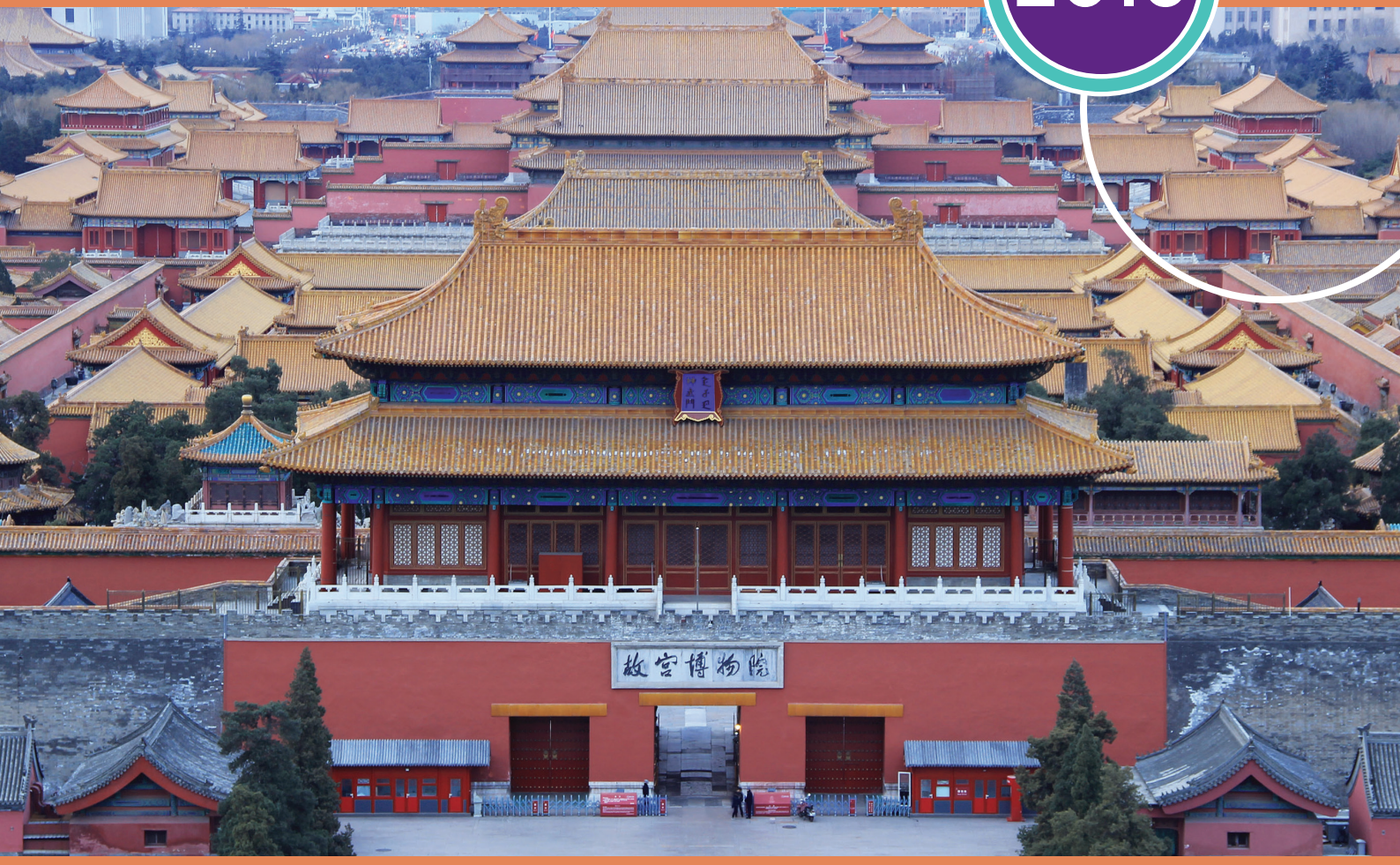
第八届药物信息协会(DIA)中国年会

8th DIA China Annual Meeting

2016年5月15-18日 | 北京国家会议中心 | 中国

May 15-18, 2016 | China National Convention Center, Beijing

2016



2016 年 5 月 15 日 —— 会前专题研讨会
2016 年 5 月 16-18 日 —— 会议和展览

15 May, 2016 - Preconference Workshop
16-18 May, 2016 - Conference and Exhibition

DIA DEVELOP INNOVATE ADVANCE

SUNDAY, 15 MAY | PRCONFERENCE WORKSHOPS

Workshop 1 (Half Day)	13:30 - 17:30	Inspection Readiness
Workshop 2 (Full Day)	08:30 - 17:00	Medical Coding
Workshop 3 (Full Day)	08:30 - 17:00	Strategy and Key Considerations for Simultaneous Filing of Innovative Drugs in China and Abroad
Workshop 4 (Full Day)	08:30 - 17:00	CDISC Standards for Clinical Trial
Workshop 5 (Full Day)	08:30 - 17:00	MSLs Practice during New Product Launch
Workshop 6 (Full Day)	08:30 - 17:00	Aim at Drug Market - Preclinical and Documentation Strategy

Workshop 1

SUNDAY, 15 MAY | 13:30 – 17:30

Inspection Readiness

Given that China is slated to become the world's largest pharmaceutical market, the number of both domestic and global clinical trials conducted in China has been growing exponentially over the years. Although foreign inspections by FDA, PMDA and EMA are increasing in China, they are still relatively few in numbers and the majority of researchers participating in global trials have not experienced it.

The recent mandate by CFDA for NDA applicants to perform self-inspections and the unannounced on-site inspections conducted by CFDA in recent months calls for the need to demystify inspections, how to be ready for any inspection, how to interpret the GCP non-compliances and distinguish the significance of these non-compliances so as to stay on top of the current changes and the associated challenges in the dynamic and complex world of clinical research in China.

FEATURED TOPICS

- An overview of inspection the different types of inspections and their focus; the inspection process and expectations by the different foreign authorities
- What to do to be "inspection-ready". How do you prepare for an inspection?
- The common GCP findings in inspections and in particular how to interpret and rate these findings in relation to the benefit risk balance on the rights, safety or well-being of the trial subjects and/or the quality and integrity of data.
- Discussion on best practices considerations and challenges locally to meet ICH GCP standards in terms of inspection readiness for both announced and unannounced inspection
- The aftermath: how to address findings in a non-bureaucratic way and use them as an opportunity for improvement

LEARNING OBJECTIVES

- Explain the inspection process by the different foreign authorities, why they are necessary and what is involved to run and host the different types of inspections successfully
- Stimulate a thought process and engage in a discussion to differentiate findings that are likely to influence the benefit-risk evaluations from those that may or less likely to influence the benefit-risk evaluations impacting ethics compliance and data integrity
- Understand and the local system vulnerabilities and learn the holistic approach to be ready for inspections from experts with real-life inspection experience
- Understand how to best address findings and use them as improvement tools
- Targeted Audience
- Clinical research professionals from sponsor companies, CROs, site staff

Workshop 2

SUNDAY, 15 MAY | 08:30-17:00

Medical Coding

MedDRA stands for Medical Dictionary for Regulatory Activities. It is the new international medical terminology designed to facilitate the coding, retrieval, presentation, and communication of medical information throughout the medical product regulatory cycle.

This workshop on MedDRA will provide some basic information on MedDRA background information, MedDRA coding basics, Standardized MedDRA Queries (SMQs). MedDRA versioning and browser/coding tool will be introduced.

