[Translation]

Application Guidelines

Strengthening Program for Pharmaceutical Startup Ecosystem/ Venture Capital Registration (6^{th} call for proposals)

April 2025

Declaration of Intent to Apply Deadline	Wednesday, May 7, 2025 at noon (Observe strictly)
Deadline for uploading of Application Documents	Tuesday, May 13, 2025 at noon (Observe strictly)

Japan Agency for Medical Research and Development (AMED)

Division of Medical Ecosystem Development
Department of Medical Innovation Ecosystem

<e-mail address for inquiries> v-eco”AT”amed.go.jp

Message from AMED

Japan Agency for Medical Research and Development (AMED)
President Hitoshi Nakagama, M.D., D.M.Sc.

Initiatives to Promote Social Co-creation

All AMED R & D projects contribute to solving health and medical issues in Japan, and it is necessary to promote practical applications while gaining the understanding and trust of society while ensuring the safety and security of the people through dialogue and cooperation with society. In order to put R&D results into practical use as soon as possible, deliver them to patients and their families, and contribute to the development of society, AMED projects identify and examine ethical, legal, and social issues (ELSI) from the early stages of R&D, and promote R&D that incorporates measures to address them into research plans, etc.

In addition, in conducting R&D in the medical field, it is necessary to improve the field of medical R&D, and as a result, contribute to the dissemination and return of research results to society in a better manner. For this purpose, it is important to actively share the significance of medical R&D and the benefits it brings to society with society, to create R&D results that respond to society's needs through patient and public involvement (PPI) from the planning stage of R&D, and to expand collaboration between researchers and patients and citizens based on equal partnerships. From this perspective, in order to fulfill our mission of putting research results in the medical field to practical use as early as possible and delivering them to patients and families while supporting each patient and supporting the three LIFEs (生命, 生活 and 人生), AMED will promote PPI initiatives in which researchers incorporate the knowledge of patients and citizens in the medical R&D process.

Initiatives to Promote Diversity in Research and Development

"Diversity" is a source of innovation and an essential element for realizing individual happiness and creative value. AMED places importance on diversity in all areas and roles that participate in research and development related to health and medicine, and its mission is to deliver the latest pharmaceuticals and medical technologies to people in Japan and around the world who need them as soon as possible. In other words, AMED aims to achieve its mission by encouraging the participation of people with diverse expertise and values derived from nationality, gender, age, background, etc., and by striving to foster an environment in which they can fully demonstrate their abilities and insights.

One of the important initiatives related to diversity in research and development in the health and medical fields is the creation of an environment that enables women researchers to further flourish. In various fields of research in Japan, the ratio of women researchers in gender equality is low compared to the situation in Western countries. In the AMED project, we will promote the active promotion and participation of excellent women researchers and support the implementation of research that takes into account life events such as childbirth, childcare, and nursing care in the course of carrying out research.

In addition, in the AMED project, we will promote the promotion of diverse human resources for experts engaged in problem assessment and problem management that do not impose excessive burdens on researchers while appropriately advancing research to support them, and we will enhance our functions as a research funding agency.

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Chapter 1. Program Outline

These Application Guidelines describes the conditions and contents of the call for proposals from venture capital (Hereinafter referred to as "VC".) for the Strengthening Program for Pharmaceutical Startup Ecosystem (hereinafter referred to as the "Program".) conducted by the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED".).

AMED will promote investment and support activities in Japan by VCs that invest in pharmaceutical startups (Hereinafter referred to as "Pharmaceutical Startups".) that develop innovative technologies that contribute to the development of pharmaceuticals, etc., in this Program, and will provide commercialization support for Pharmaceutical Startups while utilizing their knowledge and support functions.

This call for proposals will recruit VCs that support Pharmaceutical Startups. VCs who wish to participate in this Program should apply in accordance with these Application Guidelines. A separate call for proposals will be made for Pharmaceutical Startups eligible for grants from AMED.

Since this Program will be implemented based on the government budget, the contents of the call for proposals and the implementation plan after adoption may be changed or cancelled due to changes in government policy.

1.1 Overview of Program, Current Status, Direction, Goals and Results

1.1.1 Background and Program Objectives

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" [*1] 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 Points of Comprehensive Economic Measures for the Implementation of the "New Capitalist Grand Design and Implementation Plan"" 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. Pharmaceutical startups, which are Japanese subsidiaries of foreign corporations established for fund-raising or commercialization in overseas markets, will also be eligible for support.

*1 "Strategy for Strengthening Vaccine Development and Production Systems" (approved by the Cabinet on June 1, 2021) http://www.kantei.go.jp/jp/singi/kenkouiryou/senryaku/r030601vaccine_kaihatu.pdf

1.1.2 Outline of this Program

In this Program, AMED grants subsidies for the practical development of pharmaceutical products carried out by Pharmaceutical Startups, with the requirement that more than 1/3 of the subsidized costs be invested by Registered VCs.

This Program involves two stages: (1) Call for Proposals for VCs registered by AMED; and (2) Call for Proposals from Pharmaceutical Startups invested by Registered VCs. The results of the adoption of (1) Call for Proposals for VCs and the list of contacts of Registered VCs are posted on the website (*) of this Program.

