Provisional Translation (as of April 2014) *

PMDA/CPE Notification No. 0327003
March 27, 2014

To: As specified in the Appendix separately

From: Takao Yamori, Ph.D.
Director, Center for Product Evaluation of
Pharmaceuticals and Medical Devices Agency

Re: Request for Electronic Clinical Study Data for Pilot Project (FY 2014)

First, we would like to express our gratitude for your understanding and continuous support for the services of the Pharmaceuticals and Medical Devices Agency (PMDA).

PMDA has been making efforts to promote future utilization of electronic clinical study data, with the following details to be included in the third mid-term plan starting in FY 2014: develop a framework for PMDA to enable electronic submission of clinical study data for application of new drugs from FY2016; and improve quality of review and consultation by conducting PMDA-initiated analyses using the clinical study data and by giving indications and advice based on those analyses results. Specifically, PMDA has organized a joint working group with the industry to discuss regulatory and technical issues, and, with the cooperation of your member companies, has introduced a basic system at PMDA and confirmed its feasibility in FY 2013.

Based on these results, in FY 2014, PMDA will be making efforts to issue a basic policy for electronic submission of study data in the near future, and to further examine the content of the succeeding practical notifications. Therefore, further examination is required by actually using the electronic study data to determine the necessary electronic data and to examine the methods for utilizing the electronic data in the regulatory review process.
In this regard, because a pilot project will be conducted again in FY 2014, your member companies are kindly requested to cooperate in providing electronic clinical study data for the purpose of examining the future utilization of electronically submitted data and the regulatory review process.

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Although participation in this pilot project is not mandatory, as in FY 2013, the following electronic data are requested to be provided (see attachment for details). The data that we will be requesting will also be discussed individually in detail with those companies willing to cooperate in this pilot project.

○ Clinical data in conformance to CDISC

1. Data of drug products that are either approved, currently under regulatory review, or scheduled to be reviewed;
2. Data summarized according to the CDISC standards (SDTM and ADaM), and each defined in Define.xml or in a corresponding definition file;
3. Series of datasets from clinical studies that include those of Japanese subjects, along with the analysis program.

○ Blood concentration data for population pharmacokinetic analysis

1. Data of drug products that are either approved, currently under regulatory review, or scheduled to be reviewed;
2. Data summarized in a format used in the software for population pharmacokinetic analysis, NONMEM;
3. Datasets for population pharmacokinetic analysis that include those of Japanese subjects, along with the main model program.

As in FY 2013, the data submitted for this pilot project will be used only for the purpose of testing the future utilization of electronic study data and the regulatory review process at PMDA, and there will be no influence on the regulatory review of the products concerned.

Specific requests for cooperation will be made individually to your member companies at a later date. However, we would appreciate it if you contact us at the below e-mail address by Thursday April 17 if there are any member companies offering to participate in this pilot project regardless of our request.
Any inquiries about this project may also be directed to the e-mail address below.

We appreciate your understanding regarding this pilot project and your support in requesting your member companies for cooperation. Thank you.

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Contact:
E-mail: electronicdata@pmda.go.jp
Task Force for Advanced Review and Consultation with Electronic Data
Pharmaceuticals and Medical Devices Agency

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(Attachment)

Details of the Electronic Clinical Data to be submitted

○ Clinical data in conformance to CDISC

- Target products
  - New drugs (including follow-on biologics) that are either approved, currently under regulatory review, or scheduled to be reviewed by September 30, 2014.

-Target studies
  - Clinical studies (phases II and III) that include data of Japanese subjects and that indicate the main evidence supporting the efficacy, safety, and dosage and administration in the application data. More than one study per one application (if possible, please submit data from multiple studies included in the application data package).

-Data standard to be used
  - Data should be in conformance with the Clinical Data Interchange Standards Consortium (CDISC) standards
  - As a principle regarding data coding, controlled terminology and code lists recommended by the CDISC are to be used, and the values are to be in SI units.

-Target clinical study data
  - Clinical study data summarized using Study Data Tabulation Model (SDTM) and its definition files such as Define.XML
  - Analysis datasets summarized using Analysis Data Model (ADaM) and its definition files such as Define.XML
  - Analysis program basically intended for ADaM datasets
  - Program for creating ADaM datasets, if created from SCTM datasets

○ Blood concentration data for population pharmacokinetic analysis

-Target products
  - New drugs (including follow-on biologics) that are either approved, currently under regulatory review, or scheduled to be reviewed by September 30, 2014.

-Target analysis
  - Datasets for population pharmacokinetic analysis of blood concentration data that includes those of Japanese subjects obtained from one or more clinical studies, and that is used in the application data to explain the efficacy, safety, and/or dosage and administration.

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-Analysis data format to be used

- Datasets in the format used in the program for population pharmacokinetic analysis, NONMEM (hereinafter referred to as the NONMEM analysis datasets).

○ Target data for analysis

- Analysis datasets for NONMEM and the definition of variables
- Data measured in the clinical trials but excluded from the population pharmacokinetics analysis should be included in the datasets with the flag indicating exclusion. Program of the primary analysis and output of the analysis result.

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