Translation

FY2023 Strengthening Program for Pharmaceutical Startup Ecosystem / Venture Capital Registration
(Third call for proposals)

Explanation of Call for Proposal

October 2023

Department of Intellectual Property and Technology Transfer
Japan Agency for Medical Research and Development

Translation

Precautions

- This document describes the outline of Application Guidelines for Strengthening Program for Pharmaceutical Startup Ecosystem/Venture Capital Registration (3rd round).
- Before applying, please be sure to confirm the description in the main body of the Application Guidelines.
- The Application Guidelines and other materials may be revised during the Application period. In this case, we will notify you on our website*.
- If there is any discrepancy between this document and the Application Guidelines, the Application Guidelines shall prevail.
- Before preparing the proposal documents, please be sure to review the Registration Agreement, the Application explanatory materials, and the frequently asked questions (FAQs) posted on the Calls for Proposals page*.

*Calls for Proposals page: https://www.amed.go.jp/koubo/19/02/1902B_00045.html

Translation

Table of Contents

Translation

1. About Our Program

Translation

1-1 Program Outline (Background)

Application Guidelines
P. 1,2

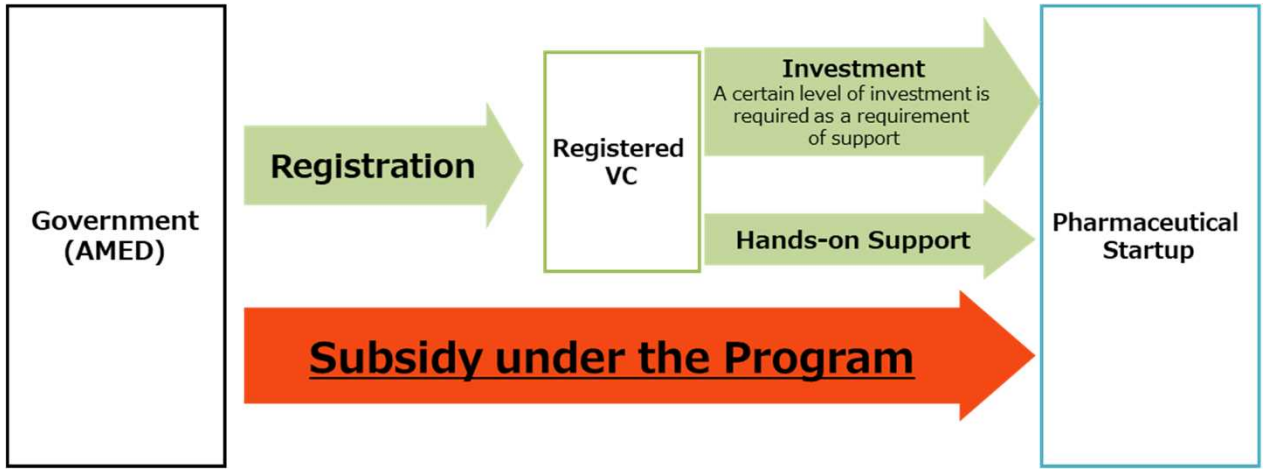
- Most new drugs in recent years have been developed by pharmaceutical startup companies, and it is startups that were the first to successfully develop vaccines in the pandemic of COVID-19. The development of new drugs requires a large amount of funding, but it is at the moment more difficult to secure the necessary funds in the pharmaceutical startup ecosystem in Japan, compared with those in Europe or the United States.
- In response to this situation, under the "Strategy for Strengthening Vaccine Development and Production System" approved by the Cabinet in June 2021, this Program was established to support pharmaceutical startups that develop for practical application of technologies related to vaccines and therapeutic drugs for infectious diseases. Furthermore, in October 2022, the “Priorities for Comprehensive Economic Measures for the Implementation of the "Grand Design and Action Plan for a New Capitalism"(Draft) " included the following statement regarding this Program: "In the future, we will strengthen its support by expanding the scope to include drug discovery fields other than those related to infectious diseases, where it is difficult to raise funds."
- To solve the shortage of large-scale development funds, this Program supports pharmaceutical startup development and commercialization, especially those engaged in non-clinical, Phase I, Phase II or exploratory clinical trials on the condition that they also receive funding from venture capital firms registered by AMED (hereinafter referred to as “Registered VC”) specializing in drug development and providing hands-on business management and commercialization support.
- In particular, to achieve sufficient sales and growth of pharmaceutical startup, we will actively support plans to commercialize in overseas markets in addition to Japan.

