Provisional Translation (as of August 2026)*

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September 20, 2024

To: Directors of Prefectural Health Departments (Bureaus)

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

Points to Consider for Evaluation of Efficacy and Safety Using Information Collected as Electromagnetic Records via Information and Communications Devices in Clinical Trials and Post-marketing Clinical Studies

Clinical trials and post-marketing clinical studies of drugs, medical devices, and regenerative medical products (referred to as “drugs, etc.” in the Annex) should be conducted in accordance with the Ministerial Ordinance on Good Clinical Practice for Drugs (Ministry of Health and Welfare Ordinance No. 28 of 1997), the Ministerial Ordinance on Good Clinical Practice for Medical Devices (Ministry of Health, Labour and Welfare (MHLW) Ordinance No. 36 of 2005), and the Ministerial Ordinance on Good Clinical Practice for Regenerative Medical Products (MHLW Ordinance No. 89 of 2014) (referred to as “GCP Ordinances” in the Annex).

In consideration of the recent progress of information and communication technology and subsequent decentralization and improved efficiency of clinical trials by utilizing this technology, we provide the points to consider for the evaluation of efficacy and safety using electromagnetic means in the Annex.

Please fully inform these points to the related business operators, medical institutions, etc. under your administration.

Please note that the copy of this notification will also be released to the related organizations listed separately, the 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.

Note

Federation of Pharmaceutical Manufacturers' Associations of JAPAN
Japan Pharmaceutical Manufacturers Association (JPMA)
Japan-Based Executive Committee of Pharmaceutical Research and Manufacturers of America
European Federation of Pharmaceutical Industries and Associations
Japan Medical Association
Japan Dental Association
Japan Pharmaceutical Association
Japanese Society of Hospital Pharmacists
Japanese Nursing Association
Japan CRO Association
Japan Association of Site Management Organizations
The Japan Federation of Medical Devices Associations
Forum for Innovative Regenerative Medicine
American Medical Devices and Diagnostics Manufacturers' Association
European Business Council Medical Equipment and IVD Committee
Association of Registered Certification Bodies under the Pharmaceuticals and Medical Devices Act
Japan Municipal Hospital Association
Japan Hospital Association
All Japan Hospital Association
Association of Japanese Healthcare Corporations
Japan Psychiatric Hospitals Association
Welfare Division, Local Public Service Personnel Department, Local Administration Bureau, Ministry of Internal Affairs and Communications
Medical Education Division, Higher Education Bureau, Ministry of Education, Culture, Sports, Science and Technology
Health & Medical Division, Bureau of Personnel & Education, Ministry of Defense
Hospital Management Department, Business Division, Japan Post Holdings Co., Ltd.
National Federation of Health Insurance Societies
Federation of National Public Service Personnel Mutual Aid Associations
SEMPOS
Japan National Health Insurance Clinics and Hospitals Association
JA Zenkouren
Japanese Red Cross Society
Japan Organization of Occupational Health and Safety
National Hospital Organization
Japan Community Healthcare Organization

(Annex)

Points to Consider for Evaluation of Efficacy and Safety Using Information Collected as Electromagnetic Records via Information and Communications Devices in Clinical Trials and Post-marketing Clinical Studies

*In this document, “sponsor” shall be read as “sponsor-investigator” for investigator-initiated clinical trials, and “clinical trial” shall be read as “post-marketing clinical study” for post-marketing clinical studies.

1 Positioning of this guidance

In clinical trials, it has become possible to collect data from subjects and evaluate efficacy and safety by using information and communications devices. This guidance summarizes the points to consider when these are performed. This guidance shows the current thinking, and it may need to be reviewed based on technological progress, etc.

In conducting clinical trials, this guidance as well as related notifications, guidelines, etc. should be referred to as appropriate. If there is any question about the handling of individual cases, the Pharmaceuticals and Medical Devices Agency should be consulted as needed.

2 Definitions of terms used in this guidance

Information and communications devices

Devices that are capable of collecting data on subjects as electromagnetic records (i.e., records created by electronic, magnetic, or any other methods that is not perceivable by human senses and that are provided for information processing by a computer) and transmitting such information through a telecommunication line. Such devices are categorized into devices that function exclusively for communication purposes and devices that are equipped with communication functions, and these include video call systems, mobile devices, wearable devices, etc.

Video call system

A system that enables calls while mutually recognizing each other’s status through transmission and reception of audio and video.

