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DIA

Aspiration to Drive Healthcare Innovation

2019 DIA CHINA Annual Meeting

DIA中国年会

5月20-23日 | 北京国际会议中心

May 20-23, 2019 | Beijing International Convention Center

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Director, Shanghai Lung Cancer Center
Shanghai Jiaotong University, China

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Harbour Biomed (HBM), China

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Innovative Breakthrough in Therapy

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Xiaoxiang CHEN, MD
Chief Development Officer, Harbour Biomed

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Head of China Development Unit, AstraZeneca

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Vice President, Takeda

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Everest Medicines

Reako REN
Head of SMO Services, WuXi Apptec

Data and Data Standard

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Beijing Clinical Service Center

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

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Principal statistician, Biostatistics & Data Science,
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Chief Executive Officer, BJ Bioscience Inc.

Xiangyang ZHU, PhD
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Generic Drug, CMC & GMP

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Shenyang Pharmaceutical University, China

Medical Affairs & Medical Writing

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Xiaoling WANG
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PV and Risk Management

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Drug Safety Unit Regional Head (DRH), APAC
Pfizer

Conny MO
Partner and Senior Medical Safety Advisor
Beijing RHGT Co., Ltd.

Howe LI, MD, PhD
Founder and CEO, DeltaMed

Patient Engagement

Dayao ZHAO, PhD
Former Vice President and Lead
China Drug Development
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Artificial Intelligence in Healthcare

Tong GUO, PhD
Vice President and Head of Sales, Greater China
IQVIA

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Peking Union Medical College Hospital

Zaiqi WANG, PhD
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Jesse LIU
PV QA Manager, AstraZeneca

Lanna CHEN
Clinical Project Director, Zai Laboratory

Joice HU
Associate Director, Medical,
dMed Biopharmaceutical Co., Ltd.

PROGRAM **TOPICS** | The ICH day and 14 themes designed to advance health care outcomes through innovation and regulatory reforms

ICH Day

Pre-Conference


Opening Plenary


China Regulatory
Special Session


Regulatory Science


Innovative Breakthrough in Therapy


Clinical Trials, Operations and
Quality Compliance


Data and Data Standards


Quantitative Science


Biologics Development


Generic Drug, CMC & GMP


Medical Affairs & Medical Writing


Pharmacovigilance and
Risk Management

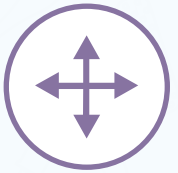

Patient Engagement


Artificial Intelligence in Healthcare


Preclinical Development and
Early Phase Clinical Research


Professional Development


Hot Topics and Late Breakers


White Paper Showcase


DIA China Community Exchange &
Engage Session


DIA China
Innovation Theater Activities

Monday, May 20th | 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 Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has successfully attracted regulators around the world to join and ensure greater coordination among the participating regulatory agencies. The purpose of ICH is to promote public health through international harmonisation of technical requirements that contributes to the timely introduction of new medicines and continued availability of the approved medicines to patients, to the prevention of unnecessary duplication of clinical trials in humans, to the development, registration and manufacturing of safe, effective, and high quality medicines in an efficient and cost-effective manner, and to the minimization of the use of animal testing without compromising safety and effectiveness.

In June 2017, CFDA joined ICH as the 8th regulatory member globally during ICH Montréal meeting, and became the member of ICH Management Committee in June 2018. This is a key milestone that reflects CFDA's reform has eventually brought China's regulatory authority, Pharma companies and drug development institutions into a new era – gradually converge and implement the international highest technical standards and guidelines.

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

Monday, May 20th | ICH DAY

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

M1: MedDRA and MedDRA SMQ

PROGRAM CO-CHAIRS

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

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

PROGRAM COMMITTEE

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

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

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

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

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

Agenda

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

Monday, May 20th | ICH DAY

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

M4 & M8: Introduction of CTD Application Technology Highlights

PROGRAM CHAIR

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

PROGRAM COMMITTEE

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

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

Angela LI
Engineer, Regulatory Affairs, Beijing Clinical Service Center

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

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

Learning Objectives

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

Monday, May 20th | ICH DAY

ICH Recognised Training Programme

Targeted Audience

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

Agenda

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

Monday, May 20th | ICH DAY

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

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

PROGRAM CO-CHAIRS

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

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

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

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

Monday, May 20th | ICH DAY

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

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

PROGRAM CO-CHAIRS

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

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

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

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

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

Monday, May 20th | ICH DAY

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

E2: Pharmacovigilance

PROGRAM CO-CHAIRS

Chenglin LI
Director of Drug Safety and Pharmacovigilance, BeiGene

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

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

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

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 1 | 8:30 - 12:00 | 305ABCD, 3RD FLOOR

Real World Evidence Supporting Drug Development and Regulatory Decision Making

PROGRAM CO-CHAIRS

Ling SU, PhD
Professor, Shenyang Pharmaceutical University
Venture Partner, Lilly Asia Ventures

Janet LYU
Head of Regulatory Affairs, Asia Pacific, Roche Product Development

8:30 - 8:45	RWE for Regulatory Decision Making	**Ling SU, PhD** Professor, Shenyang Pharmaceutical University Venture Partner, Lilly Asia Ventures
8:45 - 9:15	Overview of Methodologies	**Xin SUN, PhD** Professor, Dean, China Cochrance Center, West China School of Medicine/West China Hospital, Sichuan University
9:15 - 9:35	EMA Perspective	**Agnes SAINT-RAYMOND, MD** Head of International Affairs Head of Portfolio Board European Medicines Agency
9:35 - 10:00	US FDA Guidance and Perspective – Device	**LCDR Scott C. GONZALEZ** Acting International Program and Policy Analyst - Medical Devices, FDA China Office
10:00 - 10:30	Tea Break	
10:30 - 11:00	US FDA Example(s) – Drug	**Kun HE, PhD** Chief Statistician, R&G PharmaStudies, Co. Ltd.
11:00 - 11:40	Industry Examples	**Yue WANG, PhD** Vice President and Head, Biometrics, R&D China, Global R&D Oncology, Astrazeneca **Chao ZHU, PhD** Director and Head of Statistics and Statistical Computation, Eli Lilly and Company (China)
11:40 - 12:00	Q&A and Panel Discussion	

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 2 | 8:30 - 12:00 | HALL 2-B, 2ND FLOOR

cQMS: from Concept to Practice

PROGRAM CHAIR

Liping ZHOU
Director, Quality Assurance, Asia Pacific, MSD R&D (China) Co., Ltd.

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Heidi LIU
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BioResearch Quality & Compliance, Johnson & Johnson

Cathy LIU
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Zhenying DAI
Senior Compliance Manager, Quality Medicine, Boehringer-Ingelheim

Sharon REINHARD
Executive Director, MRL QA QMS, MSD

Hannah CHEN
Consultant, Integral Consulting

Amy JIANG
Head of Operations, Sanofi China R&D Center

Xiaogang XU
Associated Director, Quality Assurance, APAC, Zigzag

This workshop aims to address the growing business needs relating to development/enhancement of clinical Quality Management System (cQMS) within R&D based pharmaceutical companies.
The speakers will lead you through:

- key elements and considering points to develop a fit-for-purpose cQMS
- cQMS Pragmatic approach - Do it right from the start
- assessment of cQMS from auditors' perspective

This workshop is designed to be an interactive session, active participation and contribution from audience is expected.

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 3 | 8:30 - 12:00 | 307, 3RD FLOOR | English Only

Auditing eSource

PROGRAM CHAIR

Ellyne SETIAWAN
Head of Quality Medicine, ROPU-TCM, Boehringer Ingelheim

Matt JONES
Managing Director, Digital Quality Associates Ltd. UK

This workshop will focus on 2 examples of eSource system, workshop session to look at risk assessing 2-3 eSource systems, and working on an audit plan and agenda to perform the audits. This incorporates both risk assessment techniques and audit strategy/ planning.

Agenda

8:30 - 9:00	**Introduction and Overview of Topic**
9:00 - 10:00	**Introduction to 2 sScenarios** • eCOA • IRT
10:00 - 12:00	Aim of Workshop: Produce a Risk-based Audit Plan • Review key risks for each topic • Use risk management techniques to score risks • Prioritize risks and key areas of review • Complete a risk-based audit plan based on conclusions Identify Audit Targets for Each Topic Feedback to Rest of Group from Each Cohort

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 4 | 8:30 - 12:15 | 305E, 3RD FLOOR

Standardization and Practice of Central Medical Imaging Assessment

PROGRAM CHAIR

Wen HE, MD, PhD
Chief Physician, Director of Department of Radiology, Beijing Friendship Hospital
Professor of Clinical Diagnostics & Doctoral Supervisor at Capital Medical University

PROGRAM COMMITTEE

Rengui WANG, MD, PhD
Director of Department of Radiology, Beijing Shijitan Hospital

Chun XU, PhD
Chief Medical Officer, Beijing Clinical Service Center

Jie HUANG
Product Management Manager, m-Clinical Solution Shanghai

Medical imaging assessment plays a prominent role in diagnosis of human diseases and evaluations of clinical efficacy and safety of investigational drugs in medical research. In recent years, the National Medical Products Administration and National Health Commission have also continuously introduced policies that support the development of medical imaging industry. With the ever-increasing demand for standardization of clinical study procedures and data after China joins the ICH, and with the constant emergence of innovative drugs in China, especially new drugs for serious life-threatening diseases, such as tumor and cardiovascular disease, whose clinical efficacies require precise assessment, the standards for central medical imaging assessment start to take on an increasing importance in the quality and credibility of clinical study results. As a result, how to establish a professional, reliable and comprehensive clinical medical imaging center service both offers a new opportunity and presents a new challenge to the current field of clinical study. This workshop will focus on both domestic and international drug-regulatory standards pertaining to medical imaging assessment, and launch discussions on establishing a professional medical assessment mechanism for central imaging assessment, ensuring central imaging assessment procedures, data standards and data transmission process, and evaluating the uniform quality requirements for document management. Through this training, participants can gain knowledge about the basic drug-regulatory requirements for medical imaging assessment and master key points for practicing central imaging assessment.

Targeted Audience:

- Clinical trial project management personnel
- Clinical trial investigators
- Clinical research associates
- Clinical medical monitors
- Clinical data management personnel
- Clinical research assistants
- Clinical trial QA and QC personnel
- Clinical researchers at study sites

Agenda

8:30–9:15	Drug-regulatory Standards and General Procedures of Medical Imaging Assessment
	Dr. Wen HE
9:15–10:00	Value and Mode of Service of Independent Central Medical Imaging Assessment
	Dr. Rengui WANG
10:00–10:15	Tea Break
10:15–11:00	Data Standard and Electronic Process Requirements for Central Medical Imaging
	Jie HUANG
11:00–11:45	Experience Sharing of Independent Imaging Centers in New Drug Clinical Development
	Dr. Chun XU
11:45–12:15	Panel Discussion

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 5 | 8:30 - 12:30 | 201AB, 2ND FLOOR | English Only

ICH based Nonclinical Development Program: General Components, Major Hurdles and Possible Solutions

PROGRAM CHAIR

Beatriz Silva LIMA, PhD
Professor and Advisory Board, Pharmacological Sciences
University of Lisbon and NDA Advisory Services, Portugal

PROGRAM CO-CHAIR

Pei HU, MD
Professor, Clinical Pharmacological Research Center, Peking Union Medical College Hospital

Course is divided in 2 parts. In Part 1 Will be described the components of the Nonclinical and clinical development program for innovative molecule according to ICH guidelines: including species selection, study interpretation, problem solving. Ongoing paradigm transformations towards reduction of animal use (3Rs). Frequently emerging problems, their possible solutions and strategies for their early prediction will be discussed with the participants. In Part 2 will include group discussion on selected Case Studies.

Agenda

8:30-10:45	**Overview of the Nonclinical Development Plan of Innovative Molecules** ICH Required Studies, Study Interpretation (ICH M3R1) • Pharmacology (Primary and Secondary) • Safety Pharmacology (ICH S7a and S7b) • Pharmacokinetics and Toxicokinetics (including metabolites testing; ICH M7) • Toxicology Studies (Single and Repeated dose studies (ICH S4); genotoxicity studies (ICH S2R1), carcinogenicity studies (ICH S1R),reproductive toxicity studies (ICH S5R1), juvenile animal studies (ICH S11) Human Risk Assessment of Preclinical Findings Particular Aspects of Biopharmaceuticals (ICH S6R1)
	Coffee break and distribution of case studies
11:00-12:00	**Group Work on Case Studies** planning the nonclinical development of molecules with selected therapeutic indications or conditions of use, including species selection aspects, complete vs abridged developments etc.
12:00-12:30	**Presentation of Each Group Conclusions on Case Study**

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 6 | 8:30 - 12:00 | HALL 2-C, 2ND FLOOR | English Only

Executive Perspectives on Development, Regulatory and Commercial Aspects of Biosimilars

PROGRAM CO-CHAIRS

Hoss A. DOWLAT, PhD
Vice President, PharmaBio Consulting (Life Sciences), Regulatory Affairs EU-USA, Medicines-Drugs, Germany

Joe ZHANG, MD, PhD
Chief Executive Officer, BJ Bioscience Inc.

This half-day preconference seminar focuses on the development, regulatory affairs (RA), market penetration and acceptance by the prescriber of biosimilars in Europe and the United States (US), and emergence in China. An international expert will share rich experiences on biosimilars in Europe and US. The EU and US lessons learnt can be vital for China.
This will enable delegates understand the latest trends and quality, non-clinical and clinical requirements of the EMA and FDA and thereby help local companies with insights into international biosimilar strategies and practices.

Learning Objectives

- An overview of the biosimilars and biologics progress in the EU and USA including the Players in the field.
- Examine change of mindset on biosimilars by the US FDA (since 2012) or EU EMA (since 2006) and advances (2018 and beyond) in China.
- Insights into EMA and FDA Biosimilars development and regulatory framework, and future prospects in China.
- Gain understanding of scope of comparability vs. similarity requirements,
- significance of bioequivalence studies, circumstances of clinical waivers and reliance on transnational bridging studies.
- Be initiated into the success and importance of biosimilars worldwide and relevance to modern China and its progressive Chinese Pharma industry.

Targeted Audience

- Managers, Directors, Vice Presidents interested planning or actively working on biosimilars, also, and/or biologics/biotech medicines
- Business development
- Business Strategy and Operations
- Regulatory affairs; EMA, FDA and international
- Commercial Affairs
- Portfolio Management
- Pricing and Reimbursement
- Heads of R&D
- Scientific Affairs
- Drug Safety and pharmacovigilance
- Marketing and Sales
- Intellectual property
- Product development
- Chemistry, manufacturing and control, development, QC & QA
- Quality and pharmaceutical development

ICH Day

Pre-Conference

Opening Plenary

China Regulatory Special Session

Regulatory Science

Innovative Breakthrough in Therapy

Clinical Trials, Operations and Quality Compliance

Data and Data Standard

Quantitative Science

Biologics Development

Generic Drug, CMC & GMP

Medical Writing & Medical Affairs

PV and Risk Management

Patient Engagement

Artificial Intelligence in Healthcare

Preclinical Development & Early Phase Clinical Research

Professional Development

Hot Topics and Late Breakers

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Agenda

8:30-9:45	**Current Biologics and Biosimilars FDA and EMA Regulatory Framework, Definitions, Principles, Regional Implementation** Update on CORE Principles of Biosimilars 1. Fundamentals of biosimilars 2. How are biosimilars defined and classified 3. Extrapolation and interchangeability differing by region 4. Basic principles of targeted development, current experiences 5. The importance of marketed originator as reference medicine 6. Evolving Quality driven program at basis of biosimilarity, 7. Pivotal role of a bioequivalence PK/PD study to biosimilarity; but when is it insufficient as a standalone clinical?
9:45-10:50	**Biologics and Biosimilars FDA and EMA Quality Aspects** • Similarity or Comparability by Quality Processes and Testing & Confirmatory in vitro Foundation of Biosimilarity • Immunogenicity a Fundamental Concern • Examples of monoclonal antibodies (mAbs) class: Case studies of mAbs exemplifying biosimilar principles and EMA/FDA policy and regulations
10:50-11:30	**Biologics and Biosimilars FDA and EMA Clinical Aspects** • Similarity concept applied to clinical program. • Immunogenicity risk at core of approach: Clinical testing strategies against the chosen reference product to confirm Quality findings and support biosimilarity • Examples of monoclonal antibodies (mAbs) class: Case studies of mAbs exemplifying biosimilar principles and EMA/FDA policy and regulations
11:30-12:15	**Workshop Exercise & Discussion: China and International Perspectives**

Tuesday, May 21st | PRE-CONFERENCE WORKSHOP

Workshop 7 | 8:30 - 12:15 | 201CD, 2ND FLOOR

Introduction of eCTD Application Technology Highlights

PROGRAM CHAIR

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

PROGRAM COMMITTEE

Sophia HUANG
Site Head, Regulatory Submission Management, Bayer Healthcare Company

Handsome JI
APAC Publishing Lead, Publishing & Product License Support, Worldwide Regulatory Operations, Pfizer (China) Research and Development

Since 2000, FDA/EMEA has established a set of standard for the submission and review of electronic international drug registration documents - Common Technical Document (CTD) specifications. This standard has become the international standard of ICH M4/M8, and has also been issued and implemented as a regulation by the drug administrations of Europe, America and Japan. As a member of ICH Drug Administrations, NMPA is actively promoting the application of CTD/eCTD in China's drug administration approval. The writing format standards and data file format requirements for the five modules of CTD are particularly critical for the New Drug Application (NDA), covering the whole life cycle phases of drug development, production, clinical study and marketing.