By going through this training, the audience will better understand the strengths and deficiencies of MedDRA, its clinical structure, the multiaxial features of MedDRA, comparative dictionary profiles, its impact on your job function and the specific skills and resources required for efficient use of MedDRA.

LEARNING OBJECTIVES

- To introduce the basic definitions and concepts that characterize MedDRA
- To demonstrate how MedDRA is used by pharmaceuticals, regulatory authorities and by contract research organizations.
- To present an overview of some of the aspects of MedDRA terminology that affect case assessment, safety surveillance, labeling, and regulatory reporting.
- To provide rules for the coding of medical data (drug safety and data management) and by using these rules, the coding of medical data will achieve a higher level of consistency and accuracy.

- Provide insights to challenges you may face when you retrieve and report data coded in MedDRA.
- Provide insights to challenges you may face when you retrieve and report data coded in MedDRA.

Workshop 3

SUNDAY, 15 MAY | 08:30-17:00

Strategy and Key Considerations for Simultaneous Filing of Innovative Drugs in China and Abroad

With a rapid growth of R&D talents and introduction of advanced technologies in biopharmaceutical research, the focus of China's pharmaceutical R&D has gradually changed from tranditiaonal generic drugs and API manufacturing to innovative drugs. In the meantime, the targeted market of pharmaceutical R&D in China is also changing from domestic to both domestic and abroad. A series of new regulations and policies issued by CFDA recently has emphasized that simultaneous filing of innovative drugs in China and the US/EU is one of the options for fast track review. Under such circumstance, more and more pharmaceutical companies in China are considering simultaneous filing strategy for their innovative drugs.

TARGET AUDIENCES

- Senior Executives
- Regulatory Affairs
- Nonclinical Safety
- CMC
- Bioanalysis and PK/PD
- Clinical Research and Development
- Portfolio Management
- Strategy

Content in Development

Workshop 4

SUNDAY, 15 MAY | 08:30-17:00

CDISC Standards for Clinical Trial

Good quality of data is critically important, and standardization is very important for improving data quality. With the standardization, we can focus more on more important points on science and planning, instead of doing it; we can develop tools to help us identify the data issues at very early time, and real time analysis or regular analysis to detect the trends. CDISC is data standard mainly for clinical trial, covering protocol presentation, CRF design, data tabulation, analysis data, data exchanging and archiving. CDISC standards provide us the common languages for us to communicate on data, and on clinical trial. Here we will do an overall introduction of CDISC standards related data management, statistics, and medical monitoring activities.

TARGETED AUDIENCE

- Data Management Professionals
- Statistics and Programming Professionals
- eSub Professionals
- Clinical Safety/Pharmacovigilance Professionals
- Training Professionals

AGENDA

Session 1: **CDISC Overview - Understand What is CDISC:**
CDISC Organization and CDISC Standards Overview
CDISC in China
SDTM Basic and Examples.
Session 2: **CDISC Standards for CRF Design - Know the Key Points to Design a Good CRF:**
CDASH Overview
CDASH Best Practice Recommendations
CDASH Conformant CRF Examples
Session 3: **Using CDISC Data in Data Management Activities - Understand CDISC Data and How to Use it in Data Management Activities.**
Real Time Analysis Based on CDISC Data
Risk/Fault Detecting Based on CDISC Data
Medical Review with CDISC Data
Session 4: **CDISC Standards to Support Common Analyses - Understand the Most Commonly Used ADaM Data Structures:**
ADaM Overview
Adding Rows vs Adding Columns to Meet Analysis Need
ADaM Examples: Data Structures and Common Analysis Supported
Session 5: **Integrated Analysis with CDISC Data - Understand How Data are Structured to Support Integrated Analysis.**
Integrated Analysis
ADaM Data to Meet Integrated Analysis Need
Integrated Analysis with ADaM Datasets Examples

Workshop 5

SUNDAY, 15 MAY | 08:30 – 17:00

How to Prepare New Product Launch - Medical Affairs Strategy and Tool Kits

Content in Development

Workshop 6

SUNDAY, 15 MAY | 08:30-17:00

Aim at Drug Market - Preclinical and Clinical Documentation Strategy

Content in Development

TUESDAY, 17 MAY | WEDNESDAY, 18 MAY

Theme 1 Rapid Evolving China Regulatory Science – Seize the Opportunity for Driving Innovation

Session 0101 | Tuesday, 17 May

08:30-10:00

ENHANCEMENT FOR POST-MARKETING DATA MANAGEMENT
SESSION CHAIR
Janet LV
Head of Regulatory, Asia Pacific, Roche

Session in Development

Session 0102 | Tuesday, 17 May

10:30-12:00

eCTD
SESSION CHAIR
Janet LV
Head of Regulatory, Asia Pacific, Roche

Session in Development

Session 0105 | Wednesday, 18 May

08:30-10:00

BEST PRACTICE FOR COMMUNICATION BETWEEN SPONSORS AND HEALTH AUTHORITIES
SESSION CHAIR
Wendy YAN, MD, MBA
Senior Vice President, Head of Regulatory/Affairs, BeiGene (Beijing) Co., Ltd.

Session in Development

Session 0106 | Wednesday, 18 May

10:30-12:00

EXPEDITED PATHWAY TO FACILITATE DRUG DEVELOPMENT
SESSION CHAIR
Wendy YAN, MD, MBA
Senior Vice President, Head of Regulatory/Affairs, BeiGene (Beijing) Co., Ltd.

Session in Development

Session 0107 | Wednesday, 18 May

13:30-15:00

HOW TO ESTABLISH PROPER IND FRAMEWORK IN CHINA - PART 1: FILING AND REVIEW PROCESS AND DOSSIER REQUIREMENT
SESSION CHAIR
Haifeng CAO, MBA
Head of Regulatory Affairs, GSK

CFDA is initiating regulatory management system reform. Industry is expecting some fundamental changes to be introduced as the mindset change has been clearly observed by published several policy paper. IND/NDA separation has been a hot topic in past years in China and many related discussions were conducted in various occasions. Exploring China IND system is becoming more and more critical now as it is not only the need of MNCs but also the domestic innovative companies. Proper IND system reflecting R&D principle will help the healthy and fast evolvement of China pharmaceutical industry from generic oriented to innovative oriented. This session is aiming to discuss this important question from filing and review process and dossier requirement perspective by introducing FDA system, sharing real experience from domestic company in China, and on that basis to propose some thoughts or suggestion to China IND system.

US FDA IND System - Process and System
Speaker Invited

Experience Sharing from Domestic Company with IND Experience in US and China
Speaker Invited

Thoughts and Suggestion on China IND System from Process and Dossier Requirement
Speaker Invited

Session 0108 | Wednesday, 18 May

15:30-17:30

HOW TO ESTABLISH PROPER IND FRAMEWORK IN CHINA - PART 2: SUPPORTING SYSTEM
SESSION CHAIR
Haifeng CAO, MBA
Head of Regulatory Affairs, GSK

CFDA is initiating regulatory management system reform. Industry is expecting some fundamental changes to be introduced as the mindset change has been clearly observed by published several policy paper. IND/NDA separation has been a hot topic in past years in China and many related discussions were conducted in various occasions. Exploring China IND system is becoming more and more critical now as it is not only the need of MNCs but also the domestic innovative companies. Proper IND system reflecting R&D principle will help the healthy and fast evolvement of China pharmaceutical industry from generic oriented to innovative oriented. This session is aiming to discuss this important question from supporting system perspective, such as IRB, clinical site inspection, clinical hold and PV, by introducing FDA system, sharing real experience from domestic company in China, and on that basis to propose some thoughts or suggestion to China IND system.

