Strengthening Program for Pharmaceutical Startup Ecosystem: 7th Call for Proposal for VC Registration

Briefing Session of Call for Proposals

October 22, 2025

Department of Medical Innovation Ecosystem
Japan Agency for Medical Research and Development (AMED)

Translation

Notes

- This document provides an overview of the Application Guidelines for 7th round of call for proposals in the Strengthening Program for Pharmaceutical Startup Ecosystem/Venture Capital Registration.
- When applying, please make sure to check the details of the Application Guidelines.
- The Application Guidelines and other materials may be revised during the call for proposals period. In such cases, the call for proposals information will be posted on the website*.
- If there is any discrepancy between this document and the contents of the Application Guidelines, the contents of the Application Guidelines will be regarded as correct.
- Before preparing the applicatuion documents, please make sure to check the VC Registration Agreement, Briefing Session of Call for Proposals, and frequently asked questions (FAQ) posted on the website*.

* Call for proposals information website https://www.amed.go.jp/koubo/03008/01/B_00003.html

Translation

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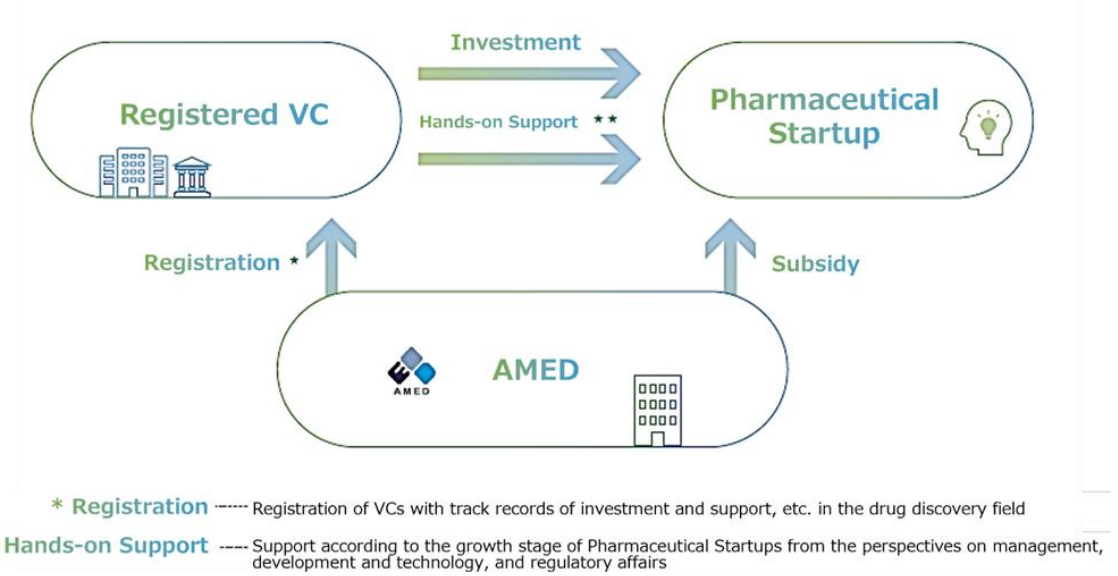
1. Program Outline

Translation

Application Guidelines; Page 1

1-1 Background and Program Objectives

- 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.



