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Lili CAO
Co-chair of 2022 DIA China Annual Meeting
Deputy Director, China International Food and Drug Exchange Center (CCFDIE), NMPA

Wendy YAN
Co-chair of 2022 DIA China Annual Meeting
VP and Head of RA, BeiGene

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Director, Shanghai Lung Cancer Center, Shanghai Jiaotong University, China
Chair, Advisory Council of China, DIA

Feng CHEN, PhD, Professor
Professor, School of Public Health, Nanjing Medical University

Zaiqi WANG, PhD
CEO, InxMed

Ning XU, MD
Executive Vice President, Head of Clinical Development, Zai Lab

Isaac MENG
Head of Medical Office R&D, I-Mab Biopharma

Mengjuan LI
HR Head, Asia Pacific R&D and Innovation, Johnson & Johnson

Tongyan WANG, PhD
Senior Vice President and Managing Director, DIA China

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战略事务负责人
ICH管理委员会主席
Associate Director for Strategic Initiatives
FDA Center for Drug Evaluation and Research

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Principal Scientific Administrator
Stakeholders and Communication
European Medicines Agency

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Associate Executive Director for International Programs
Pharmaceuticals and Medical Devices Agency(PMDA)

谭凌实 博士 | Lingshi TAN, PhD
缔脉生物医药科技（上海）有限公司
董事长兼首席执行官
Chairman and CEO of Caidya

江宁军 医学博士 | Frank N. JIANG, PhD
基石药业高级顾问
Senior Consultant, Cstone Pharmaceuticals

苏岭 博士 | Ling SU, PhD
Fellow of DIA
沈阳药科大学教授；礼来亚洲基金风险合伙人
Professor in Shenyang Pharmaceutical University
and a Venture Partner with Lilly Asia Ventures

樊代明 | Daiming FAN
教授，中国抗癌协会会长, 中国工程院院士，美国医学科学院外籍院士
Professor, President of the Chinese Anti-Cancer Association,
President of Asian Pacific Association of Gastroenterology,
Council Member of the World Gastroenterology

Peter Honig, MD, MPH
DIA全球董事会成员，独立顾问
前辉瑞高级副总裁
Independent Advisor and Board Member and Former SVP Pfizer

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默克研究所高级副总裁
兼法规事务及药品安全负责人
Executive Vice President and Head of Research and Development,
Organon & Co., Merck

Ken GETZ
Tufts药物发展研究中心资助研究项目部主任
Professor and the Director of the Center for the Study of Drug
Development, Tufts University School of Medicine

Regulatory Science

Wendy YAN
Senior Vice President, Head of Regulatory Affairs, BeiGene (Beijing) Co., Ltd.

Jessica CHANG
Vice President,
Drug Regulatory Policy, Tigermed

Irene DENG
Regulatory Affairs Head, Sanofi

Angela YAN
President, R&D and Operations
China & Asia, Kira Pharma

Xiaoyuan CHEN, MD, PhD
Director, GCP Officer,
Beijing Tsinghua Changgung Hospital

Joyce LIU
China Regulatory Affairs Head, Takeda

Clinical Drug Development

Shun LU, MD, PhD
Director, Center for Clinical Medicine of Lung Cancer, Shanghai Chest Hospital, Shanghai Jiaotong University

Jing HE, MD, PhD
SVP, Head of China R&D Global Oncology R&D, Astrazeneca

Xingli WANG, MD, PhD
ACC Member, DIA

Zhaohua CHEN
Head of Global Climical Data Services
Pfizer China R&D Center

Jessie ZOU, MD, PhD
President, Global R&D, Junshi Biosciences

Pei HU, MD, PhD
Co-founder, Beijing Lingchu Tech

Gailing LI, PhD
Chief Scientist Officer, Certara

Patient Focused Clinical Operations and Quality Management

Ning XU, MD, PhD
Executive Vice President, Head of Clinical Development and Regulatory Affairs, Zai Lab

Yang LIN
Director of Phase I Clinical Laboratory, Beijing Anzhen Hospital, Capital Medical University

Jing ZHANG, PhD
Professor of Clinical Pharmacology, Deputy Director, Institute of Antibiotics, Huashan Hospital, Fudan University

Liping ZHOU
Senior Director, QA, MSD R&D (China) Co., Ltd

Shuting LI
Vice president of Jimin Cancer Hospital affiliated to Anhui Medical University

Veronica XIA
Vice President, China GM, Labcorp

Amy JIANG
Head of Quality Office, Harbour Biomed

Clinical Needs and Trial Platform

Ning LI, MD, PhD
Chief Physician, Department of Thoracic Surgery, Cancer Hospital, Chinese Academy of Medical Sciences

Jie LI
Chief Physician, Department of Digestive Oncology, Peking University Cancer Hospital
Chairman of Ethics Committee of Peking University Cancer Hospital

Jessica LIU
Head of M&A Department, Tigermed

Data Science

Daniel LIU, PhD
Chief Science Officer
Beijing Clinical Service Center

Hualong SUN, PhD
General Manager
Meta Clinical Technology Co. Ltd

Anita SHEN
Executive Director, Head of Clinical Data Monitoring and Management (DMM),, Pfizer

Biostatistics

Feng CHEN, PhD
Professor, Dean, School of Public Health
Nanjing Medical University

Jielai XIA, PhD
Professor
Xi ‘an Air Force Military Medical University

Wei ZHANG, PhD
VP, Regional Head of Biometrics and Data Management, Asia/MENA, Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd.

Michael LEE, PhD
Vice President, Head of Biometrics
Harbour BioMed

Lihong HUANG, PhD
Department of Biostatistics
Zhongshan Hospital, Fudan University

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

CMC

Steven HU, PhD
Chief Technical Officer, Everest Medicine

Lily XIONG
Executive Director, CMC, BeiGene

Xiaoping CAO, PhD
SVP, Head of Technology Operations
JW Therapeutics

Na XU
RA Director, 3DMed

Medical Writing and Publication

Nan WANG, PhD
Vice President, Head of Medical Writing
Bayer Pharmaceuticals

PV & Drug Safety

Yuan MENG
Head of Medical Office R&D, I-Mab Biopharma

Conny MO
Founder, Medical Safety Advisor, Beijing XAJK Medical Technology, Co., Ltd.

Howe LI, MD, PhD
Chairman and CEO, Deltamed Co. Ltd

Xiaojing ZHAN
Vice President, Drug Safety, Junshi

Vera LIANG
Director and Global Safety Risk Lead, Safety Surveillance and Risk Management
Pfizer (China) R&D Co., Ltd.

Zheng JIAO
Director of Pharmacy Department, Deputy Director of GCP Center, Chest Hospital Affiliated to Shanghai Jiaotong University

Non-clinical & Animal Test

Jack XIE, PhD
Head of Preclinical Sciences and Translational Safety, Janssen R&D

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

Xiantang LI, PhD
Senior Director, Non-clinical Drug Safety, Pfizer

Translational Medicine

Xinying SU, MD, PhD
Senior Director, Translational Medicine and Diagnostic Lead, Development China, Pfizer

Yi ZHENG, PhD
Head of Translational Science Center, JnJ

Medical Affairs

Haidong CHI, MD, PhD
CMO, Lilly China

BD Roadshow

Liqun WANG, PhD
Founder, Chairman and Chief Executive Officer
NeuKio

Yi LIU
Chief Medical Officer and Senior Vice President, Caidya Biopharmaceutical Co., Ltd

POSTER REVIEW COMMITTEE (评委姓名按首字母排序)

Irene DENG
Regulatory Affairs Head, Sanofi

Howe LI, MD, PhD
Chairman and CEO, Deltamed Co. Ltd

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Chief Science Officer
Beijing Clinical Service Center

Rong SHAO
Director of Research Institute of Drug
Regulatory Science
China Pharmaceutical University

Yue YANG
Professor, School of Pharmacy
Tsinghua University

Chen YAO, PhD
Director, Department of Medical Statistics,
Peking University First Hospital

PROGRAM **TOPICS** | The ICH day and 15 themes designed to advance health care outcomes through innovation and regulatory reforms

ICH Day


Educational Workshop


Openning


Global Regulatory Townhall


BD Roadshow


Regulatory Science


Clinical Drug Development


Patient Focused Clinical Operations and Quality Management


Clinical Needs and Trial Platform


Data Science


Biostatistics


PV & Drug Safety


CMC


Translational Medicine


Non-clinical & Animal Test


Medical Writing and Publication


Pediatric Drug Development Forum


Hot Topics


Professional Development


White Paper Showcase


Community E&E

Thursday | December 8th | 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.

2022 is the 5th year since NMPA, China joined ICH Management Committee, to promote the ICH's global development strategy, DIA China 2022 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, E6R3, E8R1 and M4QR2 will be also covered.

	Plenary
	PROGRAM CO-CHAIRS NMPA Co-chair Invited **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**
8:35–8:50	**Views of Different Stakeholders on How ICH Has Contributed to Better Health and ICH's Future Capacity Building Directions in the Next 5-10 Years**
	Theresa MULLIN, PhD Associate Director for Strategic Initiatives, FDA Center for Drug Evaluation and Research Chair, ICH Management Committee
8:50–9:00	**PMDA Guidance on Patient Participation–PMDA's Consideration**
	Junko SATO, PhD Director, Office of International ProgramsPharmaceuticals and Medical Devices Agency (PMDA) A Member of the ICH Patient Centricity Working Group
9:00–9:30	**ICH's Key Achievements and Implementation in China**
	China ICH Representative Invited
9:30–10:00	**Tea Break**

Thursday | December 8th | ICH DAY

Workshop 1 | 10:00–12:00

ICH M4Q Workshop - Informational Session

PROGRAM CO-CHAIRS
China CDE Co-chair Invited

Meng YANG, PhD
Roche

Working group's expectations and updates on ICH M4Q revision. An overview introduction on the guidance revision, which could include:
- Why to revise the guideline
- What goals to achieve
- Key points/issues/considerations
- Work plan and timelines

Lawrence YU, PhD
Director, Office of New Drug Products, OPQ/CDER
U.S. Food and Drug Administration

China CDE's Expectations and Update on ICH M4Q Revision
- Background information
- CDE's considerations and expectations to the revision
- CDE's suggestions to local companies on the M4Q implementation

China CDE Speaker Invited

Industry Perspective and Expectations on ICH M4Q Revision
- Real-world challenges of M4Q implementation and harmonization
- Industry's expectations

Rodrigo PALACIOS
Global Regulatory Policy Lead for Digital Infrastructure, Roche

Panel Discussion
Invited Panelists
Quan YANG
CMC Registration Head, Novartis

Peter QIU
Lead External Advocacy China, Roche

Thursday | December 8th | ICH DAY

Workshop 2 | 10:00–12:00

E8R1

PROGRAM CO-CHAIRS

CDE Co-chair Invited

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

ICH E8R1 Guideline's Implementation in China
CDE Speaker Invited

ICH E8: Connection and Case Study with ICH E6 & E17
William WANG, PhD
Executive Director, Clinical Safety Statistics, Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories

Panel Discussion
Invited Panelists
Angela YAN
DIA ACC Member

Jiaojiao YU
Senior Project Manager, Tigermed

Yi LIU
Chief Medical Officer and Senior Vice President, Caidya Biopharmaceutical Co., Ltd

Hao WANG
Head of Clinical Operations, Roche China

Thursday | December 8th | ICH DAY

Workshop 3 | 13:30–17:20

E9(R1): Implementation and Consideration of ICH E9(R1) Estimand Framework

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

In China, we expect to implement the ICH-E9(R1) Estimand framework in 2022. However, there are still a large number of clinical trial scientists do not clearly understand the purpose, contents and specific applications of this new framework. Therefore, the DIA statistical community has built up a working group of ESTIMAND BLUEBOOK to collect and sort out specific cases in different therapeutic areas and summarize some special considerations, hoping to launch the BlueBook for reference later this year. This training will provide an overview of the ICH-E9(R1) guidelines as well as case studies from different therapeutic areas to help you better understand and apply the Estimand Framework.

Introduction of ICH-E9(R1) and Estimand Framework
Feng CHEN, PhD
Professor of Biostatistics, Nanjing Medical University
Chair of China Clinical Trial Statistics (CCTS) Working Group

Scientific Interpretation and Findings of Implementation of E9(R1) in China
CDE Speaker Invited

Experience Sharing of Implementation of E9(R1) - from Statistics Perspective
CDE Speaker Invited

Overview of Trial Design and Statistical Analysis Plan with Estimand Framework
Jiawei WEI, PhD
Novartis

Sensitivity Analysis and the Identification of Intercurrent Events
Jeannie QIU, PhD
Head of Biometrics and Data Science, FosunPharma Global R&D Center

Estimands in Oncology
Zhiyue HUANG, PhD
Roche

Estimands in Non-Oncology
Na HU
Senior Principal Statistician, Boehringer-Ingelheim

Estimands in Vaccine
Zhiwei JIANG, PhD
KeyTech

Panel Discussion

Thursday | December 8th | ICH DAY

Workshop 4 | 10:00–15:00

ICH E6 - Informational Session

PROGRAM CHAIR

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

ICH E6 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, this session would invite E6 WG professional representatives from CHINA, EU, US to share the latest updates of ICH E6. Through the sharing of guideline updates and industry advancing practice on Patient Engagement and Quality by Design, invited stakeholder representative would share their insights of the values in applying Patient Engagement and Quality by design in clinical research at the Panel session.

10:00–10:10	**Opening**
10:10–10:30	**ICH E6 R3 Global Revision Progress Update** China CDE Speaker Invited
10:30–11:20	**The Framework of "Patient Centricity" in New Drug Development** **Sally ZHANG** Head, Quality Assurance, AstraZeneca ICH E6R3 Global Expert Working Group (EWG) **Weiyi ZHENG** VP, Head of Clinical Operations, R&D China, AstraZeneca
11:20–11:35	**The Practice of "Public and Patient Participation" System in UK** **Ping JI, PhD** Professor, Associate Director, Peking University Clinical Research Institute (Shenzhen)
11:35–11:50	**Case Sharing- Patient Engagement Practice in Japan** **Kazuyuki SUZUKI** Team Lead, Patient Engagement, Novartis Japan
11:50–12:00	**Wrap Up of Morning Session** **Sally ZHANG** Head of R&D Quality Assurance APAC, AstraZeneca ICH E6 R3 Global Expert Working Group
12:10–13:30	Lunch

Thursday | December 8th | ICH DAY

13:30–14:50 **Panel Discussion: Patient Centricity - Global Landscape and Insight for Implementation in China based on ICH E6 R3**

CO-MODERATORS

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

CDE Moderator Invited

INVITED PANELISTS

Ning LI, MD, PhD
Chief Physician, Vice President of Cancer Hospital of Chinese Academy of Medical Sciences

Haiyan LI
Director of Drug Clinical Trial Institution, Chief Physician of Cardiovascular Medicine, Peking University Third Hospital

Yifeng SHEN
Chief Physician, Director of Drug Clinical Trial Institution, Shanghai Mental Health Center

Jing HE, MD, PhD
SVP, Head of China R&D Global Oncology R&D, Astrazeneca

Jason YANG, PhD
Chief Executive Officer, CStone
ICH E6 R3 Global Expert Working Group

Julia WANG
Executive Director, Clinical Operations, Eli Lilly

Hannah CHEN
GCP Consultant, Beijing XiaoTongMingDa Technology Ltd.
Founder, China QA Forum (CQAF)

14:50–15:00 **Closing**

Thursday | December 8th | ICH DAY

Workshop 5 | 10:00–15:00

ICH Q12 & Q13

PROGRAM CO-CHAIRS
CDE Co-chair Invited

Xiaoping CAO, PhD
SVP, Head of Technology Operations, JW Therapeutics

Steven HU, PhD
Chief Technical Officer, Everest Medicine

10:00–10:30	**Global Regulatory Harmonization for CMC Control Strategy** **Greg RULLO** Senior Director, Regulatory Affairs - CMC, AZ R&D
10:30–10:50	**Q12 Guideline Implementation in China** CDE Speaker Invited
10:50–11:10	**Progress on the Global Adoption and Implementation of ICH Q12** **Andrew CHANG, PhD** Vice President, Quality and Regulatory Compliance, Quality, Novo Nordisk
11:10–11:30	**Q12 Implementation case studies - Small Molecules** **Connie LANGER** Director, Pfizer
11:30-11:50	**Q12 Implementation case studies - Large Molecules** **Monica Perea-Velez, PhD** CMC Advocacy and Policy Director Development GRA CMC Excellence, GSK
11:50–12:10	**Analytical Procedure Life Cycle and Q12 & Q14** **Dr. Amanda Mesquita GUIRALDELLI** Scientific Affairs Manager, USP
12:10–13:30	Lunch
13:30–13:50	**ICH Q13 Implementation in China** CDE Speaker Invited

Thursday | December 8th | ICH DAY

13:50–14:10	**Q13 Presentation from MNC Perspective**	
	Speaker Invited	
14:10–14:30	**Q13 Presentation from Local Company Perspective**	
	Huangfei DENG Vice President, Technology, Triastek	
14:30–15:00	**Panel Discussion**	
	MODERATOR **Steven HU, PhD** Chief Technical Officer, Everest Medicine	

Thursday | December 8th | ICH DAY

Workshop 6 | 10:00–15:00

ICH Safety Guidelines: Nonclinical Safety Strategy Supporting FIH and Development of Modern Modalities

PROGRAM CO-CHAIRS

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

Jack XIE, PhD
Head of Preclinical Sciences and Translational Safety, Janssen R&D

NMPA, China 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.