Translation

1-2 Program Outline (Objective)

Application Guidelines P. 2

- In this Program, AMED subsidizes the practical development of pharmaceuticals conducted by Pharmaceutical Startups in which registered VCs invest more than 1/3 of the subsidized costs.
- 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,) 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).



Program Scheme

Translation

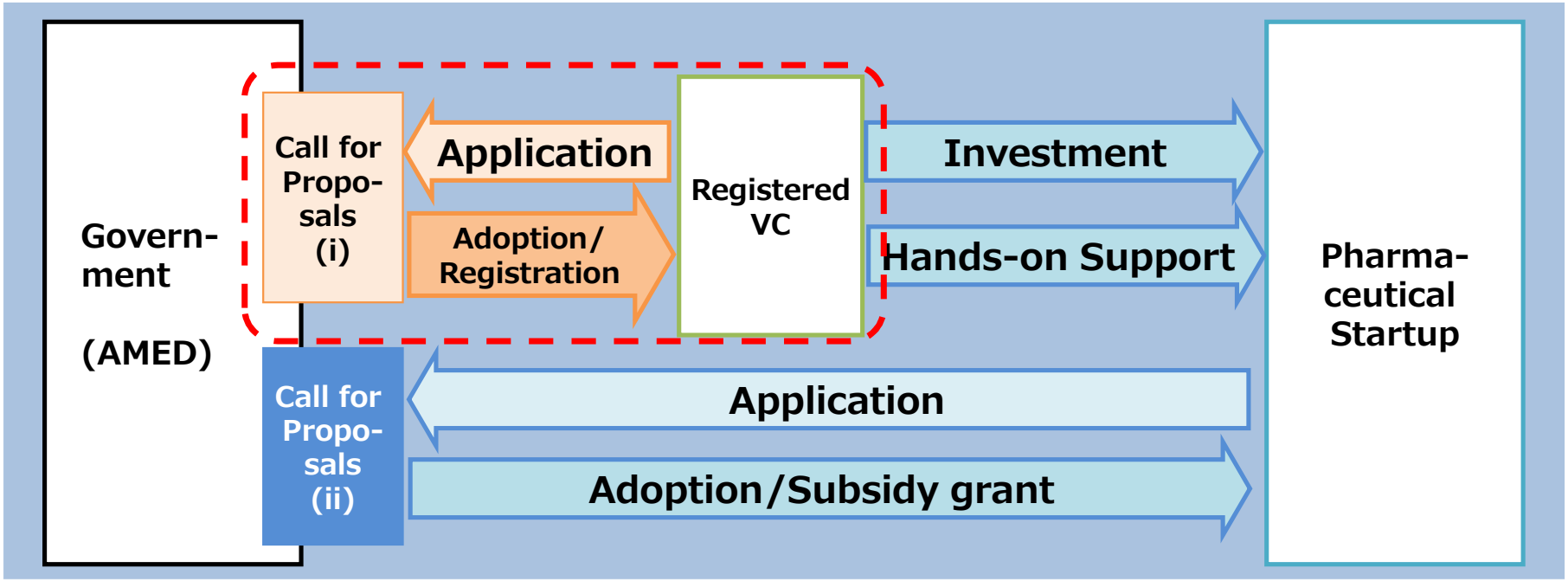
2. About Call for Proposals

Translation

2-1 Outline of Call for Proposals

Application Guidelines P. 1,2

- The call for proposals will be conducted in two stages: (i) The Call for Proposals for VC Registered by AMED(Call for Proposals for VC) and (ii) The Call for Proposals for the practical development of pharmaceuticals conducted by Pharmaceutical Startups invested by Registered VCs ((ii)Call for Proposals from Pharmaceutical Startups).
- This call is the (i)Call for Proposals for VC (dotted red line frame)



Translation

2-1 Outline of Call for Proposals

Application Guidelines P. 2

- In this Call for Proposals, AMED recruits and registers VCs which are suitable for supporting Pharmaceutical Startups engaged in non-clinical, Phase I, Phase II or exploratory clinical trials*1 and are developing innovative pharmaceuticals. ((i)Call for Proposals for VC).

*1 The scope of this Program is not limited to the clinical trial under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices but clinical studies which confirms the safety or explores the efficacy in healthy subjects or patients.

