Implementation Guidelines for Regulatory Science Strategy Consultations

June 30, 2011
Final amendment: June 5, 2023
(Effective on: June 5, 2023)

1. Details of implementation

The universities, research institutions, venture companies, etc. that have discovered currently promising seed-stage resources for the creation of innovative drugs, medical devices, regenerative medical products, etc. in Japan are lacking in the knowledge of development strategies leading to commercialization. For this reason, Pharmaceuticals and Medical Devices Agency will provide guidance and advice on planning of studies and clinical trials necessary from the final stage of selection of candidates for drugs, etc. primarily to the early stage of clinical development (up to POC [Proof of Concept] studies [around early Phase II studies]), development plans, etc. mainly for universities, research institutions, and venture companies that have discovered seed-stage resources, aiming at practical application of aforementioned promising seed-stage resources.

For regenerative medical products, etc. and the products intended for the expression of transgene in the human body for preventive purposes (excluding those falling under the category of regenerative medical products, etc.; e.g., recombinant live vaccines), guidance and advice on quality and safety from the early stage of development will also be provided.

2. Consultation categories and their scopes

The consultation categories and scopes of regulatory science strategy consultations (hereinafter referred to as "RS strategy consultations") are as follows.

(1) Consultations on strategies for drugs/medical devices/regenerative medical products, etc.

Mainly for universities, research institutions, and venture companies, guidance and advice will be provided for consultations on planning, etc. of studies and clinical trials necessary from the final stage of selection of candidates for drugs, medical devices, or regenerative medical products, etc. to the early stage of clinical development (up to POC [Proof of Concept] studies [around early Phase II studies]). If a university or research institution conducts a study on its own initiative for a product of high medical needs that meets all of the following requirements, confirmatory studies after the early stage of clinical development are also covered in consultations.

- Items reviewed or selected in the "Study Group on Unapproved and Off-label Drugs of High Medical Need" or "Study Group on the Early Introduction of Medical Devices, etc. with High Medical Need"
- All or part of the expenses of confirmatory studies (matching fund, etc.) are covered by public research funds.

The consultation categories are shown in [1] to [3] below.

[1] Consultations on strategies for drugs

From the early stage of development, for the approval of drugs in the future, guidance and advice will be provided for the consultations on matters requiring data evaluation in necessary studies, etc. based on pre-consultations (limited to the cases where a drug candidate compound or a compound, etc. with a certain activity has been obtained, in principle).

[2] Consultations on strategies for medical devices

From the early stage of development, for the approval of medical devices or in vitro diagnostics in the future, guidance and advice will be provided for the consultations on matters requiring data evaluation in necessary studies, etc. based on pre-consultations (limited to the cases where there is a draft or prototype related to the specification and design of the medical device, etc., in principle).

[3] Consultations on strategies for regenerative medical products, etc.

From the early stage of development, for the approval of the regenerative medical products, etc. in the future, guidance and advice will be provided for the consultations on matters requiring data evaluation in necessary studies, etc. based on pre-consultations (limited to the cases where a product candidate for the regenerative medical product, etc. or prototype, etc. with certain efficacy has been obtained, in principle).

(2) Consultations on quality and safety of regenerative medical products, etc.

[1] Consultations on quality and safety of regenerative medical products, etc.

Guidance and advice will be provided on regenerative medical products, etc. or the products intended for the

expression of transgene in the human body for preventive purposes (excluding those falling under the category of regenerative medical products, etc.; e.g., recombinant live vaccines) from the early stage of development before the submission of clinical trial notification.

If the consulter wishes to have a consultation on matters other than the quality and safety, such as clinical trial protocols, etc. related to the relevant product, the consultation will be provided in the consultation category corresponding to the relevant product among the above (1).

Consultations on the quality and safety of regenerative medical products, etc. are conducted for the same product of the same consultation applicant and may be conducted on more than one day to the extent necessary for sufficient confirmation of the quality and safety of the product concerned before the submission of clinical trial notification. In this case, for universities and research institutions, or venture companies meeting separately specified requirements (that refer to the "separately specified requirements" stipulated in the attached table of Pharmaceuticals and Medical Devices Agency Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, the same applies hereinafter), the consultation fee will be the fee for one consultation. For companies not falling into the category of venture companies meeting separately specified requirements, the consultation fee will be the fee for one consultation up to the third consultation, if consultation is provided on more than one day. For the fourth and subsequent consultations, please apply for [2]Additional consultations on quality and safety of regenerative medical products, etc.

In one consultation, either quality or safety only can be discussed, in principle. Please consult on quality and safety individually, in one or more consultation each.

[2] Additional consultations on quality and safety of regenerative medical products, etc.

After the consultation on the quality and safety of a regenerative medical product, etc., for the same product of the same consultation applicant, guidance and advice will be provided on matters related to quality and safety to the extent necessary for sufficient confirmation of the quality and safety of the product concerned before the submission of clinical trial notification.

This is the consultation category in cases where companies not falling into the category of venture companies meeting separately specified requirements receive the fourth or subsequent consultation after three [1] consultations on quality and safety of regenerative medical products, etc.

(3) Consultations on strategies including development plans

Guidance and advice will be provided on general way of thinking of and proceeding with the planning of studies such as development plan roadmap. Specific development plans for individual items (e.g. sufficiency of non-clinical studies and appropriateness of endpoints in clinical studies) are handled in the above (1). Companies, etc. other than universities, research institutions, and venture companies are also assumed to be the main target.

3. Type of consultations

A pre-consultation meeting will be held in advance, and then a face-to-face advice will be given based on the results of the pre-consultation. For the flow of consultation, refer to "Flow of RS strategy consultation" in Appendix 1.

If necessary, the contents of operation, procedures, etc. of RS strategy consultations will be explained in regulatory science general consultation (see "Implementation Guidelines for Regulatory Science General Consultations"[PMDA Notification No. 0316001 dated March 16, 2017], hereinafter referred to as "RS general consultations") before the pre-consultation.

Pre-consultation	・ For efficient face-to-face advice, a meeting will be held in advance to organize the contents (scope) of consultation and issues to be discussed in the face-to-face advice and confirm the contents of materials. ・ A technical expert from the Division of Innovation Support and Pharmaceuticals Affairs Consultations or the Consultation Division of Kansai Branch and, as necessary, review staff of the office in charge will attend the meeting.
Face-to-face advice	・ The review team of the office in charge will scrutinize the materials submitted by the consulter, tell the applicant the official opinion of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") on each consultation item for the planned clinical trials and approval application, and provide specific guidance and advice. ・ In consultations on strategies including development plans, however, the technical experts from Division of Innovation Support and Pharmaceuticals Affairs Consultations will explain in principle, and review staff of the office in charge will be present as necessary.

When applying for an RS strategy consultation, please apply for a pre-consultation in advance and have a meeting with the persons in charge at PMDA on the items shown above. The applicant will be asked to apply for face-to-face advice based on the results of the pre-consultation.

The subjects of the face-to-face advice shall correspond to the priority categories (shown below) in principle, and be expected to be promising (for example, drugs for which substance patents are being applied or have been obtained, medical devices for which there are drafts or prototypes related to their specifications or design, and regenerative medical products, etc. for which there are prototypes with certain efficacy or which are likely to be practically applied as innovative drugs, medical devices, or regenerative medical products, etc. in the future). However, depending on the status of receipt of applications for face-to-face advice by PMDA, applications for consultations for other items may be accepted.

Applications for pre-consultations are accepted regardless of the following.

Priority categories
• Regenerative medical products, etc. • Oncology products • Products for intractable diseases and orphan diseases • Pediatric products • Products using particularly innovative technologies other than the above (Note) There is no order for categories.

4. Pre-consultations

(1) Method and location of implementation

Pre-consultations are provided in face-to-face meeting or online meeting format, or combination of both. Please indicate your preference in the “Desired implementation method” column of the application form. Even in the case of a face-to-face meeting format, some of the PMDA's attendees may participate in the online meeting format.

Consultations in face-to-face meeting format will take place in Tokyo, Osaka, or Kobe, according to the applicant’s preference. Even if the preferred format is online meeting, please be sure to select the desired location in the “Desired location” column of the application form. If the preferred location is Kobe (PMDA Strategy Consultation and Coordination Center, Foundation for Biomedical Research and Innovation at Kobe), please contact PMDA Strategy Consultation and Coordination Center in advance.

Please note that we may not be able to meet your request for reasons such as meeting rooms.

(2) Application method

Please enter necessary information in “Application Form for Questions at Pre-consultations of Regulatory Science Strategy Consultations” (Attached Form 1) and submit it by e-mail or fax to Division of Innovation Support and Pharmaceuticals Affairs Consultations, Office of Review Management with other materials to be used in the meeting. If a pre-consultation for a consultation on strategies including development plans is desired, please state “Requesting consultation on strategies including development plans” in the remarks column of the application form.

If the preferred format is online meeting, please submit Form No. 57 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004, hereinafter referred to as “Administrative Instructions for the Statement of Operating Procedures”), "Basic Confirmation Items for Implementation of Consultations via Online Meeting" (Attachment 7 to this Implementation Guidelines) as well.

Regardless of the implementation method and location, the application should be submitted to the same address.

(Contact for application and inquiry)
Division of Innovation Support and Pharmaceuticals Affairs Consultations, Office of Review Management, Pharmaceuticals and Medical Devices Agency
E-mail address yakujisenryaku@pmda.go.jp
Phone 03-3506-9562 (for inquiries)
Fax 03-3506-9593

(Time when applications and inquiries are received)
From Monday to Friday (excluding national holidays, etc.)

(3) Notification of schedule, etc. of pre-consultations

After receiving the application form, the person in charge at PMDA will notify the schedule, etc. by phone or e-mail. Depending on the contents of questions in pre-consultation, answers may be given over the phone.

(4) Implementation of pre-consultations

Each meeting should be within 30 minutes. In a face-to-face meeting, the number of attendees should usually be about 5 per consultation due to the size of the meeting room, but if more people wish to attend, please consult the person in charge.

(5) Other

The persons in charge at PMDA may make inquiries about the contents of questions in advance.

Details of the pre-consultation meeting will not be recorded.

5. Face-to-face advice

(1) Implementation method

Face-to-face advice is provided in face-to-face meeting or online meeting format, combination of both, or using the video conferencing system at the Kansai Branch. Please indicate your preference in the "Implementation method" column of the request form for scheduling. Even in the case of a face-to-face meeting format, some of the PMDA's attendees may participate in the online meeting format.

Face-to-face advice will take place in Tokyo or Osaka.

If the applicant wishes to have face-to-face advice using the video conferencing system at the Kansai Branch, please take procedures according to "6. If face-to-face advice using the video conferencing system at the Kansai Branch is desired." The video conferencing system at the Kansai Branch and the online meeting system cannot be used at the same time.