Evaluation of efficacy and safety using information collected as electromagnetic records via information and communications devices

To collect data on subjects as electromagnetic records using information and communications devices and evaluate efficacy and safety in the clinical trial based on the collected data. Examples include, but are not limited to, the following.

(i) The investigator, etc. interviews and examines subjects using information and communications devices. In this process, subjects themselves may report symptoms etc.

using information and communications devices.

(ii) Subjects themselves transmit their data to the investigator, etc. using information and communications devices such as wearable devices. Wearable devices, etc. are categorized into those which are used within the approved use and those which have not received regulatory approval and are used under appropriate quality assurance and precision control.

Compliance inspection

Document-based inspection and GCP on-site inspection, etc. for the application documents for approval of drugs, etc.

3 Basic principles

(1) For evaluation of efficacy and safety using information collected as electromagnetic records via information and communications devices, its appropriateness should be assessed before the start of the clinical trial. In assessing the appropriateness of performing such evaluation, the risks in clinical evaluation, the risks related to handling of personal information, etc. (hereinafter collectively referred to as "risks associated with evaluation using information and communications devices"), in addition to the subjects to be enrolled and the trial design, should be taken into consideration, and, where necessary, experts in relevant fields and regulatory authorities should be consulted. When it is determined appropriate, the evaluation of efficacy and safety using information collected as electromagnetic records via information and communications devices may be performed, provided that it is specified in the protocol.

Examples of the risks associated with evaluation using information and communications devices include, but are not limited to, the following.

(a) Risks related to clinical evaluation

- Impact of troubles with information and communications devices, network connectivity failures, etc. on measured values (mechanical factors)
- Impact of inappropriate usage and inappropriate measurement timing on measured values (human factors)
- Variability/bias in measured values, differences in the number of reported adverse events, and discrepancies in the timing of data acquisition, etc., arising from differences in the performance of information and communications devices, differences in communication and measurement environments, or differences among subjects in how they operate the devices and in literacy related to information and communications devices
- Act of impersonation in which a person other than the subject, etc. fraudulently makes entries, modifications, etc., as if the person were the subject, etc.
- Inadequate record retention or inadvertent deletion of records due to mechanical or human factors

- Ensuring appropriate quality and accuracy when data are collected using wearable devices, etc. that have not received regulatory approval

(b) Risks related to handling of personal information
- Security of information and communications devices
- Ensuring privacy of subjects when performing the evaluation (e.g., location of subjects)

(2) As described in "Handling of the Clinical Trial Notifications, etc. by Persons Who Intend to Sponsor Clinical Trials for Drugs" (PSEHB/PED Notification No. 0831-10 issued by the Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated August 31, 2020), etc. (hereinafter referred to as "Notification on Clinical Trial Notifications, etc."), if the information and communications devices are considered as "devices equivalent to those used in the clinical trial," the information and communications devices should be used in the trial by following the below points regardless of whether it has been approved or not in Japan or in foreign countries.

(i) When used as devices equivalent to those used in the clinical trial, relevant information should be described in the Clinical Trial Notification in accordance with the Notification on Clinical Trial Notifications, etc.

(ii) When malfunctions occur in information and communications devices that are equivalent to devices used in the clinical trial, they should be reported to the Minister of Health, Labour and Welfare within the specified period of time in accordance with Article 274-2 of the Ministerial Ordinance for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health and Welfare Ordinance No. 1 of 1961).

(3) Even when collecting information via information and communications devices, it is necessary to ensure safety in the same manner as in-person visit-based clinical trials. It should be considered, in particular, for subjects in remote locations from the medical institution where necessary.

(4) When information and communications devices communicate with medical information systems in medical institutions, or when the information and communications devices fall under the category of medical information systems and information systems handling medical information covered by "Guideline for Safety Management of Medical Information Systems, Version 6.0" (MHLW, May 2023) (hereinafter referred to as "Medical Information Systems Guideline") and "Safety Management Guideline for Business Operators Who Provide Information Systems and Services Handling Medical Information, Version 1.1" (Ministry of Internal Affairs and Communications and Ministry of Economy, Trade and Industry, issued in August 2020, revised in July 2023), these guidelines should be complied

with.

4 Points to be considered, etc.

(1) Evaluation of efficacy and safety through video call systems

(a) Appropriateness/Equivalence

(i) The sponsor should be able to explain the appropriateness of performing the evaluation of efficacy and safety via a video call system, including the equivalence of evaluation via a video call system and face-to-face evaluation.

