CNDA/DIA Joint ICH Day

May 22 | Beijing International Convention Center

Since its inception in 1990, founded by the drug regulatory agencies of the US, EU, and Japan along with industry associations, to its reform and establishment of the non-profit, non-governmental legal entity under Swiss law in 2015, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has successfully attracted regulators around the world to join and ensure greater coordination among the participating regulatory agencies. The purpose of ICH is to promote public health through international harmonisation of technical requirements that contributes to the timely introduction of new medicines and continued availability of the approved medicines to patients, to the prevention of unnecessary duplication of clinical trials in humans, to the development, registration and manufacturing of safe, effective, and high quality medicines in an efficient and cost-effective manner, and to the minimization of the use of animal testing without compromising safety and effectiveness.

In June 2017, CFDA joined ICH as the 8th regulatory member globally during ICH Montréal meeting. This is a key milestone that reflects CFDA's reform has eventually brought China's regulatory authority, Pharma companies and drug development institutions into a new era – gradually converge and implement the international highest technical standards and guidelines. CFDA will actively participate in the design and enacting of international rules, to speed up the international innovative products to China and to fulfill the unmet medical needs of China, at the same time, to improve the innovation ability and international competitiveness of the Chinese pharmaceutical industry.

CNDA (former CFDA)/DIA Joint ICH Day will invite the core members from international regulatory agencies, industry and academia of ICH committee and working group, to share the latest development of ICH, the specific requirements of Tier 2 technical guidelines and experiences of ICH implementation in China and other countries as well as the ICH training strategies. The joint training will include parallel workshops on E2/M1, E6, E9 & E17, E14 and M4/M8 guidelines.

OBJECTIVES

- Introduce ICH's reform and its new vision of global development
- Discuss key impact of ICH updates to international regulatory agencies and industry
- Share CNDA's implementation progress and challenges of ICH guidelines
- DIA's Contribution to ICH's global promotion as a neutral platform
- Training on ICH Tier 2 guidelines

AGENDA

Tuesday, May 22, 2018 | ICH Day					
8:30-10:00	2nd Floor, Hall 2-I | **ICH Plenary Session**				
10:00-10:30	Tea Break				
10:30-17:00 *(Lunch & Tea Break in Between)*	2nd Floor 201AB **E2 & M1** Pharmacovigilance and MedDRA	2nd Floor 201CD **E6(R2)** GCP	2nd Floor, Hall 2-II **E9** Statistical Principles for Clinical Trials 2nd Floor, Hall 2-II **E17** General Principles for Planing and Design of Multi-Regional Clinical Trials	2nd Floor 203AB **E14** The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	2nd Floor 203CD **M4 & M8** Requirements and Significance of eCTD Implementation

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DIA CHINA Wechat Subscription

Tuesday, May 22th | ICH DAY

8:30-10:00	**ICH Plenary Session**
	Opening Remarks from Leader of the China National Drug Administration CNDA Speaker Invited
	ICH's Today & Tomorrow - Harmonization for Better Health **Lenita LINDSTRÖM-GOMMERS** Chair, ICH Assembly Senior Expert, European Commission, Belgium
	ICH's Reform and Its New Vision of Global Development **Toshiyoshi TOMINAGA, PhD** Vice-Chair of both the ICH Management Committee and the ICH Assembly Associate Executive Diretor, International Program, PMDA
	CNDA's Contribution in Internationalization of ICH CNDA Speaker Invited
	ICH Special Forum – ICH's Impact to the Development of Innovative and Generic Drugs – ICH's Implementation and Training
	INVITED PANELISTS: **Lenita LINDSTRÖM-GOMMERS** Chair, ICH Assembly Senior Expert, European Commission, Belgium
	Toshiyoshi TOMINAGA, PhD Vice-Chair of both the ICH Management Committee and the ICH Assembly Associate Executive Diretor, International Program, PMDA
	Pär TELLNER Director, Team Leader and ICH Coordinator, EFPIA
	FDA Panelist Invited
	CNDA Panelist Invited
	DIA Panelist Invited
10:00-10:30	Tea Break