(2) Request for scheduling of face-to-face advice

When a decision is made as a result of the pre-consultation to implement face-to-face advice, a meeting for the advice will be scheduled. In the application form for face-to-face advice for each consultation category in Form Nos. 28 to 32 (Attachment 1 to 5 of this notification) of Administrative Instructions for the Statement of Operating Procedures, please correct "application form" in the title to "request form for scheduling" and "We apply for face-to-face advice as described above" under the remarks column to "We request for scheduling of face-to-face advice as described above," enter necessary information, and submit it to the Review Management Division, Office of Review Management by e-mail, in principle. If it is difficult to submit it by e-mail, submit it by fax.

If the preferred format is online meeting, please submit Form No. 57 of Administrative Instructions for the Statement of Operating Procedures, "Basic Confirmation Items for Implementation of Consultations via Online Meeting" (Attachment 7 to this Implementation Guidelines) as well.

(Address for submission of request form for scheduling and contact for inquiries about application)
Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013
Review Management Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency
E-mail address yakujisenryaku@pmda.go.jp
Phone 03-3506-9556 (for inquiries)
Fax 03-3506-9443

(Contact for inquiries about application)
Division of Innovation Support and Pharmaceuticals Affairs Consultations, Office of Review Management, Pharmaceuticals and Medical Devices Agency
Phone 03-3506-9562

(Time when requests or inquiries are received)

Consultations on strategies for drugs	Usually, on the first business day of the month 2 months before the month in which the consultation is conducted (As this may change at the end of the year and the beginning of the year, please check the PMDA website.) Regardless of the method of submission, submission must be received by the above date.
Consultations on strategies for medical devices	
Consultations on strategies for regenerative medical products, etc.	
Consultations on quality and safety of regenerative medical products, etc.	At any time
Additional consultations on quality and safety of regenerative medical products, etc.	
Consultations on strategies including development plans	

(Opening hours)
10:00 a.m. to 4:00 p.m.

(Attachments)
If universities or research institutions conducting studies by themselves wish to consult regarding confirmatory studies after the early stage of clinical development in consultations on strategies for drugs, consultations on strategies for medical devices, or consultations on strategies for regenerative medical products, etc., they should attach the documents [1] and [2] below to confirm that their items meet the requirements.

[1] The list of requested items for "Study Group on Unapproved and Off-label Drugs of High Medical Need" or the list of selected items for "Study Group on the Early Introduction of Medical Devices, etc. with High Medical Need" (indicate the applicable part of the lists by, for example, marking the applicable item)
[2] Breakdown of the public research funds that cover all or part of the confirmatory studies of the item concerned, materials that facilitate the understanding of the research theme, and a copy of the notice of grant decision

(3) Consultation fees, etc. and application for application of requirements for low fees

1) Consultation fees and requirements for low fees

The consultation fees are shown below. Consultations on the quality and safety of regenerative medical products, etc. are conducted for the same item of the same consultation applicant and may be conducted on more than one day to the extent necessary for sufficient confirmation of the quality and safety of the product concerned before the submission of clinical trial notification (the request form for scheduling face-to-face advice needs to be submitted for each consultation).

In this case, for universities and research institutions or venture companies that meet separately specified requirements, the consultation fee will be the fee for one consultation.

For companies not falling into the category of venture companies meeting separately specified requirements, the consultation fee will be the fee for one consultation up to the third consultation, if consultation is provided on more than one day. For the fourth and subsequent consultations, the fee for additional consultations on quality and safety of regenerative medical products, etc. will be charged.

However, among consultations on regenerative medical products, etc., if any consultation on matters other than the quality and safety such as clinical trial protocols is also provided, fees according to the consultation category need to be paid separately. In this case, it is possible to continue to have a consultation on clinical trial protocols, etc. following the consultation on quality and safety.

(Table of consultation fees)

Consultation category	Fee (per consultation*1)	Fee for universities, research institutions, and venture companies meeting separately specified requirements (per consultation*1)
Consultations on strategies for drugs	1,541,600 yen	154,100 yen
Consultations on strategies for medical devices*2	874,000 yen	87,400 yen
Consultations on strategies for regenerative medical products, etc.	874,000 yen	87,400 yen
Consultations on quality and safety of regenerative medical products, etc.	1,541,600 yen	154,100 yen
Additional consultations on quality and safety of regenerative medical products, etc.	496,800 yen	
Consultations on strategies including development plans	73,600 yen	

*1: The consultation time per consultation for face-to-face advice is about 2 hours. However, consultations on strategies including development plans should be about 30 minutes.

*2: For in vitro diagnostics, the fee for consultations on strategies for medical devices is applied.

(Universities, research institutions, and venture companies meeting the separately specified requirements)

(Requirements for low fees)

In principle, all of the following requirements must be met.

○ Universities and research institutions

- Have not received research funds for the seed-stage resources concerned in the amount exceeding the following amount (approximate) from the government
  Consultations on strategies for drugs or consultations on quality and safety of regenerative medical products, etc.: 90 million yen
  Consultations on strategies for medical devices or consultations on strategies for regenerative medical products, etc.: 50 million yen
- Have not received research funds for the practical application of seed-stage resources from pharmaceutical companies or companies developing medical devices, etc. under joint research agreements, etc. with the companies concerned for the seed-stage resources concerned

○ Venture companies

- Being a small or medium-sized company (number of employees is 300 or less or capital is 300 million yen or less)
- No other corporation has shares or investments that are 1/2 or more of the total number of shares or total amount of investment.
- Multiple corporations do not have shares or investments that are 2/3 or more of the total number of shares or total amount of investment.
- In the preceding business year, the profit is not recorded, or the profit is recorded but there was no business revenue.

(Note)

For application of requirements for low fees for venture companies, please pay attention to the following points.

[1] As for the "corporations" included in the above items related to venture companies, handling of investment partnerships, etc. such as venture capitals shall be judged individually in accordance with the application of relevant laws, regulations, standards, etc.

[2] Regarding profit, if development expenses are recorded as deferred assets for accounting purposes, the amount equivalent to the profit in the case of processing them as expenses shall be referred to.

[3] If there are special circumstances, etc. in the settlement of accounts for the preceding business year

and it is considered necessary to make a judgment based on the settlement status in the preceding two periods, the judgment shall be made after the submission and confirmation of the related materials.

2) Application for application of requirements for low consultation fees

In relation to consultation fees, if the applicant applies for the consultation under the category of "universities, research institutions, and venture companies meeting separately specified requirements" shown in the consultation fee table in 1) above, PMDA needs to confirm whether or not the consultation applicant falls under the category of "universities, research institutions, and venture companies meeting separately specified requirements." In order to confirm this applicability, the following "application documents for application of requirements for low consultation fees for regulatory science strategy consultations" will be required. Please submit these documents to Review Management Division, Office of Review Management by e-mail, in principle. If it is difficult to submit them by e-mail, contact Review Management Division. In the case of a high volume of documents, the applicant may be asked to submit them by postal mail or bring them to the Division. In that case, write "Application documents for application of requirements for low consultation fees for regulatory science strategy consultations" in red on the front of the envelope.

(Application documents for application of requirements for low consultation fees for regulatory science strategy consultations)

○ Universities and research institutions

[1] Application Form for Application of Requirements for Low Consultation Fees for Regulatory Science Strategy Consultations (Attached Form 2)

[2] Breakdown of all research funds related to the seed-stage resources concerned that the representative of the research concerned has obtained, the materials that facilitate the understanding of the research theme, and a copy of the notice of grant decision (for 3 business years including the previous business year)

○ Venture companies

[1] Application Form for Application of Requirements for Low Consultation Fees for Regulatory Science Strategy Consultations (Attached Form 3)

[2] Copy of the business report, balance sheet, profit and loss statement, and Attached Table 2 of corporate tax return for the previous business year (or shareholder [investor] register). However, if the capital exceeds 300 million yen, documents with which the number of employees can be checked, such as a copy of the tax return for estimated insurance premium for labor insurance and the rough estimate of increase.

(Where to apply)

Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013

Review Management Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency

Phone (direct) 03-3506-9556

E-mail addressyakujisenryaku@pmda.go.jp

(Deadline)

Must be received by the date of receipt of the request form for scheduling in (2) above.

After the applicability to "universities, research institutions, and venture companies meeting separately specified requirements" is confirmed based on the submitted materials, PMDA will inform the applicant whether the applicant is applicable or not, and of the category of the fee to be transferred in advance.

(4) Notification of schedule, etc. of face-to-face advice

After the receipt of the request form for scheduling in (2) above, the person in charge at PMDA will contact to arrange the date and time of face-to-face advice. Once the date and time, location, etc. are determined, the information will be sent to the contact of the consulter by fax as the "Information on face-to-face advice."

However, consultations on GMP may require visits to manufacturing facilities, etc. and it may take a certain number of days to determine the date and time of face-to-face advice. Therefore, even before the date and time are determined, the deadline for submission of the application form, etc. may be notified to the contact of the consulter by fax.

(5) Transfer of fees for face-to-face advice and application for face-to-face advice

Please transfer the fee designated by PMDA from a commercial bank, etc. within 15 business days counting from the day after the receipt of the fax of the date and time, etc. described in (4) above or by the date of delivery of materials, whichever comes first, enter necessary information in the application form for face-to-face advice for each consultation category, and submit it to Review Management Division, Office of Review Management by e-mail, in principle, with an attached copy of the transfer receipt, etc. If it is difficult to submit it by e-mail, contact Review Management Division, Office of Review Management.

For details of the amount of the fee and the method of transfer, refer to "Fees for Review, etc. Conducted by the Pharmaceuticals and Medical Devices Agency" (PMDA Notification No. 1121002 of the Pharmaceuticals and Medical Devices Agency, dated November 21, 2014).

(6) Submission of materials for face-to-face advice

Please submit the materials for face-to-face advice to Review Management Division, Office of Review Management as follows.

For consultations on strategies including development plans, it is not necessary to submit materials, but the person in charge at PMDA may make inquiries in advance about the contents of questions.

[1] How to submit materials

Please submit the materials for face-to-face advice by any of the following methods.

- Submission of electronic media (CD or DVD) by postal mail or bringing them in person
- Online submission using the application electronic data system (gateway system)

When submitting the consultation materials, check the points to consider posted on the PMDA website in advance.

If necessary, the consulter may be asked to submit certain materials separately printed on paper.

[2] Deadline for submission of materials

Please submit them by the following date and time, in principle. The submitted electronic media will be discarded by PMDA, in principle.

Consultations on strategies for drugs	By 3 p.m. on the first business day of the week, which is 5 weeks before the scheduled date of face-to-face advice (must be received)
Consultations on strategies for regenerative medical products, etc.	
Consultations on quality and safety of regenerative medical products, etc.	
Additional consultations on quality and safety of regenerative medical products, etc.	
Consultations on strategies for medical devices	By 3 p.m. on the first business day of the week, which is 3 weeks before the scheduled date of face-to-face advice (must be received)

* However, if the year-end and the beginning of the year, etc. are included, the deadline will be the day designated by PMDA earlier than the above (for the annual schedule, see the "Scheduled face-to-face advice (RS strategy consultations)" on the PMDA's website).

