PSEHB Notification No. 0831-6
August 31, 2020

To: Prefectural Governors

Director-General of Pharmaceutical Safety
and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Notifications of Clinical Trial Plans, etc. for Equipment/Devices, etc.

Notifications, etc. of the plans, etc. of clinical trials for equipment/devices, etc. have been handled in accordance with PFSB Notification No. 0709004 dated July 9, 2007, “Notifications, etc. of Clinical Trial Plans, etc. for Equipment/Devices, etc." (hereinafter referred to as the “Previous Director-General Notification”). With the enforcement of the Ministerial Ordinance on the Development of Related Ministerial Ordinances in Accordance with Enforcement of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ordinance No. 155 of the Ministry of Health, Labour and Welfare in 2020), the following provisions have been developed for the notifications of the plans, etc. of clinical trials for equipment/devices, etc. to be conducted by persons who intend to sponsor clinical trials and sponsor-investigators. Please inform related businesses under your jurisdiction of this matter and provide instructions to them.

Note

1. Notifications of clinical trial plans

(1) The person who intends to sponsor a clinical trial and the person who intends to be a sponsor-investigator must submit the notification of the clinical trial plan on the following equipment/devices in accordance with the provisions of Article 80-2, Paragraph 2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; hereinafter referred to as the “Act”) and Article 274 of the Regulation 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; hereinafter referred to as the “Regulation”).

A Equipment/Devices, etc. with a structure and principle different from those of medical devices that have already been approved for marketing

B Equipment/Devices, etc. with the same structure and principle as those of medical devices that have already been approved for marketing and a different form of use

C Equipment/Devices, etc. with the same structure and principle as those of medical devices that have already been approved for marketing and different intended use, indications, or an operation or usage method (except for those specified in B)

D Equipment/Devices, etc. with the same structure and principle as those of medical

devices that have been approved for marketing as the medical devices with structure and principle different from those of medical devices that have already been approved for marketing for which the survey period specified in Article 23-2-9, Paragraph 1 of the Act (if the period has been extended in accordance with the provision in the same article, Paragraph 2, the period after the extension) has not passed after the date of approval for marketing (except for those specified in B and C)

E Equipment/Devices, etc. expected to become biological products (except for those specified in A to D)

F Equipment/Devices, etc. manufactured by applying genetic recombination technology (except for those specified in A to E)

(2) Notifications of plans for clinical trials to be conducted by persons who intend to sponsor clinical trials or persons who intend to be sponsor-investigators shall be made by using Attached Form 1, in accordance with the provisions of Article 269 of the Regulation that are applied with modifications in Article 275 of the Regulation and attaching a summary of study results related to the safety, performance, etc. of the test device concerned, other information on the test device concerned, and the reason for judging the request for the clinical trial scientifically valid. However, when foreign manufacturers request clinical trials in Japan, the clinical trial plans shall be notified using Attached Form 2.

(3) When the party that submitted a notification on a clinical trial has changed matters related to the notification or has discontinued or completed the clinical trial related to the notification, the party should submit the notification of the change, discontinuation, or completion using Attached Forms 3, 5, or 7, respectively. When a foreign manufacturer who submitted a clinical trial notification as described in (2) above has changed matters related to the notification or has discontinued or completed the clinical trial related to the notification, the manufacturer should submit the notification of the change, discontinuation, or completion using Attached Forms 4, 6 or 8, respectively.

(4) A person who intends to sponsor a clinical trial or a person who intends to be a sponsor-investigator is allowed to submit the notification for the clinical trial plan after the start of the trial in relation to Article 80-2, Paragraph 2 of the Act and Article 272 of the Regulation that is applied with modifications in Article 275 of the Regulation, if the clinical trial meets all the following criteria. However, for this clinical trial, the notification of the clinical trial plan must be submitted within 30 days after the start of the clinical trial pursuant to Article 80-2, Paragraph 2 of the Act.