General Requirements for Nonclinical Package Supporting FIH
Qingli WANG, PhD
Director, Office of Pharmacology and Toxicology, CDE, NMPA, China

Animal Species Selection for Biologics Nonclinical Safety Study
Xiaobo CEN, PhD
CEO, WestChina Frontier Biotech

Dose Levels Selection in Toxicology Study, Human Safety Starting Dose and Exposure Ceiling Based on Toxicology Outcomes
Jack XIE, PhD
Head of Preclinical Sciences and Translational Safety, Janssen R&D

Safety Pharmacology Studies Considerations for FIH
CDE Speaker Invited

Nonclinical Safety Evaluation and ICH S12 Updates on Nonclinical Biodistribution Study of Gene Therapy Product
CDE Speaker Invited

Nonclinical Safety Evaluation on Cellular Therapy Product
Jing MA, PhD
Chief Advisor, Shanghai Lingang Economic Development Group Co., Ltd.

Panel Discussion
All Speakers

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 1 | 15:30 - 18:00

Labeling Management

PROGRAM CO-CHAIRS

Xiaoyuan CHEN, MD, PhD
Director, GCP Officer, Beijing Tsinghua Changgung Hospital

Rose GAO
RA Head, Novartis

The History, Current Status and Prevision of China Drug Labeling Management System Guideline

CDE Speaker Invited

Experience Learning of International Drug Labeling Management System

Lei ZHANG
JnJ

Yang LIU

Experience and Suggestions on Drafting New Drug Labeling - Industrial Perspective

Kun XIA
Head of Ophthalmology and Neurology Registry, Novartis

Hongying WEI
Medical Director of Jiangsu Hausen Pharmaceutical Group Co., LTD

BeiGene Speaker Invited

Panel Discussion

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 2 | 15:30- 18:00

Regulatory Requirements of Medical Coding in Clinical Trials

PROGRAM CHAIR

Daniel LIU, PhD

Chief Scientific Officer, Clinical Service Center

NMPA is requesting to implement the ICH M1 related to medical coding practice in China clinical trials on July 1 2022. MedDRA is one of the ICH guidelines published, which is adapted in the drug R&D process of regulatory managements from IND to NDA life cycle, ensuring the scientific and regulatory compliance of entry, index, assessment and reporting of clinical data. This session is discussing how to implement this MeDRA practice in a process of clinical trials execution, making relative clinical staffs compliant well with the regulatory MedDRA expectations by NMPA for pharmaceutical enterprises in China.

15:00–15:30	**Outlines of MedDRA**	**Yuxiu LIU, Professor** Professor and Chief Physician, Department of Critical Case Medicinent of General Hospital Eastern Zone of China
15:30–16:30	**Coding Rule and Techinques of MedDRA**	**Pansie ZHANG** Senior Coding Specialist, Merck (China)
16:30–17:00	**MedDRA Coding Exercises**	**Pansie ZHANG** Senior Coding Specialist, Merck (China)
17:00–18:00	**Outline of MedDRA SMQ Reporting Analysis**	**Junchao CHEN, PhD** Medical Officer, MSSO

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 3 | 15:30 - 18:00 |

Real World Data Progress - Quality, Standard and Application

PROGRAM COMMITTEE

Ling SU, PhD
Fellow of DIA
Professor in Shenyang Pharmaceutical University and a Venture Partner with Lilly Asia Ventures

Ting WU, PhD
Senior Director, Lilly

Shanmei LIAO, PhD
Head, Post-market Statistics, BeiGene

Haijun CAO, PhD
Asia Non-Oncology Lead, Takeda China

Qiang LI, PhD
BI

Shusen LIU
Head of Medical Research and Innovation, Janssen Department of Medicine

A Case Study of Phase III Ranomized Trial with Hybrid Control
Shuyi SHEN
Product Development China Clinical Science Head, Roche

Real-world Evidence as Part of the Totality-of-Evidence to Inform Indications in a New Population
Jeff LANGE
Observational Research Director, Amgen

Panel Discussion: Real Data Quality and Standard

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 4 | 15:30 - 18:30

Inspection Readiness via a Comprehensive PV QMS

PROGRAM CO-CHAIRS

Winnie WU
Director of Medical Insights and PMO, Boehringer Ingelheim

Hellen ZHANG
Senior Director of PV, Beigene

China has entered the stage of full implementation of the "GVP". The "Guideline for Pharmacovigilance Inspection (Draft for Comment)" issued by NMPA standardizes the principles for drug regulatory authorities to carry out pharmacovigilance inspection. It indicates that inspection will become the norm in the field of pharmacovigilance.

Under this environment, it is an urgent need to understand the regulatory requirements properly, enhance the PV quality management system, establish the capability of the inspection readiness, including the timely identification of problems of the PV system, develop the effective CAPA in a timely manner, so that we have the confidence to take the inspection in stride.

This workshop will focus on PV inspection readiness and capability establishment to have deep discussion with participants

China PV Inspection Guideline and Practice Sharing
NMPA Speaker Invited

Foreign PV Inspection Experience sharing & Learning
Speaker Invited

Panel Discussion – Elements of a Smooth Inspection
Panelists Invited

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 5 | 15:30 - 18:00

Target Trial Emulation

PROGRAM CO-CHAIRS

Lihong Huang, PhD
Department of Biostatistics, Zhongshan Hospital, Fudan University

Jiawei WEI, PhD
Director, Biostatistics, Novartis

The Target Trial was formally proposed by Hernan and Robins in 2016. The process of using observational data to complete the Target test according to the set plan is Target Trial Emulation. The aim is to bridge the gap between RCT and observational research and link observational research with RCT.

It is a new concept of RWS, which applies the design and analysis ideas of RCT to observational research, improves the level of evidence of observational research, and facilitates the transformation from RWD to RWE. Duplicate RCT was presented at the DIA 2020 Annual Meeting and case studies were presented. We hope to discuss this topic in depth this year.

New Concept of RWS: The Value of Simulated Target Trials

Zhao YANG, PhD
Supervisor, Department of Biostatistics, Nanjing Medical University

Causal Inference as the Glue: Lessons from Target Trial Emulation in Register Epidemiology

Theis LANGE
Head of Department, Professor, Department of Public Health, University of Copenhagen

Challenges in the Emulation of Target Trials and Design Approximations to Address Them.

Garcia de Albeniz Martinez XABIER
Director of Epidemiology at RTI Health Solutions, Visiting Scientist at CAUSALab of Harvard T.H. Chan School of Public Health

Defining Causal Questions for a Single-Arm Trial with an External Control Arm: An Application of the Target Trial Framework in Oncology.

CO-PRESENTERS

Lisa Hampson
Director, Biostatistics, Novartis

Yi CHENG
Deputy Director, Biostatistics, Novartis

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 6 | 15:30 - 18:00

When Medical Affairs Meet Clinical Development

PROGRAM COMMITTEE

Haidong CHI, MD, PhD
CMO, Lilly

Yi LIU
Chief Medical Officer and Senior Vice President, Caidya Biopharmaceutical Co., Ltd

Haijun CAO
Asia Non-Oncology Lead, Takeda China

How do New Therapies Stand out from the Competition

MA REPRESENTATIVE
Jie CHEN
CMO, Beiheng Biotech

CLINICAL REPRESENTATIVE
Wei WANG
Clinical Development VP, Head of MA, CARsgen Therapeutics

Panel Discussion
MODERATOR
Yi LIU
Chief Medical Officer and Senior Vice President, Caidya Biopharmaceutical Co., Ltd

Value Maximization in Phase III Clinical Study

MA REPRESENTATIVE
Zihuan GUO
Head, Oncology Area, Takeda

CLINICAL REPRESENTATIVE
Jin WANG
Chief Medical Officer, Abbotz Pharmaceuticals

Panel Discussion
MODERATOR
Haidong CHI, MD, PhD
CMO, Lilly

INVITED PANELIST
Mu SUN
Vice President, BD, NeuKio

Clinical Study or the Real World Study? This is a Question

MA REPRESENTATIVE
Haijun TIAN, PhD
Executive Director, RWS, Novartis

CLINICAL REPRESENTATIVE
Yue WANG, PhD
Head of Digitalization and Data Innovation, Vice President, Astrazeneca Global R&D China Center

Panel Discussion
MODERATOR
Haijun CAO
Asia Non-Oncology Lead, Takeda China

INVITED PANELISTS

Tong GUO, PhD
Vice President, BD, IQVIA

Liheng MA
Pfizer

Thursday | December 8th, 2022 | Pre-conference Short Courses

Short Course 7 | 16:00 - 17:30

PIC/S Forum

MODERATOR
Xiangyu WANG
NMPA

16:00 - 16:10	**Welcome Address**	NMPA Speaker Invited
16:10 - 16:40	**Revised Quality Risk Management Requirements of ICH Q9**	**Kevin ODONNELL** Member of PIC/S Member of HPRA
16:40-17:10	**Related Requirements of Asepsis Appendix**	**Ian Thrussell**
17:10-17:30	**Introduction of Clinical Trial Appendix**	CFDI Speaker Invited

Friday | December 9th | OPENING PLENARY

9:00–9:05	**Welcome** **WANG Tongyan, PhD** Managing Director, DIA China
9:05–9:15	**Program Co-chaimen Welcome Address** **Lili CAO** Co-chair of 2022 DIA China Annual Meeting Deputy Director, China International Food and Drug Exchange Center (CCFDIE), NMPA **Wendy YAN** Co-chair of 2022 DIA China Annual Meeting VP and Head of RA, BeiGene
9:15–9:30	**Welcome Speech of Leader of The National Medical Product Administration**
9:30–9:35	**Welcome Speech of Leader of Ministry of Science and Technology**
9:35–9:40	**Welcome Speech of Suzhou Local Government**
9:40–10:05	**Keynote Speech 1 | Innovative Achievements of NMPA** NMPA Commissioner Invited
10:05–10:30	**Keynote Speech 2** **Innovation and Collaboration: The Role of Clinical Trials and International Collaboration** **Emer Cooke** Executive Director, EMA

ICH Day

Educational Workshop

Opening Plenary

Global Regulatory Townhall

China Regulatory Special Session

Regulatory Science

Drug Clinical Development

Patient Centered Clinical Operations and Quality Management

Clinical Needs and Trial Platform

Data Science

Biostatistics

PV & Drug Safety

CMC

Translational Medicines

Non-clinical & Animal Test

Medical Writing and Publication

Pediatric Drug Development Forum

Hot Topics

Friday | December 9th | OPENING PLENARY

10:30–11:20 **Opening Special Forum: Collaboration, Innovation – China Innovative Drug Globalization Pathway**

MODERATOR

Shun LU, MD
Director, Center for Clinical Medicine of Lung Cancer, Shanghai Chest Hospital, Shanghai Jiaotong University

INVITED PANELISTS

CDE Panelist Invited

WANG Yongjun, Professor
President, Beijing Tiantan Hospital

Zili LI, MD
Vice President, Head of Asia Pacific R&D, Janssen Research & Development

Weikang TAO, PhD
Vice President and General Manager, Qilu Global Innovative Drug Research and Development

Jin Wang
Partner, McKinsey & Company

11:20–11:50 **2022 DIA China Inspire Award Ceremony**

Friday | December 9th
Global Regulatory Modernization Townhall

Global Regulatory Modernization Townhall on May 20 will invite the regulators from China NMPA, US FDA, EMA and PMDA to share their regulatory responses and key innovative initiatives to against COVID-19 Pandemic in order to save people and protect public health, also their lessons learned.

13:30–15:00

Regulatory Responses and Key Innovative Initiatives to Against COVID-19 Pandemic

MODERATOR
NMPA Moderator Invited

13:40–14:00 NMPA Update
Department of Registration, NMPA

14:00–14:20 FDA Update
Kevin B Bugin, MS, PhD, RAC
Deputy Director of Operations
Office of New Drugs, CDER, FDA

14:20–14:40 PMDA Update
Nobumasa Nakashima, PhD
Associated Executive Director for International Programs
Pharmaceuticals and Medical Devices Agency (PMDA)

14:40–15:00 EMA Update
Alexis NOLTE
Head, Human Medicine Division, EMA

Friday | December 9th
Global Regulatory Modernization Townhall

15:00–17:00	**NMPA Townhall**
	Promote Global Regulatory Collaboration NMPA Department of Science, Technology, and International Cooperation Speaker Invited
	Key Initiatives to Accelerate Drug Review and Approval Process NMPA CDE Speaker Invited
	5 Years Review of China Drug Inspection NMPA CFDI Speaker Invited
	Drug Safety NMPA CDR Speaker Invited
17:00–17:05	**Thanks Address by DIA Global CEO**
	Barbara Lopez KUNZ Global CEO, DIA
17:05–17:10	**Closing**

Regulatory Science - *China Regulatory Modernization*

THEME LEAD

Wendy Yan
Senior Vice President, Head of Regulatory Affairs
BeiGene (Beijing) Co., Ltd.

Angela YAN
President, R&D and Operations, China & Asia, Kira Pharma

Jianqing CHANG
Vice President, Drug Regulatory Policy, Tigermed

Xiaoyuan CHEN, PhD
Director, GCP Officer, Beijing Tsinghua Changgung Hospital

Irene DENG
Vice President, Regulatory Affairs Head, Sanofi

Joyce LIU
China Regulatory Affairs Head, Takeda

Session 0101 | December 10, 2022

08:30–10:00

Expedited Program under New Regulations - Considerations & Practices

SESSION CO-CHAIRS

Lihua PAN
Head of China Regulatory Policy, Global RA, GDD, Novartis

Lei ZHANG
RA Head, Janssen

Speeding up the review policy is one of the important international measures to encourage drug innovation and benefit patients as soon as possible. With the introduction of new drug administration laws, registration regulations and guidelines to speed up review and approval, for example

Breakthrough therapeutics, conditional approval, AD hoc approval procedures, and existing guidelines such as priority review and approval have been updated. This topic is intended to invite representatives of drug regulatory bodies and industry from the regulatory

To explore the mechanisms of accelerated review and approval at home and abroad from the institutional and industry perspectives, share successful cases and suggestions, and guide the industry to accelerate drug development process.

CDE Expedited Review Policy Analysis and Suggestions
CDE Speaker Invited

China and the United States to Speed up the Case Sharing and Thinking
Yanyan WEI
RA Group Lead, Novartis

China Synchronous R&D and Submission Sharing and Thinking
Jian CHEN
Head of Immune Inflammation Regulation, Boehringer Ingelheim

Review and Approve Case Study
Hui YAN
Senior Director, Pharmaceutical Affairs, BeiGene

Regulatory Science - *China Regulatory Modernization*

Session 0102 | December 10, 2022

10:30–12:00

Challenges and Considerations from Accelerated Approval to Full Approval

SESSION CHAIR
Wendy YAN
SVP, Chief Regulatory Officer, Beigene

After formal implementation of accelerated approval in China, dozens of products have been approved under this pathway. In the coming years both health authorities and sponsors will be faced with how to achieve full approval through confirmatory clinical trials and how to deal with the various possibilities of the results from confirmatory trials.

