恪守临床价值导向，引领药物研发新趋势
Drug Innovation Driven by Unmet Medical Needs

# 2017 中国国际药物信息大会暨第九届DIA中国年会

5月21-24日 上海国际会议中心

# 9th DIA China Annual Meeting

May 21-24 | Shanghai International Convention Center

## 会议手册
## Final Program

2017 年 5 月 21 日 —— 会前专题研讨会
2017 年 5 月 22–24 日 —— 会议和展览

21 May, 2017 – Preconference Workshop
22-24 May, 2017 – Conference and Exhibition

主办单位 / Host

DIA

CCFDIE

## 大会指导委员会 STEERING COMMITTEE

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再鼎制药执行副总裁，
临床研发及法规事务负责人

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Head of Clinical Development
and Regulatory Affairs, Zai Lab

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China Center for Food and Drug
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北京协和医院临床药理中心
I期临床研究室

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Head of Regulatory, Asia Pacific,
Roche (China) Ltd.

邵颖 博士
上海复星医药集团副总裁兼研发
中心主任

**Ying SHAO, PhD**
Vice President and Director of
R&D Center, Shanghai Fosun
Pharmaceutical (Group) Co., Ltd.

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沈阳药科大学教授，
药品监管科学研究所所长
礼来亚洲基金风险合伙人

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Professor and Director,
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Science, Shenyang
Pharmaceutical University
Venture Partner, Lilly Asia
Ventures

王劲松 医学博士
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朱立红 工商管理硕士
DIA中国区董事总经理

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

# 2017中国国际药物信息大会暨第九届DIA中国年会

本届年会以“恪守临床价值导向，引领药物研发新趋势” 为主题，第九届DIA中国年会以回归“临床价值”这一药物研发本质，夯实新药研发基础，促进高质量的新药开发，切实满足患者的需求。年会将吸引来自各大洲及地区的2000多名药政法规、药物研发、健康产业的参会者，超过100个展位的形象展示，直击中国药物研发与法规创新带来的变革。顺应变革，主办方为参会者带来“DIAmond钻石经典分会研讨”与适合中小规模新型研发企业的“创新港展示”两大创新会议展览形式。

### 特色专题

- 监管科学
- CFDA专场
- 多方合作，共同打造高质量临床研究
- 肿瘤药物开发
- 变革中的定量科学
- 恪守临床价值，满足患者需求
- 生物制品与生物类似物的开发与监管
- 患者安全——持续关注的焦点
- 创新药物早期研发战略与战术
- 立足中国的新药开发和创业论坛
- 罕见病论坛
- 热点话题

## 大会组织委员会 PROGRAM COMMITTEE

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国家食品药品监督管理总局
中国食品药品国际交流中心
(CCFDIE)对外合作处处长

**Lili CAO**
Director, Division of External Cooperation, CCFDIE, CFDA

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泰格医药科技股份公司
执行副总裁兼董事会秘书

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辉瑞中国医学部副总裁

**Chengming GU, MD**
Vice President, Pfizer China Medical, Global Established Pharma

**郭翔 博士**
默沙东研发（中国）有限公司
生物统计高级总监

**Tony GUO, PhD**
Senior Director, Biostatistics, MSD R&D (China) Co, Ltd.

**黄钦 博士**
国家食品药品监督管理总局
药品审评中心

**Qin HUANG, PhD**
Center for Drug Evaluation, CFDA

**梁冰**
辉瑞全球安全及药政事务部
安全监测及风险管理 高级总监

**Vera LIANG, MD**
Senior Director, Disease Area Cluster Leader Generics and sterile injectables, Shanghai Site Head, Safety Surveillance and Risk Management, Pfizer

**蔺亚萌**
罗氏（中国）投资有限公司
CMC政策法规资深经理

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

**刘晓曦 博士**
和铂生物医药副总裁
早期研发与科学运营

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

**宁志强 医学博士**
深圳微芯生物科技有限责任公司
研发执行副总裁

**Zhiqiang NING, MD, PhD**
Executive Vice President, R&D Shenzhen Chipscreen Biosciences Ltd.

**裘行敏**
辉瑞公司全球安全及药政事务部
安全监测及风险管理总监

**Middle QIU**
Director, Safety Surveillance and Risk Management, Worldwide Regulatory and Safety, Pfizer

**曲鹏 博士**
辉瑞（中国）研究开发有限公司
统计部高级总监

**Roger QU, PhD**
Head of Clinical Statistics, Pfizer R&D Center

**孙华龙 医学博士**
美达临床数据技术有限公司
总经理

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

**王莉 医学博士**
礼来中国首席医学官，药物研发及医学事物中心副总裁

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

**王敏 医学博士**
启明创维创业投资管理（上海）有限公司投资合伙人

**Min IRWIN, MD, PhD**
Venture Partner, Qiming Weichuang Venture Capital Management (Shanghai) Co. Ltd.

**闫小军 工商管理硕士**
百济神州高级副总裁及药政事务部负责人

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

**杨青 博士**
药明康德执行副总裁
首席商务官,首席战略官

**Steve YANG, PhD**
Executive Vice President Chief Business Officer and Chief Strategy Officer, WuXi AppTec (Shanghai) Co., Ltd.

## 大会组织委员会 PROGRAM COMMITTEE

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先声药业临床前研发负责人

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Head of Preclinical R&D
Simcere Pharmaceuticals

**赵大尧 医学博士**
辉瑞中国副总裁
中国药物开发部负责人

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

## 壁报评审委员 POSTER REVIEW COMMITTEE

**冯平辉 博士，副教授**
南加州大学分子微生物学和免疫学系

**Pinghui FENG, PhD**
Associate Professor with Tenure, Department of Molecular Microbiology and Immunology, University of Southern California

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默沙东全球副总裁
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Global Vice President and General Manager, China R&D Center, MSD

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**Gefei ZENG, PhD**
Head of Strategic Planning and Research Informatics, MSD China R&D

## DIA会员服务与权益

成为DIA会员，让您拥有与业界高层、学术同仁开展交流合作、提高专业水平，扩大人脉，拓宽跨领域知识的机会。

**搭建全球网络**
- 加强全球性合作，了解和推进跨学科领域的解决方案
- 与DIA各团体间展开互动交流，发展领导能力，拜师交友
- 享有在同行编审的DIA学术期刊《医疗创新与监管科学》上发表论文的机会

**拓展职业机会**
- DIA举办的世界知名研讨交流汇集精英领袖、探讨健康产品开发和监管科学问题
- DIA提供的精选课程可以帮助和提高您的专业技能
- DIA职业发展中心为您提供寻找就业的机会

**增强知识**
- DIA为您提供每日快讯
- DIA全球论坛和会员刊物让您学习到最新的医疗健康产品和监管科学信息
- 向同行编审的DIA学术期刊《医疗创新与监管科学》提交您的 论文，并浏览最新文献

**DIA会员权益**
- 全球200多场活动注册优惠，包括：年会、培训、论坛讲座等
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- 《医疗创新与监管科学》— DIA2013年全新推出，收录了40年间相关科学文献的索引和存档，可在线阅读和下载（每年6期）
- 《全球论坛》— 电子版期刊，以监管法规和全球新闻实时动态为特色（每年6期）
- 企业和服务机构的名录册
- DIA会员联络网 — 学术沙龙 (DIA Community)为全球会员提供互动交流、知识分享的网络平台
- DIA官网资源信息库 — 通过便捷的搜索和分类功能，查阅、下载DIA全球活动视频、会议文件和相关报告、展览等信息
- DIA每日快讯 — 实时发布全球制药、生物技术及医疗器械领域的新闻快讯
- 职业中心 — 在线搜索专业兴趣领域，寻求职业发展机会，提交简历档案并得到保护

# 主旨讲演嘉宾 KEYNOTE SPEAKERS

**陆舜 教授**
上海市胸科医院肺部肿瘤临床医学中心主任 上海交通大学博士研究生导师

**Shun LU, Professor**
Director of Center for Clinical Medicine of Lung Cancer
Doctoral Advisor,Shanghai Jiaotong University

陆舜教授是上海市胸科医院肺部肿瘤临床医学中心主任。目前担任中国临床肿瘤学会（CSCO）副秘书长、国家食品药品监督管理总局药品审评中心新药审评专家、上海市医学会肿瘤学会主任委员、ASCO多学科诊治小组（MCMC）成员，国际肺癌研究会（IASLC）组织委员会委员。陆教授目前还担任The Oncologist杂志编委和the Journal of Thoracic Oncology副主编。

陆教授主要从事胸部肿瘤的多学科综合治疗、靶向治疗以及免疫治疗方面的研究。是上海市医学领军人才，上海市优秀学术带头人。作为负责人主持科技部国际合作项目一项，863重大课题子课题二项，国家自然基金项目一项。陆教授在长期的临床与研究工作中成果丰硕，在Chest、JTO、Plos One、Oncoltarget等杂志发表论文100余篇，其中SCI收录45篇。

Prof. Shun Lu is Director of Center for clinical medicine of lung cancer at Shanghai Chest Hospital, Shanghai Jiao Tong University. He is vice executive secretary of Chinese Society of Clinical Oncology (CSCO), new drug review expert of the Center for Drug Evaluation, CFDA , director of Oncology Society Chinese Medical Association Shanghai Branch, a member of ASCO multidisciplinary treatment teams and a member of the International Association Study of Lung Cancer (IASCL). He currently serves on the editorial board of The Oncologist and is the associate editor of the Journal of Thoracic Oncology.

Prof. Lu's main research interests are multidisciplinary synthetic therapy on lung cancer, targeted therapy and immunotherapy. He has been appointed as one of excellent scientific leaders in medical research in Shanghai. He is active in oncology research and has been principal investigator or steering committee member of 1 international cooperation program of Ministry of Science and Technology, 2 national 863 programs, and 1 program of National Natural Science Foundation of China. He has published more than 100 papers in peer-reviewed journals, including Chest, JTO, Plos One and Oncoltarget, 45 SCI included.

# SUNDAY, 21 MAY | PRCONFERENCE WORKSHOPS

| | | | |
|---|---|---|---|
| Workshop 1 (Full Day) | 08:30–17:30 | | Transformation of Generic Drug Enterprise under New Policy and Regulatory Environment |
| Workshop 2 (Half Day) | 13:30–17:30 | | Risk Management in Clinical Trial: From Protecting Safety, Right, and Welfare of Study Subjects to Ensuring Safety Data Integrity |
| Workshop 3 (Half Day) | 08:30–12:00 | | Statistics for Medical Affairs |
| Workshop 4 (Full Day) | 08:30–17:00 | | Data Process Review |
| Workshop 5 (Half Day) | 13:30–17:30 | | CFDA/DIA Joint Workshop on ICH |

Workshop 1

**SUNDAY, 21 MAY**

Simultaneous Translation

08:30 – 17:30 | 5th Floor, 5D+E

## Transformation of Generic Drug Enterprise under New Policy and Regulatory Environment

### MODULE 1: OPPORTUNITY AND CHALLENGE FROM CONSISTENCY EVALUATION OF GENERIC DRUGS

PROGRAM CHAIR

**Benny LI, PhD**
Senior Vice President, Jiangsu Hansoh Pharmaceutical Group Co., Ltd.
Executive General Manager, Shanghai Hansoh Medical and Pharmaceutical Biotechnology Co., Ltd.

Introduction
This module is constructed in a form of open discussions led by 2-3 distinguished speakers from local and global pharmaceutical companies who will present on key topics followed by open discussions from the participants in this forum. It is aimed to shape up bold vision and strategic planning on the generic drug industry to provide the participants with new ideas and inspirations.

08:30 – 10:00

Development of Regulatory Review Processes and Technical Requirements for Generic Drugs in China

**Jianhong YANG**
Yeehong Business School, Shenyang Pharmaceutical University

Impact of Generic Drug Consistency Evaluation on Multi-national Pharmaceutical Companies (MNCs) Operating in China

**Ping LIU, PhD**
Head of Clinical Pharmacology, Pfizer China

- Impact on Original Drugs: Market Competition, Pricing, and Medical Insurance Policy
- Opportunity of Branded Generic Drugs?

Impact of Generic Drug Consistency Evaluation on Local Pharmaceutical Companies:

**Jiefeng LEI**
CEO & Co-Founder, Shanghai Anbison Lab. Co., Ltd.

- Challenge of Local Generic Drugs
- Opportunity of Local Generic Drugs Expanding to EU and US Marketplaces

10:00 – 10:30 Tea Break

10:30 – 11:00 Q&A and Open Discussion

### MODULE 2: UNDERSTANDING AND LEARNING FROM GLOBAL GENERIC DRUG EVALUATION

Introduction
This module is divided into two parts (Japan and EU/US), consisted of presentations and Q&A. It is aimed to allow participants better understanding the evaluation system and technical requirements of generic drugs in each countries, thereby to grasp the underlying rationales of China regulatory and technical requirements as a meaningful reference to shape up local generic drugs development strategies.

11:00 – 12:00

Part One: Japan Drug Quality Re-evaluation Project: Introduction and Relevant Technical Requirements

**Koji INAGAKI**
General Manager, Established Product Development, Santen Pharmaceutical Co., Ltd., Japan

Q&A

12:00 – 13:30 Lunch

13:30 – 14:30

Part Two: Regulatory system and technical requirements of EU/US for generic drugs

- Introduction of US Regulatory Development and Technical Requirements for Generic Drugs

  **Dale CONNER, PharmD**
  Director, Office of Bioequivalence, Office of Generic Drugs, FDA/CDER

- Reference to European and US Registration Regulations

  **Alexander HÖNEL, MD, PhD, MBA**
  Quality Experts at The Inspectors Network Consulting and Training Services

- Q&A

14:30 – 15:00 Tea Break

# SUNDAY, 21 MAY | PRCONFERENCE WORKSHOPS

## MODULE 3: CHALLENGE AND BOTTLENECK IN DEVELOPMENT OF GENERIC DRUGS

Introduction
This module is constructed in a form of presentation and case study in groups. It is aimed to provide participants with deep understanding of critical path and practical solutions to overcome difficulties and challenges in generic drug development.