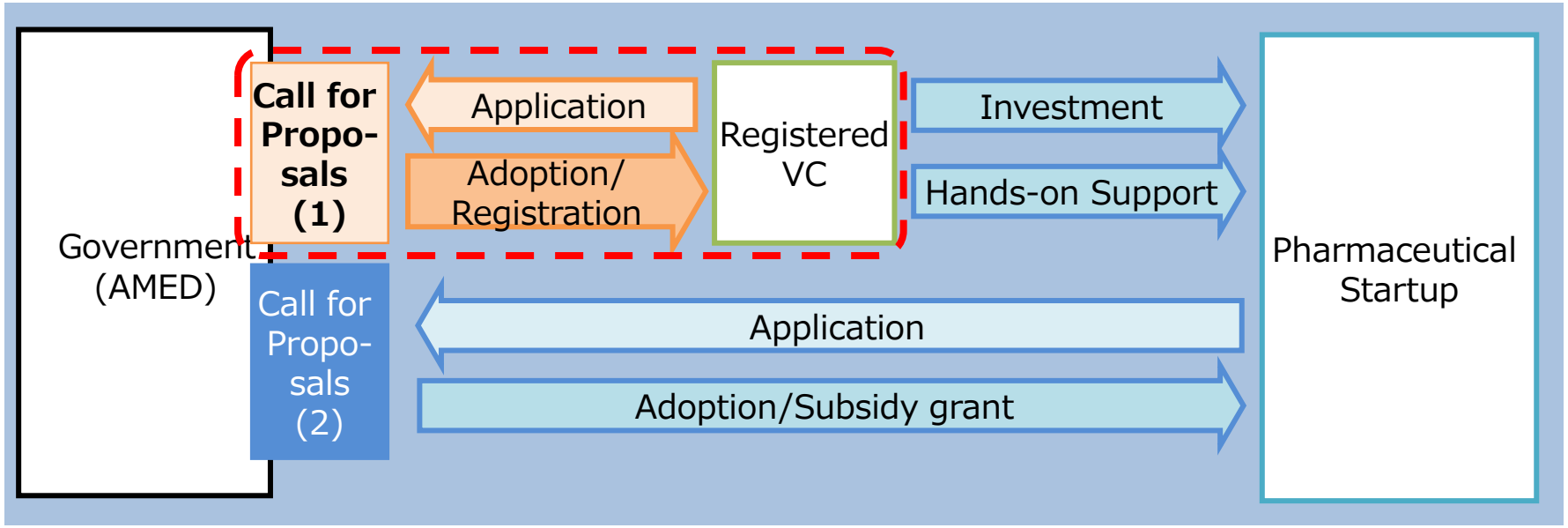
Translation

Application Guidelines; Page 2

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

* 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



Translation

【Ref.】Pharmaceutical Venture Capital Image that METI seeks

- 創薬ベンチャーエコシステム強化に資する最大限のリターンを得るためには、**薬を世界に届けるための投資・Exitを行うベンチャーキャピタル**が必要。
- そのために重要な**以下の観点を踏まえて認定VCの更新要件を設定することを検討中**。

薬を世界に届ける投資 ・ Exitを行うVC

創薬ベンチャーの成功に向けた観点

① **パイプラインのグローバル開発による価値最大化**

生み出す医薬品の価値最大化のため、マーケットを国内だけではなく、積極的に海外にも求める。積極的にFDAをはじめとした各国規制当局の承認を目指し、そこに至るまでのロードマップを描くことができる（CRO・CDMOとのつながり含め）。

② **M&Aに積極的**

医薬品に関する開発・承認取得・販売のノウハウを持つ企業によるM&Aを基本としたExit戦略を描く。

③ **IPOの場合には医薬品上市のためのIPOを行う**

IPOを目指す場合、創薬ベンチャーによる医薬品上市のためのIPOを行う。東証へのスモールIPOの直後に売り抜けるといったExit戦略を取らない。（100億程度ではなく、上場後の資金調達を見据えた十分な時価総額でのIPOをリード。）

VCの資金調達力の強化に向けた観点

④ **VCとしての成長（後継ファンド組成）**

現在運用しているファンドよりも大きい金額で後継ファンド組成ができている。（令和13年末までにファンドサイズ2倍が達成できる道筋が描けている。）

⑤ **VC運用資金の民間からの調達**

運用資金として、政府系資金だけでなく機関投資家・民間金融機関・民間事業会社から出資を受けることができている。

METI
Bio-subcommittee Report
on Aug 19, 2024

https://www.meti.go.jp/shingikai/sankoshin/shomu_ryutsu/bio/20240819_report.html

Translation

Application Guidelines; Page 3

1-3 Composition of Program

Program Implementation System

- AMED assigns a Program Supervisor (PS) and a Program Officer (PO).
- 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.

Registration Period

- Two business years from the date of registration*
  → The registration period for the VCs to be registered in this call is scheduled from April 2026 to March 2028.
- 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. There is no limit to the number of renewals, but the maximum registration period will be until the end of March 2032.

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

2. Application Requirements

Translation

2-1 Application Requirements for Registered VC

Application Guidelines; Page 4

- The applicant must be a **corporation**[*1] that **invests in startups as a business** and **provides hands-on supports to Pharmaceutical Startups** in commercialization (Venture Capital, Corporate Venture Capital[*2]).

  *1 (In the case where investment and hands-on activities are conducted by separate companies) In cases where the investment function and the hands-on support function are shared with separate 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.

- 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. The applicant must also agree no requests will be accommodated to modify the matters set forth in the Registration Agreement nor to prepare a side letter or other documents.

