Provisional Translation (as of April 2019) *

(Attachment 8)

Supporting Document on Consultation on Data Format of Submission of Electronic Study Data

The contents to be described in the material for application of consultation on data format of submission of electronic study data will vary depending on the objectives of consultation but items described in the following section 1 to 4 are useful for the consultation. Format for describing the listed items are shown in the appendix of this attachment.

For some of the information in section 1 and 2 etc., please fill them in duplicate with the application form.

1. Basic information

Code of active ingredient
Brand name (planned)
Non-proprietary name
Dosage form / Strength
Proposed indication (planned)
Proposed dosage and administration (planned)
Submission year and month (planned)
Consultation applicant
Information of contact person (name, division name, telephone number)

2. Consultation contents

3. Overview of clinical data package and clinical study

(1) Planned clinical data package

Describe all studies which are in the clinical data package regardless of submission of electronic data

(2) Clinical studies/ analyses for which electronic data submission is planned

Describe the overall design of the study/analysis for which electronic data submission is planned

4. Information on the studies (clinical studies, integrated analysis, clinical pharmacological studies and so on) for which electronic data are planned to be submitted conforming to the CDISC standards

In this section, please select the form corresponding to the study or analysis to be submitted (clinical studies, integrated analysis, clinical pharmacology analyses and so on) and describe the information either completed or planned at the timing of consultation. However if the content regarding conformance to the CDISC standards of individual studies and integrated analysis, and the content of clinical pharmacology analyses to be submitted are included in the consultation on data format of submission of electronic study data, consultation applicant needs to include as much information as possible in this part.

Regarding the studies described in (3), please also describe the details of CDISC conformance in (1).

(1) Study information which is planned to be submitted as electronic data (Clinical studies which conform to the CDISC standards, describe per study)
   ① Information about clinical study (study number, summary of study design, date of data base lock)
   ② Information about the electronic data
      · Conformance to the CDISC standards
      · CDISC conformance of submission data (version)
      · Conformance to other standards (Controlled Terminology, MedDRA, etc.)
      · The relationship between the submission data and CSR
      · Data which are used in CSR but NOT included in SDTM / ADaM datasets to be submitted
      · File format of SDTM and ADaM datasets
      · File size of electronic data (total)
      · Planned submission datasets (SDTM, ADaM and other explanatory documents)
   ③ Information about conformity of the electronic data to the CDISC standards

- Tools used for data validation
- Remarks regarding the conformance

④ Analysis information

- Whether submission of analysis programs is possible or not (whether submission of macros is possible or not, submission of specifications)
- The software and its version used for the analysis, and analysis environment

(2) Study information which is planned to be submitted as electronic data (integrated analysis)
① Objective of analysis and the information of study population
② Electronic data information
③ Analysis information

(3) Study information which is planned to be submitted as electronic data (Clinical pharmacology, standard pharmacokinetic analysis)
① Clinical studies information
② Electronic data information
③ Analysis information
④ Datasets information

(4) Study information which is planned to be submitted as electronic data (Clinical pharmacology, population analysis)
① Objective of analysis and the information of target population
② Electronic data information
③ Analysis information
④ Outputs information
⑤ Datasets information

(5) Study information which is planned to be submitted as electronic data (Clinical pharmacology, physiologically based pharmacokinetic analyses (PBPK) model analysis)
① Analysis information
② Electronic data information
③ Clinical study information

Provisional Translation (as of April 2019) *

Supplementation

Document on Consultation on Data Format of Submission of Electronic Study Data - Template

1. **Basic information**

Code of active ingredient	
Brand name (planned)	
Non-proprietary name	
Dosage form / Strength	
Proposed indication (planned)	
Proposed dosage and administration (planned)	
Submission year and month (planned)	
Consultation applicant	
Information of contact person (name, division, telephone number)	

2. **Consultation contents**

3. **Overview of clinical data package and clinical study**

(1) Planned clinical data package

Classification	Study number (or report number)	Evaluation/Reference

- Please describe all the studies 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 and PPK analysis.

(2) Clinical studies / analyses for which electronic data submission is planned

① Individual clinical study

Study number (or report number)	Study region	Study population	Study design	Treatment (Dosage and administration), Duration	Sample size of each treatment group	Efficacy / Safety endpoint	Status

- Please describe the summary of design for the study which electronic data submission is planned.
- In the column "Status", please describe the either category; planning, ongoing, or completed.