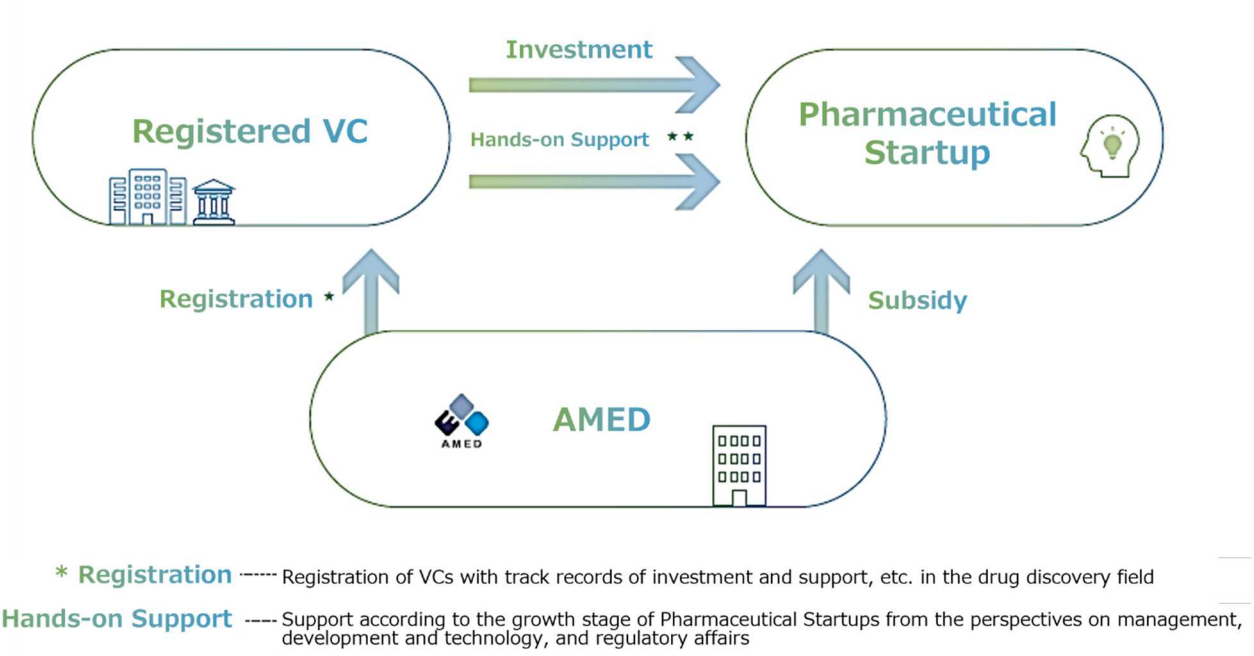
In this call for proposals, AMED will solicit and register VCs suitable for supporting Pharmaceutical Startups *3 engaged in innovative technology development in non-clinical, phase 1, phase 2, or exploratory clinical trials *2 ((1) Call for Proposals for VCs).

*2 This Program is not limited to the clinical trials under the act on ensuring the quality, efficacy, and safety of pharmaceuticals, medical devices, etc., but also includes clinical trials for confirming safety and exploring efficacy in healthy volunteers or patients.

*3 Call for Proposals from Pharmaceutical Startups

A Pharmaceutical Startup that receives a certain amount of investment from a Registered VC may apply for Call for Proposals from Pharmaceutical Startups of this Program ((2) Call for Proposals from Pharmaceutical Startups). In doing so, the Registered VC is required to use the funds listed in the Application Form for this Call for Proposals and to nominate hands-on members listed in the Application Form.

(*) Program website https://www.amed.go.jp/program/list/19/02/005.html



Program Scheme

Please review all the information listed on the website (*) of Call for Proposals for VC Registration and frequently asked questions (FAQ) before making the application.

(*) Call for Proposals Information website https://www.amed.go.jp/koubo/19/02/1902B_00070.html

1.2 Composition of Program

1.2.1 Program Implementation System

AMED promotes R&D through six integrated projects, including pharmaceuticals, medical devices and healthcare, regenerative/cellular medicine and gene therapy, genomic data infrastructure, basic disease research, and seed development and research infrastructure, as well as through fund projects, based on the "R&D Promotion Plan for Medical Fields"(*) stipulated by the national government. In addition, in order to ensure efficient utilization of competitive research funds and smooth implementation to produce excellent results, a Program Director (hereinafter referred to as "PD".) is assigned to each integrated project, and a Program Supervisor (hereinafter referred to as "PS".) and a Program Officer (hereinafter referred to as "PO".) are assigned to each program.

PS, PO, etc. will grasp the progress of the entire Program and provide necessary guidance and advice for the smooth promotion of the Program. In addition, research institutions and researchers are obliged to cooperate with PS, PO, etc.

Based on guidance and advice provided by PS, PO, etc., the plan of supporting Subsidized Projects may be reviewed or suspended (including early termination due to the achievement of the plan.) as necessary.

The following PS and PO are assigned to manage this Program. (PO may be added or replaced depending on the progress of the Program.)