- Registration period: 2 business years*2 from the date of registration
  - An interim evaluation will be conducted in the second business year, and a review will be conducted to determine whether registration can be renewed based on the status of activities as Registered VC.
  - There is no limit to the number of times the registration can be renewed, but the longest registration period is until the end of March 2032.

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

Translation

2-2 Application Requirements, Compliance Matters, etc.

Application Guidelines P. 3

AMED

(1) Application Requirements for Registered VC

- It is a corporation*1 having a function of investing in startups as a business, and having a function of supporting Pharmaceutical Startups in commercialization (venture capital, corporate venture capital*2).
- Including its parent company and subsidiaries, it does not fall under an organized crime group, a member of an organized crime group, a company or a person involved with an organized crime group, a corporate racketeer, or any other antisocial force (hereinafter referred to as “Antisocial Forces”) or it is not involved with a person pertaining to Antisocial Forces.
- It agrees with the matters set forth in the Registration Agreement*3, and if registered, it will conclude a Registration Agreement.

*1 If the investment function and the commercialization support function are shared with other companies that are a wholly owned parent company and a wholly owned subsidiary, or another company that is controlled by the same person based on service agreement, etc., please notify AMED in advance. After consultation, specify the relationships and roles of multiple institutions, and apply on behalf of the institution that is primarily in charge of this Program. If adopted, a registration agreement will be signed by multiple parties, including related organizations.

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

*3 The Registration Agreement post on the Calls for Proposals page:
https://www.amed.go.jp/koubo/19/02/1902B_00045.html

Translation

2-2 Application Requirements, Compliance Matters, etc.

Application Guidelines
P. 3,4

(2) Registered VC's Compliance Matters

The Registered VC shall:

- Proactively promote the efforts leading to discovering and supporting of Pharmaceutical Startups in the target technology areas, strengthening of Pharmaceutical Startup Ecosystem in Japan, and strengthening of coordination with global drug development community;
- Build a good relationship with the adopted Pharmaceutical Startup, provide hands-on support pursuant to the support plan submitted, and promote its commercialization in the form which will maximize the value of the adopted Pharmaceutical Startup;
- Maintain healthy cash management and capital policy by the Pharmaceutical Startup during the Subsidized Project Period (so that the Subsidized Project of the Pharmaceutical Startup will not be affected by capital shortage) and aim at the progress of the pharmaceutical development in accordance with the Subsidized Project Plan Sheet and the business expansion of the adopted Pharmaceutical Startup;
- Make efforts to increase the amount of the fund when subsequently establishing a fund;
- Not obtain guidance fees, commissions, or any other consideration for hands-on support or any other support from the adopted Pharmaceutical Startup;
- Not, by leveraging this Program, execute any agreement that will unreasonably restrict the future business development of an adopted Pharmaceutical Startup*;
- Appropriately protect the information learned in the course of operations such as the business plan, etc. of the Pharmaceutical Startup in which it invests;
- Report the progress of hands-on support periodically (and upon request of AMED) to AMED;
- Cooperate in publication of information such as questionnaire surveys by AMED and posting, etc. of corporate information, activities status, etc. on AMED's website (contents to be posted will be confirmed by you before publication);
- Other matters set forth in Registration Agreement

*Refer to "Important Notes on Agreements pertaining to Sound Venture Investment In Japan" (March 2018, Ministry of Economy, Trade and Industry, revised March 2020)

https://www.meti.go.jp/policy/newbusiness/data/ryuizikou_r.pdf (In Japanese)

(3) Obligations of Payment to AMED

- A Registered VC investing in a Pharmaceutical Startup who has received Subsidy grant shall, if having sold shares within one (1) year*1 after receiving the Grant Decision of the Subsidy of this Program*2, pay up to 2/3*3 of the sales amount to AMED.

*1 If a Pharmaceutical Startup received the Grant Decision of the Subsidy from AMED after adoption or Stage-Gate Go decision, within one (1) year from such date

*2 It excludes sell-off to a pharmaceutical company (Those who have obtained authorization of marketing authorization or manufacturing of pharmaceuticals, or marketing authorization or manufacturing of regenerative medicine products under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) or those who are engaged in research and development of pharmaceuticals or regenerative medicine products.)

