Provisional Translation (as of June 2022) *

Procedures for Preparation of Explanation of Electronic Study Data (Form B)

These explanatory documents should be attached to the item of Consultation on exemption of submission of electronic study data. The following points should be addressed when filling out the "Explanation of Electronic Study Data" (Form B).

・Information should be provided in all relevant sections from the “1. Basic Information” section to the "5. Information on the clinical studies, integrated analyses, and clinical pharmacology for which electronic data are expected to be submitted in a format other than the CDISC standards" section.

・All applicable checkboxes should be checked.

・In the “3.2.3 Clinical studies/ analyses for which applicants desire to be exempt to submit electronic study data” section, describe the start date of studies and analyses which applicants desire to be exempt to submit electronic study data, according to the “Notification on Handling of Submission of Electronic Study Data for New Drug Applications” (PSEHB/PED Notification No. 0401-10, by the Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated April 1, 2022) and the “Question and Answer Guide Regarding “Notification on Handling of Submission of Electronic Study Data for New Drug Applications”” (Administrative Notice of the Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated April 1, 2022).
Regarding orphan drugs, describe which study is expected to be submitted in a format other than the CDISC standards.

・In the “4. Situation of holding data” section, describe the process from data acquisition to the current status of holding data, and the content of data including compliance with data standards.

・In the “5. Information on the clinical studies, integrated analyses, and clinical pharmacology analyses for which electronic data are expected to be submitted in a format other than the CDISC standards” section, select the form corresponding to the studies to be submitted and describe the information either completed or planned at the timing of consultation. For clinical studies in which standard pharmacokinetic analyses are performed, the contents regarding to the clinical studies should be described in section 5.1, and the contents regarding standard pharmacokinetic analysis and/or pharmacodynamic analysis should be described in section 5.2.

・When describing more than one clinical study or analysis in the “5. Information on the clinical studies, integrated analyses, and clinical pharmacology analyses for which electronic data are expected to be submitted in a format other than the CDISC standards” section, duplicate the format of the relevant clinical study, integrated analysis, or clinical pharmacology analysis (Title parts and tables of paragraphs 5.1.1 and 5.1.2, etc.) and describe each clinical study or analysis. For example, if there are two clinical studies that are not CDISC-conformant, Study A and Study B, section numbers such as "5.1.1. Study A" and "5.1.2 Study B" should be assigned and the contents of each study should be described.

Provisional Translation (as of June 2022) *

〔Form B〕

Explanation of Electronic Study Data

1. Basic information

Code of active ingredient	
Brand name (planned)	
Non-proprietary name	
Dosage form / Strength	
Indication (planned)	
Dosage and administration (planned)	
Submission year and month (planned)	
With designation (or planned) as orphan drug or not	
Consultation applicant	
Information of contact person (name, division, telephone number)	
Date of preparation of this document	
Remarks	

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3. Overview of clinical data package

3.1. Planned clinical data package (Clinical studies and analyses)

Classification	Study number、Analysis name (or report name)	Evaluation/Reference

(Note)

- Please describe all studies and analyses included in the clinical data package regardless of submission of electronic data.
- In the column “classification”, please describe the information including Phase I, Phase II, Phase III, clinical

pharmacology study, integrated summary of safety, integrated summary of efficacy, population analysis, PBPK model analysis, etc.

3.2. Clinical studies/analyses for which electronic data submission is planned

3.2.1. Individual clinical study

Study number (or report name)	Summary of individual clinical studies	
	Study region(s)	
	Study population	
	Study design	
	Treatment (Dosage and Administration)	
	Duration of administration	
	Sample size of each treatment group	
	Efficacy endpoint(s)	
	Safety endpoint(s)	
	Status	
	Study region(s)	
	Study population	
	Study design	
	Treatment (Dosage and Administration)	
	Duration of administration	
	Sample size of each treatment group	
	Efficacy endpoint(s)	
	Safety endpoint(s)	
	Status	

(Note)

- Please describe the design summary of clinical studies/analyses for which electronic data will be submitted.
- "Study design" includes "double-blind randomized controlled studies", "unblinded, uncontrolled study", etc.
- The number of subjects enrolled will be described in "Sample size of each treatment group", if the clinical study has been completed. The planned sample size will be described if the clinical study is ongoing.
- "Status" includes information of each clinical study, such as "Planning", "Ongoing" or "Completed".