- PS: Osamu Inagaki (former secretary of the Pharmaceutical Evaluation Committee of the Japan Pharmaceutical Manufacturers Association)
- PO: Chika Hashimoto (representative of Galasus GK)
- PO: Yoshiharu Hayashi (Chairman, Public Interest Incorporated Foundation, SENSHIN Medical Research Foundation)

(*) https://www.kantei.go.jp/jp/singi/kenkouiryou/senryaku/index.html

1.2.2 Registration Period

Two business years from the date of registration *4

The interim evaluation will be conducted in the second business year, and the decision to renew the registration will be made based on the status of activities as a Registered VC in addition to the mandatory requirements when registered stipulated in Section 4.2.2. There is no limit to the number of renewals, but the maximum registration period will be until the end of March 2032.

After registration, we will check the status of activities (sourcing activities, investment activities, etc.) every business year. There is a possibility that the registration will be cancelled as a result of the activity status.

At the end of the registration period, if there are Subsidized Projects in this Program that are still in the subsidized project period, you may continue activities as a Registered VC only for those projects.

*4 The business year of this Program is from April 1 to March 31 of the following year.

Chapter 2. Application Requirements

2.1 Application Requirements for Registered VC

- The applicant must be a corporation *1 that invests in startups as a business and supports Pharmaceutical Startups in commercialization (Venture Capital, Corporate Venture Capital *2).
- The applicant must not fall under the category of an organized crime group, a member of an organized crime group, an organized crime group related company or related person, a racketeer, or any other anti-social forces (Hereinafter referred to as "Anti-social Forces".), including a parent company or a subsidiary, or be involved with any person related to Anti-social Forces.
- The applicant must agree to the matters set forth in the Registration Agreement *3 and conclude the Registration Agreement upon registered.

*1 In cases where the investment function and the commercialization support function are shared with other companies having a relationship between the wholly owning parent company and the wholly owned subsidiary company, or with another company having a controlling relationship with the same person based on service agreement, etc., the applicant should consult with AMED in advance, specify the relationship and roles of the multiple organizations, and apply on behalf of the organization primarily in charge of this Program. If the application is adopted, the Registration Agreement shall be concluded by multiple parties including the related organizations.

*2 Except in the case of carrying out direct investment from the main account of a corporation whose major business is not investment.

*3 The Registration Agreement is posted on the Call for Proposals Information website.

Call for Proposals Information website https://www.amed.go.jp/koubo/19/02/1902B_00070.html

2.2 Restriction on Eligibility in Participation, etc.

2.2.1 Restrictions on VCs whose application and participation eligibility are restricted under other competitive research funding programs, etc.

With regard to VCs, in which misconduct, etc. has been found and applications and eligibility for participation have been restricted in research funds other than the Program under the jurisdiction of the national government or an Incorporated Administrative Agency, etc., for which all or part of the source funds are financed from the national treasury (This includes, but is not limited to, grants for operating expenses such as competitive research expenses.)(This includes a program in which a new call for proposal begins after fiscal 2023. The program that ended in fiscal 2022 or earlier is also subject to this requirement.), application and eligibility for participation in the Program will be restricted during the period when the restriction is imposed. If it becomes clear that an application or participation in the Program has been made after the adoption or approval, the adoption or approval of the Program may be rescinded.

2.2.2 Cases of Suspected Misconduct under Other Competitive Research Funding Programs

If a VC is accused of having committed misconduct under another competitive research funding program (including completed programs), the VC is obliged to report to AMED that the

misconduct has entered the investigation. In response to the report, AMED may revoke adoption or registration.

【Cautionary notes】

Based on the "Procedures for Suspension of Subsidies under the Jurisdiction of the Ministry of Economy, Trade and Industry and Suspension of Nomination for Contracts (established on February 1, 2003)," institutions, etc. subject to suspension of nominations cannot apply for this call for proposals.

If an institution, etc. is subject to suspension of nominations after applying but before the approval is decided and announced, it will be deemed that it has lost the eligibility to apply.

Details are available on the the Ministry of Economy, Trade and Industry website. For details, see the following:

- Suspension of Subsidies, etc., and Suspension of Nomination for Contracts
  https://www.meti.go.jp/information_2/publicoffer/shimeiteishi.html
- List of businesses currently suspended
  https://www.meti.go.jp/information_2/downloadfiles/shimeiteishi.pdf

2.3 Registered VC's Compliance Matters

Please observe the following.

- Proactively promote initiatives that lead to the discovery and support of pharmaceutical startups in target technology areas, the strengthening of the Japanese pharmaceutical startup ecosystem, and the strengthening of cooperation with the global drug discovery community.
- Build a good relationship with the adopted Pharmaceutical Startups, provide hands-on support in accordance with the submitted support plan, and promote the commercialization of the adopted Pharmaceutical Startups in a way that maximizes their value.
- Maintain a sound cash flow and capital policy for the Pharmaceutical Startups during the subsidized project period (so that the subsidized project will not be affected by funds shortage) and aim to advance pharmaceutical development in accordance with the subsidized project plan and expand the business of the adopted Pharmaceutical Startups.
- Endeavor to increase the amount raised when the next fund is established.
- Do not collect coaching fees or other charges for hands-on and other support from adopted Pharmaceutical Startups.
- Do not enter into agreements that unreasonably restrict future business development of the adopted pharmaceutical startups, by leveraging this Program. *4
- Ensure appropriate protection of information obtained during operations, such as the business plan of the Pharmaceutical Startup to which the investment is made.
- Report on the progress of hands-on support to AMED on a regular basis (and in response to requests from AMED).
- Cooperate in the disclosure of information, including questionnaires from AMED and the posting of corporate information and activities on AMED's website (At the time of publication, we ask you to confirm the content of the publication in advance).
- Other matters specified in the Registration Agreement.

