

APEC Harmonization Center - Recent Updates -

November 9, 2010

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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

2010 Multi-Regional Clinical Trials Seoul Workshop – Issues Discussed

1. Intrinsic vs. Extrinsic Factors in MRCT
2. Data Quality
 - 1) Regional Differences in Data
 - 2) Common Review template
3. Ethnic Factors

2010 Multi-Regional Clinical Trials Seoul Workshop – Issues Discussed

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

Korea-China-Japan Tripartite Activities 2010- Results

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

APEC Harmonization Center

2010 AHC WORKSHOP ON MEDICAL DEVICES

USE OF CLINICAL EVIDENCE

IN THE MEDICAL DEVICE PREMARKET CONFORMITY
ASSESSMENT PROCESS

- ✓ Date : 15(Mon)-16(Tue) November
- ✓ Venue : Ritz-Carlton Hotel Seoul
- ✓ Hosted by : Korea Food and Drug Administration (KFDA)
- ✓ Organized by : Korea Health Industry Development Institute (KHIDI)
- ✓ Supported by : APEC Life Sciences Innovation Forum (LSIF)

MORE INFO. 

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

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