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

  Call for Proposals Information website https://www.amed.go.jp/koubo/03008/01/B_00003.html

2-2 Restrictions on Participation Eligibility and Registered VC's Compliance Matters

Translation

Application Guidelines; Page 4&5

- 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.
- 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.
- 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.
- Ensure appropriate protection of information obtained in the course of 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.

Translation

Application Guidelines; Page 6

2-3 Obligation of Payment to AMED

- If a Registered VC that invests in a subsidized Pharmaceutical Startup sells its shares within one year*1 after receiving the grant decision for this Program*2, a maximum of 2/3*3 of the sales amount must be paid to AMED.

*1 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.

*2 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).

*3 Amount to be paid = sales amount x {subsidy amount under this Program / (subsidy amount under this Program + total amount of investment by Registered VCs)}

Translation

Application Guidelines; Page 6

2-4 Revocation of Registered VC

- If no longer meets the application requirements
- If it is found that the applicant has not complied with the requirements
- If the payment obligations mentioned in the previous page are imposed on a Registered VC who invests in an adopted Pharmaceutical Startup as a Lead VC
- If the Application documents are found to be false
- If the Program has not been substantially utilized for a certain period of time
- If AMED finds it grossly inappropriate to continue registration
- Other cases that fall under the provisions of the Registration Agreement

Translation

2-5 Pharmaceutical Startups in the Scope of Support

Application Guidelines; Page 6&7

2.6.1 Call for Proposals from Pharmaceutical Startups

- 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.
- 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.
- 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

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.
- 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 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.

3. Preparation and Submission of Application Documents

Translation

Application Guidelines; Page 10

3-1 Application Documents

No.	Mandatory/ Optional	Necessary Application Documents	How to obtain
1	**Mandatory**	Application Form (MS Word)	Download from the website of the Call for Proposals *
2	**Mandatory**	Application Form Attachment (MS 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	

- Please make sure to check "To prepare the application" section of the Application Form template (MS Word).
- The Application Form Attachment (MS Excel) will be used to manage the registration status as a Registered VC even after being adopted and certified in this call.
- 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.

* Call for Proposals Information website: https://www.amed.go.jp/koubo/03008/01/B_00003.html

Revised

Translation

3-1 Application Documents

Attachment_3a to Application Form

Attachment to Application Form

3a_Application Funds: List of LPs based in other countries and regions outside Japan

- Types/categories of LP ⇒ (e.g.) Family office, Operating company, Financial institution
- Has the source of funds been verified as clean and compliant? ⇒ Yes or No
- Remarks ⇒ Please write any points regarding the soundness and transparency of funding sources.

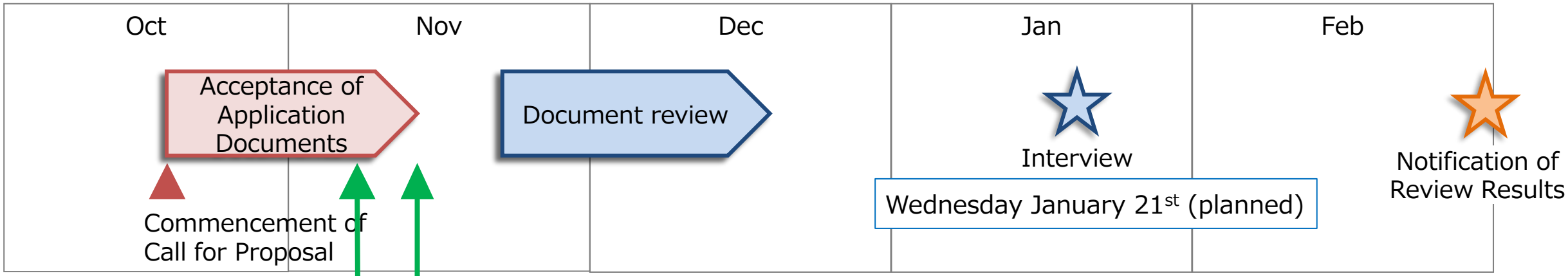
Changes from the 6th call

39			10						
40	日本以外の国や地域を拠点とするLPリスト		名称	LPの種類 (例：ファミリーオフィス)	本拠地のある国/地域	出資金額	通貨単位をプルダウンで選択してください↓	資金源がクリーンかつコンプライアンス上問題がないかを確認済みか？	備考 資金源の健全性・透明性についての留意点などがあれば記載してください。
41		ファンドに日本以外の国や地域のLPが含まれる場合はすべてについて記載してください。（行が足りなければ追加してください）	1						
42			2						
43			3						
44			4						
45			5						

Translation

Application Guidelines; Page 10~12

3-2 Procedures for Application



Declaration of Intent to Apply

Deadline: Wednesday, November 5 [noon] (Observe strictly)

Upload Application Documents

Deadline: Wednesday, November 12 [noon] (Observe strictly)

We will not accept submissions without a declaration of intent to apply by the due date.