Session in Development

TUESDAY, 17 MAY | WEDNESDAY, 18 MAY

Theme 2 China Food and Drug Administration (CFDA) Town Hall

Session 0203 & 0204 | Tuesday, 17 May

13:30-17:30

CHINA FOOD AND DRUG ADMINISTRATION (CFDA) TOWN HALL

Session in Development

Theme 3 Innovative Breakthrough in Therapy

Session 0301 | Tuesday, 17 May

08:30 – 10:00

ADVANCEMENT OF NSCLC MANAGEMENT - IMPLICATION OF PRECISION MEDICINE TO PERSONALIZED CARE
SESSION CHAIR
George CHEN, MD, MBA
Vice President and Head of Global Medicine Development China, AstraZeneca (China)

Overview of Advancement in NSCLC Management
Speaker Invited

Case Study: Discovery and Development of 1st and 3rd Generation EGFR TKI
Speaker Invited

Role and Advancement of cDx in NSCLC Management
Speaker Invited

Session 0302 | Tuesday, 17 May

10:30-12:00

BREAKTHROUGH OF DRUG DEVELOPMENT IN RESPIRATORY DISEASES
SESSION CHAIR
Irwin WANG, MD, PhD
Vice President, Medicines Development, GlaxoSmithKline

This session will update the current advances in Asthma and COPD treatment. As well some discussions on current unmet medical needs and new medicine development.

Current Clinical Progression on Treatment of Asthma and COPD
Speaker Invited

The Landscape of Innovative Medicines in Asthma and COPDI
Speaker Invited

Optimization of Clinical Development for Respiratory Diseases in China - From the Agency Perspective
Speaker Invited

Panel Discussion: Opportunities and Challenges with Current China Environment Situation

Session 0305 | Wednesday, 18 May

08:30-10:00

INNOVATIVE MEDICINES IN CARDIOVASCULAR MADE HUGE IMPACT ON CARDIOVASCULAR TREATMENT
SESSION CHAIR
Irwin WANG, MD, PhD
Vice President, Medicines Development, GlaxoSmithKline

Session in Development

Session 0306 | Wednesday, 18 May

10:30-12:00

HEPATITIS
SESSION CHAIR
Jessica LIU
Vice President Clinical Development, General Medicine BU, Asia-Pacific Region, INC Research

Session in Development

Session 0307 | Wednesday, 18 May

13:30-15:00

INNOVATION AND CHALLENGES IN VACCINE PRODUCT CLINICAL DEVELOPMENT
SESSION CHAIR
Anna DU
Sanofi Pasteur China External R&D

Session in Development

Theme 4 Clinical Trial Sites in China – Bottleneck or the Anchor for Quality Clinical Trials

Session 0401 | Tuesday, 17 May

08:30 – 10:00

CFDA INSPECTION: WHETHER A BRIGHT SUNNY SKY WILL APPEAR AFTER HAZE SWEPT OFF
SESSION CHAIR
Shuting LI, MD
Vice Director, GCP Center, the Cancer Hospital of Chinese Academy of Medical Sciences

Last year CFDA started the strictest inspections of IND clinical trials, as a result, hundreds of enterprises, CRO and research institutions have been involved, and nearly one thousand IND applications have been withdrawn. Clinical trial sites and industries have undergone the great movement of inspections. After this movement people wonder whether the haze can be swept off, a clean environment of clinical trials can appear, and

what is the right way to do clinical trials, all this become a hot topic for both sites and drug companies/CROs to consider and discuss. In this session speakers from pharmaceutical companies, CROs and research sites will give their views and discuss it respectively.

It's Really Hard for Clinical Sites to Say "I love you"
Yongchuan CHEN
Director, GCP Office, Southwest Hospital

The Common Road of Pursuit: Co-operation, Win-Win, and Promotion
Peilin MA
Director, Drug Research Institute of Clinical Research Center, Qilu Pharmaceutical Co., Ltd.

Panel Discussion: To Improve the Quality: Based on the Respective Responsibilities and Trust to Reach a Common View and Double-Win

Above Speakers and Invited Panelists:
Shuting LI, MD
Vice Director, GCP Center, the Cancer Hospital of Chinese Academy of Medical Sciences
Xiangjian WANG
Vice President, Chia Tai Tianqing Pharmaceutical Group Co. Ltd.
Shuqi LI
Vice President, R&G Pharma Studies Co., Ltd., Inc.

Session 0402 | Tuesday, 17 May

10:30-12:00

RISK BASED QUALITY CONTROL: HOW TO HAVE A GOOD COOPERATION BETWEEN CRA AND CRC?

SESSION CHAIR
Shuting LI, MD
Vice Director, GCP Center, the Cancer Hospital of Chinese Academy of Medical Sciences

Risk based monitoring is a new method of quality control recommended by foreign drug companies. After a period of implementation in our country, the investigators/CRCs and sponsors/CRAs have got some experience, and also met some problems. Therefore, how to carry out a risk-based monitoring and meanwhile ensure the quality control of clinical trials in this country is one of the hot topics nowadays. In this session panelists including sponsors and SMOs will have a thorough discussion from respective aspects. The focus is on how to have a good collaboration between CRAs and CRCs

Current Clinical Research Monitoring Practice, Problems and Considerations
George GUO
Global Monitoring Operation Country Head, Novartis Pharmaceuticals

Risk Based Monitoring: the New Challenge to CRCs
Mingli XU
General Manager, Beijing HMO Medicine Technology Co.,Ltd

Panel Discussion: Risk Based monitoring: Do You Know Where the Risk Is?

Above Speakers and Invited Panelists:
Shuting LI, MD
Vice Director, GCP Center, the Cancer Hospital of Chinese Academy of Medical Sciences
Jianhui SUN
Study Management Lead, Pfizer
Arron LIU
General Manager, Beijing Linkstart –SMO
Yue WANG
Clinical Research Coordinator, SMO-Clinplus Co.Ltd.

Operational Excellence – China's Own Challenges and Unique Opportunity

Session 0505 | Wednesday, 18 May

08:30-10:00

CHINA'S UNIQUE OPPORTUNITIES FOR CLINICAL OPERATIONS

SESSION CHAIR
Amy JIANG
Quality Operations, China/AP R&D, Sanofi

It's full of challenges to conduct high quality clinical trials in China. From clinical operations stake holder's point view, what are the main challenges, especially in recent years?

Session in Development

Session 0506 | Wednesday, 18 May

10:30-12:00

OPERATIONAL EXCELLENCE – CHINA OWN CHALLENGES AND UNIQUE OPPORTUNITIES

SESSION CHAIR
Christina PING
Chief Executive Officer, Chelsea Clinical Research, China

Given the large patient population and diverse diseases, China has its resources and professionals to contribute more evidence-based data to health care industry.

Session in Development

Session 0507 | Wednesday, 18 May

13:30-15:00

TO BE OPERATIONAL EXCELLENCE IN CLINICAL TRIALS

SESSION CHAIR
Amy JIANG
Quality Operations, China/AP R&D, Sanofi

With all these challenges and opportunities, what is the best way to conduct high quality clinical trial in China?