15:00 – 16:00

How to develop high quality generic drugs: key considerations about quality control

**Yongjian YANG, PhD**
Chief Pharmacist and Head of Chemical Drugs Department at Shanghai Institute for Food and Drug Control (SIFDC)

How to develop high quality generic drugs: key considerations in BE study

**Xuening LI, Chief Pharmacist, PhD, Professor**
Deputy Director of Clinical Trials, Zhongshan Hospital Affiliated Fudan University

How to transform generic drug development under new policy and circumstance: R&D model, external resources, supporting policies

**Yuli XIE, PhD**
General Manager, Suzhou Autopharm Biopharmaceutical Co., Ltd.

Case study, group discussions and summary

16:00 – 17:00 Group Discussions

Workshop 2

**SUNDAY, 21 MAY**
13:30–17:30 | 5th Floor, 5F

## Risk Management in Clinical Trial: From Protecting Safety, Right, and Welfare of Study Subjects to Ensuring Safety Data Integrity

### PROGRAM COMMITTEE

**Conny MO**
Medical Safety Advisor, Beijing RHGT Information Company

**Sean ZHAO, PhD**
Executive Medical Director, US Patient Safety Surveillance, AstraZeneca Pharmaceuticals LP, Wilmington DE

### AGENDA

Risk Management Activities in Clinical Trials: Key Considerations in the Processes of Clinical Trial Design:
- Medical ethics
- Characteristics of study population
- Safety profile of Investigational medicinal products
- Approach of risk assessment and evaluation
- Approach of risk mitigation activities
- Capture of complete exposure and safety data

Risk Management Activities in Clinical Trials: Key Consideration in the Processes of Clinical Trial Execution:
- Known risk issue monitoring, assessment, evaluation, and mitigation
- New safety information identification, evaluation, and management
- Urgent safety event management
- Study protocol and procedure update in manage newly identified risk during clinical trials

Transforming clinical trial risk management knowledge to enhance postmarketing risk management activities:
- Post marketing risk assessment and evaluation: a continuation of risk management activities in product life cycle
- Establish risk mitigation strategy based on knowledge established by clinical trial risk assessment, evaluation and minimization activities trial
- Conduct postmarketing surveillance programs

### TARGET AUDIENCE

- Medical and Device Regulatory Authorities
- Clinical Research and Development Personnel/Project Leader
- Pharmacovigilance Safety Officer
- HCPs
- Drug Epidemiologist
- CRO
- QA
- Medical Affairs
- Medical Affairs Leader
- Regulatory Affairs Officer

# SUNDAY, 21 MAY | PRCONFERENCE WORKSHOPS

Workshop 3

**SUNDAY, 21 MAY**
08:30–12:00 | 5th Floor, 5F

## Statistics for Medical Affairs

### PROGRAM COMMITTEE

**Xiaoxiang CHEN, MD**
Vice President, Medicine Development,
Greater China, Boehringer Ingelheim

**Tony GUO, PhD**
Senior Director, Biostatistics,
MSD R&D (China) Co, Ltd.

**Eugen LI**
Medical Affairs China Group I Director,
Clinical Development and Medical Affairs
Boehringer Ingelheim

**Jeannie QIU**
Senior Statistician, Data Sciences & Analytics
Bayer Healthcare Company Limited

**Knightley WEI**
Senior Director, Medical Affair, MD
China Medical Affair-Women Health/Bone/Pain/MSS Franchise
Hangzhou MSD Pharmaceutical Co. Ltd

Are you a medical information, medical communications, or medical affairs professional? Are you able to discuss and answer questions about the statistical analysis section of a clinical trial? Can you identify strengths and weakness in study design, or detect potential bias?

This course is designed to help medical affairs professionals and others in the pharmaceutical industry evaluate statistical data presented in medical literature. Through sharing and discussing plenty of cases and examples, it will help users apply statistical concepts when evaluating literature, identify strengths and weaknesses in study design, and detect potential bias in the presentation of statistics.

The goal of this course is not to turn you into a statistician, but rather on understanding what you are reading when you are evaluating medical literature. We hope one outcome of your taking this module is that you are comfortable "speaking the language" of statistics and discussing your questions or issues with your company's statisticians. We encourage regular communication with professional statisticians in the event that you have questions when reviewing literature.

### LEARNING OBJECTIVES

Upon completion of this Course, learners should be able to:
- Identify potential bias in the presentation of statistical data
- Discuss the statistical concepts of population, sample, bias, distribution, and variability
- Discuss types of data, summary measures, and estimation
- Discuss hypotheses testing, Type I and Type II errors, statistical power, sample size, confidence intervals, and P-values
- Interpret the results of research papers and abstracts
- Distinguish among study designs, and identify techniques used to avoid bias
- Use basic statistical terminology

### TARGET AUDIENCES

- Medical Affairs
- Medical Communications
- Medical Information
- Medical Writing
- MSL

### AGENDA

| | |
|---|---|
| 08:30-08:35 | Welcome Remarks |
| 08:35-08:50 | Why MA should learn Biostatistics and how to collaborate with Statistician |

**Eugen LI**
Medical Affairs China Group I Director, Clinical Development and Medical Affairs
Boehringer Ingelheim

| | |
|---|---|
| 08:50-11:20 | Study Development Methodology and Biostatistics |

**Tony GUO, PhD**
Senior Director, Biostatistics, MSD R&D (China) Co, Ltd.

**Jeannie QIU**
Senior Statistician, Data Sciences & Analytics, Bayer Healthcare Company Limited

Basic Statistical Concepts
- Statistical concepts
- Basic statistics

Hypothesis Testing
- The philosophy of statistical testing
- The null and alternative hypothesis
- Endpoints
- Type I and Type II errors
- Statistical power
- Sample size determination (Continuous,Binary,and Time-to-Event Endpoints)
- P-value
- Confidence intervals
- Common test statistics

Study Designs
- Objectives of study designs
- Techniques to reduce or avoid bias
- Study Designs in Phase I Clinical Trials
- Study Designs in Phase II to IV Clinical Trials
- Observational studies (Cross-sectional, Case-control, Matched-pairs case control,and Cohort studies)

Expended Topics
- Usage and Mis-use of Statistics in Literatures
- Superiority, Non-Inferiority and Equivalence Trials
- Multiple Comparisons/ Multiplicity
- RR vs. OR, RR vs. HR, and Median time vs. HR
- Plots in Survival Analysis (Kaplan-Meier Curve, Waterfall plot, Volcano plot, Forest plot)
- Event Prediction in Oncology Study
- Statistical Considerations when Planning the Analysis

| | |
|---|---|
| 11:20-12:10 | Case Discussion from Clinical and statistical |

**Leslie MENG, PhD**
Principal Biostatistician, Boehringer Ingelheim (China) Investment Co.,Ltd

**Sheng QI, MD**
TAH Stroke/CV, Boehringer Ingelheim China

Q&A All speakers above

# SUNDAY, 21 MAY | PRCONFERENCE WORKSHOPS

Workshop 4

**SUNDAY, 21 MAY**
08:30–17:00 | 5th Floor, 5B+C

## Data Process Review

### PROGRAM CHAIR

**Hualong Sun, MD, PhD**
General Manager, Meta Clinical Technology

### PROGRAM COMMITTEE

**Charles YAN, PhD**
Senior Director, Data Management, Jiang Su Hong Rui Medicine Co., Ltd.

**Delia PU**
Manger, Global Data Management,PAREXEL International

**Dorothy DAI**
Manger, Clinical Data Management, Meta Clinical Technology

### INTRODUCTION

Success of clinical studies depends on quality and integrity of its final database. Currently Data management mainly focuses on the data issues in data points, and neglects the error occurs in database set-up, programming, and other processes. This training try to introduce the Data Process Review to industry, and help to improve data quality in clinical trials. Let attendee know how to apply Process Review to their projects in accordance with project specification Data Management Plan (DMP) for the following software types (RAVE, Oracle Clinical and other EDC systems):

- Finalize the pre-defined Process Review sections of the DMP
- Perform Early Process Review and Completed Subject Review according to DMP
- Identify errors and trends, and apply recommended remediation during the review process
- Effectively collaborate with other functional groups (e.g., Clinical Programming, Data Entry, Biostatistics, and DML, etc.)
- Fulfill their responsibilities working with Biostatistics in the overall review of the data to ensure the data is sensible prior to submitting the final dataset transfer during the locking phase

In the training, it be introduce what is the process of data process review and challenges, and will discuss the difference between early process review and completed subject review. Also a dummy study, query report and listings will be provided for practice.

### TARGET ATTENDEE

- Clinical project management
- Clinical data management
- Clinical monitor
- Clinical research professionals
- Clinical research assistant
- QA/QC professionals QA/QC
- Clinical investigator and coordinator

### AGENDA

| | |
|---|---|
| 8:30 – 9:30 | Introduction of Data Process Review |

- Purpose of data process review
- How to describe the data process review in Data management plan
- The process of data process review
- The components of data process review
- Roles and responsibilities of data process review

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| 9:30 – 10:30 | Early Data Process Review |

- Trigger Point of implementation early data process review
- The tasks of early data process review
- Image and Data Quality Review
- Discrepancies and Queries Review
- Review of Query Reports
- Off-Line Listings Review
- Review Protocol Deviation (PD) Listings
- Local Lab Review Process Review
- Review Missing Data Points
- SAE Reconciliation Process Review
- Process Metrics Review

| | |
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| 10:30 – 10:45 | Coffee Break |
| 10:45 – 12:00 | Practice of Data Process Review |
| 12:00 – 13:00 | Lunch Break |
| 13:00 – 14:00 | Completed Subject Review |

- Trigger Point of implementation completed subject review
- The tasks of completed subject review
- Completed subject review planning
- Review of Data Entry Quality
- Queries Review
- Off-Line Validation Review
- Review Protocol Deviation (PD) Listings
- SAE Reconciliation Process Review
- Missing data points review
- Process Metrics Review

| | |
|---|---|
| 14:00 – 14:45 | Apply Electronic Technology to Data Process Review |
| 14:45 – 15:00 | Coffee Break |
| 15:00 – 15:45 | Practice of Completed Subject Review |
| 15:45 – 16:30 | Group discussion: Challenges and opportunities of Data Process Review |
| 16:30 – 17:00 | Wrap up |

# SUNDAY, 21 MAY | PRCONFERENCE WORKSHOPS

Workshop 5

**SUNDAY, 21 MAY**

Simultaneous Translation

13:30 - 18:00 | 5th Floor, Yangtze River Hall

## CFDA/DIA Joint Workshop on ICH

Since its inception in 1990, founded by the drug regulatory agencies of the US, EU, and Japan along with industry associations, ICH has gradually evolved to coordinate work by each region's scientific experts; harmonize the technical requirements for pharmaceutical quality, safety and efficacy; and promote consistent science-based standards for pharmaceutical product registration requirements. Building on a 25-year track record of success, ICH announced a major organizational change at the end of 2015. ICH association, a non-profit, non-governmental legal entity under Swiss law, is now welcoming regulators around the world to join and ensuring greater coordination among the participating regulatory agencies. Today, there are common expectations from multiple parties including regulators, industry, academic institutions that China Food and Drug Administration (CFDA) joins the ICH community as one of the major drug regulatory agencies worldwide. CFDA will participate in the design of international regulatory technical guidelines, improve the ability of drug supervision, and ensure the safety and efficacy of medical products consumed by Chinese patients. Facing the globalization trend and competition, strengthening international exchange and cooperation becomes an inevitable strategy for different regulatory authorities to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.

### PURPOSE

- Introduction to the latest ICH reform and its global vision
- Updates on main ICH Guidelines and impacts on regulatory agency and industry
- CFDA's perspectives toward ICH guidelines
- DIA's contribution to ICH – as a neutral platform

### AGENDA

13:30 – 13:45 Opening Session

CHAIR
**Rong SHU**
Deputy Director-General
China Center for Food and Drug Internation Exchange

Keynote Speaker
**Lin YUAN**
Director General
Department of International Cooperation, CFDA

13:45 – 14:30 Session 1: ICH Reform and DIA Contribution

SESSION CHAIR
**Rong SHU**
Deputy Director-General
China Center for Food and Drug Internation Exchange

Overview of ICH Reform and Future Direction

**Theresa MULLIN, PhD**
Director, Office of Strategic Programs, CDER/FDA

Impact of ICH Reform to Japan and the region

**Naoyuki YASUDA**
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)

DIA's Contribution to ICH

**Barbara KUNZ**
Global Chief Executive, DIA

14:30 – 15:30 Session 2: Updates on ICH Guidelines

SESSION CHAIR

**Zili LI, MD, MPH**
Associate Director, Global Affairs
Office of Generic Drugs, CDER/FDA

E6 – Impact on Clinical Research Standards

**Hironobu SAITO, PhD**
Vice President, Oncology Clinical Development Departent, DaiichiSankyo, Japan
Vice Chairman, ICH Committee, Japan Pharmaceutical Manufacturers Association (JPMA)

E-17 – Impact on Global Drug Development Strategy

**Vibeke BJERREGAARD**
Senior Regulatory Affairs Manager, Novo Nordisk A/S, Denmark
Member of Expert Working Group for ICH E 17

ICH Quality Guidelines updates and impact

**Wassim NASHABEH, PhD**
Vice President, Technical Regulatory Policy & International Operations, Roche
Member of the Expert Working Group for the ICH on Q11,Q3D and Q12

15:30 – 15:45 Tea Break

# SUNDAY, 21 MAY | PRCONFERENCE WORKSHOPS

15:45 – 16:45 **Session 3: CFDA's perspectives on ICH Guidelines and Implementation**

SESSION CHAIR

**Xiangyu WANG**
Director, International Organization Division,
Department of International Cooperation, CFDA

Q1 – Stability on New Drug Substance and Products

**Center for Drug Evaluation, CFDA**

Q7A – Inspection on GMP for API

**Center for Food and Drug Inspection, CFDA**

E6 – GCP Implementation in China

**Department of Drug and Cosmetics Registration, CFDA**

E-17 – Management of International Multi-Regional Clinical Trials

**Department of Drug and Cosmetics Registration, CFDA**

16:45 – 17:15 **Session 4: China Pharmaceutical Industry's Prospectives on ICH**

SESSION CHAIR

**Rong SHU**
Deputy Director-General
China Center for Food and Drug Internation Exchange

**Ruilin SONG**
Executive President
China Pharmaceutical Innovation and Research Development Association

**Leon WANG**
Global Executive Vice President,
International and China President, AstraZeneca

**Zhengqing LI, PhD**
Global Vice President and General Manager, China R&D Center, MSD

**Kerry L BLANCHARD, MD, PhD**
Senior Vice President of China MDU & External Innovation
Eli Lilly and Company
Lilly China

