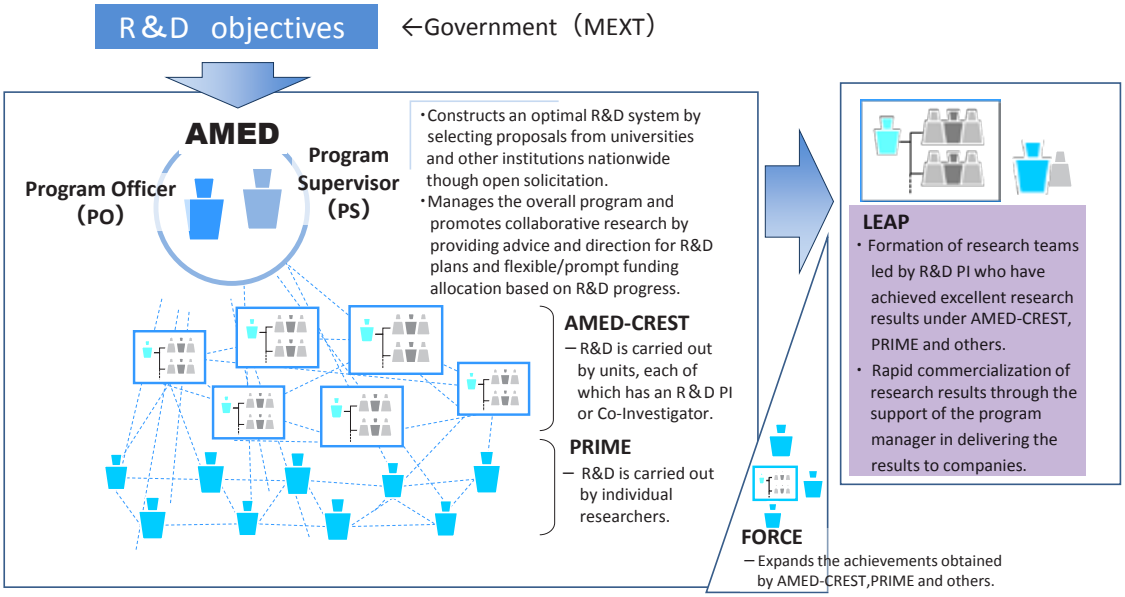
LEAP

Objectives/Characteristics

LEAP (incubation-type, Leading Advanced Projects for medical innovation) is one of the programs promoted by the Advanced Research and Development Programs for Medical Innovation. The program aims to accelerate development of exceptional R&D results generated through unit-type (AMED-CREST) and solo-type (PRIME) projects implemented under the Advanced Research and Development Programs for Medical Innovation, passing on this follow of R&D to companies and venture businesses.
In concrete terms, the technical feasibility of world-leading exceptional R&D results are proven and presented, and rights to these R&D results are appropriately acquired, through the innovation-orientated R&D management of the Program Manager (PM). Through this, it is anticipated that the flow of R&D based on top scientific results will be turned towards medical applications and be passed on to companies, clinicians, and other programs, leading to the future development of innovative drugs, medical devices, and medical technologies, thereby giving birth to a tide of R&D that expands towards social change.



MEXT: Ministry of Education, Culture, Sports, Science and Technology

Program Supervisor (PS)

TAKIMOTO-KAMIMURA Midori

Director, The Chem-Bio Informatics Society, CBI Research Institute, Quantum-Structural life Science Laboratories

Program Officer (PO)

UCHIDA Takahiro

Founder and CEO, Sanamedi, Inc.

OGAWA Atsushi

General Manager of Japan, ICON plc

R&D Period and R&D Costs

The R&D period and costs for a single R&D project are basically as follows

Program	R&D Period	Annual R&D Costs (direct cost)
LEAP	Up to five years	Up to 300 million yen

Proposed R&D costs are examined as part of the selection process. Actual R&D budgets are determined after examination and approval of R&D project plans.

R&D Organization

The Program Manager (PM) works in cooperation with the R&D Principal Investigator (PI) to manage the overall R&D team, including other research collaborators, promoting R&D aimed at proving and presenting technical feasibility.