3.2.2. Integrated analysis, population analysis or PBPK model analysis

Analysis name (or report name)	Summary of each analysis			
	Objective of the analysis (Summary)	Number of subjects analyzed	Endpoint(s)	Status
	Summary of individual clinical studies included in the analysis			
	Study name	Study population	Dosage and administration	Number of subjects
	☐			
	☐			
	☐			
	Objective of the analysis (Summary)	Number of subjects analyzed	Endpoint(s)	Status
	Summary of individual clinical studies included in the analysis			
	Study name	Study population	Dosage and administration	Number of subjects
	☐			

	☐			
	☐			

(Note)

- "Objective of the analysis (Summary)" includes "integrated summary of efficacy", "population pharmacokinetic analysis", "PBPK model analysis", etc.
- In the column “Status”, describe the status of each analysis, including either category; “Planning”, “Ongoing” or “Completed”.
- In the area “Summary of individual clinical studies included in the analysis”, check the box and provide only "Study name" will be sufficient for the studies for which electronic data will be submitted.
- In the case of PBPK model analyses, “Analysis name (or report name)”, “Objective of the analysis”, and “Status” will be sufficient.

3.2.3. Clinical studies/analyses for which applicants desire to be exempt to submit electronic study data

Studies or analyses for which exemption is requested (Study number, analysis name, or report name)	Date of enrollment of the first subject	Submission of non-CDISC format electronic data (Y/N)

4. Situation of holding data

Describe summary of situation that an applicant has the data of clinical studies. If more than one study/analysis will be consulted, describe the information about each study/analysis.

Summary of situation of holding data

For clinical studies in a format other than CDISC standards, following table, for example, can be used to describe the situation of holding status and submission of files corresponding to those that should be submitted in case of the CDISC-conformant study data per clinical study.

<Study dataset>

Study number (or report name)	Dataset	Definition file	Reviewer’s guide or corresponding document	aCRF or corresponding document

<Analysis dataset>

Study number (or report name)	Dataset	Definition file	Reviewer’s guide or corresponding document	Program for creating analysis dataset	Program for analysis or specifications that show the analysis algorithm

5. Information on the clinical studies, integrated analyses, and clinical pharmacology for which electronic data are expected to be submitted in a format other than the CDISC standards

5.1. Clinical studies submitted in a format other than CDISC standard (To be described for each study)

In this section, only the contents that have already been decided or planned at the time of the consultation

should be described. For undecided/unknown contents, describe the situation. For clinical studies for which standard pharmacokinetic and/or pharmacodynamic analyses are performed, the contents regarding standard pharmacokinetic and/or pharmacodynamic analyses should also be included in Section 5.2. The "(Study number or report name)" may include the Study ID, but in such case, the relationship to “study number (or report name)” in Section 3.2.1 should be identified.

5.1.1. Study A (Study number or report name)

a. Information about clinical study
Summary of clinical study design (An excerpt from the protocol will be acceptable.):

b. Information about the electronic data
Data at the cut-off point which is prior to the data cut-off point for submission ☐ Submitted ☐ Not submitted
Describe the data which are used in CSR but not included in datasets to be submitted:

Standards and those versions used for creating datasets		
Standard	Version	Notes
MedDRA		
(Drug code)		
(Others)		(Purpose of Use)

The datasets planned to be submitted as electronic data, etc. (Information that would correspond to the SDTM datasets if it were CDISC-conformant)	
Study datasets	
File name (including extensions)	Contents
Definition file of study datasets, others	
File name (including extensions)	Contents

