主办单位 | Host

DIA

10th Years Anniversary

2018中国国际药物信息大会暨第十届DIA中国年会

The 10th DIA China Annual Meeting

5月22日 ICH 主题日

5月23-25日 会议、展览及交流互动 | 北京国际会议中心

May 22 ICH Day

May 23-25 Conference, Exhibition, Networking & Exchanges

Beijing International Convention Center

STEERING COMMITTEE

Pei HU, MD, Prof.
Director, Phase I Unit
Clinical Pharmacological Research Center
Peking Union Medical College

Bin XUE
Director-General
China Center for Food and Drug International Exchange China NDA

Ruyi HE, MD
Chief Scientist
Center for Drug Evaluation, China NDA

Jingsong WANG, MD
CEO
Harbour Biomed (HBM), China

Shun LU, MD, PhD
Director, Shanghai Lung Cancer Center
Shanghai Jiaotong University, China

Xianglin ZHANG
Dean, Yeehong Business School
Shenyang Pharmaceutical University, China

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

INTERNATIONAL ADVISORY COMMITTEE

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Senior Advisor, Strategic Programs, CDER
US Food and Drug Administration

Mac LUMPKIN, MD
Deputy Director, Integrated Delivery
Lead for Global Regulatory Systems Initiatives
Bill and Melinda Gates Foundation

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Chairman, CISCRP, Director of Sponsored Research
Tufts Center For the Study of Drug Development

Sandra MILLIGAN, MD, JD
Chair, Fellows of DIAHead of Regulatory Affairs and Safety
Merck Research Laboratories

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

PROGRAM COMMITTEE

Regulatory Science

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

Irene DENG
Head of China Regulatory Affairs, Sanofi

China NDA Townhall

Jin CUI
China Center for Food and Drug International Exchange (CCFDIE)

Innovative Breakthrough in Therapy

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

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

Jessica LIU
Vice President, Head of International Business
TigerMed Medical

Sunny ZHU
Chief Medical Officer, Infectious Diseases, Everest Medicines

Clinical Development

Hannah CHEN
Director, Asia Pacific Strategy Lead
BioResearch Quality & Compliance, Janssen

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

Reako REN
Head of SMO Services, WuXi Apptec

Quantitative Science

Luyan DAI, PhD
Executive Director, Clinical Development
Harbour Biomed

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

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

CMC & Generic Drug

Xianglin ZHANG
Dean, Yeehong Business School
Shenyang Pharmaceutical University, China

Biologics & Biosimilar Development

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

Medical Affairs & Medical Writing

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

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

Safety & Pharmacovigilance

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

PROGRAM COMMITTEE

Patient Engagement

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

Jane CAI, PhD
Senior Advisor
Chinese Organization for Rare Disorders
Former Managing Director, DIA China

Big Data Research and Artificial Intelligence in Healthcare

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

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

Medical Devices

Amber WANG
Vice President, Regulatory Affairs & QA,
SmithNephew

POSTER REVIEW COMMITTEE

Benny LI, PhD
Chief Medical Officer
Hansoh Pharmaceutical Group Co. Ltd.

Kevin LI
Head of Study Management China,
Clinical Pharmacology Asia/PC,
Global Development Beijing, Bayer Healthcare
Company Limited

Huayan DUAN
Associate Director, Project
Management,Harbour BioMed

Jeannie QIU
Associate Director, Biometrics, BeiGene

Dorothy DAI
Associate Director , Clinical Data Management,
Meta Clinical Technology Co. Ltd.

Yolanda WANG
Drug Safety Project Manager, PV, dMed

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

- ICH Day
- Opening Plenary
- Regulatory Science
- China NDA Townhall
- Innovative Breakthrough in Therapy
- Clinical Development
- Quantitative Science
- Biologics and Biosimilars
- Generic Drug, CMC & GMP Inspection
- Medical Writing & Medical Affairs
- Pharmacovigilance & Safety
- Patient Engagement
- Artificial Intelligence in Healthcare
- Medical Devices
- Hot Topics and Late Breakers
- White Paper Showcase
- DIA China Community Exchange & Engage Session
- DIA China Innovation Theater Activities

Tuesday, May 22th | 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. 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. CFDA will actively participate in the design and enacting of international rules, to speed up the international innovative products to China and to fulfill the unmet medical needs of China, at the same time, to improve the innovation ability and international competitiveness of the Chinese pharmaceutical industry.

CNDA (former CFDA)/DIA Joint ICH Day will invite the core members from international regulatory agencies, industry and academia of ICH committee and working group, to share the latest development of ICH, the specific requirements of Tier 2 technical guidelines and experiences of ICH implementation in China and other countries as well as the ICH training strategies. The joint training will include parallel workshops on E2/M1, E6, E9 & E17, E14 and M4/M8 guidelines.

OBJECTIVES

- Introduce ICH's reform and its new vision of global development
- Discuss key impact of ICH updates to international regulatory agencies and industry
- Share CNDA's implementation progress and challenges of ICH guidelines
- DIA's Contribution to ICH's global promotion as a neutral platform
- Training on ICH Tier 2 guidelines

8:30-10:00
2nd Floor
Hall 2-I

ICH Plenary Session

Opening Remarks from China National Drug Administration

Lin YUAN
Director General, Department of International Cooperation, China NDA

ICH's Today and Tomorrow: Current ICH Priorities and Challenges in Implementing the ICH Reform

Lenita LINDSTRÖM-GOMMERS
Chair, ICH Assembly
Senior Expert, European Commission, Belgium

ICH's Guideline Development and New Topics Selection

Toshiyoshi TOMINAGA, PhD
Vice-Chair of both the ICH Management Committee and the ICH Assembly
Associate Executive Director, International Program, PMDA

Updates on the Implementation of ICH guidelines in China

Siyuan ZHOU
Director, China ICH Office

Tuesday, May 22th | ICH DAY

ICH Special Forum
Opportunities and Challenges of ICH implementation at Global Scale

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

ALL SPEAKERS ABOVE AND INVITED PANELISTS
Xiaoling QIN
Deputy Director General, Department of International Cooperation, China NDA

Pär TELLNER
Director, Team Leader and ICH Coordinator, EFPIA

10:00-10:30	Tea Break

Tuesday, May 22th | ICH DAY

Workshop 1 | 2nd Floor, 201AB

E2 & M1: Pharmacovigilance and MedDRA

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

Jan PETRACEK, MD
CEO, PrimeVigilance, UK

Julia ZHU, MD, PhD
Director, Drug Safety & Pharmacovigilance, dMed Biopharmaceutical Co., Ltd.

10:30–12:00	**MedDRA: FDA's Perspectives** **Sonja BRAJOVIC, MD** Medical Officer, CDER Regulatory Science Staff, FDA • MedDRA as an ICH Initiative • ICH MedDRA Points to Consider Workgroup • MedDRA implementation at FDA • Current MedDRA Use at FDA CDER
12:00–13:30	Lunch
13:30–15:00	**ICH E2A** **Jan PETRACEK, MD** CEO, PrimeVigilance, UK • Introduction and Background of E2A • Definitions and Terminology in Clinical Safety Data Management • Standards for Expedited Reporting in Clinical Safety Data Management
15:00–15:30	Tea Break

Tuesday, May 22th | ICH DAY

15:30–17:00 **Practical Consideration**

Jan PETRACEK, MD
CEO, PrimeVigilance, UK

Expectedness of ADR: RSI in IB
Any guidance on how to develop the reference safety information in IB? What information should be included?
How to determine the known ADRs of the product based on observed events?

Other Observations to be Reported in an Expedited Way?
How to determine what situation other than single SUSARs that needs rapid communication with RA?
In these situation, how to do the rapid communication? By what format? Within what kind of time frame?

Experience in Managing Blinded Therapy Cases
When and how to perform the single case unblinding? What needs more attention when preparing unblinded ICSRs?
How to handle the cases of active comparator?

Tuesday, May 22th | ICH DAY

Workshop 2 | 2nd Floor, 201CD

E6(R2): GCP

PROGRAM CHAIR
Hannah CHEN
Director, Asia Pacific Strategy Lead
BioResearch Quality & Compliance, Janssen

10:30–10:50	**E6 Updates/Addendum** **Agnes SAINT-RAYMOND, MD** Head of International Affairs, Head of Portfolio Board, European Medicines Agency
10:50–12:30	**cQMS** Clinical QMS Conceptual Framework **Deborah DRISCOLL** Vice President, Quality Assurance, Merck Research Laboratory Risk Assessment **Helen WONG** Regional Director, Clinical Quality Management Asia-Pacific, Global Clinical Trial Operations, MSD, HK Issue Management **Ellyne SETIAWAN** Head of Quality Medicine, ROPU-TCM, Boehringer Ingelheim Assessment of cQMS **Carol BYE** Vice President, Medical Quality Assurance, Pfizer UK Sharing of Best Practice on cQMS **Lynn EVENS** Head of Quality Planning and Strategy, Bio Research Quality and Compliance, JnJ
12:30–13:30	Lunch

Tuesday, May 22th | ICH DAY

ICH Recognised Training Programme

13:30–16:00 **RBM**

RBM Methodology
Marion WOLFS
Director, Risk Management and Central Monitoring, TA Lead Oncology Heme, Janssen R&D

Risk Assessment Categorization Tool (RACT)
Helen WONG
Regional Director, Clinical Quality Management Asia-Pacific, Global Clinical Trial Operations, MSD, HK

Central monitoring capability
Marion WOLFS
Director, Risk Management and Central Monitoring, TA Lead Oncology Heme, Janssen R&D

SDV/SDR
Sarah YUE
Site Monitor Manager, Regional Clinical Operation, BMS

RBM Data trending
Yan YU
AD, Site Monitor Management, Regional Clinical Operation, BMS

16:00–17:00 **Panel Discussion:** Regulatory Authorities' Opinion on Clinical QMS and RBM

MODERATOR
Hannah CHEN

INVITED PANELISTS:
Agnes SAINT-RAYMOND, MD
CFDI Panelist Invited
Deborah DRISCOLL
Marion WOLFS

Tuesday, May 22th | ICH DAY

Workshop 3 | 2nd Floor, Hall 2-II

E9 (R1): Estimands and Sensitivity Analysis in Clinical Trials

PROGRAM CHAIR

Lian LIU, PhD
Director, Biostatistics, Novartis

PROGRAM COMMITTEE MEMBERS

Vlad DRAGALIN, PhD
Vice President, Scientific Fellow
Quantitative Sciences,
Janssen Pharmaceutical Companies at Johnson & Johnson
Member of the ICH E9(R1) EWG

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

Ivan CHAN, PhD
Vice President, Pipeline Statistics and Programming,
Data and Statistical Sciences, Abbvie, USA

10:30–10:40	**Welcome and Introduction**
10:40–11:00	**Background and History of ICH E9-R1**
	China CDE Speaker Invited
11:00–11:30	**Opportunities and Challenges in implementing Estimands in Clinical Trials**
	Vlad DRAGALIN, PhD
11:30–12:00	**Personal Opinion on Estimand**
	Feng CHEN, PhD
12:00–13:30	Lunch Break
13:30–14:00	**Opportunities and Challenges in implementing Estimands in Clinical Trials**
	Ivan CHAN, PhD
14:00–14:30	**Panel Discussion**
	Speakers above and Invited Panelists: **Prof. Jielai XIA** **Luyan DAI, PhD** **Tony GUO, PhD**
14:30–15:00	Tea Break

Tuesday, May 22th | ICH DAY

Workshop 4 | 2nd Floor, Hall 2-II

E17: General Principles for Planning and Design of Multi-Regional Clinical Trials

PROGRAM CHAIR

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

PROGRAM COMMITTEE MEMBERS

Yoshiaki UYAMA, PhD
Director, Office of Medical Informatics and Epidemiology
Pharmaceutical and Medical Devices Agency (PMDA), Japan

Gang CHEN, PhD
Chief Scientific Officer, R&G PharmaStudies
Guest Professor, Peking University Clinical Research Institute

Inger MOLLERUP
Regulatory Consultant, CMR, Novo Nordisk, Switzerland

15:00–15:40	Overview of ICH E17 Guideline	
		Yoshiaki UYAMA, PhD
15:40–16:20	MRCT Consistency Assessment Across Regions - ICHE17 Implantation	
		Gang CHEN, PhD
16:20–17:00	A Case Study for MRCT: LEADER Outcome Study	
		Inger MOLLERUP
17:00–18:00	Joint Panel Discussion on E9 & E17	

Tuesday, May 22th | ICH DAY

Workshop 5 | 2nd Floor, 203AB

E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs

PROGRAM CO-CHAIRS

Haiyan LI
Professor of Cardiology, Director, Drug Clinical Trial Center, Peking University Third Hospital

Boaz MENDZELEVSKI, MD
Consultant, Cardiac Safety Consultants Ltd., UK

ICH E14 Questions and Answers document was revised in December 2015 to allow for concentration-QTc (C-QTc) modeling to be used as the primary analysis for assessing the QTc interval prolongation risk of new drugs. Thus, sponsors of pharmaceutical products now can either perform smaller TQT studies or use C-QTc modeling with high quality electrocardiogram (ECG) measurements in single- and/or multiple- dose escalation (SAD/MAD) studies during early-phase clinical development as an alternative to meet the regulatory requirements of the ICH E14 guideline. The objective of this program is to discuss recommendations for designing studies to use C-QTc modeling as the primary analysis, conducting a C-QTc analysis and reporting the results QT Studies in China.

