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
The 10th DIA China Annual Meeting

**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

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  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

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- **Ron FITZMARTIN, PhD**
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- **Sandra MILLIGAN, MD, JD**
  Chair, Fellows of DIA
  Head 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

Xiaolan 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
The 10th DIA China Annual Meeting

**PROGRAM TOPICS**

ICH Day

Opening Plenary

Regulatory Science

ICH Day Opening Plenary

Clinical Development

Quantitative Science

ICH

Generic Drug, CMC & GMP Inspection

Medical Writing & Medical Affairs

Biologics and Biosimilars

Artificial Intelligence in Healthcare

Medical Devices

Patient Engagement

DIA China Community Exchange & Engage Session

DIA China Innovation Theater Activities

Pharmacovigilance & Safety

White Paper Showcase

China NDA Townhall

Innovative Breakthrough in Therapy

Hot Topics and Late Breakers
ICH Day | ICH DAY

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

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<th>Time</th>
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| 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

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 22\textsuperscript{th}** | **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

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<th>Time</th>
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<td>10:30–10:40</td>
<td>Welcome and Introduction</td>
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| 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                       |
**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

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

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<th>Time</th>
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<tr>
<td>10:30-10:35</td>
<td><strong>Chairman Welcome and Opening Comments</strong></td>
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|            | 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 I QT)**  
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**

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<tr>
<td>15:00–16:15</td>
<td><strong>Session 3: QT Analysis and Cardiac Safety Strategies for China</strong></td>
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<td><strong>MODERATOR</strong></td>
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<td>Yaning WANG, PhD</td>
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<td>Regulatory Expert</td>
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<td><strong>Overview of Concentration-QT Analysis Methodology</strong></td>
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<td>Yaning WANG, PhD</td>
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<td><strong>Application of Concentration - QT Analysis based on Data from Phase 1 Trials</strong></td>
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<td>Jiang LIU, PhD</td>
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<td>Regulatory Expert</td>
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<td><strong>Considerations for Cardiovascular Risk Monitoring in Late Phase and Post-approval</strong></td>
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<td>Gailing LI, PhD</td>
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<td>Senior Director, Clinical Pharmacology</td>
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<td>Johnson &amp; Johnson (China) Investment Ltd</td>
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<td>16:15–17:15</td>
<td><strong>Panel Discussion: Study Design, Quality control and The Implementation Strategy of QT Studies in China</strong></td>
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<td><strong>MODERATOR</strong></td>
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<td>Haiyan LI</td>
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<td>Professor of Cardiology</td>
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<td>Director, Drug Clinical Trial Center, Peking University Third Hospital</td>
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<td>All Speakers &amp; CFDA Representative, ICH E14 Working Group in China</td>
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<tr>
<td>17:15–17:30</td>
<td><strong>Workshop Ends</strong></td>
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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

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<tr>
<td>10:30–11:00</td>
<td><strong>Introduction of ICH Guideline M4: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use</strong></td>
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<td>Hualong SUN, MD, PhD</td>
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<td>• Objective of CTD</td>
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<td>• General Principle</td>
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<td>• Modules of CTD</td>
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<td>11:00–11:30</td>
<td><strong>The Structure and Format of CTD/eCTD</strong></td>
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<td>Handsome JI</td>
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<td>• CTD Triangle</td>
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<td>• Difference of CTD from eCTD Structure</td>
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<tr>
<td>11:30–12:00</td>
<td><strong>Manage Trial Master Files for eCTD Implementation</strong></td>
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<td>Daniel LIU, PhD</td>
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<td>• eTMF Regulatory Standards</td>
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<td>• How to Manage TMF While Implement eCTD</td>
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<td>12:00–13:30</td>
<td>Lunch Break</td>
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<td>13:30–14:00</td>
<td><strong>Management of eCTD Life Cycle</strong></td>
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<td>Handsome JI</td>
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<td>14:00–14:30</td>
<td><strong>Overview of eCTD Specifications</strong></td>
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<td>Bruce SUN</td>
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<td>• Composition of eCTD Specifications</td>
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<td>• Process of eCTD Specifications Creation</td>
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<td>• How to Review/Interpret/Implement eCTD Specification</td>
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<td>14:30–15:00</td>
<td><strong>Strategies &amp; Tools to Build a Successful Submission of eCTD</strong></td>
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<td>15:00–15:30</td>
<td>Tea Break</td>
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<td>15:30–16:00</td>
<td><strong>Global eCTD Transition and Case Study</strong></td>
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<td>• Global eCTD Transition Status Quo</td>
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<td>• eCTD Case Study (US/EU/Japan/Thailand)</td>
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<td>• Validation Failure and Technical Rejection Avoidance</td>
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<td>16:00–16:30</td>
<td><strong>Building the eCTD - Practical Approaches to Compiling Electronic Submissions</strong></td>
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<td>16:30–17:00</td>
<td><strong>The Opportunities and Challenges of Submission to China NDA and FDA/EMA in Clinical Data/Dossier for China Domestic Pharmaceutical Companies</strong></td>
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<td>Hualong SUN, MD, PhD</td>
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<tr>
<td>17:00–17:30</td>
<td><strong>Panel Discussion</strong></td>
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**Wednesday, May 23rd | OPENING PLENARY**

