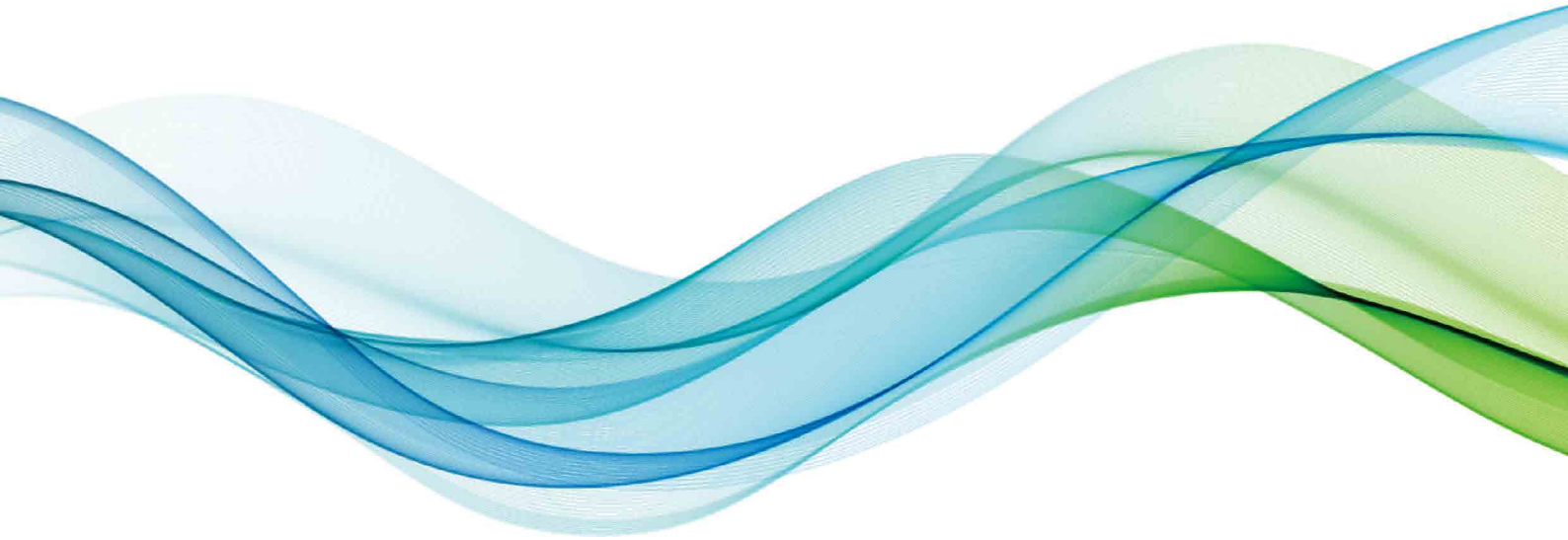


Strengthening Program for Pharmaceutical Startup Ecosystem



Japan Agency for Medical Research and Development



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Strengthening Program for Pharmaceutical Startup Ecosystem

Program Outline

Most new drugs in recent years have been developed by pharmaceutical startups, and it is pharmaceutical startups that have succeeded in the development of vaccines early in the current pandemic. Although a large amount of money is required for the development of new drugs, it is difficult to secure the necessary development funds smoothly in Japan's pharmaceutical startup ecosystem compared to Europe and the United States.

In response to this situation, under the "Strategy for Strengthening Vaccine Development and Production Systems" approved by the Cabinet in June 2021, this Program was established to support pharmaceutical startup companies engaged in the commercialization and development of technologies related to vaccines and therapeutics for infectious diseases. Furthermore, in October 2022, the "Priority Issues in a Comprehensive Economic Package regarding the Implementation of the "Grand Design and Action Plan for a New Form of Capitalism"" stated that this Program "In the future, the government plans to expand the scope of support to drug discovery fields that are difficult to raise funds for, other than those related to infectious diseases."