17:15 – 18:00 **Session 5: Panel Discussion "Expectation on ICH and its Implementation in China"**

SESSION CHAIR

**Ling SU, PhD**
Professor and Director, Institute of Drug Regulatory Science, Shenyang Pharmaceutical University
Venture Partner, Lilly Asia Ventures

**Theresa MULLIN, PhD**
Director, Office of Strategic Programs, CDER/FDA

**Jerome LEPEINTRE**
Minister Counsellor of the EU Delegation to China

**Xiaoying ZHENG**
Director, Institute of Population Research/WHO Reproductive Health and Population Science Research Center, Peking University

**Yue YANG, Professor**
Director, International Food and Drug Policy and Law Research Center, Shenyang Pharmaceutical University

**Ming XU**
Vice President, China Chamber of Commerce for Import and Export of Medicines & Health Products

**Hualin SONG**
Professor, Law School of Nankai University

# MONDAY 22 MAY | OPENING PLENARY

## Opening Plenary Session | Monday, 22 May

Simultaneous Translation

13:30-17:00 | 7th Floor, Grand Ballroom

### INTRODUCTION AND ACKNOWLEDGEMENT

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

### OPENING REMARK

**Barbara Lopez KUNZ**
Global Chief Executive, DIA

### WELCOME ADDRESS

**Ning XU, MD, MBA**
Executive Vice President, Head of Clinical Development and Regulatory Affairs, Zai Lab
9th DIA China Annual Meeting Program Co-Chair

**Bin XUE**
Director-General, China Center for Food and Drug International Exchange, CFDA
9th DIA China Annual Meeting Program Co-Chair

### WELCOME ADDRESS FROM CFDA

**CFDA Speaker Invited**

### AWARD CEREMONY

DIA China Lifetime Achievement to Health Award
DIA China Excellence in Service Award

### KEYNOTE ADDRESS:

**Shun LU, Professor**
Director of Center for Clinical Medicine of Lung Cancer,
Doctoral Advisor,Shanghai Jiaotong University

### SPECIAL FORUM: VALUE PROPOSITION OF MEETING UNMET MEDICAL NEEDS IN NEW DRUG DEVELOPMENT – A MULTIFACETED PARADIGM

MODERATOR

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

Being patient centric and meeting unmet medical needs are the core principles in new drug development. Nevertheless, various stakeholders involved in the development, regulation and the use of medicinal products may inevitably have different perspectives and focuses. In this forum, expert panelists will examine several key issues on the value proposition of meeting unmet medical needs and discuss its implications in drug development, regulation and patient care, such as,

- The nature of clinical value and the approaches to maximize the clinical value in new drug development;
- The essence and practice of "patient-centric drug development"; and The meaning and application of "real-world" data

INVITED PANELISTS

**CFDA CDE Panelist Invited**

**Theresa MULLIN, PhD**
Director, Office of Strategic Programs, CDER, US FDA

**Shun LU, MD**
Director, Shanghai Lung Cancer Center, Shanghai Chest Hospital; Professor, Shanghai Jiaotong University

**Frank JIANG, MD, PhD**
CEO, CStone Pharmaceuticals

**Rachel YANG, MD, PhD**
Director, International Affairs, Chinese Organization for Rare Diseases (CORD)

## Welcome Reception | Monday, 22 May

17:00-19:00 | 1st Floor, Exhibition Area, Mandarin Hall

DIA

| | |
|---|---|
| Vision | DIA is your **essential partner** in catalyzing knowledge creation and sharing to accelerate health product development |
| Mission | DIA is the **global forum** for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide |
| Core Values | Neutrality & Integrity; Accountability & Trust; Respect & Dignity Responsibility & Diversity; Passion & Engagement; |

# TUESDAY, 23 MAY | WEDNESDAY, 24 MAY

# THEME 1

Theme 1

## Regulatory Science

### Session 0101 | MAY 23, 2017

Simultaneous Translation

08:30-10:00 | 3rd Floor, Yellow River Hall

**WORLDWIDE REGULATORY SCIENCE EMERGING FOCUS**
SESSION CHAIR

**Vicky HAN**
Senior Director, Policy Group Lead for Asia Pacific, Global Regulatory Affairs, Janssen Asia Pacific

The R&D new medicine is very diversity in this century, Microbiome, Antimicrobial Resistance, Big Data, 3D Printing, and Precision Medicines have come spotlight in the world and drawn high attention by pharmaceutical industry and regulators. More and more drug-device combinations are introduced as part of precision medicines and personalized treatment, such as the Companion Diagnostic for identifying and treating targeted patients. In addition, beyond of vaccine and treatment medicine, the innovative method of interception of disease progression is exploring for elimination the disease. The antibiotics invention has saved uncountable lives, meanwhile the bacteria and virus have been evolving to counter antibiotics, WHO has organized key stakeholders including academia and regulators to discuss the antimicrobial resistance challenge and explore solutions. To accelerating introduction of new medicine to patient, the regulators and drug makers start to seek opinions from HTA (Health Technology Assessment) and patient groups. It is also noticed the 21st Century Cure Act has been endorsed in December 2016 in the US to enforce FDA further improvement. Indeed, there are many hot topics in the dynamics world. This DIA will focus on 3 topics:

Antimicrobial Resistance

**Edward COX, MD, MPH**
Director, Office of Antimicrobial Products,
within the Office of New Drugs, FDA/CDER

Diseases interception

**Adam HACKER, PhD**
Vice President, Head of Vaccine and Scientific Innovation Projects, Global Regulatory Affairs, Janssen-Cilag Ltd, Johnson & Johnson

Companion Diagnostic

**Jinjie HU, PhD**
Senior Consultant, Biologics Consulting Group, INC.
Chair of the FDA Alumni Association International Network (FDAAA)
Former Senior Reviewer, Office of Blood Research and Review, US FDA/CBER

### Session 0102 | MAY 23, 2017

Simultaneous Translation

10:30-12:00 | 3rd Floor, Yellow River Hall

**CONSIDERATION AND DISCUSSION OF IMPLEMENTING ICH GUIDELINE IN CHINA**
SESSION CHAIR

**Xianglin ZHANG**
Dean of Yeehong Business School, Shenyang Pharmaceutical University

Building on 25 years of successful harmonization, ICH announced significant organizational changes on 23 October 2015. ICH association, a non-profit and non-governmental legal entity is established the new Assembly as the over-arching governing body to facilitate future growth through the participation of new members.

Opportunity, Challenges and Recommendation to Implement: ICH Guidelines in China

**Zhen CHEN, Professor**
Zhengzhou University and Researcher of Yeehong Business School

Global Harmonization or Convergence on Technical Requirement and Its Impact to Regulatory Framework

**Florence HOUN, MD, MPH**
Vice President, Global Regulatory Science, Celgene Member and Former Chair of FDA Alumni Association International Network (FDAAA)

*Panel Discussion: Impact to Innovation, Generic, Internationalization and Regulatory Reform by Implementation of ICH Guidelines in China*
Above Speakers and

**Zili LI, MD, MPH**
Associate Director, Global Affairs Office of Generic Drugs, CDER/FDA

### Session 0105 | MAY 24, 2017

Simultaneous Translation

08:30-10:00 | 3rd Floor, Yellow River Hall

**REGULATORY SCIENCE AND REVIEW QUALITY: LEARNING GOOD PRACTICE FROM THE OTHER COMPETENT REGULATORY BODIES**
SESSION CHAIR

**Janet LU**
Head of Regulatory, Asia Pacific, Roche (China) Ltd.

It is always a global hot topic of all regulatory bodies to improve the quality of drug review and approval. This session will introduce the basic concept and principle of regulatory science, present data on the performance on various agencies (FDA, EMA, PMDA, etc.) on drug review and approval and discuss key factors in regulatory science fostering regulatory quality. In particular, a detailed description on PMDA's evolution will be given.

Learning and Improving --- Achievements in Regulatory Science Benefit Agencies' Drug Evaluation

**Yin LI, PhD**
Product and Solution Consultant, Clarivate Analytics

Basic Concepts and Principles of Regulatory Science

**Yue YANG, Professor**
Director, International Food and Drug Policy and Law Research Center, Shenyang Pharmaceutical University

*Panel Discussion*

## Session 0106 | MAY 24, 2017

Simultaneous Translation

10:30-12:00 | 3rd Floor, Yellow River Hall

### CONSIDERATION AND CASE STUDY OF EXPEDITING DEVELOPMENT AND REVIEW OF NEW DRUGS

SESSION CHAIR

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

Over the years, health authorities from many countries released guidelines or programs to expedite the development and review of innovation drugs. In this session, speakers from both health authorities and industry will elaborate the expedited program and guidance and sharing the successful cases.

EU PRIME as a New Way to Further Support Drug Development

**Yamin WANG, PhD**
Independent Consultant, Germany

Expediting Drug Development at the US FDA

**Mark J. GOLDBERGER, MD, MPH**
Independent Consultant, Mark Goldberger MD MPH LLC.
Member of FDA Alumni Association International Network (FDAAA)
Former Director, the Office of Antimicrobial Products, within the Office of New Drugs, FDA/CDER

Topic TBD

**Xiaoyuan CHEN**
Office of Clinical Review I, Center for Drug Evaluation, CFDA

## Session 0107 | MAY 24, 2017

Simultaneous Translation

13:30-15:00 | 3rd Floor, Yellow River Hall

### PRODUCTS REGULATORY SUPERVISION AND QUALITY CONTROL

SESSION CHAIR

**Ying SHAO, PhD**
Vice President and Director of R&D Center, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

With the continuous improvement of the quality management ability of Chinese pharmaceutical enterprises and harmonization of technical standards, China Food and Drug Administration (CFDA) is constantly exploring new ways of life cycle management. As an important measure to ensure drug quality during the product life cycle, the reform of GXP system is imperative. Since the State Council issued the "Opinions on Reforming the Review and Approval System for Drugs and Medical Devices " in August 2015, CFDA has started to explore a new GXP system, which is based on regulatory science, risk-assessment and balances efficiency and cost, to solve the issues of data integrity, inconsistent standards and loss of efficiency. Several measures are under development, such as review-based and risk-based inspection, highly professional and full-time inspection team, etc.. In this session we will invite representatives from CFDA and US FDA and industry to share their experience on GXP management and quality management, and to discuss the trend of China's GXP system.

International GXP Supervision Model

**Lane CHRISTENSEN, PhD**
Assistant Country Director, FDA China Office

Trend of Global Quality Supervision from Industry Perspective

**Andrew CHANG, PhD**
Vice President, Product Supply Quality, Novo Nordisk Inc., USA

Today's China GXP and Transformation Trends

**CFDI Speaker Invited**

## Session 0108 | MAY 24, 2017

Simultaneous Translation

15:30-17:00 | 3rd Floor, Yellow River Hall

## DIAmond Session

### TO ACCELERATE REGULATORY APPROVAL OF AND PATIENT'S ACCESS TO SAFE, EFFECTIVE AND QUALITY MEDICINE —— THE ROLE OF GOOD REVIEW AND SUBMISSION PRACTICE

SESSION CHAIR

**Vicky HAN**
Senior Director, Policy Group Lead for Asia Pacific, Global Regulatory Affairs, Janssen Asia Pacific

It requires the joint effort of regulatory agencies and pharmaceutical industry to accelerate regulatory approval of and patient's access to safe, effective and quality medicine. The Good review practice for the regulatory agencies and good submission practice for the industries play a critical role. The session is not designed to provide detailed regulatory review processes nor the instructions on how to conduct each submissions to regulatory agencies. Instead speakers will share their thoughts on the importance of such practices from both agency and industry perspectives, and also outline the guiding principles that go beyond the period of drug application submission and regulatory review to encourage effective communication and a robust drug development program over the entire drug development process. The audiences of the session will gain a strategic view on the critical role of good review practice and good submission practice and the session will benefit the audiences from both new drug and generic drug industry in their strategic drug development and registration planning from a global perspective.

CFDA Review and Submission Best Practice Sharing

**Qingzhu HUANG**
Office of Operations Management, Center for Drug Evaluation, CFDA

APEC Working Group Review and Submission Best Practice Sharing -- from Regulator's Perspective

**Chyn-liang HUANG**

APEC Working Group Review and Submission Best Practice Sharing -- from Industry's Perspective

**Shinji HATAKEYAMA, PhD.**

Good Submission Best Practice

**Helen PU**
Associate Director of Regulatory Affairs, Roche China

*Panel Discussion*

1. The importance of good submission practice for achieving a higher first cycle approval of ANDA in the US
2. How important of Effective Communication? any examples to help understand it
3. Does the Development Strategy impact to good review & submission practice?
4. How to improve the Planning of Application and Dossier Preparation, and the expectations from regulators?
5. What and how to improve the Core Capacity for Regulators and Industry?
6. Good Submission Practice - maximizing the benefit of US GDUDA program

Above Speakers and

**Zili LI, MD, MPH**
Associate Director for Global Affairs Office of Generic Drugs, FDA/CDER

Theme 2

## CFDA Townhall

**Session 0203 & 0204 | MAY 23, 2017** Simultaneous Translation

13:30-17:00
3rd Floor, Auditorium (Main Session)
3rd Floor, Yellow River Hall (Live Satellite)

## DIAmond Session

SESSION CHAIR
Director of International Cooperation Department, CFDA or Division of External Cooperation, CCFDIE, CFDA

Department of Drug and Cosmetics Registration will introduce the developments of related regulations, mainly focus on the following items: Adjustment of Drug registration classification, launch a pilot project on Marketing Authorization Holder system. Adjustment on Provisions for Drug Degistration, also the Drug Registry has already released a DFC (drafted for comments)on the Reform of Imported drug registration regulation and will introduce the background information and implementation plan of this issue.