(7) Contents to be included in materials for face-to-face advice

Please prepare the materials by including the development concept, according to the method for compiling materials recommended by the person in charge at PMDA at the pre-consultation. In preparation of materials, please also refer to the sections, etc. corresponding to the contents of each consultation, among "8. Contents to be included in materials for face-to-face advice" in Attachment 1, "8. Contents to be included in consultation materials" in Attachment 8, and "3. Necessary materials for each consultation" in Attachment 13 of PMDA Notification No. 0302070 of the Pharmaceuticals and Medical Devices Agency, dated March 2, 2012, "Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency."

For the development of regenerative medical products, etc., please refer to the following pages of the PMDA's website as well for the contents of materials to be attached at the time of consultation when preparing these materials.

- Regenerative medical products, etc.
  https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/ctp/0007.html
- Gene therapy-related information
  https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/ctp/0006.html
- Application related to the Cartagena Act

https://www.pmda.go.jp/review-services/drug-reviews/cartagena-act/0003.html

(8) Implementation of face-to-face advice

[1] The persons in charge at PMDA may make inquiries about the contents of consultation in advance.

[2] For consultations on strategies for drugs, consultations on strategies for regenerative medical products, etc., or consultations on quality and safety of regenerative medical products, etc., the opinion of PMDA on the contents of each consultation will be presented in writing before the face-to-face advice. If the consulter and PMDA agree, the advice may end with the written advice without holding any meeting.

[3] Please notify the person in charge at PMDA of the number of attendees, whether or not any expert on the side of the consulter or non-Japanese attendee will be present (including whether or not any interpreter will attend), and the equipment to be used for presentation, by the day before the face-to-face advice.

[4] The number of attendees should usually be up to 15 per consultation due to the size of the meeting room.

[5] On the day of the face-to-face advice, please tell the receptionist at PMDA that you have an appointment for face-to-face advice and the receptionist will show you the way.

[6] The consultation time shall be about 2 hours per consultation. However, consultations on strategies including development plans should be about 30 minutes.

[7] On the day of the advice, please make a presentation on the outline of consultation items for about 10 minutes. For consultations on strategies including development plans, please make a presentation in about 5 minutes. After that, the consultation will be provided. Regarding the timing of submission of presentation materials (copy), please consult the person in charge at PMDA in advance.

(9) Communication of record of face-to-face advice

After the face-to-face advice (including the cases where it ended with written advice), PMDA will prepare a record, have the consulter check the contents, and send it to the consulter.

6. If face-to-face advice using the video conferencing system at the Kansai Branch is desired

Face-to-face advice for all categories of RS strategy consultations can be provided at the Kansai Branch using its video conferencing system. In this case, the consulter needs to separately apply for the use of the video conferencing system at the Kansai Branch and pay the usage fee. The application method is as follows.

If a consultation on quality and safety of regenerative medical products, etc. is held on more than one day, the procedures for application for use and usage fee are required for each use.

(1) Scheduling

Those who wish to use the video conferencing system at Kansai Branch should change “Application Form for Use of Video Conferencing System at the Kansai Branch in Regulatory Science Strategy Consultations” to “Request form for scheduling of use of video conferencing system at Kansai Branch in regulatory science strategy consultations” in the title part of Form No. 36 of Administrative Instructions for the Statement of Operating Procedures (Attachment 6 of this notification), enter necessary information, and submit it to Review Management Division, Office of Review Management by e-mail, in principle, together with the request form for scheduling of face-to-face advice. If it is difficult to submit it by e-mail, submit it by fax. Please note that the application forms that arrive outside the designated hours are not accepted.

(Where to apply)
Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013
Review Management Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency
Phone (direct) 03-3506-9556
E-mail address yakujisenryaku@pmda.go.jp
Fax 03-3506-9443

(Opening hours)
Same as the opening hours for each consultation. (See “5. (2) Request for scheduling of face-to-face advice.”)

(2) Notification of scheduling results

Whether or not the video conferencing system at the Kansai Branch can be used will be communicated by fax from Review Management Division, Office of Review Management to the contact of the consulter as “Information on face-to-face advice” together with the results of scheduling of face-to-face advice.

(3) Transfer of usage fee and application

If it is determined possible to use the video conferencing system at the Kansai Branch, please transfer the fee related to the use of video conferencing system at Kansai Branch with the fee for the applicable consultation category from a commercial bank, etc. within 15 business days counting from the day after receiving the "Information on face-to-face advice," enter necessary information in the "application form for face-to-face advice" for each consultation category and the "Application Form for Use of the Video Conferencing System at Kansai Branch in Regulatory Science Strategy Consultations," and submit them to Review Management Division, Office of Review Management by e-mail, in principle, with an attached copy of the transfer receipt, etc. If it is difficult to submit it by e-mail, contact Review Management Division, Office of Review Management.

The usage fee for the video conferencing system at the Kansai Branch will be reduced from the amount specified in Attached Table of Administrative Instructions for the Statement of Operating Procedures during the implementation period of the "Project for establishing the support system at Kansai Branch of the Pharmaceuticals and Medical Devices Agency" by the Osaka prefectural government. However, the amount of usage fee, etc. may be reviewed based on the actual use, etc.

(4) If use of video conferencing system at the Kansai Branch is desired after submission of request form for scheduling of face-to-face advice

If the consulter did not wish to use the video conferencing system at the Kansai Branch at the time of submission of the request form for scheduling of face-to-face advice, but later wishes to use the system for special reasons, please describe the reason for wishing to use it in the Remarks column and submit the "Request form for scheduling of use of video conferencing system at Kansai Branch in regulatory science strategy consultations," referring to 6. (1) of the present implementation guidelines. After the request form for scheduling is received, the status, etc. of use of the video conferencing system at the Kansai Branch will be checked and it will be notified whether or not the video conferencing system at Kansai Branch can be used as described in 6. (2) of the present implementation guidelines.

If being notified that the video conferencing system of the Kansai Branch can be used, please transfer the usage fee related to the use of the video conferencing system at Kansai Branch from a commercial bank, etc., within 15 business days counting from the day after being notified or by the day before the implementation of face-to-face advice of the applicable consultation category, whichever comes first, enter necessary information in the "Application Form for Use of Video Conferencing System at Kansai Branch in Regulatory Science Strategy Consultations," attach a copy of the transfer receipt, etc., and submit it to Review Management Division, Office of Review Management by e-mail, in principle. If it is difficult to submit it by e-mail, contact Review Management Division, Office of Review Management.

When the date of face-to-face advice is approaching, please contact Review Management Division, Office of Review Management by phone, as your request may not be met.

(5) Cancellation of use of the video conferencing system at the Kansai Branch

1) When cancelling the use of the video conferencing system at Kansai Branch after applying for the use in cases where, for example, the implementation of applicable consultation ended with written advice only, please enter necessary information in Form No. 31 of Administrative Instructions for Collection of Fees for Reviews, etc., Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 5 in 2004, hereinafter referred to as "Administrative Instructions for Collection of Fees"), "Request form for reimbursement of fees for review, etc. paid in error," and submit it to Review Management Division, Office of Review Management by e-mail, in principle. If it is difficult to submit it by e-mail, contact Review Management Division, Office of Review Management. The usage fee will be refunded in full.

2) When cancelling the consultation itself, please cancel the consultation using Form No. 33, "Request for cancellation of face-to-face advice," and Form No. 34, "Request form for reimbursement of fees for review, etc. for drugs, etc.," of Administrative Instructions for the Statement of Operating Procedures, enter necessary information in Form No. 31 of Administrative Instructions for Collection of Fees, "Request form for reimbursement of fees for review, etc. paid in error," and submit it to Review Management Division, Office of Review Management in the same manner as (5) 1). Half the consultation fee and the full amount of the usage fee for the video conferencing system at the Kansai Branch will be refunded.

In the remarks column of the "Request for cancellation of face-to-face advice," enter "Consultation in which use of the video conferencing system at the Kansai Branch was requested."

3) When changing the date of face-to-face advice because of the convenience of the applicant, the application for the use of the video conferencing system at the Kansai Branch needs to be made again. Please submit Form No. 33, "Request for cancellation of face-to-face advice," and Form No. 34, "Request form for reimbursement

of fees for review, etc. for drugs, etc.," of Administrative Instructions for the Statement of Operating Procedures and Form No. 31 of Administrative Instructions for Collection of Fees, "Request form for reimbursement of fees for review, etc. paid in error," to Review Management Division, Office of Review Management in the same manner as (5) 1). Half the consultation fees and the full amount of the usage fee for the video conferencing system will be refunded.

In the remarks column of the "Request for cancellation of face-to-face advice," enter "Consultation in which use of the video conferencing system at the Kansai Branch was requested."

(6) Points to consider in use of a video conferencing system at the Kansai Branch

1) Since the meeting rooms available for the use of the video conferencing system at the Kansai Branch are limited, please enter multiple dates distributed throughout the preferred month, for example, in the beginning, middle, and last part, as preferred dates of face-to-face advice. If the requests for the use of the video conferencing system at the Kansai Branch are concentrated at certain timing, priority will be given to the face-to-face advice requiring voice recording.

2) The video conferencing system at the Kansai Branch cannot be used for pre-consultations.

7. Cancellation and schedule change of face-to-face advice

(1) When cancelling face-to-face advice after its application before the date of implementation at the convenience of the applicant, enter necessary information in Form No. 33 of Administrative Instructions for the Statement of Operating Procedures, "Request for withdrawal of application for face-to-face advice," and submit it to Review Management Division, Office of Review Management by e-mail, in principle. If it is difficult to submit it by e-mail, contact Review Management Division, Office of Review Management. If the applicant enters necessary information in Form 34 of Administrative Instructions for the Statement of Operating Procedures, "Request form for reimbursement of fees for review, etc. for drugs, etc.," and submits to Review Management Division, Office of Review Management, half of the fee will be refunded.

(2) When changing the implementation date at the convenience of the applicant, the applicant will be asked to submit the "Request for withdrawal of application for face-to-face advice" and apply again. If the applicant enters necessary information in "Request form for reimbursement of fees for review, etc. for drugs, etc.," and submits to Review Management Division, Office of Review Management, half of the fee will be refunded.

(3) When the implementation date is to be changed at the convenience of PMDA or when PMDA considers that the change of implementation date is inevitable, submission of "Request for withdrawal of application for face-to-face advice" is not necessary.

(4) Even in cancellation, if PMDA considers it inevitable and the applicant enters necessary information in "Request form for reimbursement of fees for review, etc. for drugs, etc." and submits to Review Management Division, Office of Review Management, the fee will be fully refunded.

(5) In the case of a consultation on quality and safety of regenerative medical products, etc. provided on more than one day for a venture company that does not meet separately specified requirements, one consultation is considered to have been provided if the consultation is cancelled at the convenience of the applicant on or after the submission date of the materials for face-to-face advice before the implementation date.