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② **Integrated analysis, the population analysis or PBPK analysis**

Report number	Objectives	Number of subjects analyzed	Endpoint	Status
	Clinical study synopses included in the analysis			
	Study name	Study population	Dosage and administration	Number of subjects
	Objectives	Number of subjects analyzed	Endpoint	Status
	Clinical study synopses included in the analysis			
	Study name	Study population	Endpoint	Number of subjects

- In the column “Status”, please describe the either category; planning, ongoing or completed.
- In the column “Clinical study synopses included in the analysis”, please fill only "Study name" for the studies which electronic data submission is planned.
- In the case of PBPK model analyses, please fill “Report number”, “Objectives”, and “Status”.

4. Information on the studies (clinical studies, integrated analysis, clinical pharmacological studies and so on) for which electronic data are planned to be submitted conforming to the CDISC standards

(1) Study information which is planned to be submitted as electronic data (Clinical studies which conform to the CDISC standards, describe per study)

In this section, it is acceptable to describe only the information for ongoing or planned at the timing of consultation. However in case the topic regarding CDISC conformance in individual studies is included in the consultation contents, sponsor needs to include as much information as possible in this part.

Information about clinical study
Study number (or report number):
Study design summary:
Data cut-off date (planned date, if the study is ongoing):
Information about the electronic data
CDISC Conformance (SDTM) ☐ Data collection with CDASH format ☐ Data collection with NON-CDASH format and data conversion to SDTM format (Including the planning stage) ☐ Data conversion from NON-SDTM to SDTM format (Including the planning stage) CDISC Conformance（ADaM） ☐ Creating ADaM from SDTM datasets (Including the planning stage) ☐ Creating ADaM from NON-SDTM datasets (Including the planning stage) Analysis datasets used for interim analysis ☐ Submit ☐ Not submit

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Describe the data which are used in CSR but not included in SDTM or ADaM datasets to be submitted:

Standards and those versions used for creating datasets
If the version used at the time of dataset creation differs from that used at the time of dataset validation, please enter the version used at the time of validation in the column "Notes".

Standard	Version	Notes
SDTM SDTM IG		
ADaM ADaM IG		
Define-XML	SDTM : ADaM :	
Controlled Terminology	SDTM : ADaM :	
MedDRA		
WHODD		
(Others)		(Use)

The file format of SDTM and ADaM:
File size of electronic data (total): The total file size in corresponding clinical study.

The dataset planned to be submitted as electronic data (SDTM)						
Definition file	☐Define-XML					
Data guide	☐Study Data Reviewer's Guide					
Data set	Submission Please tick for domains to be submitted. Please do not change the order or delete the domains which are not be submitted.					
TA	☐					
TD	☐					
TE	☐					
TV	☐					
TI	☐					
TS	☐					
Data set	Please tick the most suitable one if the domain is planned to be submitted			Please tick the corresponding one		RELREC
	Efficacy	Safety	Other	SUPP	Including Japanese	Related dataset
CO	☐	☐	☐	☐	☐	
DM	☐	☐	☐	☐	☐	
SE	☐	☐	☐	☐	☐	
SV	☐	☐	☐	☐	☐	
CM	☐	☐	☐	☐	☐	
EC	☐	☐	☐	☐	☐	
EX	☐	☐	☐	☐	☐	
SU	☐	☐	☐	☐	☐	
PR	☐	☐	☐	☐	☐	
AE	☐	☐	☐	☐	☐	
CE	☐	☐	☐	☐	☐	
DS	☐	☐	☐	☐	☐	

DV	☐	☐	☐	☐	☐	
HO	☐	☐	☐	☐	☐	
MH	☐	☐	☐	☐	☐	
DA	☐	☐	☐	☐	☐	
DD	☐	☐	☐	☐	☐	
EG	☐	☐	☐	☐	☐	
IE	☐	☐	☐	☐	☐	
IS	☐	☐	☐	☐	☐	
LB	☐	☐	☐	☐	☐	
MB	☐	☐	☐	☐	☐	
MI	☐	☐	☐	☐	☐	
MO	☐	☐	☐	☐	☐	
MS	☐	☐	☐	☐	☐	
PC	☐	☐	☐	☐	☐	
PP	☐	☐	☐	☐	☐	
PE	☐	☐	☐	☐	☐	
QS	☐	☐	☐	☐	☐	
RP	☐	☐	☐	☐	☐	
RS	☐	☐	☐	☐	☐	
SC	☐	☐	☐	☐	☐	
SS	☐	☐	☐	☐	☐	
TU	☐	☐	☐	☐	☐	
TR	☐	☐	☐	☐	☐	
VS	☐	☐	☐	☐	☐	
FA	☐	☐	☐	☐	☐	
SR	☐	☐	☐	☐	☐	

