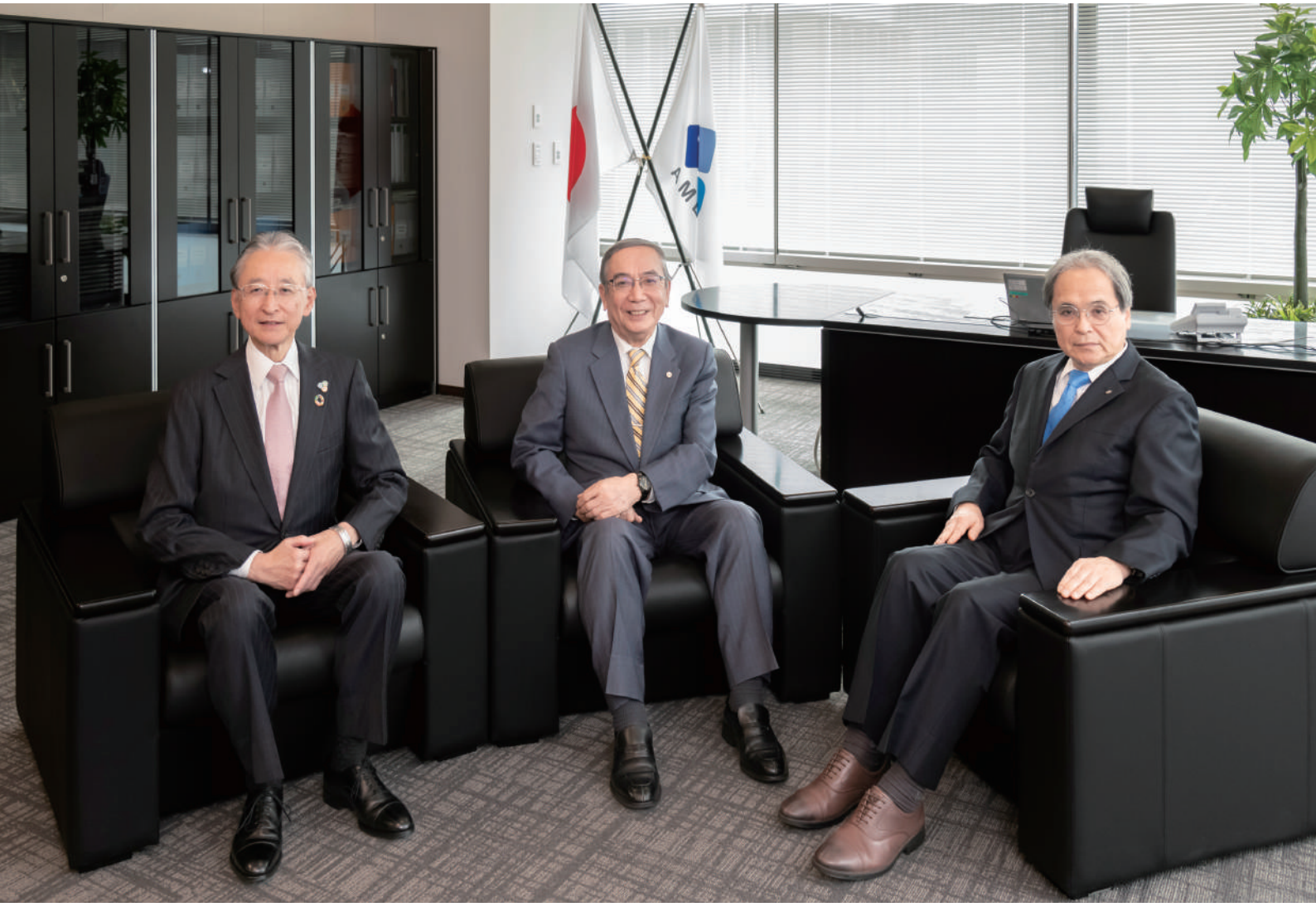
Organization

As funding agencies, we seek more opportunities for collaboration to fulfill our missions

New Energy and Industrial Technology Development Organization (NEDO)
Chairman
SAITO Tamotsu

Japan Agency for Medical Research and Development (AMED)
Chairman
MISHIMA Yoshinao

Japan Science and Technology Agency (JST)
Chairman
HASHIMOTO Kazuhito



The 10-year history and future of AMED

MISHIMA Today, Dr. Hashimoto, JST President, and Mr. Saito, NEDO Chairman, are with us. Thank you for taking time out of your busy schedules to join us.

AMED marks its 10th anniversary this year. AMED has completed its second plan period and has just started the third plan period. You are both leaders of institutions with significant social responsibilities and have extensive experience leading national research and development agencies. I hope that you will share your frank opinions about AMED's future through this trialogue.

I would like to discuss the functions that national funding research and development agencies are expected to fulfill and the associated challenges. I also would like to discuss future tripartite cooperation. Please feel free to share your vision.

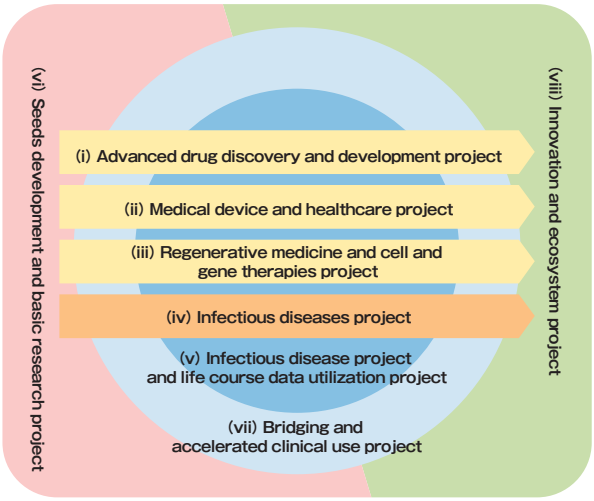
Now, let me explain how AMED worked to fulfill its mission throughout the first and second midterm plan periods and what we want to achieve during the third plan period, which will start in the next business year. Since it was founded in 2015, AMED has developed mechanisms to consistently support research and development projects in the medical field from basic research to practical application. During the midterm objective period starting in 2020, the second plan period, we defined several integrated projects according to different modalities (“modality” means methodology for developing medical technology). Modalities constituted one axis of the midterm plan, whereas disease areas constitute another axis, with each modality intersecting with each disease area. This has helped the academic community become more aware of practical applications. Indeed, new medical technologies, for example drug delivery systems (DDS), were applied to different diseases. We have included additional projects to prepare for the third plan period, for example, infectious disease project and life course data utilization project.

In addition, the third plan will employ funds from the Innovation Ecosystem Project to provide seamless support to clinical trials, which would require greater funding, for practical application. The plan will also manage exit-oriented research and development efforts. As a funding agency, we will improve our ability to develop research and our analysis capabilities. We will also support research and development efforts that will directly provide solutions to social issues.

In June, the government released the guidelines for its health and medical strategy. The guidelines state that AMED has the task of developing mechanisms for providing consistent support for basic research and practical application. In accordance with the guidelines, we will work to put research results to practical use and increase their visibility.

I would appreciate it if you could share your experiences, focuses, and solutions. I would like Dr. Hashimoto to go first.

Vision of Eight integrated projects in the third plan period



*The eight integrated projects outlined in the FY 2025 budgetary allocations to the medical research and development segment (set forth by the Headquarters for Healthcare Policy on August 8, 2024)

Importance of technological development and organizational reform in line with policy objectives

HASHIMOTO I joined JST in April 2022. Before then, I used to be an Executive Member of the Council for Science, Technology and Innovation for nine years. I am currently involved in the government's overall science and technology policy as the Science and Technology Advisor to the Cabinet. One of the concerns that I have in this advisory position is the lack of understanding about how individual funding programs

are intended to work within the context of overall Japanese governmental science and technology policy.

For example, JST has many different funding programs. Each program has distinct policy objectives. JST personnel understand to a certain extent the objectives of those individual programs. The Japanese government has many funding programs. The individual programs are organized into different portfolios, which drive national science and technology policies. Very few people understand all of the national funding programs at JST. You could say that JST personnel allocate individual projects to individual frontline scientists without understanding the overall picture. As a result, some grant beneficiary scientists may follow a course different from the originally intended course, despite sincere efforts for each project' s objective, because they lack a sufficient understanding of the overarching policy.

MISHIMA I agree with you. I think your viewpoint is very important.

HASHIMOTO Therefore, I always try to clearly explain the objectives of specific projects to JST personnel, to the relevant program review panels, and then to the frontline scientists at presentation sessions during calls for proposals. I will explain the functions of the projects in the overall national policy.

On the other hand, the government develops policies based on information from the scientists, but I often feel that information from frontline scientists is not sufficiently communicated to policymakers. As a result, I often think that even if we create new programs after much effort, frontline scientists feel that the projects do not fit into what is expected. I recognize that one of the expected roles of a funding agency is to accurately connect information from the frontline to the government, so I tell JST personnel to talk to as many scientists as possible and deliver fresh information to the government.

MISHIMA Thank you so much for your very insightful input. You assume a very important position with a perspective on the overall policy. At the same time, you provide careful support to frontline personnel and scientists in many different science and technology fields. Your story makes a very important point. Please share your experience, Mr. Saito.

SAITO First of all, congratulations on the 10th anniversary of AMED. When AMED was founded, NEDO transferred its medical technology projects to AMED. Consequently, all medical projects, from basic research to practical application, were consolidated into AMED and put under its centralized guidance. I know that many achievements have been made so far. I am very happy with all the developments.

I have been in office as chairman of NEDO since April of last year. Previously, I led IHI, and so I work as chairman with a business perspective. Recently, NEDO has had more projects with more diversified themes that include carbon neutral technology, semiconductors, and a more resilient supply chain for economic national security. I realize that people have great expectations for NEDO at home and abroad. NEDO is challenged by the need to manage those workloads. We are working to improve project management practices and increase back-office support. The NEDO Chairman serves a term of five years. If NEDO policy changes every time the chairman is replaced, NEDO personnel will be confused every five years. To prevent such upset, we want to develop an organizational culture that encourages personnel

SAITO Tamotsu

Born in Yamagata Prefecture. After graduating from the Faculty of Engineering at the University of Tokyo, he joined Ishikawajima-Harima Heavy Industries (currently IHI) and worked in the technical field of the aerospace business. He became IHI' s representative director and CEO in April 2012. He took office as IHI representative director and chairman in 2017 and became an advisor to IHI in 2020. In April 2023, he took office as Chairman of the New Energy and Industrial Technology Development Organization.

to think autonomously, create their own vision, and decide what they want to be.

Last July, NEDO carried out the most drastic organizational restructuring since it was transformed into an independent administrative institution. First, we renamed our departments in a manner to straightforwardly reflect the policy issues. The administrative departments were then reorganized to ensure that they made decisions cross-sectionally in response to consultations by the operational departments, and to provide solid support to the other departments. NEDO has a matrix organizational structure in place. I believe that NEDO should have the organizational capabilities of speedily delivering research and development achievements in reaction to environmental changes and a wide range of social issues.

MISHIMA Thank you for your valuable input. At AMED, a significant number of personnel are replaced every two years, not every five years, so we face difficulty in developing an effective organizational culture. You have told us that NEDO has embarked on a significant undertaking. It' s an amazing story.

Create a system that seamlessly connects basic research to applied research

MISHIMA Next, please share any viewpoints that any viewpoints that are applicable to AMED and the connection of basic to applied research and any advice for its future.