The implementation of these regulations also directly affects the international certification of China's import and export of drugs. Currently, the global drug registration standards have been transformed from paper-based CTD to electronic CTD (eCTD). Access to the electronic submission data and its data files, and the life cycle management and filing of the created files have been standardized. The transformation from CTD to eCTD is not just an electronic process.

It covers a number of systematized standards, such as document management specifications, medical coding specifications, file granularity specifications, data transmission specifications, and system structuring standards. During this training, the document architecture of CTD, writing requirements, specification requirements and categories of data and its data files, specification requirements for document management, and application format requirements for eCTD will be discussed.

Agenda

8:30 – 9:30	**Requirements for NDA -Compliant Study Data and Coding Standards**
	Sophia HUANG
9:30 – 10:30	**Requirements for eCTD System Construction and Preparation of Registration Document and Data**
	Handsome JI
10:30 – 10:45	Tea Break
10:45 – 12:00	**Drug Administration Standards of eTMF System and Its Relationship to CTD**
	Speaker Invited
12:00	**Summary**

Tuesday, May 21st | OPENING PLENARY

14:00–15:40
Hall 1
2nd Floor

Opening Plenary

INTRODUCTION AND ACKNOWLEDGEMENT
Carol ZHU, MBA
Senior Vice President and Managing Director, DIA China

DIA GLOBAL CEO REMARK
Barbara Lopez KUNZ
Global Chief Executive, DIA

PROGRAM CHAIR WELCOME ADDRESS
Shun LU, MD, PhD
Director, Center for Clinical Medicine of Lung Cancer
Shanghai Chest Hospital, Shanghai Jiaotong University
Chair of the 2019 DIA China Annual Meeting Program

US FDA REMARK
Mark ABDOO
Associate Commissioner for Global Policy and Strategy
U.S. Food and Drug Administration (FDA)

DIA China Inspire Award Ceremony

KEYNOTE ADDRESS 1 | **Regulatory Science in Japan**
Tatsuya KONDO, MD, PhD
Honorary Director of the National Center for Global Health and Medicine
Former Chief Executive of Pharmaceuticals and Medical Devices Agency (PMDA)

Keynote ADDRESS 2 | **Translating Human Immunobiology to Medicine**
Yongjun LIU, PhD
Global Head of Research,Sanofi

15:40–16:00 Tea Break

Tuesday, May 21st | OPENING PLENARY

16:00–16:45
Hall 1
2nd Floor

Special Forum | **Regulatory Science to Foster Bio-medical Innovation**

MODERATOR
Lingshi TAN, PhD
DIA Global Board of Director
Chairman and Chief Executive Officer, dMed Biopharmaceutical Co.,Ltd.

Regulatory science is a term coined back perhaps in the 1970s and has become one of the most used regulatory phrases. It has a similar definition in different regulatory agencies. For example, US FDA defines regulatory science as "the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products". EMA refers to "regulatory science" as "the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medical products and that inform regulatory decision-making throughout the lifecycle of a medicine".

2018 is a banner year for pharmaceutical innovation. For example, FDA last year approved a record number of new drugs, including 59 NME by CDER and 2 recombinant therapies by CBER. For the first time, more than half of NME approved (34) are orphan drugs, which are for rare diseases with unmet medical needs.

As the advancement in science and technology accelerates, more novel and complex therapies are being developed. These new therapies, including but not limited to, immunotherapy, gene therapy, cell therapy, and tissue-engineered medicines, hold the promise of future healthcare solutions.

It is imperative for regulators to advance regulatory science not only to keep pace with the accelerating bio-medical innovations, but also to be proactive in facilitating the translation of these innovations to new therapies.

During the panel discussion, the distinguished panelist from each regulatory agency will explain the new policies to meet the current regulatory challenges, share his/her insight on agency's strategic plan to promote regulatory science and how to expand/deepen collaborations between agencies, and (if time permit) discuss the challenge of balancing innovation with patient access to new medicines.

Key Topics:
· New policy toward advanced therapy (gene/ cell therapy, use of AI and RWE)
· Biosimilars policy and its impact
· What are the views on current ICH development and its impact to the emerging countries?
· What are the major challenges at each regulatory authority

INVITED PANELISTS
Junko SATO, PhD
Office Director, Office of International Programs, PMDA

Leigh VERBOIS, PhD
Director, Office of Global Operations, Office of Global Policy and Strategy (OGPS) , FDA

Agnes Saint-Raymond, MD
Head of International Affairs, Head of Portfolio Board, EMA

Ruyi HE, MD, PhD
Adjunct Professor, Director of Academic Committee, Center for Regulatory Science, School of Medicine , Tsinghua University
Chief Medical Officer, SDIC Fund Management Co

17:00–18:30 **Welcome Reception**

China Regulatory Special Session

May 22, 2019

14:00 - 15:30
Hall 1
2nd Floor

China Regulatory Special Session
Part 1: The Amendment of the Pharmaceutical Administration Law of China and Its Influences

Year 2018 is an important year for the reform of National Medical Products of Administration (NMPA). Various policy reforms and pilot works were carried out in an orderly manner, including MAH pilot, consistency evaluation of generic drugs, drug-related review, priority review of innovative drugs, and 4+7 pilot procurement of drugs with target quantity, etc., and it was planned to make an independent law on vaccine management and revise the existing Law on Pharmaceutical Administration. On Jan. 4, 2019, the opinion-soliciting draft of the Law on Vaccine Management of the People's Republic of China was published.

In April 2018, the revised drafted of the Law on Pharmaceutical Administration was submitted for the second deliberation to the 13th Standing Committee of the National People's Congress. Focusing on the prominent problems with pharmaceutical administration, the revised draft has revised partial legal terms in terms of encouraging the development of new drugs, strengthening the management on drug production, reinforcing the supervision on drug price, etc., aiming to encourage the innovation of drugs, and ensure safe and effective drug guarantee for people's health.

Out of the considerations about the influences of the Amendment of the Pharmaceutical Administration Law of China, we invited domestic most authoritative industrial development leaders, academic experts, and legal experts to share their opinions and predictions about pharmaceutical administration rules and regulations.

14:00 - 14:30 **Keynote Speech: The Progress and Influence of the Amendment of the Pharmaceutical Administration Law of China**

Ruilin SONG
Executive President, China Pharmaceutical Innovation and Research Development Association (PhIRDA)

14:30 - 15:30 **Panel Discussion: the Amendment of the Pharmaceutical Administration Law of China and Its Influences**

MODERATOR
Ruilin SONG
Executive President, China Pharmaceutical Innovation and Research Development Association (PhIRDA)

INVITED PANELISTS
Zhi-ang WU, PhD
Professor, Director, Research Center, Yeehong Business School
President, Beijing Yeedozencom

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

Shaoyu CHEN, JD
Managing Partner, Shanghai Office, Arnold & Porter LLP

Dan ZHANG, PhD
Executive Chairman, Fountain Medical Development Ltd.

Yinxiang WANG, PhD
Chairman & Chief Executive Officer, Jacobio Pharmaceuticals

15:30 - 16:00 Tea Break

China Regulatory Special Session

16:00 - 17:30
Hall 1
2nd Floor

China Regulatory Special Session
Part 2: The Value Assessment Model and Payment Model of Pharmaceutical Solutions and Its Impact on Patients, Society and Sustainable Innovation

The charm of biomedicine innovation rests with constantly solving the non-satisfied clinical medical needs at the front end of human life line. The emergence of new therapy methods needs the intervention of commercial insurance and policy-based means of payment. For the intervention of any means of payment, it is necessary to consider appraising the value and determining the social and economic value of disease treatment, and present them in a quantitative way. After the reform over the past several years, we are pleased to see that the traditional way of appraisal only based on price minimization has been increasingly rethought and questioned. A scientific and reasonable model of value assessment is already on the way.

Health technology assessment (HTA), a "value-based" assessment tool, has been rapidly pushed to the forefront in recent years on how to make innovative drugs and appropriate technologies more accessible and achieve the highest efficiency and quality of health services at a given cost.

In 2017, the negotiation on the admittance of Catalogue of Drugs for Basic National Medical Insurance introduced the comprehensive sanitation technology appraisal methods including pharmacoeconomics, etc. for the first time, and such methods were continuously applied to the negotiation on 17 kinds of anti-cancer drugs which were successfully incorporated into the Catalogue of Drugs for Basic National Medical Insurance at the end of last year. Meanwhile, since 2018, policy environment has begun to differentiate significantly between innovative drugs and generic drugs. The medical collection method of procurement of drugs with target quantity will directly affect the business mode of Chinese pharmaceutical enterprises. Will the enterprises winning the bid for "4+7" endeavor to realize breakeven by reducing costs, and make up for the price with quantity? How shall international and domestic innovative research & development enterprises cope with the research and development input under the compression of profit space? How shall we realize the mutual substitution of generic drugs and primary drugs clinically by supporting the superior and washing out the inferior, gradually solve the quality problems of the drugs already appearing in the market, and enhance the development quality and international competitiveness of Chinese pharmaceutical industry?

16:00 - 16:30 **Keynote Speech: Implementation and Development of Health Technical and Economic Assessment (HTA) in China**

Kun ZHAO
Director, Health Technology Assessment Division
China National Health Development Research Center

16:30 - 17:30 **Panel Discussion**

MODERATOR
Yi FENG
Vice President of Research & Development, Chief Strategic Officer, Kelun

INVITED PANELISTS
Kun ZHAO
Director, Health Technology Assessment Division
China National Health Development Research Center

Ning LI, PhD
Chief Director, Chief Executive Officer and General Manager, Junshi Pharma

Benny LI, PhD
Chief Medical Officer, TigerMed

Jianjun ZOU, MD, PhD
Vice President,Global Clinical Development and Medical Affairs, Chief Medical Officer, Hengrui Medicine

Bo ZHU
Senior Director, Medical Products Market Access, RDPAC

Regulatory Science

THEME CO-LEADERS

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

Irene DENG
Head of China Regulatory Affairs, Sanofi

Ling SU, PhD
Professor, Shenyang Pharmaceutical University, Venture Partner, Lilly Asia Ventures

Session 0101 | May 22, 2019

08:30-10:00
HALL 3
1ST FLOOR

Advancement in Regulatory Science – Views from the Representative of Major Regulatory Agencies

SESSION CHAIR
Ling SU, PhD
Professor, Shenyang Pharmaceutical University, Venture Partner, Lilly Asia Ventures

Regulatory science is a discipline of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of medical products. In recent years, international regulatory agencies have been very active in research and collaboration in regulatory science, resulting in substantial progress both in expediting approval of innovative medicines while responding to the new, challenging advancement in science and in enhancing the capability to ensure the favorable risk-benefit profile of medicinal products post-approval. In this session, the representative from major regulatory agencies will share their experience and insight on research and application of regulatory science and will discuss the topics of enhancing regulatory capability and international collaboration.

Views from US FDA
Leigh VERBOIS, PhD
Director, Office of Global Operations, Office of Global Policy and Strategy (OGPS) , FDA

Views from EMA
Agnes Saint-Raymond, MD
Head of International Affairs
Head of Portfolio Board
European Medicines Agency

Views from PMDA
Junko SATO, PhD
Office Director, Office of International Programs, PMDA

Regulatory Science

Session 0102 | May 22, 2019

10:30–12:00
HALL 3
1ST FLOOR

Overview of Genetic Product (CAR-T) Governance and Industry Experience Sharing

SESSION CHAIR
May LI
Executive Director, Regulatory Affairs, BeiGene

The development and application of CAR-T products in China have shown a booming trend since two CAR-T products of Novartis and Gilead approved in 2017. For example, 26 genetic products in China submitted IND to NMPA for treatment of hematologic malignancies, 4 products were approved, and the registration trials initiated. In addition, many investigators initiated clinical trials covered various tumors (including solid tumors).

From autogenous CAR-T to UCAR-T, hematologic malignancies to solid tumor, and CRISPR technology in CAR-T, the competition is fierce with rapid emerging technology. Meanwhile, with rapid progress of CAR-T application and booming of CAR-T clinical trials, exploring the best way for quality control, scientific based development and governance genetic products are the common goals for the industry and regulatory agency.

In this session, expertise from Health Authority, MNC and local innovation company will be invited to share their view and experience on genetic products registration guidance, registration strategy and QbD in manufacturing etc.

Overview of Regulation and Guidance of Cellular Products
Jianqing CHANG
Vice President, Regulatory Affairs, Tigermed

Foresee Pharmaceutical Evolution Future - Delivering Kymriah® to Patients
Wei LI
Senior Regulatory Manager, Global Drug Development Drug Regulatory Affairs, Novartis

Comply Regulatory Science to Accelerate the Development of CAR-T Industrialization
Xiaodong SONG
Vice President, Hrain Biotechnology

Regulatory Science

Session 0105 | May 23, 2019

08:30–10:00
HALL 3
1ST FLOOR

The Acceptance to the Foreign Clinical Data

SESSION CHAIR
Irene DENG
Head of China Regulatory Affairs, Sanofi

To improve the efficiency of the development and reduce the cost, it is more and more the trend to be globalized for the development program. In this way, how to interpret the foreign data would be critical issue faced by both agency and industry. On last August, CDE released the guidance on acceptance foreign data as the basis to guide the industry. In the meanwhile, the discussion on ICH E17 progressing quickly. In this section, we would invite the speakers from agency and industry to share their insights.

The Progress of PMDA to Accept the Foreign Data
Yoko AOI, PhD
Principal Reviewer, Office of New Drug V, PMDA

The Industry Insights on Foreign Data Acceptance
Jun SHI, PhD
Senior Vice President, Early Development and Translational Medicine and Clinical Pharmacology (TMCP), dMed Biopharmaceutical Co.,Ltd.

The Industry Insights on Foreign Data Acceptance
Mary SUN
Pharmacist, Clinical & Regulatory, Zai Laboratory

Session 0106 | May 23, 2019

10:30–12:00
HALL 3
1ST FLOOR

Overseas Hot Topics in Regulatory Science: Regarding Accelerate the Drug Development, Review & Approval, and Dynamic Labeling Update

SESSION CHAIR
Amy ZHAO
Associate Director, Regulatory Affairs, Roche Product Development Shanghai

EMA's PRIME Program – the Reflection and Real Case Sharing
Agnes SAINT-RAYMOND, MD
Head of International Affairs, Head of Portfolio Board, European Medicines Agency

FDA Real-Time Oncology Review & Assessment Aid - Case Sharing
Rose GAO
Head of Regulatory Intelligence and Capability Building, Drug Regulatory Affairs, Novartis

Product Information in a Digital Healthcare Ecosystem - The Roles of eLabeling and AI-assisted Regulatory Decision Making
Karl GRAHAM-SIEGENTHALER
Global Regulatory Group Director for Personalized Healthcare, Roche, Switzerland

Regulatory Science

Session 0107 | May 23, 2019

13:30-15:00
HALL 3
1ST FLOOR

Challenges, Opportunities and Experiences Sharing after China New IND Policy Effective

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

NMPA issued a new policy about adjustment on IND evaluation and approval process. This long-anticipated policy will significantly shorten IND approval timeline and pave the way for China and global simultaneous drug development, meanwhile expedite new drug development in China. However, the industry will face challenging on how to effectively manage the pre-IND meeting, and how to better preparation IND package to make sure the IND approval smoothly. In this session, the CDE reviewer will introduce and interpret the new policy, and speakers from industry will share their experience on managing pre-IND meeting and preparation of IND package.