10:30–10:35	**Chairman Welcome and Opening Comments** **Haiyan LI, MD** Professor of Cardiology, Director, Drug Clinical Trial Center, Peking University Third Hospital
10:35–11:00	**Keynote Lecture: CV Safety in Basic and Clinical Research: From Ion Channels to Clinical Assessments** **Ganxin YAN, MD, PhD** Professor of Medicine at Thomas Jefferson University, Professor at Lankenau Institute for Medical Research and Xi'an Jiaotong University
11:00–12:00	**Session 1: Regulatory Sciences** MODERATOR **Boaz MENDZELEVSKI, MD** Consultant, Cardiac Safety Consultants Ltd., UK Overview of the S7B Guideline CDE Speaker Invited Overview of the E14 Guideline (including TQT and IQT) CDE Speaker Invited CiPA - a Regulatory Paradigm Shift **David STRAUSS, MD, PhD** Director, Division of Applied Regulatory Science, Office of Translational Sciences, Office of Clinical Pharmacology, FDA
12:00–13:00	Lunch Break

Tuesday, May 22th | ICH DAY

13:00–14:30 **Session 2: QT Study Design and Operations**

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

Translational and Early Phase Cardiac Safety Assessments
Jorg TAUBEL, MD
Chief Executive Officer, Richmond Pharmacology Limited, St George's University of London, UK

Considerations for IQT Study Designing and Conducting in China
Haiyan LI
Professor of Cardiology
Director, Drug Clinical Trial Center, Peking University Third Hospital

Quality Control of QT Study Operation
Haiyan LI
Professor of Cardiology
Director, Drug Clinical Trial Center, Peking University Third Hospital

Overview of Quality Control System of ECG Core Lab (including ECG analyses methodology)
Boaz MENDZELEVSKI, MD
Consultant, Cardiac Safety Consultants Ltd., UK

Panel Discussion
MODERATOR
Haiyan LI
Professor of Cardiology
Director, Drug Clinical Trial Center, Peking University Third Hospital

Panelist: Session 2 Speakers and
Dr. Yaning WANG
Dr. Jiang LIU

14:30–15:00 Tea Break

Tuesday, May 22th | ICH DAY

15:00–16:15 **Session 3: QT Analysis and Cardiac Safety Strategies for China**

MODERATOR
Yaning WANG, PhD
Regulatory Expert

Overview of Concentration-QT Analysis Methodology
Yaning WANG, PhD
Regulatory Expert

Application of Concentration - QT Analysis based on Data from Phase 1 Trials
Jiang LIU, PhD
Regulatory Expert

Considerations for Cardiovascular Risk Monitoring in Late Phase and Post-approval
Gailing LI, PhD
Senior Director, Clinical Pharmacology
Johnson & Johnson (China) Investment Ltd

16:15–17:15 **Panel Discussion: Study Design, Quality control and The Implementation Strategy of QT Studies in China**

MODERATOR
Haiyan LI
Professor of Cardiology
Director, Drug Clinical Trial Center, Peking University Third Hospital

All Speakers & CFDA Representative, ICH E14 Working Group in China

17:15–17:30 **Workshop Ends**

Tuesday, May 22th | ICH DAY

Workshop 6 | 2nd Floor, 203CD

M4 & M8: Requirements and Significance of eCTD Implementation

Since China have joined ICH as a member, China NDA clearly requires industry apply ICH guidelines for Clinical development and regulatory submission in China. From 1st February 2018, ICH Guideline M4: "Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use" start to apply to the submission in Category 1, 5.1 of Chemical Drug Registration, and Category 1 of biological products for Treatment and Category 1 of biological products for prevention of 1. In the meanwhile, more and more Chinese domestic pharmaceutical companies conduct clinical trials abroad, and would do submission to FDA/EMA/PMDA. However, lots of Chinese domestic companies are not familiar with the regulatory requirement, structures. Modules, and format on CTD, until now there is no domestic eCTD system to support regulatory submission. Therefore DIA will invite the global/domestic experts of CTD/eCTD to introduce the regulatory requirements of CTD/eCTD, how to create eCTD specification, and share successful cases in eCTD submission.

PROGRAM CHAIR

Hualong SUN, MD, PhD
General Manager, Meta Clinical Technology

PROGRAM COMMITTEE

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

Titus MODSCHING
Business Analyst, Client Enablement, Regulatory Solutions, PAREXEL International GmbH

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

Bruce SUN
Publishing Team Lead (Established Market) , Publishing & Product License Support , Worldwide Regulatory Operations , Pfizer (China) Research and Development

10:30–11:00 **Introduction of ICH Guideline M4: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use**

Hualong SUN, MD, PhD

- Objective of CTD
- General Principle
- Modules of CTD

11:00–11:30 **The Structure and Format of CTD/eCTD**

Handsome JI

- CTD Triangle
- Difference of CTD from eCTD Structure

Tuesday, May 22th | ICH DAY

11:30–12:00	**Manage Trial Master Files for eCTD Implementation** **Daniel LIU, PhD** • eTMF Regulatory Standards • How to Manage TMF While Implement eCTD
12:00–13:30	Lunch Break
13:30–14:00	**Management of eCTD Life Cycle** **Handsome JI**
14:00–14:30	**Overview of eCTD Specifications** **Bruce SUN** • Composition of eCTD Specifications • Process of eCTD Specifications Creation • How to Review/Interpret/Implement eCTD Specification
14:30–15:00	**Strategies & Tools to Build a Successful Submission of eCTD** **Titus MODSCHING**
15:00–15:30	Tea Break
15:30–16:00	**Global eCTD Transition and Case Study** **Bruce SUN** • Global eCTD Transition Status Quo • eCTD Case Study (US/EU/Japan/Thailand) • Validation Failure and Technical Rejection Avoidance
16:00–16:30	**Building the eCTD - Practical Approaches to Compiling Electronic Submissions** **Titus MODSCHING**
16:30–17:00	**The Opportunities and Challenges of Submission to China NDA and FDA/EMA in Clinical Data/Dossier for China Domestic Pharmaceutical Companies** **Hualong SUN, MD, PhD**
17:00–17:30	**Panel Discussion**

Wednesday, May 23rd | OPENING PLENARY

14:00–15:45
2nd Floor
Hall 1

Opening Plenary

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

WELCOME ADDRESS FROM CHINA NDA
China NDA Speaker Confirmed

PROGRAM CO-CHAIRS WELCOME ADDRESSES
XUE Bin
Director-General, China Center for Food and Drug International Exchange, China NDA
10th DIA China Annual Meeting Program Co-Chair

Pei HU, MD, PhD
Professor, Director, Phase I Unit Clinical Pharmacological Research Center, Peking Union Medical College
10th DIA China Annual Meeting Program Co-Chair

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

KEYNOTE ADDRESS 1
Chen WANG, MD, PhD
President, Chinese Academy of Medical Sciences and Peking Union Medical College
Academician of the Chinese Academy of Engineering
Director, National Respiratory Clinical Research Center

KEYNOTE ADDRESS 2
Yinuo LI, PhD
Director, China Country Office
Bill & Melinda Gates Foundation

15:40–16:00 Tea Break

Wednesday, May 23rd | OPENING PLENARY

16:00–16:45 **Special Forum: Therapeutic Innovation and Regulatory Science: An Essential Tension?**

CO-MODERATORS

Barbara Lopez KUNZ
Global Chief Executive, DIA

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

China's position in the global pharmaceuticals market is undergoing significant change, shifting from an international manufacturing base and a market mostly of generics to a promising strategic market and an emerging innovation center. The regulatory environment in China is also changing rapidly, as the CFDA (now CNDA) has been implementing a series of overarching and comprehensive reform measures since mid-2015 and became a regulatory member of ICH in June 2017. In this forum, the panelists will discuss how the knowledge-based educational platforms such as our DIA community should focus on to catalyze this evolution:

a. Promoting and advancing regulatory science to help establish a modern regulatory framework and system to set the stage for innovative drug development;

b. Investing in knowledge and capability building in therapeutic innovation to facilitate China's biopharmaceutical industry transforming from a follower to a true innovator?

INVITED PANELISTS

Chen WANG, MD, PhD
President, Chinese Academy of Medical Sciences and Peking Union Medical College
Academician of the Chinese Academy of Engineering
Director, National Respiratory Clinical Research Center

Alex NG, MD
Deputy Director, China Country Office, Head of Health and Innovation

Edward COX, MD, MPH
Director of the Office of Antimicrobial Products, CDER, FDA

Bruce REED, PhD
Director, Division of Neuroscience, Development and Aging, Center for Scientific Review, The National Institutes of Health

Agnes SAINT-RAYMOND, MD
Head of International Affairs
Head of Portfolio Board, European Medicines Agency

Toshiyoshi TOMINAGA, PhD
Vice-Chair of both the ICH Management Committee and the ICH Assembly
Associate Executive Director , International Program, PMDA

Wednesday, May 23rd | OPENING PLENARY

16:45–18:00 **Welcome Reception**
1st Floor
Exhibition Area

18:00–20:00 **DIA China 10th Anniversary and Award Ceremony** (Invitation Only)
2nd Floor
Hall 1

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

ADVISOR
Ruyi HE, MD
Chief Scientist, Center for Drug Evaluation, China NDA

Session 0101 | MAY 24, 2018

08:30-10:00
2nd Floor
Hall 2-C

DIAmond Session

Real-world Evidence Defined and Re-defined: Regulatory and Practical Considerations for Drug Development – Part 1

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

Real-world evidence (RWE) is playing an increasing role in drug development and regulatory decision-making. However, issues around data sources, validity and methodologies and result communication pose challenges to its application and impact. In this session, representatives from regulatory agency, academia and the industry will discuss and clarify the current thinking and issues around the use of RWE to support drug development and approval and will share experience and insight on use of RWE:

- What does RWE mean for drug development and regulatory decision-making?
- What is the current thinking from regulatory agencies' perspective?
- How drugmakers view RWE studies and how are they using RWE in drug development?
- What are the opportunities RWE can offer and what are the pitfalls to avoid?
- What are the new data sources? Will they become a viable alternative to clinical trials?

Real-world Evidence for Drug Development and Regulatory Decision Making
Arnold CHAN
Director, Department of Medical Research, Taiwan University Hospital

FDA Current Thinking and Practice on REW in Drug Development and Regulatory Decision Making
Gerald DAL PAN, MD, MHS
Director, Office of Surveillance and Epidemiology, CDER, FDA

EMA Current Thinking and Practice on REW in Drug Development and Regulatory Decision Making
Agnes SAINT-RAYMOND, MD
Head of International Affairs
Head of Portfolio Board
European Medicines Agency

China CDE's View on Real-world Evidence
CDE Speaker Invited

Regulatory Science

Session 0102 | MAY 24, 2018

10:30-12:00
2nd Floor
Hall 2-C

Real-world Evidence Defined and Re-defined: Regulatory and Practical Considerations for Drug Development - Part 2

SESSION CHAIR
Yi NING, SD, MD
Professor, Executive Director, Peking University Meinian Institute of Health

When and How to Use RWE in Pre and Post-approval Stages to Support Drug Development
Yi NING, SD, MD
Professor, Executive Director, Peking University Meinian Institute of Health

Synergies from RCT and Real-world Data Analyses
Senthil SOCKALINGHAM
Vice President and Head of Real World Insights Asia, IQVIA Rds East Asia Pte Ltd., Singapore

Panel Discussion
All Speakers from session 0101 & 0102 and Invited Panelist:
Nancy MYERS, JD
President, Catalyst Healthcare Consulting, Inc

Session 0105 | MAY 25, 2018

08:30-10:00
2nd Floor
Hall 3

How MRCT Serves China Registration Better when CFDA Becomes Formal ICH Member – Part 1

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

In November 2017, the ICH guideline of general principles on planning and designing Multi-regional Clinical Trials (E17) reached step 4 for fully adoption in ICH regions. Along with the China's reform on Drug Review and Approval system to expedite the innovation, speakers from Chinese, Japanese agencies, and industry will get together and share their own views and reflections with regard to the impact of E17 to the clinical development and drug approval. It will be specifically discussed about how to accelerate drug approval in China by better leveraging MRCT in China.

Clinical Development with the E5 and E17
Joseph SCHEEREN, PharmD
Senior Vice President, Senior Advisor R&D, Bayer AG, Germany
DIA Chair-elect

Impact to Clinical Development and Drug Approval in China, from CDE Reviewer's Perspectives
CDE Speaker Invited

Regulatory Science

Impact to Clinical Development and Drug Approval in Japan from PMDA's Perspective
Yasuto OTSUBO
Principal Reviewer, Office of New Drug II, Pharmaceuticals and Medical Devices Agency (PMDA)

Impact to Clinical Development Plan from the Statistics Perspectives
Anny Yue YIN, PhD
Senior Director, Biostatistics, CStone Pharmaceuticals

Session 0106 | MAY 25, 2018

10:30–12:00
2nd Floor
Hall 3

How MRCT Serves China Registration Better when CFDA Becomes Formal ICH Member – Part 2

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

Oncology Product Development and Approval
Yanping DONG
Senior Manager of Regulatory Affairs,Roche Product Development, Asia Pacific

Non-oncology Product Development and Approval
Yan GONG
Director, Head of DRA, the China Market, Boehringer Ingelheim

Panel Disucssion
1. How to justify the MRCT is sufficient to support the registration in China in future? Is minimal patient number still required? From both regulator and industries' perspectives
2. How to plan and design MRCT? If China plans to participate, what are the major considerations?

All Speakers from Session 0105 & 0106

Regulatory Science

Session 0107 | MAY 25, 2018

13:30-15:00
2nd Floor
Hall 3

Priority Review and Conditional Approval

SESSION CHAIR
Irene DENG
Head of China Regulatory Affairs, Sanofi

Innovation treatment bring the hopes to the patients, but inherent with the risk and challenges. The good regulatory science is the booster to accelerate the innovation treatment, and best mitigate the risk. The priority review and conditional approval is the two key components to accelerate the development of the innovative drugs. In global, there had accumulated the experience and good practice. In China, China NDA has implemented the priority review in 2016 and achieved the stepwise success. While, the conditional approval starting its pilot steps. By taking the good practice of global, how to establish the suitable China regulatory scheme on priority review and conditional approval would be discussed here.

Priority Review and Conditional Approval in EU
Ana HIDALGO-SIMON, MD, PhD
Head of Specialised Scientific Disciplines Department
Human Medicines Research & Development Support Division, EMA

Priority Review and Conditional Approval in FDA
Zhihong LI, PhD
Vice President, International Regulatory Affairs, Fountain Medical Development, USA

Priority Review and Conditional Approval in China
China NDA Speaker Invited

Panel Discussion: Priority Review and Conditional Approval
All Speakers and Invited Panelists
Yongjiang HEI, MD, PhD
Chief Medical Officer, Clinical Development, QiLu Pharmaceutical Ltd.

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

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

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

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

Regulatory Science

Session 0108 | May 25, 2018

15:30–17:00
2nd Floor
Hall 3

MAH Pilot Program in China: Experience and Reflection

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

MAH Perspective
Min DONG, PhD
Senior Vice President, Clinical Development & Regulatory Affairs, EOC Pharma

The Implementation of MAH under China Regulatory Reform
Jiali LUO, PhD
Boehringer-Ingelheim

Observations to the Implementation of the MAH System
Chen YANG
Senior Counsel, Sidley Austin LLP

China NDA Townhall

THEME LEADER
Jin CUI
China Center for Food and Drug International Exchange (CCFDIE)

Session 0203 & 0204 | May 24, 2018

13:30–17:00
2nd Floor
Hall 1

DIAmond Session

China NDA Townhall - Part 1 & Part 2

The China NDA Townhall this year will focus on:

- Amendment Progress of Drug Administration Law, MAH, Data Protection, and Patent Linkage
- ICH New Guideline, CDE's Drug Review & Approval Reform Progress
- Overseas Inspection, GLP, GCP and GMP Inspection Findings
- New Initiatives on Medical Devices Review and Approval

Innovative Breakthrough in Therapy

What's New in Antibacterial Drug Development

THEME CO-LEADERS

Mark GOLDBERGER, MD
Member FDAAA
Former Director, Office of Drug Evaluation IV, FDA
Independent Consultant Mark Goldberger MD MPH LLC

Sunny ZHU
Chief Medical Officer, Infectious Diseases, Everest Medicines

This session aims to provide Chinese academics, researchers, industry, and others updates on progress in antibacterial drug development to address antimicrobial resistance including both progress and challenges. The first session will focus on regulatory issues associated with antibacterial development for multi-drug resistant bacteria. The second session will focus on clinical development issues associated with antibacterial development for multi-drug resistant bacteria.

