AGENDA

MULTI-REGIONAL CLINICAL TRIALS SEOUL WORKSHOP

– INAUGURAL WORKSHOP OF THE APEC HARMONIZATION CENTER

Day One

Monday, June 15, 2009	
10:30 – 11:00	Registration and Check-in
11:00 – 12:00	**Inauguration Ceremony (Grand Ballroom)**
12:00 – 13:00	**Luncheon (Triangle Foyer)**
13:00 – 13:30	**Welcome and Introduction**
13:30 – 15:00	**Plenary I: The Value and Challenges of Multi-Regional Clinical Trials (Grand Ballroom)** ***Description:*** Large-scale clinical trials, conducted on a global scale, are often the basis for regulatory approval of new drug therapies. While these trials offer access to broad, diverse patient populations, they are not without logistical challenges, including issues related to the quality of trial conduct. Furthermore, the diversity of patients and medical practice patterns open a host of questions on how to interpret trial results and their applicability to both the broad and the specific trial populations. These issues can result in significant debate when it comes to product approval and labeling.
15:00 – 15:30	**Refreshment Break**
15:30 – 17:00	**Plenary II : Intra-Regional Efforts to Streamline the Conduct of Clinical Trials: The Tripartite Initiative and the ASEAN Pharmaceutical Product Working Group (Grand Ballroom)** ***Description:*** There are many differences within and between regions that can have an impact on the conduct and design of clinical trials. Recognizing that Asia has been rapidly gaining importance as a venue of world wide drug development, the Ministers of Health of Korea, Japan, and China have affirmed the significance of *clarifying ethnic factors in clinical data*, in order to facilitate drug development. This session will focus discussion on the clinical concerns leading to the Tripartite Agreement entered into by the Ministers of Health for Korea, Japan, and China, and the resulting work plan intended to resolve some of these concerns. This session will also serve to provide an update on the ASEAN Pharmaceutical Product Working Group and its efforts to harmonize compliance requirements in the conduct of clinical trials within the ASEAN region.
	Short Break – Please remain seated
17:00 – 18:30	**Plenary III: ICH: Overview and Recent Developments (Grand Ballroom)** ***Description:*** ICH has produced an extensive series of guidelines that together provide a solid framework for guiding drug development and registration. A

	proper understanding of ICH guidelines is essential to ensuring the appropriate design, conduct, monitoring and assessment of clinical trials that meet the expectations of regulatory bodies. In addition to defining an international standard for GCP (E6), ICH guidelines address trial design (E8), statistical considerations (E9), choice of controls (E10) and special populations (E7 and E11). The development of the CTD has also been important in structuring information in a consistent format within marketing applications, thereby providing a basis for enhanced regulatory communication
18:30 -	**Opening Night Reception (Hosted by KFDA-Diamond Hall)**

Day Two

Tuesday, June 16, 2009	
8:00 – 8:30	**Registration**
8:30 – 10:30	**Plenary IV: Multi-Regional Clinical Trial Design Issues that Clinical Researchers Should Understand in Order to Succeed (Grand Ballroom)** ***Description:*** Multi-regional trials pose important statistical challenges with regard to study design, appropriate methods of analysis, and interpretation of results. This session will consider aspects such as the importance of a quality protocol, issues of study design including challenges and opportunities involving endpoint selection, choice of appropriate analysis methods, presentation of trial results, investigation of the level of consistency of results across regions, and the implications of trans-cultural factors on these issues.
10:30 – 11:00	**Refreshment Break**
11:00 – 12:00	**Plenary V: Operational Aspects (Grand Ballroom)** ***Description:*** This session will cover the importance of planning and implementation aspects for Multi-Regional trials, training and certification of institutions, investigator sites, investigators and staff, Good Clinical Practice, Quality Assurance (Monitoring/QC/Audits of sites); Data Management issues, CRO interfaces, etc…
12:00 – 13:00	**Luncheon**
13:00 – 15:00	**Plenary VI: Regulatory Guidance/Perspectives/Issues (Grand Ballroom)** ***Description:*** Regulatory Agencies within APEC will discuss their views on the *implementation* of ICH clinical guidelines, including adaptations of those guidelines. Topics relevant to this session include implementation of ICH E5, placebo-controlled trials, and other clinical aspects of drug development. This session will also present the perspective of industry on challenges to international clinical development.
15:00 – 15:30	**Refreshment Break**