Interpretation and Advise on Implementation of New IND Policy in China
Xiaoyuan CHEN, MD, PhD
Director, GCP Office, Beijing Tsinghua Changgung Hospital

Organizing Effective Pre-IND Meeting
Yingyu LIN
Senior Regulatory Affairs Manager, Regulatory Affairs, Bayer

Preparation High Quality IND Package and Management IND Amendments
Lily XIONG
Director, Regulatory Affairs, BeiGene

Innovative Breakthrough in Therapy

Innovative Breakthrough in Rare Disease

THEME CO-LEADERS

Lin WANG
Head of Takeda Development Center Asia, Vice President, Takeda

Ben WU
Head of Rare Disease Business, CANBRIDGE LIFE SCIENCES

Session 0201-1 | May 22, 2019

08:30-10:00
HALL 2-B
2ND FLOOR

Innovative Breakthrough in Rare Disease - Part 1

SESSION CHAIR
Ben WU
Head of Rare Disease Business, CANBRIDGE LIFE SCIENCES

Prospects for the Prevention and Treatment of Rare Diseases in China
Lan FENG
EDeputy Secretary-General, China Alliance of Rare Diseases (CARD)

Rare Diseases, Not Only Knowledge and Technology
Dingguo LI
President, Shanghai Foundation for Rare Disease

Current Status of Diagnosis and Treatment of Fabry Disease
Yan MENG, MD, PhD
Professor, Pediatric, Chinese PLA General Hospital

Panel Discussion: Patient Organization and Construction of Social Support System for Rare Diseases
MODERATOR
Kevin HUANG
Director, Chinese Organization for Rare Disorders (CORD)

INVITED PANELISTS
Yu ZHENG
Director, Zhengyu Mucopolysaccharide Rare Disease Care Center

Innovative Breakthrough in Therapy

Session 0202-1 | May 22, 2019

10:30-12:00
HALL 2-B
2ND FLOOR

Innovative Breakthrough in Rare Disease - Part 2

SESSION CHAIR
Lin WANG
Head of Takeda Development Center Asia, Vice President, Takeda

Establishment and Improvement of the Rare Disease Treatment and Insurance System
Shuyang ZHANG, MD, PhD
Vice President, Beijing Union Medical College Hospital

Opportunities and Challenges of Drug Research and Development for Rare Diseases in China
James XUE, MBA
Founder, Chairman and Chief Executive Officer, CANBRIDGE LIFE SCIENCES

Drug Development in Rare Hematology Disorders
Björn MELLGARD, MD, PhD
Global Program Lead, Rare Disease, Takeda

Panel Discussion
All Speakers above and Invited Panelists
Hongfei GU
Lymphoma Patient Association

Dan CURRAN, MD
Head of Rare Disease, Takeda R&D

Innovative Breakthrough in Therapy

Oncology Drug Development Breakthrough

THEME CO-LEADERS

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

George LIU, PhD
Head of Early Development and Scientific Operation, Harbour Biomed

George CHEN, MD
Senior VP, Global Medicines Development, Head of China Development Unit, AstraZeneca

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Session 0201-2 | May 22, 2019

08:30-10:00
HALL 2-C
2ND FLOOR

The Clinical Development, Statistics and CDx Considerations of Oncology Drug

SESSION CHAIR
George CHEN, MD
Senior VP, Global Medicines Development, Head of China Development Unit, AstraZeneca

Past and Current of Cancer Biological and IO Drug Development
Charles FERTE, MD, PhD
Medical Director, Early Clinical Development Immuno-Oncology, MedImmune

Statistical Considerations for Cancer Drug Development - with a China Focus
Yue WANG, PhD
Vice President and Head, Biometrics, R&D China, Global R&D Oncology, Astrazeneca

Biomarkers and CDX Consideration and Strategy
Lucy YIN, PhD
Director, Head of Precision Medicine Diagnostic Development China , Precision Medicine China, Global R&D Oncology, Astrazeneca

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Innovative Breakthrough in Therapy

Session 0202-2 | May 22, 2019

10:30-12:00
HALL 2-C
2ND FLOOR

The Clinical Design, Endpoint and Regulatory Considerations in the Generation of Precision Medicine - Part 1

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

George LIU, PhD
Head of Early Development and Scientific Operation, Harbour Biomed

Regulatory Requirements for Approval of Gene Sequencing with Diagnosis
Yunfeng LV
Vice Director, Clinical & Biostatistics Division II, Center for Medical Device Evaluation, NMPA

Rare Gene-Driven, Single Arm, Umbrella Trial Design: - A Case Sharing to the Considerations for Clinical Trial Design
Shun LU, MD, PhD
Director, Center for Clinical Medicine of Lung Cancer, Shanghai Chest Hospital, Shanghai Jiaotong University

EMA'S Regulatory Requirements and Considerations for Precision Medicine
Agnes Saint-Raymond, MD
Head of International Affairs, Head of Portfolio Board, EMA

The Differentiation Clinical Development of Immu-oncology - Experience Sharing from the Local Pharma
Jianjun ZOU, MD, PhD
Vice President,Global Clinical Development and Medical Affairs, Chief Medical Officer, Hengrui Medicine

Session 0205 | May 23, 2019

8:30-10:00
HALL 2-C
2ND FLOOR

The Clinical Design, Endpoint and Regulatory Considerations in the Generation of Precision Medicine - Part 2

SESSION CO-CHAIRS
Zefei JIANG, Prof.
Director, Breast Cancer Department, The Fifth Medical Center of PLA General Hospital
Secretary General, Chinese Society of Clinical Oncology (CSCO)

Zhiqiang NING, MD, PhD
Executive Vice President, Clinical Research & Development, Shenzhen Chipscreen Biosciences Co., Ltd.

Data Requirement for Supporting NDA of Oncology Drug
Xiaoyuan CHEN, MD, PhD
Director, GCP Office, Beijing Tsinghua Changgung Hospital

Key Considerations of Clinical Trial Design of Innovative Oncology Drugs in the Era of Precision Medicine
Zefei JIANG, Prof.
Director, Breast Cancer Department, The Fifth Medical Center of PLA General Hospital
Secretary General, Chinese Society of Clinical Oncology (CSCO)

Beyond PD1 PDL-1 Generation: Oncology Drug Development and Regulatory Consideration
Walt CAO, PhD
Head of Clinical Pharmacology and Pharmacometrics, 3D Medicines
Former Senior Clinical Pharmacology Reviewer, FDA

Innovative Breakthrough in Therapy

Session 0206 | May 23, 2019

10:30-12:00
HALL 2-C
2ND FLOOR

The Accessibility, Development Strategy and Trends of Oncology Drug

SESSION CHAIR
Joan SHEN, MD, PhD
Vice President, Head of R&D, I-Mab Biopharma

To be or not to be - The questions of PD1/PDL1 Clinical Development in the Crowded World of Immuno - Oncology
Yongjiang HEI, MD, PhD
Chief Medical Officer, Oncology, Zai Laboratory

The Strategy and Implementation of China - US IND Application and Simultaneous Development
Joan SHEN, MD, PhD
Vice President, Head of R&D, I-Mab Biopharma

Panel Discussion
Moderator
Hongtao LU, PhD
Chief Scientific Officer, Elpiscience

Panelists
All Speakers Above and Invited Panelist
George CHEN, MD
Senior VP, Global Medicines Development, Head of China Development Unit, AstraZeneca

Shanshan JIA, PhD
Vice President, China Reform Venture Capital Investment Management (Shenzhen) Ltd.

Innovative Breakthrough in Therapy

Innovative Breakthrough in Immune Disease

THEME LEADER
Xiaoxiang CHEN, MD
Chief Development Officer, Harbour Biomed

Session 0207 | May 23, 2019

13:30-15:00
HALL 2-C
2ND FLOOR

Innovative Breakthrough in Immune Disease Part 1- Innovation in Immunology- How this Change Our Therapeutic Landscape?

SESSION CHAIR
Luyan DAI, PhD
Head, Clinical Research, Harbour Biomed

Versatile Innovations Revolving Immunology Therapy Areas – Innovative Targets & Research Development
Joan SHEN, PhD
Vice President, Head of R&D, I-Mab Biopharma

Targeting Type 17 Cells for the Treatment of Autoimmune Diseases
Jianfei YANG, PhD
Head, Discovery Immunology, Harbour BioMed

IFN Pathway and Treatment Innovation for Autoimmune Diseases
Jie SONG, MD, PhD
Physician, Associate Director in GMD R&D China, AstraZeneca

Session 0208 | May 23, 2019

15:00-17:00
HALL 2-C
2ND FLOOR

Innovative Breakthrough in Immune Disease Part 2 - Advances in Immunotherapy

SESSION CHAIR
James FAN
Medical Director, Pharmacovigilance, PPD

This session aims to provide a platform for the exchange of views on the advances of immunotherapy from CRO, pharma and biotech perspectives, to stimulate further breakthroughs in fundamental understanding and advances towards new drug development in this fascinating field; Review the recent advices and new trend of immunotherapy in various therapeutic area;
Describe the challenges and strategies in immunotherapy and also share the experience and lessons learned from global MNC perspective.

Immunotherapy in Oncology
Binh NGUYEN, MD, PhD
Vice President, Global Product Development, PPD

Immunotherapy Advances in Non-oncology Area
Carrie ZHOU, MD, PhD
Medical Director, DTC Asia, Takeda

From Clinical Unmet Needs and Commercialization to Understand Inflammation & Immunology Drug Development in China
Michael WU
Medical Director, Everstar Pharm

Clinical Development, Operations and Quality Compliance

THEME CO-LEADERS

Hannah CHEN
Consultant, Integral Consulting

Sunny ZHU
Chief Medical Officer, Infectious Diseases, Everest Medicines

Reako REN
Head of SMO Services, WuXi Apptec

Session 0301 | May 22, 2019

08:30-10:00
203CD
2ND FLOOR

Site Management: Best Practice for Site Operation?

SESSION CO-CHAIRS

Lucy LIU
Director of GCP office, Fudan University Shanghai Cancer Center

Cathy HUANG
VClinical Operation Vice President, , Jiangsu Hengrui Pharma.

Site Activation and Close-out: Can We Speed up Further?
Yan WU
Vice President, Shanghai Hutchison MediPharma

Site Operation Excellence: Our Experiences
Lucy LIU
Director of GCP office, Fudan University Shanghai Cancer Center

Panel Discussion | Patient Recruitment in a “Hot” Disease Area
Moderator
Cathy HUANG
Clinical Operation Vice President, , Jiangsu Hengrui Pharma.

Invited Panelists:
The Speakers Above and

Shuhong LIU
Head of Clinical Development, Sanofi

Weixia LI
Director, WuXi MedKey SMO

Richard ZHANG
Clinical Operation Vice President, LIVZON MABPHARM INC.

Clinical Development, Operations and Quality Compliance

Session 0302 | May 22, 2019

10:30-12:00
203CD
2ND FLOOR

Vendor Management and Collaboration

SESSION CO-CHAIRS
Reako REN
Head of SMO Services, WuXi Apptec

Xin ZHANG
Vice President, Global Clinical Medical Affairs, Shanghai Henlius Biotech, Inc.

Vendor Selection and Management in Specialized Service
Richard ZHANG
Clinical Operation Vice President, LIVZON MABPHARM INC.

Phase I Studies in Patients: What is the Optimal Model
Xia ZHAO
Phase I Center, No.1 Hospital, Peking University

Case Sharing: Effective Multiple Collaboration Makes Success in Challengeable Projects
Shuangchun SHAO
Director, Clinical, Shanghai MedKey SMO

Panel Discussion | Excellence in Collaboration, What We Can Do to Improve for Better Operation Result
Moderator
Reako REN
Head of SMO Services, WuXi Apptec

Invited Panelists
All Speakers above and
Susan SU
General Manager, Life Sciences Division, DTW Group

Xin ZHANG
Vice President, Global Clinical Medical Affairs, Shanghai Henlius Biotech, Inc.

Clinical Development, Operations and Quality Compliance

Session 0305 | May 23, 2019

08:30-10:00
203CD
2ND FLOOR

Synergized Quality Management in Clinical Research - Perspectives from Authority, GCP Office and Sponsor

SESSION CHAIR
Liping ZHOU
Director, Quality Assurance, Asia Pacific, MSD R&D (China) Co., Ltd.

Quality has becoming a crucial differentiator in Clinical research. Since Jul2015, various quality management (QM) approach has been initiated/enhanced by the key players of Clinical trial eco-systems, e.g. sponsor, GCP office in hospital, CRO, etc. How can the stakeholders synergize the efforts to ensure the clinical trial quality? What kind of proactive risk-based approach can be applied? How to ensure effective patient access from QM perspective, etc? These hot topics are going to be addressed in this session.

Clinical Trial Quality Management—Key Players' Focus from Inspectors' Perspective
Zhengqi LI

GCP Office Role in Clinical Trial Quality Management
Ning LI
GCP Office Director, CAMP

Clinical Trial Quality Management from Sponsor Perspective
Jolie WEINTRAUB
Executive Director, MRL QA, Merck

Panel Discussion: to address the challenges around quality management in clinical trial, e.g. 100% re-SDV at the end of study as requested by GCP office; synergized effort among involved stakeholders to ensure quality, etc.
All Speakers Above and Invited Panelists:
Fangmin WANG, MBA
Deputy Director, Shanghai Center for Drug Evaluation and Inspection

Yifeng SHEN, MD, PhD
Executive Director, ChinaARO-P
Director of GCP OfficeMember of IRBShanghai Mental Health Center
Shanghai Jiaotong University Medical School

Hua BAI
Attending Physician, Clinical Pharmacology Research Center, Peking Union Medical College Hospital

Hannah CHEN
Consultant, Integral Consulting

Clinical Development, Operations and Quality Compliance

Session 0306 | May 23, 2019

10:30-12:00
203CD
2ND FLOOR

Quality by Design

SESSION CHAIR
Sunny ZHU
Chief Medical Officer, Infectious Diseases, Everest Medicines

Quality by Design in Real World Evidence
Deborah DRISCROLL
Vice President, Quality Assurance, Merck Research Laboratory

Precision Medicine Trials - Learnings over Impact, Barriers, and Enablers
Angela QU, MD, PhD
Senior Director, Biomarker and Genomic Medicine, PAREXEL International

Using Data Analytics to Create Learnings and Change from Audits and Inspections of Clinical Trials
Joanne NORTH
Analytics Lead, Metrics, Reporting and Analytics, BioResearch Quality and Compliance, Janssen, UK

Session 0307 | May 23, 2019

13:30-15:00
203CD
2ND FLOOR

Clinical Trial Enabler in New Era

SESSION CHAIR
Paul DAI
Head of Clinical Operations, TDC, Asia, Takeda

With the evolving technology and science in Clinical Development, what can be utilized to ensure clinical trial quality, to secure effective science transformation, and to enhance patient centricity? International professionals are going to bring the most up-to-date global practice and to share their insights with audience.

Digital Health - a New Era for Clinical Trial
Matt JONES
Managing Director, Digital Qaulity Associates Ltd. UK

Employing eLabels in Clinical Trials
Keris HUANG
Clinical Research Director, Global Clinical Trial Operations, MSD Taiwan

Demystifying Technology Selection in Mobile Clinical Trials
Philip CORAN, JD
Senior Principal Global Compliance and Strategy, Medidata Solutions

Data & Data Standards

THEME LEADERS

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

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

Session 0401 | May 22, 2019

08:30-10:00
201AB
2ND FLOOR

How Integrated e-clinical System Can Improve Clinical Data in Quality and Efficiency – Part 1: eClinical Solution and Its Application in Quality Improvement

SESSION CHAIR

Feng CHENG, MBA
General Manager of China, Business Development, OmniComm Systems, Inc.

The complexity of drug research and development makes it impossible for traditional R&D management methods to fit current complex processes with tremendous data. Data in its collection, management, integration, sharing, aggregation and monitoring has brought great challenges. Therefore, the use of information technology to manage clinical research processes and data, and to provide timely information for decision-making has become an urgent requirement in China. This session will invite speakers from domestic and global information enterprises to share their experiences in the integration of clinical information.

Trends in e-Clinical Development
Jeyaseelan JEYARAJ
Senior Director, Solutions Consulting, Asia Pacific, Health Sciences Global Business Unit, Oracle, India

Integrated eClinical Solution, Practices and Experiences
Yonglong ZHUANG, PhD
General Manager, BioKnow

Panel Discussion:
INVITED PANELISTS
Hadrian FU
CEO, Shanghai Zenith Medical Teck Co., Ltd.

Chico FAN
Vice President, Marketing & Strategy, ePharma Healthcare Technology Co.

Maggie (Chunfeng) FU
Senior Director, CDM and Site Head of Dalian GSDM, Clinical Data Management of China & Australia Covance

Data & Data Standards

Session 0402 | May 22, 2019

10:30-12:00
201AB
2ND FLOOR

How Integrated e-clinical System Can Improve Clinical Data in Quality and Efficiency – Part 2: eHealth Records in Clinical Trials

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

This session will interpret the FDA's guidance and explore how to use medical electronic data to support the collection and cleansing of clinical research data, and in particular, to share strategies on how to use medical electronic data to interface with EDC to improve data quality and efficiency.

FDA Guideline Interpretation: Use of Electronic Health Record Data in Clinical Investigations
Tai XIE, PhD
CEO, Brightech International , Adjunct Assistant Professor, Biostatistics Department, School of Public Health , Rutgers University

Use eHR to Accelerate Clinical Research
Chen YAO, Prof.
Vice Director, Peking University Clinical Research Institute

eHR to EDC eSource Strategies in Clinical Trial
Feng CHENG, MBA
General Manager of China, Business Development, OmniComm Systems, Inc.

Session 0405 | May 23, 2019

08:30-10:00
201AB
2ND FLOOR

Operation and Challenges of Data Standardization

SESSION CHAIR
Carrie ZHANG
Head of Clinical Data Center, Shanghai Henlius Biotech , Inc.

Standardized clinical trial data play the key role in trial data collection, transfer, and integrated data analysis within or cross multiple studies. In this session, international senior industry professionals will be invited to introduce most recent progress globally in data standards, share and discuss best practice for data standards challenge and operation in China.

