Outline of execution plan of the pilot project in FY 2013 (draft)

9/1/2013

○ Purpose

To confirm the clinical data submitted as a part of approval application for new drugs is appropriately stored and managed with in-house system and persons in charge can analyze the stored data by utilizing introduced software.

○ Data to be used

Clinical data including those of Japanese subjects, which was amassed according to the CDISC standards, and are under regulatory review or going to be filed to PMDA (more than 1 clinical study per 1 product, around 3 products)

○ Period (tentative)

From October 2013 to March 2014

Data collection: October - December 2013

Data analysis: January - March 2014

○ Content of implementation

- Confirm that the submitted clinical data is appropriately stored and managed, and appointed reviewers can access the data.
- Confirm that the submitted clinical data is amassed according to the CDISC standards.
- Confirm that the data could be converted to suitable formats depending on software to use.
- Confirm that the features of subject population and each endpoint can be recognized visually and subgroup analyses by major factors can be performed through the use of the browser/exploratory data analysis software.
- Confirm that the primary analyses of primary endpoints that were planned and conducted in the clinical studies and subgroup analyses by the major factors can be performed through the use of the statistical analysis software. When analysis programs are submitted with the data, confirm the content of the programs and the results by conducting the analyses according to the programs.
- Confirm that other introduced software can be used for the submitted clinical data.

○ Persons in charge

Persons in charge of this project and reviewers in charge of product review of submitted clinical data.