*3 Payment amount=sales amount x {subsidy amount under this Program / (subsidy amount under this Program + total amount of investment by Registered VC)}

(4) Deregistration of registered VC

i. If application requirements referred to in the above-mentioned (1) are no longer conformed to;
ii. if compliance matters referred to in the above-mentioned (2) are found to be not complied with;
iii. if the obligations of payment set forth in the above-mentioned (3) are imposed on a Registered VC who invests in an adopted Pharmaceutical Startup as a Lead VC;
iv. if it is found there is falsehood in Application Documents;
v. if Registered VC is not substantially utilized this Program for a certain period of time;
vi. if AMED finds it extremely inappropriate to continue registration;
vii. if otherwise falling under any of the matters set forth in Registration Agreement.

Translation

2-3 Evaluation Items

Application Guidelines
P. 5,6

- Conformity to Program Objectives
  - Corporate outline, key area as a VC, investment achievements, investment indexes, etc.
- Ability to carry out fundraising
  - Outline of the fund scheduled to be utilized in this Program, investment capacity, future fund establishment plan, etc.
- Sourcing capability
  - Contents and achievements of sourcing activities in the drug discovery field (development program, financial support during seed stage and early stage, Entrepreneur in Residence, wet lab, office leasing, etc.), due diligence ability, status of investment under review, etc.
- Hands-on capability
  - Providing integrated support and timely and appropriate advice according to the growth stage of Pharmaceutical Startups from the following perspectives:

1) Management Perspective
   Business planning (global business strategy, capital policy, financing and operation plan, Exit strategy (especially M&A)), internal management, progress management, public relations and external communication, human resource support, introduction to pharmaceutical companies, etc. and other sales channels.
2) Perspectives on Development and Technology
   POC acquisition, resolution of technological issues (formulation, mass production, etc.), securing competitive advantage (intellectual property strategy, differentiation strategy, etc.), CMO/CDMO and CRO collaboration, etc.
3) Regulatory Affairs Perspective
   FDA/PMDA compliance, GCP compliance, GMP compliance, etc.

Translation

2-3 Evaluation Items: Mandatory Requirements

Application Guidelines P. 6

In reviewing the evaluation items on the previous page, the following points are 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, BD (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

Translation

2-3 Evaluation Items: Mandatory Requirements (Supplement)

About "Drug Discovery Field"

FAQ, Application Form Appendix

- In addition to the development of pharmaceuticals and regenerative medicine products, this program targets technology development related to pharmaceuticals, such as technology to create seeds for pharmaceuticals and regenerative medicine products (pharmaceutical platform technology). The technologies illustrated below are not covered in this program.
- The technologies exemplified below are not covered.
  - Medical Device/Medical Technology
  - DTx (Therapeutic Apps, VR)
  - Research reagent development, analytical services, non-clinical testing contract
  - Clinical testing
  - Diagnostic Reagent Development
  - AI, etc.

About the "Fund Specialized in Investing in the Drug Discovery Field"

- The basic idea is that 100% of the funds used to invest in startup companies will be invested in the field of drug discovery and the decision will be made based on comprehensive evaluation, including the members who manage the fund.
- This includes those that have reached the end of their operational period.

Translation

2-3 Evaluation Items: Mandatory Requirements (Supplement)

FAQ Application Form Appendix_2a, 2b

- **About " Lead VC"**
  - In this Call for Proposals, if the VC is investing as a lead* in one funding round.

    * Investors (excluding business companies such as pharmaceutical companies) has invested the largest amount among the investors and take a leading role in fundraising and hands-on activities). If investors (excluding business companies such as pharmaceutical companies) are not the largest investor among the investors, it may be accepted as a lead. If applicable, please write the reason(s) why you are participating as a lead.
- **About" Newly established VC or fund "**
  - The "fund" referred to here must be "a fund that specializes in making investments in the drug discovery field.
- **About "Particularly high-quality support to Pharmaceutical Startups." in Mandatory Requirement i**
  - It refers to obtaining a very high rating in the four evaluation items shown in Application Guidelines 4. (2).
- **About "Members who make investment decisions or provide expert advice on investment decisions as hands-on members" in Mandatory Requirements iv, v**
  - It will be a key member of your company, equivalent to a member making investment decisions, who will provide expert advice on investment decisions members and provide hands-on.
- **About "Global experience" in terms of experience conducting global clinical trials, experience in providing hands-on support for global clinical trials, etc." in Mandatory Requirement v**
  - This refers to experience in countries other than Japan. The screening will be conducted with a particular focus on the United States.