International Updated Progress in Data Standards
Zibao ZHANG, PhD
Executive Director, Business Development, dMed Biopharmaceutical Co.,Ltd.

Current Status and Trends of Data Standardization in Clinical Trials in China
Joey WANG
Senior Manager of Statistic Programming, Meta Clinical Technology

Clinical Outcomes Assessments (COA) - Regulation and Practical Sharing
Baoying GE
Associated Director, Clinical Data Management, Global Data Management & Standards, MSD

Panel Discussion: All Speakers above and Invited Panelist
Zhiyang CHEN, PhD
Vice President, Professional Services, Medidata Solutions

Data & Data Standards

Session 0406 | May 23, 2019

10:30-12:00
201AB
2ND FLOOR

Key Concerns of Medical Monitoring

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

ICH GCP 5.18 and NMPA guidances of Good Clinical Practice (item 50) are emphasizing the importance of medical monitoring compliances in clinical trials, especially on roles of medical monitors on relevant medical directions. In medical monitoring, it should be understood well for medical monitors to check which elements, key parameters, and risky control of trial data to ensure validity and scientificity of medical data verification from standpoints of medical associated with data management views. This theme will present what and how medical monitoring play in assurance of clinical data quality and integrity, focusing on safety monitoring and RBM procedures, and introduction of global regulatory requirements of medical monitoring in clinical trials.

Medical Monitoring and the Relationship between Clinical Trials and Data Management - Global Regulatory Perspective
Dimitri FITSIALOS
CEO, Integrated Therapeutic Solutions, Inc

Risk-based Medical Monitoring on Data Quality
Yazhong DENG
General Manager, TrustCRO

Medical Reviewing Practice of Safety Data in Clinical Trials
Murphy LIU, MD
Executive Director, Medical and Clinical Strategy,Beijing Clinical Service Center

Data & Data Standards

Session 0407 | May 23, 2019

13:30-15:00
201AB
2ND FLOOR

Regulation and Practice of Independent Data Monitoring Committee

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

IDMC is not widely implemented in China. According to increase of innovative drug development, the IDMC is more significantly in clinical trials. In this session, we will introduce the regulation requirement and operations of IDMC, and discuss the challenges and benefits from points of view of statistical, data management, and pharmacovigilliance.

ICH Requirement and Statistical Considerations on IDMC
Ying WU, PhD
Peking University Clinical Research Institute

IDMC Operations and Challenges
Wei ZHANG
Head of Data Management, GSK China R&D

Safety Management by IDMC
Hualong SUN, MD, PhD
General Manager, Meta Clinical Technology Co. Ltd

Session 0408 | May 23, 2019

15:30-17:00
201AB
2ND FLOOR

Randomization and Clinical Trial Supply Management

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

Randomization is fundamental to clinical trials. It eliminates selection bias and enables treatment group balance. Clinical trial supply management assures that the right medical supplies are delivered to the right patient at the right time.
In recent years, the CDE has paid more and more attention to the whole life cycle management of trial supply. Trial supply management has become one of the key areas in clinical inspection

Theory and Practice of Randomization
Chris GUO, PhD
Vice President, Biometrics, Fountain Medical Development LTD.

RTSM: How Best to Manage Complex Dosing Schemes and Multiple Response Criteria in Oncology Trials
Eric FORSTHOFFER
Vice President, Global MIT & eClinical Solutions, Bioclinica USA

Clinical Trial Supply Management: Lessons Learned
Ruolin ZHANG
Vice President, Clinical Data Management, Bioknow

Quantitative Science

THEME CO-LEADERS

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

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

Harry HUA
Principal statistician, Biostatistics & Data Science, Shanghai, Boehringer Ingelheim

Session 0501 | May 22, 2019

08:30-10:00
201CD
2ND FLOOR

Challenges and Opportunities for Statisticians in the Era of New Technology and Innovative Design

SESSION CHAIR

Fan XIA, PhD
Associate Director, Biostatistics, BeiGene

This changing environment and development needs in pharmaceutical industry provide statisticians with uncertainties on traditional responsibilities in operational tasks, but also with more opportunities in data science innovation and strategic development through life cycle of pharmaceutical R&D and beyond, such as patient access.

The advent of new technology and the discussions around the use of innovative designs need the statisticians to continuously develop professional skills and ability to innovate and to implement. At the same time, in-depth collaboration with cross-functional key players especially clinicians and opportunities of supporting leadership and entrepreneurial development may also define new role for pharmaceutical statisticians.

With inviting pharmaceutical R&D leaders, regulatory senior representatives and leading medical expert, the session will discuss challenges, future role and opportunities for statisticians, clinician-statistician collaboration, etc from different perspectives. We look to the discussions to help shape the future of the China statistical community in pharmaceutical industry.

Invited Panelists:

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

Lai WANG, PhD
Senior Vice President, Global Research, Clinical Operation& Biometrics and APAC Clinical Development, BeiGene Ltd.

Gang CHEN, PhD
Chief Scientific Officer, Senior Vice President, R&G PharmaStudies Co., Ltd.

Wei ZHANG, PhD
Corporate Vice President, Head of Medicine, Greater China, Boehringer Ingelheim

Anny-Yue YIN, PhD
Associate Vice President, Biometrics and Medical Writing, CStone Pharmaceutical

Quantitative Science

Session 0502 | May 22, 2019

10:30-12:00
201CD
2ND FLOOR

The Use of Biomarker and Data Analysis in Clinical Development

SESSION CO-CHAIRS

Michael LEE, PhD
Senior Director, Biometrics, Harbour BioMed

Ping YAN, PhD
Senior Director of Biostatistics, Jiangsu Hengrui Medicine Ltd. Co.

The use of biomarker in drug development is becoming increasingly important for optimizing drug development process and increasing the success rate of drug development. In this session, we will focus on the recent development in biomarker identification/selection in clinical trial design, and biomarker data analysis in oncology and immune-oncology area. Researchers and statistical scientists from leading global and local pharmaceutical companies and academia are invited.

Pathway-based Biomarker Identification with Crosstalk Analysis for Robust Prognosis Prediction in Hepatocellular Cancer
Zhangsheng YU, PhD
Department of Bioinformatics and Biostatistics, Department of Mathematics, Shanghai Jiao Tong University

The Use of Biomarker in Drug Clinical Development
Song SHI, PhD
Associate Director of Translational Medicine, Jiangsu Hengrui Medicine Ltd. Co.

Utilizing R Package, Shiny App and Markdown to Streamline and Standardize Biomarker Analysis
Ning LENG, PhD
Senior Statistical Scientist, Biostatistics, Genentech, US

Biomarker Development in Checkpoint Immunotherapy
Xin GAN, PhD
Associate Director of Discovery Oncology, Harbour BioMed

Quantitative Science

Session 0505 | May 23, 2019

08:30-10:00
201CD
2ND FLOOR

Risk based Monitoring/ Management

SESSION CHAIR
Yun LU
Associate Director, Shanghai Biostatistics and Programming Site Head, PPD

Following guideline from ICH E6 (R2) Section 5.0.4: "The Sponsor should decide which risks to reduce and/or which risks to accept", Risk Based Monitoring (RBM) aims to reduce risk and enhance human subject protection and clinical trial data quality while reducing full SDV (Source Data Verification).

The application, benefits, process and execution of Predefined Quality Tolerance Limits, which to identify systematic issues that can impact subject safety or reliability of trial results, Model Based Data Analysis in optimization of RBM and Data Analytic in central monitoring will be presented and discussed by invited global and local leaders and experts.

Quality Tolerance Limits (QTLs) – What, Why, When and How
Ping-Chung CHANG
Senior Director, APAC Biostatistics and programming regional head, PPD

Use of Multivariate Data Analysis in Optimization of Risk Based Monitoring of Multicenter Trials
Xiaoqiang XUE, PhD
Director, CSDD, Decision Sciences, IQVIA

Data Analytic and Programming in Central Monitoring
Yidi WANG
Senior Biostatistician, Biometrics, BeiGene, Beijing, Co., Ltd.

Quantitative Science

Session 0506 | May 23, 2019

10:30-12:00
201CD
2ND FLOOR

Patients Centric Clinical Development

SESSION CHAIR
Meng CHEN, PhD
Director, Biometrics China site head, Roche

Clinical trials are designed for investigator-collected data that are essential to understand a molecule's safety and efficacy profile. Even though capturing patients' perspective on disease or treatment outcomes is included in clinical trials, these assessments are often not widely recognized as scientifically robust or methodologically rigorous. FDA is developing a series of guidance documents on patient-focused drug development to facilitate the advancement and use of systematic approaches to collect and use meaningful patient input that can better inform regulatory decision making. These guidance documents provide incentives for sponsors to invest in collecting more patient-relevant data of high quality. Ongoing public interactions with FDA and EMA also demonstrate regulators and payers' intent to reach out to patients to better understand unmet medical need, choice of endpoint and patients' preference for treatments. To date it is largely unclear how the NMPA considers the use of patient-generated evidence as part of the totality of evidence.

The objective of this session would be to present a few case examples on the collection and/or submission of patient-relevant evidence, to foster discussions on how such evidence could be used within the risk benefit framework for decision making.

Patient Focused Drug Development in a Global Environment
Elisabeth Piault-Louis
Associate Director, PCOR Oncology, Genentech

Application of Health-related Quality-of-life Data in Cancer Clinical Trials – a Case Study
Julie CONG, PhD
Associate Director Biostatistics, Boehringer-Ingelheim

Patient-centric Outcomes Research to Support Value Proposition
Ke WANG, PhD
Senior Consultant, China Health Outcomes, Eli Lilly and Company

Advantages and Challenges of eCOA (Electronic Clinical Outcome Assessments)
Jessie ZHAO
Global Study Manager, Roche

Quantitative Science

Session 0507 | May 23, 2019

13:30-15:00
201CD
2ND FLOOR

Oncology Dose Escalation Design

SESSION CO-CHAIRS

Xiaoni LIU, PhD
Biostatistics China Site Head, Novartis

Grace GAO
Principal Statistician, Statistics & Decision Sciences, Janssen R&D

Over the years, it has been receiving increasing attention on the oncology phase I dose escalation design with the variety of possible designs growing quickly. In this section, experts in varied fields will share their journey and considerations on the study design and conduct in practice. In addition, as the joint effort, the discussion will also be focusing on the outstanding issues and controversies that continue to exist from statistical, clinical and operational perspective.

An Established Model-based Framework and Its Application for Dose Finding in Oncology Field

Blanky TU
Translational Clinical Oncology
Clinical Operations Group Head (ad-interim), Novartis

Experience Sharing on Dose Escalation Studies: Pain and Gain

Stephen L. CHAN, PhD
Associate Professor, Department of Clinical Oncology, The Chinese University of Hong Kong
Specialist in Medical Oncology, Prince of Wales Hospital, Shatin, NT, Hong Kong

Panel Discussion

Above Speakers and Invited Panelists

Gailing LI, PhD
Senior Director, Clinical Pharmacology
Johnson & Johnson (China) Investment Ltd.

Jianyong SUN
Associate Director, Early Development Biostatistics, Novartis

Quantitative Science

Session 0508 | May 23, 2019

15:30-17:00

201CD
2ND FLOOR

Current Trend in Regulatory Science and Industry - Master Protocol and Adaptive Design

SESSION CO-CHAIRS
Yong WANG, PhD
Vice President, Biometrics, WuXi Clinical

Fei JI
Research Advisor, Lilly

In the effort of making drug development more efficient and lowering the cost, FDA proposed important principles for modern clinical trial designs and approaches in drug development. New draft guidance on the use of adaptive designs and master protocols was released in 2018.

Modernized clinical trial design approaches aim to increase the amount of information about a new product's safety and benefits, to improve patient access, to react to clinical evidence as it's being collected with great flexibility. They are also more complex than ever.

Because of the complexity of the trials designed within these frameworks, and the potential regulatory impact, it's important that we understand the guidance on how to conduct well designed trials that protect patient safety and obtain quality data needed to support drug approval.

Challenges and Regulatory Requirement in Adaptive Design Trials
Martin ROESSNER
Corporate Vice President of Biostatistics, PAREXEL International

The Applications and Challenges of Master Protocol Design in Cancer Study
Gang CHEN, PhD
Chief Science Officer& Senior Vice President, R&G PharmaStudies Co., Ltd.

Panel Discussion
Panelists - All Speakers above and Invited Panelists:
Kun HE, PhD
Chief Statistician, R&G PharmaStudies, Co. Ltd.

Chao ZHU
Director and Head of Statistics and Statistical Computation, Eli Lilly and Company (China)

Biologics Development

THEME CO-LEADERS

Melly LIN
Senior Regulatory Manager, CMC Policy, Roche (China) Holding Ltd.

Joe ZHANG, MD, PhD
Chief Executive Officer, BJ Bioscience Inc.

Xiangyang ZHU, PhD
CEO of Shanghai Huaota Biopharma Co., Ltd

Session 0601 & 0602 | May 22, 2019

08:30-12:00
HALL 2-A
2ND FLOOR

CMC Changes from Clinical Development to Approval and Post Approval During the Life Cycle of Biological Medicinal Products: the Regulatory Requirements and GMP Requirements - Part 1 & Part 2

SESSION CO-CHAIRS

Zero WU
Regulatory Affairs Director
Novo Nordisk (China) Pharmaceuticals Co., Ltd.

Haiqiong HE
Director, Regulatory CMC, BeiGene

In the lifecycle of a biological medicinal product, CMC changes (process, site, equipment, etc) to the drug substance or drug product are often unavoidable. When such changes occur, it is crucial for the sponsors to demonstrate comparability between pre-change and post-change product to ensure that the safety and efficacy of the product remains no change. The biggest challenge therein, lies in what constitutes "comparability"? How do you know what may/may not be affected and what needs to be tested? When do you need to conduct such assessments? How much information is sufficient? What techniques should you use to obtain the best possible comparison? What are the expectations from Agencies on comparability under the changing regulatory environment? How to plan and execute those changes under GMP to follow the best practice? These are all those questions which the sponsors are challenged following CMC changes.

This session will include several presentations covering CMC changes during clinical development and post approval and will highlight the approach taken to demonstrate comparability and to effectively communicate these changes to regulators. The expectations from the regulators on such CMC changes and comparability studies will be also addressed together with the GMP management of those CMC changes. An open forum discussion in the end of the session will give the opportunity to the audience to share experiences.

CMC Changes Overview
Michele DOUGHERTY, PhD
Vice President, CMC Regulatory, DataRevive LLC, US

GMP Requirements during the Clinical Development Phases for Biological Products
Audrey JIA, PhD
CMC and Regulatory Lead, DataRevive LLC, US

Biologics Development

Case Study of Process Change during Clinical Development
Zheru ZHANG, PhD
President, I-Mab Biopharma

CMC Changes during Clinical Stages and Comparability in ICH Countries
Andrew CHANG, PhD
Vice President, Quality and Regulatory Compliamce, Quality, Novo Nordisk

Panel Discussion
All Speakers from Session 0601 & 0602
and Invited Panelist
Kai GAO, PhD
Professor, School of Life Science, Shanghai University

Session 0605 | May 23, 2019

08:30-10:00
HALL 2-A
2ND FLOOR

Innovative Biologics Process Development

SESSION CHAIR
Xiangyang ZHU, PhD
CEO of Shanghai Huaota Biopharma Co., Ltd

With more and more biological Biotherapeutical drugs ending phase III clinical trials and entering the market for an approval, we need a more complete understanding of process development, process validation, scale-up and GMP production, and quality control as well as relevant regulations. This section is mainly to provide you with such an opportunity to have a deeper understanding of the process from the view of regulations, process verification and the example from a new product listed on the China market.

Topic TBD
Speaker Invited

Key Factors from Process Lock to Commercial Production
Raphael GRAETER
Head of Process Validation, Quality, Boehringer Ingelheim Biopharmaceutical s (China) Ltd.

"Tuoyi" - Experience Sharing of Process Verification during the NDA Process of the First PD-1 Monoclonal Antibody in China
Hui FENG, PhD
Chief Operations Officer, TopAlliance

Biologics Development

Session 0606 | May 23, 2019

10:30-12:00
HALL 2-A
2ND FLOOR

Quality Control and Clinical Development Regulatory Considerations of Gene/Cell Products

SESSION CHAIR
Joe ZHANG, MD, PhD
Chief Executive Officer, BJMab Biopharmaceutic

As an important emerging therapeutic approach, cell/gene therapy is becoming a hot research area in the world. However, due to its unique properties, the R&D and manufacture of this new class of therapeutics is different from those of traditional drugs. How to ensure the quality and mitigate clinical risk of these products are among the challenges faced by pharmaceutical industry and regulatory authorities around the world. In this session, invited speakers from regulatory authority and leading players from China and overseas will share and discuss their thinking and strategy on how to cope with the above challenges based on their first hand experience.