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>14:00-15:45</td>
<td>Opening Plenary</td>
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<td>2nd Floor</td>
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<td>Hall 1</td>
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**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

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<tr>
<th>Time</th>
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<td>15:40–16:00</td>
<td>Tea Break</td>
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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
<table>
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<tr>
<td>16:45</td>
<td>Welcome Reception</td>
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<tr>
<td>18:00</td>
<td>DIA China 10th Anniversary and Award Ceremony (Invitation Only)</td>
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**Location:**
- 1st Floor, Exhibition Area
- 2nd Floor, Hall 1
Regulatory Science

Session 0101 | MAY 24, 2018
08:30-10:00
2nd Floor
Hall 2-C

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
**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
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 Discussion
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
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

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


**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

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

Zhigiang 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

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, Q2 Solutions

Utility of Organoid 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**

**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**

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**Session 0306-2 | MAY 25, 2018**

**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

ICH 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.

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**Session 0307-2 | MAY 25, 2018**

**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

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<thead>
<tr>
<th>Breakthrough of Therapeutic Development in Liver Disease</th>
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<tbody>
<tr>
<td><strong>SESSION CHAIR</strong></td>
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<td>Shelly XU, MD</td>
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<td>Chief Executive Officer, Teddy Central Lab</td>
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<td><strong>Future Perspective on Novel Mechanisms of Action for HBV Cure</strong></td>
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<td>Gregory FANNING</td>
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<td>Head of China Discovery Center, Janssen China R&amp;D</td>
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<td><strong>Curing HBV based on Pro-apoptosis Theory</strong></td>
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<td>David YANG, PhD</td>
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<td>President, Ascentage Pharma</td>
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**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, Asclepis 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

THME 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

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, emphasizes 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 Hong Kong’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

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
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

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 University 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

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 MediPharma

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

Gun 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
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
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

<table>
<thead>
<tr>
<th>Quality Specification of Clinical Data in Clinical Trials</th>
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<tbody>
<tr>
<td>Session Chair Invited</td>
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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
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
**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.

**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.
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 policies, 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
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
# 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
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
### 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.

**Bo HUANG, PhD**
Director, Clinical Statistics, Pfizer Global Product Development, USA

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

**Lilian BU**
Senior Statistical Scientist, Biometrics, Roche

**Fan XIA, PhD**
Senior Principal Statistician, Biometrics, Beigene
Biologics & Biosimilar Development

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 biosimilar. 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 biosimilar. In addition, during panel discussions, several 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
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 biosimilars.

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
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
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
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
### Session 0701 | MAY 24, 2018

**GMP Inspection – FDA Special Session**

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

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

**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 competitiveness. 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
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
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
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

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

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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

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### Session 0901 | MAY 24, 2018

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

<table>
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<tr>
<th>How to Improve Safety Reporting in Clinical Trial - Different Perspective from HA and Industry</th>
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<tr>
<td><strong>SESSION CO-CHAIRS</strong></td>
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</table>
| 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 Trials**

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
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

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.

**Cardiovascular Safety In Oncology Drug Development - CDE’s Perspective**
Conny MO  
Medical Safety Advisor/Partner, Beijing RHGT information Co., Ltd

The objective of this Session is to discuss Cardiovascular Safety in Oncology Drug Development from Regulatory, Academia and Industry's perspective.
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

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
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

**DiAmend 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
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 intelligentized age of medical science has already begun.
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
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 Statistics 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

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
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 Discussion
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. Strategy 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
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
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
### Session 1401-1 | MAY 24, 2018

**08:30–10:00**

3rd Floor, 302

<table>
<thead>
<tr>
<th>The evolved solution to the constant problem: patient recruitment and patient outcome</th>
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| **SESSION CHAIR**
Steven SONG  
VP, Business Solution, Jsure Health |

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

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### Session 1402-1 | MAY 24, 2018

**10:30–12:00**

3rd Floor, 302

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<thead>
<tr>
<th>Innovative Drug Clinical Research &amp; Development in the New Era</th>
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| **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
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 definitely 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

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
How does the 3AUDIT help manage the quality of drugs throughout 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 throughout 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 throughout 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
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

