

Track

11

The 4th Global Pharmaceutical Key Opinion Leaders (GPKOL) International Symposium 2015

How to Design and Conduct Global Clinical Trials for Drugs

PHARM FAIR 2015

April 9(Thu), 09:00 ~ 16:30 / Room.300

The 4th GPKOL International Symposium this year will focus on design and conduct of global clinical trials for pharmaceuticals to help Korean pharmaceutical companies to develop products with global commercial potential. Experts with years of experience in pharmaceutical companies, regulatory authority, and clinical contract research organizations in advanced countries will share their expertise and insights about how to successfully design and conduct global clinical trials. This symposium will serve as a learning as well as networking opportunity for the participating companies with their sights set on going globally.

09:00 ~ 09:30 **Registration**

09:30 ~ 09:40 **Opening Speech**

Kee Taig Jung, President, Korea Health Industry Development Institute(KHIDI), Korea

09:40 ~ 09:45 **Congratulatory Address**

Kyung Ho Lee, President, Korea Pharmaceutical Manufacturers Association(KPMA), Korea

09:45 ~ 09:50 **Introduction**

Dr. Harry Shin, Korea Health Industry Development Institute(KHIDI), Korea

Keynote Speech

09:50 ~ 10:30 - Overview of Clinical Development

- Preclinical Trial Strategies for Successful Clinical Development

Dooman Alexander Oh, Akros Pharma, USA

SESSION 1. DEVELOPING CLINICAL TRIAL STRATEGIES FROM THE SPONSOR'S PERSPECTIVES 10:35 ~ 12:05

SESSION CHAIR **Dr. Harry Shin**, Korea Health Industry Development Institute(KHIDI), Korea

10:35 ~ 11:15 **Clinical Drug Development Based on Modeling & Simulations: A Tool to Increase Return of Investment**

Holly H.C., Ph.D., Kimko, J&J USA, USA

11:15 ~ 11:55 **Challenges and Strategies Entering into Global Clinical Development in US : Tgf Beta Inhibitor**

Jeong-Yong Kim, Ph.D., National Onco Venture, Korea

11:55 ~ 12:05 Q&A

12:05 ~ 12:55 Lunch

SESSION 2. TRENDS IN CLINICAL TRIAL DESIGN AND PROJECT MANAGEMENT

12:55 ~ 14:50

SESSION CHAIR **Dr. Kang Shin-Hong**, JW Pharm, Korea

13:00 ~ 13:40 **Personalized Health Care Including Basket Trials as one of New Methods of Clinical Development**
Hisanori Takanashi, Ph.D., Chugai-pharm Japan

13:40 ~ 14:20 **Successful Project Management of Global/Regional Clinical Trials**
Stephane Gouteux, Director and Head of Asia Oncology for Project Leadership, Quintile's Singapore, Singapore

14:20 ~ 14:30 Q&A

14:30 ~ 14:50 Session Break

SESSION 3. CLINICAL TRIALS FROM REGULATOR'S PERSPECTIVES

14:55 ~ 16:30

SESSION CHAIR **Dr. Han Yong-Hae**, Enzychem, Korea

14:55 ~ 15:35 **How to Design Successful Global Clinical Trials from the Regulator's Perspective**
Sang M. Chung, Ph.D., FDA, USA

15:35 ~ 16:15 **Success and Failure Cases of Global Clinical Trials and How to avoid Failures**
J.Fred Pritchard, Vice President, Global Drug Development, Celerion, USA

16:15 ~ 16:30 Q&A