

Provisional Translation (as of March 16, 2009) *

Administrative Notice
June 23, 2006

To: Pharmaceutical Affairs Divisions,
Health Departments (Bureaus),
Prefectural Governments

From: Office of Medical Device Evaluation,
Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Re: Q&A for the Handling of Clinical Trial Results on Medical Devices Obtained in
Foreign Countries

The handling of clinical trial results on medical devices obtained in foreign countries is specified in PFSB/ELD/OMDE (*Yakushokuki*) Notification No.0331006 by the Director of Office of Medical Devices Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated March 31, 2006. The attached Q&A has been prepared for the same notification. You are requested to notify relevant business parties and organizations under your jurisdiction of the information below.

Please note that copies of this administrative notice will be sent to the Chief Executive of the Pharmaceuticals and Medical Devices Agency; the Chairperson of the Japan Federation of Medical Devices Associations; the Chairperson of the Medical Devices and Diagnostics Subcommittee, the American Chamber of Commerce in Japan; the Chairperson of the Medical Equipment Committee, the European Business Council in Japan; and the Chairperson of the Association of Registered Certification Bodies Under the Pharmaceutical Affairs Law.

* 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 Japanese text shall prevail.

(Attachment)

(General)

- Q1. The notification states that approval application documents for clinical trials that are applied to the transitional measures stipulated in Articles 2 and 3 of the Supplementary Provisions of GCP for Medical Devices are those collected or prepared on and before April 1, 2005. What are the specific conditions for handling such clinical trials?
- A1. Such clinical trials are handled according to the Notification by the Director-General of the Pharmaceutical and Food Safety Bureau, regarding GCP for Medical Devices (PFSB (*Yakushoku*) Notification No.0720003, dated July 20, 2005). (II. Application Timing of Ministerial Ordinance for GCP, 1. Collection and Preparation Standards for Approval Application Documents)

(Eligible countries and regions)

- Q2. When the standards such as GCP for medical devices, as defined in the laws and ordinances related to pharmaceutical affairs in the country or region where the clinical trial was conducted, differ from Japan's GCP for Medical Devices, or even when no standards such as GCP for medical devices are stipulated in the laws and ordinances, would the clinical trial conducted according to Japan's GCP for Medical Devices be acceptable?
- A2. It is acceptable if you provide technical documents showing that the clinical trial was conducted according to Japan's GCP for Medical Devices and those technical documents are considered appropriate.
- Q3. Is it acceptable that a clinical trial is conducted according to standards that differ from Japan's GCP for Medical Devices if comparison is made on the differences between the standards and Japan's GCP for Medical Devices, and it is verified that the differences do not affect the reliability of the clinical trial?
- A3. It would be acceptable if you attach technical documents showing that the differences do not affect the reliability of the clinical trial, and those technical documents are appropriate.

(Points to consider when using the clinical trial data generated in foreign countries)

- Q4. (2)-⑥ states, "Attach technical documents on the quality of the medical device used for the clinical trial." Can you be more specific on what technical documents are necessary?
- A4. They should be data and technical documents that support the information on quality provided in the investigator's brochure.

(Essential documents for the conduct of a clinical trial)

- Q5. The notification states, "Documents that are equivalent to or more stringent than the essential documents for GCP for Medical Devices should be prepared." Even when documents that are equivalent to the documents as stipulated in the "Essential documents for the GCP for Medical Devices" are not available in the country or region where the clinical study was conducted, would the clinical trial be acceptable if the ethics and reliability can be ensured by providing substitute documents of equivalent or the same contents?

A5. If it is judged that the ethics and reliability can be ensured by providing substitute technical documents etc., and the technical documents are attached in an appropriate manner, it is acceptable.

(Clinical study report)

Q6. Should the “sponsor responsible for the clinical trial” be the person who has signed the clinical trial contract?

A6. He/she should be the responsible person in the organization as a clinical trial sponsor in the country or region where the clinical trial was conducted. Even if he/she is not the person who has signed the contract, it is acceptable if it is evident that the person is the responsible person.

Q7. Should the signature on the clinical study report (CSR) be the original?

A7. Electronic signature would be acceptable, as stipulated in “Use of Electromagnetic Recording and Electronic Signature in Applications, etc., for Approval or License for Drugs” (PFBSB (*Yakushoku*) Notification No.0401022 by the Director-General of Pharmaceutical and Food Safety Bureau, dated April 1, 2005).

(Miscellaneous)

Q8. In 2-(1)-② “Individuals involved in clinical trial,” if the person in charge is unavailable due to retirement or transfer, can another person act in his or her place?

A8. It is acceptable if the other individual has taken over the duties from the predecessor appropriately and is able to provide the necessary cooperation.