In order to resolve the shortage of sources of development funds on a large scale, this Program registers VCs that provide hands-on commercialization support specializing in drug discovery, and supports the development and commercialization carried out by Pharmaceutical Startups in the development stage of non-clinical, phase 1, phase 2, or exploratory clinical trials, with the requirement of investment by the registered VCs (Hereinafter referred to as "Registered VC".), thereby raising the foundation of Japan's pharmaceutical startup ecosystem. In particular, we will actively support commercialization plans in overseas markets in addition to Japan in order to achieve sufficient sales and growth.

Program Supervisor (PS)



Former chairperson of Drug
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Program Objective

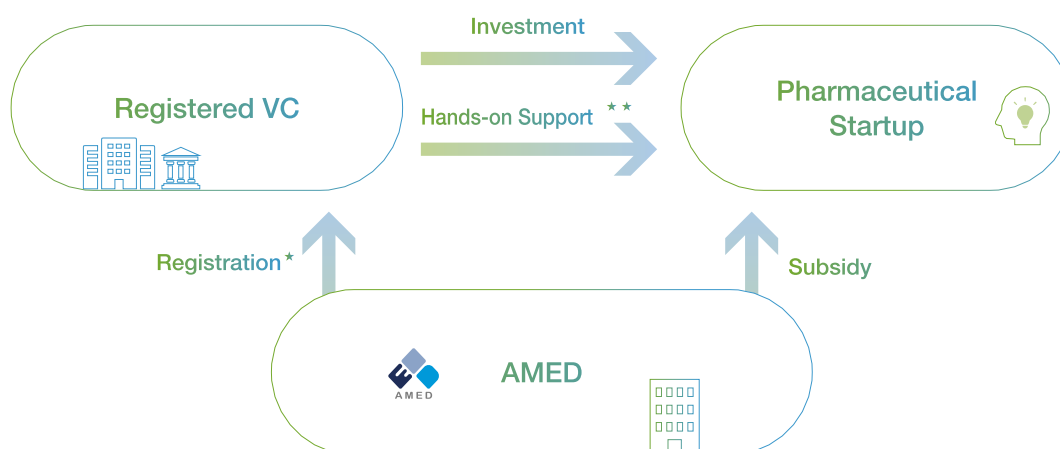
In order to strengthen the Pharmaceutical Startup Ecosystem in Japan, we aim to build the effective and synergistic cycle by creating as many successful examples of global standards as possible.



Program Scheme

In this Program, AMED subsidizes the practical development of pharmaceuticals conducted by Pharmaceutical Startups in which registered VCs invest more than 1/3 of total expenses covered by the Subsidy.

This Program makes two stages of calls for proposals, which are Call for Proposals for VC Registered by AMED ((i) **Call for Proposals for VC Registration**), and Call for Proposals for the practical development of pharmaceuticals conducted by Pharmaceutical Startups invested by Registered VCs ((ii) **Call for Proposals from Pharmaceutical Startups**).



★ **Registration** Registration of VCs with track records of investment and support, etc. in the drug discovery field

★★ **Hands-on Support** Support according to the growth stage of Pharmaceutical Startups from the perspectives on management, development and technology, and regulatory affairs

Call for Proposals for VC Registration

Requirements for certified VCs

- As a lead investor, invest more than 1 billion yen in the startup from the initial investment to the end of the Subsidized Project Period.
- Consistently support the startup as a lead investor during the Subsidized Project Period.

The definition of "lead" in this program is, in principle, the investor who has the largest amount of investment during the period covered by this program, and the investor who plays a leading role in fundraising and hands-on activities.

Registration Period

- 2 business years from the date of registration (Up to the end of the business year in which this program ends)
- An evaluation is conducted every 2 business years to determine whether or not registration can be renewed.
No limit on number of renewals.

