星期一 | 5月20日 | ICH 主题日
Monday, May 20th | ICH DAY

国际人用药品注册技术协调委员会（ICH）是一个技术性非政府组织，发布关于药品安全、有效性和质量的国际技术标准和规范。自1990年由美国、欧共体和日本三方药品监管部门和行业协会共同发起成立， 到2015年10月在瑞士注册成为国际组织，经过二十多年的发展，ICH从机制上为进一步推动监管机构之间的协调提供了保障。其发布的技术指南已经得到全球主要国家药品监管机构接受和实施，成为主要的监管机构批准药品上市的基础，ICH被公认为药品注册领域的核心国际规则的协调机制。ICH之目的在于通过推动国际协调的技术标准，加快新药的准入和对已经批准的药品的持续供给。同时避免不必要的重复性临床试验， 更高效和更经济地开发、注册和生产安全有效高质的药品，也减少实验动物的使用。

继前CFDA（现NMPA)在2017年6月正式成为ICH全球第8个监管机构成员后，2018年6月国家药品监督管理局再传捷报，当选为ICH管理委员会成员，这是一个里程碑式的进程，意味着中国的药品监管部门、制药行业和研发机构将逐步转化和实施国际最高技术标准和指南，并积极参与国际规则制定，将推动国际创新药品早日进入中国市场，满足临床用药需求，同时提升国内制药产业创新能力和国际竞争力。

在日益健全且利好的法规环境下，更需要药研领域的各方同仁在能力上的提升以及对国际标准认知的统一。
为此，DIA中国2019将延续“ICH主题日”，就E2、E9、E17、M1、以及M4/M8相关内容开启培训和探讨。

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, and became the member of ICH Management Committee in June 2018. 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.

This year, ICH Day will invite the core members from international regulatory agencies, industry and academia of ICH committee and expert working group, to share the latest development of ICH, the specific requirements of Tier 4 technical guidelines and experiences of ICH implementation in China and other countries as well as the ICH training strategies. The training will include parallel workshops on M1, E2, E9 & E17 and M4/M8 guidelines.

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Workshop 1 | 9:00 - 16:00 | 203AB, 2ND FLOOR

M1: MedDRA and MedDRA SMQ

PROGRAM CO-CHAIRS

Charles YAN, PhD
Head, Clinical Data Science Center, Hengrui Medicine

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

PROGRAM COMMITTEE

Anna ZHAO-WONG, MD, PhD
Deputy Director, MedDRA MSSO

Joy ZHU
Associate Coding Manager,Clinical Data Coordination
IQVIA (Legacy Quintiles)

Sandy ZHANG
Director, Safety Risk Lead, Safety Surveillance and Risk Management
Worldwide Safety and Regulatory, Pfizer

Phil TREGUNNO
Group Manager, Vigilance Intelligence and Research Group (VIRG), MHRA

Center of Drug Evaluation (CDE) issued the implementation roadmap on 5 ICH Tier II Guidelines 25Jan2018, as of May 1, 2018, serious and unexpected adverse drug reactions (SUSAR) reported during the clinical trial of the drug apply to “E2A: Management of Clinical Safety Data: Definitions and Criteria for Fast Reporting” “M1: MedDRA) “And” E2B (R3): Management of Clinical Safety Data: Data Elements for Individual Safety Report Transmission “. Since the formal requirement on MedDRA implementation, Clinical Trial sponsors are mandatory to use MedDRA coding for SUSARs submitted to Chinese Health Authority, talent on MedDRA coding are greatly needed and qualification of the coder with good practice become a key factors on right coding and correct assessment of the SUSAR. Experience sharing from Japan and UK on the implementation of MedDRA will bring the audience with tips for the early stage.

Agenda

9:00 - 9:30	**MedDRA Overview**
	Dr. Charles YAN
9:30 - 10:00	**The Use of MedDRA in the Review of New Drug Applications at FDA - Remote Presentation**
	Christopher D. BREDER, MD, PhD Medical Officer, Office of New Drug, CDER, FDA FDA Topic Leader ICH M1 PTC Group
10:00 - 10:30	Tea Break
10:30 - 12:00	**Best Practice on MedDRA Coding Process and Qualification**
	Dr. Anna ZHAO-WONG **Joy ZHU**
12:00 - 13:30	Lunch
13:30 - 14:30	**MedDRA SMQ Introduction**
	Sandy ZHANG
14:30 - 15:30	**Experience Sharing on MedDRA Implementation in UK**
	Phil TREGUNNO
15:30 - 16:00	**Panel Discussion**

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Workshop 2 | 9:00 - 17:00 | 201CD, 2ND FLOOR

M4 & M8: Introduction of CTD Application Technology Highlights

PROGRAM CHAIR

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

PROGRAM COMMITTEE

Randy ZHANG, PharmD
Senior Scientist, Preclinical Development & Safety, Janssen (China) Research & Development

Angela LI
Engineer, Regulatory Affairs, Beijing Clinical Service Center

Nan WANG, PhD
Head, Medical Writing, GM, CN/FIN, Bayer Healthcare Co. Ltd.