8. Other

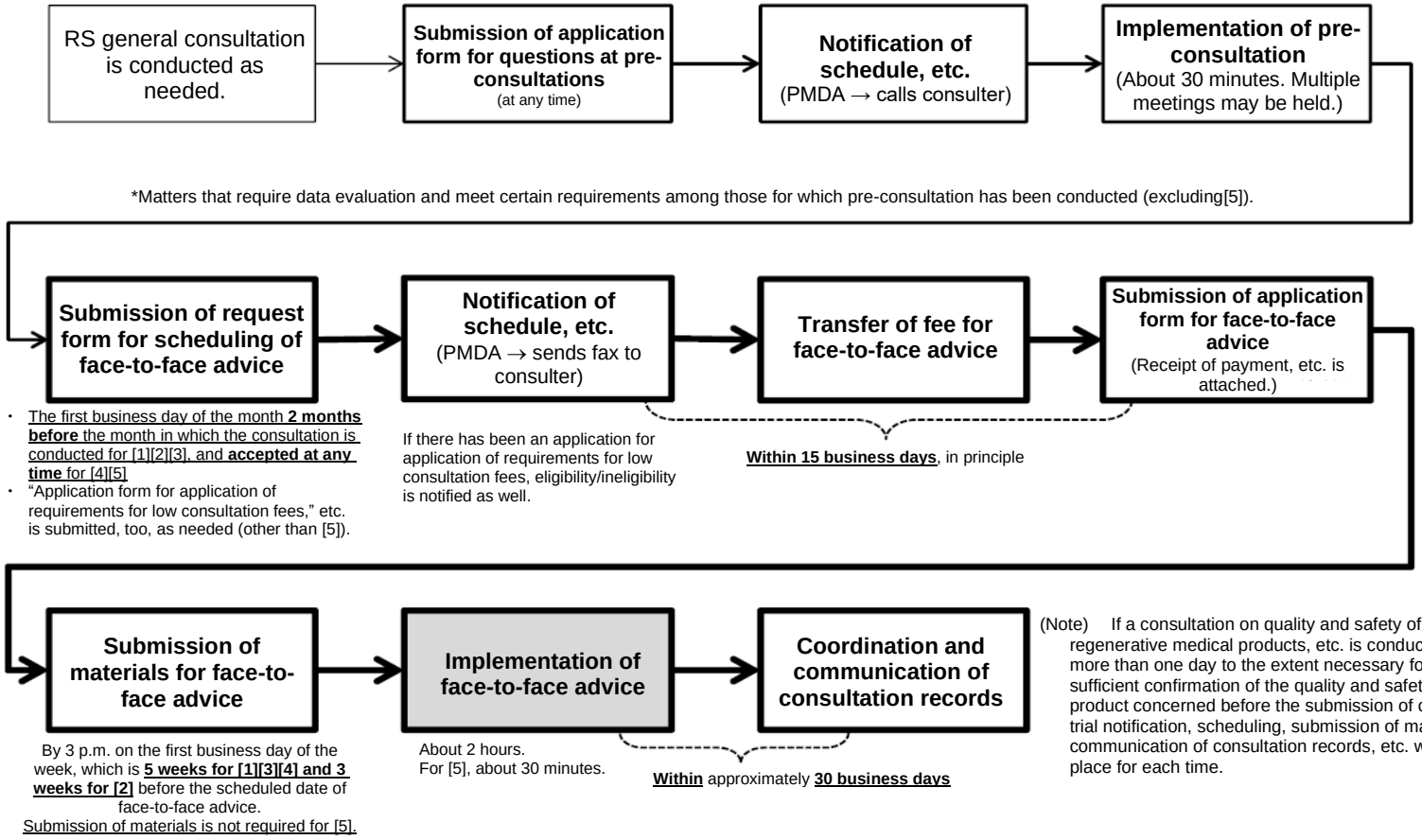
(1) Information related to consultation items obtained during the RS general consultations will not be published without the consent of the consulter.

(2) The laboratory, manufacturing equipment, etc. of the consulter may be visited if PMDA judges it necessary for proper and smooth conduct of the face-to-face advice.

(Appendix 1)

Flow of RS strategy consultation

[Type of face-to-face advice]
- [1] Consultations on strategies for drugs
- [2] Consultations on strategies for medical devices
- [3] Consultations on strategies for regenerative medical products, etc.
- [4] Consultations on quality and safety of regenerative medical products, etc.
- [5] Consultations on strategies including development plans



(Note) If a consultation on quality and safety of regenerative medical products, etc. is conducted on more than one day to the extent necessary for sufficient confirmation of the quality and safety of the product concerned before the submission of clinical trial notification, scheduling, submission of materials, communication of consultation records, etc. will take place for each time.

(Appendix 2)

Review Categories of New Drugs, Medical Devices, and Regenerative Medical Products, etc.

1. New drugs or regenerative medical products, etc.

Review category	Target
Review category 1	Gastrointestinal drugs, dermatologic drugs, immunosuppressants, other (not classified into other categories)
Review category 2	Cardiovascular drugs, antiparkinson drugs, drugs for Alzheimer's disease
Review category 3-1	Central nervous system drugs, peripheral nervous system drugs. Anesthetic drugs are excluded.
Review category 3-2	Anesthetic drugs, sensory organ drugs (excluding drugs for inflammatory diseases), narcotics
Review category 4	Antibacterial drugs, antiviral drugs (excluding AIDS drugs), antifungal drugs, antiprotozoal drugs, anthelmintic drugs
Review category 5	Urogenital/anal drugs, combination drugs
Review category 6-1	Respiratory tract drugs, anti-allergy drugs (excluding dermatologic drugs), sensory organ drugs (drugs for inflammatory diseases)
Review category 6-2	Hormone drugs, drugs for metabolic disorders (diabetes, osteoporosis, gout, inborn errors of metabolism, etc.)
Oncology drugs	Antineoplastic drugs
AIDS drugs	Anti-HIV drugs
Radiopharmaceuticals	Radiopharmaceuticals
In vivo diagnostics	Contrast media, reagents for function tests (excluding in vitro diagnostics)
Bio-CMC	Bio-CMC, follow-on biologics
Vaccines	Vaccines (limited to those related to prevention of infections), antitoxins
Blood products	Blood products
Regenerative medical products	Regenerative medical products, etc. manufactured by processing cell tissues
Gene therapy products	Regenerative medical products, etc. for gene therapy, Cartagena

(Note)

[1] Immunosuppressants for transplantation, antidotes, drugs for renal diseases, etc. fall into Review category 1.

[2] “Gastrointestinal drugs” in Review category 1 include drugs for liver diseases and drugs for pancreatic diseases. “Dermatologic drugs” do not include dermatological drugs other than those for external use or external drugs generally intended for absorption into the body.

[3] Ophthalmic drugs, etc. containing antibiotics as active ingredients fall into Review category 4, not Review category 3-1, Review category 3-2, and Review category 6-1.

[4] “Combination drugs” in Review category 5 mainly refer to combination prescription drugs with similar formulations. Other combination drugs fall into the categories applicable to proposed indications.

[5] “Anti-allergic drugs” in Review category 6-1 are oral drugs. Among “anti-allergic drugs,” drugs for external use fall into Review category 1.

[6] “Hormone drugs, drugs for metabolic disorders” in Review category 6-2 include anti-diabetic drugs, osteoporosis drugs, hormone drugs other than digestive hormones, antipodagric agents, and drugs for inborn errors of metabolism. However, among hormone drugs, urogenital drugs fall into Review category 5, not Review category 6-2.

2. Medical devices (including the categories that include in vitro diagnostics)

Review category	Target
Robotics, IoT and other fields	Innovative medical devices mainly utilizing robot technology, advanced IoT technology, etc., medical devices related to multiple departments, and medical devices not belonging to other categories
Orthopedic/plastic fields	・ Medical devices mainly related to knee/upper limb joints, hip/finger joints, etc. in the orthopedic category ・ Among medical devices in orthopedic category, mainly plates/screws and intramedullary nails/fixation materials for spine, etc., and related instruments/machines; medical devices in plastic surgery and dermatology fields
Psychiatric, neurological, respiratory, cerebral/vascular fields	・ Materials used in cerebral/cardiovascular (excluding cardiac), respiratory, psychiatric/neurological fields ・ Machines used in cerebral/cardiovascular (excluding cardiac), respiratory, psychiatric/neurological fields
Digestive organ/reproductive fields	Mainly digestive system, urinary system, and obstetrics and gynecology fields
Dental and oral fields	Mainly dental field
Ophthalmologic/ otolaryngologic fields	Mainly ophthalmologic and otolaryngologic fields
Cardiopulmonary and cardiovascular fields	・ Materials mainly related to the heart among cardiovascular medical devices ・ Machines mainly related to the heart among cardiovascular medical devices
Program field	Medical devices mainly consisting of single program
In vitro diagnostic field	Mainly laboratory test field (related to in vitro diagnostics)

(Attached Form 1)

Application Form for Questions at Pre-consultations of Regulatory Science Strategy Consultations

Month DD, YYYY

<table>
<tr><td colspan="2">Subject of consultation</td><td>☐ Drugs
☐ Medical devices (including in vitro diagnostics)
☐ Regenerative medical products, etc.</td></tr>
<tr><td colspan="2">Name of applicant</td><td></td></tr>
<tr><td rowspan="5">Contact information</td><td>Contact name</td><td></td></tr>
<tr><td>Department</td><td></td></tr>
<tr><td>Phone number</td><td></td></tr>
<tr><td>Fax number</td><td></td></tr>
<tr><td>E-mail address</td><td></td></tr>
<tr><td colspan="2">List of attendees
(name, affiliation)</td><td></td></tr>
<tr><td colspan="2">Review category</td><td></td></tr>
<tr><td colspan="3">[Details of consultation] (Fill in according to the precautions on the next page.)
<table><tr><td>Title</td><td></td></tr></table>
<Background of consultation, outline of product and seed-stage resources, etc.>

<Questions>
1.

2.</td></tr>
<tr><td colspan="2">Desired implementation method</td><td>Face-to-face meeting format
Online meeting format
(If some attendees would like to attend in person and others would like to participate in online meetings, please circle both.)</td></tr>
<tr><td colspan="2">Desired location
(Select also in the case of online meeting)</td><td>Tokyo Osaka (Kansai Branch) Kobe
(Please consult PMDA Strategy Consultation and Coordination Center in advance)</td></tr>
<tr><td colspan="2">Desired dates for pre-consultation meeting</td><td></td></tr>
<tr><td colspan="3">For the consultation on a project adopted by Japan Agency for Medical Research and Development (AMED), <u>if the applicant agrees</u> to the sharing of information related to the present consultation between AMED and PMDA under appropriate information management in order to manage the progress of the research project at AMED based on the conditions given by AMED for the adoption of the project by AMED, please enter the project control number of AMED.</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="2">Consultation previously received for this item</td><td>Receipt number of face-to-face advice:
Date of pre-consultation meeting, introductory consultation, or RS general consultation:</td></tr>
<tr><td colspan="2">Remarks</td><td></td></tr>
</table>

(Note)

1 The paper size should be Japan Industrial Standard A4.

2 When all of the required information cannot be entered in the specified column, enter "as per appendix ( )" in the column and attach the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for subject of consultation

Please tick the item applicable to the product to be discussed.