National Institutes For Food and Drug Control (NIFDC) will improve the treatment standard of generic drug and set the consistency evaluation on generic drug. According to requirement of the No.44 of 2015, No.8 of 2016 that a clear deadline of carry out the consistency evaluation was set. "13th Five-Year" drug safety plan released on Feb2017 also emphasized the further requirement of drug quality. NIFDC will introduce the following items: the work they have already done, the released 10 policy documents and 5 technical guidelines, the circular training they carried out for interpreting these documents and guidelines, Information on Acceptance of the record application of reference product and drugs variety. Also they will introduce their priorities in 2017, listing as follows: the development of technical guidelines for key evaluation, the problems on reference product, the problems on BE test, Orange book, explore consistency evaluation method on injections.

Center for Drug Evaluation will introduce the drug review report of 2016, including the following items: Improve the efficiency of review and approval; Elimination of the backlog of registration; Review and approval of Traditional Chinese Medicine before the deadline, also for drug produced by ethnic groups; Review and approval of chemical drug and vaccines application on time. In the meanwhile, they have taken some measurements in their work: introduce the way of project management and grading in their daily work, increase the number of talents for review, optimize the review and approval procedure. All measurements mentioned above are aimed to achieve two goals: to improve the efficiency of review and approval, encourage Research & Development.

Besides, they will give an instruction on the key point of their work in 2017: further encourage R&D, speed up the review and approval of new drugs, accelerate the review of clinical drug in urgent need, Introduction of more talent, enhance the technical skills of the review, construction of eCTD.

Inspection center will summarize their GCP and GMP inspection work of 2016, also they will give an instruction on their key point of GCP and GMP inspection work of 2017. Including enhance the quality of clinical trial, Site inspection on drug registration, GMP inspection overseas, construction of professional inspectors team etc.


## Multi-collaborations – A Pathway to High Quality Studies

### Session 0301 | MAY 23, 2017

Simultaneous Translation

08:30-10:00 | 7th Floor, Pearl Hall

**PROGRESS AND IMPACT OF NEW REGULATIONS ON CLINICAL RESEARCH**

SESSION CHAIR

**Hannah CHEN**
China Head, Quality Planning & Strategy, BioResearch Quality & Compliance, Janssen

ICH GCP and Chinese GCP has revised recently, this guideline has been amended to encourage implementation of improved and more efficient approaches to clinical trial process while continuing to ensure human subject protection and reliability of trial results. Sponsor responsibilities related to quality management system, risk-based monitoring and use of computerized system; investigator responsibilities related to source document and data integrity are the most important areas of focus of the revision. This session will discuss the impact of the new requirements.

Area of Focus of ICH GCP R2 and China GCP

**Peter SCHIEMANN, PhD**
Managing Partner, Widler & Schiemann Ltd.

FDA/EMA Inspection on Electronic Source Documents Focusing on Data Integrity

**Alexander HÖNEL, MD, PhD, MBA**
Quality Experts at The Inspectors Network Consulting and Training Services

Data Integrity from Investigator Perspective

**Yifeng SHEN, MD, PhD**
Director, GCP Office, Shanghai Metal Health Center

### Session 0302 | MAY 23, 2017

10:30-12:00 | 7th Floor, Pearl Hall


**IMPROVING CLINICAL STUDY QUALITY VIA MULTI-COLLABORATIONS**

SESSION CHAIR

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

Data integrity and Risk based monitoring have been hot topics in the area of Clinical trial quality management in China. Representatives from sponsor, CRO, GCP office and investigator site will be invited to this panel to address these two topics from the aspects of 1.) Roles & Responsibility 2.) Effective communication 3.) Infrastructure build-up/enhancement. Based on the regulation requirement, the panel discussion is to reach a consensus on the values of multi-stakeholders in ensuring clinical trial quality management.

*Panel Discussion*

**Hannah CHEN**
China Head, Quality Planning & Strategy, BioResearch Quality & Compliance, Janssen

**Joyce LAI**
Regional Director, Clinical Data Management, Global Data Management & Standards, MSD R&D (China) Co., Ltd.

**Yifeng SHEN, MD, PhD**
Director, GCP Office, Shanghai Metal Health Center

**Lisa SUN, MD, MPH**
Asia Pacific QA, Bristol Myers Squibb, China

**Fangmin WANG**
Shanghai Municipal Food and Drug Administration

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

**Veronica XIA**
Vice President, QuintilesIMS

**Zhao YAN, PhD**
Tianjin Medical University Cancer Institute & Hospital

### Session 0305 | MAY 24, 2017

08:30-10:00 | 7th Floor, Pearl Hall

**HIGH QUALITY OF CLINICAL RESEARCH COMES FROM RISK-MANAGEMENT DRIVEN PROJECT MANAGEMENT SYSTEM**

SESSION CO-CHAIRS

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

**Tina TIAN**
Director, GCO Strategic Operations & Clinical Trial Head IDV, China R&D and Medical Affairs, Janssen Research & Development, Janssen (China) R&D Center, a Division of Johnson & Johnson (China) Investment Ltd.

One of the key drivers of the clinical study success, is how we can better control and mitigate various risks during the entire study life cycle. During the study design , planning, execution and closure stage, following approaches will always have a significant impact on study progress as well as study result - How to pre-identify different level of risks, how to integrate available resources to eliminate or mitigate risks. With current regulatory change, and with recent ICH GCP requirement update, the clinical operation environment tends to be more and more complicated than before. Such changing environment requires all functions' efforts from a study team, to have seamless cooperation, to effectively utilize advanced study management and risk management skills/tools in a more flexible way, so that we are able to eliminate/mitigate various risks covering entire study phase, and ensure the final success of the clinical study. In this section, we invited experts from clinical trial institution, sponsor and CRO to share risk management experiences in clinical study from 3 different aspects, and to discuss with all colleagues together to further improve the clinical study quality.

## TUESDAY, 23 MAY | WEDNESDAY, 24 MAY THEME 3

Clinical Study Quality Management & Improvement by Instruction

**Hua BAI, MD**
Assistant Director, Clinical Pharmacology Research Center, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences

Risk Management in Clinical Trials in Global Pharmaceutical Companies

**Rui CHEN**
Senior Clinical Trials Operation Manager, Sanofi

Risk Management in CRO

**Wencheng XU**
Director of Portfolio, WuXi AppTec

**Wei WU**
Associate Researcher, Drug Clinical Trail Institute, Beijing Anzhen Hospital of Capital Medical University

### Session 0306 | MAY 24, 2017

10:30-12:00 | 7th Floor, Pearl Hall

**RESPONSIBILITIES AND MANAGEMENT OF STAKEHOLDERS IN CLINICAL RESEARCH**
SESSION CHAIR

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

This session will focus on multiple cooperation and mutually beneficial symbiosis during clinical trial stage. It will starts with the considerations on clinical trial vendor selection and management from sponsor's aspect, to highly the importance of the collaboration by multiple stakeholders. Then the discussion will mainly focus on CRC service and Central lab as 2 mostly commonly utilized function service in clinical trials, by engaging the people management of GCP office, Investigator and Sponsor and vendor, as well as training on them. This session provides an insight for improving the clinical trial implementation and obtaining high quality results of clinical study.

Mutually Beneficial Symbiosis in Clinical Trial – Vendor Service Selection Management and Cooperation

**Helen JIANG, PhD**
Senior Vice President, Chief Medical Officer, Qingfeng Pharmaceutical Group Shanghai Branch

CRC Role and Function Healthy Development Coming from Clinical Trial Society Strong Support

**Shuting LI, MD**
Former Director, GCP Center, the Cancer Hospital of Chinese Academy of Medical Sciences

*Debate and Panel Discussion*
Central Lab's Role in High Quality Clinical Trial
DEBATE CO-CHAIRS

**Yan WU, MD. MSc**
Executive Director, Head of Clinical Operation, Hutchison MediPharma Ltd.

**Jenny ZHANG**
Vice President and General Manager, Asia Pacific, Q Squared Solutions, Quintiles Quest Joint Venture

DEBATERS

**Andy LIU**
China General Manager, Covance Central Laboratory Service

**Hao WANG**
Senior Director, China Clinical Operations, BMS

**Liedong XU, MSE, MBA**
China Head of Clinical Research Department, Covance

**Shirley XU**
General Manager, Shanghai Guanghe Medical Technology Co., Ltd.

**Maggie ZHOU**
Head of Scientific & Clinical Procurement China, South Korea, Australia & New Zealand, China

### Session 0307 | MAY 24, 2017

13:30-15:00 | 7th Floor, Pearl Hall

**HOW TO ENSURE THE DATA INTEGRITY IN CLINICAL TRIALS**
SESSION CHAIR

**Yazhong DENG**
General Manager, Beijing Trust Medicine Consulting Ltd.

By the cooperation from multiparty in clinical trial, apply new technology to find and analyze the risks in sites, clinical monitoring, and data management to improve data quality in clinical trials, and ensure data integrity

Challenges of Data Integrity Where the Sponsor Outsources Their Clinical Trials to CROs

**Simon LI, MD, PhD**
Chief Medical Officer, Vice President, CSPC Pharma

Data Integrity and Compliance in Bio-Analysis Practice

**Zheming GU, PhD**
General Manager, Value Pharmaceutical Services Co., Ltd.

Apply Technology to Analyze Risk Sources at Site, Clinical Monitoring and DM Level

**Carrie ZHANG**
CEO, Data Management&Statistics Branch Company, Panacea Technology Co., Ltd.

*Panel Discussion*

### Session 0308 | MAY 24, 2017

Simultaneous Translation

15:30-17:00 | 7th Floor, Pearl Hall

**APPLY NEW TECHNOLOGY/METHOD TO IMPROVE DATA QUALITY IN CLINICAL TRIAL**
SESSION CHAIR

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

Apply Data Method to Ensure / Improve Quality of Clinical Trial

**Wenjun BAO, PhD**
Chief Scientist, Senior R&D Manager, JMP Life Sciences, SAS Institute Inc. USA

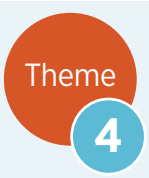
Advanced Technology in Data Monitoring

**Eric HERBEL**
President, Integrated Clinical Systems, Inc.

Quality Gates for Data Management Activities

**Lobo LOO**
Associate Director, Global Data Operations,
MSD R&D (China) Co., Ltd.

*Panel Discussion*
Above Speakers




## Oncology Drug Development

### Session 0401 | MAY23, 2017

08:30-10:00 | 5th Floor, 5B+C; 5J Live Satellite

**TARGET DISCOVERY & PRECLINICAL DEVELOPMENT**
SESSION CHAIR

**Zhiqiang NING, MD, PhD**
Executive Vice President, R&D,
Shenzhen Chipscreen Biosciences Ltd.

With the rapid progress in understanding of tumor initiation and development mechanisms along with the proof of concepts and applications of relevant new drugs clinically, overall strategies have been considered in targeting tumor cell itself as well as its complex surrounding microenvironment. As the first session of the "anti-tumor drug development" theme, speakers will focus on what we have learnt about tumor microenvironment and the potentials in targeting these complex components as an overall strategy, including the design and discovery of small molecular drugs and the development of preclinical animal efficacy models.

Potential Strategies Targeting Tumor Microenvironment in Future Cancer Treatments

**Xianping LU, PhD**
CEO & Chief Scientific Officer, Chipscreen Biosciences, Ltd.
Shenzhen, China

New Small Molecule Technologies and Mindsets for Anti-Cancer Drug Discovery

**Yuli XIE, PhD**
General Manager, Suzhou Autopharm Biopharmaceutical Co., Ltd.

Trends in Preclinical Efficacy Evaluations

**Yuelei SHEN, PhD**
Chairman & CEO, Biocytogen

### Session 0402 | MAY 23, 2017

10:30-12:00 | 5th Floor, 5B+C; 5J Live Satellite

**EARLY STAGE CLINICAL DEVELOPMENT**
SESSION CHAIR

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

Early clinical development is critical for new oncology product. With examples, several key elements for FIH study design will be discussed such as starting dose, selection of population and indication, escalation method and biomarker integration. Meanwhile the role of adaptive trials and several newer trial types, such as basket trials, umbrella trials or master protocols in obtaining approvals or label expansions by regulatory agencies will be discussed.

Considerations for Early Clinical Development of Oncology Product

**Yu WANG, MD. PhD**
CSO, Beijing PANACRO

Dose Selection and Determination for Oncology Development

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

The Role of Novel Clinical Trial Designs in Oncology Drug Development

**Mithat Gönen, PhD**
Chief of Biostatistics Service, Memorial Sloan Kettering Cancer Center, USA

### Session 0405 | MAY 24, 2017

08:30-10:00 | 5th Floor, 5B+C; 5J Live Satellite

**LATE STAGE CLINICAL DEVELOPMENT**
SESSION CHAIR

**Yongjiang HEI, MD, PhD**
Chief Medical Officer, Ambrx, Inc., USA

Overall development strategy including regulatory strategy and clinical trial design strategies; Phase 2 trial design and go/no go decision for entering phase 3 trials; Trial conduct and data analysis; Drug manufacturing and supply for late phase clinical trials; Regulatory interactions during the late phase trials.

Perspectives on the Strategies and Challenges to Leverage Global Programs to Gain Oncology Drug Approvals in China

**Joan SHEN, MD, PhD**
Vice President, Development Head, China R&D and Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

Commercialization of Innovative Oncology Products Derived from China-Based R&D: How to Achieve Clinical and Commercial Success

**Jessie ZOU, MD, PhD**
Vice President, Clinical Research and Development, Jiangsu Hengrui Medicine, Co., Ltd.

## TUESDAY, 23 MAY | WEDNESDAY, 24 MAY

## THEME 4

### Clinical Trial Design to Optimize Oncology Drug Development

**Lixia WANG, PhD**
Senior Vice President, Biometrics, Health Economic and Outcome Research, CTI BioPharma Corp.

### Session 0406 | MAY 24, 2017

10:30-12:00 | 5th Floor, 5B+C; 5J Live Satellite

**IMMUNO ONCOLOGY**
SESSION CHAIR

**Chen DONG, PhD**
Professor, School of Life Sciences
Professor and Vice Dean , School of Medicine, Tsinghua University

Immuno Oncology has made significant breakthrough. It is expected more significant progresses will be achieved in the coming years. In this session, we will discuss the latest IO research and development progresses from both academia and the pharmaceutical industry. Clinical trial design and operation will also be discussed during this session.

