Provisional Translation (as of April 2019) *

(Attachment 8-2)

Supporting Document on Consultation on Exemption of Submission of Electronic Study data

The contents to be described in the material for application of consultation on exemption 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. In addition, regarding electronic data are expected to be submitted in another format than the CDISC standards, items in the following section 5 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)
With designation as orphan drug or not
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

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 for which electronic data submission is planned

(3) Clinical studies/ analyses which applicants desire to be exempt to submit electronic study data

Describe the timing of conduct of studies and analyses which applicants desire to be exempt to submit electronic study data, according to the "Basic Principles on Electronic Submission of Study Data for New Drug Applications" and the "Question and Answer Guide Regarding the Basic Principles on Electronic Submission of Study Data for New Drug Applications".

Regarding orphan drugs, describe which study is expected to be submitted in another format than the CDISC standards.

4. Circumstances of holding data

Describe the process from data acquisition to the current status of holding data, and the content of data including compliance with data standards.

5. Information on the studies for which electronic data are expected to be submitted in another format than the CDISC standards

In this section, please select the form corresponding to the studies to be submitted and describe the information either completed or planned at the timing of consultation.

(1) Study information which is planned to be submitted as electronic data (describe per study)

① Information about clinical study (study number, summary of study design, initiation date)

② Information about the electronic data

- Presence or absence of analysis datasets used for interim analysis
- Data which are used in CSR but NOT included in datasets to be submitted
- Standards and those versions used for creating datasets (MedDRA, etc.)
- File size of electronic data (total)
- Planned submission study datasets, etc.
- Planned submission analysis datasets, etc.

③ 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 in the analysis, and analysis environment

Provisional Translation (as of April 2019) *

Supplementation

Document on Consultation on Exemption 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)	
With designation as orphan drug or not	
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

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

(3) Clinical studies/ analyses which applicants desire to be exempt to submit electronic study data

4. Circumstances of holding data

5. Information on the studies for which electronic data are expected to be submitted in another format than the CDISC standards

(1) ●● study

Information about clinical study		
Study number (or report number):		
Study design summary:		
Initiation date (the date when the first subject was enrolled):		
Information about the electronic data		
Analysis datasets used for interim analysis ☐ Submit ☐ Not submit		
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		

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

(Drug code)		
(Others)		(Use)
File size of electronic data (total): The total file size in corresponding clinical study.		
The study 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 the extension)	Contents	
Definition file of datasets, others		
File name (including the extension)	Contents	
The analysis datasets planned to be submitted as electronic data, etc.		
Analysis datasets		
File name (including the extension)	Contents (corresponding endpoints, analysis, etc.)	
Definition file of analysis datasets, others		
File name (including the extension)	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 etc.):		