Some Thinking for the Development of CAR-T Products under the New Regulatory Environment
Lei LIU
Associate Clinical Development Medical Director, Novartis Global Development Department. China

Preclinical Safety Evaluation of Cell Therapy Products
Xingchao GENG, PhD
Deputy Director, National Center for Safety Evaluation of Drugs (NCSED)
National Institutes for Food and Drug Control (NIFDC)

The Challenges in CAR-T Manufacturing Process and Analytical Method Development
Xinpo JIANG, PhD
Senior Director, Product Development/Analytical, Legend Biotech Nanjing Corporation

Biologics Development

Session 0607 | May 23, 2019

13:30-15:00
HALL 2-A
2ND FLOOR

Clinical Trial Design of Biologics

SESSION CHAIR
Helen PU
Group Leader for ONCO 2 of PDR China, Roche (China) Holding Ltd

Increasing the efficiency of clinical trials, reducing costs, shortening timeline, and improving patient access to innovative medical products have been the direction that the industry is constantly striving to advance. In recent years, with a series of initiatives by regulators to encourage innovation, some innovative clinical trial designs (such as seamless trials design/adaptive designs/quantitative pharmacology/ master protocol designs) are gradually being piloted.

This session will introduce and discuss some innovative clinical trial designs from the perspectives of clinical pharmacology, clinical science and statistics through some real cases of biologics. After the presentation, there will be a mini panel discussion on the role of these innovative trial designs in the clinical development of drugs and the challenges and opportunities encountered.

Application of Quantitative Clinical Pharmacology in mAb Development
Yan REN, PhD
Director, Clinical Pharmacology, BeiGene

EMA Perspective: Regulatory Expectation on the Clinical Design of Biologics
Agnes SAINT-RAYMOND, MD
Head of International Affairs, Head of Portfolio Board, European Medicines Agency

Statistical Considerations in the Design of Clinical Trials for Biologics
Anny-Yue YIN, PhD
Associate Vice President, Biometrics and Medical Writing, CStone Pharmaceutical

Panel Discussion: All Speakers above and Invited Panelist:
Xuan LIU, MD, PhD
Physician, Global R&D Oncology Unit, AstraZeneca

Biologics Development

Session 0608 | May 23, 2019

15:30-17:00
HALL 2-A
2ND FLOOR

(Multi) Supply for Biological Products

SESSION CHAIR
Carlos O. GARNER
Vice-President, Global Regulatory Affairs, Regulatory, Lilly Global Regulatory Affairs-North America

In recent years, the proportion of biological products in the R&D pipeline of big pharmaceutical companies has been dramatically increasing, and the corresponding amount of clinical trials and marketing authorization applications in China have also increased year by year. China Regulators require more stringent risk management and control over the entire life cycle of biological products vs chemical drugs. For example,

- Supply of Clinical Samples: Clinical trials conducted in China, where clinical samples are only allowed to be produced from the same clinical supply site (in Europe and the United States, multiple clinical supply sites are allowed).
- Supply of Commercial Products: BLA application is only allowed to state one manufacturing site (in Europe and the United States, one license holder can entrust multiple manufacturers to produce);
- In the production section: mixed batch production is not allowed in China at present (that is, different batches liquid are not allowed to be mixed to prepare final preparations, each batch of preparations must be prepared by the same batch of raw liquids; in Europe and the United States, as long as each batch of raw liquids meets the quality requirements, mixing is allowed to prepare final preparations).

The aim of this session is to discuss the feasibility and risk control of multi-site supply of clinical trial samples and commercially manufactured products, as well as the quality control principles of mixed batch production of biological products.

Comparability Assessments to Support Manufacturing Site Changes for Biologics
Allison J. WOLF
Principal Research Scientist, Global Regulatory Affairs CMC, Lilly

Realizing the Potential of CMC Acceleration in Transforming Patient Access to New, Innovative Therapies - An Amgen Perspective
Roger GREENE
AExecutive Director, Regulatory Affairs CMC, Amgen, US

Regulatory Challenges in Maintaining Stable Drug Supply
Melly LIN
Senior Regulatory Manager, CMC Policy, Roche (China) Holding Ltd.

Generic Drug, CMC & GMP

Session 0701 | May 22, 2019

08:30-10:00
203AB
2ND FLOOR

Generic Drug Development Strategies under New Regulatory Environment - DIA/FDA/Yeehong Joint Session

SESSION CO-CHAIRS
Zhiang WU
Director, Research Center, Yeehong Business School

Lane CHRISTENSEN, PhD
Assistant Country Director, China Office, Office of International Programs, U.S. Food and Drug Administration

Using Generic drugs to replace original drug in order to reduce the government medical expenses plays the important role in medical insurance system for every counties. With the progress of adjustment about the definition and consistency evaluation of generic drugs in China, the "4+7" pilot purchase with volume was launched at the end of 2018, also indicating the arrival of the low profit of generic drugs. How to adjust the generic drug market layout and formulate generic drug research and development strategy are the new challenges to domestic generic drug research and development. The control actions of medicine shortage and drug adjustment policy taken by agencies is also the major concerns of the generic drugs company at the same time.

The session will invite the speakers from US FDA and industry to share the US generic drug development experiences in past 30 years, FDA's actions to prevent medicine shortage to ensure the supply chain, so as to provide reference for China's generic drug development.

Lesson Learned from the Development Path of Generic Drugs in the US
Yuexia LI, PhD
Vice President (Technical), PAREXEL Consulting, North America

FDA's Actions to Prevent Medicine Shortage to Ensure the Supply Chain
Ilisa BERNSTEIN
Deputy Director of the Office of Compliance, CDER, FDA

China's Generic Drug Development Strategy under New Regulatory Environment
Jifeng LEI
Chief Executive Officer, Anbison
Researcher, Yeehong Business College

Panel Discussion

Generic Drug, CMC & GMP

Session 0702 | May 22, 2019

10:30-12:00
203AB
2ND FLOOR

Life Cycle Generic Drugs Quality Assurance - DIA/FDA/Yeehong Joint Session

SESSION CO-CHAIRS

Lane CHRISTENSEN, PhD
Assistant Country Director, China Office, Office of International Programs, U.S. Food and Drug Administration

Jianhong YANG
Executive Director, Yeehong Business School

The core of replacing original drugs with generic drugs is to ensure the quality consistency of generic during the whole life cycle. Regulatory authorities from all over the world take the life cycle quality management as one of their most important considerations. As the main body of drug quality, generic drug manufacturers need to follow the GMP requirements about quality control system. Its continuous improvement in the life cycle requires the establishment of scientific based risk assessment and control strategies to ensure the products meet the expected quality, safety and effectiveness.

This session will focus on the importance of scientific considerations about continuous improvement, data quality and compliance to generic drugs life cycle quality management.

The Global Harmonization of GMP Standards and Quality Systems – PIC/S Perspectives
Susan LASKA
Chair of the Sub-Committee on Strategic Development, PIC/S
Senior Advisor for Medical Products to the Assistant Commissioner for Operations, ORA, FDA

Quality Risk Management - EU GMP Requirements - Implementation at Mmanufacturing Level
Andrei SPINEI
Scientific Administrator, Manufacturing Quality and Supply Chain Integrity, EMA

Data Quality and Compliance under GMP Requirements
Alonza CRUSE
Director of the Office of Pharmaceutical Quality Operations, ORA, FDA

Panel Discussion: Life Cycle Generic Drugs Quality Assurance
Panelists
All Speakers from Session 0701 & 0702

Medical Writing & Medical Affairs

Medical Writing

THEME LEADER

Xiaoling WANG

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

Session 0801 | May 22, 2019

08:30-10:00
305AB
3RD FLOOR

The Corner Stone of the NDA Submission: Preparation of the Clinical Study Report in Compliant with ICH E3 Guideline

SESSION CHAIR

Julia COOPER, PhD

Vice President, Head of Global Medical Writing Services, PAREXEL International Limited

With the progress of implementing ICH guidelines in China, the ICH E3 guideline (on Clinical Study Report, CSR) will be implemented in China as a tier 3 guidance. Preparing the CSR in the framework of ICH E3 is an important component of implementing ICH guidelines and accepting foreign data in China. It will also make the submission to other ICH countries/regions, such as US and EU, easier for China local sponsors.

This session will put this topic in perspective, inviting experienced speakers in the field to dissect and analyze the key points and implications of the guideline, and share practical and operational experiences of the CSR preparation, taking current China local regulatory requirement into full consideration. The topics of this session will cover from writing of the CSR body to preparation of the CSR appendices.

Under the ICH Umbrella, Why and How Should we Embrace ICH E3 Requirements to Develop Clinical Study Report
Ning ZHENG, PhD
Head of Medical Writing,Clinical Science and Medical Affairs, dMed Biopharmaceutical Co., Ltd.

How to Manage the Development of Clinical Study Report: Comparison of ICH E3 and NMPA Requirements
Jing ZHU
Clinical Reporting Manager, Clinical Medical Regulatory & Quality, Novo Nordisk China Pharmaceuticals

Trend in the CSR Preparation Requirements: Simplicity and Efficiency
Joan AFFLECK
Executive Director, Head of Medical Writing, Global Clinical Trial Operations, Merck, USA

Medical Writing & Medical Affairs

Session 0802 | May 22, 2019

10:30-12:00
305AB
3RD FLOOR

Development of Critical Clinical Documents in Compliance with ICH Guidance at the IND, NDA and Post-marketing Stages

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

High quality submission dossier is always requested by all the health authorities. Cross-functional experts work together to develop the critical clinical documents to support the submission. With the implementation of the ICH guidance in China, those clinical documents are prepared under the ICH framework and fulfill global standard in all ICH regions.

This session will provide an overview of the key clinical documents at the IND, NDA and post-marketing stages. We will use several documents as examples to discuss the document development, which will play the key role in the submission and the scientific communication with regulatory authority, via multi-functional joint efforts.

How to Prepare the Briefing Documents to Support Successful Scientific Communication Meeting with the Health Authorities
Bruce XUE, PhD
Head, Executive Director, Biostatistics & Data Sciences, TopAlliance Pharmaceutical Co., Ltd.

How to Prepare the Clinical Overview and Clinical Summaries
Helen WANG, PhD
Medical Writing Team Lead, Clinical Documentation, Sanofi R&D China

Medical Writing of Pharmacovigilance Documents throughout the Lifecycle of a Medicinal Product
Rui YANG, PhD
Director, Medical Writing Service,Parexel

Medical Writing & Medical Affairs

Medical Affairs

THEME LEADERS

Haidong CHI, MD, PhD
Chief Medical Officer, Lilly China

Yi LIU
Vice President, Clinical Science and Medical Affairs, dMed Biopharmaceutical Co., Ltd.

Session 0805 | May 23, 2019

8:30–10:00
305AB
3RD FLOOR

Post-market Real World Study

SESSION CHAIR
Qiang LI, PhD
Regional Epidemiology Lead Asia, Boehringer Ingelheim

This session will discuss the utilization of real world data and the challenges, the reliability and feasibility of real world data, and how to use real world evidence to support drug administration.

Utilization of Real World Data and Challenges
Siyuan ZHAN
Professor, Director, Department of Epidemiology and Biostatistics, School of Public Health, Peking University

Questions about the Reliability, Feasibility and Support for Drug Administration in Real World Evidence
Naiqing ZHAO
Associate Director, Health Statistics, School of Public Health, Fudan University

Case Study: The EMPRISE Study
Kui LIU
Senior Medical Advisor, Boehringer Ingelheim China

Session 0806 | May 23, 2019

10:00–12:00
305AB
3RD FLOOR

Medical Ethics Considerations under New Eco-system

SESSION CHAIR
Zhi LI
Head, Medical Affairs, Boehringer Ingelheim

From Gene Editing to Infant Malaria to Fight Cancer: be Aware of the Ethical Risks of Clinical Research in China
Liming WANG
Professor, Life Sciences institute, Zhejiang University

How to Do the Ethical Review Work Well under the New Regulatory Environment
Qi LU
Director, Ethics Office, Shanghai Renji Hospital

Ethical Considerations in Medical Affairs
Zhi LI
Director, Medical Affairs I, Boehringer Ingelheim

Medical Writing & Medical Affairs

Session 0807 | May 23, 2019

13:30–15:00
305AB
3RD FLOOR

Building-up Biopharma's Medical Affairs System

SESSION CHAIR
Yi LIU
Vice President, Clinical Science and Medical Affairs, dMed Biopharmaceutical Co., Ltd.

Medical Affairs Team Building for Innovative Biopharmaceutical Companies
Jay QU
Senior Medical Director, TopAlliance

Medical Research Reconstructs Benign Medical Interactions
Bo SHI
Marketing Director, Medical, Jiangsu Xinchen Medical, Hengrui Medicine

Medical Science Driven Life Cycle Product Management
Hui ZHOU
Vice President, Medical Science and Strategy, Oncology, Innovent Bio

Session 0808 | May 23, 2019

15:30–17:00
305AB
3RD FLOOR

Experiences Sharing on New Product Launch

SESSION CHAIR
Li WANG, MD, PhD
Senior Vice President, Lilly China Drug Development and Medical Affairs Center, Lilly China

Bridging China and Global: New Product's Launch in China Market
Qiong WU, MD, PhD
Disease Area Head, China Medical Department
Shanghai, Bristol-Myers Squibb

Medical Affairs and First in Class Drug's Launch in China
Liheng MA
Medical Affairs Director of Oncology China, Pfizer Investment Co.,Ltd.

Value of Medical Affairs in Merging Product's Launch
James JIN, PhD
Senior Medical Director, Lilly China

Pharmacovigilance & Risk Management

THEME LEADERS

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

Conny MO
Partner and Senior Medical Safety Advisor, Beijing RHGT Co., Ltd.

Howe LI, MD, PhD
Founder and CEO, DeltaMed

Session 0901 | May 22, 2019

08:30-10:00
305CD
3RD FLOOR

Safety Risk Management throughout Product Lifecycle to Prevent Patient Safety

- The Scientific Advices and Special Recommendations from Healthcare Professionals

SESSION CHAIR
Conny MO
Partner and Senior Medical Safety Advisor, Beijing RHGT Co., Ltd.

The concept "Risk Management throughout Product Life Cycle" was widely accepted in China industry and regulatory agency. In the recent years, regulators and industry already initiated kinds of communications and conversations on how patient safety should be well considered during product lifecycle risk management.
In this session, we would like to continue to discuss how subject/patient safety should be prioritized from the investigator and HCP's clinical practices perspective, our physicians and pharmacist from the different national hospitals will share their scientific view, insights and experiences covering the area of ethical review, drug induced liver injury, and cardiovascular toxicities.

The Key Considerations and Current Practices on Research Ethics and Ethical Review to Ensuring Study Subject Safety
Dayou WANG
Professor, Chief pharmacist, Pharmacy Department, Huashan Sub-Hospital of Fudan University

DILI in Clinical Practices and Its Importance in Drug Development
Chengwei CHEN
Chief Editor, Chinese Hepatology

Immune Checkpoint-Inhibitor Associated Cardiovascular Toxicities
Haiyan LI
Professor of Cardiology, Director, Drug Clinical Trial Center, Peking University Third Hospital

Pharmacovigilance & Risk Management

Session 0902 | May 22, 2019

10:30-12:00
305CD
3RD FLOOR

PV Methodologies and Advancement in Postmarketing Drug Safety Surveillance

SESSION CO-CHAIRS

Conny MO
Partner and Senior Medical Safety Advisor, Beijing RHGT Co., Ltd.

Yuhong WANG
Head of Patient Safety, Sinovant Sciences Co., Ltd

Postmarketing Drug Safety Surveillance is part of drug safety management throughout the drug lifecycle. With recently accelerated and prioritized regulatory review, how industry will continue to conduct postmarketing drug safety surveillance and make their decisions based on the risk-benefit evaluation timely?

In this session, we would like to bring knowledge and experience highlighted from postmarketing safety surveillance methodology level and technology advancement. Our discussion will include post approval research and surveillance, utilization of real world data and active surveillance topics.
As per the regulatory requirements for China RMP, an effectiveness assessment of risk minimization measures is requested to be submitted within a defined timeline after the implementation of RMP. It's a new challenge to the MAHs who make and implement the RMPs. Prof. Jan Petracek will share his experiences in the effectiveness assessment of risk minimization measures defined in the RMP in this session.

An Overview on Methodology of Postmarketing Drug Safety Surveillance

Phil TREGUNNO
Group Manager of the MHRA's Vigilance Intelligence and Research Group (VIRG), MHRA

Utilization of Real World Data (RWD) in Post Marketing Surveilliance

Conny MO
Partner and Senior Medical Safety Advisor, Beijing RHGT Co., Ltd.

Considerations and practices on Post Marketing Active Surveilliance Approaches

Minshi SU
Director, PV, SihuanPharm

Effectiveness Assessment of the Additional Risk Minimization Measures Defined in the RMP

Jan PETRACEK, MD
Chief Executive Officer, PrimeVigilance

Pharmacovigilance & Risk Management

Session 0905 | May 23, 2019

08:30-10:00
305CD
3RD FLOOR

Safety Requirements for IND Application Preparation

SESSION CHAIR
Howe LI, MD, PhD
Founder and CEO, DeltaMed

Center of Drug Evaluation (CDE) issued new requirements and procedure of IND application last year. Company can initiate clinical trial 60 days after submitting IND application if there are no additional comments or inquires from CDE, but new guidance requires more strict risk management to protect subject safety. Company faces the challenge to build up sufficient pharmacovigilance and risk management system; improve risk control plan in protocol; case processing for ICSR and evaluation; signal detection and aggregate report; and drug life-cycle risk/benefit management.