### The Overall Progress and Development Trend of Immuno Oncology Field

**Chen DONG, PhD**
Professor, School of Life Sciences
Professor and Vice Dean , School of Medicine, Tsinghua University

### The Progress of Immune Oncology Treatment

**Lianshan ZHANG, PhD**
Vice President, Jiangsu Heng Rui Medicine Co., Ltd.

### Considerations on Immuno Oncology Clinical Trials Design and Operations

**Forrest H. ANTHONY, MD, PhD**
Senior Director, Head of Oncology Center of Excellence - North America, Research and Development Solutions, Quintiles

### Session 0407 | MAY 24, 2017

13:30-15:00 | 5th Floor, 5B+C; 5J Live Satellite

**PRECISION MEDICINE & IN-VITRO DIAGNOSIS**
SESSION CHAIR

**Zefei JIANG, MD, PhD**
Director, Breast Cancer Department, Affiliated Hospital to Military Academy Of Medical Sciences (Beijing 307 Hospital)

In-vitro diagnostics (IVD) are tightly companioned with precision medicine and clinical trials that are driven by biomarker analysis. Speakers from this session will present current development and applications of IVD techniques with their regulatory paths both in China and Western countries. Particular attention will be paid to the advantages and limits of IVD techniques in precision medicine as well as biomarker-guided clinical trials.

### Precision Medicine, View from Oncology Physicians

**Zefei JIANG, MD, PhD**
Director, Breast Cancer Department, Affiliated Hospital to Military Academy Of Medical Sciences (Beijing 307 Hospital)

### IVD Technologies in Precision Medicine and Oncology Product Development

**Hao LIU**
Chief Medical Officer, Medical Department, Burning Rock Dx, China

### IVD Introduction and Regulation in China and US/EMEA

**Jinjie HU, PhD**
Senior Consultant, Biologics Consulting Group, INC.
Chair of the FDA Alumni Association International Network (FDAAA)
Former Senior Reviewer, Office of Blood Research and Review, US FDA/CBER

## Session 0408 | May 24, 2017

15:30-17:00 | 5th Floor, 5B+C; 5J Live Satellite

### REGULATORY & WORLD-WIDE DEVELOPMENT

SESSION CHAIR

**Irene DENG**
Vice President, Head of China Regulatory Affairs, AstraZeneca

Best Regulatory Science to Support Oncology Development
If talking about oncology development, the impression would be "fast pace" which means:

1) Introduce more new advanced science and innovative technology, such as Immunology and companion diagnostic;
2) Different to convential development approach from Phase I-III;
3) High Expectation from the public to the fast approval in order to save life-threaten disease once the signal shows the efficacy and safety profile acceptable.

In this way, to best support the development of oncology drug, what do the regulatory science and China regulatory framework should be advanced? The experienced RA profession and Development lead will provide their insight on it.

How Regulatory Science to Support the Earlier Stage Development

**Lin ZHU**
Director, Head of China Regulatory Affairs, Jiangsu Heng Rui Medicine Co., Ltd.

How Regulatory Science to Support the Late Stage Development and Breakthrough Therapy to Market

**Lei ZHANG**
Senior Director, Head of China Regulatory Affairs, XiAn Janssen Pharmaceutical Ltd.

*Panel Discussion:*
To best facilitate the development of oncology drug, what do the regulatory science and China regulatory framework should be advanced? Will have the in-depth discussion around clinical trial approval acceleration, global data recognition and companion diagnosis regulation.

All Speakers and

**George CHEN, MD, PhD**
Senior Vice President, Global Medicines Development, Head of China Development Unit (CDU), AstraZeneca

**Joan SHEN, MD, PhD**
Vice President, Development Head, China R&D and Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

**Hua MU, MD, PhD**
Chief Scientific Officer, Simcere Pharmarceutical Group

**Zhiqiang NING, MD, PhD**
Executive Vice President, R&D, Shenzhen Chipscreen Biosciences Ltd.


## Quantitative Science in Transformation

## Session 0501 | MAY 23, 2017

08:00-10:00 | 3rd Floor, 3C+D

### QUANTITATIVE SCIENCE AND NEW REGULATORY GUIDANCE

SESSION CO-CHAIRS

**Cathy LIU, PhD**
Associate Director, Clinical Statistics, Pfizer (China) R&D Co., Ltd.

**Zhiwei JIANG, PhD**
Senior Scientist, Biostatistics and Research Decision Sciences (BARDS), Asia-Pacific, Merck Research Laboratories

This session will focus on the impact and implementation of multi-regional regulatory statistical guidance on the drug and medical device development. Recent regulatory documents from CFDA, FDA, EMA, etc, on important statistical issues such as conduct of Multi-Regional Clinical Trials (MRCT), biosimilarity, adaptive design, and general statistical principles will be discussed.

Global and China Regulatory Statistical Guidance

**Yong WANG, PhD**
Senior Director, Biostatistics, APAC, Parexel

*Panel Discussion*
Above Speaker and

**CFDA CDE Panelist Invited**

**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

**Tony GUO, PhD**
Senior Director, Biostatistics, MSD R&D (China) Co., Ltd.

**Nicole F. LI, PhD**
Director, Biostatistics, AP Site Head of Biostatistics Roche PDY, Shanghai

**Tao WANG, PhD**
Director, Head of Biostatistics and Programming, Jiangsu Hengrui Medicine Co., Ltd.

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

# TUESDAY, 23 MAY | WEDNESDAY, 24 MAY

# THEME 5

## Session 0502 | MAY 23, 2017

10:00-12:00 | 3rd Floor, 3C+D

### CDISC/EDC GUIDELINES AND IMPLEMENTATION

SESSION CO-CHAIRS

**Yazhong DENG**
General Manager, Beijing Trust Medicine Consulting Ltd.

**Zibao ZHANG, PhD**
Senior Director, Biostatistics and Programming, dMed Company Limited

In this session, the recent regulatory guidelines about CDISC standard and EDC techniques/implementation in China will be updated. Then some solutions and case studies from global and China will be provided followed by panel discussion.

Updates of Recent CDISC Standard and EDC Related Regulatory Guidance from CFDA Perspective

**Jun WANG, PhD**
Deputy Director, Office of Biostatistics and Clinical Pharmacology, Center for Drug Evaluation, CFDA

Enabling the Use of CDISC through EDC and Your Data Management Platform for Today and for Future Data Collection Sources

**Jim STREETER**
Global Vice President, Life Sciences Product Strategy, Oracle Health Sciences

Utilize Vendor-Neutral Model to Deliver Reusability and Traceability across Multiple EDC Platforms

**Haiping YU**
Technical Operation Lead, Clinical Data Management, dMed Biopharmaceutical Co., Ltd.

*Panel Discussion*
Above Speakers and

**Li HAN**
Manager, Late Phase Oncology, Clinical Data Management, Biometrics, Roche (China) Holding Ltd.

**Dong MA**
Vice President, Clinical Research Department, Jiaxing Taimei Medical Technology Co., Ltd.

## Session 0505 | MAY 24, 2017

08:30-10:00 | 3rd Floor, 3C+D

### UTILIZATION OF REAL WORLD DATA FOR DRUG DEVELOPMENT AND DRUG EVALUATION

SESSION CO-CHAIRS

**Luyan DAI, PhD**
Director, Head of Biostatistics China, Biostatistics & Data Sciences Asia, Boehringer Ingelheim Utilization of Real World Data for Drug Development and Drug Evaluation

**Roger QU, PhD**
Head of Clinical Statistics, Pfizer R&D Center

Given the challenge of more efficient design of clinical program, the real world data has more opportunity and value to help design clinical studies, post-approval evaluation of efficacy and safety (this is especially relevant since China has requirement of 5 year license renewal for any approved drug

Salford Lung Study, Pragmatic Trials on COPD and Asthma Patients

**Bingming YI, PhD**[1]
Head of Statistics, Programming, Epi, and Data Management, GSK

**Lucy FRITH**[2]
Director, Clinical Statistics, Respiratory GSK

Evaluation of Blood Pressure Variability Using Existing Clinical Database

**Ping YAN, PhD**
Director, Clinical Statistics, Pfizer (China) Research and Development Center

Application of Medical Standard of Care Data

**Yong WANG, PhD**
Senior Director, Biostatistics, APAC, Parexel

## Session 0505-2 | MAY 24, 2017

08:30-10:00 | 3rd Floor, 3G

### CLINICAL DATA-- REGULATORY REQUIREMENT

SESSION CHAIR

**Charles YAN, PhD**
Head of Clinical Data Science Center, Jiangsu Heng Rui Medicine Co., Ltd.

The quality and integrity of the clinical data are the foundation of the most objective and scientific assessment on the drug safety and efficacy. Under the current environment, CFDA put more efforts to focus on the data integrity and reality. This session will introduce the latest regulatory requirements on clinical trial data in their capture, management, statistical analysis report and submission.

Standard and Requirements for Clinical Data in China

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

Technical Guidelines for Electronic Data Acquisition of CFDA Clinical Trials

**CFDA CDE Speaker Invited**

Panel Discussion: Standardized Requirements of Clinical Data in China

**Above Speakers and**

**Yazhong DENG**
General Manager, Beijing Trust Medicine Consulting Ltd.

**Hadrian FU, PhD**
General Manager, Shanghai Cares Bio-tech Co., Ltd.

# TUESDAY, 23 MAY | WEDNESDAY, 24 MAY THEME 5

## Session 0506 | MAY 24, 2017

10:30-12:00 | 3rd Floor, 3C+D

### ACCELERATE DRUG DEVELOPMENT WITH INNOVATIVE STATISTICAL METHOD

SESSION CHAIR

**Tony GUO, PhD**
Senior Director, Biostatistics, MSD R&D (China) Co, Ltd.

In recent years, the drug development has become more and more challenging with longer timeline and higher expense. New study design including adaptive design and global simultaneous development were implemented to speed up the process such that the unmet medical needs can be addressed in many disease areas. Statistics plays a critical rule in the development and implementation of the new designs. In this session two presentations will focus on the cost-effective strategies for development of new cancer immunotherapies and extension strategy to accelerate China development. The presentations will be followed by a panel discussion consisted of panelists including senior R&D leader and regulatory reviewers.

Cost Effective Strategies for Development of Immunotherapies

**Cong CHEN, PhD**
Director, Early Oncology Biostatistics, MSD

China Extension Design Helps to Accelerate China Development

**Nicole F. LI, PhD**
Director, Biostatistics, AP Site Head of Biostatistics Roche PDY, Shanghai

*Panel Discussion*
Above Speaker and
CFDA CDE Speaker Invited

## Session 0507 | MAY 24, 2017

13:30-15:00 | 3rd Floor, 3C+D

### STATISTICAL CONSIDERATIONS IN CLINICAL DEVELOPMENT

SESSION CHAIR

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

Statistics plays roles of varying importance in various factors affecting the clinical development as Carter, Scheaffer, and Marks (1986) stated that: “Statistics is unique among academic disciplines in that statistical thought is needed at every stage of virtually all research investigations including planning the study, selecting the sample, managing the data, and interpreting the results.” In each factor/stage, there are vastly rich statistical techniques that one can choose from. This session will provide a flavor on some of those factors.

Missing Data Handling in Biosimilar Evaluation and Tipping Point Analysis

**Shanmei LIAO**
Associate Director, Biostatistics, Pfizer

Using Critical Success Factors (CSFs) to Facilitate Decision Making in Drug Development

**MaryAnn Morgan COX, PhD**
Principal Research Scientist, Statistics & Advanced Analytics, Eli Lilly, United States

A Bayesian Hierarchical Model to Account for Excessive Zero Counts for the Safety Signal Detection

**Aileen ZHU, PhD**
Principal Biostatistician, Biostatistics, Novartis

## Session 0508 | MAY 24, 2017

15:30-17:00 | 3rd Floor, 3C+D

### NEW IDEAS AND EMERGING TRENDS IN STATISTICAL METHODS FOR MULTI-REGIONAL CLINICAL TRIALS

SESSION CHAIR

**Anny-Yue YIN, PhD**
Senior Director, Biostatistics, CStone Pharmaceuticals Co., Ltd.

MRCT should be a familiar topic to the audience of DIA China. Just as the drug development is rapidly evolving, we keep encountering new issues and generating new ideas in the process of designing, executing, and analyzing MRCTs. In this session, we will discuss solutions to those issues as well as innovative designs in MRCT.

Challenges in Interpretation of MRCT Results—Cases beyond PLATO

**Jerry WANG, PhD[1]**
Head of Global Biostatistics & Epidemiology and Medical Writing China, Merck Serono

**Wenfeng CHEN[2], Fay GAO[3]**

Statistical Issues in Non-Inferiority MRCTs

**Zhiwei JIANG, PhD**
Senior Scientist, Biostatistics and Research Decision Sciences (BARDS), Asia-Pacific, Merck Research Laboratories

Beyond Traditional MRCT Designs: Extensions and More

**Xiongwen TANG, PhD**
Statistical Scientist, Roche (China) Holding Ltd.

*Panel Discussion*
Above Speakers and

**Zhangsheng YU, PhD, Professor**
Associate Director, SJTU-Yale Joint Center for Biostatistics

# TUESDAY, 23 MAY | WEDNESDAY, 24 MAY

THEME 6


## Focus on Medical Value to Satisfy Unmet Patient Needs

### Session 0601 | MAY23, 2017

Simultaneous Translation

08:30-10:00 | 3rd Floor, 3I+J

**THE EVOLVEMENT OF MEDICAL AFFAIRS IN NEW ERA**
SESSION CHAIRS

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

Pharmaceutical industry is undergoing fundamental changes in China: the deepening of healthcare reform; the strengthening of government regulation and compliance; the emerging of innovative enterprises; and the increasing use of big data in the medical field... How can we grasp the trend of medical affairs in such dynamic environment? With keynote speeches and expert panel, this section will focus on how medical affairs could satisfy unmet patient needs through focusing on medical value in new era.