Session 0301 | MAY 24, 2018

08:30-10:00
2nd Floor
Hall 2-A

Addressing Challenges in the Development of Drugs for Multi-Drug Resistant Bacteria: A Growing Public Health Crisis – Part 1 Regulatory Issues

SESSION CHAIR
Jinjie HU, PhD
FDAAAIN Chair
President, Axteria BioMed Consulting

Update from the US FDA
Edward COX, MD, MPH
Director of the Office of Antimicrobial Products, CDER, FDA

Update from the China NDA
China NDA Speaker Invited

Anti-Infective Development: New Tools – A Better Result?
Mark GOLDBERGER, MD, MPH
Member FDAAA
Former Director, Office of Drug Evaluation IV, FDA
Independent Consultant Mark Goldberger MD MPH LLC

Innovative Breakthrough in Therapy

Session 0302 | MAY 24, 2018

10:30-12:00
2nd Floor
Hall 2-A

Addressing Challenges in the Development of Drugs for Multi-Drug Resistant Bacteria: A Growing Public Health Crisis – Part 2 Clinical Development

SESSION CO-CHAIRS
Mark GOLDERGER, MD, MPH
Member FDAAA
Former Director, Office of Drug Evaluation IV, FDA
Independent Consultant Mark Goldberger MD MPH LLC

Zhengyu YUAN, PhD
Chief Executive Officer, MicuRx Pharmaceuticals, Inc.

Critical Pre-Clinical and Clinical trial Issues to be Addressed and Common Mistakes That Can Derail a Program
Sumathi NAMBIAR, MD, MPH
Director, Division of Anti-Infective Products, Office of Antimicrobial Products, CDER, FDA

PKPD and Its Value in Clinical Development of Antibacterial Drug
Jing ZHANG, PhD
Professor of Clinical Pharmacology
Vice Director, Institute of Antibiotics
Huashan Hospital, Fudan University

How Molecular and Novel Diagnostic Technologies for the Detection of Antimicrobial Resistance Markers can Expedite a Clinical Program
Jinjie HU, PhD
FDAAAIN Chair
President, Axteria BioMed Consulting

Panel Discussion: Summarize the Current State of Antimicrobial Development and to Accept Q&A from Audience
Panelists: All Speakers from Session 0301 & 0302

Innovative Breakthrough in Therapy

Oncology Drug Development Breakthrough

THEME CO-LEADERS

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

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

ADVISOR

Shun LU, MD, PhD
Director, Shanghai Lung Cancer Center, Shanghai Jiaotong University, China

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Session 0305-1 | MAY 25, 2018

08:30-10:00
2nd Floor
Hall 2-A

Checkpoint Inhibitors: Monotherapy vs. Combination Therapy

SESSION CHAIR

Shun LU, MD, PhD
Director, Shanghai Lung Cancer Center, Shanghai Jiaotong University, China

Monotherapy vs. Combination Therapy - from the Clinician Perspective
Yong HE, MD, PhD
Professor, Director, Respiratory Medicine, Daping Hospital

Topic TBD
Lei YU, PhD
Chief Scientific Officer, Unicar Therapy

Targeting Tumor Microenvironment Beyond T cell Checkpoints
Yiping RONG, PhD
Head of Discovery Biology, Harbour BioMed

Innovative Breakthrough in Therapy

Session 0306-1 | MAY 25, 2018

10:30-12:00
2nd Floor
Hall 2-A

New Approach for Oncotherapy Development

SESSION CHAIR
Yongjiang HEI, MD, PhD
Chief Medical Officer, Clinical Development, QiLu Pharmaceutical Ltd.

ADC in Oncology
Yongjiang HEI, MD, PhD
Chief Medical Officer, Clinical Development, QiLu Pharmaceutical Ltd.

Bispecific Antibodies in Oncology
Minmin QIN, PhD
Senior Vice President, Head of CMC, Harbour Biomed

Oncolytic Viruses: Leading Edge of Tumor Immunotherapy
Min LIANG, PhD
General Manager, TOT Shanghai R&D Center

Session 0307-1 | MAY 25, 2018

13:30-15:00
2nd Floor
Hall 2-A

Development of Innovative CAR-T Therapy

SESSION CHAIR
Ting HE, PhD
Chief Executive Officer, Immunochina Pharmaceuticals

Emerging evidence has been showing that CAR-T therapy is quite promising for treatment of leukemia. In this session, strategies for improvement of this technology and targets beyond hematological malignancies will be discussed.

The Significance and Prospective of Automated CAR-T Cell Manufacturing
Min WANG
Manager, CAR-T Department, PersonGen Biomedicine

Engineering CAR-T for Improving Cancer Immunotherapy
Yarong LIU, PhD
Director of Research and Development, HRAIN Biotechnology Co., Ltd.

Improved CAR-T Manufacture Process Leading to Long-lasting Response
Ting HE, PhD
Chief Executive Officer, Immunochina Pharmaceuticals

EU's CAR-T Therapy Breakthrough
Agnes SAINT-RAYMOND, MD
Head of International Affairs, Head of Portfolio Board, EMA

Innovative Breakthrough in Therapy

Session 0308-1 | MAY 25, 2018

15:30-17:30
2nd Floor
Hall 2-A

Next-generation Sequencing and Predictive Biomarkers in Cancer Therapies

SESSION CHAIR
Jun LUO, PhD
Associate Professor, Urology, Oncology
Hinman Endowed Chair, Department of Urology, Johns Hopkins Hospital

Discovery, Validation, and Clinical Implementation of Cancer Biomarkers
Jun LUO, PhD
Associate Professor, Urology, Oncology
Hinman Endowed Chair, Department of Urology, Johns Hopkins Hospital

Immune-Check Point Patient Stratification: A Central Laboratory Perspective
Patrice HUGO, PhD
Chief Scientific Officer, Q^2 Solutions

Utility of Organloid Culture in Precision Cancer Medicine
Dong GAO, PhD
Principal Investigator, Shanghai Institute of Biochemistry and Cell Biology, Chinese Academy of Sciences

Liquid Biopsy and Companion Diagnostics
Shidong JIA, MD, PhD
Chief Executive Officer, Predicine, Inc.

Innovative Breakthrough in Therapy

Therapeutics for Hepatitis Cure by 2030 - Breakthrough of Novel Therapies in Liver Disease

THEME CO-LEADERS

Jinlin HOU, Professor
Director of Department of Infectious Diseases & Hepatology Unit, Nanfang Hospital, Southern Medical University
Former President of APASL 2017

Jessica LIU, MD
Vice President, Head of International Business, TigerMed Medical

The Liver Diseases sessions proposed the urgent needs for novel therapeutics towards hepatitis cure by 2030 from the perspectives of clinicians and investigators by reviewing the pathogenic understanding and clinical management of major liver disease. Share between clinicians, drug regulatory professionals and industry leaders from USA and China: current understanding of pathogenesis mechanisms as well as treatment endpoints for non-alcoholic fatty liver disease, liver fibrosis, and hepatocellular carcinoma, and expectations to the pipeline of development and approval of new drugs.

Session 0305-2 | MAY 25, 2018

08:30-10:00
2nd Floor
Hall 2-B

DIAmond Session

Unmet Needs in Current Therapies for Liver Disease

SESSION CHAIRS

Jinlin HOU, Professor
Director of Department of Infectious Diseases & Hepatology Unit, Nanfang Hospital, Southern Medical University
Former President of APASL 2017

Progression, Clinical Outcomes and Therapeutic Targets of Chronic Liver Disease
Jinlin HOU, Professor
Director of Department of Infectious Diseases & Hepatology Unit, Nanfang Hospital, Southern Medical University
Former President of APASL 2017

Pharmacotherapy for NASH – Appraisal of Current Status and Future Trends
Nikolai NAOUMOV, MD, PhD
Executive Director, Hepatology Science and Innovation, Global Drug Development,
Development Unit Immunology & Dermatology, NOVARTIS, Switzerland

Intermediate Surrogate Markers and Long-term Outcomes for Anti-liver Fibrosis Therapy
Yury POPOV, MD, PhD
Assistant Professor of Medicine, Director of Liver Research, Beth Israel Deaconess Medical Center, Harvard Medical School

Kinase Inhibitors, Immunotherapies, Other Systemic and Combination Therapies in Chinese HCC Patients
Xiufeng LIU
Director, Medical Department, the 81th Hospital of People's Liberation Army (PLA)

Innovative Breakthrough in Therapy

Session 0306-2 | MAY 25, 2018

10:30-12:00
2nd Floor
Hall 2-B

Clinical Endpoints for Viral Hepatitis Therapy: Perspectives from Regulatory Professionals

SESSION CHAIR
Jessica LIU, MD
Vice President, Head of International Business, TigerMed Medical

Appropriate Design of Primary Endpoint in Clinical Trials of Viral Hepatitis
CDE Speaker Invited

The Importance Role of DILI in New Drug Development
Chengwei CHEN
Professor, Chief Editor, Chinese Hepatology

FDA Guideline on Clinical Development of Viral Hepatitis Therapies
Edward COX, MD, MPH
Director of the Office of Antimicrobial Products, CDER, FDA

Working with FDA on Defining the Evaluation Endpoints and Biomarkers in Design of Clinical Trials for Viral Hepatitis Therapy
John FLAHERTY
Senior Director, Clinical Research, Liver Disease Therapeutics, Gilead Sciences, Inc.

Panel Discussion: focusing on scientific and feasible regulatory guideline set up and execution in anti-virus therapies on hepatitis.

Session 0307-2 | MAY 25, 2018

13:30–15:00
2nd Floor
Hall 2-B

Immunotherapy for HBV Functional Cure

SESSION CHAIR
Hong REN
President, The Second Affiliated Hospital of Chongqing Medical University

Clinical Immunology in Viral Hepatitis and Hepatocellular Carcinoma
Fusheng WANG, Professor
Academician, Chinese Academy of Sciences
Professor, 302 Hospital of People's Liberation Army (PLA)

A New HBV Therapeutic Vaccine
Junqi NIU, MD, PhD
Chair and Professor, Department of Hepatology, First Teaching Hospital
University of Jilin

Chimigen HBV: A Novel Immunotherapy for Treating Chronic HBV Infections
Rajan GEORGE, PhD
President and Chief Scientific Officer, Chimigen Inc.

Innovative Breakthrough in Therapy

Session 0308-2 | MAY 25, 2018

15:30–17:30
2nd Floor
Hall 2-B

Breakthrough of Therapeutic Development in Liver Disease

SESSION CHAIR
Shelly XU, MD
Chief Executive Officer, Teddy Central Lab

Future Perspective on Novel Mechanisms of Action for HBV Cure
Gregory FANNING
Head of China Discovery Center, Janssen China R&D

Curing HBV based on Pro-apoptosis Theory
David YANG, PhD
President, Ascentage Pharma

Antisense Oligonucleotide: a Potential New Therapy for Chronic Hepatitis B?
Xinwei ZHANG
Physician Project Leader, Institute for Infectious Diseases and Public Health(IIDPH)GSK R&D

Therapeutic Pipeline for HCV
Jinzi WU, PhD
Founder, Ascletis BioScience Co.,Ltd.

Roche R&D in HBV and Commitment in China
Lu GAO, PhD
Senior Director, Head of Virology China, Virology China
Immunology, Inflammation and Infectious Diseases, Roche Innovation Center Shanghai

Key Points on Design of Clinical Study for NASH Therapy based on Preclinical Data
Min XU, PhD
Chief Executive Officer, PegBio

Clinical Development

THEME CO-LEADERS

Hannah CHEN
Director, Asia Pacific Strategy Lead, BioResearch Quality & Compliance, Janssen

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

Reako REN
Head of SMO Services, WuXi Apptec

ADVISOR

Pei HU, MD, PhD
Director, Phase I Unit, Clinical Pharmacological Research Center
Peking Union Medical College, China

Session 0401 | MAY 24, 2018

08:30-10:00
2nd Floor
Hall 3

DIAmond Session

Hospital Presidents Forum – Part 1

SESSION CHAIR

Lixin JIANG, MD
Vice President, Fuwai Hospital, Chinese Academy of Medical Sciences
Assistant to Director, National Center for Cardiovascular Diseases

Clinical Research is the driving force for modern medicine, as well as the fundamental support to meet healthcare demands of the general population. Clinical Research also is a key link in drug innovation. Healthy China 2030 clearly articulates the goal to “Eradicate the threat of a number of critical diseases”.
The forum will start with the Ministry of Science and Technology’s plan about establishment and development of China’s clinical research system, emphases the important and urgency of upgrading the overall abilities of China’s clinical research system. The experiences sharing from the leading academic leaders and hospital chiefs in the field of clinical research will help the audiences to learn challenges and solutions from their build-up system. The forum will also focus on the most concerned challenges such as: Key elements of the clinical research system, education and training for medical talents, incentive plan etc. to have the in-depth discussion.

Ministry of Science and Technology’s Plan about Establishment and Development of China’s Clinical Research System
Yuanbin WU
Director-General, Department of S&T for Social Development, Ministry of Science and Technology

Clinical Research System of National Center for Cardiovascular Diseases
Lixin JIANG, MD
Vice President, Fuwai Hospital, Chinese Academy of Medical Sciences
Assistant to Director, National Center for Cardiovascular Diseases

Clinical Development

Clinical Research System of Peking University Third Hospital
Jie QIAO, MD, PhD
Academician of the Chinese Academy of Engineering
President, Peking University Third Hospital

The Development of Regional Ethics
Jun ZHAO
Secretary of Party Committee, Jiangsu Province Hospital

Experience Sharing from University of HongKong's Clinical Trials Centre
Henry YAU, MBA
Managing Director & Honorary Assistant Professor, Clinical Trials Centre, The University of Hong Kong

Session 0402 | MAY 24, 2018

10:30-12:00
2nd Floor
Hall 3

DIAmond Session

Hospital Presidents Forum – Part 2

SESSION CHAIR
Jin WANG
Partner, McKinsey & Company

RDPAC Study: Deepening the Drug Innovation Ecosystem Reform - A Plan to Design and Build China's Clinical Research System
Mingqiang ZHANG, PhD
Chair, RDPAC
Vice President, Amgen R&D

Panel Discussion
Invited Panelists: All Speakers from Session 0401 & 0402, and Invited Panelists:
Chinese Hospital Association Panelist Invited

Clinical Development

Session 0405 | MAY 25, 2018

08:30-10:00
2nd Floor
Hall 2-C

How Collaboration is Driving Innovation in Research & Development

SESSION CHAIR
Janice CHANG
Senior Vice President, Operations, TransCelerate

Harnessing the power of industry collaboration truly can alter the healthcare landscape as we know it today. This session will discuss the how and why behind today's collaborations, and share perspectives around how collaboration amongst industry, global health authorities, patients and investigator sites can
test the bounds of innovation and accelerate the prevention, diagnosis, treatment, and — ultimately — cures.

This thought-provoking session will bring together a diverse panel of leaders a candid and innovative conversation discussing:
- How innovative new technologies can decrease study times by reducing administrative burdens between sites, CROs and Sponsors.
- How intelligent automation capabilities have the potential to support and improve the execution of Pharmacovigilance activities.
- How data sharing amongst industry sponsors in improving decision making and even reducing the # of patients receiving placebo in clinical studies.
- What's required to move to achieve a future state of fully-automated, dynamic, study start-up readiness will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators

INVITED PANELISTS
Dalvir GILL
Chief Executive Officer, TransCelerate

Songlin XUE, MD, PhD
Executive Vice President and Global Head of Pharmacovigilance, Astellas

QingAn JIAO
Senior Director, Head of GCO China, Janssen Pharmaceutical Ltd.

