

PSEHB Notification No. 0831-8

August 31, 2020

To: Prefectural Governors

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

Reports of Adverse Reactions, etc. in Clinical Trials to Pharmaceuticals and Medical Devices Agency

Handling of reports of adverse reactions, etc. in clinical trials to Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) has been shown in “Reports of Adverse Reactions, etc. in Clinical Trials to Pharmaceuticals and Medical Devices Agency” (PFSB Notification No. 0330001 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated March 30, 2004).

With the enforcement of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 63 of 2019) and 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), we have recently decided to change the handling of the above reports as follows. Please be aware of these changes and inform related businesses, etc. under your jurisdiction of them.

The “Enforcement of Ministerial Ordinance for Partial Revision of the Ministerial Ordinance for Enforcement of the Pharmaceutical Affairs Act Related to Notification of Clinical Trial Plans for Drugs and Reporting of Adverse Reactions, etc. Related to Clinical Trials on Drugs” (PFSB Notification No. 0229011 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare dated February 29, 2008) will be abolished.

Note

1. Definition of terms

The terms in Article 273 used with modifications in Article 279 of 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) are defined as follows.

- (1) “Events suspected to be adverse reactions” are events other than those for which a causal relationship can be ruled out. The events for which a causal relationship is unknown are also included.
- (2) “Infections suspected to be caused by their use” refer to infections including those for which contamination of the study drug concerned, etc. (the study drug concerned or drugs used overseas with the same ingredients as those of the study drug concerned, the same applies hereinafter) of biological origin with a pathogen (e.g., viral hepatitis, HIV infection, etc. suspected to be caused by blood products). Tests of markers for viruses such as HBV (hepatitis B virus), HCV (hepatitis C virus), and HIV turning positive are also subject to reporting of infections.
- (3) “Events not expected from the Investigator’s Brochure of the test drug concerned or existing scientific findings on the study drugs, etc. other than the test drug concerned” are events not described in the materials used for the latest judgment of expectedness at the time of evaluation of adverse reactions, etc. (the Investigator’s Brochure and documents describing scientific findings [the package insert, interview form, academic papers, etc.]; hereinafter referred to as “Investigator's Brochure, etc.”) or events that are described in these materials, but are not consistent with the description in nature, severity of symptoms, or occurrence tendency. For example, a serious case that is unexpected should be reported even if the name of the adverse reaction is listed in the Investigator’s Brochure, etc.
- (4) “Disability” refers to the onset of incapacity that interferes with daily life.
- (5) “Situations involving no risk of affecting safety judgment related to subject protection in the clinical trial concerned” refer to the situations including those where the obtained safety information does not include sufficient information that contributes to medical evaluation and it is difficult to obtain additional information that contributes to the evaluation in consideration of the information sources, occurrence status, etc., or where the contents of the obtained safety information are significantly different from the status of use in subjects of the clinical trial concerned and therefore there is no risk of affecting the safety judgment related to subject protection.

Specifically, the situations where it is impossible to judge whether the safety information is true or not as it has been derived from anonymous postings of adverse events on the internet or provision of information or inquiries from consumers or other non-healthcare professionals to the call center, which makes medical discussion or collection of additional information difficult, or the cases of adverse reactions that occurred with the routes of administration different from those used in the clinical trial and are adverse events, etc. unique to the route of administration used are applicable. However, even in the case of such information, if the accumulation of information indicates an increase in the number, frequency, etc. of diseases, etc. suspected to be adverse reactions to the study drugs concerned, etc. or infections suspected to be caused by their use, the change in such tendency needs to be reported separately.

- (6) “Drugs used overseas with the same ingredients as those of the study drug concerned” refer to drugs used overseas (including those being used in clinical trials) with the same ingredients as

those of the study drug concerned, including those with different routes of administration, dosage and administration, indications, etc.