- R&D is implemented by the R&D PI.
- One PM is assigned to each R&D project. The R&D PI presents a PM candidate proposal at the time of R&D proposal submission.
- The R&D PI has responsibility for the R&D project overall, and promotes R&D necessary for proving and presenting technical feasibility as indicated by the PM. The PM works in cooperation with the R&D PI in carrying out management of the R&D projects for which they are responsible.
- The PM and R&D PI organize an appropriate R&D system that is necessary and sufficient for proving and presenting technical feasibility.
- Based on evaluations and advice provided by the Project Evaluation Committee, the PM proactively builds networks through dialogue with experts, mutual cooperation among participating researchers, and collaboration with individuals and institutions both in Japan and overseas while simultaneously utilizing these networks to promote R&D results with a view to developing them for medical application.

※ PS and PO participate in the preliminary evaluation as a program evaluation committee member and may be possible to participate in the mid-term and post-evaluations as observers.

Started in 2020 LEAP

Development of MuSK-activating drugs for the treatment of intractable neuromuscular diseases

SUGA Hiroaki
Professor, Graduate School of Science, The University of Tokyo

Program Manager KUBO Yuichi
Project Senior Specialist, Graduate School of Science, The University of Tokyo

This project develops drugs that apply to the medical treatment of intractable neuromuscular diseases including myasthenia gravis, amyotrophic lateral sclerosis, and sarcopenia via a mechanism of specific activation of the muscle specific receptor tyrosine kinase. We will develop two distinct modality molecules with unique pharmacological properties, aiming at to deliver either or both molecules to a preclinical phase.

Started in 2021 LEAP

Innovation in molecular design and production of mRNA based on chemistry and its application to vaccines

ABE Hiroshi
Professor, Graduate School of Science, Department of Chemistry, Nagoya University

Program Manager KIM Shokaku
Designated Professor, Graduate School of Science, Nagoya University

Current mRNA drugs have issues to be solved in terms of (1) manufacturing cost, (2) mass synthesis, (3) quality and purity, (4) storage management, (5) stability and sustainability, (6) translation efficiency, and (7) delivery. In this research, we will develop a unique platform technology for mRNA drug discovery to solve the above issues. In addition, in order to cope with current or future pandemics, we will establish a production technology for chemically modified mRNA and establish a base for stable supply in cooperation with pharmaceutical companies.

Started in 2022 LEAP

Seeds and modality development to enhance health and longevity from enhanced motor function

ASAHARA Hiroshi
Professor, Department of Systems Bio Medicine, Graduate School and Faculty of Medicine, Institute of Science Tokyo

Program Manager SHIMOKAWA Teruhiko
Professor, special, Center for Medical Innovation, Institute of Science Tokyo

In the super-aging society, the human locomotor function is linked to medical issues as a new group of diseases such as locomotive syndrome and frailty, as well as to the proposed concepts of "healthy life expectancy" and "healthy longevity society." For diseases, injuries, and aging of the locomotor organs that control this function, we will develop new seeds and modalities related to nucleic acid medicine, bioligament, and cell activation compounds for joint tissue diseases, leading to new treatment methods.

Started in 2023 LEAP

Development of immune system-humanized animal by design chromosome and the drug discovery application

KAZUKI Yasuhiro
Professor, Chromosome Engineering Research Center, Tottori University

Program Manager SAITO Hironobu
Specially appointed Professor, Chromosome Engineering Research Center, Tottori University

The difficulty in predicting human immune responses through in vitro tests and animal experiments is one of the major factors that reduces the probability of success in drug development. In this research, we will use our unique chromosome engineering technology to develop a variety of human immune system-transchromosomic (TC) mouse models that faithfully reproduces the foreign antigen-recognition system of human cellular and humoral immunity. The TC mouse group is useful as a platform that contributes to accelerating research and development of effective and safe biopharmaceuticals.

Started in 2024 LEAP

Therapeutic and diagnostic methods for kidney disease targeting tertiary lymphoid tissues

YANAGITA Motoko
Professor, Kyoto University Graduate School of Medicine

Program Manager SUZUKI Shinobu Innovation Design Expert, Program-Specific Professor, Kyoto University Office of Institutional Advancement and Communications

Chronic kidney disease (CKD) is a highly prevalent condition that progresses to end-stage kidney disease; however, current treatments do not completely prevent its progression. Through the AMED-CREST study, the Principal Investigator identified the formation of tertiary lymphoid structures (TLSs) in the kidney as CKD progressed. Furthermore, the inhibition of TLS formation has been observed to improve kidney function and ameliorate kidney injuries, thus presenting a promising novel therapeutic target. The objective of this research project is to develop therapeutic and diagnostic methodologies targeting TLSs for clinical applications.