The dataset planned to be submitted as electronic data (ADaM) Please fill in the dataset name and the contents in the column.	
Definition file	☐Define-XML Submission of Analysis Results Metadata ☐Submit ☐ Included in Define-XML ☐ Other ( ) ☐Not submit
Data guide	☐ Analysis Data Reviewer's Guide
Dataset	Contents of the dataset
Submission of ADaM creation program ☐Submit ☐Not submit (The reason:)	
The dataset planned to be submitted as electronic data (Other)	
Annotated CRF	☐Submit ☐Not submit

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Information about conformity of the electronic data to the CDISC standards (Validation report attachment is acceptable)	
SDTM	
Validation tool and version:	
Remarks about conformance - Please describe the CDISC (SDTM) conformance	
Dataset	Contents
ADaM	
Validation tool and version:	
Remarks about conformance - Please describe the CDISC (ADaM) conformance	
Dataset	Contents

Analysis information

Submission of analysis programs

☐Submit with macro code

☐Programs are submitted, but the macro code are not submitted (The reason:)

☐Submit the specification including the analysis algorithm

☐Not submit (The reason:)

☐Submit the specification including the analysis algorithm

☐Other ( )

Software used in the analysis

In case different software were used among the programs, please specify the corresponding software for each program.

Software name (version) :

Software execution environment (operating system, version):

(2) Study information which is planned to be submitted as electronic data (integrated analysis)

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

If the dataset used for integrated analysis is different from the individual analysis in each study (e.g. data cut-off date), please also describe using the form on 4-(1)

Objective of analysis and the information of subject population

Objective of analysis:

Information about clinical studies which is included in the analytical data set

Study number (or report number)	Objective	Attachment number

Information about the electronic data

Standards and those versions used for preparing datasets

If the version used at the time of dataset creation differs from that used at the time of dataset validation, please enter the version used at the time of validation in the column "Notes".

Standard	Version	Notes
SDTM SDTM IG		

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ADaM ADaM IG		
Define-XML	SDTM: ADaM:	
Controlled Terminology	SDTM: ADaM:	
MedDRA		
WHODD		
(Other)		(Use)
File size of electronic data (total):		
The dataset planned to be submitted as electronic data		
SDTM	Dataset: Definition file ☐Define-XML Data guide ☐Study Data Reviewer's Guide	
ADaM	Dataset: Definition file ☐Define-XML The Analysis Results Metadata ☐Submit ☐ Included in Define-XML ☐ Other ( ) ☐Not submit Data guide ☐Analysis Data Reviewer's Guide	
(Other)	Dataset (contents): ( )	
Information about the conformity of electronic data to the CDISC standards (Validation report attachment is acceptable.)		
SDTM		
Validation tool and version:		
Remarks about conformance - Please describe the CDISC (SDTM) conformance		
Dataset	Contents	
ADaM		
Validation tool and version:		
Remarks about conformance - Please describe the CDISC (ADaM) conformance		
Dataset	Contents	
Analysis information		
Submission of analysis program ☐Submit with macro code ☐Program is submitted, but the macro code is not submitted (The reason:) ☐Submit the specification including the analysis algorithm ☐Not submit (The reason:) ☐Submit the specification including the analysis algorithm ☐Other ( )		

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Software used in the analysis Software name (version) : Software execution environment (operating system, version):

(3) Study information which is planned to be submitted as electronic data (Clinical pharmacology, Standard pharmacokinetic analysis)

In this section, please describe the information on standard pharmacokinetic analysis within clinical pharmacology per study number (or report number). If multiple considerations are taken in a study (or report), it is acceptable to describe the information per each purpose. In addition to this section, describe the information related to CDISC conformance into section 4. (1). It is acceptable to describe only the information for ongoing or planned at the timing of consultation. However if the consultation contents include the special topic on the datasets or other files to be submitted, sponsor needs to include as much information as possible in this part.