IND Safety Package Preparation and Risk Evaluation during Clinical Trial
Howe LI, MD, PhD
Founder and CEO, DeltaMed

How to Build up Sufficient Pharmacovigilance and Risk Management System
Hellen ZHANG
General Manager, JOINN MedSafe Co., Ltd.

Case Study for Protocol Risk Control Plan
Joyce LIU
Medical Safety Officer, I-Mab BioPharma

Session 0906 | May 23, 2019

10:30-12:00
305CD
3RD FLOOR

Real World Data in PV

SESSION CHAIR
Lynn ZHOU
PV Head for China, Asia and JPAC, Global Pharmacovigilance, Sanofi

Experiences and Case Sharing on China's Real World Safety Evaluation
Siyan ZHAN
Professor, Director, Department of Epidemiology and Biostatistics, School of Public Health, Peking University

Real World Data for Safety Assessment
Arnold CHAN
Director, Department of Medical Research, Taiwan University Hospital

Using Real World Data for the Evaluation of Risk Minimization Interventions in the US and EU
Jingping MO, MD, PhD
Senior Director, Epidemiology, Worldwide Safety and Regulatory, Pfizer

Pharmacovigilance & Risk Management

Session 0907 | May 23, 2019

13:30-15:00
305CD
3RD FLOOR

Risk Management Plan Preparation

SESSION CHAIR
Howe LI, MD, PhD
Founder and CEO, DeltaMed

Center of Drug Evaluation (CDE) issued risk management plan (RMP) guidance for NDA package last year. How to build efficient process to prepare Risk Management Plan (RMP) is a big challenge for company. We will have CDE officer and well-known international expert to discuss this topic.

CDE Guidance for Risk Management Plan
Howe LI, MD, PhD
Founder and CEO, DeltaMed

How to Prepare in-house Risk Management Plan Process
Chen HUANG
Deputy Medical Director, Drug Safety Science, Roche R&D Center

Case Study for Risk Management Plan (RMP) Preparation
Jan PETRACEK, MD
Chief Executive Officer, PrimeVigilance

Pharmacovigilance & Risk Management

Session 0908 | May 23, 2019

15:30-17:00
305CD
3RD FLOOR

Patient Centric Labeling as Risk Minimization Measures

SESSION CHAIR
Dorothy JIANG
Senior Hub Labeling Manager, Asia Labeling Hub, Pfizer (China) R&D Center

As a legally-bound document to present the drug's benefit/risk profile, labeling is one of the most important risk minimization measures for patient safety. After China joined ICH, global simultaneous clinical development makes it ever more important to draft/maintain drug labels for the benefit of Healthcare Professionals (HCPs) and patients. This session will discuss the current challenges for labeling and future trends from patient centric point of view. How does the industry draft/update the safety labeling to meet regulatory expectations under the current regulatory framework? The regulators will also share knowledge on reviewing drug labeling and patient labeling. Meanwhile, we will further discuss e-labeling for patients, which is one of the trends for labeling innovation and future digital health. This session will also discuss how to utilize the real world evidence for labeling updates.

Drug Labeling Activity in PMDA - both for Healthcare Professionals and Patients
Ryota KIMURA
Reviewer, Safety Department 1, PMDA

Evaluation of Adverse Drug Reaction for Drug Labeling: Key Learning from the FDA Guidance
Xiaoyan YANG
Director, PV and Drug Safety, BeiGene Ltd

E-labeling for Future Digital Health as Patient-centric Risk Management Measure
Rie MATSUI
Director, Regional Labeling Head for APAC, International Labeling Group, Pfizer Japan

Panel Discussion
All Speakers above and Invited Panelist
Wenya WANG, PhD
Researcher, Institute of Regulatory Science, Tsinghua University

Patient Engagement

THEME LEADER
Dayao ZHAO, PhD
Former Vice President and Lead, China Drug Development, Pfizer

ADVISOR
Kenneth GETZ
Chairman, CISCRP
Director of Sponsored Research, Tufts Center for the Study of Drug Development

Designing, developing and approving therapies that deliver meaningful health improvements for patients is our ultimate goal. To do so requires collaboration and partnership among patients, industry, payers, and regulators, and mechanisms for collaboration are evolving rapidly. An , clear patient voice that understands the challenges in the development of therapies is critical to success, as are the right processes and culture in industry and regulatory agencies to get the most out of the collaboration. DIA ensures impactful patient involvement in the health care product life cycle by convening the leaders in this space, sharing insights and best practices, and ensuring that our members and stakeholders are helping to set the future agenda.

This theme, composed of 4 sessions, will address meaningful patient engagement from global perspectives, China's progress, as well talks between patient groups and industry to deliver the messages of:

- How do we meaningfully engage patients and incorporate their voices into decision-making throughout the medical product life cycle?
- How do we become truly patient- (and people-) centric in our approach?
- How do we operationalize patient-centric approaches in our day-to-day work?
- How can we measure the effectiveness of our efforts, both for patient outcomes and to meet the needs of other stakeholders such as industry and regulatory decision-makers?
- What have we learned that can be used to drive more meaningful patient engagement?
- How do stakeholders best work together to leverage their collective power and expertise to promote meaningful involvement of patients?

Patient Engagement

Session 1005 | May 23, 2019

08:30-10:00
307, 3RD FLOOR

Patient Initiatives Program - The Global Perspectives

SESSION CHAIR
David YOSHII
Senior Director, Global Site Solutions, PAREXEL International

EMA's Perspective - Reinforce Patient Relevance in Evidence Generation
Agnes SAINT-RAYMOND, MD
Head of International Affairs
Head of Portfolio Board
European Medicines Agency

Implemented Patient Centricity Innovative Initiatives: Patient Data Access Initiative and Global Trial Finder
Jun LI
Asia Pacific Director of Regulatory Compliance,BioResearch Regulatory Compliance, J&J

Patient Centric Protocol in Study Design
David YOSHII
Senior Director, Global Site Solutions, PAREXEL International

Patient Engagement

Session 1006 | May 23, 2019

10:30-12:00
307, 3RD FLOOR

Patient Centricity Clinical Development

SESSION CHAIR
Jun LI
Asia Pacific Director of Regulatory Compliance, BioResearch Regulatory Compliance, J&J

High quality clinical trials are the core in the drug development. We have been facing challenges and struggles to recruit patients, maintain them in the trials, and as well for those remaining in the study, to keep good compliance with the procedures required by the protocol. Traditionally, the way to try to tackle the challenges has been to increase the recruitment volume, that has proved costly in time as well as resources. Ultimately this would result in delays in the registration of innovative drugs, and delays in patient access to the safer and more effective new drugs.

The concept of Patient Centricity has been the hot topic recent years, and it's expected to more effectively solve the problems during clinical development. The fundamentals for Patient Centricity are for the drug developers to partner with the patients from the onset of the development programs, with a great consideration for the patients regarding their burdens during the participation in the trials. We need to listen to the patient and work with them to find out mutually acceptable solutions and clearly communicate in a timely manner.
We invited expertise speakers to share their experiences from different aspects, e.g., protocol development, clinical operations and excavation of trials, and how AI could help tackle the challenges and problems we are facing. Panel discussion is to be arranged to encourage interactive and fruitful discussions on hot topics around this subject.

DIA - Tufts CSDD Patient Engagement in Drug Development
Yaritza Peña
Research Analyst
Tufts Center for the Study of Drug Development

Listening to Patient Voices
Xiaokang ZHANG
GCDO Trial Leader, Global Clinical Development and Operation, Janssen (China) Research & Development Center

Data-driven Patient's Experience Optimization in Clinical Trial
Zhi HE
Vice Chairman & Chief Strategy Officer, HLT Group
President, HLT Pharma

Panel Discussion
The Speakers Above and Invited Panelists
Maggie GU
Vice President, Clinical Operation, Junshi Pharma

David YOSHII
Senior Director, Global Site Solutions, PAREXEL International

Artificial Intelligence in Healthcare

THEME LEADER
Tong GUO, PhD
Vice President and Head of Sales, Greater China, IQVIA

From discovery to development, advanced analytics, artificial intelligence (AI) and the Internet of Medical Things (IoMT) has the potential to improve speed and efficiency at every stage of clinical research. Clinical research is still a slow, inefficient and expensive process. The high costs associated with the research and development of therapeutics ultimately affects the cost of health care. The human cost is with the patients and caregivers.

Artificial intelligence (AI) has the potential to transform the pharmaceutical industry, making the hunt for new pharmaceuticals quicker and more effective. With AI comes the potential to improve drug approval rates, reduce development costs, get medications to patients faster and help patients comply with their treatments. AI has been used as a powerful tool to identify targets for drug development, and with the ability to simulate and accelerate research processes, AI helps more drugs to be discovered and come to market quickly. The talk will focus on the latest advances in artificial intelligence for discovery, development and real-world evidence collection of drugs and geroprotectors.

The theme will focus on AI's recent advances from global perspectives, its applications in drug discovery, preclinical, and CMC, also solutions in conducting clinical trials. Panel discussion will allow the in-depth interaction and discussion with the audiences.

Session 1105 | May 23, 2019

8:30–10:00
203AB
2ND FLOOR

AI in Drug Development: Recent Advances from Global Perspective

SESSION CHAIR
PJ CHEN
Senior Vice President, APRINOIA Therapeutics

Artificial Intelligence will Transform Drug Development – Myths and Reality
Isabelle de ZEGHER, MD
Vice President, Integrated Solutions, PAREXEL, Belgium

Molecular Diagnostics and Drug Development in Personalized Medicine: The Role of AI
Marcus HACKER, MD
Professor, Director of the Clinical Department of Nuclear Medicine, General Hospital of Vienna, Austria
Professor of Medical University of Vienna

AI for Drug Discovery, Biomarker Development & Aging Research
Alex ZHAVORONKOV, PhD
CEO & Founder, Insilico Medicine, US

Big Data & Artificial Intelligence to Aid Patient Recruitment For Clinical Trials Involving Biosimilars and Rare Diseases
Raymond HUML
Vice President, Strategic Drug Development, IQVIA
Head, Global Biosimilars Strategic Planning
Biosimilars Center of Excellence

Artificial Intelligence in Healthcare

Session 1106 | May 23, 2019

10:30–12:00
203AB
2ND FLOOR

AI in Drug Development: Applications in Drug Discovery, Preclinical and CMC

SESSION CHAIR
Xing LI
CEO & Founder, Beijing Deep Intelligent Pharma Co., Ltd.

AI Drives Multi - Biomarkers Development
Catherine C.L. WONG
Professor, Peking University Health Science Center

Application of AI Algorithm in Drug Discovery
Zheng GUAN
Head of AI Drug Discovery, Deep Intelligent Pharma

AI Applications in Large Molecular CMC
Shuhei NARITA
Deputy Manager, Corporate Business Development Department, CMIC Holdings, Japan

Session 1107 | May 23, 2019

13:30–15:00
203AB
2ND FLOOR

AI and Automation in Conducting Clinical Trials: Solutions and Applications

SESSION CHAIR
Gaoyang LI
Data Scientist, Bayer

Embedding Big Data Analytics into Cloud Platforms to Improve Clinical Trial Performance with Business Intelligence
Jim Bob WARD
CEO & President, DATATRAK International, Inc.

The Analytics Revolution: Opportunities and Threats for Disrupting Clinical Development Operations
Zhiyang CHEN, PhD
Vice President, Professional Services, Medidata Solution

An Innovative Risk-Based Approach of TMF Quality Control Process
Jingsha WU
Quality Performance Management Lead, Quality Performance and Risk Management, Pfizer

Remote Clinical Trials Case Study
Sean CHENG
Digital Trials Lead Asia - Global Clinical Operations, Boehringer Ingelheim (China) Investment

Artificial Intelligence in Healthcare

Session 1108 | May 23, 2019

15:30–17:00
203AB
2ND FLOOR

Panel Discussion: AI's Myths and Reality

SESSION CO-CHAIRS

Tong GUO, PhD
Vice President and Head of Sales, Greater China, IQVIA

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

Invited Panelists

Isabelle de ZEGHER
Vice President, Integrated Solutions, PAREXEL, Belgium

Alex ZHAVORONKOV, PhD
CEO & Founder, Insilico Medicine, UK

Xing LI
CEO & Founder, Beijing Deep Intelligent Pharma Co., Ltd.

Catherine C.L. WONG
Professor, Peking University Health Science Center

Marcus HACKER, MD
Professor, Director of the Clinical Department of Nuclear Medicine, General Hospital of Vienna, Austria
Professor of Medical University of Vienna

Raymond HUML
Vice President, Strategic Drug Development, IQVIA

Zhiyang CHEN, PhD
Vice President, Professional Services, Medidata Solutions

Simranjit SINGH
CEO, Guardant Health Asia, Middle East & Africa (AMEA)

Preclinical Development and Early Phase Clinical Research

THEME CO-LEADERS

Pei HU, MD
Director, Clinical Pharmacological Research Center, Peking Union Medical College Hospital

Zaiqi WANG, PhD
CEO, InxMed

It is anticipated that numerous NMEs with me too in nature will enter early clinical development in China. But NMEs with real differentiation including first in class are emerging. Among NMEs under development, virtually 50% of NMEs drug development are oncology drugs. As the capacity and capability of early clinical development in China is emerging, we need to:

- Have a much high level of strategic view to invent new drugs by addressing real unmet medical need in 5-10 years
- How to effectively profile our me-too drugs to chose the winner?
- How to create value by having different clinical program using biomarkers or combination etc?
- How to use adaptive design including cohort expansion to increase efficiency of early trial?
- How to do the novel target first in class molecule human testing?
- How to best leverage the regulatory reform to do early development both in US and China/Asia?

In the DIA 2019, we will have global leading experts to provide their view and prospective.
In our sessions, we will have a separate track for oncology and non-oncology; me too and novel target or combination to be covered in both oncology and non-oncology session. In each session we will start with real unmet medical need by leading practicing physician. Then by leading regulatory and early clinical developing experts.

Session 1205 | May 23, 2019

08:30-10:00
2B, 2ND FLOOR

The Current Landscape and Pain Point of China Drug Development

SESSION CHAIR
Zaiqi WANG, PhD
CEO, InxMed

From the Clinical Perspective
Pei HU, MD
Director, Clinical Pharmacological Research Center, Peking Union Medical College Hospital

Challenges of Dose Selection in Early Clinical Trials
Yaning WANG, PhD
Regulatory Expert

Preclinical Development and Early Phase Clinical Research

Session 1206 | May 23, 2019

10:30-12:00
2B, 2ND FLOOR

Oncology Drug Early Phase Development

SESSION CHAIRS
Pei HU, MD
Director, Clinical Pharmacological Research Center, Peking Union Medical College Hospital

Research Strategies and Progress in Cancer Drug Development - Case Study of Icotinib
Yuankai SHI, MD, PhD
Professor, Vice President, Cancer Hospital Chinese Academy of Medical Sciences

New Trends in Early Cancer Clinical Trials
Yaning WANG, PhD
Regulatory Expert

Differentiation Strategy of Early Stage Cancer Drug Development - Seamless Study Design
Ning XU, MD
Executive Vice President, Head of Clinical Development and Regulatory Affairs, Zai Lab

Oncology Drug Early Development Experience in Japan
Toshio SHIMIZU, MD, PhD
Head of Physicians, Early Phase 1 Drug Development Unit, Department of Experimental Therapeutics
National Cancer Center Hospital (NCCH) Japan

Session 1207 | May 23, 2019

13:30-15:00
2B, 2ND FLOOR

Non-Oncology Drug Early Phase Development

SESSION CHAIR
Zaiqi WANG, PhD
CEO, InxMed

Drug Development in Pulmonary Arterial Hypertension, A Deadly Cardiovascular Disease
Zhi-Cheng JING, MD, PhD
Director, Office of Scientific Research
Director, Thrombosis and Vascular Medicine Center
Deputy Director, Dept. of Medicine, Fu Wai Hospital, State Key Lab of Cardiovascular Disease, National Center for Cardiovascular Disease

The Role of Clinical Pharmacology/Quantitative Pharmacology in Differentiated Development
Yang HE, PhD
Chief Consultant, EXDA Consulting LLC., US

Development Differentiation of Autoimmune Diseases: from Target Signaling Pathways to Disease and Patient Selection
Guliang XIA, MD, PhD
Head of Immunology Discovery, Roche R&D Center China

Preclinical Development and Early Phase Clinical Research

Session 1208 | May 23, 2019

15:30-17:00
2B, 2ND FLOOR

Translational Considerations from Nonclinical to Early Clinical

SESSION CO-CHAIRS

Pei HU, MD
Director, Clinical Pharmacological Research Center, Peking Union Medical College Hospital

Zaiqi WANG, PhD
CEO, InxMed

Some Considerations during the Transition from Preclinical to Clinical Development
Ping LIU, PhD
General Manager, Linking Truth Technology (LTT) Co. Ltd.