Evaluation Items

- | | |
|------------------------------------|------------------------------------|
| ■ Conformity to Program Objectives | ■ Ability to carry out fundraising |
| ■ Sourcing capability | ■ Hands-on capability |

Mandatory Requirements

- (i) Investing 1/3 or more of its total investment as a VC in the drug discovery field in the last 5 years.
(If the applicant has a fund specialized in investing in the drug discovery field, or if the applicant is evaluated as capable of providing particularly high-quality support to Pharmaceutical Startups in the evaluation items, the applicant will be considered for reviewing even if the applicant does not satisfy (i)).
- (ii) The applicant must have a track record of supporting clinical trials conducted by the Pharmaceutical Startup in which it has invested as a Lead VC.
(In the cases of a newly established VC or fund, the requirement (ii) may be subject to review in light of the past performance of the individual*¹ to whom the VC belongs.)
- (iii) The applicant must have a track record of dispatching directors to the Pharmaceutical Startups in which it has invested as a Lead VC.
(In the case of a newly established VC or fund, the requirement (iii) may be subject to review in light of the past performance of the individual*¹ to whom the VC belongs.)
- (iv) Members*² who make investment decisions or provide expert advice on investment decisions as hands-on members have experience in drug development at pharmaceutical companies, etc. (regulatory affairs, business development, development planning, etc.) or have important experience (review by organizations such as PMDA and FDA, etc.) in advancing drug development.
- (v) Members*² who make investment decisions or provide expert advice on investment decisions as hands-on members have experience in global drug development (experience in conducting global clinical trials, experience in providing hands-on support for global clinical trials, etc.).

* 1 Members who make investment decisions or provide expert advice on investment decisions as hands-on members.

* 2 General partner, partner, etc.

Plan of call for Proposals

The Call for Proposals are scheduled to be held periodically several times a year.

* Please check the latest Application Guidelines

List of Registered VCs

(As of August 2026)

Registered VC
4BIO Partners LLP
Angel Bridge Inc.
ANRI Inc.
ANV Management, LLC
Astellas Venture Management LLC
B Capital Group Management, L.P.
Beyond Next Ventures Inc.
Blackstone Life Sciences
Catalys Pacific, LLC
Cure Ventures Management, LP
Curie Bio Operations, LLC
D3LLC
DBJ Capital Co., Ltd.
DCI Partners Co., Ltd.
Deerfield Management Company, L.P.
Eight Roads Ventures Japan (Eight Roads Capital Advisors Hong Kong Limited)
EQT Life Sciences
Fast Track Initiative, Inc.
F-Prime Capital Partners (Impresa Management LLC)
JAFCO Group Co., Ltd.
JIC Venture Growth Investments Co., Ltd.
Keio Innovation Initiative, Inc.
Kyoto University Innovation Capital Co., Ltd.
Mission BioCapital
Mitsubishi UFJ Capital Co., Ltd.
Miyako Capital Inc.
Newton Biocapital Partners
OSAKA University Venture Capital Co., Ltd.
RA Capital Management, L.P.
Remiges Ventures, Inc. / RDiscovery, KK
Saisei Ventures LLC
SV Health Managers LLP
Taiho Innovations, LLC
Taiho Ventures, LLC
The Column Group LLC
The University of Tokyo Edge Capital Partners Co., Ltd. (UTEC)
TPG Life Sciences Innovations (TPG Global, LLC)
UTokyo Innovation Platform Co., Ltd.

The Latest Outlines of Registered VCs



Call for Proposals from Pharmaceutical Startups

Target of Call for Proposals

Field	Scale of Expenses Covered by Subsidy (Including indirect costs and Registered VC investment)	Subsidized Project Period
#1 Innovative technological development for development of infectious disease vaccines and therapeutic drugs.	[amount of money] (upper limit) 10 billion yen (Accept even if the upper limit is exceeded)	Up to September 2031 (Set for each Adopted Project)
#2 Innovative technological development for development of pharmaceuticals etc. for diseases other than infectious diseases.	AMED Subsidy covers up to 2/3 of the expenses.	

- The applicant must have received, or be scheduled to receive in the future, investment from a Registered VC (must include the lead VC) in the amount of 1/3 or more of the expenses covered by the Subsidy.
- Pre-clinical study, Phase 1 clinical study, Phase 2 clinical study or Exploratory clinical study is covered.
- "Pharmaceuticals, etc." includes pharmaceuticals and regenerative medicine products.
- You must have filed a domestic or foreign patent application for the development candidate products. However, if you have not filed an application at the time of application for strategic reasons, please provide details of your strategy (development strategy, intellectual property strategy, business strategy, pharmaceutical strategy, etc.) in your proposal.
- If the final development candidate product has not been determined, proposals to conduct non-clinical studies to determine the final development candidate product are also accepted.
- If all Stage Gate Evaluations stipulated in the Subsidized Project Plan are passed, the Subsidized Project is up to September 2031.