Shuchen LU, PhD
Head of China Regulatory CMC, Regulatory Affairs, Novartis

Since 2000, FDA/EMEA has established a set of standard for the submission and review of electronic international drug registration documents - Common Technical Document (CTD) specifications. This standard has become the international standard of ICH M4/M8, and has also been issued and implemented as a regulation by the drug administrations of Europe, America and Japan. As a member of ICH Drug Administrations, NMPA is actively promoting the application of CTD/eCTD in China's drug administration approval. The writing format standards and data file format requirements for the five modules of CTD are particularly critical for the New Drug Application (NDA), covering the whole life cycle phases of drug development, production, clinical study and marketing. The implementation of these regulations also directly affects the international certification of China's import and export of drugs. Currently, the global drug registration standards have been transformed from paper-based CTD to electronic CTD (eCTD). Access to the electronic submission data and its data files, and the life cycle management and filing of the created files have been standardized. The transformation from CTD to eCTD is not just an electronic process. It covers a number of systematized standards, such as document management specifications, medical coding specifications, file granularity specifications, data transmission specifications, and system structuring standards. During this training, the document architecture of CTD, writing requirements, specification requirements and categories of data and its data files, specification requirements for document management, and application format requirements for eCTD will be discussed.

Learning Objectives

- Understand the drug administration standards and requirements of CTD/eCTD
- Know the CTD content module requirements
- Learn the eCTD format application data model
- Acquaint CTD-compliant data and data file specifications
- Understand the Trial Master File (TMF) management specification requirements and life cycle procedures
- Know the interrelationship between TMF and CTD module
- Understand the preparation process of eCTD registration data
- Communicate common problems in CTD document management
- Focus on the regulatory specifications and system requirements for the eCTF system

Targeted Audience

- Clinical trial data management personnel
- Clinical trial drug administration professionals
- Clinical trial project management personnel
- Clinical trial statisticians
- Clinical trial supervisor
- Clinical trial QA and QC personnel
- Clinical trial medical writers
- Clinical trial investigators
- Clinical trial electronic system management personnel

Agenda

9:00-10:10	**Essentials of Writing and NMPA Technical Requirements for CTD Module 1**
	Yumin LI
10:10-10:30	Tea Break
10:30-11:45	**Essentials of Writing and Technical Standards of CTD Module 3 and Module 2**
	Dr. Shuchen LU
11:45-12:15	**Panel Discussion - CMC Requirement in Module 1, 2 & 3**
12:15-13:30	Lunch
13:30-14:45	**Essentials of Writing and Technical Standards of CTD Module 4 and Module 2**
	Dr. Randy ZHANG
14:45-15:15	Tea Break
15:15-16:30	**Essentials of Writing and Technical Standards of CTD Module 5 and Module 2**
	Dr. Nan WANG
16:30-17:00	**Expert Interaction and Discussion on Essentials of CTD Writing and Technical Requirements**

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Workshop 3 | 9:00 - 12:00 | 201AB, 2ND FLOOR

E9(R1): ICH E9 (R1) and Estimand in Clinical Trial

PROGRAM CO-CHAIRS

Tony GUO, PhD
Executive Director, Head of Biometrics China, BeiGene

Feng CHEN, PhD
Nanjing Medical University, Dean of Graduate School
Chair of China Association of Biostatistics (CABS)
Chair of China Clinical Trial Statistics (CCTS) Working Group

In the E9 session of ICH day, the invited CDE speaker, who is also a ICH E9 working group member, will give an overview of the E9 guidance as well as an update of the recent work of the work group. Two speakers from industry will share their experience and case studies, with one in Oncology area and the other one from non-oncology area.

9:00-9:30	**Discussion about the Completeness of Study Protocol based on the Concept of E9/R1** **Naiqing ZHAO** Associate Director, Health Statistics, School of Public Health, Fudan University
9:30-10:00	**Cases Sharing: on Definitions and Analysis Strategies for Oncology Endpoints in the Estimand Framework** **Fan XIA, PhD** Associate Director, Biostatistics, BeiGene
10:00-10:30	Tea Break
10:30-11:30	**Estimand Discussion with Health Authorities (FDA/EMA) for Pivotal Studies** **Eva HUA** Associate Director, Biostatistics, Novartis
11:30-12:00	**Panel Discussion**
12:00-13:30	Lunch

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Workshop 4 | 13:30 - 17:00 | 201AB, 2ND FLOOR