Please note that we cannot accept applications after the due date.

Translation

Application Guidelines; Page 10&11

3-3 How to submit Application Documents

1	Declaration of Intent to Apply	Please send it by e-mail. • To: v-eco“AT”amed.go.jp (Please change the“ AT” part to @) • Subject: Strengthening Program for Pharmaceutical Startup Ecosystem (Venture Capital Registration) • Text: (1) name of corporation, (2) Contact person name, (3) Contact phone number, (4) Contact e-mail address	Deadline: Noon on Wednesday, November 5
2	Upload Test	We will send you the URL for submitting the Application documents. Please test if you can upload it.	
3	Application Document Upload	Please upload the Appliaction document. Please note that applications cannot be accepted after the deadline.	Deadline: Noon on Wednesday, November 12
4	Confirm Upload	Application documents can be exchanged until the deadline for submissions. Please make sure your submission is up to date.	

- Please allow time to express your intention to apply and upload.
- The Application Documents are 5 or 6 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."
- Do not set a password for the file.
- Set the file name to VC26, _ (underbar), legal entity name other than K.K. (abbreviated), and document name.
  Example: VC26_AMED_ document name. (extension)

Translation

Application Guidelines; Page 10&11

3-3 How to submit Application Documents

Preparing for Upload

Declaration of intent to apply
Deadline: Wednesday, November 5 at noon

URL for submitting Application documents and Guide to upload test

With dummy data Upload test

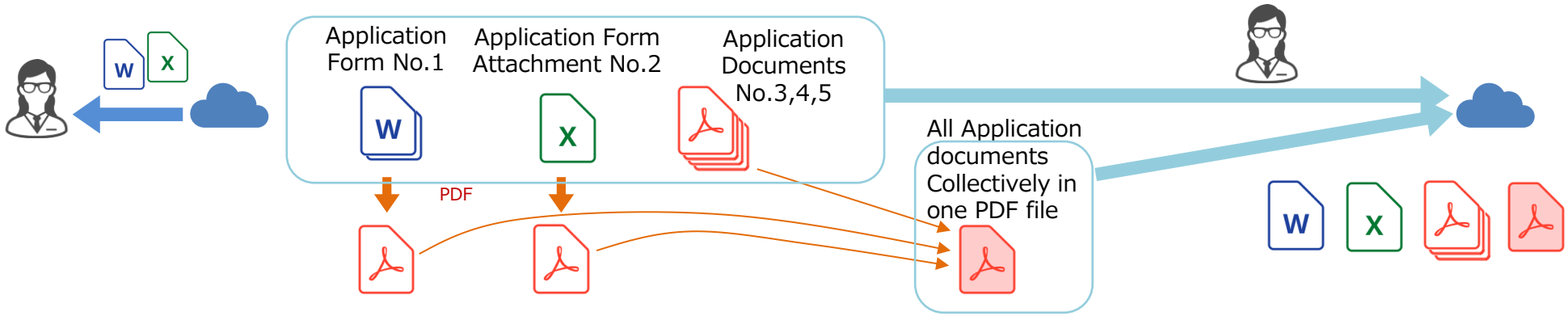
Preparation and Upload of Application Documents