HASHIMOTO As a member of the Industrial Competitiveness Council, I was somewhat involved in the establishment of AMED. Therefore, I know a little about the issues that were considered in differentiating the mission of AMED from those of JST and NEDO. When AMED was established, the government tried to collect all the budgets for medical research and development projects from the relevant ministries and assigned them to AMED. Just as Mr. Saito said, NEDO's operations in the medical technology field were transferred to AMED. JST also decided to transfer all of its operations in the pharmaceutical fields. Any organization would naturally be motivated to protect the size of their budget if this move was to happen to them. Apparently, JST also wanted to minimize the amount that would be taken

from its budget. I guess that the same thing probably happened at NEDO. As a result, the government probably made the decision to draw clear demarcation lines between AMED and other funding agencies, even if the lines were somewhat fuzzy, to indicate their remits.

As for JST, the line was drawn between basic medical research projects and applied research. The former remained under the remit of JST, while the latter was transferred to AMED. Of course, no one can distinguish clearly applied research in drug discovery from basic research in the life sciences and biotechnology. However, the policymakers drew the line anyway. So, of course, problems would arise eventually. Indeed, a few years later, voices were raised from the field saying that this division did not fit the reality of research.

MISHIMA I see. Such controversy, intentions, and expectations have existed from that time to the present.

HASHIMOTO So, the government also probably found this situation unfavorable and allowed JST and AMED to jointly operate programs for basic research in drug discovery or overlap funding programs to some degree. However, the ambiguities may not have been fully communicated to the officials in charge at the ministries and funding agencies. Frontline scientists may also not fully understand. I think the lack of understanding may be partly attributable to cultural differences between the medicine/pharmacy and science/engineering/agriculture communities. I imagine the same thing is happening between NEDO and AMED. Even if

some discretion over the remits is left to frontline scientists, this problem cannot be overcome. Rather, clear guidelines should be established in a top-down manner. I hope today's trialogue will catalyze the movement.

MISHIMA The point you made about how to effectively connect basic research to practical application is a crucial point for AMED. Of course, when AMED was established, the focus could have been placed on ensuring that its organizational structure was not vertically divided in alignment with the three ministries involved. In reality, however, such vertical demarcation lines still exist somewhere. During the third plan period, we want to skillfully go beyond the ministerial boundaries or beyond the boundaries between AMED and JST to bring governmental health and medical policies to fruition. What do you think, Mr. Saito?

SAITO NEDO launched the Deep Tech Startup Support Program last business year. The healthcare category in the program accounted for 40% of all fund recipients. Startups in the pharmaceutical and drug discovery fields also accounted for some portion. I think that we need to create a system that can seamlessly support startups beyond the boundaries of AMED and NEDO.

Dr. Hashimoto earlier discussed ways to connect information from the frontline research and development field to governmental decision-makers. We believe that NEDO, which is close to both frontline enterprises and government officials, could convey their voices to the relevant departments of METI. Also, different bureaus and divisions that are in charge of NEDO projects, but the Innovation and Environment Policy Bureau of METI coordinates interactions with NEDO as a whole.

HASHIMOTO JST projects are linked to several divisions of MEXT. Until now, proposed budget requests would made jointly by JST departments and their counterpart divisions in MEXT. Each JST department and counterpart MEXT personnel discussed and finalized department-level budgetary proposals. JST compiled those budgetary proposals into a single proposal as if they were simply stapled together. This made it difficult for the JST executive team to develop an organization-level budget according to its strategic vision. JST and MEXT started the revised practices of developing the JST budgetary process in the last business year. According to the practices, department-level budgetary proposals, which were developed in consultation with the individual counterpart MEXT divisions, are adjusted and revised in accordance with the overall strategy of JST executive team, whereas the MEXT division that oversees JST (the division in charge) also in parallel adjusts the individual department-level proposals from the total perspective before JST and MEXT discuss and finalize the budgetary proposal. The decision-making process has helped JST to communicate feedback not only from the frontline but from the executive staff to MEXT. And eventually ensure that their visions are better reflected in the MEXT budget.

MISHIMA Ideally, as you just explained, I think that AMED should also develop a system that facilitates the sharing of the aligned visions with the three ministries and then undertakes assignments for the projects in which they are involved. I think it will be an important theme for the third plan period.

Recruitment of human resources to support efficient project management

HASHIMOTO There is another very important point—the relationship between the budget for agency operating expenses and other budgets. AMED has a much higher proportion of operating expenses in the total budget of AMED than other budget segments. In reality, both NEDO and JST also have a comparable budgetary composition. Why is this a problem for those funding agencies? It is because they cover the employment of full-time personnel with the agency operating expenses in the budget. In other words, although the agencies have seen the total amount of the fund budget to be managed and the personnel workload increasing, their full-time workforce has not been increased. Indeed, JST had twofold or threefold heavier workloads per employee than earlier, and I heard that NEDO had even heavier workloads per person than JST. This is a critical problem. It is not easy to increase the workforce. We have to change our approach. Otherwise, we may not continue to operate in the future.

SAITO That's right. METI is also committed to the problem, but the shortage of workforce has not been solved.

HASHIMOTO I heard that AMED faces a more serious problem. AMED has a very limited number of full-time employees, and a remarkably higher proportion of personnel

HASHIMOTO Kazuhito

Born in Hokkaido. He graduated from the Faculty of Science at the University of Tokyo and completed a master' s course at the Graduate School of Science at the same university. He specialized in physical chemistry and obtained a doctorate in science. Later he served as a member of the Governmental Industrial Competitiveness Council and the Council for Science, Technology and Innovation. In 2022, he took office as the Science and Technology Advisor to the Cabinet. He also assumed the post of President of the Japan Science and Technology Agency in April 2022.

dispatched from other institutions because of the background that led to its founding. I think it must be very difficult to operate the agency with such organizational vulnerability. The government should be well aware of this, so I think we need to appeal to them about the hardships a little more.

MISHIMA We understand the need to develop an organizational culture among AMED personnel. Indeed, we conducted a series of one-on-one interviews with many different personnel. We have also come to see the differences in organizational characteristics between AMED and other funding agencies. In order to create a good organizational environment while working on more than 2,000 projects a year, I think it is very important to aggressively recruit excellent human resources, including mid-career hires, offer permanent employment to them, and create a better organizational culture.

HASHIMOTO JST has started a new personnel system with an annual salary and year-limit contract system. The plan is to cover the employment costs not by the agency operating expense budget but by the project-level administrative expense budgets. Generally, apart from the agency operating expense budget, the project-level administrative expense budgets have time limits because the projects have their own lifetime of five to ten years at most. However, I believe that such time-limited projects are likely to be successively proposed and implemented in the foreseeable future. Therefore, we decided to use the project-level administrative expenses to cover agency employment costs for the new year-limit contract system, although the contract system is somewhat uncertain and has risks by its nature. We plan to employ more people with expertise in funding activities. I believe that if AMED and NEDO also put such a system in place, the Japanese human resource market will have more people with expertise in funding activities.

SAITO NEDO also wants to implement an annual salary system. If our organization is to implement an employment system comparable to what is known as job-based employment by companies, it is necessary to implement an annual salary system that is independent of the traditional job-position-based salary schedule, I think. However, the question is when and for what job positions the annual salary system should be offered. NEDO had approximately 900 employees six years ago, but now its payroll has grown to 1,600. About 30% are permanent employees, 30% are seconded from companies and government agencies, and 40% are fixed-term employees, making it a very diverse organization with great potential. On the other hand, when it comes to the NEDO culture, permanent employees have to bear the organizational culture. As you know, work-style reform has been an important social issue. We operate NEDO keeping in mind a flexible working environment that suits individual employees. We hope to provide 1,600 different work styles for our 1,600 employees.

MISHIMA As for permanent employees, approximately 400 people work for AMED. If part-time employees are also counted, which has increased slightly over the past two years. As a result, it has numbered approximately 600 to 700 staff. Even so, we still only have 30 to 40 permanent employees and want to aggressively recruit and hire qualified mid-career people. I think a larger budget for this purpose would be better. Offering high salaries or wage increases have been

very important incentives in the context of recruitment. All of these concerns are addressed in the third plan policy, and we want to make every effort to achieve this.

HASHIMOTO As I said earlier, AMED has a smaller number of full-time employees by far. JST has 1,500 employees in total, of which about 600 are permanent staff. The majority of the rest are fixed-term employees. Since the permanent employees constitute the core of the organization, we will treat future employees who receive an annual salary as I mentioned earlier in the same way as conventional full-time employees.

MISHIMA On this matter, I believe our three institutions will have more opportunities to coordinate our efforts.

Acceleration of practical application by connecting cutting-edge technologies with market needs

HASHIMOTO Dr. Mishima was previously the director of the Technology and Innovation Strategy Center (TSC, formerly the Technology Strategy Research Center), at NEDO. TSC is a think tank, isn't it? JST also has a think tank known as the Center for Research and Development Strategy (CRDS). Probably, the important function of a think tank is to obtain the latest information on research and development from around the world. Information on cutting-edge research and development achievements is owned by frontline scientists. As funding agencies, we are in an advantageous position to collect information from those scientists. We bring it to the government and interact with it to create funding programs. I think that the entire process is very important. Regardless of whether AMED will create such an organization, it is important for us, the funding agencies, to cooperate in promoting the think tank function or the information gathering function. However, unfortunately, it seems that CRDS and TSC have not been cooperating very much so far. In the future, the three institutions, including AMED, should work together to strengthen the research function for identifying and collecting cutting-edge research information.

MISHIMA It has been said for a long time that AMED does not have a think tank function, but in fact, we have included the strengthening of the think tank function in our third plan. Although we cannot currently start the capability to continuously search what is happening in research frontier areas around the world and what is emerging, we want to operate a think tank function during the third plan period. To do so, we must first find and recruit visionary people who can envisage the possible mechanisms that will connect and bring projects with comparable goals across different ministerial jurisdictions into practical application.

SAITO Policymakers place considerable expectations about technological intelligence functions on us. Specifically, they demand that NEDO provide technological intelligence, which is crucial for the government to identify frontier areas—domains that the government must focus on going forward. We are also paying close attention to how the market is evolving in order to anticipate whether specific projects are viable for commercialization. We must also strengthen our

marketing function; fortunately, many companies are participating in NEDO projects. If we can tactically access market information and work together with JST and AMED to find new frontiers, we will find a different landscape before us, I think.

HASHIMOTO I think that would be effective. JST also recognizes the importance of the market. Unfortunately, we have no way of obtaining that information. However, it is very important to share cutting-edge research and market information and use that information in projects and for policy development. I think we should strengthen our collaboration. Let's work together.

MISHIMA AMED founded the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), and approximately 30 additional employees were recruited. Backed by those human resources, Dr. Hamaguchi Michinari, Director General of SCARDA, conducted a thorough literature review and collected information overseas, and I think AMED is on track to implement think tank functionality as far as vaccine development is concerned. I think we need to form comparable structures in other medical fields as well.

I went to Boston the other day and saw how startups grow there, and how many academic scientists are startup CEOs. I think AMED should adopt such ambitious practices if at all possible. Looking at Japan, few young people are willing to take risks. The taking-no-risk culture is entrenched in Japan. However, I believe that AMED has great potential, and I want to mobilize it to support and grow research and development projects in pharmaceuticals, medical devices, and regenerative medicine technologies and to achieve their practical application.

HASHIMOTO I understand that drug discovery requires huge amounts of capital as biopharmaceuticals has gained more ground in the medical fields. It has become a barrier for Japanese pharmaceutical companies to compete in the field. Overseas, a business model has been built. First, university-based startups develop seeds, and then venture capital firms invest in those startups. When the venture capital firms prove promising, mega-pharma companies heavily invest in those venture capital firms. Japanese startups and venture capital firms are both less vigorous. Therefore, now the government is very enthusiastic about connecting the results of basic research at universities to startups and creating an ecosystem for venture capital firms.