- (7) "Implementation of actions that prevent the occurrence or spread of public health hazards including discontinuation of manufacturing, import, or marketing, recall, and disposal of drugs used overseas with the same ingredients as those of the study drug concerned" includes discontinuation of manufacturing, etc. overseas in light of efficacy or safety, changes in indications, dosage and administration, or manufacturing methods, and revision of important precautions with distribution of doctor letters. However, the reports on drug products with different routes of administration can be omitted if, for example, the safety information clearly depends on the route of administration.
- (8) "For study drugs other than test drugs, actions that prevent the occurrence or spread of public health hazards in combined use with the test drugs" refer to measures to prevent the occurrence or spread of public health hazards related to study drugs other than test drugs that is likely in concomitant use with the test drugs in the clinical trial concerned.
- (9) "There is a risk of cancer or other serious diseases, disabilities, or death" indicates the onset or possible onset of clinically significant diseases (e.g. cancer, deafness, blindness, etc.) attributable to adverse reactions to the test drugs concerned, etc. or infections due to their use based on the epidemiological survey reports, results of studies in animals, etc. and physical or chemical tests, etc.
- (10) "Marked changes in the tendency of occurrence such as the number of cases, frequency, and conditions of occurrence of diseases, etc. suspected to be adverse reactions or infections suspected to be caused by their use" are observed clear changes in the number of cases, frequency, conditions of occurrence (for example, the number of cases or frequency as a whole has not changed so greatly, but the number of cases or frequency is found to have particularly increased in light of specific ages, complications, dosage and administration, etc. when stratified), symptoms, severity, etc. of diseases suspected to be adverse reactions of the test drugs concerned, etc. or infections suspected to be caused by their use.
- (11) The phrase, a drug "does not have the efficacy or effect on the disease investigated in a clinical trial," refers to the absence of efficacy or effect on the disease targeted in the clinical trial based on precise and objective clinical studies, other animal studies, etc. on the test drug concerned, etc. or their active ingredients.
- (12) "Research reports" refer to reports such as research reports published in academic journals, etc. in Japan or overseas or reports of in-house research or research conducted by related companies.
- (13) Regarding "research reports considered not to affect the evaluation of efficacy and safety for the diseases investigated in a clinical trial of the test drug concerned, etc.," for example, research reports on adverse reactions expected in the clinical trial for which safety measures for subjects have already been taken (exclusion of certain subjects from the trial, appropriate examination plans developed in the trial, etc.) or diseases, etc. suspected to be adverse reactions to the test drugs concerned, etc. or infections suspected to be caused by their use showing no increase in the number of cases, frequency, etc. are assumed.

2. Reporting deadline, etc.

Reports of adverse reactions, etc. in clinical trials should be made within 7 days if they correspond to Article 273, Paragraph 1, Item 1 or Paragraph 2, Item 1 and within 15 days if they correspond to Article 273, Paragraph 1, Item 2 or Paragraph 2, Item 2 of the Regulation.

3. Report forms

The reports based on Article 273 of the Regulation shall be as follows.

(1) Reporting by the sponsor of the clinical trial

In paper-based submission of the reports based on Article 273, Paragraph 1 and Paragraph 2, Item 1 and Item 2, (a) and (b) of the Regulation, use Attached Form 1 and 2. For reports based on (c) and (d) of the same item, use Attached Form 3 and 4, and Attached Form 5 and 6.

For reports of adverse reactions, etc. in clinical trials by the sponsor of the clinical trial, these reporting documents may be replaced by CD-R (ROM) or DVD-R (ROM) in which the items listed in each attached form mentioned above are recorded and a document describing the necessary information such as the name and address of the reporter and the date of reporting. In principle, reports shall be made by the electronic data processing system specified in the Ministerial Ordinance for Enforcement of the Act on Promotion, etc. of Regulatory Administration by Utilizing Information and Communication Technology Related to Laws and Regulations under the Jurisdiction of the Ministry of Health, Labour and Welfare (Ministry of Health, Labour and Welfare Ordinance No. 40 of 2003).