(2) Column for name of applicant

For a corporation, please enter the name of the corporation.

(3) Column for review category

Please select and enter the applicable category from Appendix 2, "Review Categories of New Drugs, Medical Devices, and Regenerative Medical Products, etc.," of "Implementation Guidelines for Regulatory Science Strategy Consultations."

(4) Column for details of consultation

Add the title (include the product name, development code, etc. if possible), and summarize the background of the application for this consultation (including the product outline, etc.) and the contents of questions in a concise manner (with bullet points). Please note in advance that questions other than those described in this column cannot be answered.

(5) Column for desired implementation method

Please select either face-to-face meeting format or online meeting format. If some attendees would like to make a visit and others would like to participate online, please circle both.

(6) Column for desired location

Please select desired location of pre-consultation meeting from Tokyo, Osaka (Kansai Branch), and Kobe by circling one. Please select one even when the preferred format is online meeting so that a PMDA department can continue to be in charge in the case of a switch to face-to-face meeting format or for the next consultation.

For Kobe, please consult PMDA Strategy Consultation and Coordination Center in advance.

(7) Column for desired dates for pre-consultation meeting

Enter multiple desired dates for the meeting.

(8) Column for consultation previously received for this item

If "RS strategy consultation" has been provided once before this application, please enter the receipt number of the face-to-face advice concerned. If any pre-consultation, introductory consultation, or RS general consultation has been provided, please enter the date of consultation, etc. as much as possible.

(9) Remarks

If a pre-consultation for a consultation on strategies including development plans is desired, please state "Requesting consultation on strategies including development plans." Enter any other supplementary information.

Note) In consultations on strategies including development plans, guidance and advice will be provided on general way of thinking of and proceeding with the planning of studies such as development plan roadmap. Specific development plans for individual items (e.g. sufficiency of non-clinical studies and appropriateness of endpoints in clinical studies) are applicable to consultations on strategies for drugs/medical devices/regenerative medical products, etc.

(Attached Form 2)

Application Form for Application of Requirements for Low Consultation Fees for Regulatory Science Strategy Consultations
(universities and research institutions)

To Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency

As shown in the attached materials, we meet the following two requirements. Therefore, we apply for the application of the low consultation fees for regulatory science strategy consultation.

Note

1. Have not received research funds for the seed-stage resources concerned in the amount exceeding the following amount (approximate) from the government
   - Consultations on strategies for drugs or consultations on quality and safety of regenerative medical products, etc.: 90 million yen
   - Consultations on strategies for medical devices or consultations on strategies for regenerative medical products, etc.: 50 million yen

2. Have not received research funds for the practical application of seed-stage resources from pharmaceutical companies or companies developing medical devices, etc. under joint research agreements, etc. with the companies concerned for the seed-stage resources concerned

Month DD, YYYY
Address (location of main office)
Name of university or research institution
Name of applicant

Contact information of the person in charge (phone, fax, e-mail address)
Name of person in charge

(Attached Form 3)

Application Form for Application of Requirements for Low Consultation Fees for Regulatory Science Strategy Consultations
(venture companies)

To Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency

As shown in the attached materials, our company meets the following four requirements. Therefore, we apply for the application of the low consultation fees for regulatory science strategy consultation.

Note

1. Being a small or medium-sized company (number of employees is 300 or less or capital is 300 million yen or less)
2. No other corporation has shares or investments that are 1/2 or more of the total number of shares or total amount of investment.
3. Multiple corporations do not have shares or investments that are 2/3 or more of the total number of shares or total amount of investment.
4. In the preceding business year, the profit is not recorded, or the profit is recorded but there was no business revenue.

Month DD, YYYY
Address (location of main office)
Company name
Name of applicant (representative)

Contact information of the person in charge (phone, fax, e-mail address)
Name of person in charge

(Attachment 1)
Form No. 28 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Application Form for Face-to-face Advice in Consultations on Strategies for Drugs

Review category	
Name of test drug, investigational ingredient code, etc.	Name of test drug: Investigational ingredient code:
Proposed non-proprietary name, etc. (name of pharmaceutical ingredient)	
Route of administration/dosage form	
Information on quality and stability, etc.	
Proposed therapeutic category	
Proposed indication	
Purpose of the proposed clinical trial	
Fee category	☐ Consultations on strategies for drugs ☐ Consultations on strategies for drugs (universities, research institutions, and venture companies meeting the separately specified requirements)
Outline of consultation	
Type of consultation	☐ First-in-human study ☐ Global clinical trial ☐ Consultation on use of real world data
Names and affiliations of experts consulted at the time of preparation of protocol	
Prior pre-consultations and face-to-face advice on the same drug (including clinical trial consultations, etc.)	
	☐ With regard to this application, the applicant has agreed with PMDA on proceeding to the RS strategy consultation face-to-face advice in the pre-consultation of RS strategy consultation.
Approval status in major developed countries	
Name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)	
Name and address to which consultation records, etc. should be sent	- -
For the consultation on a project adopted by Japan Agency for Medical Research and Development (AMED), <u>if the applicant agrees</u> to the sharing of the record of face-to-face advice (minutes) and related information between AMED and PMDA under appropriate information management in order to manage the progress of the research project at AMED based on the conditions given by AMED for the adoption of the project by AMED, please enter the project control number of AMED.	
Desired consultation dates/scheduled consultation date, receipt number	
Desired implementation method/planned implementation method	
Remarks	

We apply for face-to-face advice as described above.
Month DD, YYYY

Address (for a corporation, location of main office)
Name (for a corporation, name and title and name of the representative)
(vendor code)

To Director of Center for Product Evaluation,
Pharmaceuticals and Medical Devices Agency

(Note)

1 The paper size should be Japan Industrial Standard A4, and the form should be submitted in a text-recognizable electronic file.

2 When all of the required information cannot be entered in the specified column, enter "as per appendix ( )" in the column and attach the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for review category

Please select and enter the applicable category from Appendix 2, "Review Categories of New Drugs, Medical Devices, and Regenerative Medical Products, etc.," of "Implementation Guidelines for Regulatory Science Strategy Consultations."

(2) Column for name of test drug, investigational ingredient code, etc.

Please enter the name of the test drug, the investigational ingredient code (investigational ingredient code to be presented in the clinical trial protocol), etc.

(3) Column for proposed non-proprietary name, etc. (name of pharmaceutical ingredient)

For the ingredient name, if there is a non-proprietary name (JAN or INN), enter it (English name and Japanese name), and if there is no non-proprietary name, enter the chemical name (English name).

(4) Column for route of administration/dosage form

Please enter the route of administration (rectal administration, intravenous infusion, etc.) and dosage form (suppository, injection, etc.).

(5) Column for information on quality and stability, etc.

In the case of consultation on quality and stability, etc., please enter the information available at the time of the consultation, such as information on quality (provisional specifications, excipients, etc.), information on stability (stability tests of drug substance and drug product), and information on manufacturing (whether it takes place at the company/its own research laboratory or is outsourced, etc.).

(6) Column for proposed therapeutic category

Please enter the therapeutic category and the therapeutic category code number (3 digits) in parentheses at the end.

(7) Column for proposed indication

Please enter the indications expected from the pharmacology referring to similar drugs.

(8) Column for purpose of the proposed clinical trial

Please enter the purpose of the proposed clinical trial and the phase of development.

(9) Column for fee category

Please tick the applicable consultation category.

(10) Column for outline of consultation

Please enter the specific details of consultation. If the content does not fit in the column, please enter "See Appendix ( ) for details" and attach the appendix. In the column, enter a brief outline that summarizes key points in approximately 1 to 5 lines (bullet points for consultation items, etc., only text, no tables or figures).

(11) Column for type of consultation

Please tick the applicable item if the contents of consultation correspond to the following in the case of consultation on clinical trial protocols.

- "First-in-human study"
- "Global clinical trial"

Please also tick "consultation on use of real world data" if consulting on use of real world data such as registries or databases.

(12) Column for names and affiliations of experts consulted at the time of preparation of protocol

In the case of consultations on clinical trial protocols, if any external experts provided guidance or advice for the preparation of clinical trial protocols, please enter their names and affiliations. Please place a circle before the names of external experts planning to participate in the face-to-face advice.

(13) Column for prior pre-consultations and face-to-face advice on the same drug (including clinical trial consultations, etc.)

If any face-to-face advice (including clinical trial consultation) has been conducted in the past for the same drug, please enter its receipt number, classification of face-to-face advice (including clinical trial consultation), and date of advice. If any pre-consultation has been conducted in the past for the same drug, please enter the date of implementation. Please fill out the column in the same way if a consultation has been provided on the drug with the same active ingredient and a different route of administration, indication, formulation, etc. from the present application, and report to that effect in parenthesis after the date.

When submitting a request form for scheduling and an application form, it is necessary that, regarding the present application, the applicant and PMDA have agreed on proceeding to the RS strategy consultation face-to-face advice in the pre-consultation of RS strategy consultation. Please tick the box if there was an agreement.

(14) Column for approval status in major developed countries

If the indication of the drug for the present consultation has been approved in the US, the UK, Germany, France, or the EU, please enter each country, etc. where the approval was granted and the year of approval in parentheses after the country, etc. as in, for example, "US (approved in 1999)." If the indication has not been approved, but clinical trials are being conducted or the application is pending, please enter the same information, followed by the start year of clinical trials or the year of application as in, for example, "UK (clinical trials started in 2000)" or "EU (applied in 2001)."

If the drug has not been developed for the indication concerned in any of the US, the UK, Germany, France, or the EU and the drug has been approved for another indication in these countries, etc., please report to that effect as in "Germany (approved for another indication in 2002)." If the drug has been approved for the indication under consultation in countries other than the above, enter the main developed countries and the approval years as in "Canada (approved in 2003)."

(15) Column for name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)

Please enter the name, affiliation, and contact information (phone number, fax number, and e-mail address) for one person in charge as the contact person for this consultation (multiple persons are allowed in the case of joint development).

Inquiries, announcements, etc. from PMDA will be sent to the person in charge specified in this column. Please make sure that there is no error in writing or omission in writing.

In the case of a physician initiating a clinical trial, please enter the name of the medical institution and the department as affiliation.

(16) Column for desired consultation dates/scheduled consultation date, receipt number

When requesting scheduling, please enter as many desired dates of face-to-face advice (morning or afternoon) as possible. If there are dates that are not desired (morning or afternoon) or other requests regarding scheduling, please include them.

If this application is made based on the result of scheduling, please enter the result of scheduling and the receipt number issued when the request form for scheduling is received as in, for example, "as a result of scheduling, face-to-face advice is scheduled in the morning (afternoon) on Month DD, YYYY (Strategy P○○)."