MISHIMA I think it would be difficult for Japan to realize an ecosystem like the one found in Boston, the United States.

HASHIMOTO However, when it comes to the basic research capabilities of universities and other institutions, where seeds sprout, Japanese life scientists enjoy a high reputation internationally. However, currently such scientists are running off to Boston and Europe. It is urgent to create an environment that makes scientists want to stay in Japan.

MISHIMA I also think so. They may not return to Japan in the future, but in Boston, I found young, highly motivated and talented Japanese scientists. They had a mindset to take risks in a good sense. For example, they worked in Boston for one or two years, attracted venture capital, and launched startups. From their stories, I felt that Japanese people could do as well as these people if they go abroad.

Common issues for making excellent research seeds useful in society

MISHIMA When it comes to academic research results, one thing is often said—we certainly have champion data, but it is not always reproducible, which poses a barrier for companies to seriously embark on commercialization. This is an example of a commonly mentioned hurdle. Have you ever felt that we could not smoothly go forward when NEDO's results are actually being industrialized? Please share your experience.

SAITO Some existing technologies have failed to keep up with the changing market. For example, a promising technology lost its market by the time it got to the point where it could be introduced into that very market. Another issue is cost. When you move from the demonstration phase to the mass production phase, the manufacturing scale is increased, and the resulting price makes it unfeasible to match the market demand. We are struggling with this.

MISHIMA Our discussion could go on, but we will wrap it up here for today. Thank you for your input from different viewpoints, including on practical application and market launch costs. Your insights are very inspirational to me. I hope that this trialogue will catalyze future coordination and more among our three funding agencies.

(This trialogue took place on November 21, 2024)

SCARDA is committed to protecting people's lives and well-being, continuing the fight against infectious diseases.

Director General of SCARDA HAMAGUCHI Michinari, M.D., Ph.D

COVID-19 and the establishment of SCARDA

The early stage of the coronavirus disease 2019 (COVID-19) pandemic, when diagnostic systems, vaccines, and treatments were still unavailable, was a particularly challenging time for the medical community. Pre-existing public practices such as wearing masks, washing hands and gargling as well as the tireless work of Japan's health professionals might mean lower mortality in Japan compared to other G7 countries. Unfortunately, however, no vaccines were developed in a timely manner in Japan. And if mRNA technology had not been imported from overseas, Japan would have doubtless suffered significantly more casualties.

So why did Japan fail to develop its own vaccine? One possible explanation is that after major infectious diseases such as tuberculosis were almost completely eradicated in Japan, the medical community shifted their focus from infectious to chronic diseases. There have also been some heavily publicized cases of adverse reactions to vaccines, which has somewhat soured public opinion on the issue. However, I believe the root cause of slow development may be traced back to the vertical structure of Japan's science and technology community, compared to the newer "convergence" approach to technology development adopted across Europe and the US. The convergence approach allows experts from different fields to work towards a single goal and create multi-perspective solutions to social issues. It enabled the beakthrough development of mRNA vaccines, where scientists from many different fields came together to create and commercialize a vaccine in an unparalleled short span of time. The feat overturned the conventional belief that vaccine development must be a long and arduous process.

Inspired by these possibilities, the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) was set up within the Japan Agency for

Medical Research and Development (AMED). Our mission is to prepare for future pandemics by delivering safe and effective vaccines for government-listed high-priority infectious diseases to both Japan and the global community as quickly as possible. The next pandemic may break out at any time, so even during non-emergency periods we must continue to prepare by providing long-term, stable support for research.

This also means building a mechanism that goes beyond the existing vertical structure of Japan's R&D community and encourage scientists from the different

disciplines of medicine, engineering, and information science to cooperate with each other. The initiative will not only prepare against the next pandemic but also contribute to the overall progress of science and technology in Japan.

SCARDA's achievements and future challenges

In the two and a half years since SCARDA's establishment, we have set up eleven world-class vaccine R&D centers across Japan. These include five universities and six research institutes, which provide convergence spaces where corporate scientists and clinicians can collectively work under one roof to develop new technologies through multidisciplinary interactions.

Another achievement has been the rapid progress in human resource development in the fields of infectious diseases and virology. Previously, Japan's infectious disease research was limited by a shortage of human resources. Now more young scientists than ever have been inspired to enter the field, and we will ensure they are ready to lead our responses against the infectious disease crises of the future. Our third major achievement is the foundation of domestic mRNA vaccine production capabilities for respiratory viruses, meaning we can respond quickly to the threat of the next unknown infectious disease.

Yet mRNA is not the only vaccine development technology we are pursuing. The COVID-19 virus mutates very rapidly - more than 500 mutations have been found for the Omicron strain alone - meaning vaccines for specific strains have limited capacity to contain viral outbreaks. However, a “universal vaccine” technology would overcome such limitations and offer hope for significantly reducing the risk of future pandemics. One of the lessons learned from the COVID-19 pandemic is that the longer we delay our response, the more lives will be lost and the more disastrous damage done to our society. We need a greater variety of tools at our disposal, to improve both the flexibility and rapidity of our response.

Working hand-in-hand with global partners

At the 2021 G7 Summit, it was proposed that medical countermeasures (vaccines, therapeutics, and diagnostics) should be available within the first 100 days after the World Health Organization (WHO) declares a public health emergency of international concern. Yet we still cannot develop a vaccine within 100 days using conventional processes. Moderna needed approximately

11 months to develop an mRNA vaccine for COVID-19, and it was 42 months before the technology was available in Japan. To meet this 100 days challenge, we need large-scale global cooperation.

SCARDA aims to work with the Coalition for Epidemic Preparedness Innovations (CEPI) and the European Health Emergency Preparedness and Response Agency (HERA) more closely to build a cooperative global system. Indeed, SCARDA personnel is already working on placements at CEPI to participate in information sharing and strategic discussions. This type of exchange is essential for enhancing Japan's pandemic preparedness, as well as making proactive contributions to the international community.

We cannot underestimate the risk of future pandemics. If a new infectious disease emerged that had a mortality rate equivalent to the Spanish flu, which ravaged the world only around one century ago, Japan would probably suffer more than 500,000 deaths. Tangible recent threats include the Middle East respiratory syndrome (MERS) coronavirus, which had a mortality rate of over 30%, and the Nipah virus, which has an estimated mortality rate of 40% to 75%. Fortunately, these viruses have not yet entered Japan on a substantial scale, but these or similar ones may well do so in future.

Infectious diseases will continue to break out as people come into more extensive contact with nature. Environmental destruction and urban development have exposed more humans and livestock to viruses that were previously isolated from us. For example, the northward movement of tropical diseases such as dengue fever and malaria *Plasmodium* are closely related to human activities. Even traditional infectious diseases like tuberculosis, which has acquired multidrug resistance due to war, poverty and co-infection with human immunodeficiency virus (HIV), are re-emerging as threats. Globally, more than 50,000 people die from rabies each year, and the risk of a new pandemic remains high. To contain such threats, we must increase the research capabilities of Japan and cooperate more closely with international organizations.

A pandemic cannot be conquered by a single country. There is also the lingering problem of low vaccine availability in Global South regions such as Africa. To exit such a situation, we must build cross-border cooperation mechanisms. Timely information sharing, material provision, and building relationships of trust will be the keys to that mission.

Industry-academia collaboration, the driving force of the SCARDA project, and challenges

At SCARDA we are building a vaccine development system supported by industry-academia collaborations and corporate-led funding to build an effective preparedness mechanism against unknown future pandemic “Disease X”. Though companies and universities have different goals and perspectives, we believe that if they can work together and combine their skills and expertise, they will maximize their contributions to solving social issues.

The barrier is the differences in time spans and priorities for research between academia and industry. For example, university scientists tend to assume a decade or longer period for research, while companies try to obtain research results within a few years in order to satisfy their shareholders. In order to overcome the differences in perspectives and the difficulties in communication, we must create an environment of working "under one roof" that allows both parties to come together in pursuit of a common goal.

In terms of research methods, university research is mainly “curiosity driven”, and scientists usually explore their themes of interest. However, if we are to meet the needs of society, we must take a more “mission-oriented” or “endgame” approach to the research. In other words, the approach should be one of problem solving; we first must define specific goals and deadlines consistent with the future visions, and then deduce the technologies needed to achieve them. I believe that the task of building funding capabilities, a prerequisite

for supporting those efforts, is also an important role of SCARDA.

SCARDA will continue to protect people's lives and well-being

Our mission at SCARDA is to support the development of vaccines that are safer, more effective, and as economically affordable as possible. Vaccine development is not an attractive field for pharmaceutical companies because vaccines are not fully profitable, and demand drops sharply once an epidemic subsides. However, since preparation is the best defense for infectious disease control, the government must provide strategic support for vaccine development and supply systems.

In addition, the experience of the COVID-19 pandemic demonstrated that innovative platforms, such as mRNA technology, may enable a rapid response. At the same time, the process of popularizing cutting-edge technologies throughout society should also be streamlined, and domestic and international cooperation should be increased.

We must succeed in many projects and increase confidence before we can lead this field in the future. Success is the source of trust and confidence that fuels motivation to face unknown difficulties. As a technology pioneer, Japan has a responsibility to contribute to the international community through industry-academia cooperation. Japanese companies must have a strong sense of serving the public, not simply pursuing profits, and I believe this virtuous attitude can already be seen throughout Japan. Japanese universities should go beyond their own disciplines and develop a convergence-oriented mindset, contributing to Japan's position in the medical field and the well-being of all humanity.

The COVID-19 pandemic highlighted several pre-existing challenges. The lack of transparency and trust led to the spread of infection; as a result, the reactions varied significantly among countries. The pandemic reignited the debate over which is more effective: a centralized system or democracy. However, as the success of the mRNA vaccine showed, the healthy development of science and technology is the key to solving global problems beyond the differences in political regimes.

We must build a flexible platform that promotes efforts to calmly and quickly protect people's lives no matter when the next pandemic strikes, and through such efforts, we must fulfill our responsibility to meet the expectations of the people.

SCARDA will continue to enhance its response capabilities against unknown viruses and work with the international community to develop a system that can respond quickly and effectively.

The results we have achieved over the past two and a half years will serve as the foundation for future undertakings. We promise to build on the experience we have gained so far and further develop the technologies to make a significant contribution to the future of Japan and the world.

(This trialogue took place on November 20, 2024)

HAMAGUCHI Michinari, M.D., Ph.D

Born in Mie Prefecture. Graduated from the Nagoya University School of Medicine and earned his Ph.D. in medicine at Nagoya University, then pursued his research at Rockefeller University in the United States. After serving as president of Nagoya University, and president of the Japan Science and Technology Agency (JST), he was appointed director general of the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), Japan Agency for Medical Research and Development, in 2022.

Looking back over the first 10 years

Timeline of AMED

First plan period

Second plan period

Recipients of the President's Award from the Japan Agency for Medical Research and Development (AMED)

AMED's International Network

Notes:

- Company names, government agencies, organizations, and other entities are, in principle, listed using their official names at the time.
- The names of persons, organizations, titles, positions, etc., are given as they were at that time.
- The content and data presented are accurate as of March 2025.

