Provisional Translation (as of September 2013) [*]

PMDA/CPE Notification No. 0902001
September 2, 2013

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

First, we would like to express our gratitude to all of your support.

In recent drug development, the use of data-based quantitative information such as those using modeling and simulation (M&S) methods has been proactively promoted in decision-making process. Under such circumstances, the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as PMDA) recognizes the need for accumulating electronic study data, analyzing the data by advanced methods, and making use of the data in the process of its reviews and consultations. The use of such accumulated data is expected to reduce the workload of regulatory submission for sponsors, improve PMDA's evidence-based reviews and consultations, and lead to development of new guidelines, which will eventually result in the rise of the success rate of drug development.

In order to promote utilization of submitted electronic study data in the future, PMDA internally set up the Project for Constructing the Framework for Utilizing Electronic Study Data, and organized a joint working group with the industry to discuss regulatory and technical issues. It is planned to develop a basic system and confirm the feasibility of the system by the end of this fiscal year.

In this regard, your member companies are kindly requested to provide electronic clinical study data to PMDA so that the Agency may test the feasibility of the system. Participation in this

[*] 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.

pilot project is not mandatory and the details will be informed later, but PMDA will need, for example, the data that meet the following three criteria for this feasibility test:

1. data of drug products that are under regulatory review or going to be filed to PMDA;
2. data amassed and summarized according to the CDISC standards (prepared because of planned submission to the US Food and Drug Administration, or other reasons), and;
3. clinical study data including those of Japanese subjects

Please note that the electronic data provided for this pilot project is used only for the purpose of testing the system feasibility (check of the system's operational capability, data compatibility with software tools, etc.) and there will be no influence on regulatory review of the concerned products.

PMDA will contact your member companies individually with more specific plan at a later date to ask for cooperation on this pilot project. However, your member companies that are willing to participate in this pilot project, even before PMDA contacts them individually, are encouraged to contact us at the e-mail address stated below by the end of September 2013. Also, if you have any inquiries on this pilot project, please contact us at the e-mail address below.

It would be appreciated very much if you could understand this matter and take time in your busy schedule to ask for cooperation from your member companies. Thank you very much again for your cooperation in advance.

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

(Appendix)

President of the Japan Pharmaceutical Manufacturers Association
Japan Representative of the Pharmaceutical Research and Manufacturers of America
Chairman of the European Federation of Pharmaceutical Industries and Associations, Japan