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<tr>
<th>Session 1407-1</th>
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<td>3rd Floor, 302</td>
<td></td>
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<tr>
<td><strong>Practice and application of medical language intelligence technology</strong></td>
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<tr>
<td><strong>SESSION CHAIR</strong></td>
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<tr>
<td>Changfang LIU</td>
<td>Business Services Director, Beijing Atman Intelligence Technology</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Session 1405-2</th>
<th>MAY 25, 2018</th>
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<tbody>
<tr>
<td>08:30–10:00</td>
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<tr>
<td>3rd Floor, 303</td>
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<tr>
<td><strong>Strategies and Technologies in Early Clinical Drug Development to Maximize Program Outcomes</strong></td>
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<tr>
<td><strong>SESSION CHAIR</strong></td>
<td></td>
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<tr>
<td>Hua YANG</td>
<td>CSO, Pharmaron</td>
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</table>

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
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.

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
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
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
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
### Innovation Theater Activities

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

<table>
<thead>
<tr>
<th>IH01</th>
<th>16:50–17:00</th>
<th>An Integrated and Innovative Pharmaceutical Value Creator Platform to bring the Effective Medicines to the Society More Quickly</th>
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<tbody>
<tr>
<td>Jane CHIU</td>
<td>CMIC (Beijing) Pharmaceutical Services Co., Ltd.</td>
<td>Booth#N01</td>
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<table>
<thead>
<tr>
<th>IH02</th>
<th>17:05–17:15</th>
<th>Application of Medical Language Intelligence for the Pharmaceutical Industry</th>
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<tbody>
<tr>
<td>Mingxing LUO</td>
<td>Business Services Director</td>
<td>ATMAN</td>
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<tr>
<th>IH03</th>
<th>17:20–17:30</th>
<th>IRTON, Beyond Randomization</th>
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<tr>
<td>Danni LIU</td>
<td>Shanghai Shanhu Health Technology Ltd.</td>
<td>Booth#N07</td>
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<table>
<thead>
<tr>
<th>IH04</th>
<th>17:35–17:45</th>
<th>Benchmark your GCP Audit Results with Data from other Pharma and Biotech Companies – use, The Engaged Database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbara HEUMANN, PhD</td>
<td>The Engaged Database GmbH</td>
<td>Booth#N04</td>
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</table>

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

<table>
<thead>
<tr>
<th>IH05</th>
<th>10:05–10:15</th>
<th>How to Make the Clinical Trial Less Expensive?</th>
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<tbody>
<tr>
<td>David WANG</td>
<td>Wuxi Clinical Research and Medical Technology Co., Ltd</td>
<td>Booth#N06</td>
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<thead>
<tr>
<th>IH06</th>
<th>10:15–10:25</th>
<th>Conduct High-Quality Early Phase Clinical Studies Overseas</th>
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</thead>
<tbody>
<tr>
<td>Zongda ZHANG</td>
<td>Nanjing CR Medicon Pharmaceutical Technology Co., Ltd.</td>
<td>Booth#N02, N03</td>
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<table>
<thead>
<tr>
<th>IH07</th>
<th>15:05–15:15</th>
<th>Development and Challenges of CDMO in Chinese Medical Device</th>
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<tbody>
<tr>
<td>Jack HE</td>
<td>Medical Strong (Beijing) Technology Development Co., Ltd</td>
<td>Booth#N09</td>
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<thead>
<tr>
<th>IH08</th>
<th>15:15–15:25</th>
<th>Landscape of Chinese Pharmaceutical Job Market in 2018</th>
</tr>
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<tbody>
<tr>
<td>Jane LI</td>
<td>Business Partner of AF Recruiting Arcane Fire (Shanghai) Recruiting Co., Ltd.</td>
<td>Booth#N08</td>
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<tr>
<td>Event</td>
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<tr>
<td>Innovation Hub Presentation</td>
<td>May 25th, 2018</td>
<td>10:10–10:20</td>
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<tr>
<td>IH09 Speed the Early Phase Clinical Development with an Integrated Platform</td>
<td>May 25th, 2018</td>
<td>10:10–10:20</td>
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<tr>
<td>Poster</td>
<td>May 24th, 2018</td>
<td>10:30–12:00</td>
</tr>
<tr>
<td>DIA China E&amp;E (Exchange &amp; Engagement) Session</td>
<td>May 25th, 2018</td>
<td>08:30–10:00</td>
</tr>
<tr>
<td>CRC E&amp;E Session Challenges and Opportunities of SMO Industry and CRC Profession</td>
<td>May 25th, 2018</td>
<td>10:30–12:00</td>
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<tr>
<td>Clinical Project Management E&amp;E Session</td>
<td>May 25th, 2018</td>
<td>13:30–15:00</td>
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<tr>
<td>Quantitative Science E&amp;E Session</td>
<td>May 25th, 2018</td>
<td>08:30–10:00</td>
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