Goals of this Program

- Completion of phase 2 clinical study or Exploratory clinical study (POC acquisition)
- If IPO & M&A is carried out during Subsidized Project Period, the Subsidized Project will be terminated in principle.

Evaluation Items

- Compatibility with the program's purpose
- Superiority and effectiveness of technology, etc.
- Development plans and goals
- Business plan
- Support plan by Registered VC

Frequency of call for Proposals

Several times a year.

* Please check the latest Application Guidelines

List of Adopted Projects

(As of August 2026)

Adoption Year	R&D Project	Business Operator
FY2022	Development of an innovative therapeutic agent for myotonic dystrophy type1 by a sequence-specific RNA binding protein targeting pathogenic CUG-repeat RNA	EditForce, Inc.
FY2023	Clinical proof of concept study of OZTx-556, a human iPS cell-derived cardiomyocyte, in a global clinical trial for patients with severe heart failure	Orizuru Therapeutics, Inc.
FY2023	Obtaining POC in global Phase II clinical trial of a viral vector-based gene therapy	Restore Vision Inc.
FY2023	Development of K _{ATP} channel inhibitor NTX-083 for Alzheimer's disease therapy	Neusignal Therapeutics Inc.
FY2023	Research and development of mitochondria replaced autologous T cells as pharmaceutical product for the treatment of cancer	Imel Therapeutics, Inc.
FY2023	Development of hypoimmune iPS cell-derived cytotoxic T cell therapy for GPC3-positive solid cancer	Shinobi Therapeutics Co. Ltd.
FY2023	Development of a Novel Treatment for Refractory Metastatic Recurrent HER2-Negative Breast Cancer	Periotherapia Co.,Ltd.
FY2023	A novel cancer immunotherapy utilizing M2-like tumor-associated macrophage-selective nanoparticulate DDS encapsulated TLR agonist.	United Immunity, Co., Ltd.
FY2024	The Development of ASCL-derived Platelet Like Cells (ASCL-PLC) as a regenerative medicine to treat intractable cutaneous ulcer	AdipoSeeds, Inc.
FY2024	Development of SFG-02 for underactive bladder	Juro Sciences Inc.
FY2024	Development of First-in-class oral lipid metabolism regulator PRD001 and POC obtained for lipid metabolism disorder	PRD Therapeutics, Inc.
FY2024	Development of novel autologous CAR-T cell installing GITRL, for GD2-expressing refractory solid tumors	T Cell Nouveau Inc.
FY2024	Development of a new antibody drug to treat congenital tooth agenesis	Toregem BioPharma Co., Ltd.
FY2024	Development of MGT-006 as an Ulcerative Colitis Drug	Metagen Therapeutics, Inc.
FY2024	Development of a novel cell therapy using vascular endothelial stem cells for intractable skin ulcers associated with systemic sclerosis	Revascular Bio Co., Ltd.
FY2024	Development of a novel ex vivo expanded Hematopoietic Stem Cell therapy product for rare pediatric blood diseases	Celaid Therapeutics Inc.
FY2024	Development of antigen-specific immune cell therapy against autoimmune liver diseases	RegCell Co., Ltd.
FY2024	Development of pH-responsive polymeric micelles selectively delivering IL-12 to solid tumors for non-responders against existing Immunotherapy	Red Arrow Therapeutics, KK
FY2024	Development of a novel gene therapy for the neurodegenerative disease	reverSASP Therapeutics Co., Ltd.
FY2024	Development of hypoimmune allogenic iPSC-derived CD19-CAR targeting Natural Killer cell therapy for autoimmune diseases	Shinobi Therapeutics Co. Ltd.
FY2024	Development of a gene therapy pipeline using mRNA-mediated Gene Writing for severe genetic diseases	Typewriter TX Japan GK
FY2024	Development of Novel Anti-Cancer Drug by "Locking Inhibition" of Amino Acid Transporter	Atransen Pharma Ltd.
FY2024	Research and development of a first-in-class small molecule inhibitor, for the treatment of luminal cancers	CORE Biomedicine Japan GK