This session will invite experts from NMPA and FDA, as well as industry experts in China to discuss the challenges of accelerated approval and confirmatory study design.

Challenges and Recommendations for Confirmatory Clinical Studies after Accelerated Approval
Vivian ZHANG
Director, Regulatory Affairs, BeiGene

The Current Considerations of the Confirmatory Study Design and the Management of the Trial Results
CDE Speaker Invited

FDA's Thinking and Experience on Accelerated Approval and Confirmatory Study Design
Wenny DU, MSc
Director, Global Regulatory Lead (GRL) for Oncology, Amgen Inc., United States

Panel Discussion
Panelists: Above Speakers and Invited Panelists
Xiaoyuan CHEN, PhD
Executive Director of Clinical Trial Center, Tsinghua University

Lihua PAN
Head of China Regulatory Policy, Global RA, GDD, Novartis

Regulatory Science - *China Regulatory Modernization*

Session 0103-A | December 10, 2022

13:30–15:00

The Opportunity and Challenge Under the Concept of Clinical Value-Oriented Drug Innovation- Part 1

SESSION CHAIR
Jianqing CHANG
Government Regulation Affairs, Hangzhou Tigermed Consulting Co.,Ltd.

The concept of "Encouraging clinical value-oriented drug innovation" has been proposed for the first time ever since the launch of drug review and approval reform in 2015. Then this concept is re-emphasized in the new <Drug Administration Law>, the new <Drug Registration Regulation>. In the < Guideline for Clinical Development of Clinical Value-Oriented Oncology Drugs(seeking for public's opinion's version)>issued on July 2, 2021, it is focusing on clinical value-oriented and patient needs-oriented R&D. This guideline is not only a summary of the exploration, practice and accumulation of the concept that has been implemented for nearly six years for the review and approval of oncology drugs, but also applicable to all therapeutic areas, including oncology and non-oncology therapeutic areas, rare diseases and pediatric diseases, etc. Through the sharing and discussion between health authority and industry, especially with the selected cases, we hope to bring inspiration and help to the development of new drug development and registration strategies.

Progress of Review and Approval based on Clinical Value
CDE Speaker Invited

Differentiated Development Strategy based on Clinical Value -- Clinical Perspective
Bin PENG, PhD
Chief Medical Officer, Anmai Biology

Clinical Value-oriented Differentiated Development Strategy -- Registration Perspective
Irene DENG
Vice President, Regulatory Affairs Head, Sanofi

Panel Discussion
Above Speakers and Invited Panelists
Xia CHEN, MD, PhD
Senior Vice President, Chief Medical Officer, Tiger Pharmaceuticals

Regulatory Science - *China Regulatory Modernization*

Session 0104-A | December 10, 2022

16:00–17:30

The Opportunity and Challenge Under the Concept of Clinical Value-Oriented Drug Innovation- Part 2

SESSION CHAIR
Angela YAN
President, R&D and Operations, China & Asia, Kira Pharma

The concept of "Encouraging clinical value-oriented drug innovation" has been proposed for the first time ever since the launch of drug review and approval reform in 2015. Then this concept is re-emphasized in the new <Drug Administration Law>, the new <Drug Registration Regulation>. In the < Guideline for Clinical Development of Clinical Value-Oriented Oncology Drugs(seeking for public's opinion's version)>issued on July 2, 2021, it is focusing on clinical value-oriented and patient needs-oriented R&D. This guideline is not only a summary of the exploration, practice and accumulation of the concept that has been implemented for nearly six years for the review and approval of oncology drugs, but also applicable to all therapeutic areas, including oncology and non-oncology therapeutic areas, rare diseases and pediatric diseases, etc. Through the sharing and discussion between health authority and industry, especially with the selected cases, we hope to bring inspiration and help to the development of new drug development and registration strategies.

Clinical Value based Regulatory Strategy Case Sharing
Wen GU
RA Head of Specialty Care (non-rare) and Primary Care BU, Sanofi

Clinical Value based Drug Development Case Sharing - Oncology
Long CHENG, PhD
Vice President, RemeGen

Clinical Values based ICH E9(R1)
Naiqing ZHAO
Chief Scientific Officer, Caidya Biopharmaceutical Co., Ltd

Regulatory Science - *China Regulatory Modernization*

Session 0105-A | December 11, 2022

08:30–10:00

How to Further Promote the Convergence and Consistency of Global Supervision - Regulatory Innovation Trend in China, Japan, Europe and the United States

SESSION CO-CHAIRS

Fei ZHENG
Head Immunization, RA, Abbvie

Julia LUAN, PhD
Senior Director in Global Regulatory Affairs, Astrazenca

In China, Japan and the United States analyze the new regulatory trends of different national regulatory authorities by introducing the new regulations, policies, new measures and regulatory concepts introduced by China (NMPA), Japan (PMDA), the United States (FDA) and Europe (EMA) regulatory authorities in recent years.

On September 17, 2019, FDA announced a framework plan called the ORBIS project . The Orbis program is an initiative program initiated by the US FDA's Center of Excellence (OCE) in Oncology, providing a collaborative framework for the synchronous submission and review of oncology products among international drug regulatory collaborating agencies. The program is coordinated by the FDA and is similar to the Access Alliance, with members including the TGA, Health Canada, the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Sciences Agency of Singapore (has), Swissmedic, and the Brazilian National Health Surveillance Agency (ANVISA).

Further Promote Convergence and Consistency of Global Regulation – Regulatory Innovation Trends in Japan, Europe and the United States
CDE Speaker Invited

New Measures and Trends in Drug Supervision in Europe and the United States
Julia LUAN, PhD
Senior Director in Global Regulatory Affairs, Astrazenca

Introduction of Simultaneous Approval by Multiple Regulatory Authorities (ORBIS Project)
Yinghua WANG, PhD
FDA ORBIS Team member, Senior Regulatory Health Project Manager in the Oncology Center of Excellence, US FDA

ORBIS Case Sharing——Venetoclax AML Introduction
Tiesch John
Director, RA Global Regulatory Strategy, Abbvie US

Pane Discussion: My Opinion on "Regulatory Innovation in China"
PANELISTS
Speakers above and Invited Panelists
Wendy Yan
SVP, Chief Regulatory Officer, Beigene

Jing HE, PhD
SVP, Head of China R&D Global Oncology R&D, Astrazeneca

Regulatory Science - *China Regulatory Modernization*

Session 0106-A | December 11, 2022

10:30–12:00

Opportunities, Challenges and Suggestions for MAH Implementation in China

SESSION CHAIR
Jie LI
Senior Vice President, RA Head, Overland Pharma

In 2015, Chinese regulation proposed for the first time to carry out the polit of drug marketing authorization holder(MAH). In 2016, MAH polit were launched in 10 provinces/municipalities.

MAH clarifies the subject of responsibility, promotes resource optimization, greatly encourages innovation, and brings opportunities to Chinese industries. However, there are still a lot of challenges.

In this session, we invited experts from PMDA and NMPA, to learn the mature experience, to hear the considerations from health authorities. We also invited the representative from Chinese industry to hear the challenges they are facing. Let's discuss together how to better implement MAH.

Regulatory Experience of MAH Implementation in Japan
Yuji MATSUKURA
Deputy Director, Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare (MHLW)

Opportunities and Challenges Faced by Chinese Heath Authorities in the Process of MAH Implementation
NMPA Speaker Invited

Opportunities and Challenges Faced by Chinese Industries in the Process of MAH Implementation
May Li
VP, Head of Regulatory Affairs, China/Japan, Beigene

Panel Discussion
PANELISTS
Speakers above and Invited Panelist
Huina WANG
Regulatory Director, China R&D Center, Johnson & Johnson

Jianqing CHANG
Vice President, Drug Regulatory Policy, Tigermed

Regulatory Science - *Global Regulatory New Trend*

Session 0105-B | December 11, 2022

8:30–10:00

FDA Session: Communicating with the FDA: Best Practices to Overcome Drug Approval Barriers and Regulatory Challenges

SESSION CHAIR
Latasha ROBINSON
Acting Country Director, FDA China Office

Generic drugs provide significant public health benefits by providing high-quality, more affordable alternatives to brand name drugs. Approximately 90 percent of prescriptions dispensed in the United States are generic drugs that often are the product of an intricate global supply chain. The Office of Generic Drugs (OGD) is involved in efforts intended to advance the international harmonization of scientific, technical and regulatory standards for generic drug development. OGD continues global efforts with a focus on prioritizing future topics for generic harmonization that will include more complex generic drugs. The envisioned outcome of these global efforts is reduced time and cost of product development consequently improving patient access to more affordable medicines. OGD global affairs identifies opportunities and challenges as those national regulations are being developed and implemented positioning regulators proactively on the path of convergence.

Communicating with the FDA: Inspections & Remote Regulatory Assessments
Jonathan CHAPMAN
Medical Product Supervisor, FDA China Office

OGD Global Affairs Program and Global Engagement
Sarah IBRAHIM, PhD, PharmD
Associate Director for Global Generic Drug Affairs, Office of Generic Drugs (OGD); Office of Center for Drug Evaluation & Research (CDER), FDA

Q&A

Regulatory Science - *Global Regulatory New Trend*

Session 0106-B | December 11, 2022

10:30–12:00

PMDA & JPMA Joint Session, How Japanese Regulatory Authority and Industry Responded to Manage Clinical Trials under COVID-19 Pandemic

SESSION CO-CHAIRS

Nobumasa Nakashima, PhD
Associate Executive Director for International Programs and Asia Training Centre
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Sachiko NAKAGAWA, MPH
Managing Director, Japan Pharmaceutical Manufacturers Association (JPMA), Japan

Regulatory Responses to COVID-19 in Japan
Yuji MATSUKURA
Deputy Director, Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare (MHLW)

Regulatory Agility for Clinical Development under the COVID-19 Pandemic
Daisuke KOGA
Division Director, Division of Planning and Management, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)

Industry's Efforts on Clinical Trials Conduct under Pandemic
Toshiharu SANO
Vice-Chairperson, Drug Evaluation Committee, Japan
Pharmaceutical Manufacturers Association (JPMA)

Drug Clinical Development

THEME LEAD

Shun LU, MD, PhD
Director, Center for Clinical Medicine of Lung Cancer
Shanghai Chest Hospital, Shanghai Jiaotong University

Jing HE, MD, PhD
SVP, Head of China R&D Global Oncology R&D, Astrazeneca

Xingli WANG, MD, PhD
ACC Member, DIA

Zhaohua CHEN
Head of Global Climical Data Services, Pfizer China R&D Center

Jessie ZOU, MD, PhD
President, Global R&D, Junshi Biosciences

Pei HU, MD, PhD
Co-founder, Beijing Lingchu Tech

Gailing LI, PhD
Chief Scientist Officer, Certara

Non-oncology Drug Clinical Development

Session 0201-A | December 10, 2022

08:30-10:00

Drug Development in Cardiovascular Diseases – Challenges and Opportunities

SESSION CO-CHAIRS

Haiyan LI
Director of Drug Clinical Trial Institution, Chief Physician of Cardiovascular Medicine, Peking University Third Hospital

Xingli Wang, MD, PhD
ACC Member, DIA

New Progress in Drug Development of Heart Failure
Jian ZHANG, MD
Director, Professor, doctoral supervisor, Heart Failure Center, Fuwai Hospital, Chinese Academy of Medical Sciences
Director, Key Laboratory of Cardiovascular Drugs Clinical Research, National Health Commission

A Regulatory Approach to Accelerate Cardiovascular Drug Development
CDE Speaker Invited

Translational Research: Case Studies on the Transformation of Laboratory Findings into Clinical Studies
Guoping YANG
Professor, Director of Translational Medicine Center of Xiangya Third Hospital

First in class Drug Development for Cardiovascular Disease
Baoxue YANG, MD, PhD
Deputy Dean, Director, Department of Pharmacology, School of Basic Medical Sciences, Peking University

Drug Clinical Development

Session 0202-A | December 10, 2022

10:30-12:00

Neurology & Psychiatry Drug Development

SESSION CHAIR
Yifeng SHEN
Director of drug Clinical Trial Institution Office of Shanghai Mental Health Center

Global and Chinese Antidepressant Market and Clinical Development Progress Report
Yifeng SHEN
Director of drug Clinical Trial Institution Office of Shanghai Mental Health Center

Current Status of Global Alzheimer's Drug Development
Yaning WANG, PhD
CEO of Lanlai Technology
Former Director, Quantitative Pharmacology division, U.S. FDA

Session 0203-A | December 10, 2022

13:30–15:00

Breakthrough of Rheumatism Immunotherapy

SESSION CHAIR
Yingyue JU
Head of Clinical Development, Pfizer China

Focus on the hot spots and pain points of clinical research and development of immune dermatology, explore the precise treatment of immune skin diseases, and share the experience of remote clinical research of dermatology.

A New Era in Immunological Picot Research
Xinghua GAO
Director of Dermatology, Deputy Director, The First Clinical College of China Medical University

Exploration of Precise Treatment of Immune Skin Diseases
Yang CUI
Head of Immune Inflammation Research and Development, Pfizer China

Reflection on Differences in Diagnostic/Evaluation Criteria between Clinical Research and Clinical Practice
Ting LI
Deputy Chief Physician, Renji Hospital, Shanghai Jiaotong University School of Medicine

Drug Clinical Development

Session 0204-A | December 10, 2022

16:00-17:30

Vaccine Development

SESSION CO-CHAIRS

Pingping LI
Director of Life Science Investment, SDIC Investment Management Co., LTD

Shengmei MU
Senior Director, Senior Category Development Lead - Rare Disease & Vaccine, Pfizer

This session mainly focused on the evolution of COVID-19 vaccine research and development in the era of COVID-19, and the reference significance of new technology vaccines compared with vaccines of other diseases.

Interpretation of Principles for the Development of Multivalent Vaccines Guideline
CDE Speaker Invited

Progress in Sequential Strengthening of COVID-19 Vaccine Trial
Hongxing PAN
Director of Vaccine Clinical Evaluation Institute, Jiangsu Center for Disease Control and Prevention

COVID-19 Vaccine Technical Standards and Detection Perspectives
Speaker Invited

Application of mRNA Vaccine in COVID-19 and Other Diseases
Hangwen LI, PhD
CEO, StemiRNA

Building an Immune Barrier for Newborns - Global Advances in Maternal Immunity
Qiaohong LIAO
Director of Vaccine Clinical Research and Development, Pfizer (China) Research and Development Co. LTD

Session 0205-A | December 11, 2022

8:30–10:00

Infection Disease Drug Development

SESSION CHAIR
Sunny ZHU
Chief Medical Officer, Everest Medicines

New Guidance Updates of EMA/FDA for Drug Development of Anti-bacterial Products
Rienk Pijpstra
VP, Portfolio Head of Anti-bacterial Product, Pfizer

Innovative Research and Development of China's first COVID-19 Neutralizing Antibody Drug
Yao ZHANG
Vice President, Clinical Research, Brii Biosciences

Drug Clinical Development

Session 0206-A | December 11, 2022

10:30–12:00

Metabolic Endocrinology

SESSION CHAIR
Yi LIU
Chief Medical Officer and Senior Vice President, Caidya Biopharmaceutical Co., Ltd

Diabetes Drug Development: Going beyond Hypoglycemic-centric
Linong JI
Director, Department of Endocrinology, Peking University People's Hospital
Director, Peking University Diabetes Center

Medical Strategy Layout of Innovative Products in New Field
Jun YANG, PhD
Chief Medical Officer, VISEN

Design of Clinical Trial Protocol for Innovative Drugs in the Area of Diabetes and its Complications based on ICH E9R1
Naiqing ZHAO
Chief Scientist Officer, Caidya Biopharmaceutical Co., Ltd

Drug Clinical Development

Oncology Drug Clinical Development

Session 0201-B | December 10, 2022

8:30-10:00

Collaboration and Acceleration for Cancer Cure - Hot Topics in Oncology Development

SESSION CO-CHAIRS

Xiaoyuan CHEN, MD, PhD
Director, GCP Officer, Beijing Tsinghua Changgung Hospital

Ke LIU, PhD
Head of Regulatory Affairs & Strategy, Sana Biotechnology

The main objective of the session is to discuss the ways for collaboration among different stakeholders to accelerate the oncology drug development. The audience will be industry attendees from China domestic companies and multi-national companies; academicians from university, university hospitals and cancer research centers; and regulators (mainly from China NMPA).