The Current Situation and Future Trend of Global Medical Affairs

**Salvador GARCIA DE QUEVEDO, MD**
Global Vice President of Medical Affairs, Eli Lilly

The Emerging Needs for Medical Affairs Functions

**Fangning ZHANG**
Partner, McKinsey & Company, Inc.

Q&A

### Session 0602 | MAY 23, 2017

10:30-12:00 | 3rd Floor, 3I+J

**REAL-WORLD EVIDENCE AND HEALTH-OUTCOME**
SESSION CHAIR

**Yi NING, PhD**
GSK Senior Fellow
Head of Epidemiology
GSK Institute for Infectious Diseases and Public Health

Real-world research is an indispensable method for exploring unmet medical needs, optimizing clinical development, and investigating the impact of interventions on clinical practice and economic impact. Real-world research not only can reduce the limitations of traditional research, but also reflect real-world clinical effectiveness, and providing objective evidences for new drugs and device. It is of paramount importance to have an optimized study design and high-efficient implementation, to reduce the bias of real-world research, so as to help clinicians to optimize clinical practice and to improve the efficiency of health resource utilization.

Real-World Evidence - Value and distinctions from RCTs

**Haijun CAO, MD, PhD**
Head of China Health Outcomes, Lilly China

Real World Evidence Generation throughout Product Life Cycle

**Yi NING, PhD**
Senior Fellow of the Council of Fellows, Head of Epidemiology, GSK

Big Data from Real-World and Practical Examples

**Libo TAO, PhD**
Research Fellow, Health Economic Research Institute, Sun Yat-sen University

### Session 0605 | MAY 24, 2017

08:30-10:00 | 3rd Floor, 3I+J

**MULTI-CHANNELS MEDICAL COMMUNICATION**
SESSION CHAIR

**Iris KANG**
Vice President, Medical Affairs, AstraZeneca China and HK

Over decades, pharmaceutical companies are providers not only of medical products, but also of medical information. Nowadays, Medical affairs play more important role in providing medical information. This session will focus on discussing the opportunities and challenges during the transforming from traditional way of medical communication to new multi-channels medical communication.

Multi-channels Medical Communication: the View from Patient Centric

**Cherry MA**
Head of Medical Affairs, General Medicine, Allergy, R&D, Merck Serono

Digital Capacity Development in New MI Era

**Jian LI**
Medical Director, Medical Information & Compliance, Medical Affairs, AstraZeneca China

New Media for Patient Education

**Su ZHOU**
Medical Affairs Lead, Medical Department, Specialty Care China/ IVF Global, Beaufour-Ipsen

### Session 0606 | MAY 24, 2017

10:30-12:00 | 3rd Floor, 3I+J

**"MEDICAL DRIVEN" IN CROSS FUNCTIONS' EYES**
SESSION CHAIR

**James HE, PhD**
Vice President of Medical Affairs, Novartis China

Nowadays, physicians increasingly focus on the content and quality of the academic conference, and hope to apply the scientific evidence to clinical practice. At the same time, the public and government pay more attention to corporate behaviors. Under the new situation, many companies enhance the capacity of Medical Affairs to produce more comprehensive, reliable and high-quality clinical data according to unmet academic needs. And medical affairs are fully recognized as a cornerstone role. In light of this, Medical Affairs and other cross-function departments need to change the traditional model of cooperation, increasing understanding; strengthen cooperation, and advancing science-based academic communication. This could reduce the risk of noncompliance, enhance corporate public image, and provide better service to physicians and patients.

Business Leader's expectations for Medical Affairs

**Burkon WANG**
Head of Ophthalmology China, Novartis

Collaboration of Medical Affairs and Ethical/Compliance Department

**Teng REN**
Ethical & Compliance Head, Asia, Middle East and Africa, GSK

*Panel Discussion*

## Session 0607 | MAY 24, 2017

13:30-15:00 | 3rd Floor, 3I+J

### THE ROLE OF MEDICAL AFFAIRS IN PRODUCT LIFE CYCLE MANAGEMENT

SESSION CHAIR

**Frances CHANG, MD, PhD**
Vice President of Medical Affairs, Roche China

Approval of a new drug is just the start of the product life cycle. The ultimate goal of a life cycle is to continuously optimize and maximize the target patient population and use of drug, by understanding the clinical needs, identifying important clinical questions, and providing answers through different clinical strategies. In this process, Medical affairs play an important role in three key steps, i.e. understanding the clinical needs, generating clinical evidence, sharing results and improving product applications.

Data Generation in Lifecycle Management

**Eugen LI**
Medical Affairs China Group I Director, Clinical Development and Medical Affairs, Boehringer Ingelheim

Role of Medical Affairs in Product Launch

**Cindy ZHU**
Associate Director, Medical Science-Oncology, Roche

Maximizing the Medical Value for Established Product

**Knightley WEI**
Senior Director, Medical Affair, MD
China Medical Affair-Women Health/Bone/Pain/MSS Franchise
Hangzhou MSD Pharmaceutical Co., Ltd.

## Session 0608 | MAY 24, 2017

15:30-17:00 | 3rd Floor, 3I+J

### 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, Medical Affairs has become one of the fastest growing functions in pharmaceutical industry, and the number of employees is also growing rapidly. This section provides attendees an opportunity to meet with the senior leaders of Medical Affairs face to face and to discuss capability development and career planning in Medical Affairs.

*Panel Discussion:*
Medical Executives Who Attend the Conference A Few Middle Level Medical Leaders

**Frances CHANG, PhD**
Vice President of Medical Affairs, Roche China

**James HE, PhD**
Vice President of Medical Affairs, Novartis China

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


## Clinical Submission Documents - Embrace New Regulatory Requirements

## Session 0607-2 May 24, 2017

13:30-15:00 | 5th Floor, 5D+E

### DEVELOPMENT OF CLINICAL DOCUMENTS FOR REGULATORY SUBMISSION TO MEET THE CFDA REQUIREMENTS AND TO PROACTIVELY ADDRESS POTENTIAL INSPECTION POINTS

SESSION CHAIR

**Xiaoling WANG**
Head of clinical documentation
Clinical Science Operation, Sanofi R&D China

China FDA released a number of guidelines on regulatory submission over the past years. These guidelines are largely harmonized with ICH guidelines, but do contain a few unique requirements and elements beyond ICH. In practice, many companies use ICH documents as references for the development of the clinical documents for China submission. However, how to fulfill CFDA-specific requirements is a pain point for many medical writers and regulatory professionals. In addition, the self-inspection over the past two years required by CFDA gave the industry insight into the key points of CFDA inspection. In the present session, we will discuss how to develop some frequently prepared clinical documents in accordance with the requirement of China regulatory agency and to proactively address potential inspection points.

Ensure the Quality of Clinical Study Report Appendices Documents through Cross-Functional Collaboration: Proper Documentation of Study Conduct to Meet CFDA Requirements

**Fei LI, PhD**
Senior Scientific Communication Manager, Medical Department
Lilly China

Clinical Evaluation Report Development for Medical Device Registration

**Chengxue JI, MD, PhD**
Clinical Evaluation Manager, Medical & Regulatory Affair Department, Boston Scientific

The Impact of Protocol Deviation on Quality of Study and Integrity of Data, and the Way to Manage It

**Haidan WANG, MD**
Medical Director, Wuxi CDS

## Session 0608-2 May 24, 2017

15:30-17:00 | 5th Floor, 5D+E | English Only

### CROSS-FUNCTIONAL COLLABORATION TO PREPARE HIGH QUALITY CLINICAL DOCUMENTS TO SUPPORT IND, PRE-NDA AND NDA SUBMISSIONS

SESSION CHAIR

**Andrea HENNIG**
Medical Writing TA Head, General Medicine, Bayer AG Development, Pharmaceuticals

In recently years, there has been increasing requirement from health authorities around the world, including the CFDA, to continuously improve the quality of the clinical documents. Drug development professionals including medical writers are facing more challenges as well as opportunities. During the clinical development, medical writers work with experts from different functions to prepare key clinical documents to support IND, pre-NDA and NDA submissions. In this session, we are going to focus on the development of clinical study protocol, briefing document and bridging report for NDA to share our practice and perspectives. Collaboration is essential for everyone in drug development to hit our goal.

How to Effectively Develop Study Protocol Through Engaging the Internal and External Stakeholders

**Leo ZHANG**
Associate Manager, Medical Writing Services, Parexel

Development of Briefing Document to Support the Communication with Health Authority

**Nan WANG, PhD**
Head of Medical Writing General Medicine, China/Finland, Bayer HealthCare CO. Ltd

Bridging Study Evaluation/Report in Chinese Taipei and Korea

**Ning ZHENG, PhD**
Senior Medical Writer, Clinical Documentation, Sanofi


## Development and Regulation of Biologicals & Biosimilar

## Session 0701 | May 23, 2017

Simultaneous Translation

08:30-10:00 | 5th Floor, Yangtze River Hall

### CLINICAL TRIAL DESIGN OF BIOSIMILAR -- PART I

SESSION CO-CHAIRS

**Helen YANG**
Regulatory Director, Roche (China) Holding Ltd.

**Yaning WANG, PhD**

In recent years, biosimilar products are without a doubt a trending field of global pharmaceutical development. Even though biosimilar products require higher investment of technology and money compared with chemical generics, they have attracted vast attention and funding, and become a major field of research and development that pharmaceutical giants both in China and abroad cannot ignore. Multinational companies like Merck, Novartis, Pfizer and Amgen have carried out research of biosimilars with a large amount of money investment; domestic companies have also delved into biosimilar research, creating a competitive environment among enterprises like Henlius, Qilu Pharmaceutical, Hisun Pharmaceutical, INNOVENTBIO, Genor Biopharma, Hualan Bio, and CPGJ Pharmaceutical. The companies are making huge efforts on the development of drugs of all kinds of indications.

Adalimumab, the star of biosimilar drugs, have been approved worldwide of eight indications including adult moderate-severe active rheumatoid arthritis and severe active ankylosing spondylitis. Up to eight companies have been granted clinical trial approval, and more companies are at the stage of research and development. In addition, Rituximab, Trastuzumab and Cetuximab are also under the attention of many pharmaceutical companies.

CFDA issued Technical Guideline for Development and Evaluation of Biosimilars (interim) in March 2015, in which the standardized guidelines on application process, registration classes, and application materials are provided, clarifying the marketing approval process for biosimilars. In this way, patients are guaranteed to be able to access those biosimilars in time, and the quality, efficacy and safety of those biosimilars are ensured. This session will introduce the specific considerations on the design of clinical trials, and we aim to improve the implement of these guidelines in the pharmaceutical industry in China. In addition, officials from Health Canada and FDA, along with experienced researchers and representatives of the industry will introduce the key aspects on clinical trial design of biosimilars worldwide. The speakers will share their experiences and thoughts through the analysis of specific cases.

CDE Perspective: Regulatory Expectation on the Clinical Design of Biosimilar

**Xiaoyuan CHEN**
Office of Clinical Review I, Center for Drug Evaluation, CFDA

Health Canada Perspective: Regulatory Expectation on the Clinical Design of Biosimilar

**Jian WANG MD, PhD**
Chief, Clinical Evaluation Division - Haematology/Oncology, Centre for Evaluation of Radiopharmaceuticals & BiotherapeuticsBiologics and Genetic Therapies Directorate, HPFB, Health Canada

Clinical Pharmacological Consideration of the Clinical Trial Design of Biosimilar and Case Share

**Ping JI, PhD**

Clinical Considerations for Biosimilar Developments -- Case Study of Biosimilar Monoclonal Antibody Approved in EU

**Nick CECIL**
Vice President, Consulting, PAREXEL International Consulting (Tech)

# TUESDAY, 23 MAY | WEDNESDAY, 24 MAY THEME 7

## Session 0702 | May 23, 2017

Simultaneous Translation

10:30-12:00 | 5th Floor, Yangtze River Hall

### CLINICAL TRIAL DESIGN OF BIOSIMILAR -- PART II

SESSION CO-CHAIRS

**Helen YANG**
Regulatory Director, Roche (China) Holding Ltd.

**Yaning WANG, PhD**

Clinical Physician Perspective: Clinical Development and Trial Design of Biosimilars

**Junning CAO, MD, Prof.**
Fudan University Shanghai Cancer Center

*Panel Discussion*
All 0701 & 0702 above speakers and

**Yaning WANG, PhD**

## Session 0705 | May 24, 2017

Simultaneous Translation

08:30-10:00 | 5th Floor, Yangtze River Hall

### RECENT TRENDS IN THE REGULATION OF BIOPHARMACEUTICAL PRODUCTS

SESSION CO-CHAIRS

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

**Joe ZHANG, MD, PhD**
Head of Preclinical R&D Simcere Pharmaceuticals

Because of the unique advantages of biopharmaceuticals in disease treatment and a rapid growth in technologies related to such products, development of biopharmaceutical products has become a hot area in pharmaceutical R&D. In order to ensure a healthy growth of this sector, regulatory agencies from different countries have issued a series of regulations or guidelines to facilitate the review and approval of biopharmaceuticals. In this session, representatives from CFDA, Health Canada and US will present their view on recent trends in regulations of biopharmaceutical product. The panel discussion following the presentations will covering several themes, including:

- Regulatory strategies for enabling the rapid development and the potential for early marketing approval of highly promising new biotherapeutic products, the associated challenges, and progress being made;
- Regulatory updates on cell and gene therapy products and biosimilars;
- Efforts being made at international or regional harmonization, regulatory convergence, and work sharing between health authorities.