(2) Reporting by the sponsor-investigator

For reports based on Article 273, Paragraph 1 and 2, Item 1 and Item 2, (a) and (b) of the Regulation, use Attached Form 7 and 8. For reports based on (c) and (d) of the same item, use Attached Form 9 and 10, and Attached Form 11 and 12.

4. Handling for reporting

(1) Reporting by the sponsor of the clinical trial

A Regardless of the necessity of submitting a notification of the plan for the clinical trial the sponsor requested, if the sponsor obtains important findings from a public health perspective regarding the efficacy and safety of a study drug, the sponsor shall report the contents pursuant to the provisions of Article 273 of the Regulation. Even if all clinical trials related to the test drug have been completed and an application for marketing approval is pending or is being prepared regarding a drug related to the said test drug, these cases are subject to reporting until the marketing approval is granted.

B If the sponsor applies for the marketing approval of a drug related to the clinical trial concerned before the completion of all clinical trials the sponsor requested, the sponsor shall clarify the progress status of the clinical trial concerned at the time of the approval application in the data attached to the marketing application.

C For the reporting method, minimum information necessary for reporting, reports of additional information on matters reported once, etc., refer to the "Post-marketing Reports

of Adverse Reactions, etc. and Reports of Adverse Reactions, etc. in Clinical Trials According To E2B (R3) Implementation Guide” (PSEHB/PED Notification No. 0831-12, PSEHB/PSD Notification No. 0831-3 issued jointly by the Director of Pharmaceutical Evaluation Division and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated August 31, 2020).

(2) Reporting by the sponsor-investigator

- A If the sponsor-investigator obtains important findings from a public health perspective regarding the efficacy and safety of a study drug related to the clinical trial the sponsor-investigator conducts, the sponsor-investigator shall report the contents pursuant to the provisions of Article 273 of the Regulation. Even if all clinical trials related to the test drug concerned have been completed and an application for marketing approval is pending or being prepared regarding a drug related to the said test drug, these cases are subject to reporting until the marketing approval is granted.
- B If the application for marketing approval of a drug related to the clinical trial the sponsor-investigator has started is filed before the completion of the trial, the sponsor-investigator shall communicate the progress status of the clinical trial concerned at the time of the approval application to the applicant for the approval. In this case, the applicant for approval shall describe the status concerned, etc. in the data attached to the marketing application for submission.
- C For the reporting method, minimum information necessary for reporting, reports of additional information on matters reported once, etc., refer to “Reports of Adverse Reactions, etc. in Clinical Trials by Sponsor-investigators” (PSEHB/PED Notification No. 0831-13 of the Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated August 31, 2020).

5. Where to submit

Reports of adverse reactions, etc. in clinical trials shall be submitted to the Review Planning Division, Office of Review Management, PMDA.

6. Handling of extremely significant safety information obtained during clinical trials

If the sponsor obtains extremely significant safety information such as the information on unknown serious adverse reactions, which are reasonably considered attributable to the use of study drugs with active ingredients different from those of the drugs marketed by the sponsor or the party entrusted with the clinical trial (including test drugs to be marketed) (hereinafter referred to as “other companies’ study drugs”) that would be considered to be the reason for suspension or discontinuation of clinical trials, it is desirable to appropriately provide the information to the marketing authorization holders, etc. of the study drugs concerned in Japan from the perspective of subject protection and improvement of public health safety in Japan, in addition to making reports of adverse reactions, etc. based on the above laws and regulations. The methods of providing information may include, but are not limited

to, any of the following.

- (1) The sponsor makes an agreement on the exchange of safety information in advance with related companies such as the marketing authorization holders of other companies' study drugs and share the information as needed.
- (2) When the sponsor obtains extremely significant safety information on other companies' study drugs, the sponsor promptly provides the safety information to companies marketing the drugs that contain the active ingredients of these drugs.
- (3) The sponsor promptly discloses any extremely significant safety information on other companies' study drugs, etc. that has become available in some way.