Timeline of AMED First plan period

Fiscal Years	AMED activities
2015	April: Dr.Suematsu took office as the first president. Founding ceremony under the attendance of Prime Minister Abe and Minister Amari in attendance. July: Joined the International Rare Diseases Research Consortium (IRDiRC), as the first member from Japan. January: Signed a Memorandum of Cooperation (MOC) with the U.S. National Institutes of Health (NIH) on research (January 11). February: Signed a statement demanding that data and evidence from research related with Zika fever be shared in response to the zika outbreak (February 10). March: Signed a memorandum of cooperation with the Agency for Science, Technology and Research (A*STAR) of Singapore (March 16).
2016	May: Started high-level exchanges of views with the Japan Pharmaceutical Manufacturers Association (JPMA). June: Joined the Global Alliance for Chronic Diseases (GACD). Opened the first overseas AMED office in Singapore. August: Joined the Clinical Data Interchange Standards Consortium (CDISC). September: visited by Daniel Andrews, premier of the Australian state of Victoria. October: His Royal Highness of Crown Prince of Japan visited the Advanced Telecommunications Research Institute International (ATR) in Kyoto and was briefed about the research supported by the AMED. Their Majesties of Emperor and Empress of Japan visited Kyoto Prefectural University of Medicine and were briefed about the world's leading regenerative medicine research conducted there, which was supported by the AMED. November: Opened the second overseas AMED office in Washington D.C. February: Signed a memorandum of cooperation with the UK Medical Research Council (MRC) (February 1). Opened the third overseas AMED office in London. March: Signed a memorandum of cooperation with the Ministry of Health of the Republic (MOH) of Lithuania (March 9).
2017	May: AMED Symposium 2017 was held. October: Visited by the ministerial delegation from the Ministry of Health of the Kingdom of Denmark.
2018	June: Opened the R&D project database (AMEDfind). Signed a statement demanding that research evidence and data on Ebola hemorrhagic fever be widely and quickly shared in order to address the Ebola outbreak (June 29). October: Exhibited at BioJapan 2018. Signed a memorandum of cooperation with Australia's National Health and Medical Research Council (NHMRC) (October 17). January: Opened the AMED channel on YouTube. February: Signed the MOC with the US National Academy of Medicine (NAM) and participated in (February 12) its Healthy Longevity Grand Challenge.
2019	June: Visited by the assistant secretary for preparedness and response, U.S. Department of Health and Human Services (HHS). October: Exhibited at BioJapan 2019. US National Academy of Medicine (NAM) started Healthy Longevity Grand Challenge, of which AMED was a member. December: AMED Symposium 2019 was held. January: Signed a statement that data and evidence from research on the COVID-19 virus be widely and timely shared in response to the COVID-19 pandemic (January 31). March: President Suematsu left office.

President : SUEMATSU Makoto, M.D., Ph.D.

Medium term plan

Signboard unveiling ceremony

Promote the nine integrated projects
in collaboration with the related ministries.

[Interdisciplinary projects]

- Project for All-Japan drug discovery
- Project for All-Japan medical device development
- Project of Translational and Clinical Research Core Centers
- Highway Program for Realization of Regenerative Medicine
- Platform Program for Promotion of Genome Medicine

Disease area-specific]

- Japan Cancer Research Project
- Project for Psychiatric and Neurological Disorders
- Emerging /Re-emerging Infectious Disease Project of Japan
- Rare/Intractable Disease Project of Japan


People attended the AMED Symposium 2019.


People attended the AMED Symposium 2017.

Events in Japan and overseas

May: Middle East Respiratory Syndrome coronavirus (MERS CoV) infections spread in South Korea.
October: Dr. Satoshi Omura, Professor Emeritus at Kitasato University, was awarded the Nobel Prize in physiology or medicine, and Dr. Takaaki Kajita, Director of Institute for Cosmic Ray Research, The University of Tokyo, was awarded the Nobel Prize in physics.
December: The Paris Agreement was adopted at the 21st Session of the Conference of the Parties to the UN Framework Convention on Climate Change (COP21) .

April: The Kumamoto earthquake occurred and raised grave concerns about the support at medical institutions and shelters.
May: U.S. President Obama visited Hiroshima. He was the first sitting U.S. president to visit the city destroyed by atomic bomb.
June: The UK citizens voted to leave the EU (Brexit) .
January: Donald Trump became the U.S. president.

The Zika virus spread mainly in South America, and a sense of crisis mounted because of the concerns about the infection that might result in severe symptoms in pregnant women.

July: The Treaty on the Prohibition of Nuclear Weapons was adopted at the United Nations by a vote of 122 member states in favor.

Development of new anticancer drugs and immunotherapy made progress, and the advent of immune checkpoint inhibitors raised significant interest.

July: Torrential rains in western Japan caused an urgent need for medical support in the affected areas.
More than 80,000 dengue fever cases were reported in Sri Lanka.
October: Dr. Tasuku Honjo, Kyoto University Professor, was awarded the Nobel Prize in physiology or medicine.
December: Several universities and medical schools were accused of admission riggings that disadvantaged women and repeat applicants.

April: Notre Dame Cathedral in Paris, a registered World Heritage site, burned.
May: The Crown Prince acceded to the Imperial Throne on May 1, and the imperial era changed to Reiwa.
October: Dr. Akira Yoshino, Asahi Kasei Honorary fellow and Professor at Meijo University, was awarded the Nobel Prize in chemistry.
November: The Pope visited Japan for the first time in 38 years. He visited both Nagasaki and Hiroshima, and called for abolition of nuclear weapons.
January: First case of COVID-19 infection was identified in Japan.
March: Fifth generation mobile communication system (5G) service began in Japan

First case of COVID-19 coronavirus was diagnosed in Wuhan, China.

Timeline of AMED Second plan period

Fiscal Years	AMED activities
2020	April: Dr. Yoshinao Mishima took office as president. June: Signed a memorandum of cooperation with the Canadian Institutes of Health Research (June 19). October: NAM announced the first Catalyst Award winners for Healthy Longevity Grand Challenge. November: Launched a research exchange program facilitating AMED-funded researchers to join ERC research teams in Europe.
2021	June: Signed a memorandum of understanding with NordForsk (Norwegian Research Council, Academy of Finland, and Swedish Research Council) (June 23). September: NAM held Global Innovator Summit, an online event of Healthy Longevity Grand Challenge and announced the second Catalyst Award winners. March: Founded the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA). Released the AMED International Strategy.
2022	June: Visited by Frederick Chew, CEO of A*STAR Singapore's Agency. Visited by Richard Hatchett, CEO of the Coalition for Epidemic Preparedness Innovations (CEPI). September: NAM Held the 2022 Healthy Longevity Global Innovator Summit, an online event of Healthy Longevity Grand Challenge, and announced the third Catalyst Award winners. Renewed the memorandum of understanding for research cooperation with the UK Medical Research Council (September 12). October: Visited by the Prime Minister of the Republic of Lithuania. December: Signed a memorandum of cooperation (MoC) for research and development in the field of medical research with Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) (December 8). Signed a renewal letter for the memorandum of understanding to extend the memorandum of cooperation with the US National Academy of Medicine (NAM) for the Healthy Longevity Global Competition (formerly known as the Healthy Longevity Grand Challenge) (December 8).
2023	June: The Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) signed a memorandum of cooperation to strengthen collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI) (June 23). September: NAM held 2023 Healthy Longevity Global Innovator Summit,an online event of the Healthy Longevity Global Competition, and announced the 2023 Catalyst Award winners. October: Started the operation of "Call for proposals Timeline" to facilitate access to information on calls for AMED projects. Exhibited at BioJapan 2023. Signed a working arrangement on cross-border infectious disease emergency preparedness and response in the area of medical countermeasures with the Health Emergency Preparedness and Response Authority (HERA) (October 27). November: Visited by Deputy Minister of Health of Saudi Arabia Abdulaziz Al-Rumaih. "The second KHIDI-AMED Joint Symposium -Advancing Neuroscience: New Frontiers in Overcoming Dementia- was held. Received a visit by Dr. Cha Soon Do, president of the Korea Health Industry Development Institute (KHIDI). Japan-made COVID-19 virus vaccine, funded by AMED received approval for partial amendment to manufacturing and sales approval for booster immunization. December: Released the AMED Data Book FY2022. Developed R&D Project Management Support Tool (A-POST). March: Visited by the Minister of Health of the Republic of Lithuania.
2024	August: Signed a memorandum of cooperation for research with the South African Medical Research Council (August 28). September: NAM held the 2024 Innovator Summit, an online event of the Healthy Longevity Global Competition, and announced the 2024 Catalyst Award winners. October: Exhibited at BioJapan 2024.

President : MISHIMA Yoshinao, Ph.D.

Medium term plan

President holding a press conference

- Reorganize six integrated projects according to the modalities and promote research and development activities across diseases.
- Support research and development to control COVID-19 virus infections
- Build cooperative and collaborative relationship with the government
- Review the achievements and limitations of the first plan and further strengthen AMED's organization and operations
- Increase Japan's international competitiveness in the health and medical fields
- Strengthen collaboration with interdisciplinary research and science and technology think tanks

Founded SCARDA

Events in Japan and overseas

May: Crew Dragon, the first private manned spacecraft, reached the ISS.
June: RIKEN and Fujitsu's supercomputer Fugaku was awarded first place in four rankings, including the ranking for computational speed.
November: Biden won the US presidential election.
December: The capsule containing the sample separated from the asteroid explorer Hayabusa 2 returned to the Earth.
January: First Common Test for University Admissions was implemented, and approximately 40,000 health professionals were vaccinated against COVID-19 virus ahead of the public.
March: Marking the 10th anniversary of the Great East Japan Earthquake, the final government-hosted Memorial Ceremony was held at the National Theater.

As the COVID-19 pandemic spread around the world, countries implemented lockdowns and travel restrictions.

May: Mass vaccination campaigns began at large government-operated venues.
October: Dr. Syukuro Manabe, Princeton University senior meteorologist, was awarded the 2021 Nobel Prize in physics.
December: Spinal cord treatment using iPS cells were the first administered at Keio University.
February: Russia invaded Ukraine.

New COVID-19 treatments were proposed; antibody cocktail therapy and new antiviral medicines.

April: Amended Civil Code took effect, lowering the age of majority from 20 to 18.
July: World Health Organization (WHO) declared a global health emergency for the Mpox outbreak.
October: As the oldest active Japanese astronaut, Wakata Koichi made his fifth space flight.
Tokyo Institute of Technology and Tokyo Medical and Dental University agreed to merge.
November: The United Nations said the world population had reached eight billion.
January: China ended its Zero COVID policy, including strict behavioral restrictions.
March: Wheelchair tennis player Kunieda Shingo was given the People's Honor Award.

The new coronavirus variant Omicron spread, and the epidemic occurred once more in countries.
Inflation accelerated globally. Food and energy prices skyrocketed.

May: COVID-19 was reclassified into Class 5 under the Infectious Disease Act, and any preventive measures were left to individual decisions.
June: The Act on Promoting Public Understanding of Diversity in Sexual Orientation and Gender Identity (LGBT Act) was enacted.
September: The new Alzheimer's drug Lecanemab was approved for manufacture and sale.
October: Shogi player Sota Fujii became the first player ever to hold all eight major titles.
January: An earthquake occurred in the Noto region of Ishikawa Prefecture on the afternoon of the 1st, resulted in devasting damage.
February: Japan's nominal GDP, measured in dollars, fell to fourth place behind Germany.

Russia's invasion of Ukraine has continued, and the war had serious consequences, including energy and food supply crises, and refugee problems.

July: The Bank of Japan began issuing new banknotes for the first time in 20 years.
October: The Japan Confederation of A- and H-Bomb Survivors Organizations was awarded the Nobel Prize for Peace.
For the first time, the Nobel Prize in physics and chemistry was awarded for research and development of artificial intelligence (AI) .
Institute of Science Tokyo was established.
November: Donald Trump won the US presidential election.

