

Provisional Translation (as of September 2026)*

PSB/PED Notification No. 0318-1

March 18, 2026

To: Directors of Prefectural Health Departments (Bureaus)

Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Handling of Outsourcing Activities, etc. Related to the Conduct of Clinical Trials to
Partner Medical Institutions

In clinical trials and post-marketing clinical studies of drugs, when a medical institution outsources part of activities related to the conduct of a clinical trial or post-marketing clinical study to another party, pursuant to the Ministerial Ordinance on Good Clinical Practice for Drugs (Ministry of Health and Welfare Ordinance No. 28 of 1997), a contract specified in Article 39-2 of this Ministerial Ordinance shall be concluded with the party to which the activities are outsourced.

In recent years, a new form of clinical trials, such as clinical trials with decentralized elements, in which examinations, tests, and other relevant procedures can be performed without the subjects visiting the medical institutions, has been introduced in consideration of the convenience, etc. of the subjects. Therefore, the handling of outsourcing activities, etc. related to the conduct of the clinical trial to medical institutions other than those conducting the trials is presented below. Please fully inform these points to the relevant business operators, etc. under your administration.

Please note that a copy of this notification will also be released to the relevant organizations listed separately, Pharmaceuticals and Medical Devices Agency, and each Regional Bureau of Health and Welfare.

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

1. Considerations of utilizing partner medical institutions

- (1) When the sponsor or the sponsor-investigator (hereinafter referred to as the “sponsor, etc.”) judges that a part of activities related to the conduct of the clinical trial can be outsourced from the medical institutions to a medical institution other than those conducting the trial (hereinafter referred to as the “partner medical institution”) in consideration of the trial design, characteristics of the drugs used in the clinical trial, route of administration, administration procedures, and the current knowledge, etc. about the safety of the drugs used in the clinical trial, they shall prespecify the scope of activities that can be outsourced and other requirements.
- (2) The medical institution and the investigator should consider whether to utilize the partner medical institution based on the requirements specified by the sponsor, etc.

2. Requirements for partner medical institutions

The requirements to be met by the partner medical institutions shall be as listed below, and other requirements may be added according to the content of the clinical trial:

- To be capable of concluding a contract specified in Article 39-2 of the Ministerial Ordinance on Good Clinical Practice for Drugs (Ministry of Health and Welfare Ordinance No. 28 of 1997) (hereinafter referred to as the “GCP Ordinance”) and executing the outsourced activities;
- To be able to take necessary measures for subjects in case of emergency;
- To have a physician or dentist who is capable of performing the outsourced activities (hereinafter referred to as “partner physician”), and the partner physician being familiar with the information on the drugs used in the clinical trial, if the outsourced activities include administration of the drugs used in the clinical trial; and
- To allocate, in principle, a pharmacist at the partner medical institution as a person in charge of appropriately managing the drugs used in the clinical trial, if the outsourced activities include the management (such as storage, administration, retrieval, and disposal) of the drugs used in the clinical trial.

3. Scope of activities to be outsourced, etc.

- (1) The activities to be outsourced to the partner medical institution shall be described in either the protocol or the document(s) on operational framework of the trial, or documents specified in Article 39-2 of the GCP Ordinance, and the specific examples of the activities are as follows:
 - Conduct of clinical trial-related medical examinations and tests;
 - Storage of the drugs used in the clinical trial;
 - Administration and prescription of the drugs used in the clinical trial as instructed by the investigator or sub-investigator; and
 - Retrieval and disposal of the drugs used in the clinical trial.