7. Application timing

This notification shall apply from September 1, 2020. However, those who submitted a clinical trial notification as per previous rules based on the "Handling of Notifications, etc. of Clinical Trial Plans Related To Drugs by Persons Who Intend to Sponsor Clinical Trials" (PSEHB/PED Notification No. 0831-10 of the Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated August 31, 2020) and "Handling of Notifications, etc. of Clinical Trial Plans for Drugs by Persons Who Intend to Be Sponsor-investigators" (PSEHB/PED Notification No. 0831-11 of the Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated August 31, 2020) shall make reports of adverse reactions, etc. in clinical trials according to previous rules.

Attached Form 1

Drug/Study Drug Adverse Reaction/Infection Case Report Form (Japan) (Overseas)

Identification number			
Brand name/test substance identification code Approval number (country of approval)		Name of active ingredient	

Information on case identifier

Worldwide unique case identification number		First sender		Sender's country	
Safety report identifier				Sender type	
Is this a previously transmitted case?		Source and case identifier of previous transmission			
Identifier of report associated with this report					

Management information

Meet criteria for expedited reports?		Type of report		Immediate report	
Date on which the first report was received		Date of most recent information		Date of report preparation	
Base date for reporting		Comment on base date for reporting			
Complete/incomplete category		Comments on incompleton			
Not subject to reporting		Reason			
Report nullification/amendment		Reason			

Remarks

I hereby report the case of adverse reaction/infection related to the above drug/study drug as shown in the attachment.

Month DD, YYYY

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

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Attached Form 2 (1)

Identification number		Page/total number of pages
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Information on suspected drug handled by sender

Brand name	Name of active ingredient	Status category of new drugs, etc.	Risk category of over-the-counter drugs	Route of obtaining over-the-counter drugs

Reporter information

Country	Qualification	Primary source for regulatory purposes

Attachments, etc.

Literature references			
Other attachments	Are additional documents available?	List of attachments	

Study information

Study registration number	Study registration country	Study title	Sponsor study number	Study type
Number of notifications	Reference disease	Development phase	Presence or absence of patients receiving the drug	

Adverse reaction/adverse event

Significance	Unknown/ known	Name of adverse reaction/adverse event (MedDRA-LLT)	Seriousness	Duration	Outcome	Confirmation by healthcare professional	Country of occurrence	Name of adverse reaction/adverse event as reported by the primary source	Language	Translated adverse reaction/adverse event name

Case narrative including clinical course, therapeutic measures, outcome and additional relevant information

Attached Form 2 (4)

Identification number		Page/total number of pages
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Additional information on drug/study drug

Brand name/product name	Name of active ingredient	Country of origin	Country of approval	Cumulative total dose	Gestation period at time of exposure	Action taken with drug	Additional information on drug (code)	Additional information on drug (free text)

Information on evaluation

Brand name/product name	Name of active ingredient	Name of adverse reaction/adverse event subject to evaluation	Source of assessment	Evaluation method	Evaluation result	Time interval from start of treatment to onset	Time interval from last dose to onset	Presence or absence of recurrence due to re-administration

Attached Form 2 (5)

Identification number		Page/total number of pages
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Reporter's comments	Sender's comments

Sender's diagnosis/syndrome and/or reclassification of adverse reaction/adverse event

Retrospective investigation of infection	Future actions

Other reference matters, etc.