Translation

2-4 Application Period · Selection Schedule

Application Guidelines P. 7

Period of acceptance of Application Documents	**From Friday, October 6, 2023, to Wednesday, November 22, 2023, at noon (JST)(Observe strictly)** *Manifestation of Intention to Apply Deadline: Wednesday, November 15 at noon (Observe strictly) *Deadline for uploading of Application Documents: Wednesday, November 22 at noon (Observe strictly)
Document Review	Early to late December 2023 (planned)
Hearing review (Interview)	January 19th (Friday), 24th (Wednesday), 26th (Friday), 2024 (scheduled)
Notification of review results	Late February 2024 (planned)
Conclusion of registration agreement (Start of registration period)	April 1, 2024 (planned)

Publication and Notification of Review Results

- The corporate names of adopted VCs will be published at a time of publication on AMED's website, etc. Furthermore, AMED will separately send notification of review results to the applicants.
- Upon registration, various conditions may be imposed.

Translation

2-5 Points to Note of Application

Application Guidelines P. 7

- ✓ For all Application Documents, the documents received after the deadline will not be accepted.
- ✓ If not completed correctly, Application Documents may not be accepted.
- ✓ After the period of acceptance of Application Documents has ended, AMED may contact the applicants by e-mail or telephone, etc., to confirm administrative details. Please respond to such requests for confirmation promptly using the methods designated by AMED (if AMED does not receive a response, the application in question may be ineligible for review.).
- ✓ Hearing reviews may sometimes be conducted over the Internet etc..
- ✓ For VC applicants subject to reviews by interview, AMED will contact the applicants by e-mail no later than one week before the hearing review is to take place. In the case that the application is not eligible for a hearing review or hearing reviews themselves are not being conducted, the applicant will not be contacted. Please wait to receive your Notification of Review results.
- ✓ Please note that we cannot answer questions regarding the eligibility of individual applications for hearing reviews.

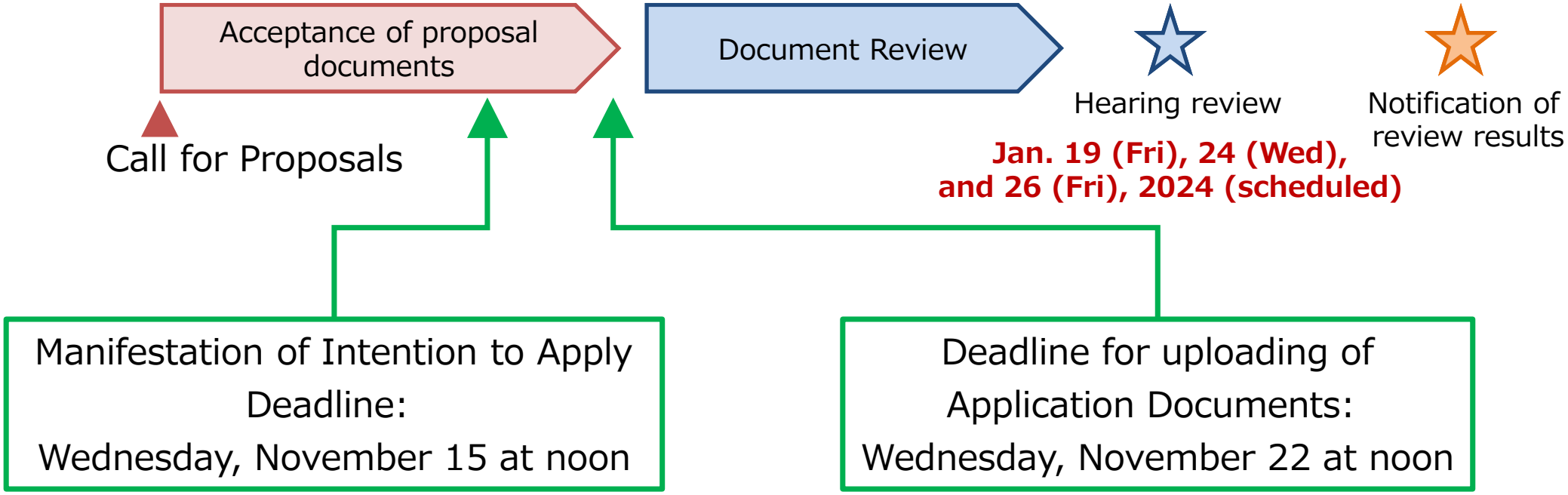
Translation

3. Application Procedures

Translation

3-1 Overall Schedule and Submission Deadline

Application Guidelines P. 7



Please note that applications will not be accepted after the deadline.