Tuesday, May 22th | ICH DAY

Workshop 1

E2 & M1: Pharmacovigilance and MedDRA

PROGRAM CO-CHAIRS

Charles YAN, PhD
Vice President, Hengrui Data Science Center

Xue TANG
Drug Safety Unit Regional Head (DRH), APAC, Pfizer

PROGRAM COMMITTEE

Jan PETRACEK, MD
CEO, PrimeVigilance, Czech Republic

Julia ZHU
DMedglobal

10:30–12:00	**MedDRA: FDA's Perspectives**
	FDA Speaker Invited
12:00–13:30	Lunch
13:30–15:00	**ICH E2A**
	Jan PETRACEK, MD CEO, PrimeVigilance, Czech Republic • Introduction and Background of E2A • Definitions and Terminology in Clinical Safety Data Management • Standards for Expedited Reporting in Clinical Safety Data Management
15:00–15:30	Tea Break
15:30–17:00	**Practical Consideration**
	Jan PETRACEK, MD CEO, PrimeVigilance, Czech Republic Expectedness of ADR: RSI in IB Any guidance on how to develop the reference safety information in IB? What information should be included? How to determine the known ADRs of the product based on observed events? Other Observations to be Reported in an Expedited Way? How to determine what situation other than single SUSARs that needs rapid communication with RA? In these situation, how to do the rapid communication? By what format? Within what kind of time frame? Experience in Managing Blinded Therapy Cases When and how to perform the single case unblinding? What needs more attention when preparing unblinded ICSRs? How to handle the cases of active comparator?

Tuesday, May 22th | ICH DAY

Workshop 2

E6(R2): GCP

PROGRAM CHAIR

Hannah CHEN
Director, Asia Pacific Strategy Lead
BioResearch Quality & Compliance, Janssen

10:30–10:50	**E6 Updates/Addendum** **Agnes Saint-Raymond, MD** Head of International Affairs Head of Portfolio Board European Medicines Agency
10:50–12:30	**cQMS** • Clinical QMS conceptual framework • Risk management • Issue management • Assessment of cQMS • Sharing of best practice on cQMS
12:30–13:30	Lunch
13:30–16:30	**RBM** • RBM methodology • RACT • Central monitoring capability • SDV/SDR • RBM Data trending • Sharing of best practice
16:30–17:30	**Penal Discussion**

Tuesday, May 22th | ICH DAY

Workshop 3

E9: Statistical Principles for Clinical Trials

PROGRAM CHAIR

Lian LIU
Novartis

10:30–10:40	**Welcome and Introduction**
10:40–11:00	**Background and History of ICH E9-R1** China CDE Speaker Invited
11:00–11:30	**Opportunities and Challenges in implementing Estimands in Clinical Trials** **Dr. Vladimir DRAGALIN** Johnson & Johnson
11:30–12:00	**Estimand in China** **Feng CHEN** Professor, Dean, School of Public Health Nanjing Medical University Chair of China Association of Biostatistics (CABS) Chair of China Clinical Trial Statistics (CCTS) Working Group
12:00–13:30	Lunch Break
13:30–14:00	**Opportunities and Challenges in implementing Estimands in Clinical Trials** **Ivan CHAN, PhD** Vice President, Pipeline Statistics and Programming Data and Statistical Sciences, Abbvie, USA
14:00–14:30	**Panel Discussion** Speakers above and Invited Panelists: **Prof. Jielai XIA** **Liansheng ZHU** **Luyan DAI** **Tony GUO** etc.

Tuesday, May 22th | ICH DAY

Workshop 5

E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs

PROGRAM CO-CHAIRS

Haiyan LI
Professor of Cardiology
Director, Drug Clinical Trial Center, Peking University Third Hospital

Boaz MENDZELEVSKI, MD
Consultant, Cardiac Safety Consultants Ltd., UK

10:30–11:00	**Keynote lecture: CV Safety in Basic and Clinical Research: From Ion Channels to Clinical Assessments** **Ganxin YAN, PhD** Professor of Medicine at Thomas Jefferson University Professor at Lankenau Institute for Medical Research and Xi'an Jiaotong University
11:00–12:00	**Session 1: Regulatory Sciences** Overview of the S7B Guideline CDE Speaker Invited Overview of the E14 Guideline (including TQT and IQT) CDE Speaker Invited CiPA - a Regulatory Paradigm Shift **David STRAUSS, PhD** Director, Division of Applied Regulatory Science Office of Translational Sciences Office of Clinical Pharmacology, FDA
12:00–13:00	Lunch Break
13:00–15:00	**Session 2: QT Study Design and Operations** Translational and Early Phase Cardiac Safety Assessments **Jorg TAUBEL, MD** Chief Executive Officer, Richmond Pharmacology Limited, St George's University of London, UK Considerations for TQT and IQT Study Design **Haiyan LI** Professor of Cardiology Director, Drug Clinical Trial Center, Peking University Third Hospital Quality control of QT Study Operation PUTH team and JnJ team Overview of Quality Control System of ECG Core Lab (including ECG analyses methodology) **Boaz MENDZELEVSKI, MD** Consultant, Cardiac Safety Consultants Ltd., UK
15:00–15:30	Tea Break
15:30–16:30	**Session 3: Exposure-Response (C-QT) Analysis Methodology** Overview of Concentration-QT Analysis Methodology **Yaning WANG, PhD** Regulatory Expert Application of Concentration - QT Analysis based on Data from Phase 1 Trials **Jiang LIU, PhD** Regulatory Expert
16:30–17:30	**Session 4: Strategy of QT Studies in China** Considerations for ECG Monitoring in Late Stage **Gailing LI** JnJ **Panel Discussion:** Including All Speakers & CNDA Representative, ICH E14 Working Group in China