As AI technology evolves, diagnostic support systems, surgical robots, and other technologies are expected to increase clinical efficiency and accuracy. Gene therapy technology will further evolve, and personalized medicine will become a more important topic.

Recipients of the President's Award

from the Japan Agency for Medical Research and Development (AMED)

Japan Medical Research and Development Grand Prize

The Japan Medical Research and Development Grand Prize honors outstanding achievements that have made significant contributions to the advancement of research and development in the medical field. The AMED President' s Award recognizes remarkable accomplishments from research and development projects supported by AMED, particularly those that encourage and inspire young researchers.

The first round 2017

The second round 2018

The thrid round 2019

The first round 2017

Understanding of the mechanism of action of CRISPR-Cas9, genome-editing tool, and discovery and practical application of novel tools

NISHIMASU Hiroshi (Assistant Professor, (Graduate) School of Science The University of Tokyo)

Development of a microwave scattered field tomographic imaging system for next-generation breast cancer screening

KIMURA Kenjirou (Associate Professor, Graduate School of Science, Division of Chemistry, Kobe University)

Development of innovative methods for creating human mini-organs

TAKEBE Takanori (Associate Professor, Graduate School of Medicine, Yokohama City University)

Understanding of the structural basis of viruses, receptors, and antibodies for development of antiviral drugs and vaccines

HASHIGUCHI Takao (Associate professor, Department of Virology, Faculty of medicine, Kyushu University)

The second round 2018

Development of a vagus nerve stimulation catheter device that minimizes myocardial necrosis during myocardial infarction

SAKU Keita（Associate Professor, Center for Disruptive Cardiovascular Medicine, Kyushu University）

Development of safer anti-metastatic drugs targeting the oxygen-sensing mechanism

SAKAMOTO Takeharu（Associate Professor, Division of Molecular Pathology, Institute of Medical Science, The University of Tokyo）

Developing the first treatment for core symptoms of autism spectrum disorder using intranasal oxytocin: application of brain imaging and genomic analysis.

YAMASUE Hidenori（Professor, Department of Psychiatry, Hamamatsu University School of Medicine）

Understanding of the control mechanism of the host immune system on pathogenic parasitic infections

YAMAMOTO Masahiro（Professor, Research Institute for Microbial Diseases, Osaka University）

The thrid round 2019

Drug discovery support in humanized mice and rats and multifunctional cells using artificial chromosome technology

KAZUKI Yasuhiro（Associate Professor, Chromosome Engineering Research Center, Graduate School of Medical Science, Tottori University）

Development and release of the first version of the Japanese Reference Genome Sequence (JG1)

TAKAYAMA Jun（Assistant Professor, Advanced Research Center for Innovations in Next-GEneration Medicine, Organization for Advanced Studies, Tohoku University）

Unraveling the Neural Basis of Somatosensory Perception and Its Memory in Pathophysiological and Physiological Conditions

MURAYAMA Masanori（Team Leader（tenured position）, Lab for Haptic Perception and Cognitive Physiology, RIKEN Center for Brain Science）

Development of low-cost mass culture technology for hematopoietic stem cells

YAMAZAKI Satoshi（Project Associate Professor, The Institute of Medical Science,The University of Tokyo）

Development of a new, minimally invasive technique for removing retinal venous thrombus using a needle-free air bubble injector

YAMANISHI Yoko（Professor, Faculty of Engineering, Department of Mechanical Engineering, Kyushu University）

The fourth round 2020

The sixth round 2023

The fifth round 2021

The seventh round 2024

The fourth round 2020

Extensive use of statistical genetics for contributing to genomic precision medicine using

OKADA Yukinori (Professor, Department of Statistical Genetics, Osaka University Graduate School of Medicine)

Establishment of cancer treatment strategy based on elucidation of the nature of cancer cells and microenvironment cells with genomic abnormalities in T-cell lymphoma

SAKATA-YANAGIMOTO Mamiko (Associate Professor, Faculty of Medicine, University of Tsukuba)

Contribution to an understanding of the transmission patterns of and immune responses to mosquito-borne infectious diseases that include dengue and Zika fevers

MOI MENG LING (Professor, Institute of Tropical Medicine Research Field of Microbiology, Nagasaki University)

The fifth round 2021

Development of Smart Care Platform (SCOP)

MIYAMOTO Takashi (Director, Social Welfare Corporation Zenkoukai)

Understanding of the mechanism of neural circuit repair in the brain and its relationship to aging from the viewpoint of the whole living system

MURAMATSU Rieko (Director, Department of Molecular Pharmacology, National Institute of Neuroscience, National Center of Neurology and Psychiatry)

Understanding of the pathogenesis of Helicobacter suis infection in the human stomach

RIMBARA Emiko (Senior Researcher, Department of Bacteriology II, National Institute of Infectious Diseases)

The sixth round 2023

Research and development of adhesive for living tissues inspired by the mechanism of adhesion in aquatic organisms

EJIMA Hirotaka (Associate Professor, School of Engineering, Department of Materials Engineering, The University of Tokyo)

Discovery of novel autoantibodies against synaptic molecules, leading to a better understanding of schizophrenia and the development of new treatments

SHIWAKU Hiroki (Associate Professor, Department of Psychiatry and Behavioral Sciences, Tokyo Medical and Dental University)

Development of a new treatment that targets lipid mediator receptors and inhibits the growth and metastasis of osteosarcoma

TAKAGI Satoshi (Staff Scientist, Div. of Experimental Chemotherapy, Cancer Chemotherapy Center, Japanese Foundation for Cancer Research)

Contribution to medical care for newborns and infants through research and development that put weight on social co-creation and genome analysis

TAKENOUCHI Toshiki (Assistant Professor/Senior Assistant Professor, School of Medicine Department of Pediatrics, Keio University)

Age-dependent trajectory of exosomal protein distribution in healthy aging and Alzheimer's disease

HOSHINO Ayuko (Professor, Research Center for Advanced Science and Technology, The University of Tokyo Intercellular Communication & Medical Science Hoshino Laboratory)

The seventh round 2024

Discovery of a novel mitochondrial disorder in tumor-infiltrating lymphocytes

TOGASHI Yosuke (Professor, Faculty of Medicine, Dentistry and Pharmaceutical Sciences, Okayama University/Okayama University Hospital)

Development of novel therapeutic approaches using bacteriophage-derived lytic enzymes

FUJIMOTO Kosuke (Associate Professor, Graduate School of Medicine, Osaka Metropolitan University/Project Associate Professor, The Institute of Medical Science, The University of Tokyo)

Nanowire-based comprehensive analysis of extracellular vesicles and its application to liquid biopsy

YASUI Takao (Professor, School of Life Science and Technology, Institute of Science Tokyo)

In vitro reconstruction of human embryo implantation using stem cells and organoid technologies

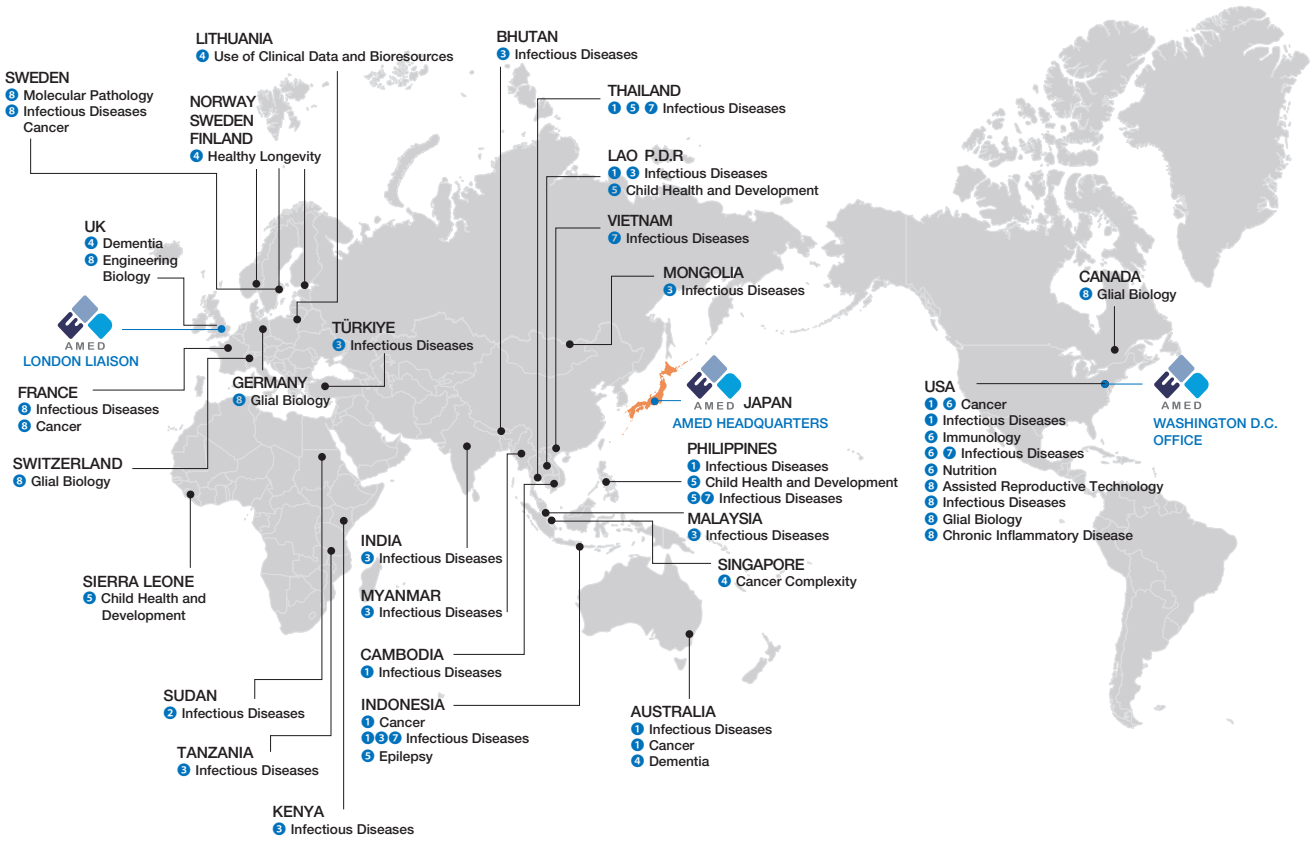
SHIBATA Shun (Assistant Professor, Tohoku University Graduate School of Medicine)

Identification and functional characterization of border-associated macrophages in the central nervous system

MASUDA Takahiro (Distinguished Professor, Division of Molecular Neuroimmunology, Medical Research Center for High Depth Omics Medical Institute of Bioregulation, Kyushu University)

AMED's International Network

collaboration with partner organizations



As of August 2024

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

International Alliances

cdisc	Clinical Data Interchange Standards Consortium
GACD	Global Alliance for Chronic Diseases
Global Alliance for Genomics & Health	Global Alliance for Genomics and Health
GLOPID-R	Global Research Collaboration for Infectious Disease Preparedness
HFSP Human Frontier Science Program	Human Frontier Science Program
HIROs	Heads of International Biomedical Research Organizations
ICRP International Cancer Research Partnership	International Cancer Research Partnership
IRDiRC	International Rare Diseases Research Consortium
jpiamr	Joint Programming Initiative on Antimicrobial Resistance
translation together	Translation Together