Recent Trends in the Regulation of Biopharmaceutical Products – from China Perspective

**CFDA Speaker Invited**

Recent Trends in the Regulation of Biopharmaceutical Products – from Canada Perspective

**Jian WANG MD, PhD**
Chief, Clinical Evaluation Division - Haematology/Oncology, Centre for Evaluation of Radiopharmaceuticals & BiotherapeuticsBiologics and Genetic Therapies Directorate, HPFB, Health Canada

Recent Trends in the Regulation of Biopharmaceutical Products – from US Perspective

**Yaning WANG, PhD**

*Panel Discussion*

## Session 0706 | May 24, 2017

Simultaneous Translation

10:30-12:00 | 5th Floor, Yangtze River Hall

### REGULATING BIOLOGICS UNDER MAH PILOT PROGRAM

SESSION CHAIR

**Jian DONG, MBA, MSc**
Vice President and Site Head of Wuxi Biomanufacturing Site, WuXi Biologics

The MAH Pilot Program has created a historic opportunity for the R&D and manufacturing of biologics in China. It is also a brand new topic and challenge to regulatory agency in China. The regulatory agency and companies of biologics R&D and manufacturing shall explore and collaborate this opportunity to ensure the MAH pilot program is successful, and will benefit Chinese patients with affordable biologics of quality as earlier as possible.

The speakers of the session come from regulatory agency of China, multinational large pharma and leading CMO. They will discuss the regulatory considerations, how to leverage international practice, and the opportunities and challenges associated with the MAH pilot program for biologics.

Post Marketing Drug Regulation Under the MAH Pilot Program

**Hua ZHANG**
Deputy Director, Shanghai Center for Drug and Inspection

Regulation of CMO for Biological Products by US FDA

**Andrew CHANG, PhD**
Vice President, Product Supply Quality, Novo Nordisk Inc., USA

Opportunities and Challenges of MAH System to Biopharmaceutical Industry in China

**Jian DONG, MBA, MSc**
Vice President and Site Head of Wuxi Biomanufacturing Site, WuXi Biologics

*Panel Discussion*

## Session 0707 | May 24, 2017

Simultaneous Translation

13:30-15:00 | 5th Floor, Yangtze River Hall

### PHARMACOMETRICS IN EARLY STAGE OF CLINICAL DEVELOPMENT

SESSION CO-CHAIRS

**Michelle CHEN**
Regulatory Director, Oncology of PDR China, Roche (China) Holding Ltd. Beijing Branch

**Xiaoyuan CHEN**
Office of Clinical Review I, Center for Drug Evaluation, CFDA

How does pharmacometrics guide drug development to optimize protocol design of clinical trial and provide theoretical rationale for decision making? How does quantitative method help agency to make regulatory decisions on drug approval

and administration? Senior experts from academia, industry and agency are invited to the session to share from different perspectives their thinking on decision making with cases from first in human, early clinical development, confirmatory clinical trial to drug review and approval.

### Application of Quantitative Method in Regulatory Decision Making

**Yaning WANG, PhD**

### FIH Strategy and Trial Design of Innovative Oncology Products

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

### Challenges and Opportunities for Dose Optimization in Biologics Development

**Jin Yan JIN, PhD**
Associate Director and Principal Scientist, Global Head of Modeling and Simulation (M&S) and OMNI Clin-Pharm Group Leader, Genentech of Roche, USA

*Panel Discussion*

## Session 0708 | May 24, 2017

Simultaneous Translation

15:30-17:00 | 5th Floor, Yangtze River Hall

**DEVELOPMENT OF CELL THERAPY AND REGULATORY CONSIDERATIONS**
SESSION CO-CHAIRS

**Joe ZHANG, MD, PhD**
Head of Preclinical R&D Simcere Pharmaceuticals

**CFDA CDE Speaker Invited**

With a rapid growth of biotechnology, a new generation of cell-based therapies such as CAR-T has emerged as one of the most innovative treatments of diseases. This new generation of cell-based 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. This session focus on the development of the new generation of innovative cell-based therapies and regulatory considerations from healthy authorities with a purpose for the audience to have a chance to learn the most updated progress in cell therapy and to discuss how to regulate such products with experts from regulatory agencies.

### Advance in Adoptive T Cell Therapy of Cancers

**Yangbing ZHAO, MD, PhD**
Associate Professor, Department of Pathology and Laboratory Medicine, University of Pennsylvania, USA

### Regulatory Considerations of Cell-based Therapies-FDA's Perspective

**Yow-Ming Chen WANG, PhD**
Biologics Team Leader, Division of Clinical Pharmacology 3, Office of Translational Sciences, Office of Clinical Pharmacology, FDA/CDER

### Regulatory Considerations of Cell-based Therapies-CFDA's Perspective

**Chenyan GAO**
Director, Office of Clinical Evaluation of Biological Products, Center for Drug Evaluation, CFDA

### The Safety Rating of Cell Therapy Products

**Jing MA, PhD**
Director, National Shanghai Center for New Drug Safety Evaluation Research Center
President, Shanghai InnoStar

*Panel Discussion*

# Theme 8 Patient Safety – A Constant Focus

## Session 0801 | MAY 23, 2017

Simultaneous Translation

08:30-10:00 | 5th Floor, 5D+E

**CURRENT DEVELOPMENT IN PHARMACOVIGILANCE – THE IMPORTANCE TO KNOW WHAT'S GOING ON**
SESSION CO-CHAIRS

**Xue TANG**
Director, Cluster Safety Lead, Pfizer

**Lynn ZHOU**
Director, China & Asia Regional Safety Lead of Sanofi

Pharmacovigilance discipline has been rapidly advancing in recent years. In this interactive session, the audience will hear the update on the technical breakthrough of the safety data evaluation, and new pharmacogenomics researches that have had the impact on the Clinical Practice. The speaker will also share the current thinking on biosimilars and what we need to consider to manage the risk of biosimilars being developed and marketed.

### Using NLP in Drug Safety - A Comparison of Coded EMR and NLP-Derived Acute Liver Disease in an IBD Population

**Xiaofeng ZHOU, PhD**
Senior Director Epidemology, Worldwide Safety & Regulatory, Pfizer Inc., USA

### Genotype guided personalized prescription to increase the drug safety

**Jae-Gook SHIN, MD, PhD, Prof.**
Department of Pharmacology and Clinical Pharmacology, Inje University College of Medicine and Inje University Busan Paik Hospital, Busan, South Korea

### Being Biosimilar Means Having Similar Systems to Manage Risk: but What Does That Mean?

**Brian EDWARDS, MD, PhD**
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd and Treasurer ISoP

# TUESDAY, 23 MAY | WEDNESDAY, 24 MAY THEME 8

## Session 0802 | MAY 23, 2017

Simultaneous Translation

10:30-12:00 | 5th Floor, 5D+E

### ESTABLISHED PRODUCTS/INJECTABLE PRODUCTS SAFETY MONITORING AND RISK MANAGEMENT

SESSION CO-CHAIRS

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

**Winnie WU**
Senior Manager, Drug Safety & Risk Management & Medical Information, Celgene

Pharmacovigilance adds value at each stage of the products' lifecycle. For products that have been marketed for many years, their safety profile should have been well established so that these medicines are safer. Is this true? How do we consider the safety surveillance and risk management help with the balance of risk and benefit to these products? This session will start with the thalidomide story where you see how a 'toxic' medicine gains new life with a good risk management system; Invited speaker from CFDA will share the experience on risk management in traditional patent Chinese medicine; An active surveillance in support of an injectable biologic product in EU will be discussed, to show the challenges as well as opportunities in managing mature products/injectable products.

#### Celgene's Risk Management for Thalidomide

**Ferdinando VEGNI, MD, MSc, PhD, DLSHTM**
Vice President, Global Drug Safety & Risk Management - International, Celgene

#### Risk Management in Traditional Patent Chinese Medicine

**Jingtian REN, PhD**
Division of Chinese Medicine Monitoring and Evaluation, Center for Drug Reevaluation, National Center for ADR Monitoring, CFDA

#### Active Surveillance in Support of An Injectable Biologic Product in EU

**Yun GU, PhD**
Director, Epidemiology, Worldwide Safety and Regulatory, Pfizer

## Session 0805 | MAY 24, 2017

Simultaneous Translation

08:30-10:00 | 5th Floor, 5D+E

### HOW TO IMPROVE SAFETY COMMUNICATION -- PERSPECTIVES FROM HEALTH AUTHORITY, HOSPITAL AND INDUSTRY

SESSION CO-CHAIRS

**Hellen ZHANG**
China PV Head, Bayer

**Qin LIN**
China PV Head/Director, MSD

The mission of pharmacovigilance is to ensure Patient Safety first. Effective safety communication among different stakeholders (health authority, hospital, pharmaceutical companies, and patients) has become increasingly important, along with the development of pharmacovigilance from reactive to proactive. This session will invite experts from Health Authority, Top Teaching Hospital and Industry to share the different perspectives and practical experience, and will have interactive discussion with the audience how to enhance the safety communications.

#### Perspective and Expectation from health authority

**Wei LIU**
Division of Operations, Center for Drug Reevaluation, National Center for ADR Monitoring, CFDA

#### Exploration and Effort from Hospital to Ensure the Patient Safety in Clinical Practice

**Liwei JI**
Department of Pharmacy, Beijing Hospital

#### Moving to Patient-Centric Pharmacovigilance - More Effective Safety Communication through Patient Engagement

**Yuhong WANG**
Global Safety Leader, Bayer

#### Optimal Use of Real-World Data to Inform Patient Safety

**Carol KORO, PhD, MS**
Executive Director, Pharmacoepidemiology, Merck Research Laboratories

## Session 0806 | MAY 24, 2017

Simultaneous Translation

10:30-12:00 | 5th Floor, 5D+E

### SAFETY IN ONCOLOGICAL TREATMENT

SESSION CO-CHAIRS

**Lawrance Mason SHIH**
Site Head, PD Safety Risk Management, Asia Pacific, Roche

**Weifeng ZHANG**
Safety Scientist, PD Safety Risk Management, Asia Pacific, Roche

In the field of new drug development, Oncology has become one of the most active research areas. Innovative oncologic drugs with novel mechanisms of action may require customized approaches to the management of specific risks that go along with these new molecular entities. At this session, the focus will be on the management of risks associated with oncologic drug development, sharing the most up-to-date understanding of novel oncologic drug risks and their management. The objective for the audience is to understand the safety risks and risk management strategies associated with novel oncologic drugs in order to maximize benefit/risk for the patients that receive these medications.

#### Prediction of Safety Profile of PI3K Isoform Inhibitors and Risk Management Strategies

**Jack HUANG, MD, PhD**
Senior Safety Science Leader, Early Clinical Development, Global Safety Risk Management, Genentech, USA

#### The Value of Pharmacoepidemiology in Risk Management and Risk Minimization of an Oncology Product: A Case Study

**Kui HUANG, MPH, PhD**
Senior Director, Epidemiology, Worldwide Safety and Regulatory, Pfizer USA

#### Challenges in the Assessment of Benefit-Risk for Oncology Medicines

**Stephen KNOWLES, MD, MBBS. MRCP. MRCGP.**
Senior Director, Global Patient Safety, Eli Lilly, USA


# The Strategy and Implementation of Early Clinical Development for Innovative Drugs

## Session 0901 | May 23, 2017

Simultaneous Translation

08:30-10:00 | 5th Floor, 5F

### STRATEGY OF CLINICAL DEVELOPMENT

SESSION CHAIR

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

Drug discovery and development has evolved in an accelerated fashion during the past 60 years from the serendipity of folk medicine and herbal remedies to present-day translational approach that relies on an understanding of disease and human biology at a molecular level. Advances in information, molecular and biomarker technologies, and quantitative pharmacology have further enabled this rapid evolution. Along with these important advances and changes, however, has come an unsustainable attrition rate that has increased the cost and failure rate of discovering and developing new drugs. Thus this session would discuss the development plan for innovative drugs, the strategy of accelerating drug development, product development strategy for successful market entry, as well as the application of biomarkers in drug development.

Strategy of Clinical Research and Develop for Novel New Drugs

**Li CHEN, PhD**
CEO of Hua Medicine

Optimizing Clinical Trials with Advanced Tools

**Dennis BASHAW, PharmD**
Director, Division of Clinical Pharmacology-3, Office of Clinical Pharmacology, Office of Translational Sciences, FDA/CDER

Phase I Antiviral Dose Escalation Study Design and Strategy

**Jinzi J WU, PhD**
CEO of Ascletis Pharmaceutical Zhejiang Co., Ltd.

## Session 0902 | May 23, 2017

10:30-12:00 | 5th Floor, 5F

### RISK MITIGATION IN EARLY DRUG DEVELOPMENT

SESSION CHAIR

**Min IRWIN, MD, PhD**
Venture Partner, Qiming Weichuang Venture Capital Management (Shanghai) Co., Ltd.

Given the tragedies occurred in several previous first-in-human studies, this session will discuss the strategy of risk mitigation in early drug development .

First Administration of Medicines to Humans. Risky Business, but How Risky? A Structured Approach

**Adam COHEN, PhD**
CEO of Centre for Human Drug Research (CHDR), Leiden, The Netherlands

Risk Benefit Analysis in Innovative Drug Development

**JuAn WANG, MD, MSc**
Research Scientist, Benefit-Risk Management, Global Patient Safety, Eli Lilly and Company, USA

Biomarker Design and Choosing

**Adam COHEN, PhD**
CEO of Centre for Human Drug Research (CHDR), Leiden, The Netherlands

## Session 0905 | May 24, 2017

Simultaneous Translation

08:30-10:00 | 5th Floor, 5F

### HOW TO IMPROVE DEVELOPMENT EFFICIENCY AND SAVE CLINICAL RESOURCE

SESSION CHAIR

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

This session will discuss the clinical development and trial design for breakthrough therapies, data mining from clinical study results, and the use of pharmacometric approach in drug development.

Clinical Trial Optimization: Making Each Patient Count

**Dennis BASHAW, PharmD**
Director, Division of Clinical Pharmacology-3, Office of Clinical Pharmacology, Office of Translational Sciences, FDA/CDER

Authority Considerations and Case Study for Novel Breakthrough Products

**Zhimin YANG**
Director, Office of Clinical Review I, Center for Drug Evaluation, CFDA

Translational Sciences and Adaptive Designs to Optimize Early Clinical Development

**John LAMBERT, PhD**
Vice President, CMO, PAREXEL

## Session 0906 | May 24, 2017

Simultaneous Translation

10:30-11:30 | 5th Floor, 5F

SESSION CHAIR

**Min IRWIN, MD, PhD**
Venture Partner, Qiming Weichuang Venture Capital Management (Shanghai) Co., Ltd.

The panel discussion will let the audience ask questions regarding the topics being addressed during the present theme. Panel participants who come from pharmaceutical industry, academic institutions, or health authorities will have mutual discussion with the audience and provide comments from their own perspectives.