Attached Form 2 (6)

Identification number		Page/total number of pages
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Parent information

Parent identification (initials)		Parent sex		Parent age		Parent height		Parent weight		Date of last menstrual period of parent	
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Information on relevant medical history and concurrent conditions of parent

Medical history (disease/surgical procedure/other)	Start date	End date	Remarks

Narrative

Relevant drug history of parent

Drug name	Start date	End date	Reason for use	Adverse reaction (only when it occurs)

Attached Form 3

Drug/Test drug Quasi-drug Cosmetic Research Report Investigation Report

Identification number			
Brand name/test substance identification code		Name of active ingredient	
Approval number (country of approval)			

Information on case identifier

Worldwide unique case identification number		First sender		Sender's country	
Safety report identifier				Sender type	
Is this a previously transmitted case?		Source and case identifier of previous transmission			
Identifier of report associated with this report					

Management information

Meet criteria for expedited reports?		Type of report			
Date on which the first report was received		Date of most recent information		Date of report preparation	
Base date for reporting		Comment on base date for reporting			
Complete/incomplete category		Comments on incompleteness			
Report nullification/amendment		Reason			

Remarks

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I hereby report the investigation results related to the above as shown in the attachment.

Month DD, YYYY

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

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Attached Form 4 (1)

Identification number		Page/total number of pages
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Information on suspected drug handled by sender

Brand name	Name of active ingredient	Status category of new drugs, etc.	Risk classification of over-the-counter drugs	Route of obtaining over-the-counter drugs

Reporter information

Country	Qualification	Primary source for regulatory purposes

Publication status, etc.

Country of publication		Publication status of study report		Clinical/nonclinical	
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Study information

Study registration number	Study registration country	Study title	Sponsor study number	Study type
Number of notifications submitted	Target disease	Development phase	Presence or absence of patients receiving the drug	

Attached Form 4 (2)

Identification number		Page/total number of pages
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Key points of report

Outline of research report

Other reference matters, etc.

Sender's comments

Future actions

Attached Form 5

Drug/Study Drug Overseas Actions Including Discontinuation of Manufacturing, etc., Recalls, and Disposal Investigation Report

Identification number			
Brand name/test substance identification code		Name of active ingredient	
Approval number (country of approval)			

Information on case identifier

Worldwide unique case identification number		First sender		Sender's country	
Safety report identifier				Sender type	
Is this a previously transmitted case?		Source and case identifier of previous transmission			
Identifier of report associated with this report					

Management information

Meet criteria for expedited reports?		Type of report		Immediate report	
Date on which the first report was received		Date of most recent information		Date of report preparation	
Base date for reporting		Comment on base date for reporting			
Complete/incomplete category		Comments on incompleteness			
Report nullification/amendment		Reason			

Remarks

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I hereby report the investigation results related to the above as shown in the attachment.

Month DD, YYYY

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

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Attached Form 6 (1)

Identification number		Page/total number of pages
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Information on suspected drug handled by sender

Brand name	Name of active ingredient	Status category of new drugs, etc.	Risk category of over-the-counter drugs	Route of obtaining over-the-counter drugs

Reporter information

Country	Qualification	Primary source for regulatory purposes

Publication status, etc.

Country of publication		Publication status of actions taken overseas	
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Study information

Study registration number	Study registration country	Study title		Sponsor study number	Study type
Number of notifications submitted	Target disease	Development phase	Presence or absence of patients receiving the drug		

Attached Form 6 (2)

Identification number		Page/total number of pages
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Key points of report

Summary of actions taken overseas

Other reference matters, etc.

Sender's comments

Future actions

(Attached Form 7)

Study Drug Adverse Reaction/Infection Case Report Form

Receipt number	Receipt number	Number of reports made to PMDA	Date on which the first report was received Month DD, YYYY	Date of most recent information for this report Month DD, YYYY	Meet criteria for expedited reports? 7 days 15 days
Test substance	Test substance identification code	Generic name			
Summary of reports of adverse reaction/infection	Information source	Country of occurrence		Type of report	
	The case concerned	Sex	Age	Disease name	
	Name of adverse reaction/infection				
	Seriousness/outcome	Seriousness		Outcome	
Investigational product in Japan	Not approved/Approved	Status category of new drugs, etc. Not approved/clinical trial for partial change ongoing (brand name of the drug:)			
	Outline of clinical trial	Target disease		Development phase	Presence or absence of patients receiving the drug
Attachments					
Remarks	The details of the case of adverse reaction/infection are shown in the attached Case Form. Batch/lot number Reporter's control number Receipt numbers of reports related to this report Reason for withdrawal in the case of withdrawal report Specific details of additional report Name of drug provider Names and affiliations of investigators at other sites conducting the study under the same protocol Contact information: Name, affiliation, phone number, and fax number of the contact person, etc.				