Translation

3-2 Documents Necessary for Application

Application Guidelines P. 7,8

Proposal Documents No.	Mandatory /Optional	Necessary Proposal Documents	Method for Obtaining
1	**Mandatory**	Application Form (Word)	Download from the Calls for Proposals page
2	**Mandatory**	Application Form Attachment (Excel)	Download from the Calls for Proposals page
3	**Mandatory**	Articles of Incorporation	
4	**Mandatory**	Materials on the fund prospectus, or investment product overview, etc.	
5	Optional	Other existing materials	

*Please ensure to read “Read This Before You Prepare Application” of the beginning of the Application (Word).
The application form and application attachments must be written in Japanese or English.
If foreign languages are used in other proposal documents, please use English.
Application Information HP https://www.amed.go.jp/koubo/19/02/1902B_00045.html

Translation

3-3 Application Procedures: Application Documents

Application Guidelines P. 7,8

1	Manifestation of Intention to Apply	Please send by e-mail. • Address: v-eco“AT”amed.go.jp (Replace “AT” with “@”.) • Subject: Strengthening Program for Pharmaceutical Startup Ecosystem (Venture Capital Registration) • Body text: (i)Corporation name, (ii)contact person name, (iii)contact telephone number, and (iv)contact e-mail address	Deadline: Wed., Nov. 15 at noon
2	Uploading Test	AMED will send you URL for submission of Application Documents. Please carry out Uploading Test.	
3	Uploading of Application Documents	Upload the Application Documents by the deadline. Please note that applications will not be accepted after the deadline.	Deadline: Wed., Nov. 22 at noon
4	Upload Confirmation	Application Documents can be replaced until the deadline of the Call for Proposals. Please make sure that the files are up-to-date at the end of the call.	

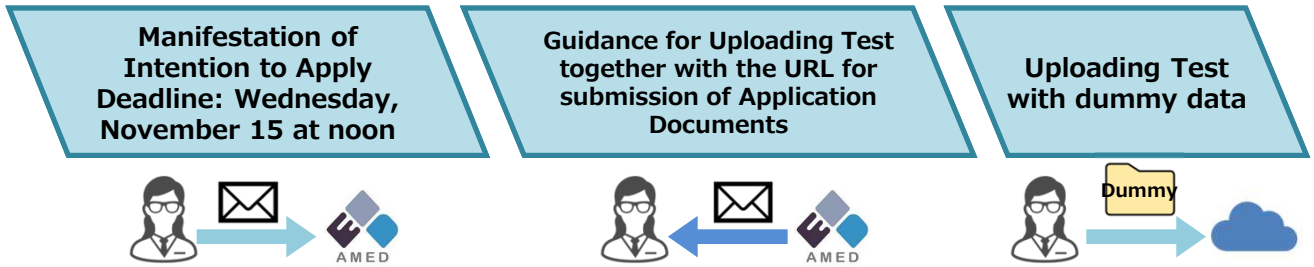
- Please allow yourself enough time for manifestation of intention and uploading.
- The Application Documents to be uploaded are the files listed in the "Application Submission Checklist" at the beginning of the Word file "Application Form" in "III.Checklist Pertaining to Files to be Uploaded" at the beginning of the Word file "Application".
- Please submit all files, individually, in a folder (each file should be no larger than 15 MB).
- Do not protect files with passwords.
- Make the file name “VC23” and “_(under score)” and “corporation name (can be abbreviated) except Kabushiki Kaisha.
  E.g. : VC23_Corporation name_AMED.docx

