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

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

- Information should be provided in all relevant sections from the “1. Basic Information” section to the "4. Information on CDISC-conformant clinical studies, integrated analyses, and clinical pharmacology analyses for which electronic data are planned to be submitted" section.
- All applicable checkboxes should be checked.
- In the “4. Information on CDISC-conformant clinical studies, integrated analyses, and clinical pharmacology analyses for which electronic data are planned to be submitted” section, select the form corresponding to the study or analysis to be submitted (clinical studies, integrated analysis, clinical pharmacology analyses, etc.) and describe the information either completed or planned at the timing of consultation. However if the contents regarding CDISC-conformant of individual studies and integrated analysis, and the contents of clinical pharmacology analyses are included in the consultation on data format of submission of electronic study data, consultation applicant needs to describe the information as possible in this part. For clinical studies for which standard pharmacokinetic analyses are performed, the contents regarding to the CDISC-conformant should be described in section 4.1, and the contents regarding standard pharmacokinetic analysis and/or pharmacodynamic analysis should be described in section 4.3.
- When describing more than one clinical study or analysis in the "4. Information on CDISC-conformant clinical studies, integrated analyses, and clinical pharmacology analyses for which electronic data are planned to be submitted" section, duplicate the format of the relevant clinical study, integrated analysis, or clinical pharmacology analysis (Title parts and tables of paragraphs 4.1.1 and 4.1.2, etc.) and describe each clinical study or analysis. For example, if there are two CDISC-conformant clinical studies, Study A and Study B, section numbers such as "4.1.1. Study A" and "4.1.2 Study B" should be assigned and the contents of each study should be described.

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〔Form A〕

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)	
Consultation applicant	
Information of contact person (name, division, telephone number)	
Date of preparation of this document	
Remarks	

(Note) When submitting electronic data after approval, please change the item name of "Submission year and month" to "Approval date/End date of reexamination period".

2. Table of contents

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Note that the Japanese format should be used for the submission.

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. When submitting electronic data after approval, please describe a list of post-marketing clinical studies that have completed or planned in this column, and enter " ― " in the column "Evaluation/Reference".
- 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, post-marketing clinical study, 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)	Implementation 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" 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.

4. Information on CDISC-conformant clinical studies, integrated analyses, and clinical pharmacology analyses for which electronic data are planned to be submitted.

Version of the validation rules used for validation of CDISC-conformant data by the applicant prior to the submission. Please note that only one version can be selected for all studies/analyses in Section 4.1 and 4.2.	

4.1. CDISC-conformant clinical studies (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. 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. The “Custom domains” field should contain the custom domains according to the standard version used.

For clinical studies for which standard pharmacokinetic and/or pharmacodynamic analyses are performed, the contents of those analyses should also be included in Section 4.3.

4.1.1. 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):
Data cut-off date (planned date, if the study is ongoing):
b. Information about the electronic data
Select one of each following item:. CDISC Conformant (data collection)

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☐ Data collection with CDASH format
☐ Data collection with non-CDASH format

CDISC Conformant (SDTM)
☐ Creating SDTM datasets (including the planning)
☐ Data conversion from non-SDTM to SDTM format (including the planning)

CDISC Conformant (ADaM)
☐ Creating ADaM from SDTM datasets (including the planning)
☐ Creating ADaM from non-SDTM datasets (including the planning)

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 SDTM or ADaM datasets to be submitted:

Reference availability of the reviewer's guide
If all of the following information (subsequent rows in this section (section b), and section c and d) are included in the reviewer's guide, it will be acceptable to refer to the reviewer's guide.
☐ Refer to the reviewer's guide (If applicable, delete the following rows)

Standards and those versions used for creating datasets
*If the version used for the validation differs from that used for the dataset creation, describe the version used for the validation in the column "Notes".

Standard	Version	Notes
SDTM SDTM IG		
ADaM ADaM IG		
Define-XML	SDTM : ADaM :	
Controlled Terminology	SDTM : ADaM :	
MedDRA		
WHODrug Global		
(Others)		(Purpose of use)

The datasets planned to be submitted (SDTM)					
Definition file	☐ define.xml				
Review's guide	☐ Study Data Reviewer's Guide				
Dataset	Submission *Check for domains to be submitted. Do not change the order or delete the domains which are not be submitted.				
TA	☐				
TD	☐				
TE	☐				
TI	☐				
TS	☐				
TV	☐				
Dataset	Check the domains which will be submitted. The domains which are not officially adopted in the standard version should be described in the "Custom domains" field.	Check the corresponding one			Notes
		SUPP	Include data in Japanese	SUPP Include data in Japanese	
AE	☐	☐	☐	☐	
CE	☐	☐	☐	☐	