Clinical Development

Session 0406 | MAY 25, 2018

10:30-12:00
2nd Floor
Hall 2-C

Clinical Trial AE Reporting—from Collection, to Processing, Analysis and Summary, to Authority Review

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

Study drug safety has always been the focus of clinical trials from quality and scientific perspective. This session is to provide a whole picture to the audience from AE data flows to best practice sharing. Hot questions from key stakeholders (e.g.disease progression as efficacy point, missing AEs, etc) would also be addressed during panel discussion session.

How to Ensure Adequate Adverse Event Reporting from Investigator/Clinical Trial Oversight Perspective
Henry YAU, MBA
Managing Director & Honorary Assistant Professor, Clinical Trials Centre, The University of Hong Kong

AE Case Processing, Analysis and Summary from Sponsor Perspective, Global Insight and Best Practice to be Shared
Jie DING
Senior Director, BARDS-AP, MSD

Safety Case Review and Drug Safety Evaluation—Consideration from Reviewer Perspective
CDE speaker Invited

Panel Discussion: Hot Topics Arising from Industry/Investigators/EC/GCP Offices Regarding Clinical Trial AE Reports
All Speakers and Invited Panelist:
Ye CAO, PhD
Director, GCP Office, Sun Yat-sen Unvierstidy Cancer Center

Hannah CHEN
Director, Asia Pacific Strategy Lead, BioResearch Quality & Compliance, Janssen

CFDI Panelist Invited

Session 0407 | MAY 25, 2018

13:30-15:00
2nd Floor
Hall 2-C

New Technology to Support Clinical Trial Activity

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

New technology help us to collect, analyze data/information relating to clinical trial conduct, indicate risk areas, which enables us to implement effective risk-based monitoring, auditing and inspection program.

Revolutionizing the Investigator Experience Through Innovative Technology Platforms
Denise REYES
Program Director, Sites Subcommittee, TransCelerate BioPharma Inc.

Data Analytics to Support Audit Program
Lynn EVENS
Head of Quality Planning and Strategy, Bio Research Quality and Compliance, JnJ

How to Implement Risk-based Inspection, Analysis and Trending of CFDI Inspection Findings
CFDI Speaker Invited

Clinical Development

Session 0408 | MAY 25, 2018

15:30-17:00
2nd Floor
Hall 2-C

The Critical Strategy and Practice of Efficient Collaborative Clinical Operation in New Environment

SESSION CHAIR
Reako REN
Head of SMO Services, WuXi Apptec

China new drug development industry is getting prosperous with the powerful reforming of China NDA to speed up new drug approval, many new clinical projects are at the edge of initiation. On the other side, we also have seen clinical design and practice is becoming more complicated than in the past, because of the more serious and scientific supervision of authorities. These cause more and more categories of vendors are involved in a clinical project, therefore, to select the most suitable vendors and effectively manage them as joint power is a key influencer for clinical operation success.

In addition, with so many new projects entering clinical phase, it would need huge qualified clinical professionals and clinical centers, deficiency of such clinical research resources is the other major paints for both sponsors and CROs.

The invited speakers will bring us answers from below topics:
- Lesson learning from successful case study on effective vendor selection and management
- Pain points in clinical research and the solutions from effective multi-party collaboration
- How do CROs and other vendors find balance between opportunities and challenges

Lesson Learning from Successful Case Study of Innovative Drug Development for Effective Vendor Selection and Management Model
Yan WU, PhD
Vice President, Hutchison Medi Pharma

How Could CRO Face the Challenges of Current Clinical Research Environment in China
Albert LIOU
Vice Chairman of the Board, Parexel International

Panel Discussion: How Do CROs and Other Vendors Find Balance between Opportunities and Challenges?
Panelists: All Speakers Above and Invited Panelists
Qun LIU
Head of Clinical Study Manager, Oncology, China Novartis Institute for BioMedical Research

Isabel HAN
Vice President, Clinical Operation, Denovo Biopharma

Xiaochun CAO
Executive Vice President & Board Secretary, Tigermed Consulting Ltd.

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

Quantitative Science

Informetric Technology

THEME LEADERS

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

Session 0501-1 | MAY 24, 2018

08:30-10:00
2nd Floor
203AB

Informetric Technology to Enhance the Quality and Integrity of Clinical Data

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

The Guidance of Electronic Data Collection (EDC) technology in Clinical Trials published by China NDA has greatly facilitate uses of electronic clinical systems in clinical researches. At present, the informetric technology plays more and more roles in data management.

This session will focus on how informetric technology can improve the efficiency and quality of clinical data management.

Using eConsent and Virtual Trials to Engage Subjects and Improve Data Integrity in Clinical Trials
Michael TUCKER
Senior Product Solutions Specialist, Medidata Solutions

Lesson Learned in Applications of EDC Technique in Clinical Data Management
Dorothy DAI
Associate Director, Clinical Data Management, Meta Clinical Technology Co. Ltd

Clinical Data Total Management
Yonglong ZHUANG, PhD
President, BioKnow

Quantitative Science

Session 0502-1 | MAY 24, 2018

10:30-12:00
2nd Floor
203AB

Information Technology to Enhance the Efficiency and Quality of Drug Development

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

Information technology used in clinical studies should meet the regulatory requirement including system validation to ensure the integrity, accurate and reliable of the clinical data. Recent China NDA's <Good Practice of Drug Data management> clearly defined the requirement of electronic system in drug development.

This session will discuss how to implement information technology to improve the quality and efficiency for drug development

How to Use Imaging and Surrogate Endpoints to Accelerate Study Development
David KIGER
Chief Commercial Officer, Commercial Sales and Marketing, BioClinica

Automation in Early Phase Study – A Total Solution for Phase I Unit
Feng SHENG
General Manager, OmniComm Systems, Inc.(China)

eClinical Solutions in China: Exploration and Practices
Yonglong ZHUANG, PhD
President, BioKnow

Quantitative Science

Data Management in Clinical Development

THEME LEADER

Hualong SUN, MD, PhD
General Manager, Meta Clinical Technology Co. Lt

Session 0505-1 | MAY 25, 2018

08:30-10:00
2nd Floor
203AB

Quality Specification of Clinical Data in Clinical Trials

Session Chair Invited

The data quality of clinical trials is increasingly valued by the industry, China NDA is asking industry's comment on "Specification of Pharmaceutical Data Management". For Chinese domestic pharmaceutical companies it is important to build up an effective quality management system, and implementation risk management, and CAPA process.

Interpretation on "Specification of Pharmaceutical Data Management"
CFDI Speaker Invited

Risk Management and Implementing an Effective CAPA Process in Clinical Data Management
Wei ZHANG
Head of Data Management, GSK Shanghai R&D

How to Build an Effective Quality Management System in Chinese Domestic Pharmaceutical Companies
Di ZHU
Senior Manager, Clinical Data Science Center, Jiangsu Hengrui Medicine CO., Ltd

Quantitative Science

Session 0506-1 | MAY 25, 2018

10:30-12:00
2nd Floor
203AB

Cross Functional Cooperation to Ensure Data Quality

SESSION CHAIR
Anita SHEN
Director, Clinical Data Management, Janssen China Research and Development

GCP asks data quality control has to be performed each step from data collection, data handling until data analysis in Clinical Trials. The different functional staff are involved in Clinical Trials, and they have different roles and responsibilities. To ensure data quality, cross functional cooperation is very important.

How to develop Medical Review Plan, Clinical Monitoring Plan and Data Management Plan with Cross Functional Cooperation
Anita SHEN
Director, Clinical Data Management, Janssen China Research and Development

CDM How to Find Some Indexes to Help Other Functions Improving Productivity and Quality
Carrie ZHANG
CEO, eClinWise, Panacea Technology Co., Ltd

Panel Discussion
All Speakers and Invited Panelists:
Zaiqi WANG, PhD
Head, Early Medical, Roche

Heidi LIU
Associate Director, AP, Quality Strategy, Johnson & Johnson

Hao WANG
Senior Director, Clinical Research Operations, BMS

Lan ZHANG, PharmD
Professor, Director, Pharmacy, Xuanwu Hospital Capital Medical University

Xiaopeng SUO
Director, SMO, Clinical Service

Quantitative Science

Session 0507-1 | MAY 25, 2018

13:30-15:00
2nd Floor
203AB

Clinical Data Management for Domestic Pharmaceutical Globalization

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

China joined ICH from June 2017, in the meanwhile more and more Chinese domestic pharmaceutical companies conduct clinical trials abroad and try to do submission to FDA/PMDA/EMA and China NDA, therefore, Clinical Data Management needs to fit the regulatory requirement change and support the globalization of Chinese domestic pharmaceutical industry

Experience Sharing on PMDA Inspections/Global Audits
Hideaki UI, PhD
Inspection Director, Office of Non-clinical and Clinical Compliance, PMDA

How to Build a Professional Data Management Team to Meet Global Requirement
Hualong SUN, MD, PhD
General Manager, Meta Clinical Technology Co. Ltd

The Challenges and Opportunities for Clinical Data Management after Joining ICH
Jessie CHEN
Chief Medical Officer, Innovent Biologics (Suzhou) Co. Ltd.

Session 0508-1 | MAY 25, 2018

15:30-17:00
2nd Floor
203AB

Clinical Data Management in Oncological Trials

SESSION CHAIR
Yazhong DENG, MBA
Chief Executive Officer, Beijing Trust Medicine Consulting Ltd.

Clinical Trials in oncology somewhat more complicated than other therapeutic areas due to longer duration and more adverse event and concomitant medication, how to collect, manage, and deliver the productive clinical data for analysis and reporting in oncology study is much challenging. In this session, we will focus on the Data Management in oncology study, discuss the data collection and data cleaning and data quality.

How to Design Productive CRF for Oncological Trials
Hongwei WANG
Director, Data Management, BeiGene

Challenges of Data Cleaning in Oncological Trials
Hadrian FU, PhD
Chief Executive Officer, Shanghai Zenith Medical Tech Co. Ltd

Integrative Data Review and Quality Oversight in Oncological Trials
Mengni LIAO
Senior Manager, Clinical Data Management
Beijing Trust Medical Consulting Co Ltd.

Quantitative Science

Biostatistics

THEME LEADER
Luyan DAI, PhD
Executive Director, Clinical Development, Harbour Biomed

Session 0501-2 | MAY 24, 2018

08:30-10:00
2nd Floor
203CD

Challenges and Opportunities in Orphan Drug Development

SESSION CHAIR
Yong WANG, PhD
Senior Director, Biostatistics, Parexel

Orphan drug development is filled with opportunities and challenges globally, in legislative polices, research, and clinical trials. The development challenges include understanding the disease, establishing the clinical relevance and cost effectiveness, difficulties in setting up clinical trials for the small populations and high cost of bringing a new product to market especially an orphan drug with limited target population and market opportunities. This session is to underscore the opportunities, successes in orphan drug development and challenges using relevant case studies, globally and domestically.

Research and Development Strategy of Gene Therapy for Single Gene Genetic Diseases
Duan MA, MD, PhD
Professor, Vice Director, Key Laboratory of Metabolism and Molecular Medicine, Ministry of Education, Fudan University

Overcoming Challenges in Rare Disease Drug Development
Chito HERNANDEZ, PhD
Vice President and Head of Biometrics, BioMarin

Development of Ataluren for Non-sense Mutation Duchenne Muscular Dystrophy (nmDMD): Challenges and Opportunities
Fengbin JIN, PhD
Senior Director, Biostatistics, PTC Therapeutics

Bayesian Applications for Extrapolation from Adult to Pediatric Data
Amy XIA, PhD
Executive Director, Biostatistics, Amgen

Quantitative Science

Session 0502-2 | MAY 24, 2018

10:30–12:00
2nd Floor
203CD

Innovative Statistics Methods in Dose Finding - Method, Status and Implementation

SESSION CO-CHAIRS
Haige SHEN, PhD
Co-founder, ZenRhyme Consulting

Liansheng ZHU, PhD
Biostatistics Site Head, China, Global Drug Development, Clinical Development & Analytics, Novartis

The request of high-speed, effective drug development has significantly increased the complexity of clinical trials in the early phase. The complex clinical development strategies call for innovation of statistical methods to balance statistical, clinical and operational considerations. How to adapt the statistical methods to the development strategy and supporting more effective and efficient decision makings in early clinical development stage dose-finding is challenging. In this session, we will focus on the methodology in oncology dose-finding, discuss the status and problems of traditional methods, give a general introduction to some innovative methods, and demonstrate good practice and challenges in implementation from clinical perspective.

Status and Problems of Traditional Dose-finding Methods
Jack LI, PhD
Senior Director of statistics, dMed Biopharmaceutical

Emerging Dose-Finding Designs in Oncology
Yuan JI, PhD
Professor of Biostatistics, Department of Public Health Sciences, The University of Chicago

Immunotherapy Dose Finding: A Rapid Enrollment Design with Ordered Groups
Xiaoqiang XUE, PhD
Scientific Advisor, Data Sciences, Safety, and Regulatory, IQVIA

Issues and Challenges of Early Phase Oncology Dose-finding from a Clinician Prospective
Andrea MYERS, MD, PhD
Global Head, Translational Clinical Oncology China, Novartis

Quantitative Science

Session 0505-2 | MAY 25, 2018

08:30-10:00
2nd Floor
203CD

Bridge the Gap between RWE vs. RCT – Part 1: Clinical Evidence for Regulatory Decision Making – What is Essential?

SESSION CHAIR
Jianing DI, PhD
Director, China Site Head
Statistics & Decision Sciences, Janssen R&D LLC

With all the hype about real world evidence (RWE) reaching a high, there have been continuous discussion about how it complements evidence coming out of randomized controlled trials (RCTs). What are the essential evidence to be extracted from an RCT? Can some of it be enhanced or replaced by RWE? What are to be considered during regulatory decision making? In this session (Part 1), we will focus on the essential considerations in designing and interpreting RCTs and how it may link to the use of RWE.

Introduction of Evidence Based Medicine
Xin SUN, PhD
Professor, Dean, China Cochrance Center, West China School of Medicine/West China Hospital, Sichuan University

Evaluating Joint Effects of Induction-Salvage Treatment Regimes on Overall Survival in Acute Leukemia
Yanxun XU, PhD
Assistant Professor, Department of Applied Mathematics & Statistics, Johns Hopkins University

Can Statistical Models Replace Randomization?
Feng CHEN, PhD
Professor, Dean, School of Public Health, Nanjing Medical University
Chair of China Association of Biostatistics (CABS)
Chair of China Clinical Trial Statistics (CCTS) Working Group

Pragmatic Trial, a Hybrid of RCT and Observational Study
Ke WANG, PhD
Senior Health Outcome Consultant, Eli Lilly China

Quantitative Science

Session 0506-2 | MAY 25, 2018

10:30-12:00
2nd Floor
203CD

Bridge the Gap between RWE vs. RCT – Part 2 - Real-World Evidence for Regulatory Decision Making – Where We Are?

