10th DIA Asia New Drug Conference in Japan

Collaboration and innovation for drug development and fostering

- Open the door of breakthrough to all patients in Asia -

April 13-14, 2016
TOC Ariake Convention Hall | Tokyo

DIAglobal.org/ANDD

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Pharmaceuticals and Medical Devices Agency

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Daiichi Sankyo Co., Ltd.

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OVERVIEW

We are proud to announce that **10th DIA Asia New Drug Conference in Japan** on April 13-14, 2016. We updated the name of this conference from "DIA Annual Conference in Japan for Asian New Drug Development" to better reflect the broad range of issues to be discussed for better drug development and fostering of innovation in Asia.

With clinical development in Asia growing so rapidly, there is a need for local regulatory authorities to quickly bring their processes and guidelines up to date and to be in alignment with the changing clinical trial environment in each country. These efforts, however, have posed a significant challenge to regulatory authorities in charge of the review and approval of new products. In addition to an increasing workload associated with precise review, regulatory authorities must now contend with faster review and approval. The pharmaceutical industry is also changing its business model in response to recent regulatory changes.

Much the same is true on labeling and pharmacovigilance, including the Risk Management Plan, recently required in East Asia countries. An increase in drug safety concerns in recent years has led to raising the regulatory hurdles. Proactive pharmacovigilance throughout the product life cycle is the way forward in Asia region. It has been a constant challenge to standardize pharmacovigilance in Asia because of varied geographical, cultural and medical practices in this region. Given these challenges, the need for cooperation and convergence has been recognized. It is crucial for sustainable and successful drug development that all stakeholders collaborate closely and early in the development process of medical treatments.

At last year's conference, regulators from four East Asian countries, including China, and regulatory affairs professionals from pharmaceutical companies in various countries had active discussions on current challenges and opportunities. This year, regulators from Asian countries and speakers with varied expertise will share their valuable experiences and insight to discuss what we can do better in the era of globalized drug development and life cycle management. A variety of hot topics that catalyze the creation of fresh ideas will be featured at the conference, including:

- The latest regulatory information
- Efficient drug development using Asia MRCT
- A real-world case study of Asia MRCT
- Efficient safety information management

The **10th DIA Asia New Drug Conference in Japan** promises to be one of the most exciting opportunities for those who are seeking to broaden their professional network. We wish you all an enjoyable and informative conference.

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

For information, contact DIA Japan
Nihonbashi Life Science Building 6F,
2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
Tel: 81-3-6214-0574 | Fax: 81-3-3278-1313
Email: Japan@DIAglobal.org

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Nihonbashi Life Science Building 6F,
2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
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9:00-9:30 REGISTRATION

9:30-9:40 WELCOME AND OPENING REMARKS

Ko Sekiguchi
Director, DIA Japan

9:40-10:20 KEYNOTE SPEECH

SESSION CHAIR

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

Asian Trends in Drug Development and Regulation

Toshiyoshi Tominaga, PhD
Associate Executive Director (for International Programs)
Pharmaceuticals and Medical Devices Agency (PMDA)

10:20-12:00 SESSION 1

Update on Regulatory Environment in East Asia

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

With the accelerated globalization of drug development in recent years, the importance of clinical development utilizing multi regional clinical trials (MRCT) especially in east Asian region is increasing mainly because of the higher similarity of ethnic factors within the region. Under such circumstances, Case of new drugs approved based on the results of MRCT in east Asian region are accumulating. In addition, since the postmarketing safety measures including the maintenance of labeling required by the regulatory agency varies in each region, Marketing Authorization Holders have to deal with each local regulations.

In this session, experts from each regulatory agency will introduce the recent regulatory issues about drug development and safety measures in each region. Furthermore, topics regarding the new framework which some regulatory agencies have started to facilitate innovative drug development will be also introduced. It is expected to be helpful for drug development and fostering in east Asian region by understanding and utilizing the updated regulatory information.

