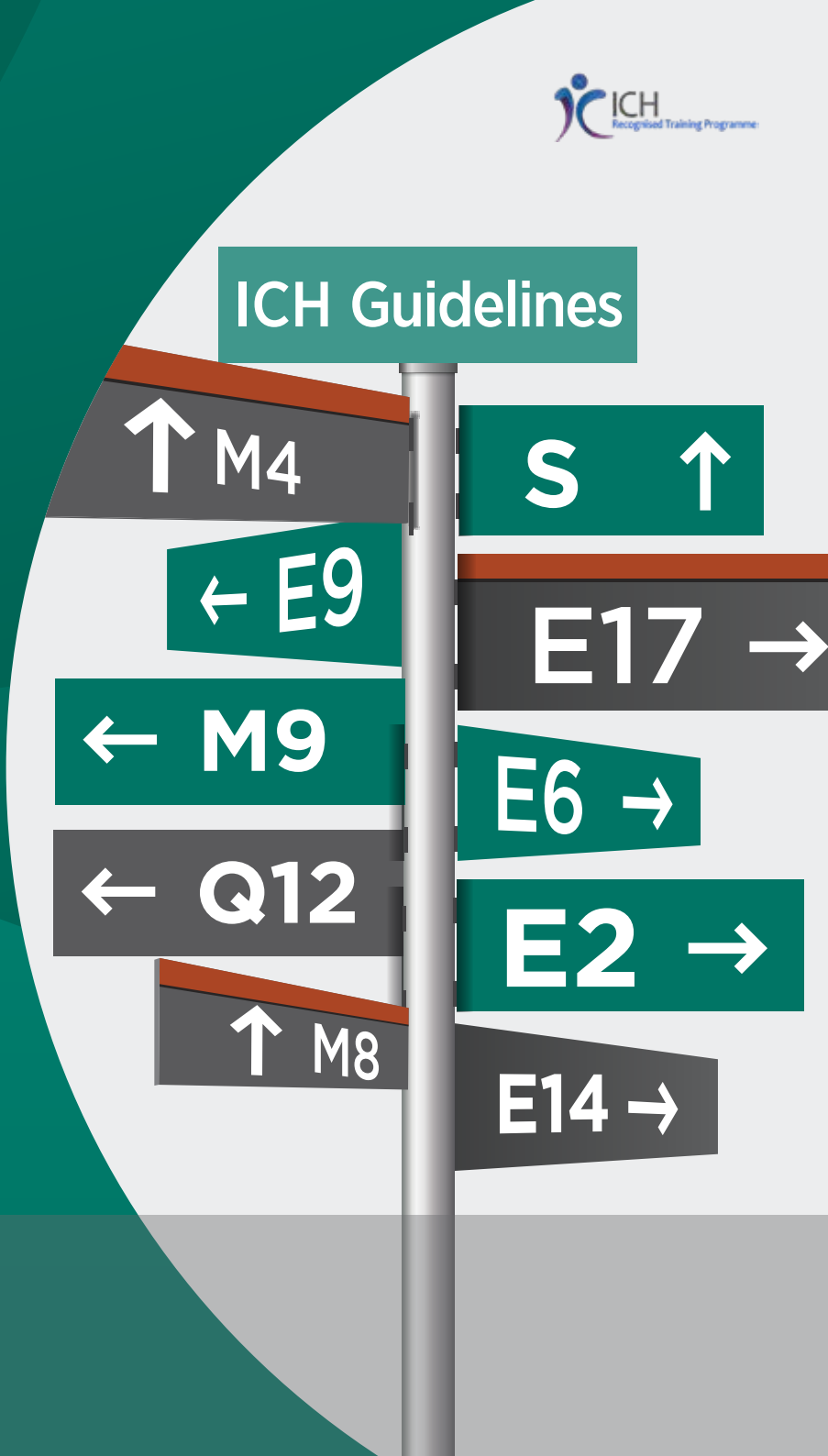
DIA CHINA

ICH Day

2021年5月20日 | 苏州国际博览中心

May 20, 2021

Suzhou International Expo Center, CHINA



Thursday | May 20 | ICH DAY

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 Harmonzation 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 harmonization 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.