Session in Development

TUESDAY, 17 MAY | WEDNESDAY, 18 MAY

Theme 6 Quantitative Science – The Backbone of Evidence Based Data Generation

Session 0601 | Tuesday, 17 May

08:30 – 10:00

BRIDGE THE REAL WORLD TO THE CLINICAL DEVELOPME NT - PART 1: METHOD & APPLICATION

SESSION CHAIR

Luyan DAI, PhD
Head of Statistics China, Biostatistics & Data Sciences Asia, Boehringer-Ingelheim

Real world evidence is essential to identifying unmet medical need, optimizing the clinical development and demonstrating the actual clinical and economic impact of interventions. The evidence enables the pharmaceutical industry to prioritize the pipeline investment more effectively and better understand underlying causes of disease and identify opportunities for indication expansion and clinical development. It also allows demonstrating the clinical and economic value of the products to payers to deploy health solutions. Laying a solid foundation to capture the quantitative evidence is critical to bridge the clinical development to the real world for the true integration of health care and therapeutics.

Biomarker Thresholding and Application in Treating Pediatric Neuroblastoma
Xiaoshan WANG, PhD
Principal Biostatistician, Harvard School of Dental Medicine, USA

Building Reliable Quantitative Evidence from Real-World Data to Drug Development and Approval
Julie CONG, PhD
Senior Associate Director, Biostatistics/Biostatistics and Data Sciences, Boehringer Ingelheim Pharmaceutical Inc., USA

Real World Evidence - Essential Component for a Holistic Value Story
Ke WANG, PhD
Senior Health Outcome Consultant, Eli Lilly and Company China

Comparative Effectiveness Study without Head to Head Clinical Data
Eric WU, PhD
Managing Principal, Analysis Group Inc.
Simeng HAN
Director of China at Analysis Group Inc.

Session 0602 | Tuesday, 17 May

10:30-12:00

BRIDGE THE REAL WORLD TO THE CLINICAL DEVELOPMENT - PART 2: EVOLVEMENT AND FUTURE DIRECTIONS

SESSION CHAIR

Luyan DAI, PhD
Head of Statistics China, Biostatistics & Data Sciences Asia, Boehringer-Ingelheim

Real World Data for Evidence-Based Medicine, an Industry Perspective to Consolidate Value, Evidence and Outcome
Yi NING, PhD
Head of Epidemiology, GSK Shanghai
Bingming YI, PhD
Head of Statistics, Epi, and Data Management, GSK Shanghai

Real World Data in Drug Development: Perspectives on Challenges and Opportunities
Marcia Levenstein, PhD
Vice President, Statistics Global Innovative Pharma, Pfizer

Panel Discussion
Invited Panelists:
Xiaoxiang CHEN
Vice President, Regional Medical Manager, Boehringer-Ingelheim
Steve SNAPINN
Vice President, Statistics and Data Management, Amgen
Marcia LEVENSTEIN, Vice President, Statistics Global Innovative Pharma, Pfizer
Eric WU
Managing Principal, Analysis Group Inc.

Session 0605 | Wednesday, 18 May

8:30 - 10:00

CLINICAL TRIAL DATA MANAGEMENT AND COLLABORATED QUALITY CONTROL

SESSION CHAIR

Carrie ZHANG
Regional Director, Clinical Data Management, Global Data Management & Standard – Asia Pacific CT, MSD R&D (China) Co., Ltd

Clinical trial data consist of EDC dataset and external dataset. Site source data control has a great influence to EDC data quality as well. This session will invite global top company data management leaders to introduce data capture and quality control approach from below dimensions.

Quality and Integrity of Clinical Trial Data under GCP Standards
Speaker Invited

External Data for Quality Trial Data Assurance – Central Lab
Speaker Invited

Good Clinical Data Management Practice (GCDMP) and Global Industry Guidelines on Data Integrity
Jessie Chen
Head of Clinical Trial Management, Pfizer Chin / SCDM BOT

Session 0606 | Wednesday, 18 May

10:30 - 12:00

GLOBAL DATA INTEGRITY VS. CFDA DATA SELF-ASSESSMENT

SESSION CHAIR

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

Quality and integrity of clinical trial data is a basis of trial analyses and relevant outcomes. According to global data integrity standard, any untrue, noncompliant, inconsistent, incomplete and fake data and data documentation will result in

the null analyses and unreliable outcomes of clinical trials as well as a worse faith and creditworthiness on sponsors and sites that were performing and generating data and data documentation. The regulatory submission from these unintegrities of data is for sure to be rejected worldwide. This session will focus on general principle and components of data integrity and share the policy, procedures, experiences and lessons learned from regulators, data management and QA practice. At the panel discussion, the invited presenters will have an interaction with attendees to further discuss the rationale and practice of CFDA data self-assessment expectations in views of GCP data integrity standpoints.

Understanding Quality and Integrity of Clinical Trials under GCP Standards
Speaker Invited

Current Strategy/Policy and Expected Practices for Trial Data Integrity
CFDA Speaker Invited

Lessons Learned of Data Unintegrity
Speaker Invited

Session 0607 | Wednesday, 18 May

13:30-15:00

EMERGING DATA STANDARDS DRIVE AND OPTIMIZE CLINICAL STATISTICAL ACTIVITIES

SESSION CHAIR
Zibao ZHANG, PhD
Associate Director, Biostatistics and Programming, Biostatistics, PPD

Protocol and SAP are key clinical trial documents to cover statistical design, analysis strategy, and detailed implementation plan. The downstream data flow and statistical activities such as CRF/eCRT/database design, data collection, analysis and report are all driven by these two documents. This session will introduce the current status and its next steps of CDISC protocol and SAP standardization efforts, and how it could reshape the clinical data flow and analysis activities. Recent updates of CDISC Analysis Data Model (ADaM) standards will be also reported and illustrated by examples. Finally the Progress of CDISC Therapeutic Areas Standards will be shared and its impacts to clinical statistical activities are to be analyzed.

What Will Happen if Protocol and SAP Are Standardized and Built into Database?
Speaker Invited

Recent Updates of Analysis Data Standards with Examples
Victor WU
Associate Director, Biostatistics and Programming, PPD

CDISC Therapeutic Areas Standards and Its Impact on Statistical Analysis
Yazhong DENG, MBA
Head of Clinical Data Analysis and Reporting Organization (CDARO), Covance, China

Session 0608-1 | Wednesday, 18 May

15:30-17:30

STATISTICAL METHOD AND APPLICATION IN DATA REVIEW

SESSION CHAIR
Wei ZHANG
Boehringer-Ingelheim

Data quality control is an integrated task involving all the clinical trial/study team members and there are lots of areas clinical data managers closely collaborate with statistician. We believe having certain level of statistical knowledge and mindset will help the trial/study team manage the data and assess data quality smarter. In this CDM, Programmer and Statistician joint session, our speakers will talk about the consideration, methodologies, challenges and implications of handling data issues especially around “Fraud’ and “Missing data” in clinical trial. Collaboration between CDMs and Statisticians will also be shared to help you better understand how data quality is monitored and assessed during the trial with the facilitation of data visualization and display.

Fraudulent Data Detection
Luyan DAI, PhD
Head of Statistics China, Biostatistics & Data Sciences Asia, Boehringer-Ingelheim
Jingwei GAO
Regional Head, Regional Statistical Programming – Pan Asia META, Boehringer-Ingelheim (China) Investment Co., Ltd.