*4 See "Important Notes on Contracts for Sound Venture Investment in Japan" (Revised by the Ministry of Economy, Trade and Industry in March 2018 and March 2022).
https://www.meti.go.jp/policy/newbusiness/data/ryuizikou_r.pdf (In Japanese)

2.4 Obligations of Payment to AMED

If a Registered VC that invests in a subsidized Pharmaceutical Startup sells its shares within one year*5 after receiving the grant decision for this Program*6, a maximum of 2/3*7 of the sales amount must be paid to AMED.

*5 If a new grant decision is received from AMED after the adoption or Stage-Gate Go decision, within one year from the date of the decision.
*6 Not applicable if shares are sold to a pharmaceutical company (A marketing authorization holder or a manufacturer of pharmaceuticals, or a marketing business or manufacturing business of regenerative medicine products based on the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices (Act No. 145 of 1960), or an R&D type business operator engaged in drug development or regenerative medicine product development).
*7 Amount to be paid = sales amount x {subsidy amount under this Program / (subsidy amount under this Program + total amount of investment by Registered VCs)}

2.5 Revocation of Registered VC

Registration may be revoked in the following cases:

(i) If the application requirements set forth above in 2.1 are no longer met.
(ii) if it is found that the applicant has not complied with the requirements set forth above in 2.3.
(iii) if the payment obligations set forth above in 2.4 are imposed on a Registered VC who invests in an adopted Pharmaceutical Startup as a Lead VC.
(iv) if the Application documents are found to be false.
(v) if the Program has not been substantially utilized for a certain period.
(vi) if AMED finds it grossly inappropriate to continue registration.
(vii) other cases that fall under the provisions of the Registration Agreement.

2.6 Pharmaceutical Startups in the Scope of Support

2.6.1 Call for Proposals from Pharmaceutical Startups

For the pharmaceutical startups to be supported, please refer to the Application Guidelines for call for proposals from Pharmaceutical Startups to be announced in future. VCs that have been adopted and registered through this Call for Proposals can apply for Call for Proposals from the Pharmaceutical Startups after the conclusion of the Registration Agreement. For an overview of past Calls for Proposals from Pharmaceutical Startups, please refer to this program website*.

* Program website https://www.amed.go.jp/program/list/19/02/005.html

The Call for Proposals from Pharmaceutical Startups is scheduled to be held periodically four times a year.

The retroactive period for investment from Registered VCs is from November 8, 2022 (the date of Cabinet decision on the supplementary budget for fiscal 2022) until the time of application.

2.6.2 Points to Consider Regarding Support

- Among the Registered VCs that support Pharmaceutical Startups, a Lead Registered VC must support consistently from the time of application to the end of the subsidized project. If a final development candidate has been determined, the investment from the Lead Registered VC must be 1 billion yen or more by collectively adding the investment made prior to the retroactive period (see 2.6.1) and from the beginning date of the retroactive period through the entire subsidized project period. If a final development candidate has not determined, the investment from the Lead Registered VC must be 100 million yen or more by collectively adding the investment made prior to the retroactive period (see 2.6.1) and from the beginning date of the retroactive period through the entire subsidized project period.
- A pharmaceutical startup that is an affiliate of an operating company, etc. cannot apply when the Lead Registered VC is an affiliate of the operating company, etc.

2.7 Points to Consider When Applying

2.7.1 Security Trade Management (Handling of Technology Leakage to Overseas Countries)

Many cutting-edge technologies are being researched at research institutions. In particular, at universities, the number of international students and foreign researchers has increased due to internationalization. As a result, cutting-edge technologies and research materials and equipment have been leaked, increasing the risk of their misuse in the development and manufacture of weapons of mass destruction. For this reason, when research institutions conduct various research activities, including research and development, they are required to take systematic measures to prevent research results that may be diverted militarily from reaching those who may engage in activities of concern, such as developers of weapons of mass destruction or terrorist groups.

In Japan, export controls * are enforced in accordance with the Foreign Exchange and Foreign Trade Act (Act No. 228 of 1949) (Hereinafter referred to as the "Foreign Exchange Act".). Therefore, in principle, if you intend to export (provide) goods or technology regulated by the Foreign Exchange Act, you need to obtain permission from the Minister of Economy, Trade and Industry. Please abide by the Foreign Exchange Act and other laws, guidelines, and notices provided by the national government. If research and development is carried out in violation of relevant laws, regulations, guidelines, etc., the approval may be revoked in addition to legal penalties and penalties.

*Currently, based on international agreements, etc., Japan's security export control system includes a system that requires permission from the Minister of Economy, Trade and Industry (list regulation) in principle when exporting (providing) goods (technologies) with certain or higher specifications and functions, such as carbon fiber and numerically

controlled machine tools, and a system that requires permission from the Minister of Economy, Trade and Industry (catch-all regulation) when exporting (providing) goods (technologies) that do not fall under list regulation and satisfy certain requirements (application requirements, consumer requirements, or in-form requirements).