- (2) Specific examples of activities to be carried out by the medical institution which concluded a contract specified in Article 39-2 of the GCP Ordinance with a partner medical institution are as follows:
 - Explanation of the content and other relevant matters of the clinical trial to subjects and obtaining their consent (including the activities to be performed at the partner medical institution);
 - Instructions for administration and prescription of the drugs used in the clinical trial;
 - Evaluations of efficacy and safety;
 - Preparation of case report forms (CRFs); and
 - Necessary reporting to the sponsor, etc. or regulatory authorities.
4. Outsourcing of activities and procedures for those activities
 - (1) The sponsor, etc. shall determine the scope of activities that can be outsourced and other requirements, specify them in the protocol or the document(s) on operational framework of the trial and present them to the medical institutions and investigators.
 - (2) Based on the requirements determined by the sponsor, etc., the medical institution and investigator shall examine whether to utilize partner medical institutions, confirm that the medical institution to be contracted fulfill the requirements and can perform the activities to be outsourced, and document them.
 - (3) The medical institution shall utilize partner medical institutions upon prior documented agreement with the sponsor, etc. In outsourcing part of activities related to the conduct of the clinical trial to a partner medical institution, information related to the partner medical institution shall be reported to the sponsor, etc. in a timely manner.
 - (4) The medical institution shall seek the opinions of the institutional review board (IRB) regarding the protocol or the document(s) on operational framework of the trial specifying the scope of activities to be outsourced to the partner medical institution and other requirements, when seeking the IRB's opinion on the appropriateness of conducting the clinical trial.
 - (5) The medical institution (the investigator or medical institution in the case of an investigator-initiated clinical trial) shall conclude a contract with the partner medical institution using a document describing the matters specified in Article 39-2 of the GCP Ordinance. This contract shall include statements that the partner medical institution shall accept monitoring and audits by the sponsor, etc., audits by the medical institution, and review by the IRB (hereinafter referred to as "monitoring, etc.") and that the partner medical institution shall retain necessary records among those specified in Article 41, Paragraph 2 of the GCP Ordinance.

- (6) The investigator shall prepare a list of activities to be assigned as specified in Article 43, Paragraph 1 of the GCP Ordinance including those for partner physicians, and obtain approval from the head of the medical institution.
- (7) The investigator shall establish a procedure for outsourced activities at the partner medical institution. However, this does not apply to cases where the outsourced activities can be performed based on the protocol, document(s) on operational framework of the trial, investigator's brochure, procedure for the management of the drugs used in the clinical trial, etc.
- (8) The investigator shall provide persons who carry out the activities outsourced to the partner medical institution with the procedure and documents necessary for performing the activities (e.g., protocol or document(s) on operational framework of the trial, investigator's brochure, and procedure for the management of the drugs used in the clinical trial). In addition, the investigator shall provide necessary training to those who perform the activities outsourced to the partner medical institution.
- (9) When handling the drugs used in the clinical trial in the partner medical institution, it shall, in principle, have a pharmacist at the partner medical institution appropriately manage the drugs used in the clinical trial in accordance with the procedure for management of the drugs used in the clinical trial prepared by the sponsor, etc.
- (10) The partner medical institution shall provide the medical institution with direct access to the information obtained and records generated in relation to the clinical trial based on the contract, etc. for outsourced activities at the partner medical institution.
- (11) The medical institution shall periodically confirm whether the activities outsourced to the partner medical institution are appropriately performed.

5. Administration, etc. of the drugs used in the clinical trial

- (1) Medical decisions and instructions for administration will be made by the investigator or sub-investigator. To ensure the safety of subjects, a procedure shall be specified so that the drugs used in the clinical trial will be administered at the partner medical institution in cases where both the investigator or sub-investigator and the partner physician determine that such administration is possible. However, it shall be noted that even if the administration of the drugs used in the clinical trial is outsourced to the partner medical institution, the investigator retains responsibility for making decisions on and evaluating safety.

- (2) If the drugs used in the clinical trial are to be sent to or retrieved from the partner medical institution, the medical institution (the investigator or medical institution in the case of an investigator-initiated clinical trial) shall conclude a contract with a party to which transportation activities are outsourced (transportation provider), pursuant to Article 39-2 of the GCP Ordinance. In such a case, the medical institution shall prespecify a procedure to ensure the quality of the drugs used in the clinical trial, confirm that they are sent or retrieved in accordance with the procedure, and document them. If the shipping company prepares standard terms and conditions including the matters stipulated in Article 39-2 of the GCP Ordinance, the medical institution may outsource the activities after verifying the contents of the terms and conditions. In such a case, the medical institution shall retain a copy of the fixed terms and conditions that have been confirmed to include the matters specified in Article 39-2 of the GCP Ordinance.