Participation in International Alliances

2015 GloPID-R (Global Research Collaboration for Infectious Disease Preparedness)
HIROs (Heads of International Biomedical Research Organizations)
IHEC (International Human Epigenome Consortium)
IRDiRC (International Rare Diseases Research Consortium)
JPIAMR (Joint Programming Initiative on Antimicrobial Resistance)
2016 GACD (Global Alliance for Chronic Diseases)
GA4GH (Global Alliance for Genomics and Health)
CDISC (Clinical Data Interchange Standards Consortium)
2018 TT (Translation Together)
2019 ICRP (International Cancer Research Partnership)

Overseas Offices

2016 - 2020 Singapore Office
2016 - Washington, D.C. Office
2017 - London Office (2022- London Liaison)

List of Memorandums of Cooperation signed with partner organizations at the time of signing

Dates of Signing	Countries or Regions	Partner Organizations
January 11, 2016	United States of America (US)	National Institutes of Health (NIH)
March 16, 2016	Singapore	Agency for Science, Technology and Research (A*STAR)
February 1, 2017	United Kingdom (UK)	Medical Research Council (MRC)
March 9, 2017	Lithuania	Ministry of Health (MOH)
April 5, 2017	Spain	State Secretariat for Research, Development and Innovation of Spain (SEIDI)
October 17, 2018	Australia	National Health and Medical Research Council (NHMRC)
February 12, 2019	US	National Academy of Medicine (NAM)
June 19, 2020	Canada	Canadian Institutes of Health Research (CIHR) *1
November 13, 2020	European Union (EU)	European Research Council (ERC) *2
June 23, 2021	Nordic countries	NordForsk, Academy of Finland (AKA), The Research Council of Norway (RCN), The Swedish Research Council (SRC)
December 8, 2022	Germany	Deutsche Forschungsgemeinschaft (DFG) *1
June 23, 2023	International organization	Coalition for Epidemic Preparedness Innovations (CEPI)
October 27, 2023	EU	Health Emergency Preparedness and Response Authority (HERA) *3
August 28, 2024	South Africa	South African Medical Research Council (SAMRC)
January 15, 2025	Israel	Ministry of Innovation, Science and Technology (MOST), Ministry of Health (MOH)

*1 Expired
*2 Implementing Arrangement
*3 Working Arrangement

List of symposiums held jointly with partner organizations

Symposiums	Countries and Partner Organizations
Japan-UK Neuroscience Symposium (2018–)	UK, Medical Research Council (MRC)
International Conference on Emerging Infectious Diseases (EID) in the Pacific Rim of the U.S.–Japan Cooperative Medical Sciences Program (USJCMSP) * (2016–)	US, National Institutes of Health (NIH)
KHIDI-AMED Joint Symposium (2023–)	Korea, Korea Health Industry Development Institute (KHIDI)

* The International Conference on EID has been held since 1996, and it has been co-hosted by AMED since 2016.

Initiatives aimed at promoting international collaboration

Start Year	Initiatives
2020	Provide opportunities for students from AMED research and development projects to participate in the Data Science Summer Institute (DSSI), internship program hosted by Lawrence Livermore National Laboratory (LLNL) in the US.
	Select projects that would contribute to healthy longevity from AMED research and development projects and registering them for the Catalyst Phase of the Healthy Longevity Global Competition sponsored by the National Academy of Medicine in the US.
2021	Provide opportunities for AMED-supported researchers to visit researchers who are supported by the European Research Council (ERC) to accelerate AMED research and development projects by strengthening Japan-EU collaboration.

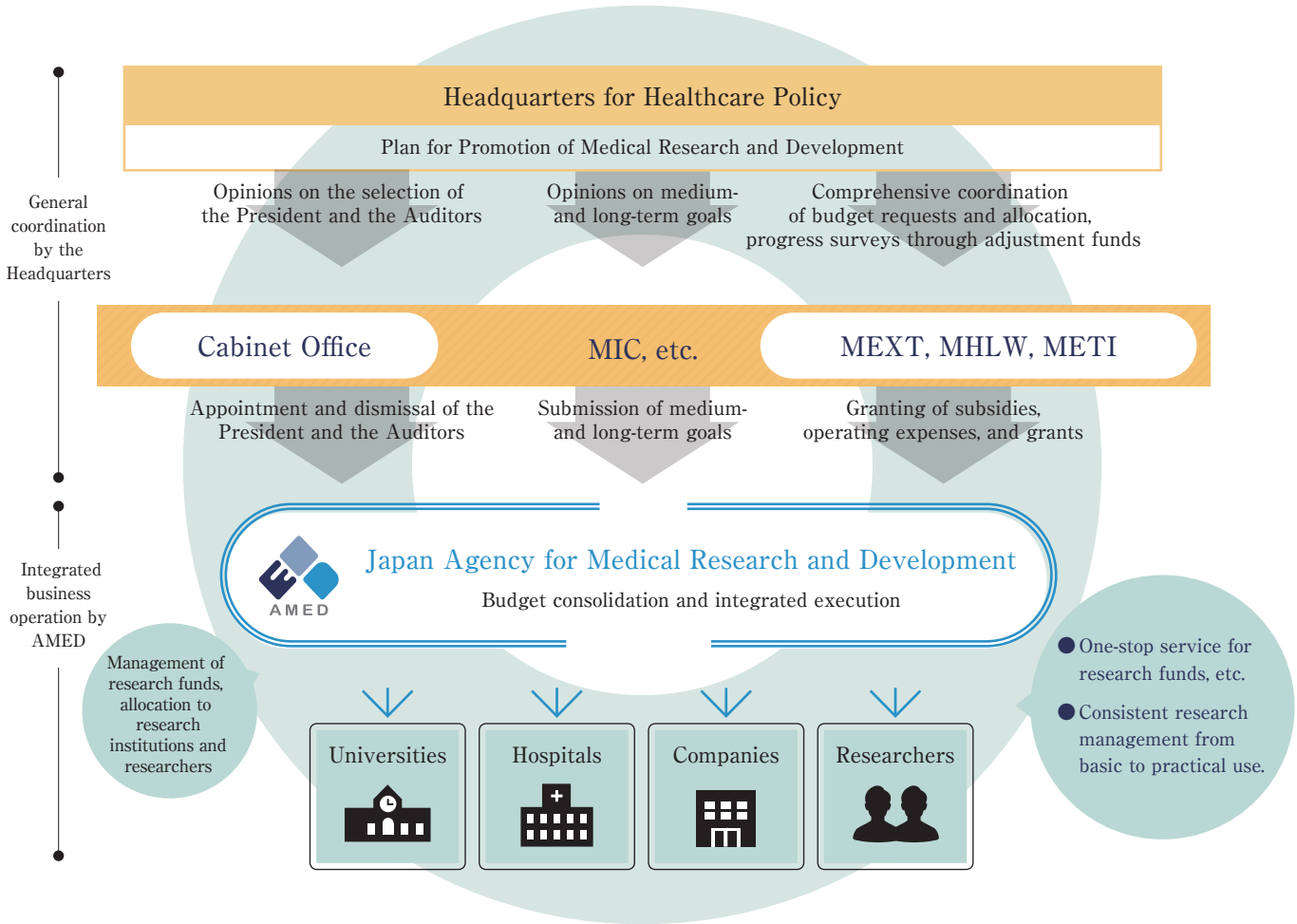
List of calls for international joint research proposals

Call for Proposals Opening Dates	Countries and Regions	Programs and Partner Organizations	Research Areas
August 4, 2015	East Asia Summit member countries	e-ASIA Joint Research Program (e-ASIA JRP) (every year later)	Health Research
July 28, 2016	US and other Asian countries	Infectious Diseases and Immunology Research: U.S.-Japan Cooperative Medical Sciences Program (USJCMSP) Collaborative Awards (every year later)	Infectious Diseases and Immunology
October 18, 2016	Singapore	Strategic International Collaborative Research Program (SICORP) ／ Agency for Science, Technology and Research (A*STAR)	Biological and Molecular Determinants of Human Ageing
March 8, 2018	US and other countries	Interstellar Initiative (joint program with the New York Academy of Sciences (NYAS)) (every year later)	Research Proposal Development through International and Interdisciplinary Collaboration
March 8, 2018	Spain	SICORP ／ State Research Agency (AEI)	Nanomedicine
May 7, 2019	Singapore	SICORP ／ Agency for Science, Technology and Research (A*STAR)	Cell Therapy - a Focus on Quality, Efficacy and Safety
June 19, 2019	UK	SICORP ／ Medical Research Council (MRC)	Infectious Diseases
December 9, 2019	UK	The Program for Technological Innovation of Regenerative Medicine ／ Medical Research Council (MRC)	Regenerative Medicine and Stem Cell Research
April 10, 2020	Germany	SICORP ／ Deutsche Forschungsgemeinschaft (DFG)	Neuroscience - Computational Connectomics
June 22, 2020	Canada	SICORP ／ Canadian Institutes of Health Research (CIHR)	Advancing Epigenetic Technologies
April 12, 2021	Lithuania	SICORP ／ Ministry of Health (MOH)	Basic Research with the Use of Clinical Data and Bioresources in Rare and Undiagnosed Diseases, and Cancer
June 24, 2021	Sweden, Norway, Finland	SICORP ／ NordForsk, Academy of Finland (AKA) , Research Council of Norway (RCN) , Swedish Research Council (SRC)	Japan-Nordic Frontier Research Projects for Healthy Longevity
April 27, 2022	Australia	SICORP ／ National Health and Medical Research Council (NHMRC)	Research and Development on the Prevention, Diagnosis and/or Treatment of Dementia
August 4, 2022	UK	SICORP ／ Medical Research Council (MRC)	Neuroscience, Neurodegenerative Disease and Dementia
May 25, 2023	Singapore	SICORP ／ Agency for Science, Technology and Research (A*STAR)	Tackling and Conquering Cancer Complexity
June 6, 2023	8 countries	Adopting Sustainable Partnerships for Innovative Research Ecosystem (ASPIRE) program ／ Alignment Call - 23 funding agencies	Health Research
January 15, 2024	UK	ASPIRE ／ Medical Research Council (MRC)	Engineering Biology
March 8, 2024	10 countries and one region	ASPIRE ／ Alignment Call - 29 funding agencies	Health Research
June 27, 2024	France	ASPIRE ／ French National Cancer Institute (INCa)	Biology and Basic Sciences for Cancer Research
July 3, 2024	Australia	ASPIRE ／ National Health and Medical Research Council (NHMRC)	System Complexity: Decoding the Spectrum of Disease
October 7, 2024	South Africa	SICORP ／ South African Medical Research Council (SAMRC)	Genomic Insights into the Pathogenesis of Cancer and Infectious Diseases
December 24, 2024	Canada	ASPIRE ／ Canadian Institutes of Health Research (CIHR)	Bringing Biology to Cancer Prevention
Planned call	Switzerland	ASPIRE ／ Swiss National Science Foundation (SNSF)	Mechanisms and Modulation of Inflammaging

About AMED

Who we are

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.



The information posted here are as of March 2025.

Overview

Name Japan Agency for Medical Research and Development (AMED)

Established April 1, 2015

Ministers in charge 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

President MISHIMA Yoshinao, PhD

Number of staff 742 (as of January 1, 2025)

Budget 124.5billion yen (FY2024)

Headquarters 20F Yomiuri Shimbun Bldg. 1-7-1 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan

Domestic Relationship

2015	Pharmaceuticals and Medical Devices Agency (PMDA)
	Japan International Cooperation Agency (JICA)
2016	Japan Science and Technology Agency (JST)
2020	National Institute of Technology and Evaluation (NITE)
	Japan International Cooperation Agency (JICA)
	Japan Science and Technology Agency (JST)
	National Agricultural Research Organization (NARO)
	Japan External Trade Organization (JETRO)
	Information-technology Promotion Agency (IPA)
	New Energy and Industrial Technology Development Organization (NEDO)
	National Institute of Advanced Industrial Science and Technology (AIST)
	Organization for Small & Medium Enterprises and Regional Innovation, JAPAN (SMRJ)
2021	Japan Aerospace Exploration Agency (JAXA)
	Pharmaceuticals and Medical Devices Agency (PMDA)
	Japan Investment Corporation (JIC)

Vision and Management Policy

AMED develops med to long-term plans in compliance with the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999) and is committed to achieving the defined objectives. Currently, AMED is in the second med to long-term plans period (five years from April 1, 2020, to March 31, 2025). The Agency drives industry-academia-government collaboration, manages research and development projects in the medical field and research data, supports practical application of scientific discoveries, implements international strategies, and increases efforts to prevent research misconduct. AMED focuses on maximizing results from scientific activities.