Technology provision as well as export of goods is subject to the foreign exchange law. In the case of providing list control technology to a foreign person (non-resident) (Includes residents who fall under the specified category *.) or in a foreign country, prior permission is required. The provision of technology includes not only providing technical information such as blueprints, specifications, manuals, samples, and prototypes on paper, email, CDs, DVDs, USB memories, etc., but also providing working knowledge through technical guidance and skills training and providing technical support at seminars. The acceptance of foreign students and activities such as joint research often involve the exchange of technology that may be subject to foreign exchange laws.

*This refers to the types of residents who are strongly affected by non-residents and refers to the specific types described in "with regard to transactions or acts that provide technology that requires permission pursuant to the provisions of Article 25, paragraph (1) of the Foreign Exchange and Foreign Trade Act and Article 17, paragraph (2) of the Foreign Exchange Order;"1. (3) Sa (1) - (3).

In addition, in accordance with the Foreign Exchange Law, it is necessary to establish a system for security trade management when exporting list regulated goods or providing list regulated technology to foreign countries during trade *. For this reason, by the time of the decision to grant subsidies, we may confirm whether the Program is scheduled to export goods and technology subject to the export regulations of the Foreign Exchange Law, and if there is an intention to export goods, we may confirm whether there is a control system. If there is an intention to export goods and there is no control system, we will request that the system be developed by the time of export or termination of the Program, whichever comes first. The confirmation status may be reported to the Ministry of Economy, Trade and Industry at the request of the Ministry of Economy, Trade and Industry. In addition, if the technology acquired through the Business is found to be in violation of regulations pertaining to the Foreign Exchange Act, the approval may be revoked.

* Exporters, etc. are obliged to comply with the "Exporters, etc. Compliance Standards" prescribed in Article 55 10, Paragraph 1 of the Foreign Exchange Act. In addition, the security trade control system here refers to the internal control system of the organization based on the control system set forth in the "Exporters, etc. Compliance Standards" to prevent unauthorized exports, etc. by appropriately exporting list-controlled goods or providing list-controlled technology to foreign countries.

Details of security trade control are available on websites such as the Ministry of Economy, Trade and Industry. For details, see the following:

- the Ministry of Economy, Trade and Industry: Security Trade Management (General)
  https://www.meti.go.jp/policy/anpo/
  (Q&A https://www.meti.go.jp/policy/anpo/qanda.html)
- the Security Trade Information Center
  https://www.cistec.or.jp/
- Guidance on the management of sensitive technologies related to security trade (for universities and research institutes)

https://www.meti.go.jp/policy/anpo/law_document/tutatu/t07sonota/t07sonota_jishukanri03.pdf

- ○ the Ministry of Economy, Trade and Industry: Handbook for Security Trade Management
  https://www.meti.go.jp/policy/anpo/seminer/shiryo/handbook.pdf
- ○ Transactions or acts of providing technology that require permission pursuant to the provisions of Article 25, Paragraph 1 of the Foreign Exchange and Foreign Trade Act and Article 17, Paragraph 2 of the Foreign Exchange Order
  https://www.meti.go.jp/policy/anpo/law_document/tutatu/t10kaisei/ekimu__tutatu.pdf

2.7.2 On the strict implementation of United Nations Security Council resolution 2321

Following North Korea's nuclear test in September 2016 and a series of ballistic missile launches, the United Nations Security Council (hereinafter referred to as "the Security Council".) adopted Security Council Resolution 2321 on November 30, 2016, which significantly added and strengthened sanctions against North Korea. In this regard, the Ministry of Education, Culture, Sports, Science and Technology issued No. 98, "Strict Implementation of United Nations Security Council Resolution 2321 (Request)," dated February 17, 2017, in conjunction with Section 28.

"Science and Technology Cooperation" in Section 11 of the main text of the resolution includes not only technology regulated by the Foreign Exchange Law but also all cooperation except for medical exchange purposes. It is important for organizations to pay attention to the strict implementation of this resolution when conducting their activities.

Regarding Security Council Resolution 2321, please refer to the following:

- ○ the Ministry of Foreign Affairs: Japanese translation of United Nations Security Council Resolution 2321 (the Ministry of Foreign Affairs Notification No. 463 (issued on December 9, 2016))
  https://www.mofa.go.jp/mofaj/files/000211409.pdf

2.7.3 Promotion of initiatives related to gender equality, etc.

The Basic Plan for Science, Technology and Innovation (approved by the Cabinet on March 26, 2021), the Basic Plan for Gender Equality (approved by the Cabinet on December 25, 2020), the "Policy package on education and human resource development for the realization of Society5.0 (decided by the Council on Science, Technology and Innovation on June 2, 2022)" and the "Common Guidelines for Developing a System for Competitive Research Funding from the Perspective of Gender Equality and Human Resource Development (February 8, 2023)" aim to create an environment that makes it easy for both men and women to continue their activities even when life events such as childbirth, childcare and nursing care occur, and to promote the appointment of excellent women as responsible persons.