I hereby report the case of adverse reaction/infection associated with the study drug as described above.
 Month DD, YYYY

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

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Entry field for PMDA	Received by:	
Review office in charge		
Instructions at the time of receipt	No/Yes ()	
Receiver's comments		
Instructions/ comments		

Receipt number/ number of reports			Related report number		Seriousness		Medical confirmation	Yes No Unknown			Processing field for PMDA
Date of most recent information		Month DD, YYYY		Date on which the first report was received	Month DD, YYYY		Date of death		Month DD, YYYY		
Meet criteria for expedited reports?		7 days 15 days		History of adverse reactions	Primary disease/complication/ past history		1: Results in death 2: Life-threatening 3: Requiring inpatient hospitalization or results in prolongation of existing hospitalization 4: Results in persistent or significant disability/incapacity 5: Congenital anomaly 6: Other medically important event or reaction		Reported cause of death (in case of death)		
Country of occurrence (information source)		Height cm									
Patient's abbreviated name		Weight kg									
Sex											
Age		Gestation period at time of exposure							Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing		
Information on study drug/drug										Occurrence status and clinical course including symptoms and treatment of adverse reaction/infection	
Name of study drug and brand name	Generic name	Suspected drug	Status category of new drugs, etc.	Route	Dosage form	Dose		Treatment period		Reason for use of study drug and drug	
						Dose/ administration	Number of times	Start date	End date		
Adverse reaction/infection											
Significance	Name of adverse reaction/adverse event (MedDRA-PT)	Name of adverse reaction/adverse event (MedDRA-LLT)		Duration	Onset date	End date	Time interval from start of treatment to onset	Time interval from last dose to onset	Outcome		
MedDRA										Version ()	

Receipt number/ number of reports			Generic name		Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing
Comments from an attending physician, etc.			Reporter's comments		
Future actions			Diagnosis, syndrome, or reclassification of adverse reaction or adverse event by reporter		
			Adverse reaction/adverse event as reported by the primary source		
Other reference matters, etc. (cumulative number of reports/status of description, etc. of PRECAUTIONS)			Literature references		
			List of materials		
			MedDRA		Version ()

Receipt number/ number of reports				Generic name		Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing	
Test	Unit	Normal range Low	Normal range High	Date			
Result							
Presence or absence of other information							
Results of tests and procedures related to diagnosis							

MedDRA

Version ()

Study Drug Adverse Reaction/Infection Case Form Information on Medical History, etc.

Receipt number/number of reports				Generic name		Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing			
Relevant medical history and concurrent conditions					Relevant drug history				
Primary disease/ complication/past history	Start date of treatment	End date of treatment	Remarks	Other narrative	Drug name	Start date	End date	Reason for use	Adverse reaction (only when it occurs)

MedDRA

Version ()

Receipt number/number of reports				Generic name		Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing				
Results of re-administration or re-exposure	Country where study drug and drug were obtained (country of approval)	Name of study drug or brand name (Lot)	Non-proprietary name-like name	Action taken with study drug, etc.	Start date	End date	Time interval from start of treatment to onset	Time interval from last dose to onset	Presence or absence of recurrence due to re-administration	Name of adverse reaction that recurred on re-administration
Causal relationship between study drug, etc. and adverse reaction, etc.	Name of adverse reaction or adverse event subject to evaluation		Source of assessment		Causal relationship between study drug, etc. and adverse reaction or adverse event (evaluation method)		Evaluation result		Additional information on study drug, etc.	
Cause of death	Reported cause of death			Presence or absence of autopsy		Autopsy-determined cause of death				
							MedDRA		Version ()	