Project Catalyst Which is an OCE Initiative to Foster the Oncology Development
Jeffery SUMMER, PhD
Associate Director for Translational Sciences, Office of Oncologic Diseases, CDER, FDA

Changes in Guidelines for Combination Therapy and Clinical Trial
China CDE Speaker Invited

Pediatric Oncology Drug Development and Unmet Needs from the Patient Group Perspective
Zhizhong LI, PhD
Director, Pediatric Oncology Foundation

Panel Discussion

Drug Clinical Development

Session 0202-B | December 10, 2022

10:30–12:00

Statistical Innovations and Practical Considerations for Oncology Drug Development

SESSION CHAIR
Meng CHEN, PhD
AZ

Progress in better understanding of cancer biology together with the competitiveness of oncology drug development has caused a shift in oncology trial designs. This session will showcase a few presentations covering the advancement in early phase oncology trial design, statistical considerations for basket trials with Bayesian hierarchical model as one example, practical considerations for master protocols, and what to consider to transform external data to external evidence.

Advanced Statistical Designs for Dose Optimization in Oncology Clinical Trials
Yuan JI, PhD
Professor of Biostatistics at University of Chicago

Statistical Considerations in Basket Trials and Master Protocol
Julie CONG, PhD
Head of Biometrics Everest Medicines

Practical Considerations for Master Protocols
Rui MIAO, PhD
Associate Director, AstraZeneca R&D China Statistics

From External Data to External Evidence – What to Consider and How to Proceed
Fan XIA, PhD
Head of Data Science Center, CSPC Pharmaceutical

Drug Clinical Development

Session 0203-B | December 10, 2022

13:30-15:00

Anti-PD1/L1 Bispecific Antibody

SESSION CHAIR
Wenjuan ZHENG
Head of China Clinical Development-Solid Tumor, VP, BeiGene

Currently, immunotherapies are widely used for the clinical treatment of various tumor types. Although immunotherapies have shown significant and long-term efficacy in cancer patients, their clinical benefits in the overall population are still low because of limitations and challenges such as low response rate and resistance development. Advances in protein engineering technology have enabled the generation of various bispecific antibodies (BsAbs) that target multiple antigens as a single molecule. BsAb based immune therapeutics may have the potential to improve clinical efficacy and safety. Therefore, the interest in the development of BsAbs has grown considerably, and there are various types of BsAbs in clinical and preclinical stages. Here, we present 3 examples of BsAbs in clinical development.

AK-104: anti-PD1/CTLA-4 -- Akesobio
Baiyong LI, PhD
CSO, Kangfang

Anti-PD-L1/4-1BB Development Consideration
Xuke QIN, PhD
Chief Medical Officer, Elpiscience

Drug Clinical Development

Session 0204-B | December 10, 2022

16:00–17:30

Development of Small Molecule Drugs & New Targets of ADC Drugs

SESSION CHAIR
Haiyi GUO
VP, Clinical Development- Heme, Beigene

BTK PROTAC: In the era of biologic immunotherapy, a variety of innovative biotechnological therapies have emerged continuously, and the research and development of small molecule drugs is facing many new challenges. However, as the most traditional form of medicine, although the current development of small molecule drugs has encountered some difficulties, it also has its advantages that are difficult to replace. With the development of new innovative technology platforms such as PROTAC, the strategies for small molecule clinical development will become more diverse. PROTAC largely combines the advantages of small molecule compounds and small molecule nucleic acids, which can solve the resistance to traditional small molecule drugs and make it possible to target a variety of "non-drug" targets for research and development. Several targeted protein degradation therapies are currently in clinical development, including PROTAC, which targets BTK.

Drug the Undruggable: PROTAC Discovery and Development
Huaqing LIU
Executive Director, Medicinal Chemistry, Beigene

AI Promotes Undruggable Target
Alex ZHAVORONKOV, PhD
CEO, Insilico Medicine

Progress and Opportunity of ADC Development
Vicky ZHANG
Senior oncology R&D Leader, Clinical Development, Pfizer China R&D Center

Session 0205-B | December 11, 2022

8:30-10:00

Application of New Technology in Oncology Drug R&D

SESSION CHAIR
Jessie ZOU, MD, PhD
President, Global R&D, Junshi Biosciences

Application of Medical Imaging Technology Fused with Artificial Intelligence in Clinical Trial
Xiaomei QI
Deputy General Manager of Imaging Science, Zhejiang Taimei Medical Technology Co., LTD

Data Science to Accelerate Drug Discovery
Weifeng WANG
Vice President, R&D, OrigiMed

Application of ctDNA-MRD Monitoring Technology in Clinical Trials of Cancer Drugs
Kaili GU
Director of Product R&D, MEdx

Drug Clinical Development

Novel Targets/New Modalities Drug Clinical Development

Session 0201-C | December 10, 2022

8:30-10:00 **Gene Therapy in Rare Diseases**

SESSION CO-CHAIRS

Hui XIONG, Professor
Director of Pediatric Neurology Department, Peking University First Hospital

Jing YANG, PhD
Head of Global Pharmaceutical Research and Development Neurological and Respiratory Area, Novartis China

Clinical Drug Discovery in SMA Gene Therapy - Experiences and Challenges
Daniel GRANT
Vice President, Novartis GDD

Basic Research and Clinical Transformation of Gene Editing in Rare Diseases
Wanjin CHEN
Professor, Director of department of Neurology, The First Affiliated Hospital of Fujian Medical University

The Important Role of AAV Vector Design and Quality Control in Gene Therapy
Guang QU, PhD
Co-founder, Suzhou Nuojiebei Biotechnology Co., LTD

Design Considerations for Clinical Studies of Rare Diseases
Hongjie ZHU, PhD
Director, Global Statistics & Data Science, BeiGene

PANEL DISCUSSION
Above Speakers and Invited Panelists
Jie LI
Chief Physician, Department of Digestive Oncology, Peking University Cancer Hospital
Chairman of Ethics Committee of Peking University Cancer Hospital

Drug Clinical Development

Session 0202-C | December 10, 2022

10:30-12:00

CAR-T Therapies – Past, Current and Future

SESSION CO-CHAIRS

Lei LIU
Head of Global RESEARCH and Development of Hematology Therapy, Novartis China

Zhitao YING, PhD
Professor, Lymphoma Department, Beijing Cancer Hospital

With the marketing of the two CART products in China, the cancer treatment in China officially opened the prelude to the CART era. How do regulatory authorities, physicians, and pharmaceutical companies cooperate to ensure that CART products are reasonably regulated risk control before approval, how to ensure reasonable clinical risk management during clinical studies and clinical application after product approval, how to manage and control during production, and the application prospects of immune cell products in multiple tumors, and we will conduct in-depth discussions on these topics.

Risk Control after Cell Therapy Clinical Studies and CAR-T Product Approval
Lei LIU
Head of Global Research and Development of Hematology Therapy, Novartis China

Clinical Observation of the Whole Process of CAR-T Therapy
Zhitao YING, PhD
Professor, Lymphoma Department, Beijing Cancer Hospital

Risk Management Prior to CAR-T Product Approval - Regulatory Perspective
CDE Speaker Invited

Development and Practice of Immune Cell Products in Solid Tumors
Yu WANG, PhD
Founder, Executive Director and CHIEF Executive Officer, co-Chief Technology Officer, Yongtai Bio

Quality Control Strategy for CAR-T Products
Ruina SHI, PhD
Vice President of Quality of Beijing Fine Arts Shenzhou Pharmaceutical Technology Co., LTD

Panel Discussion
INVITED PANELISTS
Liqun WANG, PhD
Founder, Chairman and Chief Executive Officer, NeuKio

Shihu WEI
Medical Director of Kuntuo Xincheng Pharmaceutical Research and Development (Beijing) Co., LTD

Drug Clinical Development

Session 0203-C | December 10, 2022

13:30-15:00

RNAi Therapeutics: A New Class of Transformational Medicines

SESSION CO-CHAIRS

Chenyu ZHANG
Dean, Life Science College, Nanjing University

Jianyong LI
Head, Metabolic Area, Vascular Nephrology, Novartis

An Overview of RNA-targeting Therapeutics
Yang LU, PhD
CEO, Sheng Nuo Bio

siRNA for Hypercholesterolemia: The Inclisiran Story
Anastasia LESOGOR
Heads up Clinical Development for Inclisiran, Novartis

Model-informed siRNA Clinical Research and Development
Rui CHEN, MD, PhD
Head of Phase I Study, Peking Union Hospital

Panel Discussion

Drug Clinical Development

Session 0204-C | December 10, 2022

16:00–17:30

Development of Radioligand Therapies in Oncology

SESSION CO-CHAIRS

Gloria GONG, PhD
Former China Development Unit Head, Novartis

Woody TANG
Therapeutic Area Lead, Novartis

First time in DIA China to introduce Radioligand treatment development status from regulatory, dosimetry, theragnostic, and CMC, and training of nuclear medicine specialists. It also highlights the importance of multi-disciplinary team including nuclear medicine in hospital to treat cancer patients.

RLT Development in China and in major ICH countries – Focus Areas in Technical Guidelines and its Progress
Shuang LIU
Senior Vice President of Beijing Xiantong International Pharmaceutical Technology Co., LTD

Dosimetry and CMC Consideration in RLT Development
Hongyu Li
Senior Researcher, CIRC

China Development Plan for Nuclear Medicine Challenges and Opportunities Including Theranostics Outlook
Gang HUANG
Professor, Director of Shanghai Key Laboratory of Molecular Imaging and academic leader of Nuclear Medicine of Shanghai Renji Hospital

Panel Discussion: MTD in RLT Development and Treatment
FACILITATOR
Woody TANG
Therapeutic Area Lead, Novartis

INVITED PANELISTS
Rong ZHENG
Professor, Cancer Hospital, Chinese Academy of Medical Sciences

Dr. Zhigang JI
Professor, PUMC Hospital Urology

Zheng WANG
Chief Scientific Officer, DONGCHENG AMS

Drug Clinical Development

Session 0205-C & 0206-C | December 11, 2022

8:30-12:00

AI and Digital Tools in Drug Development - Part 1 & Part 2

SESSION CO-CHAIRS

Min JIANG
Director of GCP center, Beijing Cancer Hospital

Wei ZHOU
China Compound Team Leader, Vaccine & Immunology, J&J

AI to Predict the Next COVID Outbreak for the Vaccine Enrollment
Jennings XU
Data Science Portfolio Management, Janssen Global

Decentralized Clinical Trial
Isaac R. RODRIGUEZ-CHAVEZ
SVP, Head of Scientific & Clinical Affairs, Strategy for DCTs, ICON

Decentralized Clinical Trial Case Sharing T
Scott ASKIN
Director, Global RA Program, Novartis

Perspectives on DCT from the Site
Hong FANG
GCP Center operation director, Cancer Hospital Chinese Academy of Medical Sciences (CAMS)

AI in Clinical Medicine
Tianyin WONG
Deputy Group CEO for Research and Education at SingHealth, Elected US National Academy of Medicine

FDA Approved Medidata Synthetic Control Arm for rGBM Phase III Cases
Ming ZHU
Consultant, Medidata

AI in Predicting Drug Targets
Yu ZHAO
Deputy Director of Turing Darwin Lab, Institute of Computing Technology, Chinese Academy of Sciences
Co-founder of Zheyuan Technology, Ltd. Co

Panel Discussion: Opportunities and Challenges in Digital Enabling Development
FACILITATOR
Jiming XU
CEO of Happy Life Tech

INVITED PANELISTS

Dawei WU
Cancer Hospital, Chinese Academy of Medical Sciences

Yiwei FENG
Senior Director, Clinical Operations, IQVIA

Wei LIU
Drug AI Technology Head, Tencent

David XIE
Partner at Deloitte Consulting

Drug Clinical Development

Clinical Pharmacology

Session 0205-D | December 11, 2022

8:30–10:00 **China Clinical Pharmacology's Today and Tomorrow**

SESSION CHAIR
Gailing LI, PhD
Chief Science Officer, Certara

Considerations and Expectations behind the Chinese Clinical Pharmacology Regulations and Guidelines
CDE Speakers Invited

The Role and Responsibility of Clinical Pharmacology in Lifecycle Drug Development
Ao PENG, PhD
Head, Clinical Pharmacology and Early Clinical Development, Pfizer

Confusion and Needs of Clinical Pharmacology in Drug Development of China
Rui CHEN, MD, PhD
Head of Phase I Study, Peking Union Hospital

Drug Clinical Development

Session 0206-D, | December 11, 2022

10:30–12:00

Make Clinical Pharmacology a "Symphony" of Medical & Drug Integration

SESSION CHAIR
Ziwei ZHAO, PhD
Head of Pharmaceutical Science and Early Clinical Development Department, Roche China Innovation Center

Global Hot Topic of Clinical Pharmacology - 1
Ranchi XU, PhD
Head, Clinical Pharmacology, R&D, Biogen

Global Hot Topic of Clinical Pharmacology - 2
Chen ZHAO, PhD
Professor, Nanjing Medical University, PI of Jiangsu Clinical Research and Evidence-based Medicine Center

Panel Discussion
INVITED PANELISTS
Prof. Haiyan LI
Director of Drug Clinical Trial Institution, Peking University Third Hospital, Chief Physician of Cardiovascular Medicine

Pei HU, MD, PhD
Founder, Beijing Lingchu

Jing ZHANG, MD, PhD
Professor of Clinical Pharmacology, Deputy Director, Institute of Antibiotics, Huashan Hospital, Fudan University

Yuyan JIN, PhD
SVP, Head of Non-Clinical Development, Shanghai Sanegene Bio

Kai SHEN, PhD
Head of Clinical Pharmacology Department, Jiangsu Hengrui Pharmaceutical Co., LTD

Xiao ZHU, PhD
Young Researcher, Department of Clinical Pharmacy and Pharmacy Management, School of Pharmacy, Fudan University

Xiaojie WU, PhD
Deputy Director of Phase I Clinical Research Center, Huashan Hospital, Fudan University

Jing NIE, PhD
Head of Clinical Pharmacology Team, Heyu Biomedical Technology Co., LTD

Patient Centered Clinical Operations and Quality Management

THEME LEAD

Ning XU, MD, PhD
Executive Vice President, Head of Clinical Development and Regulatory Affairs, Zai Lab

Liping ZHOU
Senior Director, QA, MSD R&D (China) Co., Ltd

Shuting LI
Vice President
Jimin Cancer Hospital affiliated to Anhui Medical University

Veronica XIA
Vice President, China GM, Labcorp Drug Development

Amy JIANG
Head of Quality Office, Harbour Biomed

Yang LIN
Director of Department of Pharmacy, Director of GCP, Head of Phase I Study
Beijing Anzhen Hospital

Jing ZHANG, PhD
Deputy Head of Antibiotics Institute, Head of Phase I center
Fudan University Affiliated Huashan Hospital

Clinical Operations

Session 0301-A | December 10, 2022

08:30–10:00

Effectively Promote the Transformation of Target Patients into Subjects by Multiple Dimensions and Channels

SESSION CHAIR
Shuting LI
Vice president of Jimin Cancer Hospital affiliated to Anhui Medical University

In recent years, clinical research on new drugs in China has developed rapidly, but it still faces great challenges in which subject recruitment is the key to the rapid development of trials. It is reported that 85% to 95% of the reasons for the delay of clinical trials are the failure to recruit qualified subjects as planned. Therefore, how to successfully convert target patients into subjects is an important problem that the whole industry needs to address.
In order to discuss the solution to the subject recruitment, the speaker has done a survey among the colleagues, and the results will be analyzed and summarized. The purpose of the survey is to study the reason of the problems andraise the investigators' awareness of clinical trial, andget through the recruitmentbottleneck to success.

In Post-epidemic (COVID-19) Era, Patient Education Will be the Better Approach to Solve Problems That Exist in Clinical Trials
Kun SONG
VP, Pharmaron(Chengdu) Clinical Service Co.,Ltd

Digital Technology Facilitates Patient Education and Recruitment
Man HE
B2B Department Director, Taimei Technology

Benevolence to Patients, Antecedence to Missions
Joeann FAN
Director of Site management, RDB, Bayer Health Care Co.Ltd.