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CM	☐	☐	☐	☐	
CO	☐	☐	☐	☐	
DA	☐	☐	☐	☐	
DD	☐	☐	☐	☐	
DM	☐	☐	☐	☐	
DS	☐	☐	☐	☐	
DV	☐	☐	☐	☐	
EC	☐	☐	☐	☐	
EG	☐	☐	☐	☐	
EX	☐	☐	☐	☐	
FA	☐	☐	☐	☐	
HO	☐	☐	☐	☐	
IE	☐	☐	☐	☐	
IS	☐	☐	☐	☐	
LB	☐	☐	☐	☐	
MB	☐	☐	☐	☐	
MH	☐	☐	☐	☐	
MI	☐	☐	☐	☐	
MO	☐	☐	☐	☐	
MS	☐	☐	☐	☐	
PC	☐	☐	☐	☐	
PE	☐	☐	☐	☐	
PP	☐	☐	☐	☐	
PR	☐	☐	☐	☐	
QS	☐	☐	☐	☐	
RELREC	☐				
RP	☐	☐	☐	☐	
RS	☐	☐	☐	☐	
SC	☐	☐	☐	☐	
SE	☐	☐	☐	☐	
SR	☐	☐	☐	☐	
SS	☐	☐	☐	☐	
SU	☐	☐	☐	☐	
SV	☐	☐	☐	☐	
TR	☐	☐	☐	☐	
TU	☐	☐	☐	☐	
VS	☐	☐	☐	☐	
Custom domains					
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
Annotated CRF	☐ Annotated CRF will be submitted				
The dataset planned to be submitted as electronic data (ADaM) *Describe the dataset name and the contents in the column.					
Definition file	☐ define.xml Submission of Analysis Results Metadata ☐ Submitted ☐ Included in define.xml ☐ Other ( ) ☐ Not submitted				
Review's guide	☐ Analysis Data Reviewer's Guide				

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Note that the Japanese format should be used for the submission.

Dataset	Contents of the dataset	Include data in Japanese (If applicable, please check)
		☐
		☐
		☐

Submission of programs for creating ADaM
- ☐ All the programs will be submitted
- ☐ Only some programs will be submitted
- ☐ Not submitted (The reason:)

The dataset planned to be submitted as electronic data (Other)

File name (include extensions)	Contents

c. Information about the conformance of the electronic data to the CDISC standards (Attachment of validation report or reviewer's guide is acceptable.)

Validation tool and version (Describe each version if versions are different between SDTM and ADaM)	

SDTM

Explanation about conformance - Describe the CDISC (SDTM) conformance

Dataset	Contents (including Rule ID)

ADaM

Explanation about conformance - Describe the CDISC (ADaM) conformance

Dataset	Contents (including Rule ID)

d. 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 are not 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: ( )

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

4.2. Integrated analysis

In this section, it is acceptable to describe only the information for ongoing or planned at the timing of consultation. For undecided/unknown contents, describe the situation. In case the topic regarding the conformance to the CDISC standards of the integrated analysis is included in the consultation contents, applicant needs to include as much information as possible in this part.

If the dataset used for integrated analysis is different from that for the individual analysis in each study (e.g. data lock date), please also describe using the form on 4.1.

4.2.1. Analysis A (Analysis name or report name)

a. Information about objective of analysis and subject population
Objective of analysis (An excerpt from the analysis plan will be sufficient):

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b. Information about the electronic data

Reference availability of the reviewer's guide

If all of the following information are included in the reviewer's guide, it will be acceptable to refer to the reviewer's guide

☐ Refer to the reviewer's guide (If applicable, delete the following rows)

Standards and those versions used for preparing datasets

*If the version used for the validation differs from that used for the dataset creation, describe the version used for the validation in the column "Notes".

Standard	Version	Notes
SDTM SDTM IG		
ADaM ADaM IG		
Define-XML	SDTM: ADaM:	
Controlled Terminology	SDTM: ADaM:	
MedDRA		
WHODrug Global		
(Other)		(Purpose of use)

The dataset planned to be submitted as electronic data	
SDTM	Dataset: Definition file ☐ define.xml Review's guide ☐ Study Data Reviewer's Guide
ADaM	Dataset: Definition file ☐ define.xml Analysis Results Metadata ☐ Submitted ☐ Included in define.xml ☐ Other ( ) ☐ Not submitted Review's guide ☐ Analysis Data Reviewer's Guide
(Other)	Dataset (contents): ( )

c. Information about the conformance of the electronic data to the CDISC standards (Attachment of validation report or reviewer's guide is acceptable.)