Receipt number/number of reports made				Generic name				Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing	
Related report number				Parent age	Parent height cm	Parent weight kg	Name of adverse reaction		
Parent's abbreviated name		Parent sex		Date of last menstrual period					
Gestation period at time of exposure				Gestation period at time of onset					
Parent's relevant medical history and concurrent conditions				Relevant drug history of parent					
Primary disease/complication/past history	Start date	End date	Remarks	Drug name	Start date	End date	Reason for use	Adverse reaction (only when it occurs)	
Parent's relevant medical history and concurrent conditions (excluding adverse reactions and adverse events)									
				MedDRA		Version ()			

(Attached Form 9)

Test Drug Research Report

Receipt number	Receipt number	Number of reports to PMDA	Date on which the first report was received Month DD, YYYY	Date of most recent information for this report Month DD, YYYY	Meet criteria for expedited reports? 7 days 15 days
Test substance	Test substance identification code	Generic name			
Test drug in Japan	Not approved/Approved	Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing (brand name of the drug: _____)			
	Outline of clinical trial	Target disease	Development phase	Presence or absence of patients receiving the drug	
Attachments					
Remarks	The details of the research report are as described in the attached Investigation Report. Batch/lot number Reporter's control number Receipt numbers of reports related to this report Reason for withdrawal in the case of withdrawal report Specific details of additional report Name of drug provider Names and affiliations of investigators at other sites conducting the study under the same protocol Contact information: Name, affiliation, phone number, and fax number of the contact person, etc.				

I hereby report the research on the test drug.
Month DD, YYYY

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

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Entry field for PMDA	Received by:
Review office in charge	
Instructions at the time of receipt	No/Yes (_____)
Receiver's comments	
Instructions/ comments	

(Attached Form 10)

Test Drug Research Report Investigation Report

Receipt number/ number of reports made			Date of report Month DD, YYYY	Date on which the first report was received Month DD, YYYY	Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing	Processing field for PMDA
Generic name			Publication status of study report		Country of publication	
Name of test drug and brand name (company name)						
Outline of research report	<input type="checkbox"/> Development of cancer, etc. <input type="checkbox"/> Change in occurrence tendency <input type="checkbox"/> No effect Problem ()					Status of description of PRECAUTIONS/other reference matters, etc.
	Reporter's comments		Future actions			

(Attached Form 11)

Study Drug Overseas Actions Including Discontinuation of Manufacturing, etc., Recalls, and Disposal Report

Receipt number	Receipt number	Number of reports made to PMDA	Date on which the first report was received Month DD, YYYY	Date of most recent information for this report Month DD, YYYY	Meet criteria for expedited reports? 7 days 15 days
Test substance	Test substance identification code	Generic name			
Investigational product in Japan	Not approved/Approved	Category of new drugs, etc. 1: Not approved 2: Clinical trial for partial change ongoing		(brand name of the drug:)	
	Outline of clinical trial	Target disease	Development phase	Presence or absence of patients receiving the drug	
Attachments					
Remarks	The details of the actions taken overseas are as described in the attached Investigation Report. Batch/lot number Reporter's control number Receipt numbers of reports related to this report Reason for withdrawal in the case of withdrawal report Specific details of additional report Name of drug provider Names and affiliations of investigators at other sites conducting the study under the same protocol Contact information: Name, affiliation, phone number, and fax number of the contact person, etc.				

I hereby report the actions taken overseas with the study drug as described above.
Month DD, YYYY

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

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

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Entry field for PMDA		Received by:	
Review office in charge			
Instructions at the time of receipt	No/Yes ()		
Receiver's comments			
Instructions /comments			