(ii) When planning a clinical trial that incorporates both evaluation via a video call system and face-to-face evaluation, the sponsor should examine the equivalence of these evaluation methods with respect to efficacy evaluation in advance. Regarding the equivalence with respect to safety evaluation, based on the risks associated with evaluation using information and communications devices, the information obtained from evaluation via a video call system may be limited compared to that obtained from face-to-face evaluation, therefore, the sponsor should also examine whether evaluation via a video call system needs to be equivalent to face-to-face evaluation, or whether appropriate evaluation can be performed even if evaluation via a video call system is not equivalent to face-to-face evaluation.

(iii) If the method, criteria, etc. for evaluation via a video call system are changed for inevitable reasons during the clinical trial, the sponsor should be able to provide justification of the change.

(b) Feasibility

(i) The sponsor should, where necessary, confirm that the video call system can be used as specified in the protocol (e.g., by conducting a test in a population similar to the trial population). The sponsor should have discussions with experts, regulatory authorities, etc. as needed.

(ii) The investigator should check in advance if the planned evaluation of efficacy and safety via a video call system is acceptable. If there is any issue for its acceptability, the investigator should discuss the resolution with the sponsor.

(c) Assurance of data reliability

(i) For a clinical trial performing evaluation via a video call system, the investigator, etc. should document whether the evaluation has been performed in person or via a video call system, in addition to the date and time of the evaluation and the person(s) who performed the evaluation.

(ii) While considering the potential risks associated with evaluation using information and communications devices, the sponsor should check in advance the method of identification of subjects in the evaluation of efficacy and safety via a video call system specified by the investigator. In

addition, the investigator, etc. should document that the identity of subjects was confirmed as specified. For the method of identification, see "Points to Consider for Informed Consent Using Electromagnetic Means in Clinical Trials and Post-marketing Clinical Trials" (PSEHB/PED Notification No. 0330-6 and PSEHB/MDED Notification No. 0330-1 issued jointly by the Director of Pharmaceutical Evaluation Division, and the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated March 30, 2023) (hereinafter referred to as "Guidance on Informed Consent Using Electromagnetic Means").

(iii) The investigator, etc. and a clinical research coordinator should, during the clinical trial, check with the subjects, etc. whether the method of use is being complied with and make efforts to have subjects, etc. comply with the clinical trial procedures.

(2) Collection of data and evaluation of efficacy and safety using mobile devices, wearable devices, etc.

(a) Appropriateness

The sponsor should be able to explain the appropriateness of using mobile devices, wearable devices, etc. in consideration of the risks associated with evaluation using information and communications devices.

(b) Feasibility

The sponsor should, where necessary, confirm whether the persons such as subjects, etc. and the investigator, etc., who use mobile devices, wearable devices, etc., can use them as specified in the protocol (e.g., confirm in a population similar to the trial population). The sponsor should have discussions with experts, regulatory authorities, etc. as needed.

(c) Assurance of data reliability

(i) When using mobile devices, wearable devices, etc., the sponsor should specify the method of confirmation that the person using the mobile devices, wearable devices, etc. is the actual user while considering the potential risks associated with evaluation using information and communications devices. The investigator, etc. and a clinical research coordinator should, during the clinical trial, check with the subjects, etc. whether the method of use is being complied with and make efforts to have subjects, etc. comply with the clinical trial procedures.

(ii) Data obtained from mobile devices, wearable devices, etc. should be appropriately retained in compliance with the provisions for record keeping in the GCP Ordinances (Articles 26 and 41 in the case of GCP for Drugs).

(iii) When using commercial mobile devices, wearable devices, etc., data collection may be affected by updates of software, operating systems, or

data processing algorithms by the manufacturer. Upon an update, the sponsor should evaluate the risks associated with the update applicable to the information and communications devices in question and take appropriate measures according to the evaluation performed and its results. Also, in case of any updates found after the fact, the sponsor should evaluate the risks associated with the update and take appropriate measures according to the evaluation performed and its results.

(iv) The sponsor should ensure that accurate data can be obtained by implementing appropriate quality assurance and precision control. In addition, the sponsor should be prepared to make these records available at the time of compliance inspection where necessary.

(d) Handling of data obtained from mobile devices, wearable devices, etc.