The analysis datasets planned to be submitted as electronic data, etc.	
Analysis datasets	
File name (including extensions)	Contents (corresponding endpoints, analysis, etc.)
Definition file of analysis datasets, others	
File name (including extensions)	Contents

c. Analysis information
Submission of analysis programs ☐ Submitted with macro code ☐ Since the macro code are not submitted, specifications that show the analysis algorithm are submitted (The reason why the macro code cannot be submitted:) ☐ Since the analysis programs cannot be submitted, specifications that show the analysis algorithm are submitted (The reason why the analysis program cannot be submitted:) If the content is included in other materials, the name of those materials: ( ) ☐ Other ( )

Software used for the analysis *In case more than one software used, describe all the names of software. Software name (version): Analysis environment (operating system, version etc.):

5.2. Standard pharmacokinetic and/or pharmacodynamic analysis of clinical pharmacology

In this section, describe the information on standard pharmacokinetic analysis and/or pharmacodynamic analysis per study number (or report name) for clinical studies in a format other than CDISC standards. If there are multiple purposes in a study (or a report), it is acceptable to describe the information per each purpose. It is acceptable to describe only the information for ongoing or planned at the timing of consultation. For undecided/unknown contents, describe the situation. The "(Study number or report name)" may include the Study ID, but in such case, the relationship to "study number (or report name)" in Section 3.2.1 should be identified.

5.2.1. Study A (Study number or report name)

a. Information about clinical study
Type of clinical studies ☐ Phase I studies for oncology drugs ☐ Phase I studies conducted on both the Japanese and Non-Japanese subjects (in case of a development utilizing multi-regional clinical studies or bridging studies) ☐ QT/QTc studies based on the ICH E14 guideline ☐ Phase I and Phase II studies of antibacterial agents, etc., where the results on pharmacokinetics or pharmacokinetics/pharmacodynamics provide a major evidence for the dosage and administration ☐ Clinical pharmacology studies for pediatrics ☐ Clinical pharmacology studies for geriatric subjects or subjects with hepatic or renal impairment ☐ Drug interactions studies ☐ Studies investigating the effect of food ☐ Bioequivalence studies ☐ Studies investigating the comparability with reference biologic products ☐ Other (Describe below)

b. Information about the electronic data	
Analysis dataset for clinical pharmacology planned to be submitted	
Contents of the dataset	File format

c. Analysis information
Analysis of the calculation of pharmacokinetic and/or pharmacodynamic parameters
Software used for the analysis Software name (version): Analysis environment (operating system, version, etc.):
Analysis specification or corresponding information for non-compartment analysis ☐ Analysis specification (PDF format) ☐ Information corresponding to analysis specification (document name, file format:) ☐ Text Output of Phoenix Projects (*.phxproj) ☐ Other ( )
Submission of analysis programs for the calculation of parameters other than a non-compartment analysis ☐ Submitted ☐ Submitted with macro code ☐ Since the macro code are not submitted, specifications that show the analysis algorithm are submitted (The reason why the macro code cannot be submitted:) ☐ Since the analysis programs cannot be submitted, specifications that show the analysis algorithm are

submitted
(The reason why the analysis programs cannot be submitted:)
If the contents are included in other materials, the name of those materials: ( )

☐ Not submitted

Analysis of statistical evaluation using pharmacokinetic and/or pharmacodynamic parameters

Software used for the analysis
Software name (version):
Analysis environment (operating system, version, etc):

Submission of analysis programs

☐ Submitted with macro code

☐ Since the macro code are not submitted, specifications that show the analysis algorithm are submitted
(The reason why the macro code cannot be submitted:)

☐ Since the analysis programs cannot be submitted, specifications that show the analysis algorithm are submitted
(The reason why the analysis programs cannot be submitted:)
If the contents are included in other materials, the name of those materials: ( )

☐ Other ( )

d. Information about dataset

Submission of dataset definition file

☐ Submitted
- ☐ define.xml
- ☐ PDF format (Name of the document:)
- ☐ Other format ( )

☐ Submitted in the analysis report, etc. (Name of the document:)

☐ Other ( )