SESSION CHAIR
Luyan DAI, PhD
Executive Director, Clinical Development, Harbour Biomed

With all the hype about real world evidence (RWE) reaching a high, there have been continuous discussion about how it complements evidence coming out of randomized controlled trials (RCTs). What are the essential evidence to be extracted from an RCT? Can some of it be enhanced or replaced by RWE? What are to be considered during regulatory decision making? In this session (Part 2), we will focus on the potential considerations in the use of RWE in support of regulatory decision making together with RCTs, as well as the current RWE landscape in China

Japanese Guidance and PMDA's Experiences in Utilizing Real World Data for Drug Safety Assessment
Yoshiaki UYAMA, PhD
Director, Office of Medical Informatics and Epidemiology
Pharmaceutical and Medical Devices Agency

Opportunities and Challenges in RWE in China
Yang XIE
Senior Principal, Head of Real World Insights, Greater China, IQVIA

Panel Discussion: Points to Consider When RCTs Meet RWE
Panelists: All Speakers from Session 0505-2 & 0506-2

Quantitative Science

Session 0507-2 | MAY 25, 2018

13:30-15:00
2nd Floor
203CD

Statistical Topics in Drug Development of Immune-Oncology

SESSION CO-CHAIRS
Anny-Yue YIN, PhD
Senior Director, Biostatistics, CStone Pharmaceuticals

Tao WANG, PhD
Senior Director, Head of Statistics and Programming Group
Department of Innovative Drug Clinical Development, Jiangsu Hengrui Medicine Co. Ltd

Statistical challenges met in immune oncology drug development will be touched and solutions to these challenges including delayed effect, crossover, response duration are proposed.

Some Statistical Considerations in the Clinical Development of Cancer Immunotherapy
Bo HUANG, PhD
Director, Clinical Statistics, Pfizer Global Product Development, USA

Considerations on Duration of Response in Immu-Oncology
Chao ZHU, PhD
Director and Head of Statistics and Statistical Computation, Eli Lilly and Company (China)

Competing Risks with Applications to an Oncology Study
Lilian BU
Senior Statistical Scientist, Biometrics, Roche

Statistical Methods to Improve Efficiency of Oncology Basket Trial in the Presence of Multiple Biomarkers and Heterogenous Treatment Effect Across Indications
Fan XIA, PhD
Senior Principal Statistician, Biometrics, Beigene

Biologics & Biosimilar 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 | MAY 24, 2018

08:30-10:00
3rd Floor
307

Recent Trends in the Regulation of Biosimilar

SESSION CO-CHAIRS

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

Haibin WANG, PhD
Senior Vice President, Zhejiang Hisun Pharmaceutical Co.Ltd.
Researcher of Yeehong Business School

Biosimilar plays an important role in increasing patient access to biotechnological products. Many countries attach great importance to the development of biosimilar and have established relevant regulations and guidelines for biosimilar. Considering the complexity of biosimilar structures and its manufacturing processes, limited pre-marketing clinical experience of biosimilar, regulatory issues related to the approval and post-marketing supervision of biosimilar have been hot spots for global regulatory authorities, such as: reference drug selection, naming and post-marketing pharmacovigilance, interchangeability, etc. CFDA issued the guidelines for the evaluation of biosimilar in 2015, since then the number of biosimilar applications in China has been increasing year by year, and the first biosimilar is expected to obtain marketing approval in the near future. Therefore, timely introduction of scientific, systematic, and internationally recognized regulatory measures in China will not only help ensure the patients' safety, but also ensure the long-term sustainable development of the biosimilar industry.

In the past half year, Yeehong Business School has conducted in-depth and systematic research on the relevant laws and regulations for biosimialr. In this session, Yeehong will share the results of this research with the industry. Speaker from Novo Nordisk will talk about the considerations on interchangeability, naming, labeling and reference drug list of biosimialr. In addition, during panel discussions, sevearl regulatory experts will share their thinking about the regulation of biosimilar and outlook for the future.

Research on Biosimilar Related Regulatory System

Jianhong YANG
Researcher, Research Center of Yeehong Business School, Shenyang Pharmaceutical University

Considerations of Biosimilar Interchangeability – Naming, Labeling, and Establishment of Reference List

Inger MOLLERUP
Regulatory Consultant, CMR, Novo Nordisk, Switzerland

Biologics & Biosimilar Development

Panel Discussion
All Speakers and Invited Panelists
Ana Hidalgo-Simon, MD, PhD
Head of Specialised Scientific Disciplines Department
Human Medicines Research & Development Support Division, EMA

Yaning WANG, PhD
Regulatory Expert

China NDA Panelist Invited

Session 0602 | MAY 24, 2018

10:30-12:00
3rd Floor
307

Clinical Trial Design of Biologics

SESSION CHAIR
Xiaolu TAO, PhD
Executive Director, DMPK and Clinical Pharmacology, Simcere Pharmaceutical Group

Since the commercialization of the first therapeutic monoclonal antibody product in 1986, therapeutic biologic products has grown significantly, esp. with the current great progress in IO and some other therapeutic areas.

Like small molecule drugs, the goal for either biologics or biosimilars is also to get the right drug to the right patient in the right dose at the right regimen. However, because biologics products are so much larger and complex than simple, small molecule medications, the translation from animal to human is not direct, and hence the clinical trial for biologics need some special considerations, such as prediction of human dose, potential immunogenicity, etc. In this session, the speakers will, from regulatory perspective and industrial perspective, elaborate clinical design for biologics and biolimiars.

EMA Perspective: Regulatory Expectation on the Clinical Design of Biosimilar
Ana HIDALGO-SIMON, MD, PhD
Head of Specialised Scientific Disciplines Department, Human Medicines Research & Development Support Division, EMA

Demonstrating Biosimilarity in the Sensitive Setting
Xiaolu TAO, PhD
Executive Director, DMPK and Clinical Pharmacology, Simcere Pharmaceutical Group

Innovative Clinical Trial Design in Rare Disease- A Case Study of Nusinersen for Spinal Muscular Atrophy
Eric MASSON, PhD
Vice President, Head Clinical Pharmacology & Pharmacometrics, Biogen

Biologics & Biosimilar Development

Session 0605 | MAY 25, 2018

08:30-10:00
3rd Floor
307

Pharmacometrics in Early Stage of Clinical Development

SESSION CHAIR
Pei HU, MD, PhD
Professor, Director, Phase I Unit Clinical Pharmacological Research Center, Peking Union Medical College

The pharmacometrics methods were rarely applied in China pharmaceutical industry for a long time, since the lack of innovative drug research and development before 2010. Along with the recent trend of many domestic drug companies switched to develop innovative drug, it is necessary to promote the domestic relevant personnel as soon as possible to understand the concept and application of pharmacometrics, which helps to quantify drug, disease and trial information to aid efficient drug development, regulatory decisions and rational drug treatment in patients.

In this session, three speakers were invited to discuss the application of pharmacometrics in early stage of clinical development from the perspective of regulators, academic institutions and industry.

First in Human Dose Selection for Immune Activating Biologics
FDA Speaker Invited

Applications of Quantitative Pharmacology in Early Stage Development of Biological Drugs
Yanguang (Carter) CAO, PhD
Assistant Professor, University of North Carolina at Chapel Hill
Adjunct Assistant Professor, SUNY Buffalo
Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy

Pharmacometrics in Biologics Clinical Development: an Industrial Perspective
Rong ZHAO, PhD
Venture Partner, Highlight Capital

Biologics & Biosimilar Development

Session 0606 | MAY 25, 2018

10:30-12:00
3rd Floor
307

Biosimilar Assessment based on Analytical and Pharmacokinetics Studies

SESSION CHAIR
Victoria CHANG, PhD
Manager, Data and Statistical Science, AbbVie, USA

The US Food and Drug Administration (FDA) recommended a stepwise approach for obtaining the totality-of-the-evidence for demonstrating biosimilarity between a proposed biosimilar product and a reference biological product in its recent guidance. The stepwise approach involves: (1) analytical studies for functional and structural characterization of critical quality attributes (CQAs) that are relevant to clinical outcomes at various stages of manufacturing process; (2) animal studies for assessment of toxicity; (3) clinical pharmacology pharmacokinetics (PK) or pharmacodynamics (PD) studies; and (4) clinical studies for assessment of immunogenicity, safety/ tolerability, and efficacy. FDA suggests that CQAs that are relevant to clinical outcomes should be identified and classified into three tiers depending on the criticality (most, mild to moderate, and least) relevant to clinical outcomes. FDA also proposes some statistical approaches for assessment of analytical similarity for CQAs from different tiers.

In this session, two FDA speakers would share their current thinking about analytical and PK biosimilarity assessment. Although there are a few FDA guidance available on assessing biosimilarity, details not mentioned in the guidance would still worth further research and discussion.

Development of Statistical Methods for Analytical Similarity Assessment
Meiyu SHEN, PhD
Expert Mathematical Statistician, Division of Biometrics VI, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA

Some thoughts on FDA Draft Guidance on Analytical Similarity Assessment
Shein-Chung CHOW, PhD
Associate Director for Biosimilar Review
Office of Translational Sciences, Center for Drug Evaluation and Research, FDA

Biologics & Biosimilar Development

Session 0607 | MAY 25, 2018

13:30-15:00
3rd Floor
307

Innovative Biologics Process Development

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

CDE Perspective
CDE Speaker Invited

Development Challenges of CMC Package for Newly Discovered Biologics
Joe ZHOU, PhD
Chief Executive Officer, Genor Biopharma Co. Ltd

Topic TBD
Jianwei ZHU, PhD
Dean, Shanghai Jiao Tong University School of Pharmacy

Session 0608 | MAY 25, 2018

15:30-17:00
3rd Floor
307

Development of Cell Therapy and Regulatory Considerations

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

With a rapid growth of biotechnology and approval of the first CAR-T therapy, cells based therapy has become a hot research area in the world including China. However, cell therapy is composed of diverse groups of cells with heterogeneous origin and a wide range of modifications. Such complexity poses new challenges for both pharmaceutical industry and regulatory agencies. Guidance on such therapies has been issued by regulatory agencies in major market areas including CFDA, which promulgated its guidance in December 2017. This session focus on regulatory considerations from healthy authorities in order to help the audience to better understand the regulations from China, EU, and the USA.

Development of Cell Therapy and Regulatory Considerations - EU Perspectives
Ana Hidalgo-Simon, MD, PhD
Head of Specialised Scientific Disciplines Department
Human Medicines Research & Development Support Division, EMA

Development of Cell Therapy and Regulatory Considerations - CDE Perspectives
CDE Speaker Invited

US Cellular and Gene Therapy Product Regulations Overview
Yong FAN, MD
Senior Consultant and Owner, A2Z Reg Solutions

Generic Drug, CMC & GMP Inspection

THEME LEADER
Xianglin ZHANG
Dean, Yeehong Business School
Shenyang Pharmaceutical University, China

Session 0701 | MAY 24, 2018

08:30-10:00
2nd Floor
201CD
English Only

GMP Inspection – FDA Special Session

SESSION CHAIR
Lane CHRISTENSEN, PhD
Assistant Country Director, China Office , Office of International Programs, FDA

10+ Years of FDA inspections in China
Ellen MORRISON
Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, FDA

Current Inspection Trend
Susan LASKA
Senior Advisor, Medical Products to the Assistant Commissioner for Operations in Office of Regulatory Affairs, FDA

Consideration for Complex and Biotech Manufacturing
Eric DONG
Consumer Safety Officer, Office of Surveillance , Office of Pharmaceutical Quality, CDER, FDA

Session 0702 | MAY 24, 2018

10:30-12:00
2nd Floor
201CD

ICH M9 Guideline: Biopharmaceutics Classification System (BCS) based Biowaivers

SESSION CHAIR
Chi-wan CHEN, PhD
Executive Director, Pfizer
Member of FDA Alumni Association

ICH M9 is currently under development to provide recommendations to support the biopharmaceutics classification system (BCS) of pharmaceutical products and the waiver of bioequivalence studies and to harmonize existing regional guidelines and support streamlined global drug development. Two members of the ICH M9 Expert Working Group – one from China NDA and the other from the U.S. pharmaceutical industry association – will discuss the scope, outline, highlights, and progress of the guideline, and identify any potential issues for harmonization from their perspectives.

ICH M9 Guideline Updates - China NDA Perspectives
CDE Speaker Invited

ICH M9 BCS Based Biowaivers: Status of Guideline Development from Concept to Adoption/Implementation
Roger NOSAL, PhD
Vice President, Global Chemistry, Manufacturing & Controls , Pfizer, USA

Generic Drug, CMC & GMP Inspection

Session 0705 & 0706 | MAY 25, 2018

08:30-12:00
2nd Floor
201CD

DIAmond Session

Quality and Innovation – Key to Success in Global Generic Drug Market - Part 1 & Part 2

SESSION CO-CHAIRS

Xianglin ZHANG
Dean, Yeehong Business School
Shenyang Pharmaceutical University, China

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

Generic medicines offer significant public health benefits globally. They are critical parts of healthcare system, offering essential medicines to the public. They provide the competition to brand name drug, cutting healthcare cost and expanding the access to existing medical treatments. Recently, China NDA had implemented a series of reform on drug review and approval; also became regulatory member of ICH. All these will ensure the development of generic drug following the international standards and generics manufacturers improving their international competiveness. The clinical equivalence of generic medicine with original medicine is the goal of development and approval of generics. However, in order to achieve this goal, and sustain the clinical equivalence of generics with the original medicine throughout the whole life cycle management, "quality" and "innovation" are the only key. In this session, we will discuss what means high quality of generic drug from multiple angles; and why innovation is such important to R&D of generics as well as registration of generic drug.

US GDUFA II: Program Goal and Key Changes

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

FDA Guidance on Good Submission and Good Review Practice – a Quality Perspective

Naiqi YA, PhD
President, eVenus Pharmaceutical Laboratories, Inc.

International Generic and Biosimilar Medicines Association (IGBA)'s View on the Importance of ICH to Generics

Deborah M. AUTOR, JD
Head of Strategic Global Quality & Regulatory Policy, Mylan, Vice Chair,
International Generic and Biosimilar Medicines Association (IGBA) Science Committee
Board Member, FDAAA, Former USFDA Deputy Commissioner and former Director, Office of Compliance, CDER, FDA

Innovative Approach to the Development and Review of Complex Generic Drug

Bing LI, PhD
Vice President, American Chinese Pharmaceutical Association

Challenges and Opportunities in Developing High Quality Generic Drugs in China

Jifeng LEI
Chief Executive Officer, Anbison, Researcher, Yeehong Business School

Panel Discussion

All Speakers and Invited Panelist:
Jianhong YANG
Researcher, Research Center of Yeehong Business School, Shenyang Pharmaceutical University

Medical Writing & Medical Affairs

Medical Writing

THEME LEADERS

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

Session 0801 | MAY 24, 2018

08:30-10:00
3rd Floor
305AB

Toward a Collaborative and Efficient Clinical Document Preparation

SESSION CHAIR

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

The CFDA joined ICH in 2017, and global simultaneous development and submission become possible. Particularly, it is critical to accelerate the submission timeline and efficiently prepare the clinical submission documents with high quality. In this session, we are going to discuss cross-functional good review practice, share experience on DSUR preparation and document life-cycle management in e-submission environment. Our aim is to better prepare our audience to embrace the opportunities and challenges under new regulatory environment.

Getting Return on Investment in Document Review
Joan AFFLECK
Head of Medical Writing, Merck

DSUR Introduction and Experience Sharing
Bryan GRIFFIN, PhD
Senior Medical Writer, Medical Writing Services, PAREXEL International

Embrace eCTD: Life Cycle Management of Clinical Submission Documents
Sophia HUANG
Associate Director, Global Submission Management & Planning, Bayer

Medical Writing & Medical Affairs

Session 0802 | MAY 24, 2018

10:30-12:00
3rd Floor
305AB

Introduction and Experience Sharing for Clinical Submission Documents after the CFDA Joins the ICH

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

In year 2017, the CFDA joined the ICH. This exciting news not only brings more opportunities to simultaneous clinical development but also placed higher demands are placed. Regulatory submission guidelines from the CFDA are largely harmonized with ICH. In the present session, we will talk about the clinical modules preparation in CTD structure, introduce documents which play critical role in the regulatory submission and share new thoughts on document preparation in both English and Chinese languages. There will be a panel discussion in this session to share CTD dossier preparation experience and to answer the questions from the audience.