Adoption Year	R&D Project	Business Operator
FY2024	Development of anti-FAPa CAR-T with a dual effect on tumor cells and the tumor microenvironment in GBM	Optieum Biotechnologies Inc.
FY2024	Development of novel antibody-drug conjugate (ADC) targeting a GPCR overexpressing solid tumors	LiberoThera Co., Ltd.
FY2025	Development of a Bacteriophage Cocktail ARW001 for the Treatment of <i>Pseudomonas aeruginosa</i> Lung Infections	Arrowsmith Inc.
FY2025	Clinical development of bispecificity allogeneic CAR-T cell therapy for CD19/CD20 positive relapsed/refractory B-cell lymphoma	AvenCell Japan KK
FY2025	Development of a CRISPR-Cas3 genome-editing cell therapy for primary immunodeficiency	C4U Corporation
FY2025	Development of ferroptosis inducing anti-cancer therapy utilizing novel mechanism	FerroptoCure Inc.
FY2025	Development of TSP-101 for cancer cachexia	Tensegrity Pharma, Inc.
FY2025	Development of cell therapy for chronic kidney disease using human iPS cell-derived nephron progenitor cells	Rege Nephro Co., Ltd.
FY2025	Development of bispecific biopharmaceuticals depleting pathogenic autoantibody-producing B cells in ulcerative colitis	Link Therapeutics Inc.
FY2025	Development of novel therapeutic drug against β -hemoglobinopathy	EpiFrontier Therapeutics
FY2025	Development of Surv.m-CRA-2-IC, A Novel, Innovative Oncolytic Virus armed with immune genes, for Treating Refractory Cancers with Infiltration, Metastasis.	Surv BioPharma Inc.
FY2025	Development of novel therapeutics using human iPS cell derived hepatoblasts for acute-on-chronic liver failure	Senno Therapeutics, Inc.
FY2025	Development of Disease-specific Treg Cell Therapy for Refractory Autoimmune Diseases	RegCell Co., Ltd.
FY2025	Development of Novel Small-Molecule Drug for Peripheral Neuropathy and Neuropathic Pain	Sanodyne Therapeutics, Inc.
FY2025	Development of in vivo CAR macrophages program for the treatment of treatment resistant solid tumors	United Immunity Co., Ltd.
FY2026	Development and Commercialization of SOL-257, an Innovative Gene Therapy for ALS that Restores the Structure and Function of Pathologically Misfolded TDP-43	SOLA Biosciences Japan GK
FY2026	Development of a novel sublingual immunotherapy using the next-generation TLR4 agonist HSO-001 for house dust mite allergic rhinitis	HISHOH Biopharma Co.
FY2026	Development and commercialization of a novel small-molecule therapeutic for the treatment of xerostomia in patients with Sjögren's syndrome	Aquelys Therapeutics Japan
FY2026	Development of SCO-240, an oral SSTR5 antagonist, for the treatment of pediatric growth hormone deficiency	SCOHIA PHARMA, Inc.
FY2026	Development of oral recombinant IgA antibodies for <i>Clostridioides difficile</i> infection, an intestinal infection prone to recurrence after antibiotic treatment	Igalphan Co., Ltd.

Projects Achieving Goals

Project Period	R&D Project	Business Operator	Goal
2024-2025	Development of a new LAT1 inhibitor for multiple sclerosis	J-Pharma Co., Ltd.	IPO



Consulting service

Now accepting interview (individual consultations) regarding applications.

*Individual consultations will not be provided during the application period.

- Persons eligible for consultation: VCs and Pharmaceutical Startups who are considering applying for this program.
- Consultation process: Please send an e-mail to the address above with your consultation matters.
- Implementation method: Online (web conference) or face-to-face interview

Contact

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Japan Agency for Medical Research and Development (AMED)

* Replace "AT" with "@".



Japan Agency for Medical Research and Development

Strengthening Program for Pharmaceutical Startup Ecosystem

Division of Medical Ecosystem Development,
Department of Medical Innovation Ecosystem



https://www.amed.go.jp/program/list/19/02/005_00014.html

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