Validation tool and version (Describe each version if versions are different between SDTM and ADaM)	

SDTM	
Explanation about conformance - Describe the CDISC (SDTM) conformance	
Dataset	Contents (including Rule ID)

ADaM	
Explanation about conformance - Describe the CDISC (ADaM) conformance	
Dataset	Contents (including Rule ID)

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d. 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 are not submitted, specifications that show the analysis algorithm are submitted (The reason why the analysis program cannot be submitted:) If the contents are included in other materials, the name of those materials: ( )	
Software used for the analyses Software name (version) : Analysis environment (operating system, version, etc.):	

4.3. 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). 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.

Information related to the CDISC-conformant data should be provided in Section 4.1 in addition to Section 4.3.

4.3.1. 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 *For datasets in ADaM format, only the dataset name in the "Dataset" column will be sufficient. In the case of dataset in a format other than ADaM format, it is acceptable to leave the "Dataset" column blank, but describe the content and file format.		
Dataset	Contents	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 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 program cannot be submitted:) If the contents are included in other materials, the name of those materials: ( ) ☐ Not submitted
Analysis for 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: ( )
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 material:)

4.4. Population analysis of the clinical pharmacology

In this section, describe the information on population analysis per report. If there are multiple purposes in 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.

4.4.1. Analysis A (Analysis name or report name)

a. Information about objective of analysis and subject population
Objective of analysis (An excerpt from the analysis plan will be sufficient):
b. Information about the electronic data
File format of analysis dataset(s):
c. Analysis information
Analysis software used for the modeling and/or simulation Software name (version) : Analysis environment (operating system, version, etc.): *If more than one analysis software are used, describe all the names of software.
The model files planned to be submitted Describe the following information (1) to (3) for each model if multiple final models will be submitted. If the

base model and the final model are identical, check "Not Submitted" in "(1) Base model", and describe the reason, and check "Submitted" in "(2) Final model".

The content of the model file:
(1) Base model
☐ Submitted
File format
☐ ASCII format
☐ Other ( )
☐ Not submitted (The reason:)
(2) Final model
☐ Submitted
File format
☐ ASCII format
☐ Other ( )
☐ Not submitted (The reason:)
(3) Models other than the base and final models
☐ Submitted (Content:)
File format
☐ ASCII format
☐ Other ( )
☐ Not submitted

Submission of files related to the simulation
☐ Submitted
Submission of programs used for simulation
☐ Submitted (Describe each content if necessary)
Content:
File format
☐ ASCII text format
☐ Other ( )
Submission of program procedures for simulation
☐ Submitted
☐ Not submitted (The reason:)
☐ Since the analysis programs are not 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 (The reason:)

d. Information about the output

(1) Submission of result files (NONMEM result file, etc.)
☐ Submitted
☐ Not submitted (The reason:)
(2) Submission of other files（e.g. files on simulation related to the population analysis）
☐ Submitted (Describe each contents if necessary)
Content:
☐ Not submitted

e. Information about dataset

Submission of dataset definition file
☐ Submitted
☐ PDF format (Name of the document:)
☐ Other format ( )
☐ Submitted in the analysis report, etc. (Name of the material:)

4.5. Physiologically based Pharmacokinetics (PBPK) Model Analysis of Clinical Pharmacology

In this section, describe the information on PBPK model analysis per report. If there are multiple purposes in

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.

4.5.1. Analysis A (analysis name or report name)

a. Analysis information
Objective of analysis: ☐ Prediction of drug interactions ☐ Drug development for pediatrics ☐ Estimation of pharmacokinetic for special population (e.g., subjects with hepatic or renal impairment) ☐ Other (Describe below)
Software name (version): Analysis environment (operating system, version, etc.):
b. Information about the electronic data
Files planned to be submitted ☐ Files containing the information of PBPK model constructed or used (file format:) ☐ Files containing the parameter (e.g., pharmacokinetic parameters and physiology parameters) used for analysis (File format:) ☐ Files containing the simulation condition information (file format:) ☐ Files about sensitivity analysis (file format:) ☐ Files containing the analysis results (file format:) ☐ Other (Describe type of file below) Type: (File format:)
c. Information about clinical study data
Submission of data of clinical studies, etc. used for PBPK model analysis (e.g. Verification of models, estimation of parameters) ☐ Submitted (Purpose of analysis:) Submission of dataset (Describe in each study below) ☐ Submitted (File format:) Content of study: ☐ Not submitted (The reason:) Submission of the dataset definition file ☐ Submitted (File format:) ☐ Submitted in the analysis report, etc. (Name of the document:) ☐ Not submitted (The reason:) ☐ Not submitted

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