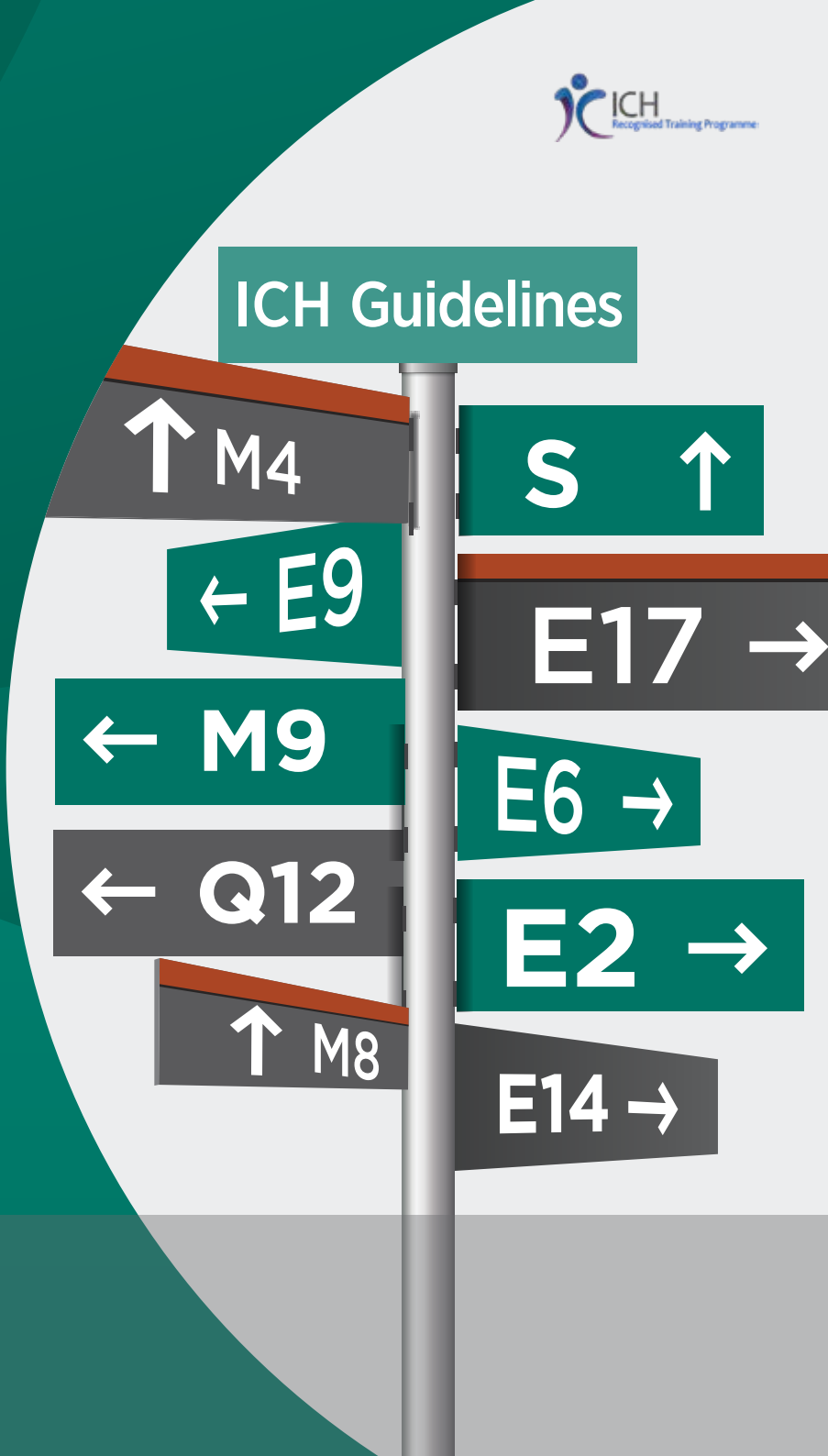
DIA CHINA

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, 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
	CO-CHAIRS INVITED
8:30–8:35	**Welcome**
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**
	NMPA Speaker Invited
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)
10:00–10:15	**The Importance of International Standards, Guidelines and Regulatory Science for Building Trust and Competency**
	Neil MCAUSLANE Director, Chemical Inspection and Regulation Service (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** **Mingli HENG** 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** **Xiaojing PEI** CDE

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Workshop 2 | 10:30–12:00
ICH E17
PROGRAM CO-CHAIRS
Jun WANG
CDE

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

ICH E17 Guideline's Implementation in China
CDE Speaker Invited

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
CDE Speaker Invited

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

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Workshop 4 | 10:30–15:00

ICH E6

PROGRAM CHAIR
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
China CDE Speaker Invited

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

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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