E17: General Principle on Planning/Designing Multi-Regional Clinical Trials

PROGRAM CO-CHAIRS

Susan WANG, PhD
Head of Biostatistics & Data Science Asia, Boehringer Ingelheim

Jielai XIA, PhD
Director, Department of Medical Statistics, 4th Military Medical University

Clinical new drug development is globalized to provide patients early access to new drugs worldwide. There are many challenges in a globalized drug development program without a harmonized process, especially when facing many different regulatory bodies with different views. To facilitate more efficient global drug development and increase the possibility of simultaneous worldwide new drug registrations and authorizations, the International conference on harmonization (ICH) initiated the process for having a harmonized guidance document on conducting multi-regional clinical trials (MRCTs) in 2016. The draft ICH E17 document on MRCTs was published for comment in 2016. The final ICH E17 Guideline reached Step 4 of the ICH Process in November 2017. It is now recommended for adoption to the regulatory bodies of ICH regions. An implementation working group has been established in the ICH assembly. Training materials with case studies supportive of harmonized implementation activities of the recently released E17 ICH Guideline on General Principles for Planning and Design of a MRCT is expected to become available on the ICH website by June 2019.

The present guideline describes the principles for planning and design of MRCTs in order to increase the acceptability of MRCTs by multiple regulatory authorities. The basic principles and key considerations for MRCTs include patient selection, choice of endpoints, selection of comparator, sample size, conduct of analysis, adherence to GCP, trial conduct, consultation with regulatory. For the ICH E 17 day at this China DIA conference, we have invited experts from regulatory and industry to present us their understanding of the guideline and their experience in implementing or reviewing of MRCTs.

13:30 - 14:30	**ICH E17- An Overview and Update Since Step 4** **Inger MOLLERUP** Regulatory Consultant, CMR, Novo Nordisk, Switzerland
14:30 - 15:00	**Clinical Pharmacology Principles in MRCT-Regulatory Perspective** **Yaning WANG, PhD** Regulatory Expert
15:10 - 15:30	Tea Break
15:30 - 16:00	**Clinical Operations Considerations for the Implementation of ICH E 17** **QingAn JIAO** Head of Global Clinical Operation, Janssen China R&D Center
16:00 - 17:00	**Panel Discussion** All Speakers above and Invited Panelists: **Ling SU, PhD** Professor, Shenyang Pharmaceutical University Venture Partner, Lilly Asia Ventures **Tony GUO, PhD** Executive Director, Head of Biometrics China, BeiGene **Yue WANG, PhD** Vice President and Head, Biometrics, R&D China, Global R&D Oncology, Astrazeneca

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Workshop 5 | 9:00 - 17:00 | 203CD, 2ND FLOOR

E2: Pharmacovigilance

PROGRAM CO-CHAIRS

Chenglin LI
Director of Drug Safety and Pharmacovigilance, BeiGene

Jia LIU
Associate Directorof Drug safety and Pharmacovigilance, dMed Biopharmaceutical Co.,Ltd.

On 25th Jan, 2018 the Center of Drug Evaluation (CDE) of NMPA issued the implementation roadmap on 5 ICH Tier II Guidelines. Till now 3 of them, E2A/E2B/M1, have been executed over 1 year. Furthermore, CDE issued an Announcement on Adjusting the Review and Approval Procedures for Drug Clinical trials (2018/50/CFDA), which contains a new article about DSUR. So how to meet the requirement of SUSAR submission and prepare an acceptable DSUR are critical to a clinical trial. In the meantime, more and more China innovative pharmaceutical enterprises tend to submit IND applications in other countries. Experience sharing from the industry and Regulatory Authority may give some tips on solving practical problems.

9:00 - 9:15	**Welcome and Introduction**
9:15 - 10:00	**Implementation of E2B R3 for Reporting of SUSARs and Approaches for Analysis** **Phil TREGUNNO** Group Manager of the MHRA's Vigilance Intelligence and Research Group (VIRG), MHRA
10:00 - 10:30	Tea Break
10:30 - 11:30	**Clinical Safety Data Management** **Xingmin QIU** Safety Risk Head, Global Safety Strategy, Safety surveillance and Risk Management Pfizer China R&D Center
11:30 - 12:00	**Q&A**
12:00 - 13:30	Lunch
13:30 - 14:30	**Cooperation, Co-function, Compliance and Realism - the Path to DSUR Accomplished in an Enterprise** **Minshi SU** Director, Pharmacovigilance, SihuanPharm
14:30 - 16:30	**Special Requirements and Experience Sharing of Pharmacovigilance in EU and USA** **Shaoli LV** cStone **Bing DU** Senior Director, Pharmacovigilance and Drug Safety, BeiGene, Ltd.
16:30 - 17:00	**Q&A**