

Concept Paper (Final)

Research Project on ethnic factors in clinical data from three countries China-Japan-Korea Working Group on Drug Clinical Trials

1. Introduction

In 2007 three Health Ministers from China, Japan and Korea agreed to cooperate to enhance Clinical Trials in the Countries. In their meeting on Dec.17, 2009, the responsible Director-Generals (DGs) from the three countries' drug regulatory authorities, i.e. SFDA, KFDA and MHLW/PMDA agreed to establish Working Group on Drug Clinical Trials (WG) to further advance the cooperation. The DG meeting tasked the WG to implement two projects: (1) Research on ethnic factors in clinical data from three countries, and (2) information on drug clinical trials. The establishment of the research project reflects the fact that the ethnic factors in clinical data are one of the crucial issues in today's global drug development.

The DGs decided that Japan should coordinate the research project and formulate its concept paper. This concept paper of the research project delineates the details and the plan of the project.

2. Research Group, its Membership and Group Coordinator

(1) Research Group

In order to pursue the research project on ethnic factors, Research Group on Ethnic Factors (RG) is established as a subsidiary body of WG. RG is a scientific discussion group among experts for making a proposal to WG and is not a decision-making body.

(2) RG members

Each country nominates up to 6 experts, who are specialized in the evaluation of ethnic factors. Those experts include reviewers who are involved in review of Multi-regional clinical trials in regulatory authority and scientists working in ethnic difference area from the academia and the industry. One of them is designated as the country's Principal Researcher (PR). One member from the regulatory authority is designated as a contact point for each country.

(3) Group Coordinator

As the coordinating party of the project, an expert from Japan serves as coordinator.

3. Objective of the Research Group (RG)

RG itself does not conduct any co-operative experiment. The mission of the RG is to make scientific discussion to achieve the objective of research on ethnic factors in Drug

clinical Trial data from three countries, described in WG Terms of Reference.

RG will submit a written report on the outcome of the discussion to WG and DG.

4. Methods and timeline of the Research Group

Methods and timeline of RG will be discussed and determined in RG.

Annex shows the Methods and Timeline determined by RG.

Annex

(1) Methods

- a. RG Coordinator coordinates the RG activities.
- b. One designated RG member from each country serves as the contact point of the country.
- c. RG members lead the internal discussion in the country.
- d. RG conducts their work by using telecommunication (teleconferences, e-mails, Webex etc.) as well as a face-to-face meeting held when necessary.
- e. RG members can submit material for discussion to RG for discussion.
- f. RG members can conduct research (wet and/or dry study) on their own or in cooperation with other RG members and submit the outcome to RG.
- g. RG discussion can include the following items, but is not limited to them;
 - Evaluation of data/material for discussion
 - Existence and magnitude of ethnic factors in clinical data
 - Implication of ethnic factors in clinical development and drug review.

(2) Timeline

- a. by December 2010, RG agrees on Methods and Timeline
- b. till fall 2011 (DG/WG meetings in Japan) RG continues discussion with telecommunication and possibly with face-to-face meetings
- c. in the DG/WG meetings in Japan held in fall 2011, RG makes a interim report to WG and DG.
- d. RG continues activities after DG/WG meetings in Japan in fall 2011.

• Document History

Adopted by the 3rd DG Meeting on September 13th, 2010. RG added the annex on December 28, 2010, confirmed by DG meeting.