Based on these considerations, AMED will provide consideration and support to enable representatives to continue their work when they are forced to temporarily withdraw from work due to a life event * or when their time to devote to work is shortened.

If you have any questions regarding the application of this support, please contact the Division in charge of this business.

*Eligible Life Events

Delivery: 6 weeks before delivery (14 weeks for multiple pregnancies) and 8 weeks after delivery

Childcare: Period until the child reaches 3 years of age

Nursing care: Period deemed necessary within a period of 6 months (You can extend it as needed.)

Chapter 3. Preparation and Submission of Application Documents

3.1 Preparation of Application Documents

3.1.1 Application Documents

No.	Mandatory/Optional	Necessary Application Documents	How to obtain
1	Mandatory	Application Form (Word)	Download from the website of the Call for Proposals
2	Mandatory	Application Form Attachment (Excel)	Download from the website of the Call for Proposals
3	Mandatory	Articles of Incorporation	
4	Mandatory	Materials on the fund prospectus, or Investment Briefing documents, etc.	
5	Optional	Other existing materials	

* Be sure to check the "To prepare the application" section at the beginning of the Application Form template (Word).

3.1.2 How to obtain the template of Application Documents

Please download the template of Application Documents prepared by AMED from the Call for Proposals Information website.

Call for Proposals Information website https://www.amed.go.jp/koubo/19/02/1902B_00070.html

3.1.3 Procedures for Application, etc.

Please prepare the Application Documents in accordance with the Application Guidelines and apply for it by the submission deadline in the following submission method. The Registration Agreement, Briefing Session Material, and Frequently Asked Questions (FAQ) are posted on the Call for proposals Information website (see 3.1.2). Please be sure to check them before preparing for the Application Documents.

Deadline for submission

1. **Deadline for declaration of intent to apply:**
   Wednesday, May 7 at noon (Observe strictly)
2. **Deadline for uploading Application Documents:**
   Tuesday, May 13 at noon (Observe strictly)

* Direct and fax submissions will not be accepted.
* Submissions without the declaration of intent to apply by the due date will not be accepted.

3.1.4 How to submit Application Documents

・ As a declaration of intent to apply, please send (1) the name of the corporation, (2) the name of the contact person, (3) the contact telephone number, and (4) the contact e-mail

address to v-eco"AT"amed.go.jp (change the "AT" part to @). The subject line should be "Strengthening Program for Pharmaceutical Startup Ecosystem (Venture Capital Registration)". **(Deadline: noon, Wednesday, May 7)**

- We will send you the uploading test information with the URL for submitting the Application Documents. After the uploading test, please upload the Application Documents by the deadline. **(Deadline: noon, Tuesday, May 13)**
- **Please allow time to express your intention to apply and upload.**
- The Application Documents are 6 or 7 files as described in "III. Checklist Pertaining to Files to be Uploaded (to be submitted)" in "Read This Before You Prepare Application" at the beginning of "Application Form." (Word file)
- Do not set a password for the file.
- Set the file name to VC25, _ (underbar), legal entity name other than K.K. (abbreviated), and document name.
- Example: VC25_AMED_ document name. (extension)
- If you resubmit the file within the deadline due to unavoidable reasons, please add a number (second time: 2) after the file name to indicate the number of submissions, and then upload it again. Please confirm that the file is the latest version at the end of the application.
- After the deadline for uploading the Application Documents, we will contact your contact person by e-mail when accepting the submitted Application Documents in about one week.

3.1.5 In cases where there is a deficiency in the acceptance of Application Documents and Application Form, etc.

- Application Documents submitted will not be returned.
- If the upload is not completed within the deadline or AMED fails to accept the application, it will be rejected.
- Application Documents submitted by persons who do not meet the application requirements or with defects will not be accepted.
- If Application Documents have defects and cannot be corrected by the submission deadline, the application will be invalid.

3.1.6 language of the Application Documents

- Please write the Application Form and the Application Form attachment in Japanese or English.
- If you use a foreign language in other Application Documents, please use English.

Chapter 4. Evaluation

4.1 Selection Schedule

The acceptance period and selection schedule for Application Documents in this Program are planned as follows at the time of commencement of the call for proposals.

Period of acceptance of Application Documents/selection schedule (Please be sure to bear in mind Notes (i) to (viii))	
Period of acceptance of Application Documents	**From Tuesday, April 15, 2025 to Tuesday, May 13, 2025 at noon (JST) (Observe strictly)** * Declaration of Intent to Apply Deadline: Wednesday, May 7 at noon (Observe strictly) * Deadline for uploading of Application Documents: Tuesday, May 13 at noon (Observe strictly)
Document Review	Late May to early June 2025 (planned)
Hearing review (Interview)	Either of July 9th (Wednesday) or 11th (Friday) 2025 (scheduled)
Notification of review results	Early September 2025 (planned)
Execution of registration agreement (Start of registration period)	October 1st (Wednesday) 2025 (planned)