Preparation of the Clinical Modules in ICH CTD Structure
Ning ZHENG
Senior Medical Writer, Clinical Documentation, Sanofi R&D

The Shot on Goal in Pharmaceutical R&D - Simultaneous Preparation of Clinical Submission Documents in both English and Chinese
Bruce XUE, PhD
Head, Medical Writing & Language Services, Janssen China R&D Center

Panel Discussion: All Speakers from Session 0801 & 0802 and Invited Panelist
Xiaoling WANG
Clinical Documentation, Clinical Science Operation, Sanofi R&D China

Medical Writing & Medical Affairs

Medical Affairs

THEME LEADER

Li WANG, MD, PhD

Chief Medical Officer & Vice President, Lilly China Drug Development & Medical Affairs Center

Session 0805 | MAY 25, 2018

8:30–10:00
3rd Floor
305AB

Multi-channel Medical Communication under New Trends

SESSION CHAIR
Jian LI
Medical Director, AstraZeneca China

MI Wisdom Service Towards a Patient Centric Model
Zhan WANG
Senior Medical Information Operational Manager, Medical Information , EMC, Pfizer

Smart Digital: Livecast Contributes to Medical Education
Senpeng CHEN
Medical Information & Intelligence, AstraZeneca Investment (CN) Co., Ltd

Physician Requirements Change from Internet Perspective
Zhimin XIA
Director of Content, DXY

Session 0806 | MAY 25, 2018

10:30–12:00
3rd Floor
305AB

Phase IV Study & Investigator Initiated Sponsored Research

SESSION CHAIR
Yi LIU
Vice President, Clinical Science & Medical Affairs, DMed

Investigator Initiated Sponsored Research (IISR) Survey Result Sharing
Yi LIU
Vice President, Clinical Science & Medical Affairs, DMed

IISR Standard Process and Quality Control System Establishment
Lily SONG
The George Institute for Global Health at Peking University Health Science Center

The IIT Standardization Process and Quality Control System
Xin WANG
Senior Manager, Medical Compliance & Medical Control, Greater China, Takeda

Panel Discussion: All Speakers

Medical Writing & Medical Affairs

Session 0807 | MAY 25, 2018

13:30–15:00
3rd Floor
305AB

Life Cycle Medical Strategy

SESSION CHAIR
Zhi LI
Director, Medical Affairs, Boehringer Ingelheim

New Product Launching Plan
Cong XU
Vice President, Investment, Lilly Asia Ventures, Vice President, Medical, Impact Therapeutics

Medical Strategy in Merging Product
Grace WANG
Associate Director, Respiratory, Boehringer Ingelheim

Post-marketing Clinical Research Design
Junhao FAN
Medical Director, FibroGen

Session 0808 | MAY 25, 2018

15:30–17:00
3rd Floor
305AB

Career Development of Medical Affairs Personnel: Face to Face with the Senior Leaders

SESSION CHAIR
Li WANG, MD, PhD
Chief Medical Officer & Vice President, Lilly China Drug Development & Medical Affairs Center

Medical affairs play a positive role in promoting medicine and science. In recent years, because of the evolvement of China pharma environment and government policy changes, Medical Affairs has become one of the fastest growing functions in pharmaceutical industry, and the number of employees is also growing rapidly and the scope of Medical Affairs has been expanded significantly. This section provides attendees an opportunity to meet with the senior leaders of Medical Affairs, having face to face interaction to discuss capability development of Medical Affairs professionals, and also get their advices on how to manage career planning.

Become Medical Affairs Top Talent by Self-Directed Excelsior Learnings
Lyra XIE, MD
Medical Director, Abbott EPD China

INVITED PANELISTS
Lyra XIE, MD, MBA
Medical Director, Abbott EPD China

XiaoXiang CHEN
Vice President, Clinical Development & Regulatory Affairs, Harbor Medicine

James JIN, MD, PhD
Senior Medical Director, Lilly China

Lei QIAN, MD, PhD
Senior Director, Clinical Strategy, Innovent Biologics

Pharmacovigilance & Safety

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

Session 0901 | MAY 24, 2018

08:30-10:00
3rd Floor
305CD

How to Improve Safety Reporting in Clinical Trial - Different Perspective from HA and Industry

SESSION CO-CHAIRS
Qin LIN
China PV Head, Director, MSD R&D (China) Co., Ltd.

Hellen ZHANG
China PV Country Head, Bayer Healthcare Co., Ltd China

Standardize the management of important safety data during drug clinical trials, ensure the safety of subjects, and promote the internationalization of technical standards. The safety reporting and monitoring in clinical trial is much more important than before. This session will invite experts from Health Authority and Industry to share the different perspectives and practical experience on how to do IND safety reporting and safety monitoring better than before, and will have interactive discussion with the audience how to improve safety reporting in clinical trial.

Large Pharma Experience with Implementing the FDA Final Rule on Expedited IND Safety Reporting
Nina STUCCIO
Associate Vice President, Head, Medical Safety Review and Clinical Trial Safety Reporting, Merck Research Laboratories, USA

Safety Oversight in Clinical Trials
Dawn REN
Global Safety Leader,
Benefit Risk management, TA Pulmonary Medicines, Pharmacovigilance, Pharmaceuticals, Bayer AG

China NDA's Expectation in Clinical Trails
CDE Speaker Invited

Pharmacovigilance & Safety

Session 0902 | MAY 24, 2018

10:30-12:00
3rd Floor
305CD

Post Marketing Safety Surveillance

SESSION CO-CHAIRS
Lynn ZHOU
PV Head for China, Asia and JPAC, Global Pharmacovigilance, Sanofi

Yuan MENG
Head, Safety, Janssen Greater China

This session will introduce overseas regulation of post marketing safety study and their practice. In addition, China PV system developed quickly in recent years, China PV expert will bring us a new topic on development of Chinese hospital sentinel site to support signal detection and safety evaluation in China.

Post Authorization Safety Study
Jan PETRACEK, MD
Chief Executive Officer, PrimeVigilance, UK

Development History and Practice of Pharmacovigilance System in Chinese Hospitals
Jianxiong DENG
Director, Center for ADR Monitoring of Guangdong

Session 0905 | MAY 25, 2018

08:30-10:00
3rd Floor
305CD

Labeling Across Product Life Cycle

SESSION CHAIR
Gao GAO
Director, Safety Surveillance and Risk Management, Worldwide Safety and Regulatory, Pfizer

Labeling is the basis of information to guide safe and effective use of drugs. It has been recognized as a key component of the routine risk minimization measures and an integral part of a company's global pharmacovigilance system.

This session aims to provide an overview of development and maintenance of safety labeling across the product life cycle. Label management involves science-based decision making process and collective cross-functional activities. It is critical to ensure timely and consistent communication of safety information through product labeling. The speakers will share global experience and examples on the evolvement of reference safety information from investigational stage, generation of adverse reaction information for the purpose of core safety information and local submission labeling, creation of initial labeling text, maintenance and update of safety labeling in the context of post-approval safety monitoring and risk management.

Evolvement of the Product Label - from Clinical Trial to Submission
Joan SHEN, MD
Vice President, Head of R&D, I-Mab Biopharma

Management of Safety Labeling at Post-marketing Stage
Rajesh AGGARWAL, PhD
Senior director, Disease Area Cluster Lead, Safety Surveillance and Risk Management, Worldwide Safety and Regulatory, Pfizer

Pharmacovigilance & Safety

Session 0906 | MAY 25, 2018

10:30-12:00
3rd Floor
305CD

PV Information System

SESSION CHAIR
James MA
China Site Lead, Information Management
Operations Center of Excellence, Global Product Development, Pfizer

CFDA joined ICH last year and started to promote the use of ICH guidelines. It will significantly improve the quality of drug safety and surveillance in China. To meet the ICH guidelines, China authority and industry have to use in-house or commerce PV information system for adverse event collection, analysis, processing and reporting. This session will introduce PV information system, its function and components, trend and best practice.

Introduction of End to End PV Information Systems
James MA
China Site Lead, Information Management
Operations Center of Excellence, Global Product Development, Pfizer

Components of An Optimized PVRM Solution
Sameer THAPAR, PhD
Director, Global Pharmacovigilance, Oracle Health Science Consulting

The Integration of SAE Management between EDC and PV System
Charles YAN, PhD
Head, Clinical Data Science Center, Hengrui Medicine

Session 0907 | MAY 25, 2018

13:30-15:00
3rd Floor
305CD

Cardiovascular Safety of Anticancer Drugs in Development

SESSION CO-CHAIRS
Haiyan LI
Professor of Cardiology, Director, Drug Clinical Trial Center, Peking University Third Hospital

Advances in treatment have led to improved survival of patients with cancer, but have also increased morbidity and mortality due to treatment side effects. Cardiovascular diseases (CVDs) are one of the most frequent of these side effects, and there is a growing concern that they may lead to premature morbidity and death among cancer survivors. The objective of this Session is to discuss Cardiovascular Safety in Oncology Drug Development from Regulatory, Academia and Industry's perspective.

Conny MO
Medical Safety Advisor/Partner, Beijing RHGT information Co., Ltd

Cardiovascular Safety In Oncology Drug Development - CDE's Perspective
CDE Speaker Invited

Pharmacovigilance & Safety

Non-Clinical Assessment of Anticancer Drug Cardiotoxicity
Stefan BRAAM, PhD
Chief Executive Officer, Ncardia, The Netherlands

Anti-cancer Therapy Induced Cardiotoxicity - Impact on Oncology Drug Development and Potential Approvability
Sean ZHAO, PhD
Executive Medical Director, US Patient Safety Surveillance, AstraZeneca Pharmaceuticals LP, Wilmington DE

Mitigating Cardiovascular Toxicity of Anticancer Drugs in Development
Boaz MENDZELEVSKI, MD
Consultant, Cardiac Safety Consultants Ltd,UK

Session 0908 | MAY 25, 2018

15:30-17:00
3rd Floor
305CD

DIAmond Session

ICH E2 Guideline Update

SESSION CHAIR
Minshi SU
Associate Director, Medical Safety, XiAn Jassen Pharmaceutical Company ltd.

E2C Update on Periodic Benefit-Risk Evaluation Report
Speaker Invited

Overview of ICH E2E and ICH E2D
Gerald DAL PAN, MD, MHS
Director, Office of Surveillance and Epidemiology, CDER, FDA

E2F Updates on Development Safety Update Report
Jan PETRACEK, MD
Chief Executive Officer, PrimeVigilance, UK

Patient Engagement

THEME CO-LEADERS

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

Jane CAI, PhD
Senior Advisor, Chinese Organization for Rare Disorders
Former Managing Director, DIA China

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 25, 2018

08:30-10:00
3rd Floor
308

DIAmond Session

Patient Initiatives Program - The Global Perspectives

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

Patient Initiative in US, Japan & Korea
Rosamund ROUND
Patient Centricity and Innovation Lead
Associate Director, Patient Recruitment Strategy Group
Parexel International

Patient Initiative in EU
Agnes SAINT-RAYMOND, MD
Head of International Affairs
Head of Portfolio Board
European Medicines Agency

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

Session 1006 | MAY 25, 2018

10:30-12:00
3rd Floor
308

China's Progress in Rare Diseases

SESSION CHAIR
Dayao ZHAO, PhD
Vice President and Lead, China Drug Development, Pfizer

Health Technology Assessment and Medical Insurance Access Plan for Rare Diseases
Kun ZHAO
Division Head, Division of Health Technology Assessment, China National Health Development Research Center

CDE's Expedited Review for Orphan Drug
CDE Speaker Invited

Current and Future of China's Rare Diseases - Clinical Physician's Perspective
Jie DING
Professor, Former Vice President, Peking University First Hospital

Patient Engagement

Session 1007 | MAY 25, 2018

13:30-15:00
3rd Floor
308

Rare Diseases Forum: The Roles of Patient Groups - Part 1

SESSION CHAIR
Jane CAI, PhD
Senior Advisor, Chinese Organization for Rare Disorders
Former Managing Director, DIA China

How to Leverage the Collaborations between Patient Groups and Pharma Companies: the Experience sharing from CORD
Kevin HUANG
President, Chinese Organization for Rare Disorders (CORD)

Cases Sharing

Patients' Voices in Drug Development
Fei HONG
Founder, MSZJ & House 086

Seizing the Collaboration Opportunities between Patient Groups and Pharma Companies
Shanshan GUAN
Head of Patient Service, Shire China

Scientific based Patient Communication and Engagement
Yun WU
Senior Manager, Patient Support and Education, Medical, Roche

Session 1008 | MAY 25, 2018

15:30–17:00
3rd Floor
308

Rare Diseases Forum: The Roles of Patient Groups - Part 2: Panel Discussion

SESSION CHAIR
Xiaowei JIN, PhD
Director, Biologics, Hua Medicine

Everyone Involved - Making Rare Diseases Public Known
Shuting LI
Secretary, Clinical Research Promotion Funds (Beijing Century Charity Foundation)

Panel Discussion
All Speakers from Session 1007 and 1008

Artificial Intelligence in Healthcare

THEME CO-LEADERS

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

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

Cloud computing, big data, artificial intelligence, etc. are words of familiarity to us. Started from the failure of Se-dol Lee in the chess game with AlphaGo last year, people realizes that the information age has entered a new chapter. Nowadays, the continuous development of intelligent information technology allows it for more and more extensive application. Also, machine learning is of great potential in increasing return for the whole medical industry, including mobile health, drug discovery and pharmaceutical analysis, treatment optimization, patient monitoring, and more. With the integration of artificial intelligence and machine learning, the objective of significant risk reduction will possibly be achieved, saving cost and increasing the efficiency of global medical information sharing. Thus, it indicates that a new intelligentialized age of medical science has already begun.

Session 1101 | MAY 24, 2018

8:30-10:00
2nd Floor
201AB

DIAmond Session

Artificial Intelligence and Big Data in the Field of Medical Reform and Drug Development - Big Data and Artificial Intelligence Theory

SESSION CHAIR
Heping ZHANG
Susan Dwight Bliss Professor, Biostatistics
Professor of Child Study and Statistics
Director, Collaborative Center for Statisitics in Science, Department of Epidemiology and Public Health, Yale School of Public Health

Farm High-dimensional Significant and Important Variables
Jianqing FAN, PhD
Professor of Statistics
Frederick L. Moore Professor
Director, Committee of Statistical Studies, Princeton University

Automated Translation of Diagnostic Codes Across Healthcare Systems
Tianxi CAI
Professor of Biostatistics, Harvard School of Public Health

Statistical Methods for Functional Microbiome Data Analysis
Hongzhe LEE
Professor of Biostatistics and Statistics
Director, Center for Statistics in Big Data
Chair, Biostatistics Graduate Program
University of Pennsylvania

AI Methods for Medical Imaging Analysis
Hongtu ZHU
Bao-Shan Jing Professorship in Diagnostic Imaging and Professor of Biostatistics, MD Anderson Cancer Center
Principal Scientist, DiDi Chuxing

Artificial Intelligence in Healthcare

Session 1102 | MAY 24, 2018

10:30-12:00
2nd Floor
201AB

AI in Application : Challenge and Solution Part 1 - Artificial Intelligence in Regulatory, Medical Affairs and Clinical

SESSION CHAIR
James MA
China Site Lead, Information Management, Operations Center of Excellence, Global Product Development, Pfizer

Machine learning and Artificial Intelligence seem to permeate our world and drug discovery & development make no exceptions. This session will discuss how Artificial Intelligence can be used in clinical trial, regulatory affair, medical information to improve quality and efficiency.