Tuesday, May 22th | ICH DAY

Workshop 6

M4 & M8: Requirements and Significance of eCTD Implementation

Since China have joined ICH as a member, CNDA clearly requires industry apply ICH guidelines for Clinical development and regulatory submission in China. From 1st February 2018, ICH Guideline M4: "Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use" start to apply to the submission in Category 1, 5.1 of Chemical Drug Registration, and Category 1 of biological products for Treatment and Category 1 of biological products for prevention of 1. In the meanwhile, more and more Chinese domestic pharmaceutical companies conduct clinical trials abroad, and would do submission to FDA/EMA/PMDA. However, lots of Chinese domestic companies are not familiar with the regulatory requirement, structures. Modules, and format on CTD, until now there is no domestic eCTD system to support regulatory submission. Therefore DIA will invite the global/domestic experts of CTD/eCTD to introduce the regulatory requirements of CTD/eCTD, how to create eCTD specification, and share successful cases in eCTD submission.

PROGRAM CHAIR

Hualong SUN, MD, PhD
General Manager, Meta Clinical Technology

PROGRAM COMMITTEE

Daniel LIU, PhD
Chief Scientific Officer, Beijing Clinical Service Center

Titus MODSCHING
Business Analyst, Client Enablement, Regulatory Solutions, PAREXEL International GmbH

Bruce SUN
Publishing Team Lead (Established Market) , Publishing & Product License Support , Worldwide Regulatory Operations , Pfizer (China) Research and Development

Handsome JI
APAC Publishing Lead , Publishing & Product License Support, Worldwide Regulatory Operations, Pfizer (China) Research and Development

10:30–11:00	**Introduction of ICH Guideline M4: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use** **Hualong SUN, MD, PhD** General Manager, Meta Clinical Technology • Objective of CTD • General Principle • Modules of CTD
11:00–11:30	**The Structure and Format of CTD/eCTD** **Handsome JI** APAC Publishing Lead, Publishing & Product License Support, Worldwide Regulatory Operations, Pfizer (China) Research and Development • CTD Triangle • Difference of CTD from eCTD Structure
11:30–12:00	**Manage Trial Master Files for eCTD Implementation** **Daniel LIU, PhD** Chief Scientific Officer, Beijing Clinical Service Center • eTMF Regulatory Standards • How to Manage TMF While Implement eCTD
12:00–13:30	Lunch Break

Tuesday, May 22th | **ICH DAY**

13:30–14:00	**Management of eCTD Life Cycle**
	Handsome JI APAC Publishing Lead, Publishing & Product License Support, Worldwide Regulatory Operations, Pfizer (China) Research and Development
14:00–14:30	**Overview of eCTD Specifications**
	Bruce Sun Publishing Team Lead (Established Market) , Publishing & Product License Support , Worldwide Regulatory Operations, Pfizer (China) Research and Development • Composition of eCTD Specifications • Process of eCTD Specifications Creation • How to Review/Interpret/Implement eCTD Specification
14:30–15:00	**Strategies & Tools to Build a Successful Submission of eCTD**
	Titus Modsching Business Analyst, Client Enablement, Regulatory Solutions, PAREXEL International GmbH
15:00–15:30	Tea Break
15:30–16:00	**Global eCTD Transition and Case Study**
	Bruce SUN Publishing Team Lead (Established Market) , Publishing & Product License Support , Worldwide Regulatory Operations , Pfizer (China) Research and Development • Global eCTD Transition Status Quo • eCTD Case Study (US/EU/Japan/Thailand) • Validation Failure and Technical Rejection Avoidance
16:00–16:30	**Building the eCTD - Practical Approaches to Compiling Electronic Submissions**
	Titus Modsching Business Analyst, Client Enablement, Regulatory Solutions, PAREXEL International GmbH
16:30–17:00	**The Opportunities and Challenges of Submission to CNDA and FDA/EMA in Clinical Data/Dossier for China Domestic Pharmaceutical Companies**
	Hualong SUN, MD, PhD General Manager, Meta Clinical Technology
17:00–17:30	**Panel Discussion**