Panel Discussion: How to enhance the roles and responsibilities of each party in industry, working together to overcome the recruitment challenges

Moderator	Invited Panelists	
George GUO Chief Medical Officer, Hinova Pharmaceuticals Inc.	**Xu CAO** Clinical Project Leader, Sanofi R&D Center Greater China	**Yu CHEN** Senior Director, Shenzhen Microchip

Patient Centered Clinical Operations and Quality Management

Session 0302-A | December 10, 2022

10:30–12:00

Win-win Collaboration of Clinical Operations

Session Chair Invited

Initiate Process Optimization and Strengthen Communication and Collaboration
Speaker Invited

Risk-based Center Monitoring
Speaker Inivted

Panel Discussion: Integrated and Efficient Management based on Data Flow from Design
INVITED PANELISTS

Simon YU, MD, PhD
Director Global Testing Services, China & Japan
Labcorp Drug Development

Peipei YANG
Deputy Director of Clinical Trial Program Management, IQVIA Biotech (China)

Mengmeng ZHANG
Deputy Director, Pharmacovigilance, Taimei Medical Technology

Confidence and Humility, Trust and Communication
Daisy CHEN
Business Partner, Human Resource, Janssen Pharmaceutical R&D and Johnson & Johnson China External Innovation Team

Patient Centered Clinical Operations and Quality Management

Session 0303-A | December 10, 2022

13:30–15:00

The Practice and Explore for DCT in Early Clinical Phase Studies

SESSION CO-CHAIRS

Jing ZHANG, PhD
Deputy Head of Antibiotics Institute, Head of Phase I Center
Fudan University Affiliated Huashan Hospital

Veronica XIA
Vice President, China GM, Labcorp Drug Development

Drug Development Clinical Trial DCT Management Exploration and Prospect
Yifei CHEN
Shanghai CDE

Case Sharing— Practice for DCT in Early Clinical Development
Dr. Jiejing HE
Huashan Hospital

Comparison of a Trial Conducted Completely Remotely and a Trial Where Some Visits Require Patients to Come to Sit
Laurie Berry, PhD, PMP
Clinical Operations Strategic Partnership Lead of Information Management COE, Pfizer

Panel Discussion: Discussion on the Clinical Practice and Development of DCT in China
MODERATOR
Veronica XIA

INVITED PANELISTS

Jing ZHANG
Deputy Head of Antibiotics Institute, Head of Phase I center, Fudan University Affiliated Huashan Hospital

Wei ZHANG, PhD
China Head of Medical and Clinical Development, Boehringer Ingelheim

Marion MARTIN, PhD
Head of Strategy and Technology Innovation, Pfizer R&D China

Jennifer LI
VP & China GM, Medidate

Kevin LIN
CEO, Shanghai Xincere Med-Tech Inc.

Patient Centered Clinical Operations and Quality Management

Session 0305-A | December 11, 2022

8:30-10:00

Emerging Technologies Empowering Clinical Operations – 1: Novel Digital Endpoints

SESSION CHAIR
Connie DAI, PhD
Vice President, Strategies and Innovation, HLT

Digital health technology is transforming the drug, device and diagnostics development process. These technologies have the potential to enable innovative trial designs, improve the patient experience, act as recruitment and retention tools, and establish novel end points in clinical studies. This session will focus on the impact of digital health technologies on clinical development operations, as existing clinical endpoints change or novel digital endpoints that could not be measured previously.

Topic TBD
Laura PIOPPO
EMA

Exploring Digital Endpoints in Neuroscience
Haiyan WU, PhD
People and Product Lead, PD Data Science, Roche China

Methodological Validation of Novel Digital Endpoints
Carrie A NORTHCOTT, PhD
Director & Project Lead, Digital Medicine & Translational Imaging, Pfizer Inc

Developing a More Complete Picture of the Patient Experience through an Integrated Approach to eCOA and Sensors
CO-PRESENTERS
Ben SCHLATKA
VP, Digital Biomarkers, Medidata

Paul O'DONOHOE
Senior Director, eCOA Product & Science, Medidata

Patient Centered Clinical Operations and Quality Management

Session 0306-A | December 11, 2022

10:30–12:00

Emerging Technologies Empowering Clinical Operations – 2: Experience and Technical Support of Digital Clinical Trials

SESSION CHAIR
Weiyi ZHENG
Vice President, Head of Operations, AstraZeneca Global R&D China Center

DCT is a new type of clinical research with patient-centered, decentralized mode and supported by digital technology and platform. Through case summary and practical technical analysis, this special session focuses on how the application of innovative technologies in the process of clinical trials can enable clinical operation, how to support the improvement of patient participation experience, reduce the burden of patients' multiple trips to the research center, so as to improve patient compliance. At the same time, the timeliness and reliability of clinical trial data collection will be further improved to provide path reference for the 2030 transformation goal of clinical trial modernization.

DCT Case Studies
Yan MA
Director, Clinical Operations, IQVIA

Evaluation of Major Digital applications in DCT
Gaoyang LI
Head of DCT, HLT

Patient Visit Choice (Remote or at Site) - Changing Complexity of Data Collection in Clinical Trials
James STREETER
Global Vice President, Life Science Customer Success. Oracle

DCT Challenges in China and Possible Solutions for HHC
Zhemin JIANG
PPD

Increase Trial Resiliency through Technologies - Mobile Clinical Solutions Implementation in the APAC Region
Kurt LUMSDEN
Head of Global Operations, GlobalCare Operations, LabCorp

Patient Centered Clinical Operations and Quality Management

Investigational Drug Management & Supply Chain

Session 0301-B | December 10, 2022

8:30-10:00 **Internal Management of Investigational Drug - from the Sponsor Perspective: Part 1**

SESSION CHAIR
Amy JIANG
Head of Quality Office, Harbour Biomed

Sponsor's Traceable Management System for Investigational Drug
Feng HE
Head, Clinical Supply Chain, Zai Lab

Sponsor's Entrustment Investigational Drug Management
Jin LI
Deputy Manager, GxP Quality, Harbour

Temperature Management of Investigational Drug
Yadan HUO
Associate Director, Clinical Operations, Clinical Development, BeiGene(Beijing)Co.,Ltd.

Panel Discussion

Patient Centered Clinical Operations and Quality Management

Session 0302-B | December 10, 2022

10:30-12:00

Internal Management of Investigational Drug - from the Sponsor Perspective: Part 2

SESSION CHAIR
Winne XU
VP, Head of Greater China, Global Clinical Operations, BeiGene

Production and Management of Investigational Vaccines
Gang ZENG
Senior Medical Director, Beijing Sinovac Biological Products Co., LTD

Preparation and Management of CAR-T in Clinical Trials
Weilin HUANG
Clinical Operations, Nanjing Legend

Countermeasures for the Management of Investigational Drug under Pandemic
CO-PRESENTERS
Yadan HUO
Associate Director, Clinical Operations, Clinical Development, BeiGene

Na SONG
Deputy Director, Clinical Supply Chain, BeiGene

Panel Discussion

Patient Centered Clinical Operations and Quality Management

Session 0303-B | December 10, 2022

13:30-15:00

Traceable Transportation of Investigational Drug from Sponsor to Clinical Site

SESSION CHAIR
Yufeng CAO
Founder of Kagan

Regulation for the Management of Investigational Drug
Lijun ZHU
Director, Quality, Kagan

Traceable Transportation Process Management System for Investigational Drug
Nan ZHANG
General Manager, China Clinical Trial, Thermo Fisher

Application and Regulation for Import and Export of Investigational Drug
Xinming HU
Assistant to General Manager, Beijing Yizhuang International Biological Reagent Logistics Center Co., LTD.

Panel Discussion
INVITED PANELISTS
Yang LIN
Director of Department of Pharmacy, Director of GCP, Head of Phase I Study, Beijing Anzhen Hospital

Feng HE
Head, Clinical Supply Chain, Zai Lab

Patient Centered Clinical Operations and Quality Management

Session 0304-B | December 10, 2022

16:00–17:30

Centralized Management of Investigational Drug in Clinical Site

SESSION CHAIR
Yang LIN
Director of Department of Pharmacy, Director of GCP, Head of Phase I Study, Beijing Anzhen Hospital

Management Model of Investigational Drug in European and American
Speaker Invited

Centralization and Intelligent Management of Investigational Drug
Yang LIN
Director of Department of Pharmacy, Director of GCP, Head of Phase I Study, Beijing Anzhen Hospital

How to Choose the Clinical Site from Investigational Drug Management Perspective - from Sponsor Perspective
April HUANG
Executive Director, Head of Clinical Operations, InnoCare Pharma

Panel Discussion
INVITED PANELISTS
Bo YU

Huan ZHOU
Deputy Director, The First Affiliated Hospital of Bengbu Medical College (Cancer Hospital Affiliated to Bengbu Medical College) Director of the National Drug Clinical Trial Institution
Executive Director of Phase I Clinical Trial Laboratory

Patient Centered Clinical Operations and Quality Management

Clinical Quality Management

Session 0303-C | December 10, 2022

13:30–15:00

Jointly Build a Quality Management System for Clinical Trials - Part 1

SESSION CO-CHAIRS

Yanfei LIU
Director, GCP Center, Fu Dan University Shanghai Cancer Center

Ying GONG
Head of Clinical Development Quality, Pfizer China R&D Center

All stakeholders involved in clinical trial quality - Sponsors, Institutions (or Hospitals), Regulatory Agencies, and Third-party Service Providers (or vendors) to form an interoperable Quality Management System (One QMS); following unified quality management standards, regularly sharing quality management reports from both sides, and exchanging action plans and results to prevent risks. Finally, to develop a shared, trusting community by building 'forward-looking' conversations.

Regulatory Expectations for Quality Management in Clinical Trials and Interpretation of the Key Points in the 2021 New Edition of Inspection Points
CFDI Speaker Invited

The Improvement of Co-construction in the Clinical Trials Quality Management System - from the Perspective of Hospital Management
Yanfei LIU
Director, GCP Center, Fu Dan University Shanghai Cancer Center

Panel Discussion

Session 0304-C, December 10, 2022

16:00–17:30

Jointly Build a Quality Management System for Clinical Trials - Part 2

SESSION CO-CHAIRS

Ying GONG
Head of Clinical Development Quality, Pfizer China R&D Center

Heidi LIU
Wesson Pharma Consulting

How to Build a Quality Management System from the Perspective of the Sponsor
Jing ZHANG
Quality Management Lead, Pfizer China R&D Center

Introduction of the Vendors' Quality Management System
Yuyan ZHU
VP, Head of Quality Management, Tigermed Consulting Ltd

Panel Discussion
INVITED PANELISTS

Yifei CHEN
Shanghai Center for Drug Evaluation and Inspection

Jun YAN
GCP Officer, GoBroad Healthcare Group

Guoqing YANG
QA Executive Director, Henlius

Patient Centered Clinical Operations and Quality Management

Session 0305-C | December 11, 2022

8:30-10:00

Quality by Design: Exploring the Opportunities and Challenges of GCP Quality from the Perspective of GCP Site Inspection

SESSION CHAIR
Sean XU
Xiao Ming Tong Da

The Orientation of Quality Management - Agency Perspective
CFDI Speaker Invited

Innovative Exploration of Site Quality Management
Yifeng SHEN
Director of drug Clinical Trial Institution Office of Shanghai Mental Health Center

The Practice and Thinking of How Sponsor to Assist the Site Quality
Jennifer HUANG
MSD

Session 0306-C | December 11, 2022

10:30-12:00

Quality by Design: Reflection from Inspection Findings and Possible Solutions

SESSION CO-CHAIRS
CFDI Session Chair Invited

Liping ZHOU
QA Head, Asia Pacific, MRL

Review of Important Findings in GCP Verification and Industry Thinking
CFDI Speaker Invited

Panel Discussion
INVITED PANELISTS
Hannah CHEN

Jifang GONG

Yanping LIU

Wei ZHANG, PhD

Clinical Needs and Trial Platform

THEME LEAD

Ning LI, MD, PhD
Chief Physician, Department of Thoracic Surgery, Cancer Hospital, Chinese Academy of Medical Sciences

Jie LI
Chief Physician, Department of Digestive Oncology, Peking University Cancer Hospital
Chairman of Ethics Committee of Peking University Cancer Hospital

Binyun QIAN, MD, PhD
Director, Shanghai Clinical Research Promotion and Development Center

Jessica LIU
Head of M&A Department, Tigermed

Session 0401-A | December 10, 2022

8:30–10:00

Overseas Clinical Trial Experience Sharing

SESSION CHAIR
Jessica LIU
Head of M&A Department, Tigermed

Overcoming Barriers in Clinical Trial Activation in Large US Academic Centers
Andrea WANG-GILLAM MD, PhD
Chief Medical Officer, Jacobio (US) Pharmaceuticals, Inc

Japan's Academic Collaborative Programs on Drug Development
Kenichi NAKAMURA, MD PhD
Director, Department of International Clinical Development/
Chief Management Officer, Clinical Research Support Office,
National Cancer Center Hospital JAPAN
Director, JCOG Operations Office

Best Practice Sharing on Clinical Research Center Management from 4 Continents in the World
Natalie WILSON
UK Business Development Manager, National Institute for Health Research, UK

Yil-Seob LEE, MD, PhD
Director, CHA Global Clinical Trials Center
CHA Bundang Medical Center, Korea

Ricardo Sobhie DIAZ, MD, PhD
Director, Retrovirology Laboratory, Federal Medical School of São Paulo, Brazil

Nyeleti Bicky MTHOMBENI
Chairperson, South African Clinical Research Association
Operations Director, OnQ Research

Clinical Needs and Trial Platform

Session 0402-A | December 10, 2022

10:30–12:00

Standardization of IIT Study

Session Chair Invited

In order to standardize the management of clinical research, improve the quality of clinical research and promote the healthy development of clinical research, the National Health Commission (NHC) issued the Management Of Investigator-initiated Clinical Research in Medical and Health Institutions.

It will be implemented on a pilot basis in Beijing, Shanghai, Guangdong and Hainan provinces from October 1, 2021. IIT research is often carried out with the joint participation of enterprises. How can IIT be actively and steadily promoted, and the management of investigatorinitiated trial carried out by health institutions is worthy of joint exploration and discussion by experts from hospitals and industry.

Reflections on Mutual Recognition of IIT Ethics
Qi LU
Chief of Ethics Officer, Shanghai Jiaotong University School of Medicine Renji Hospital

The Role and Value Of IIT: System Building and Study Innovation
Qingwei ZHAO
Director of Department of Clinical Pharmacy, The First Affiliated Hospital of Zhejiang University School of Medicine/Director of Clinical Pharmacy Research Center/Director of Office of National Drug Clinical Trial Institution

Standardization of Cooperation Model in IIT Study
Naiqing ZHAO
CSO, Caidya Biopharmaceutical Co., Ltd

Panel Discussion: How to Define the Scope of IIT Study?
INVITED PANELISTS
Xingli WANG, PhD

Tong GUO, PhD

Naiqing ZHAO

Clinical Needs and Trial Platform

Session 0403-A | December 10, 2022

13:30–15:00

Ethics Regulation

SESSION CHAIR
Jie LI
Chief Physician, Department of Digestive Oncology, Peking University Cancer Hospital
Chairman of Ethics Committee of Peking University Cancer Hospital

The Impact and Requirements on Clinical Trial and Ethical Review after the Enactment and Implementation of the Personal Information Protection Law
ian YANG, JD
Associate Researcher, Health Law Research Center, Peking University Health Science Center

New Interpretation of "Ethical Review of Life Sciences and Biomedical Clinical Trial That Involving Human Beings"
Chieko Kurihara
Bio-ethics Expert, Japan

Panel Discussion

Session 0404-A | December 10, 2022

16:00–17:30

Ethics New Technology

SESSION CHAIR
Jie LI
Chief Physician, Department of Digestive Oncology, Peking University Cancer Hospital
Chairman of Ethics Committee of Peking University Cancer Hospital

Ethical Considerations for Clinical Development of CAR-T Drugs
Jifang GONG, MD, PhD
Deputy chief physician, Department of Digestive Oncology, Peking University Cancer Hospital

Brain-machine Interface
Xueqin WANG, MD, PhD
Member of Ethics Committee and Office Director of Peking University Sixth Hospita

Panel Discussion
INVITED PANELIST
Lei LIU
Head of Global RESEARCH and Development of Hematology Therapy, Novartis China

Clinical Needs and Trial Platform

Session 0401-B | December 10, 2022

8:30–10:00

The Implementation and Difficulties in Establishment and Development of Research Hospital

SESSION CHAIR
Jing HE, MD, PhD
SVP, Head of China R&D Global Oncology R&D, Astrazeneca

The establishment of research ward hospital is an innovative attempt to solve the problem of clinical research resources being occupied by large hospitals and to improve the level and efficiency of clinical research in China. In 2020, Beijing will take the lead in selecting the first batch of qualified Research ward hospitals, now has developed the third batch of 30 hospitals in total, Shanghai and other places are also actively promoting research ward, and even more cities will promote the 14th five-year development focus on the establishment of research hospital.