Non-clinical Safety Program Support Efficient Clinical Development
Jack XIE, PhD
Leader, Site Head of Pharmaceutical Sciences Shanghai, Roche China Animal Welfare Officer, Roche Pharma Research & Early Development, Roche Innovation Center Shanghai

Panel Discussion
INVITED PANELISTS

Yan KONG, PhD
Translational Medicine Expert, Renal Cancer and Melanoma, Peking University Cancer Hospital

Toshio SHIMIZU, MD, PhD
Head of Physicians, Early Phase 1 Drug Development Unit
Department of Experimental Therapeutics
National Cancer Center Hospital (NCCH) Japan

Professional Development

THEME CO-LEADERS

Carol ZHU, MBA
Senior Vice President and Managing Director
DIA China

Yi FENG
Vice President of Research & Development, Chief Strategic Officer, Kelun

Session 1302 | May 22, 2019

10:30-12:00
305E
3RD FLOOR

Career Development in Medical Affairs

SESSION CHAIR
Vivian MAO
Vice President, Head of Medical Affairs, Medical Affairs, R&D Beijing Hub, Merck Serono

Medical Affairs function developed very fast in recent years in China. With the new innovative products launched in the market with an increasing speed, Medical Affairs grows very fast consequently. Number of medical professional increases from several hundred 3-4 years ago to the current over thousands in Chinese pharma industry. The role of Medical Affairs also extends from Medical Advisor, MSL, Medical Information, to Medical Education, HEOR, RWE/RWD & other digital solution roles step by step. The age covers from 1960's to 1990's.

With China becoming a more aging society, and Healthy China 2030 strategy implementation, focus of disease management changes from treatment to prevention. The fast-track approval for new innovative product by NMPA, and new policy like 4+7 VBP Purchasing with Quantity, bring more challenges to medical lead on new product launch, as well as LCM.

In this session, we are honored to invite some talents to share their career stories. They will dialogue with the Medical Affairs Leaders about the challenges & opportunities in the career development.

Case Sharing: the Challenges & Opportunities in the Career Development – 1
Qiang ZHANG, MD, PhD
Chief Operation Officer, Drug Development and Medical Affairs Center, Lilly

Case Sharing: the Challenges & Opportunities in the Career Development – 2
Xuhui WANG
Medical Information Cluster Lead, Great China Region, Pfizer Medical Information

Case Sharing: the Challenges & Opportunities in the Career Development – 3
Pengjian JIA
Senior Medical Capability Manager, Medical, Bristol-Myers Squibb

Case Sharing: the Challenges & Opportunities in the Career Development – 4
Tingting REN, MD, PhD
Head of GM&E Medical Affairs, Merck Group

Case Sharing: the Challenges & Opportunities in the Career Development – 5
Vivian LIN
TA Lead, CAR-T, Medical Affairs, Xi'an Janssen

Professional Development

INVITED PANELISTS:

Li WANG, MD, PhD
Senior Vice President, Lilly China Drug Development and Medical Affairs Center, Lilly China

Chengming GU
Vice President, Head of Medical, Pfizer

James HE, PhD
Vice President, Medical Affairs, GSK

Angela YAN
Senior Vice President, Regulatory Affairs and Strategy
dMed Biopharmaceutical Co.,Ltd.

Matthew TAN
Senior Director, Global Clinical Research, R&D
Bristol-Myers Squibb (China) Company

Session 1305 | May 23, 2019

08:30-10:00
305E
3RD FLOOR

Career Development of Clinical Research Professionals

SESSION CHAIR
Richard ZHANG
Clinical Operation Vice President, LIVZON MABPHARM INC.

As of now, the changing situation of Chinese pharmaceutical industry provides new opportunities and challenges for the career development of clinical development professionals. This session will provide a platform for industrial young professionals, involving different roles (investigators/clinical researchers/sponsors/CROs), different positions to preview the future of the industry, from the perspectives of their analytical talent development opportunities and challenges to the audiences.

Round Table Discussion
- Analyzing the changing of industry environment's impact on clinical development, as well the career development
- Discussing the current risks and challenges in talent development of clinical R&D
- Advising on career pathway for young professionals

INVITED PANELISTS:
Jing ZHANG, PhD
Professor of Clinical Pharmacology, Director, Phase I Unit
Deputy Director, Clinical Trial Institute
Vice Director, Institute of Antibiotics, Huashan Hospital, Shanghai Medical College, Fudan University

Xiaohui LIU
Director, China Operation, ICON

Yi HUANG
Director, Clinical Research, BeiGene

Reako REN
Head of SMO Services, WuXi Apptec

Carol ZHU, MBA
Senior Vice President and Managing Director, DIA China

Chen DUAN
CRA, ICON DOCS

Susie SUN
HR Manager, Reistone Bio

Professional Development

Session 1306 | May 23, 2019

10:30-12:00
305E
3RD FLOOR

The Changes of Pharma's IND/NDA Access Strategy and the Critical Thinking of RA Professionals under Post-ICH Market

SESSION CHAIR
Yi FENG
Vice President of Research & Development, Chief Strategic Officer, Kelun

At the decision-making level of the company, when the scientific issues of the product research and development strategy are discussed, the strategic issues of clinical access/market access will be the next major step. All stakeholders (bio pharma, local and multinational pharma, investors, patients etc.) will undoubtedly pay close attention to the characteristics of access opportunities and risks in the market after China joined ICH. In what dimensions do RA personnel who provide answers and suggestions to the company's decision-making team need to think about these questions? In the post-ICH market, what are the key thinking capacities of RA professionals? How to construct their own career development plan are the key topics to be addressed in this session. The session will invite senior RA experts from different background to communicate and discuss with the participants.

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

Irene DENG
Head of China Regulatory Affairs, Sanofi

Cailian KANG
Managing Director, Hongshang Capital Equity Investment Co., Ltd.

Professional Development

Session 1307 | May 23, 2019

13:30-15:00
305E
3RD FLOOR

Career Development of Clinical Project Manager

SESSION CO-CHAIRS

Wencheng XU
Vice President, Clinical Operation, Shenzhen Chipscreen Biosciences, Ltd.

Tina TIAN
Head of Program Management, Roche Product Development in Shanghai, Roche (China) Holding Ltd.

Following the development of "Healthy China 2030", China pharmaceutical industry is grooming under the promotion of new drug innovation, expediting and improving regulatory environment. Clinical research is on critical path of drug innovation. For both companies and individuals, the agility and speed of clinical research capability building determines whether they could leverage the hard-won "window of opportunity" for its drug innovation industry.

DIA Clinical Project Management (CPM) Community is organized with a mission to promote the professionalism in Clinical project management by advocating its systematic and academic development in China, share the trend and progression of CPM under new environment to improve and speed clinical study development.

Case Study: How to Speed Clinical Study Timeline with New Regulatory Policy of NMPA
April HUANG
Director, Clinical Start-up and Monitoring, BeiGene

Lanna CHEN
Director, Clinical Project Management, Zai Lab

The Implementation of Big Data and New Technology to Benefit Clinical Project Management
Jia LU
Business Intelligence Competency Center (BICC) Head, Clinical Sciences & Operations (CSO), Sanofi China

Panel Discussion: Key Competencies of Clinical Project Manager and Career Development under the Dynamic Clinical Development Environment
Invited Panelists
Ning XU, MD
Executive Vice President, Head of Clinical Development and Regulatory Affairs, Zai Lab

Maggie GU
Vice President, Clinical Operation, Junshi Pharma

Jiaqing XU
Director, Clinical Operation, Bayer

Xiaokang ZHANG
GCDO Trial Leader, Global Clinical Development and Operation, Janssen (China) Research & Development Center

Hot Topics and Late Breakers

Session 1401 | May 22, 2019

08:30-10:00
307, 3RD FLOOR

ICH Q12 Update and Challenge of Post Approval Variations in China

SESSION CHAIR
Melly LIN
Senior Regulatory Manager, CMC Policy, Roche (China) Holding Ltd.

There are some differences in data requirements, regulatory reporting categories as well as timeline for post-approval CMC changes among regions, which leads to the complex product lifecycle management and sometimes hinders innovation and continual improvement in the pharmaceutical and biotechnology sectors. A new ICH Quality topic, Q12 was created to address this to achieve global harmonization of post approval variation management. Several ICH EWG members were invited to this session to provide in-depth introduction of ICH Q12 and its progress. In addition, we will discuss about the challenges we are facing in post approval change management in China and the opportunities ICH Q12 will bring to address these.

Introduction of ICH Q12, Its Progress and Hot Topics
Andrew CHANG, PhD
Vice President, Quality and Regulatory Compliamce, Quality, Novo Nordisk

Case Study on How Q12 Tool (PACMP) Benefit Post Approval Change Management
Wassim NASHABEH, PhD
Vice President, Regulatory Policy and International Operations,
Genentech, A Member of the Roche Group
Topic Lead ICH Q12 EWG, Representing BIO

Hot Topics and Late Breakers

Session 1402 | May 22, 2019

10:30-12:00
307, 3RD FLOOR

Ethnicity Bridging Strategy for China to Participate in Global Early Clinical Programs

SESSION CO-CHAIRS

Ping LIU, PhD
General Manager, Linking Truth Technology (LTT) Co. Ltd.

Yuyan JIN
Head, Clinical Pharmacology and DMPK, Roche

Recent regulatory reforms encourage China to join global clinical trials as early as Phase I stage under conditions that no special ethnic differences are expected for the investigational product. The regulatory change will not only further increase contributions of China to the clinical development of innovative medicines worldwide, but also bring innovative medicines to Chinese patients earlier. However, most of the time, the dilemma is no or limited clinical data were available for a specific investigational product at the time when the clinical trial application was submitted to apply for China participation in global Phase I program, and it was difficult to assess ethnic differences in this situation. This session is intended to discuss potential preclinical (or clinical) evidence needed to adequately support the ethnicity bridging for a compound at early stage pending on the characteristics of its absorption, distribution, metabolism, and excretion, supporting China to participate in early global clinical development program.

Clinical Pharmacology Considerations of Early Ethnicity Bridging
Jean Eric CHAROIN
Global Head of Clinical Pharmacology in Immunology, Infection, and Ophthalmology, Roche

Design and Evaluation of MRCT on Early Stage Antitumor Drugs
Xiaoyuan CHEN, MD, PhD
Director, GCP Office, Beijing Tsinghua Changgung Hospital

Real-time Bridging Strategy for Early Drug Development Simultaneously in China and the US
Rui CHEN, MD, PhD
Director of Phase I Ward, Peking Union Medical College Hospital (PUMCH)

Hot Topics and Late Breakers

Session 1406 | May 23, 2019

10:30-12:00
308, 3RD FLOOR

CRC Forum - Focus on China SMO Good Service and Deepen CRC Professional Service Capabilities

SESSION CHAIR

SESSION CHAIR
Shuting LI
Secretary-General of Clinical Research Promotion Public Welfare Fund

In recent years, a large number of China's innovative drugs have entered clinical research stages, and the number of clinical trial projects has grown tremendously. The test of the ability of innovative drugs for clinical trials has made researchers face enormous challenges. How can the Clinical Research Coordinator (CRC) be able to meet the above requirements with sufficient manpower and improve the research ability to do the specific work of innovative drugs, which is an urgent problem for the SMO industry in China. This venue will discuss this.

Current Situation and Development Trend Prospect of SMO Industry in China in Recent Years
Lance GAO
General Manager, Beijing 360CQA Medical Research Co., Ltd

CRC Role & Responsibility Survey Results in 2018
Yue WANG
Vice President, SMO Clinplus co.,Ltd

Expert CRC Profile from Client Appreciation Letter and Survey
Reako REN
Head of SMO Services, WuXi Apptec

The Situation of Chinese Investigators undertake Clinical Trials of New Drugs and Cognitive Analysis on CRC Performance
Cathy CHEN
Medical & Portfolio & Marketing Director
Marketing Information Department, Beijing Linkstart Med-Tech Co.,Ltd (SMO)

Panel Discussion
MODERATOR
Shangyuan GUI
Vice President, Nanjing Huawe Medicine Technology Group co., Ltd

INVITED PANELISTS
Sijia HU
Hangzhou Simo Co., Ltd

Zheyuan WANG
Beijing Excellence Angel Medicinal Technological Progress Co., Ltd

Hot Topics and Late Breakers

Session 1407 | May 23, 2019

13:30-15:00
307, 3RD FLOOR

eCTD: Industrial Strategies under the New Regulatory Standards in China

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

Since the electronic drug approval standards was globally set up in 2000, many regulatory bodies in the ICH community have stipulated relevant regulations and standards global-wide to implement eCTD process. Recently, NMPA had adapted ICH M4 guidance of common technical documents (CTD) for human drug registration application, which is also applicable to an IND package application. This regulation would directly affect regulatory administration of import and export and marketing authorization for drug products as well. What are strategies by a pharmaceutical industry to be compliance with this new technical regulation? The presenters from domestic and oversea pharmaceutical companies will overview historical footprints and future regulatory trends of eCTD standards in the past 15 years, and share experiences of strategies implementation by sponsors to comply to this ICH technical standards.

Historic Review and Future Trends of eCTD Development in the Past 15 Years
Shawn WANG
Chief Executive Officer, MedXview Inc.

Strategies of eCTD Submission – an Industrial View
Fang ZHOU
Associate Director of AP Region, Regulatory Operation, J&J China

How to Prepare eCTD Submission by Chinese Enterprises
Meg WANG
eCTD Manager, Data Scientific Center, Hengrui

DIA China Community Exchange & Engage Session (E&E)

Regulatory Affairs Community E&E Sessions

May 22, 2019

10:00 - 10:45
Community E&E Zone 1
2nd Floor

Regulatory Affairs Community E&E Session - Part 1

MODERATOR
Handsome JI
China Publishing Hub Lead, Pfizer

DIA China RA Community & Core Team Introduction
Handsome JI
China Publishing Hub Lead, Pfizer

The Survey of China RA and the Activity Form of DIA China RA Community
Kris Wang
Associate Regulatory Affairs Director, Novo Nordisk (China) Pharmaceuticals Co., Ltd.

Advancing Regulatory Science in Every Segment of Regulatory Affairs
Victoria QU
Director, Regulatory Affairs, Global Strategic Regulatory, Abbott China

May 23, 2019

12:30 - 13:15
Community E&E Zone 2
2nd Floor

Regulatory Affairs Community E&E Session - Part 2

MODERATOR
Handsome JI
China Publishing Hub Lead, Pfizer

Discussion on strategies for dual filing of biologics in China and US
Audrey XU
RA Manager, Manager of Global Regulatory Affairs, Wuxi Biologics

Consideration and Challenge of China Drug Marketing Authorization Holder Policy
Jun LI
Manager, Global Regulatory Submission, Covance

DIA China Community Exchange & Engage Session (E&E)

Digital Health Community E&E Session

May 22, 2019

10:00 - 10:45
Community E&E Zone 2
2nd Floor

Digital Health Community E&E Session: Digital Technology Discussion in Clinical Research

MODERATOR
Juan DU
Statistical Analysis Senior Manager, dMed Biopharmaceutical Co.,Ltd.

While Digital Technologies are making changes to a broad range of business, drug development has growing demand for their landing and application. In this session, we shall brainstorm to prompt some ideas and solutions based on the topics of “Experience Sharing”, “Automation” and “Clinical Data Visualizations & Machine Learning”.

Brief Overview

Panel Discussion

Table 1: Topic: Experience Sharing about Digital Technology

- What digital platform/information you are most familiar with for clinical trials?
- Can you simply describe its concept and operation modes?
- Is there any deficiency of the digital technology that you apply? What are these deficiencies like? Do you have any clue to address them?

Table 2: Topic: Automation Using the CDISC Standards

- Do you know any tool or platform to drive automation across the clinical research data lifecycle using CDISC standards?
- Can you introduce the tool(s) briefly?
- Can it achieve the data integration between Research System (EDC, CTMS, etc.) and healthcare systems (EHR, etc.) for sponsors of clinical investigators and regulators? If not, which areas should be improved?

Table 3: Topic: Clinical Data Visualizations & Machine Learning (ML)/Artificial Intelligence (AI)

- What kind(s) of interactive visualization features would you like to have for SUBJECT and STUDY level data review, as well as data anomaly DETECTION?
- Do you have any use case of ML and AI implementation specific to the pharmaceutical industry?
- What kind(s) of challenges, complexities and undeveloped standards do we have to explore ML & AI approaches in data-driven research and drug development?