(i) Personal information included in the data to be obtained should be properly used and managed in compliance with the “Act on the Protection of Personal Information” (Act No. 57 of 2003).

(ii) The sponsor should, where necessary, pre-specify the method for handling safety information that may be obtained during data collection so that reports can be made appropriately for adverse drug reactions, or malfunctions when mobile devices, wearable devices, etc. are considered as “devices equivalent to those used in the clinical trial”.

(e) Handling of subjects

(i) The investigator, etc. should explain to persons involved in the clinical trial and subjects, etc. the appropriateness of performing the evaluation using information and communications devices, its associated risks, how to use mobile devices, wearable devices, etc., and how to deal with malfunctions.

(ii) The sponsor should pre-specify the operational procedures for evaluation using information and communications devices during the clinical trial and prepare written procedures. In particular, the sponsor should pre-specify the measures to be taken and the handling of data in the event of troubles for troubles with mobile devices, wearable devices, and networks occurred during the clinical trial, and notify the persons involved in the clinical trial including the investigator, etc. and subjects, etc. of them.

(3) Ensuring the safety of subjects

Designing a clinical trial using information and communications devices may reduce the frequency of hospital visits compared to a conventional clinical trial, resulting in a reduced opportunity of confirming the safety of subjects. In addition to reviewing the risks associated with the clinical trial to be conducted and considering the method of ensuring the safety of subjects, the sponsor should pre-specify the procedures for the management of subjects in case of emergencies, reflect them in the protocol, etc., and take appropriate measures. The investigator,

etc. should explain these measures to subjects, etc.

(4) Reliability assurance of information and communications devices

(i) Regardless of whether they are medical devices or not, information and communications devices used for the collection of information on efficacy and safety should, in principle, comply with the Annex to the "Use of Electromagnetic Records and Electronic Signatures in Submission for Application for Marketing Approval or Licensing of Drugs, etc." (PFSB Notification No. 0401022 issued by the Secretary-General of Pharmaceutical and Food Safety Bureau, MHLW, dated April 1, 2005) (hereinafter referred to as the "ER/ES Guideline"), and their computerized system validation should be performed (video call systems whose audio, images, etc., are not retained as electromagnetic records are excluded, for example). When data are directly submitted to or retained by the sponsor or the medical institution in the form of electromagnetic records, the ER/ES Guideline should be complied with, and the reliability of the data should be ensured.

(ii) It should be noted that risk assessment is required not only for information and communications devices used to collect information on efficacy and safety but also for the communications between the information and communications devices and the server that stores data or the terminal that receives information from the server, and for the data acquisition process.

(iii) If collecting data directly via information and communications devices, the sponsor should ensure its reliability by including an audit trail, etc. The audit trail should be available at the time of compliance inspection as needed.

(iv) It is acceptable to use the results of validation and verification of information and communications devices performed by the company developing the information and communications devices or a third party organization, provided that its validity is confirmed by the sponsor or medical institution who prepared the information and communications devices (hereinafter referred to as "the party who prepared the information and communications devices").

(v) If information and communications devices use wireless communication, a wireless module that has obtained a mark of technical standards conformity certification of specified radio equipment (technical conformity mark) should be used in principle according to the "Regulation on the Technical Conditions Compliance Approval for Terminal Equipment" (Ministry of Internal Affairs and Communications Ordinance No.15 of 2004).

(vi) If information and communications devices are imported from overseas, it should be used after confirming relevant laws and regulations.

(5) Security measures

(a) When the evaluation of efficacy and safety via a video call system is performed by the investigator, etc. or a clinical research coordinator, the investigator

should take measures to ensure that the investigator, etc. or the clinical research coordinator are the ones who establish a connection with subjects, etc. in order to prevent participation of third parties. Examples of expected measures are listed below. In addition, the investigator, etc. and the clinical research coordinator should pay attention to the privacy of subjects, etc. by confirming that their voice cannot be heard by other patients.

- Subjects, etc. access the designated domain, and the investigator, etc. or the clinical research coordinator operates the system to grant access.
- Only subjects, etc. are notified of the method that enables their access (e.g., by sending a URL to the registered email address of the subject and the subject, etc. accessing via the URL).