◆ Philosophy ◆

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 act as a catalyst to promote research and development to pave the way toward the creation of medical innovations.

We support collaborations between industry and academia with the aim of practical application of research outcomes.

We collaborate with partners globally to promote joint research based on international trends.

We continually improve processes for the effective management of research funding and operational efficiency.

We work to promote research integrity and ensure compliance with relevant regulations.

Function of AMED

AMED implements the PDCA (Plan-Do-Check-Act) approach to provide integrated management capabilities for specific research projects in line with the governmental Plan for the Promotion of Medical Research and Development. The Agency focuses on translating excellent basic research achievements into clinical studies and eventually practical application and improving the quality of medical care. Its goal is to realize world's highest standard of healthcare and create a healthy longevity society.

medical research and development activities.

Management capabilities by program directors (PDs), program supervisors (PSs) and program officers (POs)

- It drives research projects in line with the Plan for the Promotion of Medical Research and Development and to discover and explore forefront achievements.
- It provides comprehensive management to ensure that excellent basic research results are translated into clinical research and industrialization. (AMED monitors specific research projects and gives advice.)

PDCA cycle

Operates centralized funding capabilities

Monitoring and management capabilities for proper research activities

- It effectively prevents research misconduct (fraudulent use of research funds and misconduct in research), implements facilitating measures for compliance with the ethics code, laws and regulations, and guidelines, and audits fund grantees.

Research activities in a top-down manner according to the Plan for the Promotion of Medical Research and Development

To develop infrastructure for clinical research

Works for capacity building and organization reinforcement of clinical research core hospitals and translational research support organizations

- It supports the institutions in trying to hire relevant specialists (clinical research coordinators (CRCs), data managers (DMs), biostatisticians, and project managers)
- It supports biobanks to develop preventive medicine and associated services according to the EBM* principle

*EBM: evidence-based medicine

Support for practical applications

Provides support capabilities for research institutions to obtain intellectual property rights

- It provides management and consultation services on intellectual property rights and supports institutions in developing intellectual property rights acquisition strategies

Coordinates and helps coordination among companies to achieve practical applications

- It develops and advises on exit strategies for promising seeds under the collaboration with Pharmaceuticals and Medical Devices Agency (PMDA)
- It shares information with companies and provides matching services

Implementation of international strategies

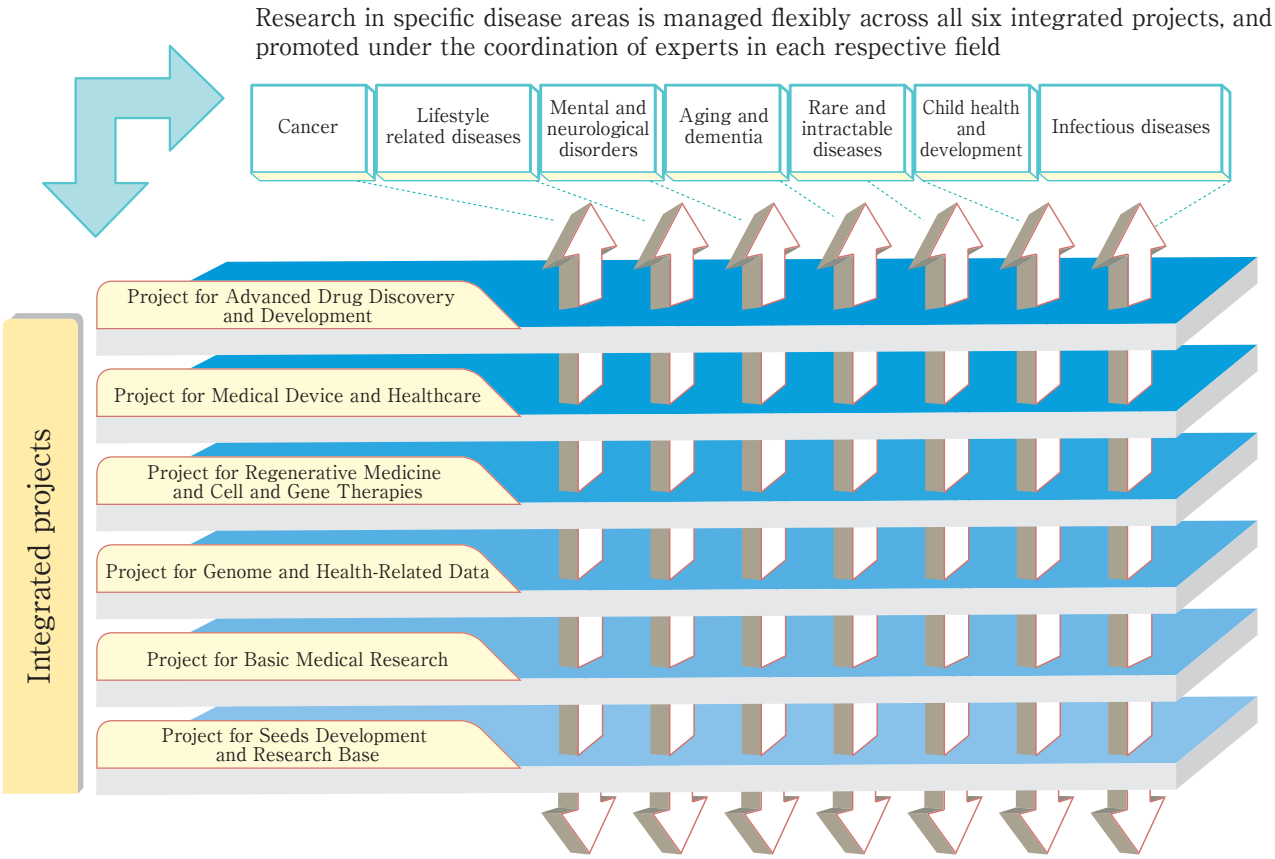
Supports for international joint research projects

- It supports joint research projects in the light of international trends
- It collaborates with overseas research and development organizations in the medical field

AMED's research and development

Six Integrated Projects

According to the governmental Plan for Promotion of Medical Research and Development for the second period, AMED unitedly promotes the medical research and development projects throughout all phases from basic research to the practical application phase. The projects are divided into six streams known as "Integrated Projects" according to the modalities (e.g., drug discovery methodologies and therapeutic tools). In addition, as a part of its efforts to address social issues in Japan, AMED identified seven major disease areas (cancer, lifestyle-related diseases [cardiovascular, diabetes, etc.], mental and neurological diseases, geriatrics and dementia, intractable diseases, growth, and infectious diseases [including drug resistant ones]) and designated disease coordinators (DCs) with extensive experience with the disease areas to ensure that the six integrated projects are managed with due consideration for the disease areas.



Funding additional research and development activities

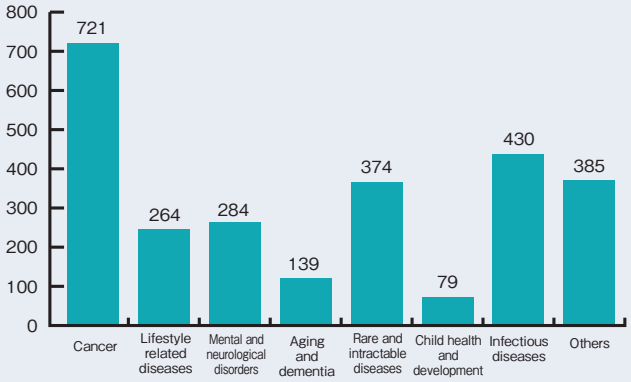
In addition to the six Integrated Projects, AMED uses the funding mechanism to support creation of advanced and urgently needed innovative technologies and mid- to long-term research and development initiatives.

- Cyclic Innovation for Clinical Empowerment (CiCLE)
- Programs relating to the Strategy for Strengthening the Vaccine Development and Production System
- Support for COVID-19 vaccine development
- Drug Discovery Venture Ecosystem Enhancement Project
- Moonshot Research and Development Program in the health and medical fields
- Adopting Sustainable Partnerships for Innovative Research Ecosystem (ASPIRE)
- Translational research program (Support program for startups belonging to medical universities)
- Medical research support program

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.

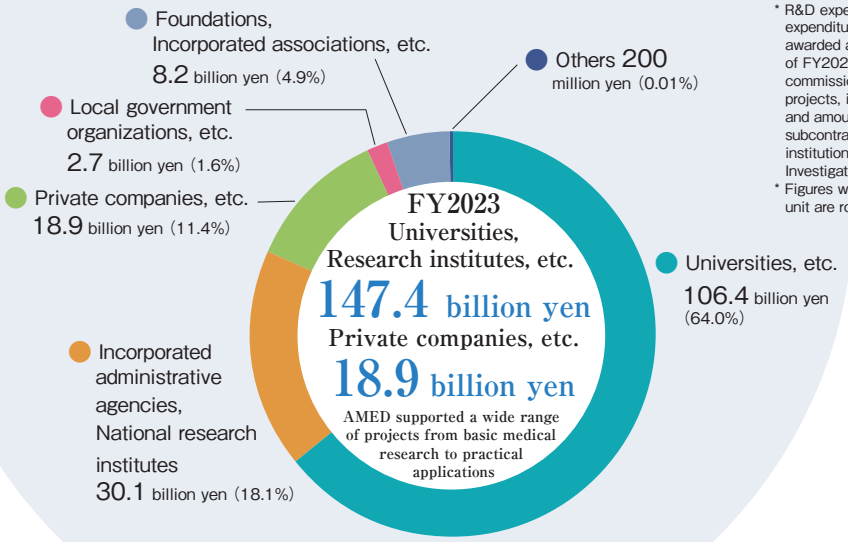
R&D projects



* The number of R&D projects is the number of projects in FY2023, including new and continuing projects.
* Based on AMED data (as of October 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.

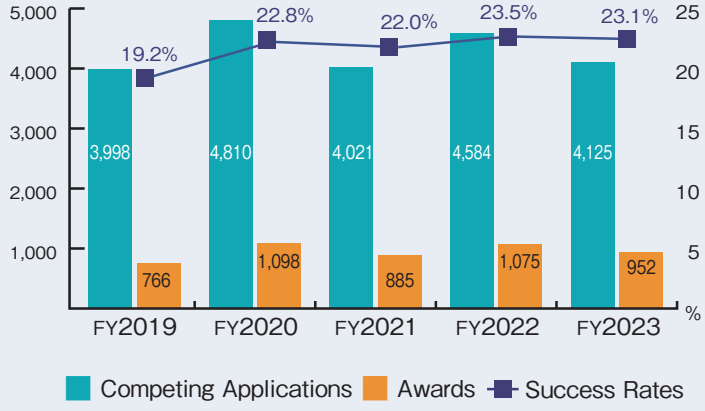
FY2023
AMED supported
2,676
R&D projects
from basic research
to practical
applications.

