Provisional Translation (as of June 2016) *

Utilization of Electronic Study Data: Summary Report of Pilot Project in FY 2015

June 30, 2016

- Purpose

  The pilot project was conducted for the following purposes:

  - To confirm that the analysis of the submitted clinical study data for new drugs using introduced software enables the reviewers to obtain the necessary for the review.
  - To consider the utilization of the analysis results in the new drug review process in the actual review situation.
  - To examine the utilization of the electronic clinical study data for efficient inspection way for reliability.

- Submission of Clinical Study Data

  - Companies were requested to cooperate in the provision of available data by September 30, 2015 based on the "Re: Request for Electronic Clinical Study Data for Pilot Project (FY 2015)" (PMDA/CPE Notification No. 1001001, October 1, 2014). Thirteen companies and facilities agreed to participate and submitted CDISC-conformant clinical study data of fourteen products in total, by December 2015. Six companies submitted data of seven products in total for standard pharmacokinetic analysis and population analysis. Six products were used for "1) The pilot conducted under the actual situation of regulatory review using the electronic study data of new drug application submitted during the data receiving period", and eight products were used for "2) The pilot conducted using the electronic study data except for the data corresponding to item 1".
  - Two companies agreed to participate "Physiologically-based Pharmacokinetic (PBPK) model analysis pilot", and submitted study data for PBPK model analysis of one drug product each, therefore two products in total, by November 2015.
  - Interviews were conducted with the applicant companies before the data submission based on the information provided in response to inquiries from PMDA (regarding the details of clinical studies and data, conformance to standards, etc.).

- Details

  The pilot project was conducted from June 2015 to May 2016 by about 190 reviewers, most of whom belonged to areas of clinical medicine, pharmacokinetics, or biostatistics, including directors and deputy-directors of each Office of New Drug. Also, about 20 staff members from the Advanced Review with Electronic Data Promotion Group, including persons in charge of IT.

In addition, about 10 GCP inspectors from Office of Non-clinical and Clinical Compliance conducted this pilot project for efficient inspection for reliability.

- Results and Future Action

  Many reviewers could present, conduct analysis for review and visualize data using the CDISC-conformant data, data for standard pharmacokinetic analysis and population analysis provided. Moreover, some reviewers could determine and analyze information necessary for review.

  The pilot project suggested that the utilization of electronic data allows reviewers to have some information that helps make inquiries to companies clearer and to consider the data from various perspectives.

  This pilot project was conducted based on the review process on the timeline of the actual review (Some products were conducted based on virtually-set timeline). This allowed reviewers to improve their understanding regarding the supposed procedures for the actual review process and the timeline and period for examination and consideration of data analysis results, such as the relationship between review team meetings and the available results of data analysis by reviewers themselves on those meetings.

  Regarding the utilization of electronic data for PBPK model analyses, reviewers who possessed a certain level of understanding in PBPK model and software proficiency could mostly reproduce the results of analyses conducted by companies. This also allowed reviewers to learn the workload for review of PBPK model analyses. Moreover, this enabled reviewers to improve their understanding regarding supposed procedures and period for reviews of PBPK model analyses for the actual new drug reviews.

  We also plan to improve various training options available to reviewers, as training on the CDISC data standards and the use of software will always be required.

- Results and Future Action (Office of Non-clinical and Clinical Compliance)

  Utilization of the CDISC-conformant clinical study data for efficient inspection way for reliability was examined. The office could progress the feasible procedures within actual timeline of document-based assessment and GCP on-site inspection and revise the notification from PMDA “Procedures for Implementation of Document-based Assessment and GCP On-site Inspection for Drug Application” (PMDA Notification No. 0511005, May 11, 2016) [Note: main text of this notification is Japanese], in order to reduce the sponsor’s workload on preparing the documents for the document-based assessment and GCP on-site inspection.