AI Application in NCD Management
Chengming GU, PhD
Vice President, Head of Medical, Pfizer Pharmaceuticals

AI Practice in Regulatory Affairs
George WU
Chief Executive Officer, DoubleBridge

AI Practice in Life Science
Jinlei LIU
Vice President, Product Development, Converge HEALTH By Deloitte

AI's Innovation in Clinical Trials
Michael MONTELLO
Vice President, Global Head of R&D Technology, IQVIA

Session 1105 | MAY 25, 2018

8:30–10:00
2nd Floor
201AB

AI in Application: Challenge and Solution Part 2 - Artificial Intelligence and Blockchain in the Field of Medical Reform and Drug Development

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

Artificial intelligence and blockchain are new technologies that have attracted great attention recently. In the field of medical research and drug development, they have brought a revolution in productivity and production relations. With these new technologies, the application of AI and blockchain will bring automation and intelligence to medical research and drug development. This section invites three speakers who will present their cutting-edge research in areas of AI and blockchain.

Curve at the New Era- Model Based Drug Development Empowered by AI
Zheng GUAN
Chief Science Officer, Founding Partner, Deep Intelligent Pharma Co., Ltd.

Opportunities and Challenges for AI in Medical Image Analysis
Xin ZHONG
Founder & CEO, 12sigma

Artificial Intelligence in Healthcare

Application Prospect of Blockchain in the Medical Field
Zongyu LIU
Director, Vcbeat Research

Session 1106 | MAY 25, 2018

10:30–12:00
2nd Floor
201AB

Panel Discussion about Application of Big Data in Clinical Trial

SESSION CO-CHAIRS
Tony GUO, PhD
Executive Director, Head of Biometrics China, BeiGene

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

With the integration of artificial intelligence and machine learning, the objective of significant risk reduction will possibly be achieved, saving cost and increasing the efficiency of global medical information sharing. Thus, it indicates that a new intelligentialized age of medical science has already begun. The session will invite top experts from the areas to discuss the applications and the possible solutions to achieve the best outcomes in healthcare.

PANELISTS
Joseph SCHEEREN, PharmD
Senior Vice President, Senior Advisor R&D, Bayer AG, Germany
DIA Chair-elect

Heping ZHANG, PhD
Susan Dwight Bliss Professor of Biostatistics
Professor of Child Study and Statistics
Director, Collaborative Center for Statisitics in Science
Yale School of Public Health, Department of Epidemiology and Public Health

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

Ross ROTHMEIER
Vice President, Technology Solutions and Innovation Labs, Medidata Solutions

Michael MONTELLO
Vice President, Global Head of R&D Technology, IQVIA

PJ CHEN
President, United BioPharma China

Gauden GALEA
WHO Representative, China Office, World Health Organization

Medical Devices

THEME LEADER
Amber WANG
Vice President, Regulatory Affairs & QA, SmithNephew

Session 1201 & 1202 | MAY 24, 2018

08:30-12:00
3rd Floor
308

New Medical Device Regulations on Market Permission Set to Accelerate Innovation Industry – Part 1 & 2

SESSION CHAIR
Amber WANG
Vice President, Regulatory Affairs & QA, SmithNephew

With the rapid development of new technology and medical device industry, the traditional medical device evaluation and approval system is facing great challenges. In order to encourage innovation, accelerate the registration and improve the market access of medical device products, the competency authority (CFDA) is fully promoting the reform of the medical approval system. Including the introduction of the special approval procedure for the innovation device and priority review device, pilot program for device MAH in Shanghai and registration quality system inspection and so on. This section will invite CFDA and FDA senior officials, industry experts to share the latest strategy and initiatives on medical device registration supervision and life cycle management, discuss with medical experts and others on how to build an innovative and efficient ecosystem for medical device assessment and approval.

The Major Regulatory Progress in Medical Device Evaluation and Approval in China
CDE Speaker Invited

CDRH's Vision for Medical Device Safety to Protect Patients and Spur Innovation, the Strategic Priorities from FDA Perspectives
William SUTTON
Assistant Country Director, FDA China Office
International Program and Policy Analyst, Medical Devices

Introduction of Innovative Medical Devices Approval Special Procedure
China NDA Speaker Invited

The Pilot Program of Medical Device Marketing Authorization Holder in Shanghai
Haihong JIANG
Associate Professor, School of Medical Device, Shanghai University of Medicine & Health Sciences

Panel Discussion
The competent authority must foster innovation that spurs the development of safer, more effective technologies and assures timely patient access. The considerations from different perspective on how to build a modernized and innovative review processes.

All Speakers Above and Invited Panelist:
Chenxi OUYANG, MD, PhD
Vice Director, Cardiovascular Disease Center, Fuwai Hospital Chinese Academy of Medical Sciences

Hot Topics and Late Breakers

Session 1302 | MAY 24, 2018

10:30–12:00
3rd Floor
305E

Clinical QMS Evolution and Effectiveness Check

SESSION CHAIR
Helen LI
Head, Medical Quality Assurance, Pfizer

Regulations governing clinical research activities have been evolving significantly in the last decade or so. Global guidance has been modernized to reflect the requirement of quality management system (QMS), and recommendations of risk-based approach and principles of risk management, issue management etc.

At this session, we have invited our CFDA Director, representatives from sponsors and an institution to share with us: How to evaluate the effectiveness of QMS implementation from a sponsor perspective? How to build up quality culture, an essential elements of cQMS? Share examples of established QMS in research institutions to oversee quality of clinical research from an academic perspective?

Modernization of the Regulations and Global guidance (E6 Addendum, E8 Evolution)
CFDI Speaker Invited

How to Oversee Effectiveness of cQMS from a Sponsor Perspective?
Carol BYE
Vice President, Medical Quality Assurance, Pfizer UK

Clinical Research Quality Management from Academic Perspective
Ping JI, MD, PhD
Vice Director, Peking University Clinical Research Institute

Hot Topics and Late Breakers

Session 1305 | MAY 25, 2018

8:30–10:00
3rd Floor
305E

DIA - BayHelix Joint BD and Investment Forum - Opportunities and Challenges: Business Development and Investing Healthcare Innovations with the Dynamic Regulatory Reforms and New IPO Routes

SESSION CHAIR
Jimmy ZHANG, PhD, MBA
Venture Partner, Lilly Asia Ventures

Tremendous positive regulatory changes have been taking place in China, including the enforcement of ICH, patent extension etc., to foster healthcare innovations. Along with the new routes to HKEX IPO paved for pre-revenue biotech companies, how the seasoned investors and inspired entrepreneurs will ride the wave in this dynamic environment?

Back Ground Presentation: China Biotech Investment Perspectives and Revolution in the Past 10 Years
Leon CHEN, PhD
Founder and Partner, 6 Dimensions Capital

Panel Disucssion
Speaker and Invited Panelists
Dan ZHANG, PhD
President and Chief Executive Officer, Fountain Med

Yinxiang WANG, PhD
President, Jacobio Pharma

Stephen LIN
Partner, Lilly Asia Ventures

Lu HUANG
Managing Director, MorningSide Ventures

Topics to be Discussed:
1. Have the regulatory changes of joining ICH, reference to Hatch-Waxman Act, and favorable review procedures of rare disease drugs etc., altered your overall strategy in business development and drug investment?
2. 2Strategy in investing and developing first-in-class drugs from China: is there any FIC in China and how to balance the benefits and risks?
3. Is there still room for fast follow-on, me-too or me-worse?
4. What are the emerging opportunities in developing drugs and devices for rare diseases?
5. What does the HKEX IPO opportunity for pre-revenue biotechs mean to investors? Will this impact the new-co offshore/onshore structure design and R&D portfolio preference?

Hot Topics and Late Breakers

Lunch Session | MAY 25, 2018

12:00–13:00
3rd Floor
305E

The Talent Development in Responding to the Booming Life Science Future

SESSION CHAIR
Clement CHEW
Associate Director for the APAC Regional Office, Barrington James

"Planning a long-term career strategy in the Asia Life Science industry has never been more challenging. With the ever changing landscape of MNCs, Consultancies and the rapidly growing Biopharma sectors, making the right career move has never been more important. Listen to senior Industry experts share their views about how the market place is changing and what they are looking for with regards experience and capability".

"Asia Life Science is one of the fastest changing Industry sectors in the world. Attracting and retaining the best talent is now one of the biggest challenges both large and small companies face today. Listen to top industry experts talk about their unique challenges and how they recruit and retain the best in Industry people"

Panelists Invited
Elisabeth SVENSSON
Senior Vice President, Marketing and Business Development, DIA Global

Amy WU
Associate Director, HR Business Partner, HR, MSD R&D (China) Co., Ltd

Mingqiang ZHANG, PhD
Vice President, Amgen R&D

QingAn JIAO
Senior Director, Head of GCO China, Janssen Pharmaceutical Ltd.

Jason YANG, MD, PhD
Chief Medical Officer, Senior Vice President, Clinical Development, CStone Pharmaceuticals

Hot Topics and Late Breakers

Session 1307 | MAY 25, 2018

13:30–15:00
3rd Floor
305E

Career Development of Clinical Research Professionals

Session Chair
Reako REN
Head of SMO Services, WuXi Apptec

In recent years China's new drug development business keeps rapid growth under expedited new drug approval process and enhanced capital/talent investment to China drug R&D industry, thousands of clinical projects are to be initiated and it causes huge demands of clinical research professionals including a need of tens of thousands. But in fact there's big gap of needs and talent pool. Under this thriving condition, how clinical professionals to develop proper career, how to keep self-improvement and better plan to make good balance between profession, interest and income.

On this session we will invite several industry professional elites for panel discussion to share their career development story, their career development perspectives, also Q&A with audience to bring answer and inspiration for audience.

INVITED PANELISTS

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

Wenjing ZHANG
Project Director, Global/APAC, Sanofi

Huijun ZHANG
Head of Clinical Operation, Covance China

Hai ZHANG
Head of Clinical Operation, Hisun Bio

Hot Topics and Late Breakers

Session 1308 | MAY 25, 2018

15:30–17:00
3rd Floor
305E

Regulatory Agency vs. Regulated Industry - Keys to A Successful Regulatory Career Path

SESSION CHAIR

Yi FENG
President, Fountain Medical Development Ltd
Former Assistant Director and Head of Review Management, China NDA/CDE

This session will provide young professionals with key knowledge and skills to advance their regulatory career in the industry, and the government, including pros and cons for governmental service versus pharmaceutical industry jobs, cultural expectations in US-based vs. China-based companies.

This is a highly interactive session based on a hypothetical case study of a young professional striving for success in this competitive and rapidly evolving field.

There are NO formal lectures and the audience and a panel of highly experienced regulatory professionals follow this young regulatory affairs professional, as she faces challenges in her career: trying to land a job, seeking advancement at her job, handling conflicts with bosses and colleagues, deciding when is it time to leave for a new horizon, how to present gaps in her career when trying to get back into the market, and looking back at her 25 years what are her regrets and her successes.
The chair will be asking the audience what she should do as each challenge arises and taking the audience down a path she chooses, providing guidance from the panel that will be applicable for one's own career.

The audience will benefit from the panel's extensive experience and unique perspectives in both regulatory agency and regulated industry.

PANELISTS

Yi FENG
President, Fountain Medical Development Ltd
Former Assistant Director and Head of Review Management, China NDA/CDE

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

Florence HOUN, MD, MPH, FACP
FDA Alumni Association
VP Regulatory Science, Celgene
Former Director, Office of Drug Evaluation III, CDER/FDA

Mark J. Goldberger, MD, MPH
FDA Alumni Association
Mark J Goldberger MD MPH LLC Consulting
Former Director, Office of Drug Evaluation IV, CDER/FDA
Former Vice President, Abbott Regulatory Intelligence and Policy

White Paper Showcase

Session 1401-1 | MAY 24, 2018

08:30–10:00
3rd Floor, 302

The evolved solution to the constant problem: patient recruitment and patient outcome

SESSION CHAIR
Steven SONG
VP, Business Solution, Jsure Heatlh

In the time of AI and "Patient Centric" era, the medical system has faced new challenge and opportunity, how to use new technology to improve the efficient, reduce cost and improve the quality? No matter in Phase I, Phase III trial, no matter in patient recruitment or patient reported outcome arena, problem means opportunity. We will invite the industry experts to address problem to transform to be opportunity so we can all move into the new era of "Patient Centric".

Health Volunteer Management with Application of AI and New Tech in Phase I Unit
Xuening LI
Director, GCO office, Clinical Pharmacology Research Center, Zhongshan Hospital

Patient Recruitment is Evolving into 2.0
Kevin LIN
CEO, Jsure Health

PRO Break into ePRO era
To be Invited

Session 1402-1 | MAY 24, 2018

10:30–12:00
3rd Floor, 302

Innovative Drug Clinical Research & Development in the New Era

SESSION CHAIR
Carrie ZHANG
Chief Executive Officer, eClinWise

As the policy of research and development innovation continues to execute and various new laws and regulations are introduced to drug industry, the domestic innovative pharmaceutical enterprises are facing unprecedented opportunities and challenges at the same time. In this seminar, we invited 3 experts to discuss the direction of innovative drugs clinical research in current situation to meet the challenges brought by the internationalization of drug research and development.

From the Perspective of Regulatory Science, the Opportunities and Challenges of Clinical Trials under Current Situation
Qin HUANG
CDE

From the Perspective of PI, the Opportunities and Challenges of Innovative Drugs Research and Development under Current Situation
Lin SHEN
Vice President, Beijing Cancer Hospital

Clinical Trial Data Management for International and Domestic Application under Current Situation
Carrie ZHANG
Chief Executive Officer, eClinWise

White Paper Showcase

Session 1401-2 | MAY 24, 2018

08:30–10:00
3rd Floor, 303

RBM of risk management in clinical trials

SESSION CHAIR
Suping LANG
CEO

Since the ICH GCP and the Chinese GCP have incorporated risk-based monitoring (RBM) into the specification at the end of 2016, the industry has had a heated discussion of RBM. From a theoretical perspective, RBM undoubtedly gives a dose of intensification to the increasingly scarce human resources in the field of clinical trials. From the operational perspective, RBM also makes higher requirements to existing project managers.

How could China's clinical trials adapt to development and how to reduce the imbalance between the growing demand for clinical trials and the requirements of high quality and data authenticity of clinical trials ? Through the development of risk management, control plans and implementation steps, the early discovery and identification of quality risks, and the adoption of effective corrective and preventive measures (CAPA) are definiitely key to improving the quality of clinical trials.