- Cautionary notes
  - (i) Please note that all Application Documents cannot be accepted after the deadline.
  - (ii) If there are any defects in the submitted documents, they may not be accepted.
  - (iii) In some cases, AMED may send administrative confirmation matters or inquiries arising during the evaluation process to the Principal Investigator by e-mail or other means. Please respond promptly to such confirmation by the method specified by AMED (if no response is received, the application may be excluded from the evaluation).
  - (iv) The interview may be conducted via the web, etc.
  - (v) In principle, VC applicants subject to the interview will be notified by e-mail no later than one week prior to the interview (We will not contact you if you are not subject to the interview or if the interview itself is not conducted. Please wait until we notify you whether to adopt it.). If there is any information update regarding the conduct or schedule of the interview, please refer to the Call for Proposals Information website.
  - (vi) We do not answer regarding the eligibility of individual applications for the interview.
  - (vii) The date of the interview cannot be changed.
  - (viii) The method of the interview may be changed or canceled due to unforeseen circumstances such as social disorder caused by an epidemic of infectious diseases or disasters. If the interview is canceled, the document evaluation period may be extended.

4.2 Method of Evaluation of Application Documents

4.2.1 Evaluation Method

For the adoption of VC in this Program, an Evaluation Committee members appointed by the AMED President will be the evaluator. The Evaluation Committee will evaluate the specified evaluation items, and AMED will adopt VC based on the evaluation results.

(A) The evaluation will be conducted in private by the Evaluation Committee established at AMED. Please note that we are unable to respond to inquiries regarding the progress of the evaluation or the evaluation itself.

(B) The Evaluation Committee will conduct a document review of the contents of the submitted Application Documents, and if they pass the review, it will conduct a further interview and evaluate them through deliberation. During the review, we may request additional submission of materials, etc.

(C) In the formal review, the following cases shall not be accepted.
  (i) If the applicant does not meet the applicant requirements
  (ii) If the Application Documents required for the application are defective

(D) After completion of the evaluation, AMED will notify the applicant of the evaluation results.

(E) The Evaluation Committee members are obliged to observe confidentiality with the aim of prohibiting leakage or plagiarism of secrets learned in the course of their duties, even after their retirement.

(F) The corporate name of the Registered VC will be disclosed on AMED's website later. The names of the Evaluation Committee members will also be disclosed on AMED's website when the results of the adoption are disclosed.

(G) From the viewpoint of conducting fair and transparent evaluation, we conduct conflict of interest management for Evaluation Committee members in accordance with AMED's Bylaw on Handling Conflict of Interest Management for Committee Members. If an Evaluation Committee member falls under any of the following conditions, he/she shall request a declaration from AMED as the subject of conflict-of-interest management and shall not participate in the evaluation of the subject matter in principle.
  (i) When the person to be evaluated is a family member
  (ii) When the person to be evaluated belongs to the same department, etc. or the same enterprise in a research institution such as a university, National Research and Development Agency, or National Institute for Testing and Research
  (iii) When the person to be evaluated has conducted close joint research within the past 3 years including the fiscal year containing the date of the Evaluation Committee meeting
  (iv) When the person to be evaluated has a close teacher-student relationship such as providing or receiving guidance on a doctoral dissertation
  (v) When the Committee member has received an economic benefit exceeding 1 million yen in any fiscal year within the past 3 years including the fiscal year containing the date of the Evaluation Committee meeting
  (vi) When the Committee member is in direct competition with the person to be evaluated
  (vii) When other serious conflicts of interest are found to exist

(H) Those who intend to apply or have applied should not approach AMED officers and employees, PS, PO, or Evaluation Committee members for evaluation and adoption.

4.2.2 Evaluation Items

○ Conformity with Program Objectives
- Overview of the corporation, priority areas as a VC, investment performance, investment indexes, etc.

○ Ability to carry out fundraising
- Overview of funds to be utilized in this Program, investment capacity, future fund establishment plans, etc.

○ Sourcing capability
- Details and results of sourcing activities in the drug discovery field (development programs, financial support during seed and early stage, Entrepreneur in Residence, wet labs and office leasing, etc.), due diligence capabilities, investment considerations, etc.

○ Hands-on capabilities
- Provision of integrated support and timely and appropriate advice based on the growth stage of Pharmaceutical Startups in the following perspectives:

1) Management perspective

Business plan (global business strategy, capital policy, funding, and investment planning, exit strategy (especially M&A)), internal management, progress management, public relations and external communication, human resource support, introduction to pharmaceutical companies, etc. and other marketing channels.

2) Development and technology perspective

Acquisition of POC, resolution of technical issues (formulation, mass production, etc.), ensuring competitive advantage (IP and differentiation strategies, etc.), CMO/CDMO and CRO collaboration, etc.

3) Regulatory affairs viewpoint

FDA/PMDA, GCP compliance, GMP compliance, etc.

The following points are mandatory requirements for the review of the above items.

(1) 1/3 or more of the total investment as a VC has been invested in the drug discovery field in the last five years. (If the applicant holds a fund that specializes in providing investment in the drug discovery field, or if the evaluation items indicate that the applicant can provide high-quality support to Pharmaceutical Startups, the applicant is subject to review even if it does not meet (1).)

(2) The applicant has a track record of supporting clinical trials conducted by the investee Pharmaceutical Startup as a lead VC. (If a VC or fund is newly established, the requirements of (2) may be subject to review considering the past performance of the individual *[1] to which the VC or fund belongs.)