A The equipment/devices, etc. concerned need to be urgently used to prevent diseases that may significantly affect the life and health of subjects and other health damages, and there is no appropriate method other than the use of the equipment/devices, etc. concerned.

B Approval, etc. of the equipment/devices, etc. concerned have been granted for their usage in countries with approval system, etc. for medical devices considered to be at the level equivalent to that in Japan, or the Minister of Health, Labour and Welfare has judged that discontinuation of the clinical trial of the equipment/devices, etc. concerned is unnecessary after conducting investigations required to prevent the occurrence of public health hazards.

C A notification of a plan of another clinical trial has already been submitted and the clinical trial is being conducted in Japan for the equipment/devices, etc. concerned.

Even in this case, the person who intends to sponsor the clinical trial or the person who intends to be the sponsor-investigator should contact the Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and

Welfare before conducting the clinical trial.

(5) The equipment/devices, etc. in the description in (4) A above, "equipment/devices, etc. concerned need to be urgently used to prevent diseases that may significantly affect the life and health of subjects and other health damages," shall be the equipment/devices, etc. used in urgent medical care and others considered to be urgently necessary in medical practice.

2. Investigations of clinical trial plans

The former part of Article 80-2, Paragraph 3 of the Act shall apply to the person who intends to sponsor a clinical trial or the person who intends to be a sponsor-investigator for equipment/devices, etc. specified in 1 (1) A to F who makes the notification for the equipment/devices, etc. to be studied in the clinical trial related to this notification for the first time. In this case, the clinical trial is subject to the investigations of clinical trial plans pursuant to the provisions of the latter part of the same paragraph.

A violation of this provision shall be established when the clinical trial contract is concluded less than 30 days after the date of notification.

3. Application timing

This notification shall apply from September 1, 2020. Until August 31, 2022, notifications may be submitted according to the previous regulations.

4. Abolition of notification

With the application of this notification, the previous Director-General Notification shall be abolished as of August 31, 2022.

Attached Form 1

Clinical Trial Notification

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name and classification					
Name and address of the manufacturing site or sales office (investigational device provider)					
Shape, structure, and principle					
Raw materials, etc.					
Manufacturing method					
Proposed intended use and indications					
Proposed operation or usage method					
Outline of clinical trial plan	Objective				
	Planned number of subjects				
	Target disease				
	Operation or usage method				
	Study period				
	Reason for the fee				
	Party that bears clinical trial expenses				
	Name and address of medical institution		Name of investigator		
	Name and address of the founder of the IRB				
	Name of subinvestigator	Quantity of study device to be delivered (received)	Planned number of subjects at each medical institution	Other (name of the notifier, etc. of the same plan to be conducted jointly, if any)	
	Name of coordinating investigator or member physicians of coordinating committee				
	Name and address of the party entrusted with the conduct (including request and preparation) and management operations of the study and range of operations entrusted				
Remarks					

I hereby notify the clinical trial plan as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

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

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. If the product concerned is an imported product, enter the name of the exporting country, the name of the manufacturer, and the brand name in the exporting country in the manufacturing process column.
3. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
4. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Attached Form 2

Clinical Trial Notification (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications submitted

Category					
Generic name and classification					
Name and address of the manufacturing site or sales office (investigational device provider)					
Shape, structure, and principle					
Raw materials, etc.					
Manufacturing method					
Proposed intended use and indications					
Proposed operation or usage method					
Outline of clinical trial plan	Objective				
	Planned number of subjects				
	Target disease				
	Operation or usage method				
	Study period				
	Reason for the fee				
	Party that bears clinical trial expenses				
	Name and address of medical institution		Name of investigator		
	Name and address of the founder of the IRB				
	Name of subinvestigator	Quantity of study device to be delivered (received)	Planned number of subjects at each medical institution	Other (name of the notifier, etc. of the same plan to be conducted jointly, if any)	
	Name of coordinating investigator or member physicians of coordinating committee				
	Name and address of the party entrusted with the conduct (including request and preparation) and management operations of the study and range of operations entrusted				
Clinical trial in-country representative	Address (for a corporation, location of its main office)				
	Name (for a corporation, its name and the name of the representative)				
Remarks					

I hereby notify the clinical trial plan as described above.

