Provisional Translation (as of August 2014) *

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

August 22, 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 consider the utilization of the electronic clinical study data for conformity inspection.

○ 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 December 31, 2014. More than one study per one application.

○ Period (tentative)

September 2014 – February 2015

Data collection: September – October 2014
Analysis: November 2014 – February 2015

○ Implementation Details

- CDISC compliant data

  - Confirm CDISC conformance of the submitted clinical study data.
  - 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.
- Examine exploratorily the utilization of the electronic clinical study data for conformity inspection by checking the electronic data in some clinical studies, which are submitted during this pilot project time, using the data visualizing/exploratory analysis software.

○ Persons in charge

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