Download Application Form template

Prepare Application Documents

Create PDF file of Application Documents

Upload Application Documents
Deadline: Noon, Wednesday, November 12



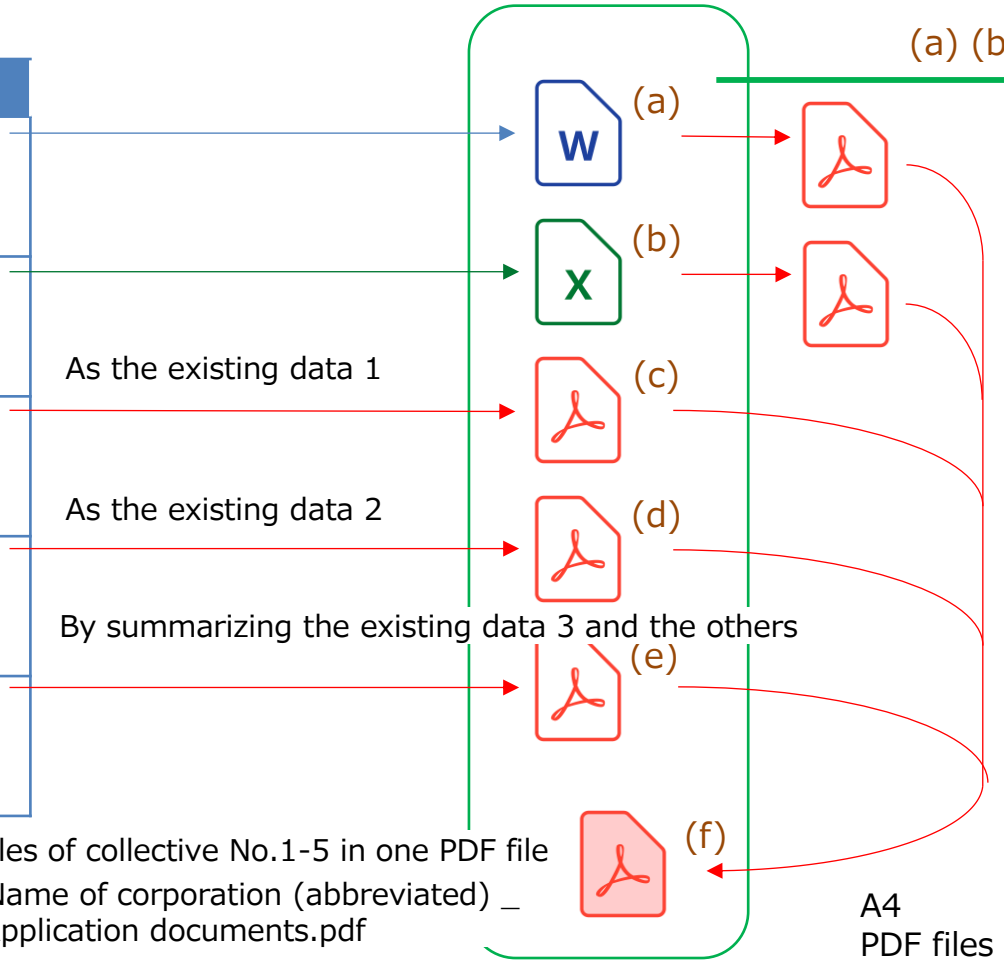
3-3 How to Submit Application Documents: Upload

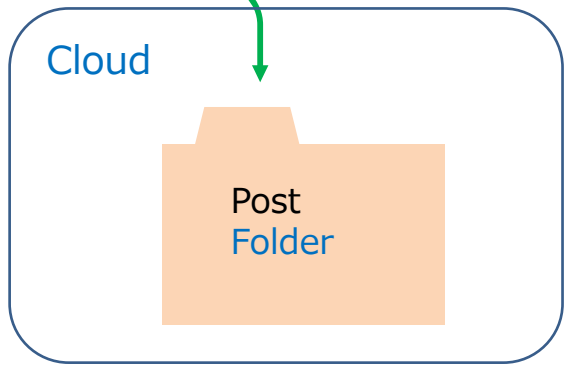
Translation

Application Form; Page 3&4

Please create an Application document file in the following procedure.

No.	Proposal document
1	**Application Form (Word)**
2	**Application Form Attachment (Excel)**
3	**Articles of Incorporation**
4	**Materials on the fund prospectus or Investment Briefing documents, etc.**
5	**Other existing materials** (Submission is optional)





Submit a total of 5 (or 6) files created

(a)~(f) is no more than 15MB each

If (f) is greater than 15BM, each file is divided into 2 (Application Form 1 and 2) so the total volume can be less than or equal to 15MB.

3-4 If there are any deficiencies in the acceptance of Application Documents and Application Form, etc.

Translation

Application Guidelines; Page 11

- 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.