Update on Regulatory Environment in MHLW/PMDA

Koushin Kiyohara, MPharm, MSc
Deputy Director, Evaluation and Licensing Division, Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare (MHLW)

Update on Regulatory Environment in MFDS (Tentative)

Myung-jung Kim
Director, Clinical Trials Management Division, Pharmaceutical Safety Bureau
Ministry of Food and Drug Safety (MFDS)

Update on Regulatory Environment in TFDA

Hsueh-Yung Tai, MS
Deputy Director, Division of Medicinal Products
TFDA

12:00-13:15 LUNCH BREAK

13:15-14:00 SPECIAL LECTURE 1

Recent Changes in Regulatory Environment in China

SESSION CHAIR

Shun Jin, MBA
Director, Regulatory Policy and Intelligence, Japan, Asia-Pacific (JAPAC)
AbbVie Pte. Ltd.

CFDA has recently published anticipated regulatory reforms. The reforms represent several changes in China's drug development and commercialization policies, which include but not limited to resolving the backlog of drug application, encouraging clinical drug development using MRCT, and pilot MAH program. Efficient development and launch of innovative new drugs is a top priority of China given growing public health problems that require rapid access to new medical treatments. China's policy changes have the significant impact the global clinical development and manufacturing strategies of multinational pharmaceutical companies. In addition, these new policies reflect China's willingness to be an active participant in global drug development and to encourage foreign companies to accelerate their drug development in China, which will provide a favorable opportunity to those who are involved in drug development.

In this lecture, an experienced speaker will address recent regulatory changes in China and future prospects of the reforms clearly and concisely to help you to have better understanding on these drastically changing issues.

Recent Changes in Regulatory Environment in China

Ling Su, PhD
Strategic Advisor, Life Sciences
Sidley Austin LLP, China

14:00-15:00 SESSION 2

Drug Development Using Asia Multi-Regional Clinical Trials –Part 1-

SESSION CO-CHAIRS

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

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

Our goal is to bring innovative new drugs to patients as soon as possible through thoughtful and efficient drug development. To achieve the purpose, multi-regional clinical trials (MRCT) is now widely recognized as an optimal and efficient drug development pathway by avoiding duplicative works. In fact, regulatory authorities have undertaken many important initiatives and released guidelines/notices to promote their countries to participate in MRCT and to use the clinical data from MRCT for regulatory application. Among them, Asia MRCT is especially expected to be a pivotal strategy for the regulatory application in the region because of ethnic similarity. On the other hands, some challenges in evaluating data from MRCTs still remain.

In this session, speakers from health authorities and pharmaceutical companies will address current status and future prospects of MRCT to help you to explore these increasingly important issues.

Regulatory Trends of MRCT (TCDE) (Tentative)

Churn-Shiouh Gau, PhD
Executive Director
TCDE

Regulatory Trends of MRCT (MFDS) (Tentative)
Sun-young Kim
Assistant Director, Clinical Trials Management Division, Pharmaceutical Safety Bureau
MFDS

PMDA's Experiences with New Drug Applications including Data from Multi Regional Clinical Trials
Akihiro Ishiguro, PhD
Deputy Review Director, Office of New Drug V
PMDA

15:00-15:30 COFFEE BREAK

15:30-16:10 SESSION 3

Drug Development Using Asia Multi-Regional Clinical Trials –Part 2-

SESSION CO-CHAIRS

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

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

Drug Development Using MRCT from Perspective of a Japanese Company
Tetsuomi Takano, RPh
Senior Director, Head of Asian Development Strategy
Astellas Pharma Inc.

Drug Development Using MRCT from Perspective of a Western Company
Yamin Wang, PhD
Vice President and Head of Regulatory Affairs, Therapeutic Area General Medicine
Bayer Pharma AG

16:10-17:15 PANEL DISCUSSION (SESSION 2 & 3)

PANELIST

All speakers in Sessions 2 and 3, as well as

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

17:30-19:00 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.

Tuesday, April 12	All times are acceptable
Wednesday, April 13	Before 8:00 AM and after 8:00 PM
Thursday, April 14	Before 8:00 AM and after 7:00 PM

8:30-9:00 REGISTRATION

9:00-9:30 SPECIAL LECTURE 2

Regulatory Environment in ASEAN

SESSION CHAIR

Shun Jin, MBA
Director, Regulatory Policy and Intelligence, Japan, Asia-Pacific (JAPAC)
AbbVie Pte. Ltd.