(17) Column for desired implementation method/planned implementation method

When requesting scheduling, please enter the desired implementation method. When making this application based on the result of scheduling, please enter the planned implementation method.

(18) Remarks column

[1] If the application is not made jointly in the case of joint development, please enter the name of the partner company, etc. of the joint development to clarify that it is a joint development.

[2] In the case of drugs that fall in the category of, or are expected to fall in the category of biological products (including specified biological products), please enter "biological product" or "possible biological product," respectively.

[3] If an application for designation of an orphan drug is being considered for this indication, please enter "Application for designation of an orphan drug being considered."

[4] In the case of investigator-initiated clinical trials, please enter "investigator-initiated clinical trial." If the investigational product provider has been designated, please enter the name of the investigational product provider.

(19) Other

Please enter the address (for a corporation, location of the main office) and the name (for a corporation, its name and the title and name of the representative). In the case of researchers at universities, research institutions, etc., please enter the name of the university, research institution, etc., the department, the title and name of the applicant.

In the case of marketing authorization holders, etc., please enter the vendor code (9 digits) in parentheses under the name. Please enter "999999999" for the vendor code if there is no vendor code and "999999888" for sponsor-investigators.

4 For the structure, etc. of consultation materials, please use the pre-consultation before submitting the consultation application form to prepare necessary and sufficient materials.

(Attachment 2)
Form No. 29 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Application Form for Face-to-face Advice in Consultations on Strategies for Medical Devices

Subject of consultation	☐ Medical devices ☐ In vitro diagnostics
Review category	
Category	
Name and identification code of test item	
Proposed generic name	
Proposed classification	
Proposed performance, intended use, and indications	
Purpose of the proposed clinical trial, etc.	
Fee category	☐ Consultations on strategies for medical devices ☐ Consultations on strategies for medical devices (universities, research institutions, and venture companies meeting the separately specified requirements)
Outline of consultation	☐ Consultation on global studies ☐ Use of overseas data ☐ Consultation on use of real world data
Names and affiliations of experts consulted at the time of preparation of protocols of clinical trials, etc.	
Prior pre-consultations and face-to-face advice on the same test item	☐ With regard to this application, the applicant has agreed with PMDA on proceeding to the RS strategy consultation face-to-face advice in the pre-consultation of RS strategy consultation.
Approval (certification) status in major developed countries	
Name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)	
Name and address to which consultation records, etc. should be sent	- -
For the consultation on a project adopted by Japan Agency for Medical Research and Development (AMED), <u>if the applicant agrees</u> to the sharing of the record of face-to-face advice (minutes) and related information between AMED and PMDA under appropriate information management in order to manage the progress of the research project at AMED based on the conditions given by AMED for the adoption of the project by AMED, please enter the project control number of AMED.	
Desired consultation dates/scheduled consultation date, receipt number	
Desired implementation method/planned implementation method	
Remarks	

We apply for face-to-face advice as described above.
Month DD, YYYY

Address (for a corporation, location of main office)
Name (for a corporation, name and title and name of the representative)
(vendor code)

To Director of Center for Product Evaluation,
Pharmaceuticals and Medical Devices Agency

(Note)

1 The paper size should be Japan Industrial Standard A4, and the form should be submitted in a text-recognizable electronic file.

2 When all of the required information cannot be entered in the specified column, enter "as per appendix ( )" in the column and attach the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for subject of consultation

Please tick the applicable subject.

(2) Column for review category

Please select and enter the applicable category from Appendix 2, "Review categories of new drugs, medical devices, and regenerative medical products, etc.," of "Implementation Guidelines for Regulatory Science Strategy Consultations."

(3) Column for category

Please enter the category according to Attached Table 1 of Cabinet Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961). No entry is necessary for in vitro diagnostics.

(4) Column for name and identification code of test item

Please enter the chemical name or identification code of the test item (code to identify the machine/equipment, etc., name, etc.).

(5) Column for proposed generic name and column for proposed classification

Please fill out these columns in accordance with the attachment of PFSB Notification No. 0311005 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated March 11, 2005, "Enforcement of 'Partial Revision of Specially Controlled Medical Devices, Controlled Medical Devices, and General Medical Devices Designated by the Minister of Health, Labour and Welfare Pursuant to the Provisions of Article 2, Paragraphs 5 to 7 of the Pharmaceutical Affairs Act' (Ministerial Announcement) and 'Partial Revision of Specially Designated Maintenance-and-Management-Required Medical Devices Designated by the Minister of Health, Labour and Welfare Pursuant to the Provisions of Article 2, Paragraph 8 of the Pharmaceutical Affairs Act' (Ministerial Announcement)." No entry is necessary for in vitro diagnostics.

(6) Column for proposed performance, intended use, and indications

Please enter the proposed performance, intended use, and indications.

(7) Column for purpose of the proposed clinical trial, etc.

Please enter the purpose of the proposed clinical trial, etc.

If the consultation will be on clinical performance studies, correlation studies, etc. for in vitro diagnostics, please clarify the purpose of these studies in this column (whether the purpose is to show the rationale for the new clinical significance or to show the correlation, etc.).

(8) Column for fee category

Please tick the applicable consultation category.

(9) Column for outline of consultation

Please enter the specific details of consultation. If the content does not fit in the column, please enter "See Appendix ( ) for details" and attach the appendix. In the column, enter a brief outline that summarizes key points in approximately 1 to 5 lines (bullet points for consultation items, etc., only text, no tables or figures).

Please tick the applicable item if the contents of consultation correspond to the following.

[1] A global study is planned and its study plan, etc. will be discussed in a consultation on clinical trial protocol.

[2] Application using overseas data is being considered.

[3] Use of real world data such as registries or databases will be discussed.

(10) Column for names and affiliations of experts consulted at the time of preparation of protocol

In cases of consultations on clinical trial protocols, if any external experts provided guidance or advice for the preparation of protocols of clinical trials, etc., please enter their names and affiliations. Please place a circle before the names of external experts planning to participate in the face-to-face advice.

(11) Column for prior pre-consultations and face-to-face advice on the same test item

If any face-to-face advice has been conducted in the past for the same test item, please enter its receipt number, classification of face-to-face advice, and date of advice. If any pre-consultation has been conducted in the past for the same test item, please enter the date of implementation. Please fill out the column in the same way if face-to-face advice has been provided on the same test item with a different intended use, indication, etc. from the present application, and report to that effect in parenthesis after the date.

When submitting a request form for scheduling and an application form, it is necessary that, regarding the present application, the applicant and PMDA have agreed on proceeding to the RS strategy consultation face-to-face advice in the pre-consultation of RS strategy consultation. Please tick the box if there was an agreement.

(12) Column for approval (certification) status in major developed countries

If the performance, intended use, and indications for the present consultation have been approved in major developed countries, etc. such as the US and the EU, please enter each country (region) where the approval or certification was granted and the year of approval or certification in parentheses after that. In the case of certification, please enter the name of the certification body (e.g. "US (approved in 2004), EU (certified in 2004, name of the certification body)").

If approval has not been granted, but clinical trials are being conducted or the application is pending, please enter the country (region) in the same way, followed by the start year of clinical trials or the year of application as in, for example, "EU (clinical trials started in 2003)" or "US (applied in 2004)."

If approval has been granted for another indication, etc., please specify to that effect as in "US (approved for another indication in 2004)."

(13) Column for name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)

Please enter the name, affiliation, and contact information (phone number, fax number, and e-mail address) for one person in charge as the contact person for this consultation (multiple persons are allowed in the case of joint development).

Inquiries, announcements, etc. from PMDA will be sent to the person in charge specified in this column. Please make sure that there is no error in writing or omission in writing.

In the case of a physician initiating a clinical trial, please enter the name of the medical institution and the department as affiliation.

(14) Column for desired consultation dates/scheduled consultation date, receipt number

When requesting scheduling, please enter as many desired dates of face-to-face advice (morning or afternoon) as possible. If there are dates that are not desired (morning or afternoon) or other requests regarding scheduling, please include them.

If this application is made based on the result of scheduling, please enter the result of scheduling and the receipt number issued when the request form for scheduling is received as in, for example, "as a result of scheduling, face-to-face advice is scheduled in the morning (afternoon) on Month DD, YYYY (Device Strategy P○○)."

(15) Column for desired implementation method/planned implementation method

When requesting scheduling, please enter the desired implementation method. When making this application based on the result of scheduling, please enter the planned implementation method.

(16) Remarks column

[1] In the case of items that fall in the category of, or are expected to fall in the category of biological products (including specified biological products), please enter "biological product" or "possible biological product," respectively.

[2] If an application for designation of an orphan medical device is being considered for this usage, please enter "Application for designation of an orphan medical device being considered."

[3] In the case of investigator-initiated clinical trials, please enter "investigator-initiated clinical trial." If the investigational device provider has been designated, please enter the name of the investigational device provider.

(17) Other

Please enter the address (for a corporation, location of the main office) and the name (for a corporation, its name and the title and name of the representative). In the case of researchers at universities, research institutions, etc., please enter the name of the university, research institution, etc., the department, the title and name of the applicant.

In the case of medical device marketing authorization holders, etc., enter the vendor code (9 digits) in parentheses under the name. Please enter "999999999" for the vendor code if there is no vendor code and "999999888" for sponsor-investigators.

4 For the structure, etc. of consultation materials, please use the pre-consultation before submitting the consultation application form to prepare necessary and sufficient materials.

(Attachment 3)
Form No. 30 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Application Form for Face-to-face Advice in Consultations on Strategies for Regenerative Medical Products, etc.

Review category	
Name or identification code of test product	
Proposed category	
Name of component cells and transgene	
Summary of administration or directions for use	
Proposed indication or performance	
Purpose of the proposed clinical trial	
Fee category	☐ Consultations on strategies for regenerative medical products, etc. ☐ Consultations on strategies for regenerative medical products, etc. (universities, research institutions, and venture companies meeting the separately specified requirements)
Outline of consultation	
Type of consultation	☐ First-in-human study ☐ Global clinical trial ☐ Consultation on use of real world data
Names and affiliations of experts consulted at the time of preparation of protocol	
Prior pre-consultations and face-to-face advice on the same test product (including clinical trial consultations, etc.)	
	☐ With regard to this application, the applicant has agreed with PMDA on proceeding to the face-to-face advice of RS strategy consultation in the pre-consultation RS strategy consultation.
Presence or absence of clinical use results as specified cell processing product, etc.	
Overseas approval status	
Name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)	
Name and address to which consultation records, etc. should be sent	- -
For the consultation on a project adopted by Japan Agency for Medical Research and Development (AMED), <u>if the applicant agrees</u> to the sharing of the record of face-to-face advice (minutes) and related information between AMED and PMDA under appropriate information management in order to manage the progress of the research project at AMED based on the conditions given by AMED for the adoption of the project by AMED, please enter the project control number of AMED.	
Desired consultation dates/scheduled consultation date, receipt number	
Desired implementation method/planned implementation method	
Remarks	

We apply for face-to-face advice as described above.
Month DD, YYYY

Address (for a corporation, location of main office)
Name (for a corporation, name and title and name of the representative)
(vendor code)

To Director of Center for Product Evaluation,
Pharmaceuticals and Medical Devices Agency

(Note)

1 The paper size should be Japan Industrial Standard A4, and the form should be submitted in a text-recognizable electronic file.