How is the research ward hospital implemented today? Does it solve the problem of insufficient research resources? Is it sustainable? What is the international experience of research hospitals worth learning from? The sector will invite industry experts from the strategic layout, practical effect, international experience and other perspectives, in-depth discussion and sharing.

Research Ward Hospital's Layout, Implementation, Feedback and Key Points Analysis
Speaker Invited

Operation Model, Development Direction and Expected Effect of Research Hospital
Chouwen ZHU
Director of Shanghai Clinical Research Center

Experience Sharing and Localization of International Clinical Research Centers
Yu TANG, MD, PhD
Head of GCP Central Office, Cancer Hospital, Chinese Academy of Medical Sciences

Panel Discussion

Clinical Needs and Trial Platform

Session 0402-B | December 10, 2022

10:30–12:00

"Not" Clinical Value Driven Clinical Study

SESSION CHAIR
Wei ZHANG, PhD
VP, Regional Head of Biometrics and Data Management, Asia/MENA, Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd.

Since November 19, 2021, China officially issued and implemented the Clinical Value-Oriented Guiding Principles for Clinical Research and Development of Anti-tumor drugs, "clinical value-oriented" and "patient-centered" have become the hottest concepts and topics, and various explanations emerge in an endless stream. So in the pharmaceutical research and development, how to embody the patient-centered? Who is the leading opinion on the value of clinical research? Who has the final say on clinical value? Front-line clinical doctors and patients should have the best say. What is needed and what is not, listen to what they say about clinical value and what they see as "Not" clinical value Driven drug R&D.

What Does "Not" Clinical Value Driven Clinical Study Look Like?
Dawei WU
Ethics Director, GCP Center, Cancer Hospital, Chinese Academy of Medical Sciences

Innovation and R&D Help Increase the Value of the Company
Cong XU
Executive Director, Eli Lilly Asia Ventures

What Kind of Clinical Research is Most Valuable to Patients?
Weiling ZHENG
Paraxel

Conflict and Compromise between Clinical Value and Commercial Value
Huiyao HUANG
Academic Secretary, GCP Center, Cancer Hospital, Chinese Academy of Medical Sciences

Data Science

THEME LEAD

Daniel LIU, PhD
Chief Scientific Officer, Clinical Service Center

Anita SHEN
Executive Director, Head of Clinical Data Monitoring & Management, Pfizer

Hualong SUN, PhD
General Manager, Meta Clinical Technology Co. Ltd

Session 0501, December 10, 2022

08:30-10:00

Regulatory Requirements and Practice of Direct Data Capture (DDC)

SESSION CHAIR
Hualong SUN, PhD
General Manager, Meta Clinical Technology Co. Ltd

At present, the data of drug clinical trials are mainly collected by Electronic Data Capture system (EDC), and most of the data need to be transcribed into the EDC system from the medical records of Investigational hospitals by the Investigators or clinical research coordinators (CRC), which not only affects the efficiency but also may have the occurrence of transcription errors. Whether to collect data directly from medical records of investigational hospitals through system tools, whether there are corresponding regulatory requirements, and the current progress at home and abroad will be shared and discussed in this topic.

Regulatory Requirements and Opportunities for Clinical Research of Director Data Capture
Hualong SUN, PhD
General Manager, Meta Clinical Co. Ltd

Practice and Case study of Director Data Capture
Wei SHI
Chief Technical Officer, Clinical Trials Express (Shanghai) Co., Ltd.

Exploration and Practice of Data Capture Information Management for Drug Clinical Trials
Hua ZHANG
Director of Drug Clinical Trial Institute, The First Affiliated Hospital of Soochow University

Data Science

Session 0502 | December 10, 2022

10:30-12:00

Source Data Management in Clinical Trials

SESSION CHAIR
Daniel LIU, PhD
Chief Scientific Officer, Clinical Service Center

Regulatory managements of the source data management in clinical trials play a key role in the compliance of data quality and integrity. Based on GCP principles, every data input in the CRF should be conformant and integrity with source data and documents, ensuring the compliance of source verification, attribution and rebuildability. With development of e-clinical technology, an e-source data is becoming a trend in clinical trials. Thus, e-clinical data should be compliant with the GCP and regulatory requirements. This session is focusing on discussions and interactions regarding the definition and types of source data and regulatory expectations. The e-source management and standards is explored as well

Global Standards of Clinical Data Quality in Clinical Trials
Zhijun WEI
Head of Clinical Data Standardization and Innovation, Novartis

Management of Source Data Life Cycle in Clinical Trials
Jian ZHANG, MD
Chief Physician, Director of Phase I Ward/Medical Oncology of Tumor Hospital Affiliated to Fudan University

Regulatory Expectations of e-Clinical System in Compliance of e-source Data Integrity
Daniel LIU, PhD
Chief Scientific Officer, Clinical Service Center

Panel Discussion: Good Practice of Source Data Regulations in Clinical Trials
Above Speakers and Invited Panelist
Yuqiu YANG
General Manager, Riehen

Data Science

Session 0503 | December 10, 2022

13:30–15:00

Data Anonymization and Data Privacy

SESSION CHAIR

Zhenglong TIAN
Chief Data Officer, Gobroad Healthcare

The 21st century alone has created 98% of all data that humankind has piled up since we started writing history. Big data makes it possible for us know more about the world. Data-driven methodology could be a bright future to accelerate drug discovery and development. However, it is critical to balance the data publicity and data privacy in order to well utilize the data information. Hence, data anonymization become more and more important. The Privacy Rule standards which address the use and disclosure of individuals' health information (known as "protected health information") by entities subject to the Privacy Rule have been mentioned in HIPAA. Also, the criticalness of anonymization has been mentioned in EMA policy 0070 and GDPR. However, there are no universally agreed approaches about how to properly perform data anonymization. In this section, some practices will be discussed in healthcare and clinical industry regarding data anonymization to ensure data privacy.

"Practice of Anonymization of Both Electronic and Non-electronic Source Data in Remote Monitoring"
Yuan HAO
Product Director of Intelligent Clinical Trial Solutions, Hlife Tech

Risk Assessment Post Data Anonymization
Joey WANG
Deputy General Manager, Meta Clinical

Best Practice for Privacy and Cybersecurity Compliance in Medical and Health Industry
Bruce ZHANG
Partner, Ernst & Young (China) Enterprise Consulting Co., LTD

Data Science

Session 0504 | December 10, 2022

16:00–17:30

Real World Data Quality Evaluation

SESSION CHAIR
Chen YAO, PhD
Director, Department of Medical Statistics, Peking University First Hospital

Academic institutions, hospitals and CROS were invited to discuss the quality evaluation and data governance of regional health big data. Discuss the significance of CDISCS-eCRF development to ensure the integrity of hospital real world data. And based on the risk of quality management concept to establish data quality management system construction thinking.

Improving Real-world Data Integrity Using Electronic Data Capture based on CDISC-CRF Data
Xiaoxia PENG
Director, Center for Clinical Epidemiology, Beijing Children's Hospital, National Center for Children's Health

Quality Evaluation and Data Governance of Regional Health Big Data
Zhike LIU
Associate Professor, School of Public Health, Peking University

Considerations for Quality Management of Real-World Data
Julia ZHU
VP, Head of QA Department, Tigermed Group

Session 0505 | December 11, 2022

08:30–10:00

Clinical Data Talent Development

SESSION CHAIR
Anita SHEN
Executive Director, Head of Clinical Data Monitoring & Management, Pfizer

With the help of policies and capital, China's pharmaceutical industry is accelerating development, and the demand for pharmaceutical R&D talents is increasing sharply. In the face of unprecedented opportunities and challenges, data management talents are the ability cornerstone and core competition

What is the force? It is hoped that initial ideas on the skill elements and grade considerations of data talent will be shared to facilitate industry consensus. At the same time, CRO is also an indispensable force in pharmaceutical research and development. How to continuously and effectively cultivate data management talents and create a funny data management team in the rapidly changing external environment Team? Senior team leaders will share valuable experiences and challenges.

Finally, the data management industry has quietly changed under the impact of new ideas and technologies. The future is here. Are you ready? In this session, we will explain the new trends in the data management industry Potential, looking forward to the future talent capacity of the new demand.

Data Science

Session 0506, December 11, 2022

10:30–12:00

How to Ensure Data Quality through Cross Functional Collaboration: Case Sharing

SESSION CHAIR
Charles YAN, PhD
Vice President, Data Science Center, Hengrui

Ensuring the data quality is always on the critical path to success in clinical trials. There are multiple functions and personnel involved in the procedure from data collection to analysis, which makes cross functional

Good Cross-Functional Collaboration in Scientific eCRF Design
Lin BIE
Assistant Director, Data Management, Hengrui

Cross-Functional Collaboration in Data Clean
Di ZONG
Senior Manager, Clinical Operation, Hengrui

How to Control Data Quality to Meet Statistical Analysis and Data Submission Needs
Chunxia CHEN
Associate Director, Statistics, Hengrui

Panel Discussion
INVITED PANELISTS
Yue ZHANG
General Manager, Data Center, Henlius

Wei ZHANG
Head of Data Management, GSK

Biostatistics

THEME LEAD

Feng CHEN, PhD
Professor, Dean, School of Public Health, Nanjing Medical University

Wei ZHANG, PhD
VP, Regional Head of Biometrics and Data Management, Asia/MENA
Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd.

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

Lihong HUANG, PhD
Department of Biostatistics, Zhongshan Hospital, Fudan University

Michael LEE, PhD
Vice President, Head of Biometrics, Harbour BioMed

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

Session 0601 | December 10, 2022

08:30–10:00

On Rare Disease Drug Development Pathway and Clinical Study Designs – Case Studies

SESSION CO-CHAIRS

Michael LEE, PhD
Senior VP, Head of Biometrics, Harbour BioMed, Inc.

Xiaoni LIU, PhD
Biostatistics China Site Head, Novartis

Unmet medical need in rare disease is getting more and more attention in the past years. There are unique challenges in rare disease drug development. CDE and FDA recently released guidance documents specific for rare disease drug development and regulatory pathway, such as CDE Guidance on Technical Aspects in Rare Disease Drug Development and FDA Rare Diseases: Common Issues in Drug Development. Speakers in this session will share their experience and thoughts on this topic.

Basket Design with Bayesian Hierarchical Model for Rare Diseases
Tong ZHU, PhD
Principal Statistician, Novartis

Case Examples for Rare Diseases: Bayesian Methods and n-of-1 Design
Jun DONG, PhD
Head of Biostatistics and Programming, Amgen China

Epidemiological Research for Rare Disease using National Insurance Data
Pei GAO, PhD
Professor, School of Public Health, Peking University

Biostatistics

Session 0602 | December 10, 2022

10:30–12:00

Practicing ICH E17 for Simultaneous Global New Drug Development & Registration

SESSION CO-CHAIRS

Yabing MAI, PhD
Head of Biostatistics and Data Science, Boehringer Ingelheim

Robert LUO
Pfizer

With the globalization of drug research and development, multi-regional clinical trial (MRCT) has attracted increasing attention. The implementation of MRCT can speed up the simultaneous development of new drugs and maintain the same level of scientific rigor in trial design when trial results are registered for review by multiple regulatory agencies. At the same time, it can optimize valuable patient resources and reduce unnecessary research and development costs. ICH E17 will better improve the acceptability of MRCT regulatory submissions worldwide by addressing specific issues and general principles of MRCT planning and design.

A review of the industry practice in the past few years shows that While China's participation in the global REGISTRATION of synchronized R&D has achieved success, it also faces many challenges. Therefore, this unit will focus on how to identify and address many challenges in the global simultaneous development and registration of new drugs through better practice of the ICH E17 guidelines. Through professional consideration and typical case sharing from experts in different fields on some key issues (such as ethnic consistency evaluation, regional sample size allocation, design and analysis method selection, etc.), some guidance can be provided for overcoming these challenges in practice and achieving true synchronization.

In-depth Experience in MRCT & E17
Bruce BINKOWITIZ
Biometrics VP, Arcutis US

MRCT & E17 Regulatory Perspective
Yaping WANG, PhD
Former FDA Reviewer

MNC Perspective
Chao ZHU, PhD
Head of Statistics and Programming, Lilly

Panel Discussion
INVITED PANELISTS
Feng CHEN, PhD
Professor, School of Public Health, Nanjing Medical University

Yan HOU, PhD
Associate Researcher, Department of Biostatistics, Peking University Health Science Center

Biostatistics

Session 0603 | December 10, 2022

13:30–15:00

Design and Considerations in Vaccine Trials

SESSION CO-CHAIRS

Prof. Yang Huan
Former China CDE

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

Considering the increasing number of vaccine studies and the development of novel vaccine technologies in recent years, investigators have encountered many specific questions in the vaccine trials, including registration strategy and trial design to provide sufficient evidence, set-up of primary study endpoints and sample sizes, and considerations of statistical analysis methods and Estimand. We hope to better guide researchers in the design of higher quality vaccine trials by discussion and communication with vaccine experts.

Review of Clinical Trial Design of New Vaccines
Jielai XIA, PhD
Professor, Xi 'an Air Force Military Medical University

Design and Considerations of COVID-19 Vaccine Trials
Jingxin LI, PhD
Researcher, Jiangsu CDC

Challenges in Vaccine Clinical Design under New Circumstances
Jie SHAO, PhD
General Manager, Clinical Center of Zhifei Biology

Methods for Evaluation of Medium and Long-term Protective Efficacy in Vaccine Trials
Zhiwei JIANG
General Manager, Beijing Kontrico Statistical Technology Co., LTD

Biostatistics

Session 0604 | December 10, 2022

16:00–17:30

Trial Design, Data Collection and Statistical Analysis for Decentralized Clinical Trials (DCTs)

SESSION CHAIR
Chao ZHU, PhD
Head of Statistics and Programming, Lilly China

In recent years, especially since the start of COVID-19 pandemic, decentralized clinical trials (DCTs) have attracted extensive attention. Some hybrid DCTs in combination with conventional site-based clinical trials, even full-mode DCTs, are increasingly used in drug development. From this perspective, this session will provide some thoughts on DCT trial design, data collection and statistical analysis and discuss issues and possible solutions when implementing DCTs in China.

Decentralized Clinical Trials (DCT): Considerations in Protocol Design
Shuyan CHENG
Digital Trials Asia Lead, Boehringer Ingelheim

Decentralized Clinical Trials (DCT): Data Considerations
Wei ZHANG
Head of Data Management, GSK China

Decentralized Clinical Trials (DCT): Statistical Considerations
Dong GUO
Head of Statistical Programming, Lilly China

Panel Discussion

Biostatistics

Session 0605 | December 11, 2022

8:30–10:00

Application and Challenge of Artificial Intelligence in the Whole Lifecycle of Drug Development

SESSION CHAIR
Yang ZHAO, PhD
Dean, Department of Biostatistics, Nanjing Medical University

Although Artificial intelligence (AI) methods such as machine learning are rarely used in the analysis of registered confirmatory clinical trial data, they are used in drug molecular discovery, clinical trial operation, real-world research and health economics evaluation

AI methods have been used more and more widely. These methods speed up the process of drug research, reduce the cost, make full use of various resources, and contribute to the quality of drugs and research itself. Experts from industry and academia will share the methods and applications of ARTIFICIAL intelligence in drug research and development, as well as the challenges it faces.