2021 is the 5th year since NMPA joined ICH Management Committee, to promote the ICH's global development strategy, DIA China 2021 ICH Day will invite the speaker from ICH core member countries to forward look the ICH's Further Initiatives from global perspectives, impact and updates for the new ICH Patient Focused Drug Development Guideline, as well ICH's Key Achievements and Implementation in China.

ICH Q series, S series, E9R1, E17, E6, and Data Standard will be also covered.

Plenary

PROGRAM CO-CHAIRS

YANG Sheng
Deputy Director, Department of Drug Registration, NMPA
NMPA Representative in ICH

Zili LI, MD, MPH
Chair, DIA Advisory Council of China
Vice President and Head of Asia Pacific R&D, Janssen Pharmaceutical Company

8:30–8:35

Welcome

YANG Sheng
Deputy Director, Department of Drug Registration, NMPA
NMPA Representative in ICH

Zili LI, MD, MPH
Chair, DIA Advisory Council of China
Vice President and Head of Asia Pacific R&D, Janssen Pharmaceutical Company

8:35–8:50

ICH's Further Initiatives/Next Steps to Promote ICH Standard Globally

Theresa MULLIN, PhD
Associate Director for Strategic Initiatives, FDA Center for Drug Evaluation and Research
Chair, ICH Management Committee

8:50–9:20

ICH's Key Achievements and Implementation in China

ZHOU Siyuan
Deputy Director, Center for Drug Evaluation, NMPA
Director, ICH China Office

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9:20–9:40	**Background, Purpose, Impact and Updates for the New ICH Patient Focused Drug Development Guideline** **Francesco PIGNATTI, MD** Head of the Office of Oncology and Haematology, Human Medicines Division, EMA
9:40–10:00	**The Latest ICH Trends in Japan** **YASUDA Naoyuki** Director, Office of International Regulatory Affairs Ministry of Health, Labour and Welfare (MHLW) MHLW Representative in ICH
10:00–10:15	**The Importance of International Standards, Guidelines and Regulatory Science for Building Trust and Competency** **Neil MCAUSLANE, PhD** Director, Centre for Innovation in Regulatory Science (CIRS)
10:15–10:30	**Tea Break**

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Workshop 1 | 10:30–15:00

Data Standardization under the ICH Requirements

PROGRAM CO-CHAIRS

Haixue WANG
Deputy Director, General of Clinical Trial Management Department, CDE, NMPA

Daniel LIU, PhD
Chief Scientific Officer, Clinical Service Center

Having become one of the core regulatory members in ICH organization, NMPA has been making efforts to promote clinical data standardization and enhance supervisions of data quality and integrity, ensuring management of clinical trials and protections of subjects' ethic rights in clinical trials. Recently, NMPA CDE also publishes the guidance of clinical data submission, requests an adoption and implementation of the 2nd level relevant ICH guidances, and also is initiating the Good Chinese GVP Practice in China, which would positively encouraged and harmonized monitoring and reporting of clinical trial data in a risk-based setting, especially on critical data and associated procedures in clinical trials. This session will discuss the regulatory requirements and challenges of the data standardization in clinical trials.

10:30–11:00	**Interpretation on Guideline of Data Submission in Drug Clinical Trials** **HENG Mingli** Reviewer, CDE
11:00–11:30	**Implementation of ICH E2B R3** **Jacky TAO** Team Manager, Information Management, Operations Center of Excellence, Pfizer
11:30–12:00	**Overview of EMA Clinical Data Publication Policy in Compliance of ICH Requirements** **Zhenglong TIAN** Chief Data Officer, VP of GoBroad Healthcare Administration, Inc
12:00–13:30	Lunch
13:30–14:00	**Requirements of Quality and Standards of Clinical Data of Drug in the Compliance of ICH Guidance** Daniel LIU, PhD Chief Scientific Officer, Clinical Service Center
14:00–14:30	**ICH-based Requirements and Cases Studies of Statistical Analysis of Clinical Data in Clinical Trials** Bob Yan, PhD Vice President, Meta Clinical Technology
14:30–15:00	**Safety Data Reporting and Risk Management in Clinical Trials** **PEI Xiaojing** Reviewer, CDE