The Association of Southeast Asian Nations (ASEAN) was established in 1967 in Bangkok. ASEAN is becoming an important part of Asian economy during recent years. There are 10 member countries now. Although there has been great efforts to harmonize the regulatory requirements in those nations, there are still a few country specific requirements existing. It is essential to understand the regulatory requirements for new drug development in this region.

The ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceuticals Product Working Group (PPWG) has focused on the regulatory harmonization efforts for more than a decade. There have been progresses achieved during the past years. An expert with long experience of with APAC and ASEAN activities will introduce ASEAN regulatory environment as well as the most updated ASEAN regulatory harmonization activities. The experience with ASEAN country specific requirements for new drug development will be also shared. It will cover ACTR (ASEAN common technical requirement), ACTD (ASEAN CTD) and recent technical guidelines.

Regulatory Environment in ASEAN

Sannie SF Chong, PhD, FRSC
Sr Director of Pharmaceutical Sciences, Pharmaceutical Services Division
Roche Singapore Technical Operations Pte Ltd

9:30-10:15 SPECIAL SESSION

Collaboration for Better Drug Development - Future Perspective on International Collaboration through ICH, APEC, etc. as a draft idea -

SESSION CHAIR

Tatsuo Kurokawa, PhD
President
Japan Self-Medication Industry

As a result of a rapid globalization in the new drug development, clinical trials are being conducted in a lot of countries. In addition, consistent global packages data including the clinical trials are being reviewed there. Demand has been increasing for globally harmonized, science-based standards for the drug development and evaluation of the medical products. Such consistent standards will improve the transparency and efficiency of the drug development and evaluation process and, ultimately, provide new innovative drugs to patients around the world promptly. Global regulatory initiatives such as ICH has supported to reduce the development times and streamline the regulatory assessment process through harmonized guidelines. Recently non-ICH countries/regions actively participate in guideline development and implement ICH's strategies and China also shows great interest. Other examples of regulatory collaboration include Asian regulatory training center to share PMDA's knowledge and experience in product reviews.

This session will address current status and future prospects of regulatory collaboration.

Contribution of PMDA to the Capacity Building - Establishment of Asia Training Center -

Junko Sato, PhD
International Coordination Officer
PMDA

Overview of ICH Reform Explanation

Hironobu Saito, PhD
Vice President, Oncology Clinical Development Department, Oncology Function, R&D Division
Daiichi Sankyo Co., Ltd.

Panel Discussion

PANELIST

All speakers in this session

10:15-10:45 COFFEE BREAK

10:45-12:00 SESSION 4

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

SESSION CO-CHAIRS

Ari Fujishiro
Associate Director, Regulatory Affairs Group, Asia Development Department, R&D Division
Daiichi Sankyo Co., Ltd.

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

With concern to accelerated progression of Asia new drug development, the global clinical development strategy has become important and be aware by all pharma industry. Each company elaborates the clinical development plan of new compound to confirm safety, efficacy, and benefit for patients as well as to accelerate the process that the new drug can bring into market to benefit patients as early as possible with best practice. Such well-established strategies and plans would contribute to expedite the approval processes of new products.

We do hope our audiences can learn from this session and understand how a meticulous clinical development plan and regulatory submission strategies for a new drug in Asia and/or global level can shorten the review process and minimize the risk from industry's point of view and their experiences. To achieve the deliverables of getting approval, comprehensive discussion in each company might be made. Through the session, the audiences will be able to learn various key factors needed to be considered at clinical development stage and review phase.

Experience of International Trial across Asia in Aripiprazole IM Depot

Naoaki Shimizu
Group Leader, Headquarters of Clinical Development Department of Clinical Management,CNS Group 3
Otsuka Pharmaceutical Co.,Ltd.

Experiences of Ruxolitinib Pan-Asian Registration Study

Hideyasu Ishibashi, PhD
Head, Oncology Early Clinical Trial Management, Oncology Development & Medical Affairs Department
Novartis Pharma K.K.