A Review of Machine Learning and Artificial intelligence Applications in the Pharmaceutical Industry
Haoda FU, PhD
Vice President, Head of Machine Learning and Artificial Intelligence Enterprise, Lilly

Machine Learning Algorithms based on Biomarkers Empowered Drug Development Decisions
Cong ZHANG
Novartis

Machine Learning, Causal Inference and Drug Clinical Trials
Yang ZHAO, PhD
Dean, Department of Biostatistics, Nanjing Medical University

Biostatistics

Session 0606 | December 11, 2022

10:30–12:00

Guidance on Risk Management: From Theory to Practical Implementation

SESSION CHAIR
Guohua (James) PAN
Senior Director, Janssen China R&D

This session will provide perspectives about the statistical guideline on centralized monitoring and share experience from the pharmaceutical industry about risk management in China and globally ranging from data management practice to statistical considerations. The session will focus on some current best practices as well as covering some novel requirements such as Quality Tolerance Limits as required by ICH E6 R2.

Centralized Monitoring and Associated Statistical Considerations
Zhenglong TIAN
Vice President, GoBroad Healthcare Group

Implementation of a Statistical Surveillance Processes in Clinical Operation
Sina Djali
Senior Director, Janssen China R&D

Quality Risk Tolerability Limit (QTL): Quantitative Tools Used in Dynamic Monitoring and Quality Assurance in Ongoing Trials
Tian LIU
Associate Director, Biostatistics, Novartis

Strategies and Implementation of Risk-based Quality Management in China
Pamela CHEN
Vice President, Tigermed

PV & Drug Safety

THEME LEAD

Yuan MENG
Head of Medical Office R&D, I-Mab Biopharma

Conny MO
Founder, Medical Safety Advisor, Beijing XAJK Medical Technology, Co., Ltd.

Vera LIANG
Drug Safety Unit Regional Head, Asia Pacific, Worldwide Safety, Pfizer

Howe LI, MD, PhD
Chairman and CEO, Deltamed Co. Ltd

Xiaojing ZHAN
Vice President, Drug Safety, Junshi

Zheng JIAO
Director of Pharmacy Department, Deputy Director of GCP Center
Chest Hospital Affiliated to Shanghai Jiaotong University

Session 0701 | December 10, 2022

08:30-10:00

Safety Considerations in Clinical Development

SESSION CHAIR
Vera LIANG
Drug Safety Unit Regional Head, Asia Pacific, Worldwide Safety, Pfizer

With the rapid growth of drug innovation, the number and complexity of clinical trials have increased significantly. Meanwhile, pharmacovigilance has become an area of focus in the pre-marketing space given the elevated attention to ensure safety of the patients who are exposed to the biopharma products, which are still in the process of investigation. Biopharmaceutical innovators, regulators and healthcare professionals have been collaborating to develop guidelines, and to advance the safety science, which drive enhanced pharmacovigilance and safety risk management earlier in drug development. The pharmaceutical industry here in China has been evolving and adapting quickly to the changes to ensure the upmost patient safety.

This session aims to provide an overview of required safety monitoring activities during clinical trials. We are honored to have the experts from the health authority and pharmaceutical industry to share their insight and experience on several topics that are considered 'hot' in today's environment.

Pharmacovigilance in Clinical Development – An Update from the Health Authority
CDE Speaker Invited

Executing an Effective Safety Monitoring in Clinical Development
Xiujing KOU, MD, PhD
Site Head, Product Development Safety, Roche Product Development China

Management of Suspected, Unexpected and Serious Adverse Reaction (SUSAR) Reports and Special Safety Concerns
Fangfang SHI, MD
Senior Director, Therapeutic Area Head
Product Safety Surveillance & Reporting, Worldwide Safety, Pfizer China R&D Center

Panel Discussion
- Clinical safety review for marketing applications
- Practical aspects of pre-approval risk assessment
- SUSAR reporting
- Safety communication during pre-approval

PV & Drug Safety

Session 0702 | December 10, 2022

10:30-12:00

Post Approval PV

SESSION CHAIR
Li ZHANG, MD, PhD
Chief pharmacist, Beijing University of Chinese Medicine Oriental Hospital

Post-marketing drug safety monitoring is the core content of pharmacovigilance activities to realize the supervision of drug life-cycle and optimize the related clinical decisions. In this session, pharmacovigilance and related experts from home and abroad are invited to discuss issues including global pharmacovigilance development trend, pharmacovigilance practice experience of medical institutions and enterprises, medical insurance payment and comprehensive drug evaluation to further improve the safety risk management level of post-marketing drug and ensure public safety use.

Modern Methods of Pharmacovigilance - a Global Perspective
Niklas Norén
Chief Science Officer, Uppsala Monitoring Centre

Construction and Practice of Phamacovigilance System of HCP
Xiaole ZHANG
President of Beijing Yaodun Public Welfare Foundation

Intelligent Automation and Real World Surveillance for Safety
Andrew BATE
VP & Head, Safety Innovation & Analytics, Global Safety, GSK

DRG Payment and Drug Overall evaluation
Lili WANG
Researcher, Center for Health Policy and Technology Evaluation, Peking University Health Science Center

PV & Drug Safety

Session 0703 | December 10, 2022

13:30–15:00

Regulatory Compliance in Drug Safety

SESSION CHAIR
Xiaojing ZHAN
Vice President, Drug Safety, Junshi

Since China officially became a member of THE ICH in 2017, the Chinese drug regulatory authority has issued a series of new regulations and updated requirements on the basis of the original, and gradually carried out closer alignment with the international general technical standards and guidelines. The pharmaceutical administration law of the People's Republic of China, the pharmaceutical marketing authorisation holder (MAH) for the announcement of adverse reactions, the example of adverse drug reactions of collection and reporting guidelines circular pharmacovigilance quality management specification and other documents in the further clear the drug marketing authorisation holder (MAH) and bidders pharmacovigilance activities actively, Obligations and standards to minimize drug safety risks, protect and promote public health. 202204 The state promulgated the new Guiding Principles for Pharmacovigilance Inspection, which provides further guidance for urging holders to further improve the pharmacovigilance system, standardize the development of pharmacovigilance activities, ensure the continuous compliance with the requirements of laws and regulations, and effectively fulfill the responsibilities of pharmacovigilance subjects.

This conference will summarize and share working practices from the perspective of MAH and research center to see how to carry out pharmacovigilance work, how to effectively manage third parties, and discuss common findings in compliance inspections.

PSMF Practical Consideration
Lynn ZHOU
PV Head, Sanofi

Vendor Management of PV
Cindy LIN
Senior PV Manager, China
Guangzhou Junxin Pharmaceutical Co., Ltd. (CSL Behring China Affiliate)

Pharmacovigilance Compliance from an Institutional Perspective
Ye CAO
Deputy director of clinical Research Department/Drug Clinical Trial Institution Office of Cancer Hospital affiliated to Sun Yat-sen University'

Common Finds in PV Inspection
Conny MO
Founder, Medical Safety Advisor, Beijing XAJK Medical Technology, Co., Ltd.

PV & Drug Safety

Session 0704 | December 10, 2022

16:00–17:30

Drug Safety in Therapeutic Areas

SESSION CO-CHAIRS

Howe LI, MD, PhD
Chairman and CEO, Deltamed Co. Ltd

Zheng JIAO
Director of Pharmacy Department, Deputy Director of GCP Center, Chest Hospital Affiliated to Shanghai Jiaotong University

Risk Consideration in FIH Study
Wei LI, MD, PhD
Director of Oncology Center Phase I, Pulmonary Hospital

Safety in the Development of Innovative Drugs for Mental Diseases
Huafang LI
Professor, Director of Clinical Research Center, Shanghai Mental Health Center

Safety Risk Discovery and Evaluation of Roxadustat
Guanqiao LI, PhD
Assistant Professor, Vanke School of Public Health and Wellness, Tsinghua University

PV & Drug Safety

Session 0705 | December 11, 2022

08:30-10:00

COVID-19 Drug Safety

SESSION CHAIR
Yuan MENG
Head of Medical Office R&D, I-Mab Biopharma

COVID-19 Vaccine Specific Safety Monitoring Requirement and Methodology
Yan CHEN
Vice President, Global Drug Safety, Pfizer

Drug Safety in Intensive Care for COVID-19
Xinyu WANG
Deputy Chief Physician, Dept. of Infectious Diseases, National Medical Center for Infectious Diseases, Huashan Hospital, Fudan University

Emergency use of the Vaccine Safety Platform
Barbara LAW
Team Member, Safety Platform for Emergency vACcines

PV & Drug Safety

Session 0706 | December 11, 2022

10:30–12:00

PV Meets Information Technology and Methodology

SESSION CHAIR
Conny MO
Founder, Medical Safety Advisor, Beijing XAJK Medical Technology, Co., Ltd.

When IT meets with Pharmacovigilance, what it means – effectiveness improvement, high-quality data, process automation of PV operation as well as signal detection in real world safety data bring us much more breakthroughs and possibilities?

The integration and development of pharmacovigilance and information technology achieves the life cycle risk management of Pharmacovigilance and ultimately contribute to patient safety.

Robotic Processing Automation RPA in Use of Pharmacovigilance Operation
William WAN
Taimei

Interactive Visualization Tools for Clinical Aggregated Data Assessment
Co-presenters
Mengchun LI
PV Director, TB Alliance

Xiao NI
Senior Director, Biostatistics, Sarepta Therapeutics

Integrating Pharmacometric Modelling into Pharmacoepidemiological Research Using Real World Safety Data
Zheng JIAO
Director of Pharmacy Department, Deputy Director of GCP Center
Chest Hospital Affiliated to Shanghai Jiaotong University

Approach of Multi-factor Analysis in Signal Detection
Conny MO
Founder, Medical Safety Advisor, Beijing XAJK Medical Technology, Co., Ltd.

CMC

THEME LEAD

Steven HU, PhD
Chief Technical Officer, Everest Medicine

Lily XIONG
Executive Director, CMC, BeiGene

Xiaoping CAO, PhD
SVP, Head of Technology Operations, JW Therapeutics

Na XU
RA Director, 3DMed

Session 0801 & 0802 | December 10, 2022

8:30–12:00

Regulatory Science in Gene and Cell Therapy - Part I and Part II

SESSION CO-CHAIRS

Irene DENG
Regulatory Affairs Head, Sanofi

Renhua KOU
Senior RA Director, BeiGene

Cell and Gene Therapy Products Regulatory Clinical Considerations and Technical Review Requirements
CDE Speaker Invited

Cell and Gene Therapy products Supervised Site Verification and Inspection Requirements
CFDI Speaker Invited

EMA's Considerations and Prospects for the Regulation of Cell and Gene Therapy Products
Patrick CELIS
EMA

FDA Considerations and Prospects for Regulation of Cell and Gene Therapy Products
Guang GAO, PhD
Senior Technology Officer, PATH

Cell and Gene Product Development Status and Case Sharing
Chunlin ZHAO
Founding Partner of Anlong Fund and Founder of Anlong Biotech

Panel Discussion

CMC

Session 0803 | December 10, 2022

13:30–15:00

CMC Development for Advanced Therapies & Technologies of Biologics

SESSION CHAIR
Steven HU, PhD
Chief Technical Officer, Everest Medicine

ADCs: Past, Present and Future
Speaker Invited

Topic TBD
Jimmy LI, PhD
Senior Vice President, WuXi Biologics

Topic TBD
Jiaqiang CAI
CSO, MediLink Therapeutics

Session 0804 | December 10, 2022

16:00–17:30

CMC Regulation and Challenges of mRNA and Cell Therapy

SESSION CO-CHAIRS
Xiaoping CAO, PhD
SVP, Head of Technology Operations, JW Therapeutics

Na XU
RA Director, 3DMed

CMC Development and Challenges of Cell Therapy
Shuyuan YAO, PhD
CEO of Hillhouse

CMC Regulatory Consideration for Cell Therapy Products
Cheng YIN, PhD
Head of Process Development, JW Therapeutics

From Technology to Medicine: Mobius Ring for Autologous Somatic Therapy of CMC
Xin'an LU, PhD
CMO, Imuno Pharma

CMC

Session 0805 | December 11, 2022

8:30-10:00

CMC Regulatory Requirements - Small Molecules Drug

SESSION CHAIR
Lily XIANG
Executive Director, CMC, BeiGene

The wave of innovation development of medicine, Chinese medicine enterprises in the face of China's regulations, to declare at the same time considering filing stage to go global, in pharmaceutical development and formation of CMC technical documents to declare to be proactive when implanted all regulatory requirements, in the limited resources, time and manpower cost under the premise of must also ensure that declare success rate. Therefore, how to coordinate the different technical requirements of various countries and optimize the priority order of declaration according to the time node of CMC development has become the top priority of each pharmaceutical enterprise.

In addition, as China became a member of the, for example, in the past six years in a more open mind incorporates more pharmaceutical related ICH guidelines, we are delighted to see China CDE review requirements and standards also adjusted to a certain extent, and CDE in China's own hard-working guidelines, drug companies colleagues at the same time of learning rules, We also need to learn from each other, and this DIA Annual Conference will strive to provide more opportunities for everyone to share and learn.

CMC Regulatory Requirements for Sino-US NDA Application of Chemical Innovation Drugs
Youxuan LI
Registered Director of Pharmaceutical Sciences, China and Asia Pacific region, BeiGene

CMC Requirements for Pediatric Drug in US
Yang WANG
Senior Registration Director, Innocare Pharma

Development and Difficulties of CMC Registration Requirements in China under Global Synchronous Development
Zhengyu WU
Director of Registration, NovoNordisk

Control Strategy Development for New Chemical Entities
Joerg SCHIEWE
Head of Global CMC Expert NCE, Boehringer Ingelheim

Panel Discussion

CMC

Session 0806 | December 11, 2022

10:30-12:00

CMC Regulatory Requirements - Biologic Drug

SESSION CHAIR
Jun LU, PhD
CMC Head, Boehringer Ingelheim

Regulatory Considerations on CMC for Application of Innovative Biologic Drugs in China and the United States
Chenshu LU
RA Director, BeiGene

Pharmaceutical Technical Requirements and Challenges for Global Application of Innovative Biologics
Wei LI
Deputy Director of registration Affairs Department of Wuxi Pharm Biotechnology Co., LTD.

Characteristics and Key points of WRITING CMC Application Materials for ADC Drugs
Xiaoning LI
Deputy Director, Registration, RemeGen

Panel Discussion
Invited Panelists
Baoquan LI
Registration, Innovent

Juhong LIU, PhD
Chief Scientific Officer, EVIVE Biotech

Translational Medicines

THEME LEAD

Xinying SU, MD, PhD
Senior Director, Translational Medicine and Diagnostic Lead, Development China, Pfizer

Yi ZHENG, PhD
Head of Translational Science Center, JnJ

Session 0903 | December 10, 2022

13:30-15:00

What Does Translational Medicine Really Mean?

SESSION CHAIR
Yi ZHENG, PhD
Head of Translational Science Center, JnJ

Translational Medicine - from T0 to T4
Xinying SU, MD, PhD
Senior Director, Translational Medicine and Diagnostic Lead, Development China, Pfizer

Translational Medicine - Perspective from Investigator
Jianming YIN
Head of Pathology Department, CICAMS

Translational Medicine - Perspective from Industry
Tianyuan ZHOU, PhD
Head of Translational Medicine China, AZ

Session 0904 | December 10, 2022

16:00–17:30

Application of Translational Medicine: Innovations

SESSION CHAIR
Xinying SU, MD, PhD
Senior Director, Translational Medicine and Diagnostic Lead, Development China, Pfizer

Gold Digger: Advanced Analytic Methodology Application in Translational Research
Xinyi YANG, PhD
Senior Scientist, AP CoE in Translational Science, Janssen AP R&D

Translation from Real World Data Intelligence to Novel Drug R&D
Qiang XU, PhD
President & CEO, Geno Micare Bio

Therapeutic Target and Efficacy Prediction in Precision Medicine for Treating Lung Cancer
Xuchao ZHANG
Associate Director, Guangdong Institute of Lung Cancer

Translational Medicines

Session 0905 | December 11, 2022

8:30-10:00

Regulation Update on Translational Medicine

SESSION CHAIR
Sharon CAI
Senior Regulatory Affairs Director, Roche Diagnostics Shanghai Ltd.