Month DD, YYYY

Address: Japanese

Foreign language (for a corporation, location of its main office)

Name: Japanese

Foreign language (for a corporation, its name and the name of the representative)

(vendor code)

Clinical trial in-country representative

Address (for a corporation, location of its main office)

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
3. Enter the contact telephone number/fax number of the clinical trial in-country representative in the remarks column.

Attached Form 3

Notification of Changes in Clinical Trial Plan

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications submitted
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name and classification					
Date of clinical trial notification and number of changes					
Reason for change	Item	Before change	After change	Date of change	Reason for change
Remarks					

I hereby notify the change in the clinical trial plan.

Month DD, YYYY

Address: (for a corporation, location of its main office)

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

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
3. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Attached Form 4

Notification of Changes in Clinical Trial Plan (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category					
Generic name and classification					
Date of clinical trial notification and number of changes					
Reason for change	Item	Before change	After change	Date of change	Reason for change
Remarks					

I hereby notify the change in the clinical trial plan.

Month DD, YYYY

Address: Japanese

Foreign language (for a corporation, location of its main office)

Name: Japanese

Foreign language (for a corporation, its name and the name of the representative)

(vendor code)

Clinical trial in-country representative

Address (for a corporation, location of its main office)

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
3. Enter the contact telephone number/fax number of the clinical trial in-country representative in the remarks column.

Attached Form 5

Clinical Trial Discontinuation Notification

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name and classification					
Date of clinical trial notification					
Timing of discontinuation					
Reason for discontinuation					
Status of subsequent actions					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify discontinuation of the clinical trial as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

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

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
3. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Attached Form 6

Clinical Trial Discontinuation Notification (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category					
Generic name and classification					
Date of clinical trial notification					
Timing of discontinuation					
Reason for discontinuation					
Status of subsequent actions					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify discontinuation of the clinical trial as described above.

Month DD, YYYY

Address: Japanese

Foreign language (for a corporation, location of its main office)

Name: Japanese

Foreign language (for a corporation, its name and the name of the representative)

(vendor code)

Clinical trial in-country representative

Address (for a corporation, location of its main office)

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter "as per appendix ( )" in the column and attach the appendix.
3. Enter the contact telephone number/fax number of the clinical trial in-country representative in the remarks column.

Attached Form 7

Clinical Trial Completion Notification

Clinical trial identification code	Type of clinical trial	Date of initial notification	Number of notifications submitted
	1: Company-sponsored clinical trials 2: Clinical trials conducted by sponsor-investigators		

Category					
Generic name and classification					
Date of clinical trial notification					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify the completion of the clinical trial as described above.

Month DD, YYYY

Address: (for a corporation, location of its main office)

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

(vendor code)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
3. Enter the name of the person in charge of the notification and the contact telephone number/fax number in the remarks column.

Attached Form 8

Clinical Trial Completion Notification (for foreign manufacturers)

Clinical trial identification code	Date of initial notification	Number of notifications

Category					
Generic name and classification					
Date of clinical trial notification					
Status at each medical institution	Name of medical institution	Quantity delivered (received)	Quantity used	Quantity collected/disposed, etc.	Number of subjects
Remarks					

I hereby notify the completion of the clinical trial as described above.

Month DD, YYYY

Address: Japanese

Foreign language (for a corporation, location of its main office)

Name: Japanese

Foreign language (for a corporation, its name and the name of the representative)

(vendor code)

Clinical trial in-country representative

Address (for a corporation, location of its main office)

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. The paper size should be Japan Industrial Standard A4.
2. When not all the required information can be entered in the specified column, enter “as per appendix ( )” in the column and attach the appendix.
3. Enter the contact telephone number/fax number of the clinical trial in-country representative in the remarks column.