Information about clinical study
Study number (or report number):
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 and so on, where the results on pharmacokinetics or pharmacokinetics/pharmacodynamics provide a major evidence for the dosage and administration ☐Clinical pharmacology studies for children ☐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 (as stated below)

Information about the electronic data		
Analysis dataset planned to be submitted in clinical pharmacology area For the column “Dataset”, please fill with ADaM dataset name if submitted data format is ADaM format, otherwise please leave blank.		
Dataset	Contents of the dataset	File format

Analysis information
Software used in the analysis Software name (version) : Software execution environment (operating system, version):
Submission of analysis program ☐Submit with macro code ☐Program is submitted, but the macro code is not submitted (The reason:) ☐Submit the specification including the analysis algorithm ☐Not submit (The reason:) ☐Submit the specification including the analysis algorithm ☐Other ( )

Submission of analysis specification or corresponding information ☐Submit ☐Analysis specification (PDF format) ☐Information corresponding to analysis specification (document name, file format:) ☐Text Output of Phoenix Projects (*.phxproj) ☐Other ( ) ☐Not submit (The reason:)
Information on dataset
Submission of dataset definition file ☐Submit ☐Define-XML ☐PDF format ☐Other ( ) ☐Not submit (The reason:)

(4) Study information which is planned to be submitted as electronic data (Clinical pharmacology, Population pharmacokinetic analysis)

In this section, please describe the information on population pharmacokinetic analysis within clinical pharmacology area per study number (or report number). If multiple considerations are taken in a study (or 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. However in case the consultation contents include the special topic on the dataset or other files to be submitted, sponsor needs to include as much information as possible in this part.

Objective of analysis and the information of subject population		
Study number (or report number):		
Objective of analysis:		
Information about clinical studies which is included in the analysis dataset		
Study number (or report number)	Objective	Attachment number
Information about the electronic data		
File format of analysis dataset:		
File size of electronic data (total):		
Analysis information		
Software used in the analysis Software name (version) : Software execution environment (operating system, version):		
The model files planned to be submitted Please describe following information (1) to (3) for each model if multiple final model to be submitted. The content of the model file: (1) Base model ☐Submit File format ☐ASCII format ☐Other ( ) ☐Not submit (The reason:)		

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(2) Final model ☐Submit File format ☐ASCII format ☐Other ( ) ☐Not submit (The reason:) (3) Other model ☐ Submit (Content:) File format ☐ASCII format ☐Other ( ) ☐Not submit
Software used for simulation Software name (version): Software execution environment (operating system, version):
Submission of programs used in simulation ☐Submit (Fill in following contents if necessary) Detail: File format ☐ASCII text format ☐Other ( ) Submission of program procedures for simulation ☐Submit ☐Not submit (The reason:) ☐Not submit (The reason:) ☐ Submit the specification including the analysis algorithm
Information on the output
(1) Submission of result files (NONMEM result file, etc.) ☐Submit ☐Not submit (The reason:) (2) Submission of other files（e.g. files on simulation based on population analysis） ☐Submit (Fill in following contents if necessary) Detail: ☐Not submit
Information on dataset
Submission of dataset definition file ☐Submit ☐Not submit (The reason:)

(5) Study information which is planned to be submitted as electronic data (Clinical pharmacology area PBPK model analysis)

In this section, please describe the information on PBPK model analysis within clinical pharmacology area per study number (or report number). If multiple considerations are taken in a study (or report), please describe the information per each purpose. Please describe only the information for ongoing or planned at the timing of consultation. However in case the consultation contents include the special topic on the dataset or other files to be submitted, sponsor needs to include as much information as possible in this part.

Information about analysis
Study number (or report number)

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Objective of analysis: ☐Prediction of drug interactions ☐Drug development for children ☐Estimation of pharmacokinetic for special group (e.g., subjects with hepatic or renal impairment) ☐Other (as stated below)
Software (version): Software execution environment (operating system, version):
Information about the electronic data
Files planned to be submitted ☐Files containing the structure of PBPK model constructed (file format:) ☐Files containing the parameter (e.g., pharmacokinetic parameters and physiology parameters) used in analysis (File format:) ☐Files containing the clinical study design simulated (file format:) ☐Files containing the information about sensitivity analysis (file format:) ☐Files containing the analysis results (file format:) ☐Other (as stated below) Type: (File format:)
Electronic data file size (total):
Information on clinical study data
Submission of data of clinical pharmacology study used in PBPK model analysis ☐Submit Submission of dataset ☐Submit (Describe in each study) Detail: ☐Not submit (The reason:) ☐Not submit
Purpose of use: File format of dataset: Submission of dataset definition file ☐Submit ☐Not submit (The reason:)

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