RBM could provide a higher level of guarantee for clinical supervision, and achieve the purpose of improving the quality of clinical trials . gcp-clinplus company(Beijing) Will jointly with industry senior experts together holding the seminar of "RBM of risk management in clinical trials" .

Value Placement and Practical Application of RBM during innovative Drug Development Process Management
Specially invited guest

Base on Risk Monitoring
Hai ZHANG

Data Statistics Implementation during Centralized Monitoring
Suping LANG

White Paper Showcase

Session 1402-2 | MAY 24, 2018

10:30–12:00
3rd Floor, 303

Covance White Paper Showcase Session: Driving Global Innovation with an Integrated Drug Development Strategy

SESSION CHAIR
Honggang BI, PhD
VP and General Manager, Covance China

In today's drug development, the application of biomarkers and CDx have delivered greater insights and empowered decision making across the drug development spectrum. In this session, you will learn how we apply recent advances in biomarkers and CDx to improve how we study oncology, cardiovascular, metabolic and renal therapies. In addition this session will showcase the key benefits of programmatic outsourcing as well as how recent Japan regulatory reform help accelerate the drug development.

Covance's Full Development Capabilities go Beyond Clinical Trial Outsourcing
Beatriz ROCHA, MD, PhD
Vice President, Head Strategic Product Development Consulting

Strategic Use of Non-Invasive Biomarkers in NASH Clinical Development
Claudia FILOZOF, MD, PhD
Executive Medical Director, CVMER (Cardiovascular, Metabolic, Endocrine, Renal) Group

Companion Diagnostics – Their Role in Clinical Trial Design
Mark ROBERTS, PhD
Senior Director, Diagnostics Development

How to Accelerate Drug Development by Leveraging Japanese New Regulations such as SAKIGAKE Designation, Conditional Early Approval System and Regenerative Medicine Law
Takefumi GEMBA, PhD
Executive Director, Clinical & Regulatory Strategy

White Paper Showcase

Session 1405-1 | MAY 25, 2018

08:30–10:00
3rd Floor, 302

How does the 3AUDIT help manage the quality of drugs through out the whole process?

SESSION CHAIR
Tan YONG
Chief Editor, Healthcare Executive

The current practice of drug safety supervision proves that the "single governance model" of government regulation is difficult to deal with many new problems in the field of drug administration. How to promote the transition from a "supervisory model" to a "governance model" in drug safety, promote social co-governance, government-led and multi-subject cooperative governance, and organize and mobilize more social resources to participate in drug safety governance while the government is regulated by law; encourage and support third-party social forces to work together with the government to control drug safety risks throughout the entire processes, so as to avoid quality and safety issues, and promote the "diversified governance model", i.e. "social co-governance model", will become a new topic for drug safety governance.

The Key Evaluation Points of the Antitumor Drugs' Clinical Trial Center for Drug Evaluation

How to Use the Method of Quality Management through out the Whole Process to Guarantee the Quality of Clinical Trial?
Kitty JIN
Deputy General Manager and Director of Quality Control Training of 3AUDIT

The Transformation of Drug Safety Management Mode.
Minhao TANG
Former Deputy Director of Shanghai Drug Administration

Interactive Dialogue: How Does the 3AUDIT Help Manage the Quality of Drugs through out the Whole Process
Chenguang WANG
Former dean of Tsinghua University school of low

Yuxia WU
Deputy General Manager of Jiangsu Hengrui Pharmaceutical Co., LTD.

Yongqing ZHUO
Former CEO, RDPAC
researcher, Center for Health Law Research at Tsinghua University Law school

Yinglian HU
Associate Professor, National School of Administration

Maozhi LIANG
Director, GCP Center of the National Drug Clinical Trial Institute of West China Hospital
Director of Phase I Clinical Laboratory and Clinical Pharmacology Laboratory

Xuliu CAI
Founder, 3AUDIT

White Paper Showcase

Session 1406-1 | MAY 25, 2018

10:30–12:00
3rd Floor, 302

Network breaking-The way to explore the "new service" in clinical research

SESSION CHAIR
Maggie GU
Vice President,Clinical Research&Operation, Shanghai Junshi Biosciences Co.,Ltd

With the arrival of spring, the wave of new technology has swept the world and the trend of interconnection of all things has become. How will technology-driven and data-enabling pose challenges to medical affairs and clinical operations? How does the silent collision of RWE and the digital world inspire us? How does the information island effect be dissolved in the specific implementation and the information gap between the sponsor and the site, the practitioner, the investigator, and the (potential) subject is broken? How to use the Internet and big data to accelerate the recruitment process? How to use the main database, artificial intelligence and sharing economy to provide new clinical research services?
We are willing to share the previous exploration cases and technical reserves for the future, and would like to embrace the unpredictable and passionate new generation of clinical research with you .

How the Internet Can be Used in Clinical Research
Sujuan LIANG
Tmall Health Care,KA Operation Advisor, Alibaba Group

Internet Economic Model Helps New Changes in Clinical Research and Operation
Dong JI
Senior Medical Director ,Heng Rui Medicine Co., Ltd

Considerations on Location and Analysis of RWE
Naiqing ZHAO
Professor, Fudan University

Big Data Driven Medical Development
Yun ZHANG
Head of Medical Affairs, Sanofi Pasteur

Data+Technology+Sharing, to Create "New Service" in Clinical Research
Yitian PENG
Co-founder, DRA100

White Paper Showcase

Session 1407-1 | MAY 25, 2018

12:00–13:30
3rd Floor, 302

Practice and application of medical language intelligence technology

SESSION CHAIR
Changfang LIU
Business Services Director, Beijing Atman Intelligence Technology

Atman is founded by AI scientists from Microsoft, provides language intelligence products such as machine translation, machine writing, knowledge graph and big data collection and mining in medical fields. Atman help medical users achieve a leap-forward improvement in the level of language intelligence and promote medical users into the era of artificial intelligence.

Atman will invite very important guests at this sub-forum to share the application of language intelligence products in the development of new drugs.

Application and Product of Machine Writing in Pharmaceutical Company
Wei LIU
CTO, Beijing Atman Intelligence Technology

Application of Neural Network Machine Translation Technology in Multinational Pharmaceutical Company
Caroline OUYANG
Manager, Jassen (China) Research & Development Center

Application of Artificial Intelligence Technology in New Drug R&D
Lurong PAN, PhD
The Global Health Drug Discovery Institute

Session 1405-2 | MAY 25, 2018

08:30–10:00
3rd Floor, 303

Strategies and Technologies in Early Clinical Drug Development to Maximize Program Outcomes

SESSION CHAIR
Hua YANG
CSO, Pharmaron

To help develop China originated innovative drugs and go to the world to benefit patients globally is our mission. The golden opportunity for us to achieve this mission is at our door step today. This session will share with audience Pharmaron's experience in clinical research and development, including
1)The current status and future perspectives of clinical studies in China;
2)First-in-human clinical research in US;
3)Utilizing 14C-drugs to manage safety risk in clinical studies, so to accelerate the drug development process in a high quality.

Clinical Development in China
Lijun XIAO
Senior Director of Regulatory Affairs, CR MedIcon

Traditional FIH design, including SAD/MAD and Scheduling dose Escalations/Strategies to Maximize Safety and Value of These Studies
Chris HICKEY
Vice President of Clinical Business Development, Pharmaron

Human 14C Metabolism Studies/Approaches to Maximize Data Outputs and Value of these Studies
Andrew SLACK
Vice President of Radiolabelled Sciences Business Development, Pharmaron

White Paper Showcase

Session 1406-2 | MAY 25, 2018

10:30–12:00
3rd Floor, 303

Trending of innovative medicine development China vs. Global— promoting the cutting-edge technology and embracing the novel therapy.

SESSION CHAIR
Yin ZHOU
Director of Business Development

With rapid expansion of the pharmaceutical market in recent years, innovative drugs have gradually become the core competence of enterprises in the intensive investment, high risk and promising return pharmaceutical industry.

China's dynamic pharmaceutical market with deep-drilling medical reform, the domestic pharmaceutical industry is in the process of critical transformation from generics to independent innovations.
WuXi CDS, as a wholly owned subsidiary of WuXi AppTec, by virtue of open-access to WuXi AppTec's platform for providing a broad and integrated portfolio of services throughout the drug R&D process.
we are expecting to discuss with the industry leaders that how Chinese enterprises retain invincible position in the fierce competition market by analyzing the trend of new drug R&D, evaluating the circumstances and reviewing the model and strategy during the forum.

Changdong LIU
Livzon Pharmaceutical Group Co., Ltd.

Hai ZHANG
ZHEJIANG HISUN PHARMACEUTICAL Co., LTD.

Session 1407-2 | MAY 25, 2018

12:00–13:30
3rd Floor, 303

The NEXT Generation of Clinical Development

SESSION CHAIR
Eunho SHIN
Head of Medidata APAC solution consultant

Medidata will show how to accelerate clinical development by using the Medidata Clinical Cloud,which optimises outcomes across study planning, site support, patient engagement, study conduct and closeout.

And see how Medidata is already powering the trials of the future with Risk-Based Monitoring, Mobile Health, eConsent, unified content management, and more.

Using eConsent and Virtual Trials to Engage Subjects and Improve Data Integrity in Clinical Trials
张志伟
Medidata China Solution Consultant

Michael TUCKER
Senior Product Solutions Specialist, Medidata Solutions

Regulated Content Management
Chuan JI
Medidata China Solution Consultant

Strategic Monitoring
Alicia HE
Medidata China Solution Consultant

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

MAY 25, 2018

8:30–10:00 **Challenges and Opportunities of SMO Industry and CRC Professionals**

SESSION CHAIR
Shuting LI
Chairman, DIA China SMO Community (CRC Home)

In recent 2 years China's new drug development business keeps rapid growth under expedited new drug approval process and enhanced capital/talent investment to China drug R&D industry, thousands of clinical projects are to be initiated and it causes huge demands of clinical research professionals including a need of over 20,000 CRCs. But so far there are only around 7000 CRCs available, and half of them are new comer with experience less than 6 months. How do we face challenges of such a big gap of CRC demanding and supplying.

How to Fill the Gap of CRC Deficiency- Learning from the Practice of Establishment and Management of the Biggest CRC Team in China
Reako REN
Head of SMO Services, WuXi Apptec

Perspective from Clinical Site in CRC Acceptance and Administration
Xin WANG
Associate Research Fellow, Clinical Trial Center, Beijing Hospital

Panel Discussion
1. Attitude on More and More Fresh Men Joining Clinical Research Industry as CRC
2. What Could Each Party of the Industry Do to Keep, Manage and Develop CRC Professionals

INVITED PANELISTS
Manrong WANG
Director, Clinical Operation, Drug Development & Medical Affairs, Lilly China

Dongning ZANG
Country Head, PPDI

10:30–12:00 **Clinical Project Management**

SESSION CO-CHAIRS

Kevin LI
Head of Study Management China, Bayer

Tina TIAN
Director, Strategic Operations and Clinical Trial Management

Clinical research facilitates drug innovation and creates an innovative pharmaceutical industry, which in turn allows for continuous improvements for the health of the patient. By release many new policy, CFDA want to improve drug development in China, The speed of clinical research capability building determines whether a company can leverage the hard-won "window of opportunity" for its drug innovation industry. The session aims to promote the exchange of clinical project management (CPM) expertise and experience, share the trend and progression of CPM under new environment to improve and speed clinical study development.

How to Speed Clinical Study Timeline with New Regulatory Policy of China NDA
Chris ZHANG
Director, Head of Site service & Start-up, China Clinical, IQVIA

Leveraging Real World Data and Digital Technologies in Clinical Operations
Fuqu WANG
Director, Janssen Clinical Innovation, Janssen R&D

Panel discussion: Impact on Clinical Research with China NDA New Policy, join ICH and New Technology Implement in Clinical Study
Panelists:
Qingan JIAO
Ning XU
Paul DAI
Sunny ZHU
Zhaolong GONG
Lijun LIU
Xia ZHAO

13:30–15:00 **Quantitative Science**

SESSION CHAIR
Roger QU, PhD
Head, Clinical Statistics, Pfizer China R&D Center

The rapid advancement in regulatory science and growth of local pharmaceutical industry in China recently, coupled with the advancement in science and technology, present golden opportunity for the value of quantitative science and clinical statistics to the drug development. This special session features overview of advancement in novel clinical statistics in recent years which brought breakthrough treatment to many of the unmet medicals and diseases. Special discussion will be followed with focus on the relevance and application to the drug development in China.

Future of Clinical Statistics --- Innovative Trial Designs, Precision Medicine, and Global Drug Development
Ivan CHAN, PhD
VP, Pipeline Statistics and Programming, Data and Statistical Sciences

An Introduction for DIA China Statistics Community
Tony GUO, PhD
Executive Director, Head of Biometrics China, BeiGene

Panel Discussion: Clinical Statistics in China
MODERATOR
Luyan DAI, PhD
Executive Director, Clinical Development, Harbour Biomed

DIA CHINA
Innovation Theater Activities

Innovation Hub Presentation | May 23rd, 2018 | 1st Floor

IH01
16:50–17:00

An Integrated and Innovative Pharmaceutical Value Creator Platform to bring the Effective Medicines to the Society More Quickly

Jane CHIU | CMIC (Beijing) Pharmaceutical Services Co.,Ltd. | Booth#N01

IH02
17:05–17:15

Application of Medical Language Intelligence for the Pharmaceutical Industry

Mingxing LUO | Business Services Director | ATMAN | Booth#N05

IH03
17:20–17:30

IRTON, Beyond Randomization

Danni LIU | Shanghai Shanhu Health Technology Ltd. | Booth#N07

IH04
17:35–17:45

Benchmark your GCP Audit Results with Data from other Pharma and Biotech Companies – use, The Engaged Database

Barbara HEUMANN, PhD | The Engaged Database GmbH | Booth#N04

Innovation Hub Presentation | May 24th, 2018 | 1st Floor

IH05
10:05–10:15

How to Make the Clinical Trial Less Expensive?

David WANG | Wuxi Clinical Research and Medical Technology Co.,Ltd | Booth#N06

IH06
10:15–10:25

Conduct High-Quality Early Phase Clinical Studies Overseas

Zongda ZHANG | Nanjing CR Medicon Pharmaceutical Technology Co., Ltd. | Booth#N02,N03

IH07
15:05–15:15

Development and Challenges of CDMO in Chinese Medical Device

Jack HE | Medical Strong (Beijing) Technology Development Co., Ltd | Booth#N09

IH08
15:15–15:25

Landscape of Chinese Pharmaceutical Job Market in 2018

Jane LI | Business Partner of AF Recruiting
Arcane Fire (Shanghai) Recruiting Co., Ltd. | Booth#N08

Innovation Hub Presentation | May 25th, 2018 | 1st Floor

IH09
10:10–10:20 Speed the Early Phase Clinical Development with an Integrated Platform

Weidong ZHONG | Nanjing CR Medicon Pharmaceutical Technology Co., Ltd. | Booth#N02,N03

Poster | May 24th, 2018 | 1st Floor

10:30–12:00 Poster Presentation & Award Ceremony

DIA China E&E (Exchange & Engagement) Session | May 25th, 2018 | 1st Floor

08:30–10:00 CRC E&E Session | Challenges and Opportunities of SMO Industry and CRC Profession

10:30–12:00 Clinical Project Management E&E Session

13:30–15:00 Quantitative Science E&E Session