2 When all of the required information cannot be entered in the specified column, enter "as per appendix ( )" in the column and attach the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for review category

Please select and enter the applicable category from Appendix 2, "Review Categories of New Drugs, Medical Devices, and Regenerative Medical Products, etc.," of "Implementation Guidelines for Regulatory Science Strategy Consultations."

(2) Column for name or identification code of test product

Please enter the name or identification code of the test product.

(3) Column for proposed category

Please enter the category referring to Attached Table 2 of Cabinet Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961).

(4) Column for name of component cells and transgene

Please enter the name that shows the overview of component cells and transgene contained in the item (for example, human [autologous] ○○-derived cell sheet, human ○○ gene ○○ viral vector, etc.).

(5) Column for summary of administration or directions for use

Enter the summary of the method of administration (route of administration, etc. such as subcutaneous injection and intravenous administration) or directions for use (transplantation site, transplantation method, etc.).

(6) Column for proposed indication or performance

Please enter the proposed indication or performance.

(7) Column for purpose of the proposed clinical trial

Please enter the purpose of the proposed clinical trial and the phase of development.

(8) Column for fee category

Please tick the applicable consultation category.

(9) Column for outline of consultation

Please enter the specific details of consultation. If the content does not fit in the column, please enter "See Appendix ( ) for details" and attach the appendix. In the column, enter a brief outline that summarizes key points in approximately 1 to 5 lines (bullet points for consultation items, etc., only text, no tables or figures).

(10) Column for type of consultation

Please tick the applicable item if the contents of consultation correspond to the following in the case of consultation on clinical trial protocols.

- First-in-human study
- Global clinical trial

Please also tick "consultation on use of real world data" if consulting on use of real world data such as registries or databases.

(11) Column for names and affiliations of experts consulted at the time of preparation of protocol

In the case of consultations on clinical trial protocols, if any external experts provided guidance or advice for the preparation of clinical trial protocols, please enter their names and affiliations. Please place a circle before the names of external experts planning to participate in the face-to-face advice.

(12) Column for prior pre-consultations and face-to-face advice on the same test product (including clinical trial consultations, etc.)

If any face-to-face advice (including clinical trial consultation) has been conducted in the past for the same test product, please enter its receipt number, classification of face-to-face advice (including clinical trial consultation), and date of advice. If any pre-consultation has been conducted in the past for the same test product, enter the date of implementation. Please fill out the column in the same way if a consultation has been provided on the test product with the same active ingredient and a different administration or directions for use, indication or performance, etc. from the present application, and report to that effect in parenthesis after the date.

When submitting a request form for scheduling and an application form, it is necessary that, regarding the present application, the applicant and PMDA have agreed on proceeding to the RS strategy consultation face-to-face advice in the pre-consultation of RS strategy consultation. Please tick the box if there was an agreement.

(13) Column for presence or absence of clinical use results as specified cell processing product, etc.

If the test product is a cell processing product, and any equivalent cell processing product has been used in clinical practice as a specified cell processing product, etc. defined in the "Act on the Safety of Regenerative Medicine," please report to that effect. If the test product is a vector intended for gene therapy and there is any precedent of use in clinical research, please report to that effect.

(14) Column for overseas approval status

If the test product for this consultation has been approved, please enter the country name, year of approval, and approved indication as in "○○ country (approved in 2003, severe burn)."

(15) Column for name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)

Please enter the name, affiliation, and contact information (phone number, fax number, and e-mail address) for one person in charge as the contact person for this consultation (multiple persons are allowed in the case of joint development).

Inquiries, announcements, etc. from PMDA will be sent to the person in charge specified in this column. Please make sure that there is no error in writing or omission in writing.

In the case of a physician initiating a clinical trial, please enter the name of the medical institution and the department as affiliation.

(16) Column for desired consultation dates/scheduled consultation date, receipt number

When requesting scheduling, please enter as many desired dates of face-to-face advice (morning or afternoon) as possible. If there are dates that are not desired (morning or afternoon) or other requests regarding scheduling, please include them.

If this application is made based on the result of scheduling, please enter the result of scheduling and the receipt number issued when the request form for scheduling is received as in, for example, "as a result of scheduling, face-to-face advice is scheduled in the morning (afternoon) on Month DD, YYYY (Regenerative Strategy P○○)."

(17) Column for desired implementation method/planned implementation method

When requesting scheduling, please enter the desired implementation method. When making this application based on the result of scheduling, please enter the planned implementation method.

(18) Remarks column

[1] If the application is not made jointly in the case of joint development, please enter the name of the partner company, etc. of the joint development to clarify that it is a joint development.

[2] In the case of investigator-initiated clinical trials, please enter "investigator-initiated clinical trial." If the test product provider has been designated, please enter the name of the test product provider.

[3] In the case of test products planned to be combination products, please indicate to that effect.

(19) Other

Please enter the address (for a corporation, location of the main office) and the name (for a corporation, its name and the title and name of the representative). In the case of researchers at universities, research institutions, etc., please enter the name of the university, research institution, etc., the department, the title and name of the applicant.

In the case of regenerative medical product, etc. marketing authorization holders, etc., enter the vendor code (9 digits) in parentheses under the name. Please enter "999999999" for the vendor code if there is no vendor code and "999999888" for sponsor-investigators.

4 For the structure, etc. of consultation materials, please use the pre-consultation before submitting the consultation application form to prepare necessary and sufficient materials.

(Attachment 4)

Form No. 31 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Application Form for Face-to-face Advice in Consultations on Quality and Safety of Regenerative Medical Products, etc.

Subject of consultation	☐ Regenerative medical products, etc. ☐ Other
Review category	
Name or identification code of test product	
Proposed category	
Name of component cells and transgene	
Summary of administration or directions for use	
Proposed indication or performance	
Fee category	☐ Consultations on quality and safety of regenerative medical products, etc. ☐ Consultations on quality and safety of regenerative medical products, etc. (universities, research institutions, and venture companies meeting the separately specified requirements) ☐ Additional consultations on quality and safety of regenerative medical products, etc.
Outline of consultation	
Names and affiliations of experts consulted at the time of preparation of consultation materials	
Prior pre-consultations and face-to-face advice on the same test product (including clinical trial consultations, etc.)	
	☐ With regard to this application, the applicant has agreed with PMDA on proceeding to RS strategy consultation face-to-face advice in RS strategy consultation pre-consultation.
Presence or absence of clinical use results as specified cell processing product, etc.	
Overseas approval status	
Name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)	
Name and address to which consultation records, etc. should be sent	- -
For the consultation on a project adopted by Japan Agency for Medical Research and Development (AMED), <u>if the applicant agrees</u> to the sharing of the record of face-to-face advice (minutes) and related information between AMED and PMDA under appropriate information management in order to manage the progress of the research project at AMED based on the conditions given by AMED for the adoption of the project by AMED, please enter the project control number of AMED.	
Desired consultation dates/scheduled consultation date, receipt number	
Desired implementation method/planned implementation method	
Remarks	

We apply for face-to-face advice as described above.

Month DD, YYYY

Address (for a corporation, location of main office)

Name (for a corporation, name and title and name of the representative)

(vendor code)

To Director of Center for Product Evaluation,
Pharmaceuticals and Medical Devices Agency

(Note)

1 The paper size should be Japan Industrial Standard A4, and the form should be submitted in a text-recognizable electronic file.

2 When all of the required information cannot be entered in the specified column, enter "as per appendix ( )" in the column and attach the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for subject of consultation

Please tick the applicable subject. Please tick "other" for the products intended for the expression of transgene in the human body for preventive purposes (excluding those falling under the category of regenerative medical products, etc.; e.g., recombinant live vaccines).

(2) Column for review category

Please select and enter the applicable category from Appendix 2, "Review Categories of New Drugs, Medical Devices, and Regenerative Medical Products, etc.," of "Implementation Guidelines for Regulatory Science Strategy Consultations."

(3) Column for name or identification code of test product

Please enter the name or identification code of the test product.

(4) Column for proposed category

Please enter the category referring to Attached Table 2 of Cabinet Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961). For recombinant live vaccine, please leave this column blank.

(5) Column for name of component cells and transgene

Please enter the name that shows the overview of component cells and transgene contained in the item (for example, human [autologous] ○○-derived cell sheet, human ○○ gene ○○ viral vector, etc.).

(6) Column for summary of administration or directions for use

Enter the summary of the method of administration (route of administration, etc. such as subcutaneous injection and intravenous administration) or directions for use (transplantation site, transplantation method, etc.).

(7) Column for proposed indication or performance

Please enter the proposed indication or performance.

(8) Column for fee category

Please tick the applicable consultation category.

(9) Column for outline of consultation

Please enter the specific details of consultation. If the content does not fit in the column, please enter "See Appendix ( ) for details" and attach the appendix. In the column, enter a brief outline that summarizes key points in approximately 1 to 5 lines (bullet points for consultation items, etc., only text, no tables or figures).

(10) Column for names and affiliations of experts consulted at the time of preparation of consultation materials

If any external experts provided guidance or advice for the preparation of consultation materials, please enter their names and affiliations. Please place a circle before the names of external experts planning to participate in the face-to-face advice.

(11) Column for prior pre-consultations and face-to-face advice on the same test product (including clinical trial consultations, etc.)

If any face-to-face advice (including clinical trial consultation) has been conducted in the past for the same test product, please enter its receipt number, classification of face-to-face advice (including clinical trial consultation), and date of advice. If any pre-consultation has been conducted in the past for the same test product, enter the date of implementation. Please fill out the column in the same way if a consultation has been provided on the test product with the same active ingredient and a different administration or directions for use, indication or performance, etc. from the present application, and report to that effect in parenthesis after the date.

When submitting a request form for scheduling and an application form, it is necessary that, regarding the present application, the applicant and PMDA have agreed on proceeding to the RS strategy consultation face-to-face advice in the pre-consultation of RS strategy consultation. Please tick the box if there was an agreement.

(12) Column for presence or absence of clinical use results as specified cell processing product, etc.

If the test product is a cell processing product, and any equivalent cell processing product has been used in clinical practice as a specified cell processing product, etc. defined in the "Act on the Safety of Regenerative Medicine," please report to that effect. If the test product is a vector intended for gene therapy and there is any precedent of use in clinical research, please report to that effect.

(13) Column for overseas approval status

If the test product for this consultation has been approved, please enter the country name, year of approval, and approved indication as in "○○ country (approved in 2003, severe burn)."

(14) Column for name, affiliation, and contact information of the person in charge of this application (phone number, fax number, e-mail address)

Please enter the name, affiliation, and contact information (phone number, fax number, and e-mail address) for one person in charge as the contact person for this consultation (multiple persons are allowed in the case of joint development).

