Utilization of Electronic Study Data: Summary Report of Pilot Project in the Second Half of FY 2014

April 22, 2015

● Purpose

The pilot project was conducted for the following purposes:

- To confirm that persons in charge in Pharmaceuticals and Medical Devices Agency (PMDA) are able to obtain the results of analyses necessary for regulatory reviews of new drugs through analyzing clinical study data using selected software in specific procedures.
- To consider the ways to utilize electronic data in the review process.
- To consider how to efficiently implement GCP compliance assessment using the clinical study data.

● Submission of Clinical Study Data

- Companies were requested to cooperate in the provision of available data by September 19, 2014 based on the "Re: Request for Electronic Clinical Study Data for Pilot Project in the Second Half of FY 2014" (PMDA/CPE Notification No. 0822001, August 22, 2014). Three companies agreed to participate and submitted CDISC-compliant clinical study data of one drug product each, therefore three products in total, by October 2014.
- As for the population pharmacokinetics (PPK) datasets, three companies which provided the analysis data for the pilot project in the first half of FY 2014 agreed to utilize the same data in the second half of the pilot project. New datasets for population pharmacokinetics/pharmacodynamics (PPK/PD) analyses were submitted by the same three companies (one drug product from each company) by October 2014.
- 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 October 2014 to January 2015 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, and GCP inspectors from the office of Non-clinical and Clinical Compliance participated in this pilot project.

● Results and Future Action

Many reviewers could present and analyze data using the CDISC-compliant data provided. Moreover, some reviewers could determine and analyze information necessary for review.

Regarding the utilization of electronic data for PPK and PPK/PD analyses, reviewers who possessed a certain level of understanding in population analysis and software proficiency could mostly reproduce the results of PPK or PPK/PD analyses described in CTD.

The pilot project suggested that the utilization of CDISC-compliant data as well as electronic data for PPK and PPK/PD analyses allows reviewers to have some information that helps make inquiries to companies clearer and to consider the data from various perspectives.

In this pilot project, the timing and the utilization policy of various analyses in the review process were adjusted to a certain degree. However, it is considered necessary to confirm the review process on the timeline of the actual review, which will be considered in the upcoming pilot project in FY 2015.

We continue to deal with issues dependent on commercial software specifications by communicating with vendors and other means.

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.

We will continue our discussions on the ways for efficient implementation of GCP compliance assessment.