Conclusion

DIA China Community Exchange & Engage Session (E&E)

Clinical Data Management E&E Session

May 23, 2019

10:00 - 10:45
Community E&E Zone 1
2nd Floor

Clinical Data Management E&E Session

MODERATOR
Mary WANG
Clinical Data Management Team Lead, Boehringer-Ingelheim

Introduction of DM Community and Activities of This Year
Mary WANG
Clinical Data Management Team Lead, Boehringer-Ingelheim

Knowledge Competition of DM
Aimee WANG
Associate Director, Clinical Data Management, IQVIA

Panel Discussion on DM Difficulties and Issues
Invited Panelists:
Charles YAN, PhD
Hualong SUN, MD, PhD
Dorothy Dai
Huayan DUAN

DIA China Community Exchange & Engage Session (E&E)

PV Community E&E Session

May 23, 2019

12:30 - 13:15
Community E&E Zone 1
2nd Floor

PV Community E&E Session: Risk Management, from IND to NDA

MODERATOR INVITED
Lynn ZHANG
Manager, Medical Safety, Xi'an Janssen Pharmaceutical Company

According to 'Announcement of China National Drug Administration on Adjusting Review and Approval Procedures for Drug Clinical Trial ([2018] No. 50)' and 'Requirement and Format of Risk Management Plan for Oncology Products NDA Submission' issued by CDE, Risk Control Plan (RCP) and Risk Management Plan (RMP) are required. Development Update Safety Report (DSUR) is also required in the process of clinical trials.

PV E&E secession on 23 May will further discuss on this topic, e.g. how to prepare RCP, DSUR and RMP; considerations and questions in implementation. There will be an interactive discussion regarding implementation difficulty and/or questions needs further clarification.

Panel Discussion:
1. Opening remark and guest introduction
2. DIA China PV Community Introduction---Mingfang Zhu
3. Guests speech

Mock case discussion, including but not limited to: question raise-up for further discussion, experience sharing by meeting attendees. Guests will comment or supplement

Invited Panelists:
Conny MO
Dr. Howe LI
Minshi SU

White Paper Showcase

Session 1501-1 | MAY 22, 2019

8:30-10:00
3rd floor, 302

Preclinical and Clinical Research & Strategies and Tactics for Registration in China and Overseas

Dr. Hua Yang
CSO, Pharmaron

We will introduce the end – end integrated clinical research platform in Pharmaron and CR Medicon, including:

- The strategy of China Pharmaceuticals Development in both domestic and overseas: Key issues of project evaluation, work in domestic, registration, cost and market
- Clinical Pharmacology Studies of New Drugs Conducted in the US Meeting the China Requirement
- Clinical metabolism studies of 14C-Labelled Drugs

The strategy of China Pharmaceuticals Development in both domestic and overseas: Key issues of project evaluation, work in domestic, registration, cost and market

Prof. Leon Sun
Chief Strategy Officer, CR Medicon

Clinical Pharmacology Studies of New Drugs Conducted in the US Meeting the China Requirement

Chris Hickey
Vice President of Clinical Business Development, Pharmaron

Clinical metabolism studies of 14C-Labelled Drugs

Andrew Slack
Vice President of Radiolabelled Sciences Business Development, Pharmaron

White Paper Showcase

Session 1502-1 | MAY 22, 2019

10:30-12:00
3rd floor, 302

Enabling Innovations through Digital Transformation

Jiaxin Chen
Marketing Director

Opening Speech
George Lee, MD
VP, Clinical Operations and Country Leader, China

Drug development timeline and cost keep increasing while reimbursement is diminishing; a paradigm shift is needed in the way we develop drug. Digital technology is set to transform how patients experience healthcare, improve clinical research and provide an environment of connected data that forms new insights.

In this session, we will provide insights on how Parexel leverages data, platform, process and expertise in clinical, regulatory and technology, to transform trial design, clinical operation and other aspects in drug development. In addition, we will discuss the gap between vision and reality of digital transformation in China; what are the opportunities and requirements for medical innovation under the new environment from regulatory perspectives.

Adaptive Trial Designs – Time to implement innovation in the big data era
Martin Roessner PhD
Corporate Vice President, Biostatistics

Can Artificial Intelligence Replace Blinded Independent Review for Medical Imaging in Clinical Trials?
Peter Steiger PhD
VP, Parexel Informatics

Sensors and AI Create Intelligent Patient Digital Assistants, Opening New Possibilities Around Patient Centricity
Dr Isabelle de Zegher, MD, MSc
VP, Integrated Solutions

Regulatory insights on China Digital Transformation
Victor Cheng M.D Ph.D
VP, Technical, RCS - REGULATORY

White Paper Showcase

Session 1501-2 & 1502-2 | MAY 22, 2019

8:30-12:00
3rd floor, 303

Clinical research quality of innovative drugs

SESSION CHAIR
Wang Nana
Clinical research quality of medical innovation

In recent years, the state has issued a series of policies to encourage pharmaceutical companies and research institutions to increase investment in R&D innovation, with promoting the innovative production capacity,accelerating the process of drug approval, supporting industrial development, and stimulating the innovative transformation of pharmaceutical companies. Pharmaceutical products will shift from the generic-based, to innovative-based.It is estimated that in 2022, domestic demand will bring a market volume of $9.2 billion to domestic CROs in China, double the amount in 2017. Meanwhile, we are in the era of demanding on more individualized/precise medical treatment. The management of medical investment risk and the construction of legal system will become an urgent issue. On this occasion, we are honored to invite experts from relevant fields to discuss the clinical research quality of medical innovation in this conference, and to jointly discuss the key issues on innovative-driven R&D and clinical trials. Your insights and involvement will be highly respected, and we're looking forward to discuss with you and contribute to the innovation of drug development in China.

Opening speech
Cai Xuliu
The founder chairman of 3AUDIT

Risk-based approach to clinical evaluation Speaker:Leadership of Center for Drug Evaluation,NMPA
Risk control and compliance management in pharmaceutical R&D
Yan Xingxing
Risk advisory director of Ernst & Young

The performance and analysis of innovative pharmaceutical companies in the capital market
Liang Jin
Managing Director of CICC

Legal system promotes pharmaceutical innovation supervision
Wang Chenguang
Former dean of the Tsinghua University School of Law, Professor of law

Planning and quality assurance for clinical trials of new drugs
Fan FAN
Senior medical consultant of 3AUDIT

3AUDIT facilitating pharmaceutical innovation
Beijing 3AUDIT Medical Services Co., Ltd.

White Paper Showcase

Session 1505 | MAY 23, 2019

8:30-10:00
3rd floor, 302

Trial.Link——Lifting the Efficiency of Clinical Trials

SESSION CHAIR
Prof. Zhongyuan Xu
Director of Pharmaceutical Clinical Evaluation Research Professional Committee, China Pharmaceutical Association; Director of GCP Institution, Nanfang Hospital

Trial.Link platform links all participants of clinical trials, including sponsors, institutions, investigators etc.. With the efficiency of data intelligence and networking, we keep making progress on standardization, informationize and large scale.

Trial.Link——Lifting the Efficiency of Clinical Trials

Trend of Clinical Trials: Professionalism, Networking and Intelligence
Prof. Zhongyuan Xu
Director of Pharmaceutical Clinical Evaluation Research Professional Committee, China Pharmaceutical Association; Director of GCP Institution, Nanfang Hospital

Efficiency of Networking in Clinical Trials
Dong Ji
CVice President,Chief Medical Officer, Shanghai Omni Pharmaceutical Co., Ltd.

Trial.Link——Lifting the Efficiency of Clinical Trials
Yitian Peng
Co-Founder of DRA100

White Paper Showcase

Session 1506-1 | MAY 23, 2019

10:30-12:00
3rd floor, 302

Conducting Clinical Trials Globally

SESSION CHAIR
Johnathan LEE
WuXi Clinical General Manager

The feasibility and operability of global clinical trials are described by U.S. Team and China Team from different perspectives, including the United States, Europe, Australia, Japan, South Korea and other countries. According to different regulatory affairs and the environment of clinical trials, it is specifically analyzed how we could operate global multi-center clinical trials in an efficient and high-quality way.

Globalized clinical development strategy and planning consideration.
Dr. Fred Hausheer
Global Chief Medical Officer

Globalized clinical trial design consideration for meeting different regulatory requirements
David Ng
VP, Biometrics

Globalized clinical trial operation consideration on compliance and efficiency
Nicole Shih
Associate Director, Portfolio Management

White Paper Showcase

Session 1506-2 | MAY 23, 2019

10:30-12:00
3ird floor, 303

How to ensure the integrity and accuracy of data as well as the safety of subjects in clinical trial with advanced digital tools.

SESSION CHAIR
Li Yin Ph.D
Chief Business Officer Chief Intelligence Officer, Proswell Medical Company

In recent years, Administrative regulations of Drug in China has experienced a constant improvement and has been integrated with international standards. As a result, pharmaceutical enterprises have to continuously improve their own abilities, or get the help from Contract Research Organisation (CRO), in order to guarantee the integrity, accuracy, and credibility of clinical trial data , as well as the safety ,right and welfare of the subjects. All of these development of digital technology has greatly enhanced the management ability and efficiency in drug research and development.

Cooperating with many outstanding digital solution platforms, Proswell has comprehensively used advanced digital tools in clinical trials and gained wider experience in many fields, such as clinical trial management, clinical registration, and pharmacovigilance. Proswell has greatly improved the compliance, quality and efficiency of clinical trials.

Especially, Clinical Resource Planning (CRP) can be comprehensively utilized in clinical trial management, electronic data and file management, statistical analysis management, human resources and financial management, etc. Electronic Trial Master File (eTMF) can provide supports to documents management with high efficiently and accurately. Electronic Common Technical Document (eCTD)can support the enterprises to successfully accomplish the electronic submission of registration documents with digital management tools. PV database of Multi-clients independent management operation can conduct input, processing, analysis, evaluation and submission of drug safety data as well as signal exploration, risk management and extensive work management in pharmacovigilance(PV) while ensuring a high confidentiality of customer safety data.

During this symposium, Proswell has invited some experts to introduce the application of these advanced tools, sharing skills and experience with our colleagues, providing optimized solutions to help enterprises carry out clinical trials, registration management and PV, etc.

Tang Xue Mei
Vice President of Operations, Medical Director, Proswell Medical Company

The Design of Proswell ETMF-- to be the owner or the slaver of tools
Arwen Lee
Director of Biostatistics&DM, Oceanus+ medicai development Co.Ltd

Electronic Drug Registration - the silhouette of electronic Common Technical Document (eCTD)
Hu Qiong
eCTD Product Director of DoubleBridge, DoubleBridge Technologies Inc.

We Bring The Future To Life
Ye Zha
Greater China Business Director, ArisGlobal

White Paper Showcase

LUNCH Exchange Session | MAY 22, 2019

12:10-12:55
2nd floor
HALL 2-C

AI empowers the future of medicine

The value and application of big medical data drives the development of the healthcare industry. Big data science and medical artificial intelligence technologies are revolutionizing clinical trials. Enhancing the predictability of clinical research, shortening the time of clinical research, improving the quality of clinical research and maximizing the value of products are innovative clinical research solutions driven by big data.

HLT PHARMA's iClinicalTrail is a clinical trial empowered by artificial intelligence. From the feasibility evaluation of research and design to the research and implementation of quality control empowered by artificial intelligence and machine learning, it runs through and empowers key clinical I-IV nodes, such as recruitment, EDC automatic input, remote SDV management and overall management, to reduce costs and improve efficiency. In February 2019, HLT joined hands with PPD to further develop the Chinese market and serve the global market to prove value and advantages through real world research.

12:10-12:30 | HLT & PPD Cooperation Announcement
HLT Presentation
Jiming Xu
HLT CEO

PPD Presentation
Pending
PPD representative

12:30 am-12:55 | iTrial / iGCP Product Introduction
Data and Value, HLT empowers the full lifecycle of drugs
Zhi He
HLT President

White Paper Showcase

LUNCH Exchange Session | MAY 22, 2019

12:10-12:55
2nd floor
HALL 2-B

Health Trend Ten: The year of change, innovation and challenge ahead

SESSION CHAIR
Leigh Householder
Managing Director, Innovation and Insights, Syneos Health

We work in an industry in the middle of radical and sustained change. Nowhere is that change happening faster than in China, a region that is quickly breaking new ground in critical areas like real world evidence development and flexible commercial strategies.

In this talk, global and regional leaders from Syneos Health will share highlights from their Health Trend Ten report and talk about the important conversations they are having with clients now about how to best respond to those market shifts in 2019 and beyond.

The Health Trend Ten report includes perspectives from people working on the frontlines of healthcare around the world and important data on how to prioritize which new expectations that are most critical for life science leaders to act on now.

In this presentation, our speakers will focus on two specific shifts:
1. Accelerating evidence: the new strategies for supporting a continuous stream of evidence relevant to both regulators and medical decision makers long past initial approval
2. Relearning launch: bold new approaches to maintaining optionality and flexibility in an ever-changing commercial environment

Throughout this talk, we hope to provide attendees with a view into what decisions, strategies and investments will ensure that their organizations lead the change ahead – rather than be left behind by it.

Local market perspective
Miranda Porter, PhD
Executive Vice President, General Manager APAC, Clinical Development, Syneos Health

Graham J. Birrell, PhD, MBA
Vice President, CNS Clinical Development, Syneos Health

Lei Zhu
Director, Regulatory Consulting, Syneos Health (Beijing) Inc. Ltd.

White Paper Showcase

LUNCH Exchange Session | MAY 22, 2019

12:10-12:55
2nd floor
201AB

New Digital & AI Era for Clinical Development

SESSION CHAIR
Wenqi Hu
DIP Senior Product Director

Digitalization has been part of our life everyday and AI is leading the next wave. This is also a new era for clinical development domain where innovation is happening at unheard-of speed.

At this luncheon seminar initiated by DIP, a world-leading AI technology company for drug R&D, we invite speakers from top pharmaceutical company, clinical trial site and CRO to tell their own stories of innovation in clinical development.

BeiGene will be sharing how their first-in-the-world E-SAE platform forms an EDC-to-Submission online process that transforms SAE reporting. Linear from Australia and CMIC from Japan will share their amazing experience with Medrio eSource that digitalizes clinical trials, leading to great efficiency improvement and cost reduction.

SAE Reporting in AI Era: E-SAE Platform of BeiGene
Dr. Bing Du
APAC Head of Safety Operations and Sr.Medical Director of PV & Drug Safety, BeiGene USA.

New EDC Era: eSource in Australian Trial Site (Linear)
Simone Knab
Enterprise Data Architect at Linear Clinical Research Ltd

New EDC Era: CMIC New Way to Clinical Development
Yoshihito KONDO
CMIC HOLDINGS - Divisional Head of Clinical Research

White Paper Showcase

New Technology & Products Showcase Session | MAY 23, 2019

9:30-10:00
3rd floor, 303

Professional Solutions for Drug Regulatory eSubmissions —— DXC Products and Services Introduction

SESSION CHAIR
Winnie Yang, MBA
Head of LS BPS China Operations/Senior eCTD Consultant

Nowadays, eCTD submissions have been widely used in Drug Applications. Is your company ready to implement this new method of electronic submissions? Do you know how to prepare a high-quality eCTD submission accurately, efficiently and economically?

DXC has the flexible softwares and professional outsourcing services which provide you the best customized, whole process solutions including task assignment, dossier authoring, archiving, eCTD publishing and regulatory lifecycle management.

In this session, DXC will introduce the new software suite - Life Sciences Connected Platform, regulatory dossier authoring tool – Writer, PDF editor – Toolbox, and eCTD publishing tool – eCTDXPress.

Improve data flows with an intuitive, integrated platform - DXC Life Sciences Connected Platform (LSCP)
Mr. William Joseph Hamilton
Sr. Product Integrator

eCTD Submissions, DXC could be your professional guide. – DXC Total Regulatory Solutions
Winnie Yang, MBA
Head of LS BPS China Operations/Senior eCTD Consultant

DIA CHINA
Innovation Theater Activities

Innovation Hub Presentation | May 21st, 2019 | 1st Floor

15:45-15:55	**Discussion about CTD Translation**	
		Jean Marie Blanc Beijing Codex Translation Co., Ltd. | Booth#N02

Innovation Hub Presentation | May 22nd, 2019 | 1st Floor

10:05-10:15	**Breaking through Mediocre, Heading for Innovation**	
		Vincent YU Genco Medical Technology Co., LTD. | Booth#N01
10:15-10:25	**IRTON 4G — Born for Complex Studies**	
		Danni LIU Shanghai Shanhu Health Technology Co., Ltd. | Booth#N05
15:05-15:15	**How to Conduct Post-marketing Intensive Surveillance Study**	
		David WANG Wuxi Clinical Research and Development Co., Ltd. | Booth#N06
15:15-15:25	**New Practice to Site Management**	
		Ryan YUAN Beijing EasyTrial MedTech Co., Ltd. | Booth#N03

Innovation Hub Presentation | May 23rd, 2019 | 1st Floor

10:05-10:15	**Medical Translation Is Not That Easy**	
		Eason REN EC Innovations | Booth#N07
10:15-10:25	**Clinical Research Design and Successful Marketing Strategy of Innovative Drugs in China**	
		Lulu WANG Beijing Highthink Pharmaceutical Technology Service Co., Ltd. | Booth#N08

Poster | May 22nd, 2019 | 1st Floor

10:30-12:00	**Poster Presentations and Award Ceremony**