(b) For the information and communications devices, if there are any end user license agreement or terms of service that enable data sharing with the company developing the information and communications devices and other potential parties, the party who prepared the information and communications equipment, etc. should consider the following measure:

- In principle, secondary utilization of data obtained from the clinical trial should be prohibited in the contract between the party who prepared the information and communications devices and the company developing the information and communications devices. If secondary utilization cannot be prohibited, possible secondary utilization of clinical trial data by the company developing the information and communications devices for the purpose such as improvement of the information and communications devices should be appropriately explained to subjects, etc., and consent for the purpose and the extent of provision in the secondary utilization should be obtained from them. The same measures should be taken if an application is installed and used on the information and communications devices owned by the subjects, etc. themselves.

(c) For security measures for information and communications devices, see the Guidance on Informed Consent Using Electromagnetic Means.

Regarding cybersecurity of medical devices, it is necessary to comply with Article 12, Paragraph 3 stipulated in the “Standards for Medical Devices Specified by the Minister of Health, Labour and Welfare Pursuant to the Provisions of Article 41, Paragraph 3 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices” (MHLW Ministerial Announcement No. 122 of 2005; hereinafter referred to as the “Essential Principles”), which was revised in accordance with the “Partial Revision of the Standards for Medical Devices Specified by the Minister of Health, Labour and Welfare Pursuant to the Provisions of Article 41, Paragraph 3 of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices” (MHLW Ministerial Announcement No. 67 of 2023). It is necessary to refer to the following notifications:

"Application of Article 12, Paragraph 3 of the Essential Principles for Medical Devices" (PSEHB/MDED Notification No. 0331-8 issued by the Director of the Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated March 31, 2023) and "Confirmation of Compliance with Article 12, Paragraph 3 of the Essential Principles for Medical Devices" (PSEHB/MDED Notification No. 0523-1 issued by the Director of the Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated May 23, 2023).

(6) Instructions for operation

(a) The party who prepared the information and communications devices should prepare a written procedure and an education/training environment to explain how to use the information and communications devices that are used to collect efficacy and safety information to persons who use the information and communications devices.

(i) The party who prepared the information and communications devices should be prepared to take appropriate measures by preparing materials for the education and training of persons who use the information and communications devices on how to use them and security risks such as information leakage and unauthorized access.

(ii) The party who prepared the information and communications devices should prepare explanatory materials that clearly describe how to use the information and communications devices for subjects, etc. The investigator, etc. should explain in advance to subjects, etc. how to use the information and communications devices and the risks associated with evaluation using the information and communications devices.

(iii) When the party who prepared the information and communications devices prepares materials for education and training through the company developing the information and communications devices, that party who prepared the information and communications devices should take responsibility for those materials.

(iv) It is acceptable for the company developing the information and communications devices to be involved as needed in the explanation about how to use the information and communications devices to the investigator, etc., a clinical research coordinator, and other relevant clinical trial personnel at the medical institution. However, the company developing the information and communications devices cannot provide the explanation to subjects, etc. specified in the provisions for written information in the GCP Ministerial Ordinance (Article 50 in the case of GCP for Drugs).

(b) The party who prepared the information and communications devices should consider preparing measures, as operating procedures, that take persons who

are not familiar with the information and communications devices into account.

(i) The understanding and familiarity with the operation of the information and communications devices and communication using them are expected to greatly vary among individuals. Therefore, prior explanation of how to operate the devices, education/training, and handling of communication troubles, etc. should be considered so that persons who use the information and communications devices can operate them appropriately.

(ii) It should also be considered that the investigator, etc. or a clinical research coordinator will be present and assist subjects, etc. with the operation of the information and communications devices where necessary. However, attention should be paid so that the investigator, etc. or the clinical research coordinator will not perform operations that should be performed by subjects, etc.

(iii) The party who prepared the information and communications devices should take measures to be able to appropriately handle troubles with the information and communications devices occurring after subjects, etc. have received an explanation about how to use the information and communications devices from the medical institution. In this case, the party who prepared the information and communications devices should, where necessary, consider measures to prevent delays in responding to inquiries from subjects, etc. due to time differences, languages, etc. If the sponsor is the party who prepared the information and communications devices, the sponsor should cooperate with the medical institution to take action.

(iv) When a help desk is set up, it should be set up after specifying how to share the contents of inquiries and responses with the medical institution.

(c) The medical institution should, where necessary, establish a contact person for the sponsor (when the sponsor has prepared the information and communications devices) or the company developing the information and communications devices in introducing and using the information and communications devices.