Institutional Classification; R&D expenditure by institution type



* Based on AMED data (as of October 2024). It excludes projects from the Cyclic Innovation for Clinical Empowerment (CiCLE).
* R&D expenditures are the total expenditure amounts for grants awarded and contracted by the end of FY2023 for all supported, commissioned or subsidized projects, including indirect costs and amounts assigned or subcontracted to other research institutions by the Principle Investigators.
* Figures with fractions less than one unit are rounded to the nearest unit.

Applications, Awards, and 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.

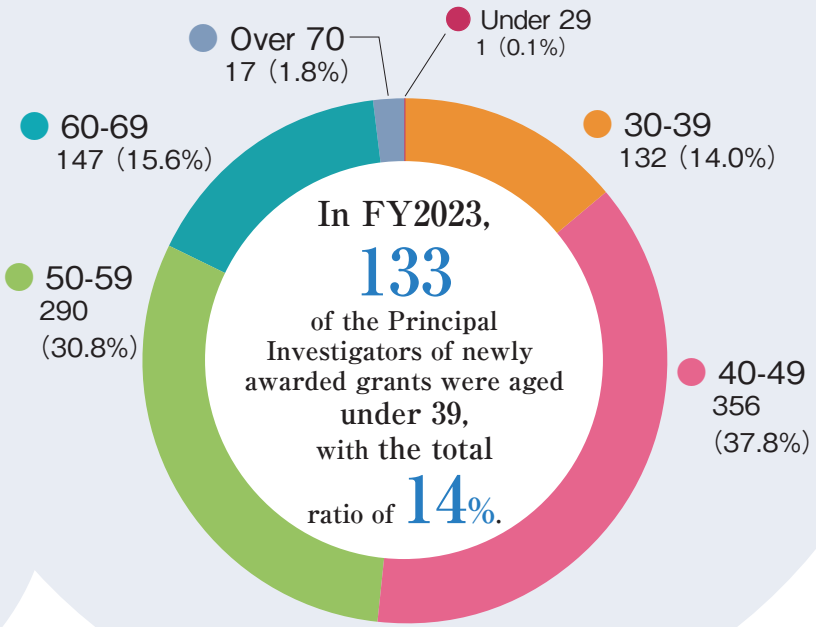
FY2023

Competing Applications **4,125**

Awards **952**

Success Rates **23.1%**

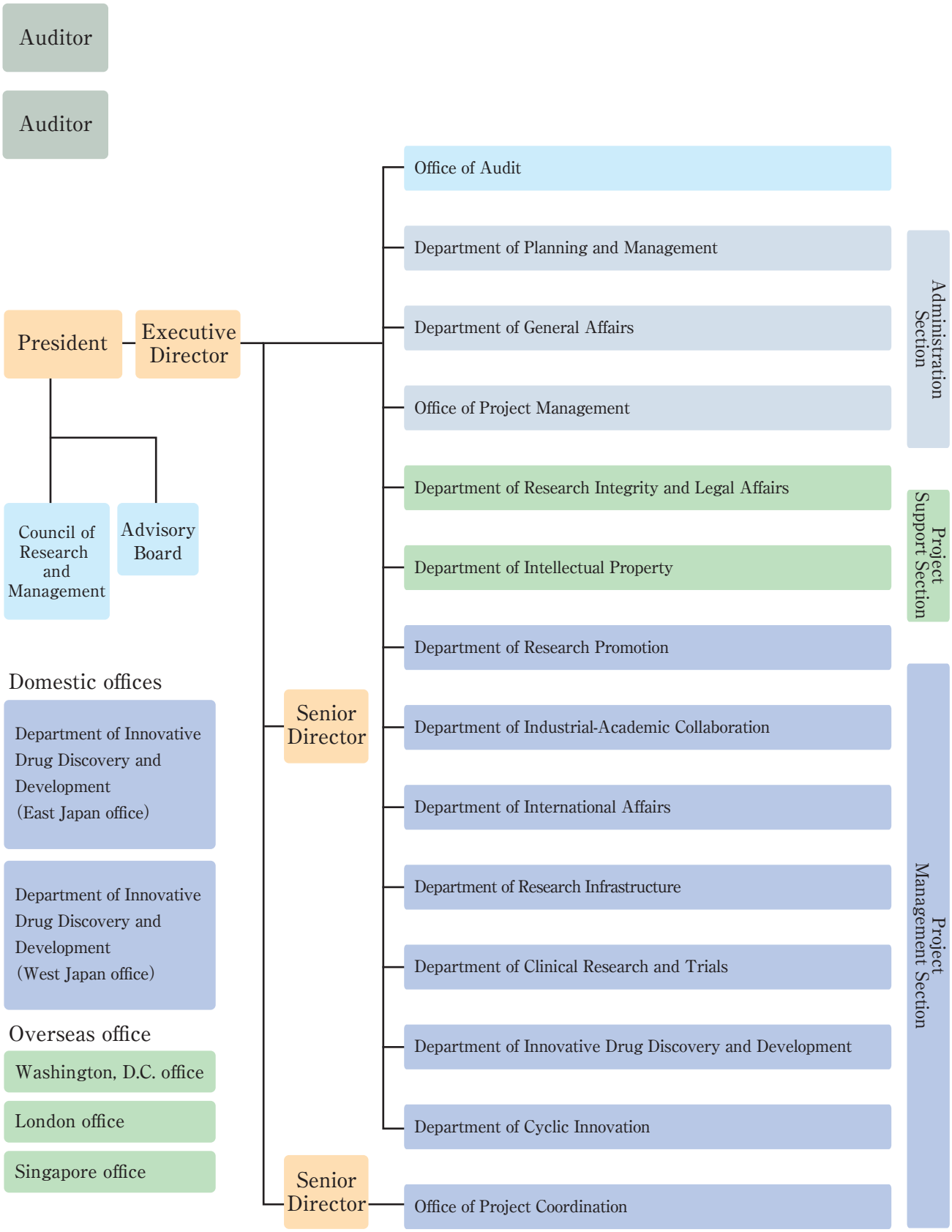
Ages of Principle Investigators of newly awarded grants



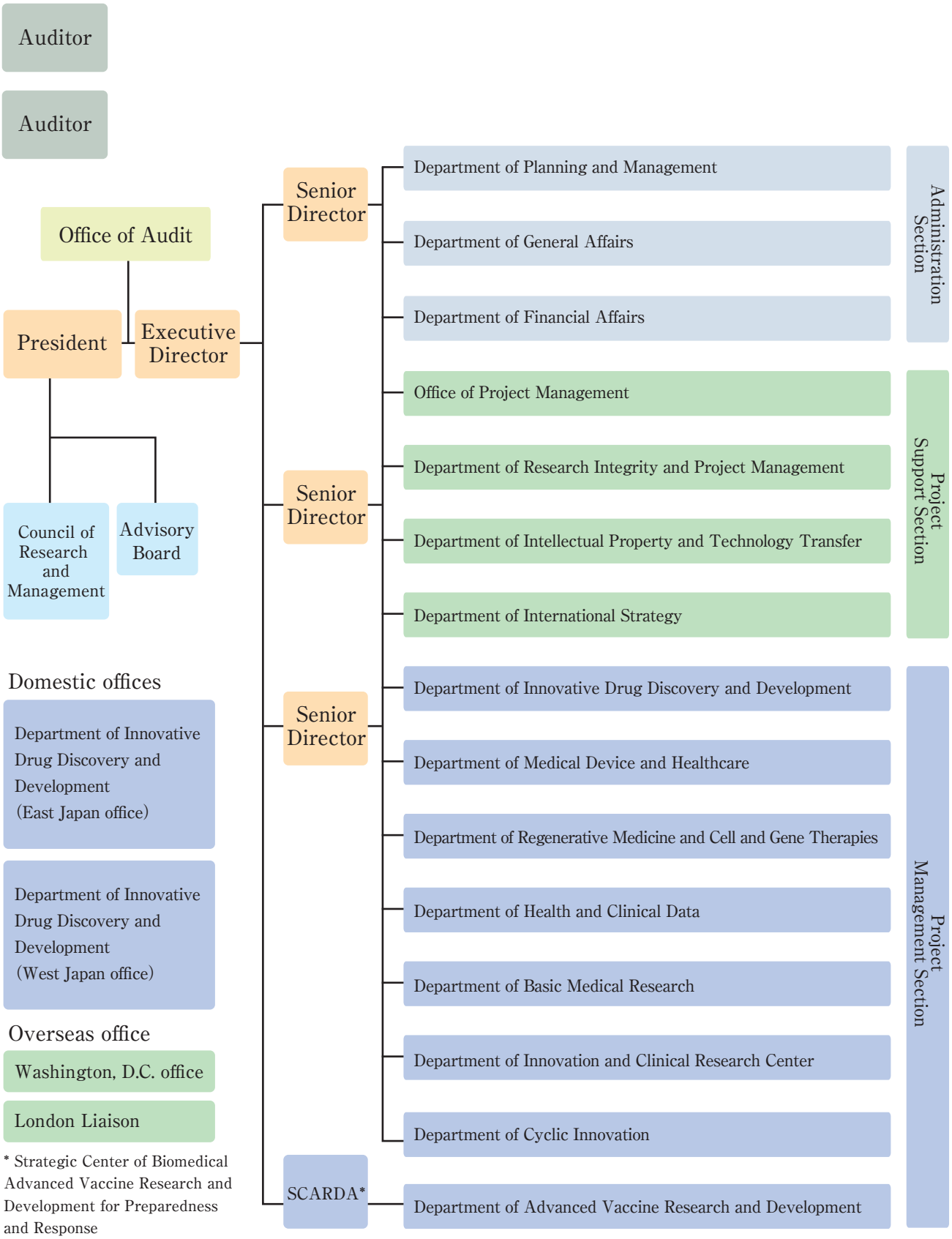
* All Principle Investigators whose projects started during FY2023.
* Ages are taken at the beginning of the fiscal year when the research started.
* Data submitted to e-Rad (as of October 2024) was used to calculate the age of the investigators (excluding any for whom date of birth was not available).

Organization

FY2019 End of 1st Plan Period



FY2024 End of 2nd Plan Period



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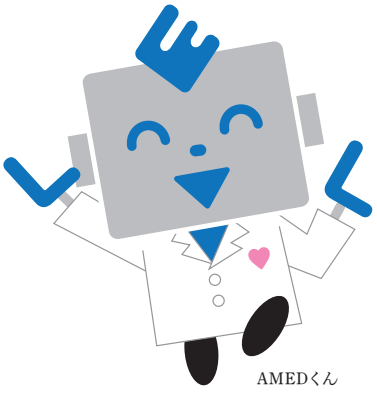
AMEDくん

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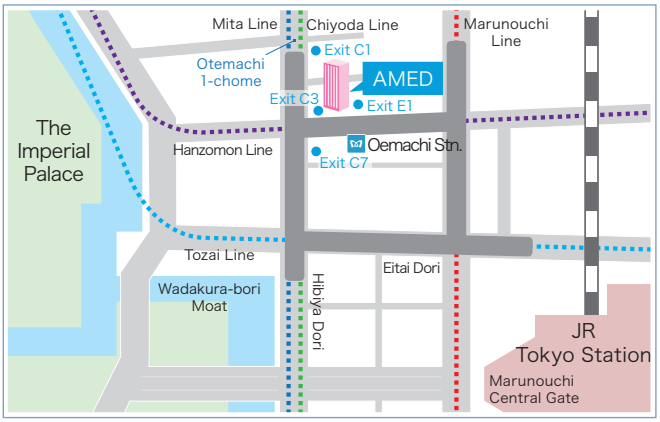

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