Provisional Translation (as of April 2014) *

Utilization of Electronic Study Data: Summary Report of Pilot Project in FY 2013

March 27, 2014

● Purpose

To confirm that the submitted clinical study data of new drugs for regulatory review can be stored and managed appropriately in the Pharmaceuticals and Medical Devices Agency (PMDA) system and that the persons in charge are able to conduct analysis using the introduced software. To confirm the feasibility of utilizing the clinical study data in PMDA.

● Submission of clinical study data

- Based on the “Re: Request for Electronic Clinical Study Data for Pilot Project" (PMDA/CPE Notification No. 0902001, September 2, 2013), companies were requested to cooperate in September 2013 in the provision of available data. From the five companies that offered to cooperate, clinical study data on five drug products, one from each company, were submitted by December 2013.
- Before submission of data, interviews were conducted with the companies based on the information that was provided regarding the confirmation items that PMDA had inquired about in advance (target drug products considered for data submission, details of clinical studies and data, conformance to standards, etc.).

● Details

From January to February 2014, the pilot project was conducted by about 80 reviewers, mostly persons in charge in the areas of clinical medicine, clinical pharmacology, and biostatistics, and about 20 staff from the Task Force for Advanced Review and Consultation with Electronic Data, including persons in charge of IT.

● Results

In the 2013 pilot project conducted for the purpose of confirming feasibility, no problem was seen regarding data storage and management within PMDA, and the actual analysis was confirmed to be feasible for the reviewers, mainly for the

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persons in charge in clinical medicine, clinical pharmacology, and biostatistics, who meet a certain level regarding knowledge of datasets and software.

Substantial training will be planned for the reviewers, and the pilot projects in the next fiscal year and thereafter will examine the process of regulatory review for when data submission becomes mandatory. In order to handle data for multiple drug products at PMDA, the conformance level to data standards must be kept high, and therefore, preparation of basic and technical notifications along with communications with industries is necessary.

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