15:30 – 17:30	**Breakout Sessions (Grand Ballroom)** ***Description:*** The focus of the Breakout Sessions will be to cover selected topics (listed below) in more depth in an interactive setting, where Session Facilitators will provide additional insights into the topics and also invite active participation from the audience to allow for issues to be further discussed. Ideally "value-added" proposals would be identified from the dialogue, such as best practices or recommendations for further action. These ideas will be shared in plenary session with the entire workshop. These reports are also expected to serve as input into the Next Steps parts of the workshop and discussions within the Regulatory Harmonization Steering Committee meeting that follows this workshop. **Session 1: Regional Specific Issues** ***Description:*** Data supporting biopharmaceutical product development have typically been generated from clinical trials conducted in the US, Western European countries, and Japan, with contributions from a few other countries with similarly developed research and development infrastructure and effective regulatory processes. Data from emerging and developing countries have generally been minimal. However, industry is rapidly globalizing product development with increasingly more clinical trials being conducted in the nontraditional regions/countries. While such globalization of clinical trials presents tremendous opportunities, many unique and challenging region-specific issues need to be addressed to allow data generated from one region to be readily usable in another region. This breakout session will discuss these issues, highlighting best practices based on participants' varied experiences. The session will also make recommendations for further action on the more challenging issues. Specifically, the session will focus discussion on region-specific scientific, regulatory and operational issues, among others. **Session 2: Site Management, Data Management and Good Clinical Practice** ***Description:*** Multi-regional trials pose operational challenges including the appropriate site management of centers, data handling and other issues addressed by GCP. This session addresses: ▪ Successful center selection, appropriate training and how to best monitor and control diverse study centers. Guidelines from regulators about minimum criteria for study site quality will be discussed. Recommendations are given as to what types of training are best suited for multinational study centers. ▪ Day-to-day data management issues associated with Multi-Regional trials, specifically, situations around AE and SAE reporting norms, translations and challenges with Pan-Asian trials. ▪ Current ethical issues fundamental to multi-country clinical trials, focusing on attaining practical solutions through audience interaction and discourse.
17:30 – 18:30	**Group Photo Session/ Break**
18:30 -	**Hospitality Reception/ Dinner**

Day Three

Wednesday, June 17, 2009	
8:00 – 8:30	**Registration**
8:30 – 10:00	**Breakout Sessions (Continued – Grand Ballroom)** **Session 3: Multi-Regional Clinical Trial Design Issues that Clinical Researchers Should Understand in Order to Succeed** ***Description:*** This session will provide an opportunity for more in-depth discussion of topics raised during the plenary session, as well as new related topics that the audience would like to bring up. The focus will be on issues related to design and analysis of global trials from a statistical perspective, such as the impact of regional treatment differences on sample size and the interpretation of test/estimation results. This session will also examine the numerous factors that can result in differences in endpoints for different regions, including regional differences in healthcare systems and medical practice, culture, disease prevalence, compliance and perceptions of patients and physicians. Discussions will focus on regional differences, particularly in patient reported outcome (PRO) measures and possible steps to address them. In particular, quantitative and qualitative interactions of treatment and region in terms of PRO measures will be discussed, in addition to potential inconsistency in PRO domain scores. Finally, logistical and statistical approaches to address regional differences in regulatory requirements for endpoints in global programs will be discussed. **Session 4: Specific Therapeutic Areas** ***Description:*** This breakout session will invite the audience to brainstorm about the challenges involved in conducting global clinical trials, using specific examples. Participants will be asked to identify the key scientific, operational, ethical, and regulatory issues that pose hurdles to the success of these trials. The group will then identify current best practices to address these issues and suggest next steps to improve these solutions.
10:00 – 10:30	**Refreshment Break**
10:30 – 11:30	**Plenary- Feedback from Breakout Sessions (Grand Ballroom)**
11:30 – 12:00	**Summary/ Next Steps/ Meeting Adjourned**
12:00 – 13:00	**Luncheon**
13:00 – 15:00	**RHSC (Regulatory Harmonization Steering Committee) Meeting (Grand Ballroom)**
15:00 – 15:30	**Refreshment Break**
15:30 – 18:30	**RHSC Meeting (Grand Ballroom)**
18:30 -	**Dinner**

Day Four

Thursday, June 18, 2009	
8:30 – 10:00	**RHSC Meeting (Grand Ballroom)**
10:00 – 10:30	**Refreshment Break**
10:30 – 12:00	**RHSC Meeting (Grand Ballroom)**
12:00 – 13:00	**Luncheon**
13:00 –	**RHSC Meeting (Closed-Flamingo)** **&** **GMP Pharmaceutical Ware Visit**

Schedule of the 1st AHC Workshop (June 15~18)

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<tr><td></td><td>15 (Mon)</td><td>16 (Tue)</td><td>17 (Wed)</td><td colspan="2">18 (Thu)</td></tr>
<tr><td>8:00 – 8:30</td><td></td><td>Registration</td><td>Registration</td><td colspan="2">Registration</td></tr>
<tr><td>8:30 – 10:00</td><td rowspan="2">RHSC preparatory Meeting</td><td rowspan="2">Multi-Regional Clinical Trial Design Issues that Clinical Researchers Should Understand in Order to Succeed</td><td>Sessions 3 - 4
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- Regional Specific Issues
- Site Management, Data Management and Good Clinical Practice</td><td rowspan="3">RHSC Meeting</td><td rowspan="3">RHSC Meeting</td></tr>
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