

Terms of Reference

China-Japan-Korea Director-General Meeting on Pharmaceutical Affairs Working Group on Drug Clinical Trials

1. Objective

China-Japan-Korea Director-General Meeting on Pharmaceutical Affairs (hereafter, DG meeting) establishes the Working Group (hereafter, WG) to perform substantive works regarding the following two projects;

- (1) research on ethnic factors in drug clinical trial data from three countries
- (2) information exchange on drug clinical trials

Projects can be added by the agreement of the three countries.

WG shall also carry out preparatory works for the DG meeting.

2. Research on Ethnic Factors in Drug Clinical Trial Data from Three Countries

(1) Objective

Ethnic factors in drug clinical trial data from three countries shall be evaluated primarily in terms of PK (and PD, if possible). Especially ethnic differences between ethnic groups in Asia shall undergo analysis. Based on the results, the possibility of sharing drug clinical trial data from three countries will be considered.

(2) Implementation

- Japan coordinates this project. The work plan and implementation of the project shall be reported by WG to DG meeting, and shall be initiated upon consensus among three countries.
- Each country designates its principal researcher and registers him/her to WG. The researchers conduct the study in each country in cooperation with the other countries' principal researchers.
- The principal researchers will report their progress to WG.
- Working group can establish a Research Group as a subsidiary body. Research Group is a scientific discussion group among experts for making a proposal to Working Group and is not a decision-making body.

3. Cooperation on Information Exchange on Drug Clinical Trials

(1) Objective

To exchange information on drug clinical trials for regular exchange and ad hoc exchange.

(2) Implementation

- Korea coordinates this project.
- Three authorities will exchange information on drug clinical trials according to the agreement on the scope of the information. This scheme does not hamper any of the

three authorities from providing information of any kind to other authorities on voluntary basis. Information will be exchanged between authorities. Authorities will share the information with each industry.

4. Procedures on WG

(1) Meetings

WG face-to-face meetings will be held at least once a year. One meeting should be held right before the DG meeting. Other meetings may be held as necessary, including teleconference. WG reports to DG meetings.

(2) Chair, proceedings, etc.

- The regulatory authority of the host country chairs the meeting.
- The chair summarizes the progress of the two projects, and reports it to the DG meeting.
- The chair makes the minutes for each meeting.
- WG Meetings are closed to the public.
- Host country coordinates the preparation of the meeting regarding the venue, documents, etc.
- Documents shared among WG participants as well as the records of WG are written in English

5. Participants

The three countries shall participate in WG on equal footings within 10 members. The WG consists of regulatory and industry representatives and, if necessary, academic experts. Each regulatory authority should make Confidentiality Agreement with the industry and academic experts from each country.

6. Cost

- Participants are responsible for their travel to and from the meeting site, their accommodations and per diem costs.
- The host country is responsible for the cost related to the infrastructure (e.g. conference rooms) of the meeting.

• Document History

Adopted by the 2rd DG Meeting on December 18th, 2009.

Adopted by the 3rd DG Meeting on September 13th, 2010(revised).