Thursday | May 20 | ICH DAY

Workshop 2 | 10:30–12:00

ICH E17

PROGRAM CHAIR

Tony GUO, PhD
Global Head of Statistics and Data Science, VP, BeiGene

ICH E17 Guideline's Implementation in China

Wang Zhaoyun
Reviewer, CDE

Case Study - China R&D's Opportunity and Challenge under ICH 17 Framework

Yan ZHAO
Vice President, Novartis

ICH E17: Connection and Case Study with ICH E8/E9

William WANG, PhD
Executive Director, Clinical Safety Statistics, Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories

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Workshop 3 | 13:30–17:20

E9(R1): Estimand

PROGRAM CO-CHAIRS

Feng CHEN, PhD
Professor of Biostatistics, Nanjing Medical University
Chair of China Clinical Trial Statistics (CCTS) Working Group

Tao WANG, PhD
Hengrui Pharma

A Brief Introduction to Estimand

Feng CHEN, PhD
Professor of Biostatistics, Nanjing Medical University
Chair of China Clinical Trial Statistics (CCTS) Working Group

Considerations for the Implementation of E9(R1) in China

LI Xinxu
Reviewer, CDE

Application and Considerations of Estimand in Immunotherapy Trial

Leslie MENG, PhD
Director of Biostatistics, BI

Application and Considerations of Estimand in Metabolic DiseaseClinical Trials

Ping YAN, PhD
Senior Director of Biostatistics, Hengrui Pharma

Application and Consideration of Estimand Framework in Oncology Trials

Jeannie QIU, PhD
Head of Biometrics and Data Science, FosunPharma Global R&D

Application and Considerations of Estimand in Vaccine studies

Zhiwei JIANG, PhD
General Manager, KeyTech

Estimand in Real World Studies

Shanmei LIAO
Senior Director, Beigene

Estimand - the Reality and the Truth

Jielai XIA, PhD
Professor of Medical Statistics, Xi'an Air Force Medical University

Thursday | May 20 | ICH DAY

Workshop 4 | 10:30–15:00

ICH E6

PROGRAM CO-CHAIRS

YANG Zhimin
CDE

Sally ZHANG
Head, Quality Assurance, AstraZeneca
ICH E6R3 Global Expert Working Group (EWG)

At present, ICH E6 and E8 is being revised with new content and trends. It is critical that essential progresses are continually communicated and understood, by the R&D industry in China and its stakeholders, to facilitate the readiness of their future implementation.

As such, ICH Day E6/E8 session shall cover the key ICH E6/E8 revisions, health authority's insights on these revisions as well as the overall QbD framework at sponsor side and a sponsor's best practice on identifying quality-by-design and critical-to-quality factors. Lastly, a panel of experts will share opinions and recommendations on what need to be done in china to prepare the implementation of the revisions for ICH E6/E8.

The High-level Summary of E6 and E8 Revision Progress and Background

ICH E6 R3 Global Renovation Progress

Guodong FANG, PhD
CMO, Fangen
ICH E6R3 Global Expert Working Group (EWG)

HA's Perspective - How E6 and E8 Revisions Influence the Clinical Development Future in China

MA Runyi
Reviewer, CDE

Update of PMDA and Japan Industry Activities in GCP Renovation

MOCHIZUKI Ryu
Coordinator, Division of Regulatory Cooperation, Office of International Programs
Pharmaceuticals and Medical Devices Agency (PMDA)

QbD - The Overall Framework and Best Practice at Sponsor Company

Ellyne Setiawan
Head of Quality China, Greater China, Boehringer Ingelheim

Liping ZHOU
QA Senior Director, MSD

Panel Discussion: Convergence Suggestions for New Revision Implementation in China

MODERATOR

Sally ZHANG
Head, Quality Assurance, AstraZeneca
ICH E6R3 Global Expert Working Group (EWG)

ALL SPEAKERS AND INVITED PANELISTS:

Hannah CHEN
Consultant, Beijing XiaoTongMingDa Technology Ltd., China

Cathy LIU
APAC Site Head for Product Development Quality (PDQ), Roche

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Workshop 5 | 10:30–15:00

ICH Q Series

PROGRAM CO-CHAIRS

Yunan MA
CDE

Xiaoping CAO, PhD
Senior Director, Head of GCMC China, Pfizer

Steven HU, PhD
Chief Technical Officer, Everest Medicine

10:30–11:00	**KASA and M4Q(R1)** **Lawrence YU, PhD** Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality (OPQ), CDER, FDA
11:00–11:30	**ICH M9 BCS Biowaivers** **Roger NOSAL** VP & Head of GCMC, Pfizer
11:30–11:50	**Overview of ICH Q12 Guideline** **Andrew CHANG, PhD** Vice President, Quality and Regulatory Compliance, Quality, Novo Nordisk
11:50–12:10	**The Implementation and Consideration of ICH Q12 in Japan from Both Regulatory and Industry Perspectives** **UEDA Mami** Principal Coordinator, Division of Regulatory Cooperation, Office of International Programs Pharmaceuticals and Medical Devices Agency (PMDA)
12:10–12:30	**Panel Discussion** MODERATOR **Xiaoping CAO, PhD** Senior Director, Head of GCMC China, Pfizer Above Speakers and Invited Panelists: **Timothy Watson** Executive Director, Pfizer ICH Q11 EWG, IWG CDE Panelist Invited
12:30–13:30	Lunch

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13:30–14:00	**ICH Q12 Implementation in China**
	CDE Speaker Invited
14:00–14:30	**Q12 Case Sharing: Using Established Conditions to Manage Post Approval CMC Changes**
	Xiaoping CAO, PhD Senior Director, Head of GCMC China, Pfizer
14:30–15:00	**Panel Discussion**
	MODERATOR Steven HU, PhD Chief Technical Officer, Everest Medicine

Thursday | May 20 | ICH DAY

Workshop 6 | 10:30–15:00

ICH Safety Guidelines: Regulatory Evolving Trend and China Implementation

PROGRAM CO-CHAIRS

Qingli WANG, PhD
Director, Office of Pharmacology and Toxicology, CDE,
NMPA

Jack XIE, PhD
Head of Non-clinical Safety China, Janssen R&D China

China NMPA Joined ICH in 2017. To date, all ICH safety guidelines were officially announced to be implemented. The ICH M3 guideline for non-clinical studies supporting human clinical trials and NDA is also expected to be in a process of implementation soon in China. In this session, the safety guidelines China implementation status and prospective will be discussed with views from both CDE and industry. Progress and prospect of ICH M3 China implementation and new scientific/regulatory trends of selected safety guidelines (ICH S1, S2, S5, S6, S9, and S11) will also be covered.

ICH Safety Guidelines China Implementation Progress and Prospective - Views from CDE

Qingli WANG, PhD
Director, Office of Pharmacology and Toxicology, CDE,
NMPA

Compliance and Implementation of ICH Safety Guidelines in China - Views from Industry

Jing MA, PhD
Chief Advisor, Shanghai Lingang Economic Development Group Co., Ltd

ICH M3: Current Status and the Process of Implementation in China

Joe (Haizhou) ZHANG, MD, PhD
CEO, BJ BioScience

ICH S1, S2, S5 and S11: Evolving Changes in Science and Regulatory Review

Jack XIE, PhD
Head of Non-clinical Safety China, Janssen R&D China

ICH S6 & S9: The Implementation and Scientific Trend of Non-clinical Evaluation of Biologics and Oncology Drugs Development in China

Xiaobo CEN, PhD
CEO, WestChina Frontier Biotech

ICH M7: Further Harmonize and Facilitate Implementation in China

Yi JIN, PhD
VP and Head of Program Management and Regulatory Affairs, WuXi Appec Suzhou

Panel Discussion

All Speakers

Host DIA

Co-host China Center for Food and Drug International Exchange (CCFDIE)

