Overview

With clinical development in Asia growing so rapidly, local regulatory authorities must quickly bring their processes and guidelines up to date and in alignment with the changing clinical trial environment throughout Asia. However, this process has posed a significant challenge not only to regulatory authorities in charge of new product review and approval but to the pharmaceutical industry developing such products. In addition to the increasing workload associated with more precise review, regulatory authorities must work with industry toward more efficient review and approval.

The 11th DIA Asia New Drug Conference in Japan will be held in Tokyo on April 17-18, 2017. In this conference, experts from industry, academia, and regulatory authorities in East Asia will share the latest regulatory updates and experiences regarding the new drug development using multi-regional clinical trials (MRCTs) and provide advice on how to maximize the efficiency and productivity of MRCTs. Another important topic is the newly-introduced ICH E17 guideline. Experts who have contributed to this guideline will explain how it was developed, provide additional updates, and discuss this guideline with you. With proactive pharmacovigilance throughout the product life cycle as the obvious way forward for safety and risk management in Asia, other critical topics include labeling and pharmacovigilance. Although the challenge to standardize pharmacovigilance across the various geographical, cultural and medical practices in Asia remains, cooperation and convergence are indispensable. The emerging ASEAN region is another critical topic this conference will explore. Experts from industry and regulatory authorities in the region will share their experiences and current information about new drug development in the ASEAN region along with advice about how to improve the value and quality of new drugs.

At last year’s DIA Asia New Drug Conference in Japan, experienced speakers from East Asia, including China, actively discussed their current challenges and opportunities. This year, regulators from Asian countries and speakers with varied expertise will discuss how to most appropriately conduct MRCTs in this new era of globalized drug development and life cycle management. Hot topics to catalyze fresh ideas will include the latest regulatory information, more efficient safety management strategies and processes, and the best approaches to MRCTs in Asia including a real-world case study.

The 11th DIA Asia New Drug Conference in Japan promises to be a most exciting opportunity for those seeking to broaden their professional network and learn how to maximize the efficiency and productivity of MRCTs in Asia.

Who Should Attend

The program will benefit those with the following interests:

- Clinical development
- Regulatory affairs
- Clinical study sites
- CROs and SMOs
- Medical affairs and market
- Academic organizations
- Regulatory agencies

Simultaneous Translation Available

Tabletop Exhibit Opportunities Available
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Regulator's Perspective for Drug Development using Asia MRCT (CDE, CFDE)
Siyuan Qian, MD
Senior Reviewer, Associate Chief Pharmacist, Office of Clinical Evaluation II, CDE, CFDA

Regulatory Perspectives of Asian MRCT (T-CDE)
I-Chun Lai, MD
Team Leader, Division of New Drugs, T-CDE

Regulatory Management of NDA and MRCT in Korea
Nam Soo Kim
Deputy Director, Biopharmaceutical Policy Division, Biopharmaceuticals and Herbal Medicine Bureau, MFDS

Review Experiences of Multi Regional Clinical Trials (MRCTs) (Asian Trials)
Nao To
Office Director, Office of New Drug III, PMDA

Industry's Perspective for Drug Development Using Asia MRCT

SESSION CO-CHAIRS
Yoshiko Komuro, PhD
Deputy Review Director, Office of New Drug II, PMDA

Koichi Miyazaki, MSc, RPh
Senior Director, Regulatory Affairs Group, Asia Development Department, R&D Division, Daiichi Sankyo Co., Ltd.

Pharmaceutical companies elaborate a new compound clinical development plan to efficiently confirm safety, efficacy and patient benefit as well as to accelerate the process of bringing the new drug to market as early as possible. Although MRCTs were established as one option for efficient drug development, ethnic factors are an important consideration when planning MRCTs. As a result, East Asian MRCT have recently been attracting close attention because of the small racial and ethnic differences in the region. For successful drug development, it is critically important to anticipate the latest trends in advance. In this session, experienced speakers will describe various development strategies and visions which will be of great benefit as you work to deliver innovative drugs to patients in Asia.

Experiences in Asia MRCT and Future Prospects
Satoshi Miki
Vice President & Board Member / Head of CoE SPEAR (Strategy & Planning for East Asia Region), UCB Japan Co. Ltd.