Translation

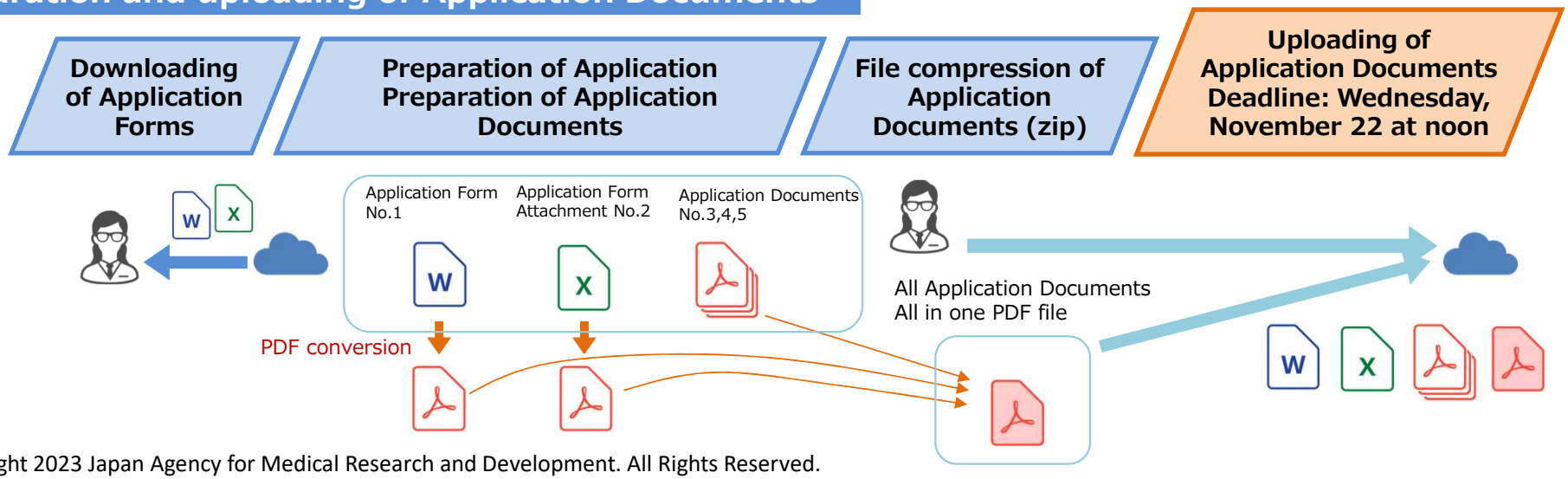
3-3 Application Procedures: Method of Documents Submission