Two New Guidance on Co-developed & follow-on Companion Diagnostic Products
CMDE Speaker Invited

Collaboration Model & Opportunities between Pharma & CDx company
Annie YIN
VP, Medical Regulatory Affairs, Roche

Worldwide Simultaneous Development of Innovative Drugs and Companion Diagnostics
Zhirong SHEN
VP, Head of Translational Discovery, Research & Medicine, BeiGene

Session 0906 | December 11, 2022

10:30-12:00

Exploring Collaboration Models in Translational Medicine

SESSION CHAIR
Xu HUANG
Associate Director, AP CoE in Translational Science, Janssen AP R&D

Construction and Development of Clinical Biological Sample Resource Network in Beijing
Lei ZHANG
General Manager of Biotechnology Research Institute of Beijing Life Science Park Co., LTD

Research Hospital Enable Translational Medicine
Shuhang WANG, MD
Cancer Hospital, Chinese Academy of Medical Sciences

Panel Discussion
Above Speakers and Invited Panelists

Non-clinical & Animal Test

THEME LEAD

Jack XIE, PhD
Head of Preclinical Sciences and Translational Safety, Janssen R&D

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

Xiantang LI, PhD
Senior Director, Non-clinical Drug Safety, Pfizer

Many international pharmaceutical companies in China try to move Pipeline to the early stage, join the global synchronous development, become contributors to early clinical studies; Local companies are also increasingly looking to do the real innovation needed for toxicology research
Clinicians also need to learn more about non-clinical knowledge expansion and collaborate more effectively with global pharmaceutical stakeholders.

The sessions hoped to attract more clinical and regulatory professionals through the well designed content and sharing their interests of the topics.

Session 1001 | December 10, 2022

08:30–10:00 **Nonclinical Data to Support Clinical Development**

SESSION CO-CHAIRS
CDE Session Chair Invited

Jack XIE, PhD
Head of Preclinical Sciences and Translational Safety, Janssen R&D

Clinical Translation of Nonclinical Drug Safety Assessment
Nasir Khan, PhD
Chief Non-clinical Safety Officer, Drug Safety Research & Development, Pfizer

Integration of Preclinical Information to Effective Clinical Dosing Strategy
Jia JI
JnJ

Nonclinical Animal Models: Recent Progresses and Clinical Translation
Chuan QIN, PhD
Dean, Chinese Academy of Med. Science

Non-clinical & Animal Test

Session 1002 | December 10, 2022

10:30-12:00

Nonclinical Assessment of New Modalities

SESSION CO-CHAIRS

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

Chuan QIN, PhD
Dean, Chinese Academy of Med. Science

Nonclinical Safety Assessment Strategy for Oncolytic virus Therapeutics
Xuedong DAI, PhD
Vice President of Beijing Saifu Pharmaceutical Research Institute Co., LTD

Nonclinical Safety Assessment Strategy for Oligonucleotide Therapeutics
Yan CHANG, PhD
General Manager, InnoStar

Nonclinical Safety Assessment Strategy for Monoclonal Antibody Therapeutics
Xiaobo CENG, PhD
CEO, West China-Frontier PharmaTech

Nonclinical Safety Assessment Strategy for Antibody Drug Conjugate (ADC) Therapeutics
Yi JIN, PhD
VP and Head of Program Management and Regulatory Affairs, WuXi Appec Suzhou

Medical Writing and Publication

THEME LEAD
Nan WANG, PhD
Senior Director, Medical Writing Services Asia-Pacific, Parexel China Co., Ltd.

Session 1101 | December 10, 2022

08:30-10:00

Value of Medical Writing in the Pharmaceutical Industry

SESSION CHAIR
Ning ZHENG, PhD
Director, Head of Medical Communication, AstraZeneca R&D China

Medical writing as a profession is booming in recent years in China, with a fast-growing number of medical writers and an even faster-growing demand from pharmaceutical companies, biotech firms, and CROs, while providing high quality submission package within timeline is a crucial step in the drug development process.

In this session, we will discuss the value medical writers could bring to the clinical submission team and how medical writing expertise can help in the communication with health authorities. In light of this, we will continue to discuss the career journey for a medical writer to develop the skillsets, build the competency, and demonstrate the value.

The Value of Medical Writing: AMWA Survey and China Status
CO-PRESENTERS
Julia COOPER, PhD, FRSC
Corporate Vice President, Head of Global Medical Writing Services, Parexel International Ltd

Xiaoling WANG
Head of Clinical Documentation China team, Clinical Science Operation, Sanofi R&D China

The Core Competency of a Medical Writer (MW)_Beyond Medical Writing
Lynnette LIN, PhD
Principle Medical Communication Scientist, Medical Communication, AstraZeneca R&D China

Panel Discussion
INVITED PANELISTS
Lei QIAN, MD, PhD
Vice President, Clinical Development, Innoventbio

Eric ZHANG, PhD
Vice President, Head of Data Science, Rundong Pharmaceutical

Marilyn LIU
RA Head, Rare Products & Diabetes & Excellence, Regulatory Affairs, Sanofi China Corporate

Medical Writing and Publication

Session 1102 | December 10, 2022

10:30-12:00

The Value of Medical Writing in Clinical Document Preparation for NDA/BLA Submissions

SESSION CHAIR
Helen WANG, PhD
Medical Writing Team lead, China Clinical Documentation, Sanofi

The importance of high-quality submission documents for a successful NDA/BLA cannot be overemphasized. Since the implementation of ICH guidelines in China, preparation of clinical documents in accordance with regulatory specifications within limited timeframes has put forward higher requirements and greater challenges for document development teams, highlighting the indispensable value of medical writing in this process.

In this session, industry experts will be invited to share from a medical writing perspective on how to author clinical documents with the health authority reviewing in mind, how to accelerate submission timelines through strategic planning and messaging, and how to efficiently coordinate the document preparation process, based on their rich experiences from various global and China NDA/BLA submissions.

Writing as a Content Strategist
Wei GONG
China RDT Lead, Roche (China) Holding Ltd

Clinical Overview Writing: How to Complete a Structured Benefit-risk Section with Health Authority Reviewers in Mind
Yingjie ZHAO
Senior Regulatory Writer, Global Drug Development (China), Novartis AG

How to Act as a Lead Medical Writer to Accelerate NDA/BLA Submission Dossier Preparation
Changhui MAO, PhD
Medical Writing Lead, Janssen China R&D Center, Johnson & Johnson (China) Investment Ltd.

Panel Discussion
INVITED PANELISTS
Yuxiao LIU
Medical Writing Associate Director, BeiGene

Jing JIE
Senior Manager, Medical Writing, Takeda Development Center Asia

Yiting LIU, PhD
Medical Writing Team Lead, Pfizer China Research & Development Center

Pediatric Drug Development Forum

Session 1201 | December 10, 2022

8:30-10:00

Pediatric Drug Development – Part 1: Pediatric Clinical Trials and Regulatory Consideration

SESSION CHAIR
Ao PENG, PhD
Head, Clinical Pharmacology and Early Clinical Development, Pfizer

CDE Pediatric Guideline Interpretation
China CDE Speaker Invited

Current Clinical Trial Status of China Pediatric Drug – Physician Perspective
Jinhu WANG, PhD
Deputy Director of Hematological Tumor Center, Children's Hospital affiliated to Zhejiang University School of Medicine

Pediatric Drug PK/PD
Jing LIU, PhD
Senior Director, Clinical Pharmacology, Pfizer

Pediatric Drug Development Forum

Session 1202 | December 10, 2022

10:30-12:00

Pediatric Drug Development – Part 2: The Use of Extrapolation in Pediatric Drug Development

SESSION CHAIR
Wei ZHAO, PhD
Professor, Clinical Pharmacy, School of Pharmacy, Shandong University

CDE Guidelines for Extrapolation Adult Medication Data to the Pediatric Population
CDE Speaker Invited

Use of Adult Extrapolation in Pediatric Drug Development - Case Sharing
Jing ZHANG, MD, PhD
Professor of Clinical Pharmacology, Deputy Director, Institute of Antibiotics, Huashan Hospital, Fudan University

The Use of Extrapolation in Pediatric Drug Development
Robert Nelson, MD, PhD
Senior Director, Pediatric Drug Development (CHILD)Johnson & Johnson, United States

Pediatric Drug Development Forum

Session 1203 | December 10, 2022

13:30–15:00

Pediatric Drug Development – Part 3: RWD & Panel Discussion

SESSION CHAIR
Jianing DI, PhD
Senior Director, China Compound Team Leader, Janssen China R&D

Considerations Related to Dosing Determination of the Licensed Drug Product, Dastuximab β Injection
Zou JUN
Hainan Women and Children's Medical Center

From Design to Real World Application
Vega Masignani
GSK

Panel Discussion
INVITED PANELISTS
CDE Panelist Invited

Ling HUANG
Hainan CDE

Jinhu WANG, PhD
Deputy Director of Hematological Tumor Center, Children's Hospital affiliated to Zhejiang University School of Medicine

Wei ZHAO, PhD
Professor, Clinical Pharmacy, School of Pharmacy, Shandong University

Zhizhong LI, PhD
Secretary General, Shiyu Children Foundation

Yongjing ZHANG, PhD
Senior Director, Asia Pacific Epidemiology Division, Johnson & Johnson

Hot Topics

Session 1301 | December 10, 2022

8:30–10:00

Market Access in Drug Development

SESSION CO-CHAIRS

Yi CHEN, PhD
Professor and Researcher, Institute of Hospital Management, Tsinghua University
Co-head of Biomedical Innovation Center, Shanghai Chuangqi Health Development Institute

Dajun YANG, PhD
Chairman of the Board, Executive Director and CEO, Ascentage Pharma

In the pharmaceutical market environment of China, the medical insurance market occupies an absolutely dominant position, and all kinds of pharmaceutical companies set the core strategy and access goal of entering the medical insurance market quickly after the product is approved. The national medical insurance catalogue has been updated for five consecutive years, entering a "new normal" of dynamic adjustment. In 2021, the National Medical Insurance Administration will require applicants to submit evidence information on five value dimensions, including effectiveness, safety, economy, innovation and fairness. For economic evidence, such as Cost Effective Analysis, pharmacoeconomic experts collect real world data to conduct pharmacoeconomic evaluation after the product is launched, which takes a long time and costs a lot. How to advance pharmacoeconomic evaluation to the clinical trial stage of drug development, collect the data required by pharmacoeconomics while collecting drug safety and efficacy, and provide supporting evidence for market access? How do pharmaceutical companies synchronously formulate new drug registration strategy and market access strategy?

The Importance of Taking Market Access Strategies into Consideration during the Clinical Trial Phase of Drug Development
Dajun YANG, PhD
Chairman of the Board, Executive Director and CEO, Ascentage Pharma

New Normal of Drug Registration and Approval and Medical Insurance Access
Yi SHAO
Executive Director, McKinsey

Implications of China's Medical Insurance Payment Environment for New Drug R&D
Yi CHEN, PhD
Professor and Researcher, Institute of Hospital Management, Tsinghua University
Co-head of Biomedical Innovation Center, Shanghai Chuangqi Health Development Institute

Panel Discussion

Hot Topics

Session 1302 | December 10, 2022

10:30–12:00

eSource Data: Opportunities and Challenges for Improving Data Acquisition Efficiency

SESSION CHAIR
Charles YAN, PhD
Vice President, Data Science Center, Hengrui

The atmosphere was tense at the DIA 2021 Annual Meeting, based on differing perspectives from speakers at eSource Session. After the meeting we all made a deep analysis and reflection, to discuss the reasons of differences, such basic agreement, namely the electronic source data is the core of clinical research is the most important assets, but because of the ownership of the data, use right and the right to know is not yet clear and normative problem has not been thoroughly solved, the electronic data acquisition must be a serious problem. This session will continue this theme, hoping that we can gradually improve the understanding of the debate, reach consensus, and guide the practice to make electronic data better used in clinical research.

Electronic Source Data: Current Difficulties and Challenges
Zhenglong TIAN
Vice President and Chief Data Officer, Gobroad Hospital Management Co., LTD

Current Situation and Future Direction of Centralized Electronic Data Collection
Yanfei LIU
Director of GCP, Fudan University Cancer Hospital

Panel Discussion
Above Speakers and Invited Panelists
Yue ZHANG
General Manager, Data Science Center, Clinical Product Development Department, Shanghai Henlius Biotechnology Co., LTD

Xin CHEN
Senior Manager, Hengrui Medical Data Science Center

Feng SHENG
Vice President of Business Development, Asia Pacific, Viedoc Information Technology Co., LTD

Hot Topics

Session 1304 | December 10, 2022

16:00–17:30

Building a Portfolio for Global: Where We Are & Where to Focus

SESSION CO-CHAIRS
Huading ZHANG
Chief Operating Officer, Alebund Inc.

Yang SONG
Head of China PMO, Janssen R&D

Chinese Biopharmaceutical Enterprises Go Global
Helen Chen
Managing Partner, L.E.K. Consulting

Strategy and Consideration of Product Pipeline of Chinese Biotech
Joan Shen
CEO, Neushen

Panel Discussion
Invited Panelists
Cyber Cao
Managing Director, Sequoia Capital

Feng Bian
Executive Director of Integrative Sciences, China R&D, BMS

Yinxiang Wang
Chairman & CEO, Jacobio Pharma

Hot Topics

Session 1305 | December 11, 2022

8:30–10:00

Agility in Clinical Project Management

SESSION CO-CHAIRS

Tina TIAN
Head of PM, Roche China Development Center

Kevin LI
VP, Clinical Operation, Everest Medicines

Under the fast changing drug development environment with fierce competitions, integrate Agile PM methodology into 'innovation through collaboration' would be quite fundamental to our future success. We need to fully leverage the advantages of developed assets, dynamic regulations and unmet medical needs through continuous iteration and deconvolution, to ensure sustainable drug development success, tailored health care solutions to patients as well as leading the future with agile innovations.

Why-What-How about Agility Management
Karen XU
Founder, Timesct

Regulatory Agility in Ages of COVID-19
Handsome JI
Regional Publishing Lead, Asia, Pfizer

Agile and Sustainable Clinical Supply Chain and Manufacturing Strategy
Vivian JIA
AD, Supply Chain Management, CMC, Everest Medicines

Panel Discussion

Hot Topics

Session 1306 | December 11, 2022

10:30–12:00

Innovation & GMP Compliance - Yeehong Joint Session

Under the policy environment of encouraging drug innovation, China's innovative drug research is in full swing. Clinical research is an important link in the research and development of innovative drugs. The quality of clinical trial samples is one of the key factors affecting the quality of clinical trials. The quality control of the preparation of clinical trial samples is very important to ensure the quality of clinical trials and the safety of subjects. Based on the gradual and uncertain characteristics of innovative drug development, the production site change during clinical research of innovative biotechnology drugs is inevitable and in line with the law of innovative research and development. How to conduct a comparable study on the production site change during clinical research based on risk and science is a scientific issue of concern in the industry. In addition, due to the complexity and particularity of biological macromolecules, the commercial production capacity of biotechnology drugs, the quality management and risk control ability, the implementation of GMP management concept and system, etc., become the bottleneck of whether the biological drug enterprises can grow bigger and stronger.

This session will discuss the key points of FDA biologic drug inspection and regulation from multiple perspectives, the quality control of sample preparation for clinical trials in China, as well as the risk assessment of production site change during the clinical period of innovative biotechnology drugs and the scientific consideration of comparability research, so as to facilitate the development of innovative drugs and the internationalization of biotechnology drugs.

FDA Biological Product Inspection
Jonathan CHAPMAN
Medical Product Supervisor, FDA China Office

Considerations for Quality Control of Investigational Medicinal Products - An Understanding of the Contents of the GMP Appendix
Lixin WANG
Deputy Director, Certification and Evaluation Center of Jiangsu Drug Administration

Scientific Considerations for Risk Assessment and Comparability of Manufacturing Site Changes During Clinical Trials of Innovative Biotechnology Drugs
Zhengyu WU
RA Director, AZ

Panel Discussion
Invited Panelist
Dongming WANG
Senior Vice President, Quality, Innovent Bio