6. Responsibilities for subjects

- (1) The investigator shall be responsible for all medical decisions related to the clinical trial, even when partner medical institutions are utilized.
- (2) The persons who perform the activities outsourced to the partner medical institution shall report to the investigator when they become aware of any trial-related injury in subjects. If any serious adverse event associated with the drugs used in the clinical trial is noted, the persons shall immediately report it to the investigator.
- (3) The sponsor, etc. shall also take necessary measures for compensation for injuries related to the activities outsourced to the partner medical institution in accordance with Article 14 or Article 15-9 of the GCP Ordinance.
- (4) The partner medical institution, together with the medical institution, shall specify the procedure for compensating injuries and other losses associated with the outsourced activities, and if any injury occurs to a subject, the partner medical institution shall address this in accordance with the procedure.
- (5) The persons who perform the activities outsourced to the partner medical institution shall report to the investigator when they become aware of any deviation from the protocol or noncompliance with other prespecified procedures, etc.
- (6) Apart from the informed consent related to the clinical trial to be obtained from the subjects at the medical institution, obtaining a separate consent from the subjects, at the discretion of the partner medical institution, for conducting some trial-related activities at the partner medical institution is not precluded.

7. Record keeping

- (1) The partner medical institution shall specify a procedure for retaining information obtained or records generated in the course of the outsourced activities. The partner medical institution shall ensure that the information or records are appropriately retained for the period specified in Article 41, Paragraph 2 of the GCP Ordinance based on the contract with the medical institution.
- (2) The medical institution shall be responsible for the retention of the information obtained or the records generated at the partner medical institution and appropriately manage the retention of such information or records.
- (3) The partner medical institution shall accept the monitoring, etc. based on the contract with the medical institution and inspection by the regulatory authorities. Also, the partner medical institution shall provide direct access to all trial-related records (i.e., documents or records (including data) to be retained) upon request of the persons who conduct monitoring, etc. based on the contract with the medical institution and the regulatory authorities.

8. Others

- (1) As for post-marketing clinical studies, activities related to the conduct of post-marketing clinical studies may be outsourced to partner medical institutions after making necessary replacement of terms in this document.
- (2) Information on the partner medical institution shall be provided as the matters to be notified in the Clinical Trial Notification, etc., in the column for “Items for each medical institution” as follows:
 - Information on the partner medical institution shall be presented in the “Name and address of the party to whom a part of activities related to the conduct of the clinical trial is outsourced (e.g., site management organization [SMO]) from the medical institution, and the scope of activities to be outsourced.” The scope of activities to be outsourced shall be mentioned as “activities as a partner medical institution.”
 - The quantities of the drugs used in the clinical trial that are used, retrieved, or destroyed at the partner medical institution shall be collectively described as the quantity information at the medical institution in the “Information on the quantities of the drugs used in the clinical trial, devices equivalent to those used in the clinical trial, and products equivalent to those used in the clinical trial.”

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Note

Federation of Pharmaceutical Manufacturers' Associations of JAPAN

Japan Pharmaceutical Manufacturers Association (JPMA)

Japan-Based Executive Committee of Pharmaceutical Research and Manufacturers of America

Japan-Based Executive Committee of European Federation of Pharmaceutical Industries and Associations

Japan CRO Association

Japan Association of Site Management Organizations

Japan Medical Association

Japan Dental Association

Japanese Society of Hospital Pharmacists

Japan Nursing Association

Japan Municipal Hospital Association

Japan Hospital Association

All Japan Hospital Association

Association of Japanese Healthcare Corporations

Japan Psychiatric Hospitals Association

Association of Japan Medical Colleges

Medical Institution Management Support Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

Research and Development Policy Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

Workers' Compensation Administration Division, Labour Standards Bureau, Ministry of Health, Labour and Welfare

Medical Education Division, Higher Education Bureau, Ministry of Education, Culture, Sports, Science and Technology

Health and Medical Division, Bureau of Personnel and Education, Ministry of Defense

Pharmaceuticals and Medical Devices Agency

Regional Bureaus of Health and Welfare