4. Evaluation

Translation

Application Guidelines; Page 12

4-1 Selection Schedule

Period for accepting Application Documents	**Wednesday, October 15, 2025 ~ Wednesday, November 12 [noon] (Observe strictly)** ● Deadline for declaration of intent to apply: Wednesday, November 5 [noon] (Observe strictly) ● Deadline for uploading Application documents: Wednesday, November 12 [noon] (Observe strictly)
Document Review	Late November ~ early December 2025 (planned)
Interview	January 21 (Wed) 2026 (planned)
Notice of Review Results	Late February 2026 (planned)
Conclusion of the Registration Agreement (Commencement of registration period)	Wednesday, April 1, 2026 (planned)

Translation

Application Guidelines; Page 13

4-2 Cautionary Notes in Application and Selection

- Please note that all Application Documents cannot be accepted after the deadline.
- If there are any defects in the submitted documents, they may not be accepted.
- 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).
- The interview may be conducted via the web, etc.
- 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 or not to adopt it.
- We do not answer regarding the eligibility of individual applications for the interview.
- The date of the hearing examination cannot be changed.

Translation

Application Guidelines; Page 13~15

4-3 Evaluation items

- Conformity with Program Objectives
  - Overview of the corporation, priority areas as 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 capability
  - 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.

Translation

4-3 Evaluation Items: Mandatory Requirements

Application Guidelines; Page 14&15

(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 is capable of providing 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 in light of 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 in light of 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 Evaluation Items: Mandatory Requirements (Supplement)

Translation

Attachment to Application Form

FAQ

AMED

Definition of "Drug Discovery Field"

- In addition to the development of pharmaceuticals and regenerative medicine products, the Program targets the development of technologies related to pharmaceuticals, such as technologies to create seeds for pharmaceuticals and regenerative medicine products (pharmaceutical platform technologies).
- The technologies exemplified below are not applicable.
  - Medical Devices/Medical Technologies
  - DTx (therapeutic apps, VR)
  - Research reagent development, analysis services, non-clinical research contract
  - Laboratory tests
  - Diagnostic agent development
  - AI etc.

"Fund dedicated to investing in the drug discovery Field"

- The basic concept of the fund is that 100% of the funds used for investment in startup companies will be invested in the field of drug discovery. The decision will be made comprehensively, including the members who manage the fund.
- This includes those that have ended the operational period.

Translation

4-3 Evaluation Items: Mandatory Requirements (Supplement)

Attachment _2a, 2b to Application Form

FAQ

About “Lead VC”

- In this Call for Proposals, this refers to the VC that is investing as a lead* in one funding round.
  *The investment is the largest among investors (excluding operating companies such as pharmaceutical companies) and plays a leading role in funding and hands-on supports. Even if the investment is not the largest among investors (excluding operating companies such as pharmaceutical companies), it may be accepted as a lead. If applicable, please write down the reason(s) why you are participating as a lead.

About "newly established VC or fund"

- The “fund” in this context should be “a fund dedicated to investing in the drug discovery field."

Mandatory Requirements (1) "high-quality support to Pharmaceutical Startups"

- This refers to achieving a very high rating on the four Evaluation Items shown in the Aplication Guidelines 4.2.2.

Mandatory requirements (4) (5) “Members who make investment decisions or members who are hands-on and provide expert advice on investment decisions"

- This refers to a key member equivalent to a member making investment decisions in your company, who will provide expert advice to the member making investment decisions and provide hands-on supports.

Mandatory Requirements (5) ““Global experience“ in terms of experience conducting global clinical trials and hands-on support for global clinical trials"

- This refers to experience in countries other than Japan. The evaluation will be made particularly with the United States in mind.

Translation

Application Guidelines; Page 15

4-4 Publication and Notification of Review Results

- The adoption results will be disclosed on the AMED website, and the applicant will separately be notified of the review results.
- Various conditions may be imposed upon registration.
- The corporate name, etc. of adopted VCs will be disclosed on the AMED website, etc. after concluding the Registration Agreement.

5. Contact

Translation

5. Contact information

- If you have any questions about this Call for Proposals, please contact here in the table.

Inquiries	Contact
Call for Proposals, and How to file the Application Documents, etc.	Division of Medical Ecosystem Development, Department of Medical Innovation Ecosystem, AMED E-mail: v-eco"AT"amed.go.jp * Make the subject of the e-mail “Strengthening Program for Pharmaceutical Startup Ecosystem (registration of venture capital),” and state the contact details for reply (corporation name, contact person name, telephone number and e-mail address) in the body text.
Conflict of Interest (COI) Management	Division of Research Integrity, Department of Research Integrity and Project Management, AMED E-mail: amedcoi"AT"amed.go.jp
Misconduct, Misuse, and Fraudulent Receipts of Money	Division of Research Integrity, Department of Research Integrity and Project Management, AMED E-mail: kouseisoudan"AT"amed.go.jp

* Please contact us by e-mail (change the address "AT" to @).

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