APEC Harmonization Center
- Recent Updates -

November 9, 2010

Sun Hee Lee, Ph.D.
Director General of Drug Evaluation Department
Korea Food & Drug Administration
I. APEC Harmonization Center- An Overview
II. 2010 Multi-Regional Clinical Trials Seoul Workshop
III. Korea-China-Japan Tripartite Activities
IV. Future Plans
APEC Harmonization Center- An Overview

[Vision and Goals of AHC]

“Establishment of the Best Harmonization Model”

- Providing access to the **best practices and guidelines**
- Promoting **collaborative actions & information-sharing activities**
- Supporting clinical trials that meet **international standards**
- Enhancing the **quality, safety, and efficacy** of therapeutic products
2010 Multi-Regional Clinical Trials Seoul Workshop

- Date: September 13-15, 2010
- Title: 2010 Multi-Regional Clinical Trials Seoul Workshop - highlighting Korea-China-Japan Tripartite Symposium
- 382 participants from APEC and Non-APEC region, including
  - More than 40 experts invited as speakers and panelists
  - 13 delegates from APEC travel-eligible economies
2010 Multi-Regional Clinical Trials Seoul Workshop

• **DAY 1**
  Session 1: Study Design of Multi-Regional Clinical Trials
  Session 2: Operational Aspects of MRCT

• **DAY 2**: Korea-China-Japan Tripartite Symposium
  Session 3: Korea-China-Japan Cooperative Research on Ethnic Factors
  Session 4: Korea-China-Japan Regulation & Expectations on MRCT

• **DAY 3**
  Session 5: Case Study: Oncology
  Session 6: Panel Discussion
1. Intrinsic vs. Extrinsic Factors in MRCT

2. Data Quality
   1) Regional Differences in Data
   2) Common Review template

3. Ethnic Factors
4. Introducing outstanding MRCT centers
5. Technical Issues
   • Reference drugs, appropriate trial endpoints, etc.
6. Future Cooperation in MRCT
Korea-China-Japan Tripartite Activities - Background and Progress

• Background
  Agreement on mutual cooperation to promote clinical trials by Health Ministers of Korea, China and Japan (2008)

• Director General Level Meeting on pharmaceutical affairs
  – Joint Research on Ethnic Factors
  – Exchange the information of clinical trials
  – 1st in Tokyo, Japan (2008), 2nd in Beijing, China (2009), 3rd in Seoul, Korea (September, 2010)

• Working Group Meeting (from 2009)
  - Regulatory Authority, Industry & academia
Results: Korea-China-Japan Tripartite DG meeting 2010

1. Finalization of Documents
   • Report on the progress in Korea-China-Japan Director-General Level Meeting since 2008.
   • Terms of Reference on the Tripartite Working Group

2. Concept Paper on the Research on Ethnic Factors in Drug Clinical Trial Data of Three Countries

3. Concept Paper on the Information Exchanges on Drug Clinical Trial Area
4. Proposals for the tripartite pharmaceutical area
   • Documentation will be provided by proposed the regulatory authorities

5. Information Sharing
   • The ToR on the WG will be open to the public

6. Discussion on the plan for the next meeting
   • The next meeting will be at Tokyo, Japan (fall 2011).
Next Steps – Future AHC Workshop Plans

- AHC workshop plans in 2010
Next Steps – Future AHC Workshop Plans

• AHC workshop plans in 2011
  – Endorsed in principle

1. Workshop co-hosted by KFDA, IFPMA, DIA in April

2. Workshop on Medical Devices, GHTF Implement

3. On discussion
Thank You for Your Attention

www.apec-ahc.org