Inquiries, announcements, etc. from PMDA will be sent to the person in charge specified in this column. Please make sure that there is no error in writing or omission in writing.

In the case of a physician initiating a clinical trial, please enter the name of the medical institution and the department as affiliation.

(15) Column for desired consultation dates/scheduled consultation date, receipt number

When requesting scheduling, please enter as many desired dates of face-to-face advice (morning or afternoon) as possible. If there are dates that are not desired (morning or afternoon) or other requests regarding scheduling, please include them.

If this application is made based on the result of scheduling, please enter the result of scheduling and the receipt number issued when the request form for scheduling is received as in, for example, "as a result of scheduling, face-to-face advice is scheduled in the morning (afternoon) on Month DD, YYYY (Regenerative Strategy Confirmation P○○)."

(16) Column for desired implementation method/planned implementation method

When requesting scheduling, please enter the desired implementation method. When making this application based on the result of scheduling, please enter the planned implementation method.

(17) Remarks column

[1] If the application is not made jointly in the case of joint development, please enter the name of the partner company, etc. of the joint development to clarify that it is a joint development.

[2] In the case of investigator-initiated clinical trials, please enter "investigator-initiated clinical trial." If the test product provider has been designated, please enter the name of the test product provider.

[3] In the case of test products planned to be combination products, please indicate to that effect.

[4] In the case of recombinant live vaccines, please indicate to that effect.

(18) Other

Please enter the address (for a corporation, location of the main office) and the name (for a corporation, its name and the title and name of the representative). In the case of researchers at universities, research institutions, etc., please enter the name of the university, research institution, etc., the department, the title and name of the applicant.

In the case of regenerative medical product, etc. or drug marketing authorization holders, etc., enter the vendor code (9 digits) in parentheses under the name. Please enter "999999999" for the vendor code if there is no vendor code and "999999888" for sponsor-investigators.

4 For the structure, etc. of consultation materials, please use the pre-consultation before submitting the consultation application form to prepare necessary and sufficient materials.

(Attachment 5)
Form No. 32 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Application Form for Face-to-face Advice in Consultations on Strategies Including Development Plans

Subject of consultation	☐ Drugs ☐ Medical devices ☐ In vitro diagnostics ☐ Regenerative medical products, etc.
Consultation applicant (For a corporation, its name)	
Name, affiliation, and contact information of the person in charge of consultation (phone number, fax number, e-mail address)	
Other attendees of consultation meeting (names, affiliations)	
Review category	
Name or investigational ingredient code of test item	
Details of consultation (title)	
Details of consultation (details of consultation)	
	☐ Consultation on use of real world data
For the consultation on a project adopted by Japan Agency for Medical Research and Development (AMED), <u>if the applicant agrees</u> to the sharing of the record of face-to-face advice (minutes) and related information between AMED and PMDA under appropriate information management in order to manage the progress of the research project at AMED based on the conditions given by AMED for the adoption of the project by AMED, please enter the project control number of AMED.	
Desired consultation dates/scheduled consultation date, receipt number	
Desired implementation method/planned implementation method	
Remarks	

We apply for face-to-face advice as described above.
Month DD, YYYY

Address (for a corporation, location of main office)
Name (for a corporation, name and title and name of the representative)
(vendor code)

To Director of Center for Product Evaluation,
Pharmaceuticals and Medical Devices Agency

(Note)

1 Using Japan Industrial Standard A4 size paper, please submit the form in a text-recognizable electronic file.

2 When all of the required information cannot be entered in the specified column, please enter "as per appendix ( )" in the column and attach the appendix.

3 Instructions for completing the application form are as follows.

(1) Column for subject of consultation

Please tick the applicable subject.

(2) Column for consultation applicant

For a corporation, please enter the name of the corporation.

(3) Column for review category

Please select and enter the applicable category from Appendix 2, "Review Categories of New Drugs, Medical Devices, and Regenerative Medical Products, etc.," of "Implementation Guidelines for Regulatory Science Strategy Consultations."

(4) Column for details of consultation

Please add the title, summarize the background of the application for these questions and the contents of the questions, and enter the summary of the item for consultation.

Please also tick "consultation on use of real world data" if consulting on use of real world data such as registries or databases.

(5) Column for desired consultation dates/scheduled consultation date, receipt number

When requesting scheduling, please enter as many desired dates of face-to-face advice (morning or afternoon) as possible. If there are dates that are not desired (morning or afternoon) or other requests regarding scheduling, please include them.

If this application is made based on the result of scheduling, please enter the result of scheduling and the receipt number issued when the request form for scheduling is received as in, for example, "as a result of scheduling, face-to-face advice is scheduled in the morning (afternoon) on Month DD, YYYY (Plan Strategy P○○)."

(6) Column for desired implementation method/planned implementation method

When requesting scheduling, please enter the desired implementation method. When making this application based on the result of scheduling, please enter the planned implementation method.

(7) Remarks column

Enter any other supplementary information.

(8) Other

Please enter the address (for a corporation, location of the main office) and the name (for a corporation, its name and the title and name of the representative). In the case of researchers at universities, research institutions, etc., please enter the name of the university, research institution, etc., the department, the title and name of the applicant.

In the case of drug marketing authorization holders, etc., enter the vendor code (9 digits) in parentheses under the name. Please enter "999999999" for the vendor code if there is no vendor code and "999999888" for sponsor-investigators.

(Attachment 6)
Form No. 36 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Application Form for Use of the Video Conferencing System at the Kansai Branch in Regulatory Science Strategy Consultations

Month DD, YYYY

Name of applicant		
Contact information	Name of the person responsible for application	
	Department	
	Phone number	( ) -
	Fax number	( ) -
	E-mail address	
Consultation category		☐ Face-to-face advice in consultations on strategies for drugs ☐ Face-to-face advice in consultations on strategies for medical devices ☐ Face-to-face advice in consultations on strategies for regenerative medical products, etc. ☐ Consultations on quality and safety of regenerative medical products, etc. ☐ Additional consultations on quality and safety of regenerative medical products, etc. ☐ Face-to-face advice in consultations on strategies including development plans
Date of submission of application		
Receipt number		
Investigational ingredient code, name or identification code of test item		
Request for use of simultaneous interpretation equipment		☐ Yes (venue for participation of non-Japanese attendants and interpreters: ☐ Tokyo ☐ Osaka) ☐ No
Remarks		

*The video conferencing system at the Kansai Branch cannot be used for pre-consultations. As usual, pre-consultations using the online meeting system can be conducted (free of charge).

(Note)

1 The paper size should be Japan Industrial Standard A4.

2 Fill out the application form for use of the video conferencing system at the Kansai Branch as follows.

(1) Column for name of applicant

For a corporation, please enter the name of the corporation.

(2) Column for contact information

Please enter the same contact information as that in the request form for scheduling of face-to-face advice or the application form for face-to-face advice.

(3) Column for consultation category

Please tick the consultation category for which video conferencing system at the Kansai Branch will be used.

(4) Column for date of application for face-to-face advice

Please enter the date of submission of the request form for scheduling of, or the date of application for face-to-face consultation using the video conferencing system at the Kansai Branch. If the application date is fixed, priority should be given to the application date.

(5) Column for receipt number

Please enter the receipt number of the face-to-face advice using the video conferencing system at the Kansai Branch. If unknown, the column can be left blank.

(6) Request for use of simultaneous interpretation equipment

Please be sure to tick “Yes” when requesting for the use of simultaneous interpretation equipment. The location of the venue where non-Japanese attendants and interpreters will participate is either Tokyo or Osaka. Please tick the applicable one.

(7) Remarks column

Please enter the number of people using the meeting room at the Kansai Branch of PMDA with face-to-face advice using the video conferencing system at the Kansai Branch.

(Attachment 7) Form No. 57 of Administrative Instructions for the Statement of Operating Procedures on Reviews and Related Services, Pharmaceuticals and Medical Devices Agency (Administrative Rules No. 4 in 2004)

Basic Confirmation Items for Implementation of Consultations via Online Meeting

Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) and the consulter of face-to-face advice, etc. (hereinafter referred to as “Consulter”) shall confirm and agree to the following with respect to the operation of face-to-face advice, meetings, etc. to be conducted by online meetings.

1. PMDA and Consulter shall, with respect to the operation of online meetings, perform the following items in good faith based on the purpose thereof.
2. The effective period of this document shall commence at the application for face-to-face advice, meetings, etc. and end on the receipt by Consulter of the record of consultation related to the online meeting concerned (or end of the online meeting if the record of consultation is not prepared). However, Items 9 and 10 shall remain effective even after the above effective period.
3. Online meetings shall be held by PMDA as the organizer (host) of the meetings through the online meeting service designated by PMDA. However, if agreed in advance between PMDA and Consulter, Consulter may conduct online meetings as the host.
4. In the course of the implementation of online meetings, PMDA shall not be liable for any security vulnerability of the online meeting service and unauthorized access due to wiretapping, etc. attributable to the said service operator.
5. Only in the case of implementation by the method described in the text of Item 3, the expenses for the use of the online meeting system shall be borne by PMDA except for the expenses for communication.
6. Consulter shall limit the attendance at online meetings to persons who have been registered in advance to attend it, and confirm the identity of the participants in online meetings on its own responsibility.
7. Consulter shall, on its own responsibility, prepare a communication line and means on the side of Consulter, and prepare microphones, connection terminals, etc. as necessary so that the exchange of voice among the interpreter, participants in the meeting room or at remote locations, and the audio recording device on the side of PMDA can be smoothly carried out in online meetings.
8. PMDA shall record, video record, etc. the online meeting held in accordance with the method described in the text of Item 3 only for the purpose of preparation of the record, etc. and promptly delete the recording after preparation of the record.
9. Consulter shall not record, video record, etc. during the implementation of online meetings (excluding the case where PMDA requests recording, video recording, etc. for the preparation of a record when the meeting is implemented by the method stipulated in the proviso of Item 3). Even in the case where the meeting is held by the method stipulated in the proviso of Item 3 and Consulter records, video records, etc. at the request of PMDA, Consulter shall follow PMDA’s instructions on the handling of such recording, video recording, etc. and shall not provide them to any person other than PMDA and registered persons stipulated in Item 6 or divulge them to outside through internet, etc.
10. From the viewpoint of prevention of unauthorized access due to wiretapping, etc. or sound leakage, etc. at the connection destination, PMDA and Consulter shall take necessary measures to prevent unauthorized access, etc. for devices and lines used by both parties for connection at the meetings. In the event of an incident, both parties shall work together to determine the cause, and if any loss occurs because of the cause of the incident, the two parties shall discuss the scope of responsibility with each other. Neither party shall be responsible for any incident attributable to the online meeting service used for the meetings or the service operator concerned.

Month DD, YYYY

PMDA	Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency
Consulter	Company name Responsible person Type of consultation/meeting

*Please fill out the section for Consulter (no seal is required) and submit it in a pdf file (the original is retained by Consulter) by the time of implementation of the meeting.