Missing Data Issues in Clinical Trials
Jielai XIA, PhD
Professor, Department of Medical Statistics, 4th Military Medical University

Data Quality Monitoring and Assessment
Speaker Invited

Session 0608-2 | Wednesday, 18 May

15:30-17:30

PHARMACEUTICAL BIOSTATISTICS GROUP OPERATING MODELS IN CHINA - WHAT THE MULTINATIONAL PHARMA COMPANIES HAVE LEARNED IN THE LAST SEVEN YEARS

SESSION CHAIR

Ouhong WANG, PhD
Director, Biostatistics, Amgen

The inaugural DIA China conference in 2009 called for the establishment of a strong local biostatistics group for multinational pharma companies operating in China. At the same time, China has emerged to become an important health care market with an increasing need for more and better medicines for the Chinese patients, and hence the need for stronger presence of drug development capabilities in China. Both internal and external factors have been strong at work since then, and the industry answered that call. Both the companies and the China drug development macro-environment have benefited from the scientific rigor brought on by the local statistical expertise. The results speak for themselves, but the way to achieve the results vary from company to company. Now, seven years later, it’s about time to examine these different operating models and learn what has worked well and what can be improved, in a “show-

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and-tell" session. Different operating models and organizational philosophies will be presented by various companies, followed by a panel discussion on the unique characteristics of these models, and possible future organizational trends. We hope to develop a better understanding on how to best operate in this environment, considering that we are part of the global biostatistics organization. The outcome will be a good reference on organizational design specifically for statisticians.

The Lilly Model
Yanping WANG
Head of Biostatistics, Lilly China

The Novartis Model
Dejun TANG, PhD
Head of Biostatistics, Novartis China

The Roche Model
Nicole LI
Head of Biostatistics, Roche China

The Boehringer-Ingelheim Model
Luyan DAI, PhD
Head of Statistics China, Biostatistics & Data Sciences Asia, Boehringer-Ingelheim

The Astra-Zeneca Model
Yue WANG
Head of Biostatistics, Astra-Zeneca China

Panel Discussion
Above Speakers and Invited Panelists:
Tony GUO, PhD
Director, Biostatistics, MSD R&D(China) Co., Ltd.
Roger QU, PhD
Head of Clinical Statistics, Pfizer R&D Center, China
Qi JIANG, PhD
Amgen

CMC & Generic Drug

Session 0701 | Tuesday, 17 May, 2016

08:30 – 10:00

ASSOCIATION OF ACCESSORIES AND PACKAGING MATERIALS REVIEW
SESSION CO-CHAIRS
Chi-Wan CHEN, PhD
FDA Alumni Association International Network Planning Committee Member
Former Deputy Director, Office of New Drug Quality Assessment, US FDA/CDER
Executive Director, Global CMC, Pfizer, USA

Zero WU
Eli Lily

Session in Development

Session 0702 | Tuesday, 17 May

10:30-12:00

ROLE OF PUBLIC STANDARD IN THE DRUG REGISTRATION
SESSION CHAIR
Wendy YU
Merck

Session in Development

Session 0703 Tuesday, 17 May

13:30 - 15:00

LIFE-CYCLE MANAGEMENT OF BIOLOGICS
SESSION CO-CHAIRS
David LIN, PhD
Member of US FDA Alumni Association
Senior Consultant, Biologics Consulting Group, USA

Duu-Gong WU, PhD
Member of US FDA Alumni Association
Director, Global Regulatory Consulting/Senior Consultant, Pharmaceutical Product Development, USA

Session in Development

Session 0705 | Wednesday, 18 May

08:30 – 10:00

INTERNATIONAL REGISTRATION OF GENERIC DRUG
SESSION CHAIR
Mingping ZHANG
Principal Consultant, PAREXEL Consulting

US ANDA Consideration
Speaker Invited

EU Generic Registration Consideration
Speaker Invited

BRICK Country Generic drug Opportunity & Challenge
Speaker Invited

Session 0706 | Wednesday, 18 May

10:30-12:00

BIOEQUIVALENCE STUDY OF GENERIC DRUG
SESSION CHAIR
Jing YANG
Professor, China Pharmaceutical University

Bioequivalence Requirement in China
Speaker Invited

Using BE Strategies in Generic Drug
Speaker Invited

The Key Considerations for Bioequivalence Study
Jing YANG
Professor, China Pharmaceutical University

TUESDAY, 17 MAY | WEDNESDAY, 18 MAY

Session 0707 | Wednesday, 18 May

13:30-15:00

BIOWAIVER: IN-VITRO DISSOLUTION

SESSION CHAIR
Fred LI, PhD
Vice President, Pharma R&D, Hua Medicine (Shanghai) Ltd.

Session in Development

Session 0708 | Wednesday, 18 May

15:30-17:30

QUALITY CONSISTENCY OF GENERIC DRUG

SESSION CHAIR
Daniel SONG, PhD
Director, CMC Regulatory Affairs, China R&D and Scientific Affairs, Janssen Pharmaceutical Companies, Johnson & Johnson

Session in Development

Biologics & Biosimilar

Session 0801 | Tuesday, 17 May

08:30 – 10:00

RECENT TRENDS IN THE REGULATION OF BIOPHARMACEUTICAL PRODUCTS

SESSION CHAIR
Janet LV
Head of Regulatory, Asia Pacific, Roche

Views in the Recent Trends in the Regulation of Biopharmaceutical Products - from CDE Perspective
CFDA Speaker Invited

Views in the Recent Trends in the Regulation of Biopharmaceutical Products - from Health Canada Perspective
Health Canada Speaker Invited

Views in the Recent Trends in the Regulation of Biopharmaceutical Products - from FDA Perspective
FDA Speaker Invited

Views in the Recent Trends in the Regulation of Biopharmaceutical Products - from WHO Perspective
WHO Speaker Invited

Session 0802 | Tuesday, 17 May

10:30-12:00

DEVELOPMENT OF BIOSIMILARS: TECHNICAL ASPECTS

SESSION CHAIR
Session Chair Invited

Consideration in the Analytical Similarity Assessment of Biosimilar
Speaker Invited

Regulatory Expectation on the Analytical Comparison Study of Biosimilar
CFDA Speaker Invited

Case Study on Biosimilar CMC Development
Speaker Invited

Session 0805 | Wednesday, 18 May

8:30-10:00

CLINICAL TRIAL DESIGN OF BIOSIMILAR - PART 1

SESSION CHAIR
Lan QIN
Group Medical Manager, Roche

Regulatory Expectation on the Clinical Design of Biosimilar
Speaker Invited

Regulatory Expectation on the Clinical Trial Design of Biosimilar
Speaker Invited

Endpoint Selection
Speaker Invited

Session 0806 | Wednesday, 18 May

10:30-12:00

CLINICAL TRIAL DESIGN OF BIOSIMILAR - PART 2

SESSION CHAIR
Lan QIN
Group Medical Manager, Roche

Statistical Consideration of the Clinical Trial Design of Biosimilar
FDA Speaker Invited

Key Considerations of Clinical Development of Biosimilars
Hoss DOWLAT, PhD
Vice President, Regulatory Affairs EU-USA, PharmaBio Consulting (Life Sciences), Germany

Session 0807 | Wednesday, 18 May

13:30-15:00

NAMING AND PHARMACOVIGILANCE FOR BIOLOGICS

SESSION CHAIR
Session Chair Invited

Current Situation on Post Approval AE Monitoring for Biologicals in China
Speaker Invited

Role of INN in Global PV System and Recent Progress on BQ Program
Speaker Invited

CFDA's Consideration on Biological Naming
Speaker Invited

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Session 0808 | Wednesday, 18 May

15:30-17:30

CUTTING EDGE TECHNOLOGIES IN BIOLOGICS DEVELOPMENT

SESSION CHAIR

Joe ZHANG, MD, PhD
Executive Deputy Head, Center of Medicinal and Translational Sciences, Shanghai CP Guojian Pharmaceuticals CO. Ltd.