2021 DIA CHINA Annual Meeting

May 20-23 | Suzhou International Expo Center, China

Co-sponsored SIP

Friday | May 21 | OPENING PLENARY

9:00–9:05	**Welcome** **WANG Tongyan, PhD** Managing Director, DIA China
9:05–9:15	**Program Co-chaimen Welcome Address** **XUE Bin** Co-chair of 2021 DIA China Annual Meeting Director-General, China International Food and Drug Exchange Center (CCFDIE), NMPA **Zili LI, MD, MPH** Co-chair of 2021 DIA China Annual Meeting VP and Head of AP R&D, Janssen Pharmaceutical
9:15–9:30	**Welcome Speech of Leader of The National Medical Product Administration**
9:30–9:35	**Welcome Speech by Chairman of DIA Global Board of Directors** **Lingshi TAN, PhD** Chairman of DIA Global Board of Directors Chairman and Chief Executive Officer, dMed Biopharmaceutical Co., Ltd.
9:35–9:40	**Welcome Speech of Suzhou Local Government**
9:40–10:05	**Keynote Speech 1 | Innovative Drug Review and Approval Achievements of NMPA** **WANG Tao, MD, PhD** Deputy Director, Center for Drug Evaluation, NMPA
10:05–10:30	**Keynote Speech 2 | FDA CBER Update: Regulatory Innovation and Modernization to Protect and Promote Public Health** **Peter MARKS, MD, PhD** Director, Center for Biologics Evaluation and Research (CBER) US Food and Drug Administration
10:30–11:00	Tea Break

Friday | May 21 | OPENING PLENARY

11:00–11:50

Opening Special Forum: China's Innovation for Global

MODERATOR

Frank JIANG, PhD
Representative, DIA Board of Directors
CEO, C-Stone Pharmaceuticals

INVITED PANELISTS

WANG Tao, MD, PhD
Deputy Director, Center for Drug Evaluation, NMPA

WU Yilong, Professor
Director, Guangdong Provincial People's Hospital Honorary President, Guangdong Lung Cancer Institute

PANG Junyong
General Manager, Suzhou Industrial Park Biological Industry Development Co., Ltd

WU Xiaobin, PhD
President, Chief Operating Officer, and General Manager of China, BeiGene

Michael YI
Co-Chief Investment Officer, Hillhouse Capital

LI Mengjuan
HR Head, Johnson & Johnson R&D

Global Regulatory Modernization Townhall - Regulatory Modernization to Protect Public Health

Global Regulatory Modernization Townhall on May 21 will invite the regulators from China NMPA, US FDA, EMA and PMDA to share their progress of regulatory modernization and key innovative initiatives to promote regulatory modernization strategy in order to protect public health.

13:30–15:30 **Innovative Initiatives to Promote Regulatory Modernization Strategy**

MODERATOR
CAO Lili
Deputy Director, China International Food and Drug Exchange Center (CCFDIE), NMPA

13:30–14:00 Enabling the Capability of China Drug Supervision
QIU Qiong
Deputy Director, Department of Policies and Regulations, NMPA

14:00–14:30 FDA Initiatives to Strengthen Regulatory Science
Vanessa SHAW-DORE
FDA Country Director, China

14:30–15:00 PMDA Update - Promoting Smooth Access for Innovative Products
UZU Shinobu
Senior Executive Director and Head of International Programs, Pharmaceuticals and Medical Devices Agency

15:00–15:30 EMA's Regulatory Science Strategy to 2025: Enabling Regulatory Science and Innovation EMA2025
Anthony HUMPHREYS
Head of Scientific Committees Regulatory Science Strategy (SciRS), EMA

15:30–16:00 Tea Break

Global Regulatory Modernization Townhall - Regulatory Modernization to Protect Public Health

16:00–17:00 **Regulatory New Initiatives of China NMPA**

MODERATOR
CAO Lili
Deputy Director, China International Food and Drug Exchange Center (CCFDIE), NMPA

16:00–16:20 Key Initiatives to Accelerate Drug Review and Approval Process
NMPA Speaker Invited

16:20–16:40 Interpretation on China's Good Pharmacovigilance Practice (GVP)
NMPA Speaker Invited

16:40–17:00 GMP Inspection Practice
LI Jianming
Deputy Director, Center for Food and Drug Inspection, NMPA

17:00–17:05 **Thanks Address by DIA Global CEO**

Barbara Lopez KUNZ
Global CEO, DIA

17:05–17:10 Closing