Industry Perspective on Development by Using Asia MRCT
Shun Jin, MBA
Head, Regulatory Affairs, Asia Pacific, Abbott Laboratories (Singapore) Pte Ltd

Panel Discussion
PANELISTS
All speakers in Sessions 2 and 3

17:30-19:30 NETWORKING RECEPTION
9:50-10:40 SESSION 4
Changes and Benefits ICH E17 Will Bring About

SESSION CHAIR
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, PMDA

The ICH-E17 guideline “General principle on planning/designing Multi-Regional Clinical Trials” is currently under consideration. This guideline suggests pooling some regions at the design stage if subjects in those regions are thought to be similar enough with respect to intrinsic and/or extrinsic factors. East Asia is expected to be effectively utilized as a pooled region given the similarities among countries. This guideline will have important implications in sample size allocation or selecting the region where the clinical study is to be conducted. In this session, speakers from PMDA and industry will present the changes that implementing this guideline will bring about, including changes in drug development strategy and specific examples of wise use of this guideline.

Changes and Benefits ICH E17 Will Bring About
- Regulatory Perspective
  Shuji Kamada
  Reviewer, Office of New Drug V, PMDA

Points to be Considered in Order to Implement E17
Guideline - Industry Perspective
Osamu Komiya
Senior Manager, Regulatory Policy, Regulatory Affairs, Pfizer Japan Inc.

12:00-13:15 LUNCH

13:15-15:30 SESSION 6
Drug Development in China; Recent Regulatory Changes and the Impacts

SESSION CHAIR
Ling Su, PhD
Venture Partner, Lilly Asia Ventures

Since August 2015, under the guidance of the State Council’s “Opinions on the Reform of Drug and Medical Device Review and Approval System,” the CFDA has revealed and implemented a series of measures to reform the regulatory system of China. Its major objectives are to improve the review and approval processes for drugs and medical devices, to encourage innovation, to ensure clinical trial data quality, and to enhance quality of generic drugs. In addition to many regulatory changes, the Drug Administration Law is also under revision. This reform will prove to have broad impact on the pharmaceutical R&D and business in China for both local and multinational companies. In this session, three regulatory experts from different types of enterprises in China and Japan will share their experience and perspectives on the ongoing reform and exchange their opinions with CFDA/CDE speakers in panel discussion.

The Evolving Multi-National Company’s China Development Strategy (tentative)
Janet Lu, MS
Head of Pharma Development Regulatory, Asia Pacific Policy and China, Roche (China) Ltd.

Challenges and Opportunities of Innovative Drug Development in China - A Biotech Company’s Perspective (tentative)
Wendy Yan
Senior Vice President and Head of Regulatory Affairs, BeiGene, Ltd.

Development Strategy Adaptations of Pharmaceutical Companies to China Regulatory Reform -Japanese Industry’s Perspective-
Tetsuomi Takano, RPh
former Astellas Pharma Inc.

Panel Discussion PANELISTS
All speakers in this Session, and
Jianwu Zhang
Principal Staff, Department of Drug and Cosmetics Registration, CFDA
Qingzhu Huang
Staff, Assistant Engineer, Office of Review Management, CDE, CFDA

15:30-16:00 COFFEE BREAK

16:00-17:25 SESSION 7
Development and Management of Strategic Labeling and Risk Management Plans from Asia and the Global Point of View

SESSION CHAIR
Rie Matsui, RPh
Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc.

Labeling and Pharmacovigilance regulations are rapidly changing and various efforts have been made in the Asian region to adjust to these evolving requirements. Since simultaneous drug development based on MRCTs including the Asian region are increasing, efficient development of patient-centric labeling and risk management plans are clearly a priority. This session will share recent experience on these topics in Asia, and discuss current challenges and future perspectives on the management of labeling and risk management plans from the Asian and global points of view.

The End to End Labelling Process
Shimon Yoshida, PhD
Head, International Labeling Group, Worldwide Safety & Regulatory, Pfizer Inc.

Labeling Management from Asia Regional Perspective
Vicky Han
Senior Director, Asia Pacific Regulatory Policy Lead, Global Regulatory Affairs, Janssen Asia Pacific, Janssen Pharmaceutical

Risk Management Plan in Asia
Gao Gao, MD
Director, Global Safety Risk Lead, Safety Surveillance and Risk Management, Pfizer China R&D Center

17:25-17:30 CLOSING REMARKS
REGISTRATION FORM: Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
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Early Bird Deadline: April 3, 2017
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