Session in Development

Theme 9 Quality System

Session 0901 | Tuesday, 17 May

08:30 – 10:00

HOW TO IMPROVE THE ETHICS REVIEW QUALITY

SESSION CHAIR

Xiuqin WANG, PhD
Deputy Director, Department of Science and Technology, Jiangsu Province Hospital, First Affiliated Hospital with Nanjing Medical University

Topic TBD
CFDA Speaker Invited

How to Build a High Quality IRB and Human Research Protection Program
Jun ZHAO
Professor, Vice President, Jiangsu Province Hospital

What Does Quality IRB Mean to Sponsor and what Does the Sponsor Expect from IRB
Heidi LIU, MD
Pfizer

Session 0902 | Tuesday, 17 May

10:30-12:00

INSPECTIONS ON QUALITY AND COMPLIANCE – WHAT ARE INSPECTORS' EXPECTATIONS

SESSION CHAIR

Jun LI
Inspection Manager, APAC Head, Johnson & Johnson

In this 90-minute session, 2-3 inspectors, to be invited (primarily) from the APAC region (e.g., from CFDA, HSA, TWFDA, MFDS, or USFDA rep. in China), to talk about their national GxP inspection programs and share their inspection experiences (e.g., inspection methodologies, and common findings, etc.)
A 30-minute panel discussion is to be organized where the invited speakers will answer any questions which interest the audience, as well as commenting on the current hot topics. Discussions could also be about inspectors' expectations/perceptions in the next few years regarding regulations and inspections.

Taiwan FDA GCP Inspection Program: Current and Future
Mei-Chen HUANG
Specialist, Division of Medicinal Products
Food and Drug Administration
Ministry of Health and Welfare, Taiwan

US FDA Policy and Strategy Towards China and APAC
US FDA Speaker Invited

China CFDA Inspection Initiatives and Efforts
CFDA Speaker Invited

Session 0905 | Wednesday, 18 May

08:30-10:00

TRANSFORM QUALITY SCIENCE FROM REACTIVE TO PROACTIVE

SESSION CHAIR

Helen LI, MD, MBA
Director, Emerging Market QA, Asia Lead, Pfizer Medical - Quality Assurance, Pfizer (China) Research and Development Co., Ltd.

How do we transform quality science from reactively respond to audit findings to proactively building up a robust and effective quality management system (QMS)?

At this session, we will illustrate industry effort, individually and collectively, in ensuring quality via effective Quality Management System. TransCelerate will share with us how pharmaceutical companies collaboratively work together on QMS, and its missions and some initiatives. We also will share one sponsor's experience of measuring effectiveness via Clinical QMS metrics. Last but not least, we will explain new requirements in the ICH E6 addendum for risk-based approaches to managing clinical trials, the expected implications with focus on sponsor vendor oversight and share necessary steps and tools that should be in place for adequate vendor oversight.

TransCelerate QMS Mission and Initiatives
Speaker Invited

Pfizer Clinical QMS: Metrics and Effectiveness
Carol BYE
Vice President, Medical Quality Assurance, Pfizer

ICH E6 New Addendum and its Requirements or Vendor Oversight
Peter SCHIEMANN, PhD
Managing Partner, Widler & Schiemann Ltd., Switzerland

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Theme 10 Pharmacovigilance

Session 1001 | Tuesday, 17 May

08:30 – 10:00

INNOVATION AND INITIATIVES OF PHARMACOVIGILANCE OPERATION IN CHINA

SESSION CO-CHAIRS

Yuan YAO
Head of Drug Safety, Merck China

Echo LI
Pharmacovigilance Associate Director, Astellas China

Product safety makes headlines every day and one of the hot spots of public concern. Government by countries (including China) continuously strengthen regulatory requirement on pharmacovigilance. With the fast development of information technology and arrival of Big Data Era in China we would like to explore the opportunities of Pharmacovigilance in this context. With insights from 3 Chinese Experts from Healthy Authority, Academy and Industry a 3D perspective will initiate our thinking and action.

Proactive Monitoring in Pharmacovigilance and Practice in China
CFDA Speaker Invited

Big Data on Pharmacovigilance
Daniel YANG, PhD
Chief Executive Officer, G2 Biopharma Services

Comparison and Reference of Pharmacovigilance Legislation
Hualin SONG, PhD
Professor, Nankai University School of Law

Session 1002 | Tuesday, 17 May

10:30-12:00

PHARMACOVIGILANCE IN A NEW ERA – HOT TOPICS

SESSION CO-CHAIRS

Miranda WANG
China PV Head, BMS
Vera LIANG
Global Safety Risk Lead and Director, Safety Surveillance and Risk Management, Pfizer China R&D Center

In recent years, along with the rapid development of information technology, the globalization of information exchange and the use of real world big data have had profound impacts on PV activities. How to establish drug safety profile earlier and better by taking advantage of these changes is a challenge facing the people engaged in PV activities in the new era. We invite some senior professionals in various fields to share with us their insights into some topics of widespread concern such as how to identify and manage drug risks in the other country, role of real world data in establishing safety profile of a newly marketed drug and how to control post-marketing drug safety report quality, in a bid to provide some inspirations to the practical work.

Risk Identification and Management- Experience from Japan
Edward Stewart GEARY, MD
Senior Vice President, Chief Medical Officer, Eisai, Japan

Role of Real World Data in Establishing Safety Profile of a Newly Marketed Drug Product
Siyan ZHAN, PhD
Professor, Deputy Director, Centre for EBM and Clinical Research
Deputy Director, Department of Epidemiology and Biostatistics
Director, Center of Postmarketing Safety Evaluation, Peking University

Safety Data Quality - a Key to Post Authorization Safety Surveillance
Howe LI, MD
Chief Medical Officer, Tigermed Consulting CO., LTD

Session 1003 | Tuesday, 17 May

13:30-15:00

DATA-DRIVEN DECISION MAKING

SESSION CO-CHAIRS

Lawrance Mason SHIH
Site Head, Safety Risk Management, Asia Pacific, Roche Product Development

Xiujing KOU
Senior Safety Science Leader, Safety Risk Management, Roche

Safety data from clinical trials, spontaneous reports, literature, and other sources has a tendency to increase over time. Making the most efficient use of the data available using integrated safety databases, data visualization tools, and focusing on the right data is critical for enabling timely decisions that are informed by the best analysis possible. This session will focus on various aspects of safety data as it pertains to making decisions.

Data Visualization for Safety Science
Josephie FONG

Integrated Safety Database, Do you Need One?
Lawrance Mason SHIH
Site Head, Safety Risk Management, Asia Pacific, Roche Product Development

Safety Endpoints That Drive Decision Making
Speaker Invited

Session 1004 | Tuesday, 17 May

15:30-17:30

EFFECTIVE AND TIMELY RISK COMMUNICATION

SESSION CHAIR

Gao GAO
Associate Director, Safety Surveillance and Risk Management, Pfizer China Research and Development

Risk communication is an integral part of risk management for medicinal products and has received increased attention over the past few years as systems have become more complex and information more rapid. It is challenging but necessary to convey balanced and accurate information about benefit and risk to all stakeholders. Risk communication tools need to be audience oriented. Effective and timely communication not only facilitates

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decision making by regulatory agencies and pharmaceutical companies but also helps ensure healthcare professionals and patients make informed therapeutic choices. Three drug safety experts will introduce and discuss the role of risk communication, communication tools, regulatory expectations, global initiatives and scientific updates.

