Provisional Translation (as of April 2014) *

Outline of Execution Plan of the Pilot Project in FY 2014 (draft)

March 27, 2014

○ Purpose

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;
And to confirm that the data for population pharmacokinetic analysis can be stored and managed appropriately with in-house system, and that persons in charge are able to analyze the stored data by utilizing introduced software.

○ Target studies

- CDISC compliant data

  Clinical studies (phases II and III) of new drugs (including follow-on biologics) that include those of Japanese subjects and that are either approved, currently under regulatory review, or scheduled to be reviewed in Japan by September 30, 2014. More than one study per one application.
- Data for population pharmacokinetic analysis

  Datasets for population pharmacokinetic analysis of blood concentration data that include those of Japanese subjects obtained from one or more clinical studies on new drugs (including follow-on biologics) and that are either approved, currently under regulatory review, or scheduled to be reviewed in Japan by September 30, 2014.

○ Period (tentative)

April 2014 – September 2014

Data collection: April – May 2014
Analysis: June – September 2014

○ Implementation Details

- CDISC compliant data

  - Confirm CDISC conformance of the submitted clinical study data.

* 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.

- Confirm that by using the data visualizing/exploratory analysis software, certain study results which are generally reported in application (distribution of background factors, results of primary and secondary efficacy endpoints, occurrence of adverse events, etc.) can be obtained.
- Confirm that by using the statistical analysis software, the results of primary endpoints and other useful results for the review can be obtained. Confirm the details of the analysis program, if submitted, and conduct analysis based on those details to confirm the results.
- Examine the extent of analysis feasible in the review process; estimated workload; and utilization of the analysis results for future review process.

➢ Data for population pharmacokinetic analysis

- Confirm that the clinical study data for the analysis using population pharmacokinetic analysis software "NONMEM" can be stored and managed appropriately with in-house system, and that persons in charge can access those data.
- Confirm that the reviewers can analyze the submitted data by using "NONMEM".
- Confirm that by using "NONMEM", the primary analysis regarding pharmacokinetics which are planned and performed in the clinical trial can be re-analyzed and the results can be obtained based on the information of analysis program.

○ Persons in charge

Includes persons in charge of the project, and reviewers from the reviewing office of each drug product whose clinical study data were submitted.