(3) The applicant has a track record of dispatching directors to the investee Pharmaceutical Startup as a lead VC. (If a VC or fund is newly established, the requirements of (3) may be subject to review considering the past performance of the individual *[1] to which the VC or fund belongs.)

(4) Members who make investment decisions *[2] or members who are hands-on and provide expert advice on investment decisions have experience in drug development at pharmaceutical companies, etc. (regulatory affairs, BD (business development),

development planning, etc.) or have important experience in advancing drug development (Review by PMDA, FDA, etc.).

(5) Members who make investment decisions *2 or members who are hands-on and provide expert advice on investment decisions have experience in global drug development (experience in conducting global clinical trials, hands-on support for global clinical trials, etc.).

*1 Members who make investment decisions or members who are hands-on and provide expert advice on investment decisions

*2 General Partners, Partners, etc.

4.3 Publication and Notification of Adoption Results

- The corporate name of the Registered VC will be disclosed on AMED's website later. In addition, regarding the results of the examination will be separately notified to the applicant in writing.
- Adoption may be subject to various conditions.
- The Evaluation Committee members will disclose their affiliations and names on AMED's website, etc. when the results of the evaluation are published.

Chapter 5. Information Handling

5.1 Handling of Information Contained in Application Documents, etc.

5.1.1 Purpose of use of information

The information contained in Application Documents regardless of whether they are adopted or not, will be used for evaluation for adoption, research trends analysis and macro analysis that contribute to AMED program management such as new business creation.

In order not to unreasonably infringe the rights and interests of the applicant and the organization to which the applicant belongs, the purpose of use of the information will be limited to the above works.

In addition, the information contained in the Application Documents regardless of whether they are adopted or not, will be appropriately managed in accordance with laws and regulations related to corporate document management, personal information protection, and information disclosure, as well as AMED regulations, etc., and the confidentiality of the information contained in the Application Documents, etc. will be strictly observed in order not to unreasonably infringe the rights and interests of the applicant and the organization to which the applicant belongs. For details, please refer to the following website *[1].

*[1] "Public Records and Archives Management System" (Cabinet Office)
https://www8.cao.go.jp/chosei/koubun/index.html (in Japanese)
"Personal Information Protection Act, etc." (Personal Information Protection Commission)
https://www.ppc.go.jp/personalinfo/
"Information Disclosure System" (the Ministry of Internal Affairs and Communications)
https://www.soumu.go.jp/main_sosiki/gyoukan/kanri/jyohokokai/index.html (in Japanese)

5.1.2 Necessary Information Disclosure and Provision of Information

Information on individual organizations that have been adopted (title, name, etc. of the organization, representative and person in charge) *2 may be organized and classified and disclosed on the AMED website.

*[2] Information will be treated as "information that is scheduled to be made public" as provided in Article 5, Item 1, (a) of the "Act on Disclosure of Information Held by Incorporated Administrative Agencies, etc." (Act No. 140 of 2001).

Chapter 6. Post-Registration Considerations

6.1 Representations and Warranties Pertaining to Misconduct, etc.

The Business Operator is required to make the following representations and warranties (A) through (C) in the registration process.

(A) The person who participates in the Program has not been imposed by the national government or an Incorporated Administrative Agency, etc. a measure to restrict application or eligibility for competitive research expenses (It includes a person who is expected to take the measures due to a finding of misconduct, etc., and excludes a person whose period of the measures has ended.).

(B) If the person who participates in the Program is a subject of the investigation based on the National Guidelines for Handling Misconduct, etc., or AMED's Rules for Handling Misconduct, etc., the person has already notified AMED of the content and has obtained AMED's understanding of the content.

(C) The Business Operator has complied with and implemented each of the matters required to be implemented by the Operator as the operator's system development stipulated in the National Guidelines for Handling Misconduct, etc., and related laws and regulations, etc. *.
*The "Guidelines for Measures against Misconduct, etc., by the national government" collectively refers to guidelines and guidelines for measures against other misconduct, etc. formulated by the national government.

Chapter 7. Contact

If you have any questions about the contents of this Call for Proposals, please contact the Divisions and Departments shown in the following table. If there is any information update, it will be posted on the Call for Proposals Information on the AMED website*, so please refer to it.

Please check the Briefing Session Material and frequently asked questions (FAQ) before contacting us. Please note that an inquiry alone is not a declaration of intent to apply.

* https://www.amed.go.jp/koubo/

Contents of inquiries	Contact details
Call for proposals, how to fill out the Application Documents, etc.	Please see the cover page of the Application Guidelines
Conflict of Interest (COI) Management	Division of Research Integrity, Department of Research Integrity and Project Management, AMED E-mail: amedcoi"AT"amed.go.jp Please check the website below before contacting us. https://www.amed.go.jp/kenkyu_kousei/riekisohan_kanri.html
Misconduct, Misuse, Fraudulent Use	Division of Research Integrity, Department of Research Integrity and Project Management, AMED E-mail: kouseisoudan"AT"amed.go.jp Please check the website below before contacting us. https://www.amed.go.jp/kenkyu_kousei/soudan_kokuhatu.html

*Change the address "AT" above to @.

Japan Agency for Medical Research and Development

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