Risk Communication – Landscape, Updates and Challenges
Brian EDWARDS, MD
Principal Consultant, Pharmacovigilance & Drug Safety, NDA Regulatory Science Ltd.

Effective Benefit Risk Communication in the US – Learning from the Past Decade from the Pharmacoepidemiology Perspective
Jasmanda WU, PhD, MPH
Senior Director, Global Pharmacovigilance & Epidemiology, Sanofi

Emergency Management and Risk Communication for Medicinal Products
Yue YANG, PhD
Professor, Shenyang Pharmaceutical University

Risk Communication in China
Speaker Invited

Necessary Elements in Successful Drug Development Activities

Session 1105 | Wednesday, 18 May

08:30 – 10:00

INHERITING AND INNOVATION: HOW MEDICAL WRITERS WORKING IN GLOBAL PHARMACEUTICAL COMPANIES SUPPORT REGULATORY REQUIREMENTS FROM DIFFERENT AUTHORITIES
SESSION CHAIR
Nan WANG, PhD
Senior Scientific Medical Writer, China Site lead, Global Medical Writing, Bayer

Medical writing was originally established in the western countries. In the past 10 years, the development of medical writing in China is fast and local expertise is establishing. With the dynamic environment, how to provide an efficient and flexible medical writing service to support the dossier preparation particular for China without compromising the consistency with global message is a hot topic. In addition, MW's role is evolving with increased legislation on transparency in many countries. Their job does not end when submission documents are prepared.

This session will discuss clinical document development for China NDA submission with a focus on the content strategy and process plan in order to support the efficient and smooth submission. In addition, the new EU regulation on disclosure of submission documents will be shared and its impact on medical writer's daily work will be discussed.

How to Effectively Develop Clinical Documents in the EU/US and China NDA Dossier
Julia COOPER, PhD
Vice President, Head of Global Medical Writing Services, PAREXEL International

How to Make a Good Plan for Clinical Documents Development in China NDA Dossier
Speaker Invited

Overview of Disclosure Requirements from Major Authorities with a Special Focus on the New EU Regulation
Florence BERGER, PhD
Global Head, Clinical Documentation, Sanofi R&D
Julia COOPER,

Session 1106 | Wednesday, 18 May

10:30-12:00

HOW DOES MEDICAL WRITING SUPPORT SUCCESSFUL DRUG DEVELOPMENT- LOCAL COMPANY PERSPECTIVE
SESSION CHAIR
Rui YANG, PhD
PAREXEL

Session in Development

Session 1107 | Wednesday, 18 May

13:30-15:00

ENSURE THE HIGH QUALITY DATA AS CPM
SESSION CHAIR
Rebecca DAI
Bayer

The Value Added by CPM in the Clinical Trial Quality Control
Speaker Invited

How to Preventing Potential Problems: Identify and Prioritize Potential Problems, and Implement Root Cause Analysis and Corrective and Preventive Action Plans
Speaker Invited

Design a GCP and SOP Compliant Project Operating Guideline (POG) for High Performance Clinical Trials
Speaker Invited

Session 1108 | Wednesday, 18 May

15:30-17:30

PROJECT RISK MANAGEMENT: DEALING WITH THE CERTAINTY OF THE UNCERTAINTY
SESSION CHAIR
Yuan LI, MD
Director, Project Management, MSD China R&D

The Basic Concepts of Project Risk Management
Speaker Invited

Real Case Sharing: to Find the Win-Win Solution by Re-Shaping the Regulatory Guideline
Speaker Invited

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Real Case Sharing: the Development Story of Iressa
Speaker Invited

Theme 12 Medical Affairs

Session 1201 | Tuesday, 17 May

08:30-10:00

MEDICAL AFFAIRS TRANSFORMATION – CMO PANEL DISCUSSION
SESSION CHAIR
Chengming GU, MBA
Medical Lead, China Medical, Pfizer Investment Co., Ltd

Session in Development

Session 1202 | Tuesday, 17 May

10:30-12:00

POST-MARKETING DATA GENERATION IN THE ERA OF PRECISION MEDICINE
SESSION CHAIR
Li WANG
Eli Lily

Session in Development

Session 1205 | Wednesday, 18 May

08:30-10:00

THE EVOLUTION OF MSLS FUNCTION AND THE FUTURE
SESSION CHAIR
Session Chair Invited

Session in Development

Session 1206 | Wednesday, 18 May

10:30-12:00

THE PARTNERSHIP OF MEDICAL AND COMMERCIAL
SESS ION CHAIR
Session Chair Invited

Session in Development

Session 1207 | Wednesday, 18 May

13:30-15:00

MEDICAL COMMUNICATIONS
SESSION CHAIR
Huafei LI
Director, Medical Communication & Project Management, Medical Affairs, Roche

Session in Development

Session 1208 | Wednesday, 18 May

15:30-17:30

HEOR AND MARKET ACCESS IN CHINA
SESSION CHAIR
Frank FAN, MD, MBA
Head of Medical Affairs Service, Quintiles Greater China

Session in Development

Theme 13 Rare Diseases

Session 1301 | Tuesday, 17 May

08:30 – 10:00

RARE DISEASES - PART 1
SESSION CHAIR
Jack XU, MD
Senior Vice President, Shanghai Clinical Research Center

Definition and Regulatory Policy of Rare Diseases
Luwen SHI
Professor, Peking University School of Pharmaceutical Sciences

Reproductive Intervention of Rare Diseases
Guangxiu LU
President, Reproductive and Genetic Hospital of CITIC Xiangya

Rare Disease Genetic Counseling
Shangzhi HUANG , MD
Professor, Peking Union Medical College, Department of Medical Cenetics

Who Collaborating Center for Community Control of Hereditary Diseases

Session 1302 | Tuesday, 17 May

10:30-12:00

RARE DISEASES - PART 2
SESSION CHAIR
Jack XU, MD
Senior Vice President, Shanghai Clinical Research Center

Role of Rare Disease Patient Organization
Kevin HUANG
President, Chinese Organization for Rare Disorders (CORD)

Rare Diseases and Orphan Drug
Weiyi ZHENG
Chief Executive Officer and Chief Operation Officer, Nora Tech

Rare Disease Clinical Phenotype and Genetic Testing
Weihong GU
Head, Movement Disorders and Neural Genetic Disease Research Center, China-Japan Friendship Hospital

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Theme 14 CRO/SMO

Session 1405 | Wednesday, 18 May

08:30-10:00

READY FOR THE BIG WORLD? – HOW CAN CHINESE PHARMACEUTICAL COMPANIES LEVERAGE CRO TO GROW BIGGER AND FASTER?

SESSION CHAIR
Jason ZHU, MD, MBA
Vice President, Deputy General Manager & Head, Customer Solutions, Quintiles Greater China

China based Drug manufacturers often team up of a highly specialized CMC talents and Molecular Designers at a top global standard, but usually have hard time developing a solid Target Product Profile and Clinical Development Strategy afterward. This will disable them to further layout a practical and commercially attractive global clinical delivery pathway. A Tailored Global clinical development approach will help drug developers well utilize their existing resources (Competitive landscape China market knowledge, Chinese patient Stand of Care knowledge, etc) to further bridge into the global component and help them realize their asset value to the targeted stage earlier.