Application Guidelines P. 7,8

Preparation of uploading



Preparation and uploading of Application Documents



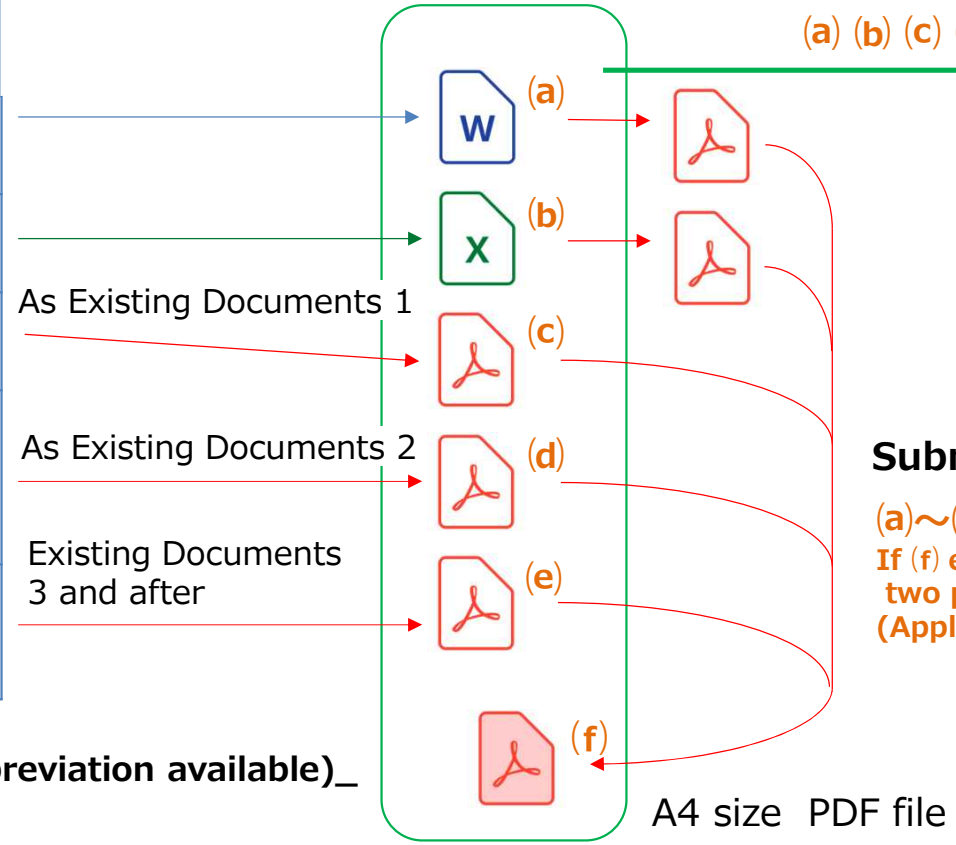
Translation

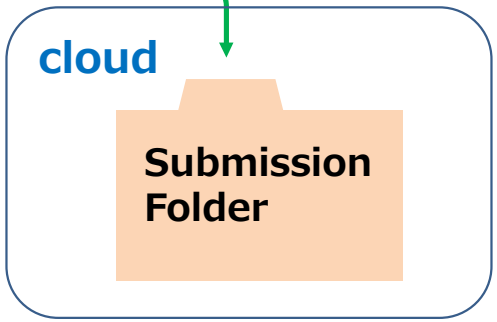
3-3 Application Procedures: Preparation of uploading

Prepare the file of Application Documents in the procedure below.

Application Form P. 3

No.	Application Documents
1	Application Form (Word)
2	Application Form Attachment (Excel)
3	**Articles of Incorporation**
4	**Materials on the fund prospectus, or investment product overview, etc.**
5	**Other existing materials** (Optional)





Submit a total of 6-7 files created

(a)～(f) Less than 15MB each

If (f) exceeds 15BM, each file is divided into two parts so that the total size is less than 15 MB (Application Forms 1 and 2)

All PDFs of No.1-5 in one file
VC23_ Corporation name (abbreviation available)_ complete application form.pdf

Translation

3-4 Application Procedures: Acceptance of Application Documents and Incomplete Applications

Application Guidelines P. 8

- Application Form (Word) and Application Form Attachment (Excel) has been changed since the previous Call for Proposals. Please be sure to submit the newest forms. Please note that older forms will not be reviewed.
- Submitted Application documents will not be returned.
- Application whose uploading is not completed or for which AMED is not able to be accepted will not be accepted.
- Proposal documents from a person who does not satisfy the application requirements or incomplete proposal documents will not be accepted.
- If Application Documents are incomplete and not corrected by the submission deadline, the application will be invalid.

Translation

4. Call for Proposal from Pharmaceutical Startups

Translation

4 Call for Proposal from Pharmaceutical Startups

Application Guidelines P. 10

- Regarding Pharmaceutical Startups eligible for support by this Program, please check the Application Guidelines of Call for Proposal from Pharmaceutical Startups that will be announced in the future. VCs that have been adopted and registered in this call for proposal can apply after the conclusion of Registration agreement.

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

  (The retroactive period for investments from Registered VCs is from November 8, 2022 (Date of Cabinet decision on the FY2022 supplementary budget) until the time of application.)

- For an overview of past Call for Proposal from Pharmaceutical Startups, please refer to the Program website*.

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

Translation

5. Contact Information

Translation

5. Contact Information

- If you have any questions about this Call for Proposals, please contact here in the table.
- Please also refer to the Frequently Asked Questions (FAQ) posted on the website of Call for Proposals.

Contents of inquiries	Contact details
Call for proposals, evaluation, how to fill the Application Documents, etc.	Division of Technology Transfer, Department of Intellectual Property and Technology Transfer, 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.
Misconduct, Misuse, Fraudulent Use	Division of Research Integrity and Legal Affairs, Department of Research Integrity and Project Management, AMED E-mail: kouseisoudan"AT"amed.go.jp
Conflict of Interest(COI) Management	Division of Research Integrity and Legal Affairs, Department of Research Integrity and Project Management, AMED E-mail: kenkyuukousei"AT"amed.go.jp

* If you have inquiries, please contact us by e-mail. (Replace “AT” in the table above with "@").
  We do not answer any inquiries by telephone.
* Please note that Inquiry only is not deemed as a manifestation of the intention to apply.

- For updated information, please refer to the website of Call for Proposals.
  (https://www.amed.go.jp/koubo/19/02/1902B_00045.html)

Translation

国立研究開発法人 日本医療研究開発機構
Japan Agency for Medical Research and Development