Bridging East and West – Oncology NCE TLC388 to Fill the Gap

George Yeh, MBA
President
Taiwan Liposome Company, Ltd.

12:00-13:15 LUNCH BREAK

13:15-14:15 SESSION 5

Excellence of Labeling Management in Asia

SESSION CO-CHAIRS

E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer
Eisai, Co., Ltd.

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

Labeling is an important risk minimization measure in the risk management plan. Local labeling management is always challenging for multinational companies.

Since labeling harmonization has not yet been established in across Asian countries as is done in the EU, we must prepare and revise for labels creation based on the regulations in each country. Labeling compliance is becoming increasingly more important.

In this session, we will present an overview of labeling regulations in Asia, labeling preparations for new drugs, actual practices for label revisions of safety information and how we should handle and manage label revisions in the Asia region, in accordance with company policies while following local regulations. In addition, we will share how to measure labeling compliance and current challenges. Furthermore, future prospects for labeling in Asia will be discussed.

Global Labeling Management

E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer
Eisai, Co., Ltd.

Labeling Regulations and Regional Best Practices for Labeling Process in Asia

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

14:15-14:35 SESSION 6

Risk Management Plan for New Drugs

SESSION CO-CHAIRS

E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer
Eisai, Co., Ltd.

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

Risk management should be conducted throughout a product's lifecycle. Pharmaceutical companies should apply risk management methodologies to detect, assess, communicate and minimize risks throughout a medicine's lifecycle to optimize its benefit/risk balance. This includes learning about and interpreting a product's benefits and risks, designing and implementing interventions to minimize a product's risks, evaluating interventions in light of new knowledge that is acquired over time, and revising interventions, when appropriate.

EMA published Module V Risk Management Systems as part of the important regulatory guidance in conjunction with the EU Good Pharmacovigilance Practices (GVP) or PV legislation that went into effect in July, 2012. US FDA provided Risk Minimization Action Plans in 2005 and it was included in FDAAA which was finally effective March 2008. Japan has been leading the implementation of RMP in Asia area and set up the legislation on risk management plan in 2013.

Early approval and launch of new drugs based on the best benefit-risk balance and controllable risk, RMP can help to verify the safety profile in a larger population, ensure sustained monitoring of the approved drug and implement risk minimization actions, to make up for the limitations of pre-approval clinical trial data and protect patient safety.

How is risk management performed in the US and Europe? Are there any experiences from which Asian countries can learn? We will share in this session view points from pharma companies, academic institutions and regulatory agencies on the role of the RMP in drug R&D. Updates on the latest status of RMP implementation worldwide will also be presented.

Overview of Regulation on RMP

E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer
Eisai, Co., Ltd.

14:35-15:05 COFFEE BREAK

15:05-16:25 SESSION 6 (CONTINUED)

Risk Management Plan for New Drugs

PMDA's Perspective

Yusuke Matsunaga, PhD
Office of Safety II
PMDA

RMP in Korea

Howard Lee, MD, PhD
Professor, Department of Clinical Pharmacology and Therapeutics, Seoul National University Hospital and College of Medicine

Professor, Department of Transdisciplinary Studies, Graduate School of Convergence Science and Technology, Seoul National University

Head, Global Strategy and Planning, Clinical Trials Center, Seoul National University Hospital

TDRF's Perspective

Wen-Wen Chen, PharmD
Deputy Executive Director
TDRF (Drug Relief Foundation)

RMP in China

J. Christophe Delumeau, MD, PhD
Head of Pharmacovigilance Asia-Pacific & China
Bayer HealthCare / Bayer South-East Asia

16:25-17:30 PANEL DISCUSSION (SESSION 5 & 6)

PANELIST

All speakers in Sessions 5 and 6, as well as

Junko Sato, PhD
International Coordination Officer
PMDA

17:30-17:35 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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The 10th DIA Asia New Drug Conference in Japan

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Early Bird Deadline: March 31, 2016

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Administrative fee that will be withheld from refund amount:
Member or Nonmember = ¥20,000
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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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CONTACT INFORMATION
Contact the DIA Japan office in Tokyo for further information.
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