Build a Partnership from Scratch- the Art of Selecting a CRO
Hualong SUN, MD, PhD
General Manager, Meta Clinical Technology

Include a CRO in Your Business Strategy – How to Manage the Relationship with the CRO in Your Daily Work
Yan WU, MD, PhD
Head, Clinical Operation and Drug Safety, Hutchison MediPharma

Begin with the End in Mind – DOs and DONTs of Planning and Conducting Global Trials
Wanhong XU, PhD
Vice President, ACEA Bioscience Inc.

Session 1406 | Wednesday, 18 May

10:30-12:00

TIME FOR AN UPGRADE – EVOLVING COOPERATION MODEL BETWEEN CROS AND PHARMACEUTICAL COMPANIES

SESSION CHAIR
Cory WILLIAMS
Vice President, Global Clinical Trial Execution
Head of Development Operations China, Pfizer

The Win-Win Dilemma - Challenges and Opportunity of Outsourcing in China
James GARNER
Head, Unit Development Office, AP R&D, Sanofi

Paradigm Shift - Global Trend in Partnership Model, Study Design etc., and Why Pharma Companies Want It
Anita SHEN
Director, Head of China Integrated Data Services, Janssen

In the Fast Lane - Challenges and Opportunities for China Domestic CROs
Hadrian FU, PhD
General Manager, Shanghai Cares Bio-tech Co. Ltd

Session 1407 | Wednesday, 18 May

13:30-15:00

A JOURNEY WITHOUT DETOUR – DATA QUALITY MATTERS

SESSION CHAIR
Zhi-Qiang NING, MD, PhD
Vice President R&D, Shenzhen Chipscreen Biosciences Ltd

Importance of Data Integrity – Observation and Reflection on the Recent Events
Juyong WANG, MD, PhD
Director, GCP Administration Office, Longhua Hospital

Good Documentation Practice on TMF in CROs and Sponsors
Winnie XU
Senior Director, Clinical Operations, Quintiles, China

Panel Discussion: In the Same Boat - The Roles and Responsibilities of Different Parties to Keep Data Integrity

Above Speakers and Invited Panelists:
Zhi-Qiang NING, MD, PhD
Vice President R&D, Shenzhen Chipscreen Biosciences Ltd
Hualong SUN, MD, MD, PhD
General Manager, Meta Clinical Technology

Session 1408 | Wednesday, 18 May

15:30-17:30

SMO/CRC – A BRIDGE OVER THE TROUBLED WATER

SESSION CHAIR
Min JIANG
Director, GCP Administration Office, Beijing Oncology Hospital

CRC's Strategy to Bridge the Expectation Gap between Sponsor and Investigator
Veronica XIA
General Manager, Kuntuo

No Weakest Link - Quality Control and Training for CRC
Jian YANG
Head of Site Management Organization, Beijing Clinical Service Center

Level up - Project Management of SMO
Reako REN
Executive Director and Head of SMO Services, WuXi AppTec (Shanghai) Co., Ltd.

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Theme 15 Information Technology

Session 1506 | Wednesday, 18 May

10:30-12:00

INFORMATION TECHNOLOGY IN CLINICAL STUDIES – PART 1: REGULATORY REQUIREMENT

SESSION CHAIR

Charles YAN, PhD
Senior Director, Data Management and Biometrics, Shanghai Hengrui Medicine Co, Ltd.

Information Technology in Clinical Research: Regulatory Requirements
Speaker Invited

21 CFR Part 11 in Clinical Research Practice
Speaker Invited

Computerization Validation in Clinical Research
Speaker Invited

Session 1507 | Wednesday, 18 May

13:30-15:00

INFORMATION TECHNOLOGY IN CLINICAL STUDIES – PART 2

SESSION CHAIR

Charles YAN, PhD
Senior Director, Data Management and Biometrics, Shanghai Hengrui Medicine Co, Ltd.

Enhance Clinical Study's Benefit and Quality by Using Information Technology
Speaker Invited

Pharmacovigilance in Clinical Studies
Speaker Invited

Clinical Project Management
Speaker Invited

Clinical Documentation Management
Speaker Invited

Session 1508 | Wednesday, 18 May

15:30-17:30

INFORMATION TECHNOLOGY IN CLINICAL STUDIES – PART 3

SESSION CHAIR

Yazhong DENG, MBA
Head of Clinical Data Analysis and Reporting Organization (CDARO), Covance, China

Session in Development

Theme 16 Medical Devices

Session 1601 | Tuesday, 17 May

08:30 – 10:00

CHALLENGES AND OPPORTUNITIES IN THE NEW REGULATORY AND INNOVATION ENVIRONMENT: POLICY AND REGULATION - PART 1

SESSION CHAIR

Jane LIN
Vice President, Strategic Medical Affairs, Johnson and Johnson Medical China

China medical device regulations have been changed dramatically in past two years. How to interpretation and implementation the regulations to accommodate the innovation have been challenging. This session will invite experienced speakers to share their perspective and best practices on the hot areas.

Global Regulation Update – FDA & EMEA
Speaker Invited

China Regulations Update of Medical Devices
CFDA Speaker Invited

CER Related Topic
Speaker Invited

Session 1602 | Tuesday, 17 May

10:30-12:00

CHALLENGES AND OPPORTUNITIES IN THE NEW REGULATORY AND INNOVATION ENVIRONMENT: POLICY AND REGULATION - PART 2

SESSION CHAIR

Annie YIN
Senior Director, Regulatory Affairs, Metronic Greater China

New Product Registration Strategy in China
Peter QU
Senior Manager, Medtronic

Special Review Process – Innovation Green Channel
Speaker Invited

Preparation and Acceptance of Oversea GMP Inspection
Mingdong ZHANG
Chief Medical Officer, Boston Scientific

Session 1603 | Tuesday, 17 May

13:30-15:00

OPPORTUNITIES IN THE NEW REGULATORY AND INNOVATION ENVIRONMENT: INDUSTRY OPPORTUNITY

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SESSION CHAIR
Jane LIN
Vice President, Strategic Medical Affairs, Johnson and Johnson Medical China

Medical Device Market Investment Opportunity
Speaker Invited

Opportunities of Post Marketing Studies in China
Amber FANG
Senior Clinical Manager, Edwards

Early Stage Drug Development

Session 1705 Wednesday, 18 May

08:30 -10:00

NON-CLINICAL SAFETY ASSESSMENT IN THE NEW DRUG DEVELOPMENT
SESSION CHAIR
James YAN, MD, PhD, DABT
Executive Vice President, Head of Early Development and Drug Safety, Zai Lab

Session in Development

Session 1706 Wednesday, 18 May

10:30 -12:00

ADME/PK AND DRUG DEVELOPMENT
SESSION CHAIR
Sylvia ZHAO, PhD
Director of Clinical Pharmacology, Translational Clinical Oncology Shanghai, China Novartis Institutes for BioMedical Research

Session in Development

Session 1707 Wednesday, 18 May

13:30 -15:00

BIOMARKERS AND TRANSLATION MEDICINE
SESSION CHAIR
Bin PENG, MD, PhD
Global Head, Oncology Translational Medicine China, China Novartis Institutes for BioMedical Research Co., Ltd.

Session in Development

Session 1707 Wednesday, 18 May

15:30 -17:30

EARLY CLINICAL DRUG DEVELOPMENT
SESSION CHAIR
Session Chair Invited

Session in Development