11th DIA Asia New Drug Conference in Japan

– Future MRCT for Innovation in Asia –

April 17-18, 2017
Tower Hall Funabori | Tokyo
DIAglobal.org/Asia2017

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PMDA

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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 advices 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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Drug Information Association
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9:00-9:30 REGISTRATION

9:30-9:40 WELCOME AND OPENING REMARKS

Ko Sekiguchi
Director, DIA Japan

9:40-10:10 KEYNOTE SPEECH

SESSION CHAIR

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

Harmonization in Asia
Toshiyoshi Tominaga, PhD
Associate Executive Director (for International Programs), PMDA

10:10-11:50 SESSION 1

Update on Regulatory Environment in East Asia

SESSION CO-CHAIRS

Jessica Lin, MSc, MBA
General Manager of Development Division, Chugai Pharma Taiwan Ltd.

Junko Sato, PhD
Office Director, Office of International Cooperation, PMDA

US FDA Commissioner Dr. Robert M. Califf has said: "A successful FDA is a critical factor for better public health in this changing world. ...we need to give consumers and patients even more confidence that their food is safe and their medical products are safe and effective." Since our Eastern Asia population is equivalent to 21.62% of the total world population (and five times America's), East Asia Regulatory Authorities have an even higher mission to provide people with more confidence in their environment and in safe, efficacious and convenient treatments to alleviate their suffering from disease.
In this session, regulatory authorities from PMDA, CFDA, MFDS and TFDA will provide highly-anticipated updates from their respective regulatory environments, and inform industry how to work closely with regulatory authorities to accelerate the review and approval process and approval for new, innovative medicines which can bring great benefit and hope to patients and their families.

Recent Topics in PMDA (Support for the practical application of innovation Advancements)
Noriatsu Kono
Coordination Officer for Review of Breakthrough Products (Sakigake), PMDA

Update on Regulatory Environment in CFDA (tentative)
Jianwu Zhang
Principal Staff, Department of Drug and Cosmetics Registration, CFDA

Update on Regulatory Environment in MFDS (tentative)
Gyu-han Chae, MSc
Deputy Director / Planning Expert, Pharmaceutical Policy Division, MFDS

Update on Regulatory Environment in TFDA
Yi-Chu Lin, PhD
Section Chief, Division of Medicinal Products, TFDA

11:50-13:05 LUNCH BREAK

13:05-14:45 SESSION 2

Regulator's Perspective for Drug Development Using Asia MRCT

SESSION CO-CHAIRS

Yoshiko Komuro, PhD
Deputy Review Director, Office of New Drug II, PMDA

Min Soo Park, MD, PhD
Professor of Pediatrics and Clinical Pharmacology, Yonsei University College of Medicine

NDAs based upon the results of MRCTs (multi-regional clinical trials) are steadily increasing. Drug development using Asian MRCTs is especially expected to be a pivotal strategy for global or Asian applications because of the high degree of similarity of ethnic factors within the region. Regulatory authorities have also released guidelines/notices to promote their respective country's participation in MRCT and to use the clinical data from MRCT for regulatory applications. On the other hand, challenges in evaluating MRCT data remain. In this session, Asian regulators will share their review experiences of NDAs using such development strategies, and the current status surrounding MRCTs in Asia. Planning development strategies, review discussion matters, and future issues will also be discussed.

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)
Naoto Kato
Office Director, Office of New Drug III, PMDA

14:45-15:15 COFFEE BREAK

15:15-17:15 SESSION 3

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

Private Social Function Policy

DIA does not allow hospitality functions to be held during any DIA meeting sessions, scheduled exhibit hours, or social events. Therefore, the hours noted below are the only hours that are acceptable for hospitality functions.

Sunday, April 16	All times are acceptable
Monday, April 17	Before 8:00 AM and after 9:00 PM
Tuesday, April 18	Before 8:00 AM and after 7:00 PM

8:30-9:00 REGISTRATION

9:00-9:50 SPECIAL LECTURE

Regulatory Environment in ASEAN

SESSION CHAIR

Shun Jin, MBA
Head, Regulatory Affairs, Asia Pacific, Abbott Laboratories (Singapore) Pte Ltd

With the economic growth and development of the regulatory system in The Association of Southeast Asian Nations (ASEAN) region, there has been more and more focus on conducting clinical trials in the region. Although there are certain regulatory challenges, ASEAN has shown many benefits to clinical trial conduct such as lower cost, ease of access to a variety of populations, a big treatment-naïve patient pool, etc. However, in order to fully realize successful development in this region, we must better understand the regulatory environment and prepare good strategies to overcome these regulatory challenges. In this session, a speaker from HSA in Singapore will share their perspective on the regulatory environment from the agency perspective, and a speaker from industry will share their regulatory experience from that perspective. This balanced overview will be helpful for strategic decision making on clinical trial initiatives in the ASEAN region.

Regulatory Perspective on Drug Development in ASEAN
Alvin Chia, PhD
Senior Regulatory Specialist, Health Sciences Authority

ASEAN Regulatory & Drug Development Environment
Kum Cheun Wong
Head Asia Pacific, Regulatory & Development Policy, Regulatory Affairs, Novartis Asia Pacific Pharmaceuticals Pte. Ltd. / Co-Chair Regulatory Affairs Committee in Singapore Pharmaceutical Association (SAPI)

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 Komiyama
Senior Manager, Regulatory Policy, Regulatory Affairs, Pfizer Japan Inc.

10:40-11:10 COFFEE BREAK

11:10-12:00 SESSION 5

Lessons Learned from Actual Experience - Case Example of Drug Approval in Asia through Global Development -

SESSION CHAIR

Ryuji Nagata, PhD
Principal, Regulatory Science Innovation Section, POC Clinical Research Inc.

New drug development is a long, complicated and expensive process. Many factors contribute to the increasing challenges of developing medicines, including changing science, increasing regulatory requirements, and clinical trial recruitment and retention. 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. One of their options is to utilize MRCT in Asia. In this session, experienced speakers will describe "specific successful cases of drug development in Asia," which will be of great benefit as you work to deliver your innovative drugs to patients in Asia.

Asia NDA Strategy Utilizing Global Clinical Study
Atsushi Nonogaki, MSc Pharm
Manager, Regulatory Affairs Group, Asia Development Department, R&D Division, Daiichi Sankyo Co., Ltd.

From MRCT to NDA: Experience from Korea
Hyun-Ju Yang
Senior Director/Pharmacist/MBA, Medical Division (CD/RA/Pricing/PV), Daiichi Sankyo Korea Co., Ltd.

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 in 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/C-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 Adaptions 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 and 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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CANCELLATION POLICY: On or before April 9, 2017

Administrative fee that will be withheld from refund amount:
Member or Nonmember = ¥20,000
Government/Academia/Nonprofit (Member or Nonmember) = ¥10,000

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but **membership is not transferable**. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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