*Panel Discussion*
All Above Speakers

Theme 10

# China-Anchored Drug Development and Entrepreneurship Forum

## Session 1001 | May 23, 2017

08:30-10:00 | 3rd Floor, 3E

### NEW DRUG DEVELOPMENT BY CHINA DOMESTICS R& D COMPANY

SESSION CHAIR

**Dalvin NI, PhD**
Vice President, Clinical Development, DDSU, WuXi ApeTec

This session mainly introduce the new drug development strategy, direction and the result of Chinese pharmaceutical companies in new drug development.

Exploration and Practice of Zhongsheng Pharma in the Course of Innovative R&D

**Xiaoxin CHEN, PhD**
Director, Innovative Drugs Division, Guangdong Zhongsheng Pharmaceutical Co., Ltd.

Exploration of New Drug R&D and Cooperation Model --Innovative Practice of Local Enterprises

**Zhengying ZHU, MD, PhD**
Chief Medical Officer, Luoxin Pharmaceutical

Yangtze River Pharmaceutical R&D Status and Prospects

**Jiong LAN, PhD**
General Manager, Shanghai Haiyan Pharma, Yangtze River Pharmaceutical Group

## Session 1002 | May 23, 2017

10:30-12:00 | 3rd Floor, 3E

### CHINESE R&D COMPANY GOING TO OVERSEAS

SESSION CHAIR

**Dalvin NI, PHD**
Vice President, Clinical Development, DDSU, WuXi ApeTec

This session focus on how Chinese pharmaceutical companies gradually start new drug development outside China, and their achievement.

The Internationalization of Luye Pharma

**Youxin LI, PhD**
President of Global R&D, R&D Center, Luye Pharma

Humanwell's Innovative Path

**Ronghua TU**
Deputy Director, Research Institute of Humanwell Pharmaceutical Co., Ltd.

Global Development of the Innovative Drugs: Strategies and Challenges

**Dajun YANG, PhD**
Chairman & CEO, Ascentage Pharma

## Session 1005 | May 24, 2017

08:30-10:00 | | 3rd Floor, 3E | English Only

### INTERNATIONAL POLICY OR PRACTICES FOR CHINESE COMPANY

SESSION CHAIR

**Florence HOUN, MD, MPH**
Vice President, Global Regulatory Science, Celgene
Member and Former Chair of FDA Alumni Association International Network (FDAAA)

US Food and Drug Administration (US FDA) is often viewed as the gold standard of regulation for new drug development and marketing applications. What are US FDA expectations of drug companies' programs and applications? Do these differ for foreign or US domestic companies? What are the common hurdles and misconceptions when interacting with the US FDA? This session will assist both industry and regulators by introducing the audience to an inside view of the US FDA from former key FDA officials.

General Principles when Dealing with the US FDA

**Florence HOUN, MD, MPH**
Vice President, Global Regulatory Science, Celgene
Member and Former Chair of FDA Alumni Association International Network (FDAAA)

What Do Companies Really Need to Know to Succeed at US FDA

**Mark J. GOLDBERGER, MD, MPH**
Independent Consultant, Mark Goldberger MD MPH LLC.
Member of FDA Alumni Association International Network (FDAAA)
Former Director, the Office of Antimicrobial Products, within the Office of New Drugs, FDA/CDER

US FDA CMC Quality Expectations

**Chi-wan CHEN, PhD**
Executive Director, Global CMC, Pfizer Inc.
FDA Alumni Association International Network Planning Committee Member
Former Deputy Director, Office of New Drug Qualtiy Assessment, FDA/CDER

## Session 1006 | May 24, 2017

10:30-12:00 | 3rd Floor, 3E

### LICENSING AND PARTNERSHIP IN R&D

SESSION CHAIR

**Jenny WU, MD, EMBA**
Vice President, Head of Product Development Service and Partnership, WuXi AppTec

In the new historical opportunity of clinical research and development of innovative drugs in China, in order to reduce the risk and improve the efficiency of R&D, the scientific and commercial values of R&D products are maximized by partnership, licensing and transaction between enterprises, enterprises and research institutes. In this section, we will discuss the process and the corresponding precautions in licensing in and licensing out, legal issues in the course of the transaction, and share the classic cases such as WuXi AppTec and AstraZeneca / Medimmune: how did they introduce the most innovative biological products into China, Jiangsu Hengrui pharmaceutical and the US Insight company to develop immuno oncology products simultaneously both in China and the United States, as well as the introduction of innovative oncolytic drug.

Basic Elements and Process of Licensing and Partnership Deals

**Jimmy Z. ZHANG, PhD, MBA**
Managing Director, Cross-border Investment, CL Investment Group

Regulatory, Legal and Compliance Issues in Product Licensing Transactions

**Chen YANG**
Partner and Head of China Life Science Practice, Sidley Austin LLP.

Product Partnership and Licensing from the Perspective of R&D -- Case Study

**Jenny WU, MD, EMBA**
Vice President, Head of Product Development Service and Partnership, WuXi AppTec

**Jessie ZOU, MD, PhD**
Vice President, Clinical Research and Development, Jiangsu Hengrui Medicine, Co., Ltd.

## Session 1007 | May 24, 2017

13:30-15:00 | 3rd Floor, 3E

### START-UP IN DRUG DEVELOPMENT

SESSION CHAIR

**Qiang LU, PhD**
Senior Vice President, Head of Operations, CStone Pharmaceuticals

Driven by the most recent scientific breakthroughs, abundant funding in the industry, availability of various discovery/development platforms, and most importantly, the huge unmet medical needs in China, especially for the China prevalent diseases, there has been a recent boom in newly found biotech companies in China, with emerging wave of entrepreneurs in charge. However, there is no mature "pathway" nor a complete mechanism covering the "3Bs" (i.e., from research Bench to clinical Bed to financial Book) for new drug discovery/development in China. In this session, we have invited 4 speakers with different past industry experience, forming their respective companies with various scope and business models. They will share their experience and prospective in playing in as well as contributing in such a dynamic "ecosystem" in China for new drug discovery and development.

China's Biotech Boom: Opportunities and Challenges

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

Biotech Startups in China: Challenges and Opportunities

**Lei JIANG, PhD**
Co-founder and CEO, Shanghai Ennova Biopharmaceuticals Co., Ltd.

How to Create A Eco-system for Supporting Drug Research and Development

**Ji LIU**
Vice General Manager, Shanghai Pharma Engine Co., Ltd. Manager, Business Promotion & Incubator Management Department, Shanghai Zhangjiang Biotech & Pharmaceutical Base Development Co., Ltd.


# Hot Topics & Late Breaker

## Session 1101 | May 23, 2017

08:30-10:00 | 3rd Floor, 3G

### BIG DATA AND ARTIFICIAL INTELLIGENCE IN CLINICAL RESEARCH AND PATIENT RECRUITMENT

SESSION CO-CHAIRS:

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

**Tong GUO, PhD**
Head of Biostatistics Africa/Asia, Quintiles IMS

This late-breaker session focuses on how to effectively implement big data analytics and data-driven methodologies in clinical research, by merging "big data" access, artificial intelligence and cognitive computing with the therapeutic expertise and clinical trial operational capabilities. The distinguished speakers will share with you the cutting-edge platform and the experiences that are successfully applying advanced analytics to accelerate clinical R&D, which include evaluating the power of data science in revolutionizing clinical trials, assessing the new era of translational medicine, discovering the potential of data analysis in the development of new trial designs, and utilizing digital networks and social media to identify site and recruit patients.

Big Data and Artificial Intelligence on Clinical Research

**Sebastien BOHN**
Offering Manager, IBM Watson Heath Clinical Development

AI Applications in Translational Medicine

**Guotong XIE**
STSM, Cognitive Healthcare, IBM Research - China

Big Data Analytics to Historical Cancer Research Data: Project Data Sphere Oncology Data-Sharing Experiment

**Speaker Invited**

Q&A

*Panel Discussion*
Above Speakers and

**Yiqing YIN, MD, PhD**
Director, Information Center, Zhongshan Hospital

**Yitian PENG, MBA**
Co-Founder, DRA100

## Session 1106 | May 24, 2017

10:30-12:00 | 3rd Floor, 3G

### LATE BREAKER: PANEL DISCUSSION ON NEW POLICY CHANGES OF IMPORTED PRODUCT REGISTRATION

SESSION CHAIR

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

CFDA recent publication on the regulatory handling of imported product (issued on March 17 2017) has drawn an immediate attention from the pharmaceutical industry. While it is targeted on the imported products, it would generate immediate impact on both international firms and domestic firms for their clinical and regulatory strategies. Already, senior executives from both international firms and domestic firms began to voice their optimistic and pessimistic views on this new policy. With such a profound impact to the industry, DIA has decided to open a special forum to discuss the implication of this new policy and how to re-design the drug development planning in this new era. DIA has formed a team of regulatory and drug development experts to have an open discussion on May 24th. This forum is open to general public and welcome the inputs and active participation from audience. Here is a short list of topics from this forum:

*Panelists*

**Xianping LU, PhD**
CEO & Chief Scientific Officer, Chipscreen Biosciences, Ltd.
Shenzhen, China

**Stephen LIN, MBA**
Partner, Lilly Asia Ventures

**Ying SHAO, PhD**
Vice President and Director of R&D Center, Shanghai Fosun Pharmaceutical

**Angela YAN**
Senior Director of Science and Regulatory, RDPAC

**Dan ZHANG, MD, PhD**
Board Director and Founder of Fountain Medical Development

Theme 12

# Rare Disease: Unsatisfied Market Demand

## Session 1207 | May 24, 2017

Simultaneous Translation

13:30-15:00 | 3rd Floor, 3G

### RARE DISEASE: UNSATISFIED MARKET DEMAND - PART I

SESSION CHAIR

**Jack XU**
Senior Vice President, Shanghai Clinical Research Center

Rare disease refers to those diseases with low morbidity, that are chronic, hereditary and often life-threatening. Rare disease is one of the greatest changes that human medicines face now. Currently there are 7000 known rare diseases, but our knowledge of them is far from complete. Low investment on research, low diagnosis rate, lack of effective therapy and few orphan drugs supported by the medical insurance system are universal phenomenon. Patients in most countries including China are confronted with the situation of no therapy, no drugs and no medical insurance.

Europe and America have explored an active and effective way for rare disease in the past 30 years. With the joint efforts of all stakeholders, there have been more than 500 orphan drugs on the market, while only no more than 30% of those have entered the Chinese market and the patients in China are now with urgent clinical requirements. In recent years, the rare disease relative fields developed rapidly in China such as effective improvement of public awareness and medical level, the active exploration for medical insurance and the strong voices from patient groups for rare diseases, even there is still considerable gap compared with developed countries. The task for settling the problem of rare disease is tough but has been made to develop in a positive and ordered way.

Chidamide: the First Orphan Drug Approved and Its Real World Clinic Study in China

**Xianping LU, PhD**
CEO & Chief Scientific Officer, Chipscreen Biosciences, Ltd.
Shenzhen, China

How Other Major Agencies Are Managing Expedited Review of Drugs Treating Rare Diseases.

**David TSUI**
Regulatory Affairs Regional Lead, Shire

Orphan Drug in China Today and Tomorrow

**Wenhua FENG, Professor**
Institute of Materia Medica
R&D Department, Chinese Academy of Medical Sciences & Peking Union Medical College

Patient Organization to Promote Rare Disease Research and Orphan Drug Innovation

**Kevin HUANG**
President, Chinese Organization for Rare Disorders (CORD)

## Session 1208 | May 24, 2017

Simultaneous Translation

15:30-17:00 | 3rd Floor, 3G

### RARE DISEASE: UNSATISFIED MARKET DEMAND - PART II

SESSION CHAIR

**Phoenix LIU**
Regulatory Country Lead-China, Shire

US FDA Review on Orphan Drugs

**Hae-Young AHN, PhD, RAC**
Deputy Director, Division of Clinical Pharmacology-3
Office of Clinical Pharmacology, U.S. FDA/CDER

Opportunities and Challenges for Orphan Drug R&D in China

**Hongyu LIU, PhD**
CEO and President, Beijing Prosit Sole Biotechnology

*Panel Discussion*

What is the reason for the completely different situation of orphan drugs industry between China and foreign countries?

Under current political background, what is the future development path of orphan drugs in China?

Theme 13

## White Paper Showcase

### Session 1301 | May 23, 2017

08:30-10:00 | 5th Floor, 5H

**SINYOO INFORMATION TECHNOLOGY WHITE PAPER SHOWCASE**

**NEW MODEL FOR REAL WORLD DATA**
SESSION CHAIR

**Yilong WU, MD, Professor**
Head of GLCI (Guangdong Lung Cancer Institute)
Chairman of CSCO (Chinese Society of Clinical Oncology)

Real world Study is becoming popular due to the restriction of RCT study in recent years, which Is yet limited by the high cost, long duration and uncontrollable data quality. Sinyoo co-established the tumor public database with pharma and PI via CSCO, in which data mining will be applicable on the basis of data classification. The database could greatly reduce the cost& duration of data procurement and provided a new way for the assessment of safety& efficacy of new drug.

The application, Opportunity and Challenge of Real World Data

**Ting WU**
Head of Real World Data/Biometrics, China Medical Affairs, Roche

New Model for Real World Study

**Xuexing WANG**
CEO, Sinyoo Information Technology (Shanghai) Co., Ltd.

### Session 1302 | May 23, 2017

10:30-12:00 | 5th Floor, 5H

**COVANCE WHITE PAPER SHOWCASE**

**OPTIMIZING CLINICAL TRIALS WITH PROTOCOL INNOVATION AND SPEEDY PATIENT RECRUITMENT**
SESSION CHAIR

**Honggang BI, PhD**
Corporate Vice President & General Manager, Covance Inc.

The rising cost of clinical trials and the increasing complexity or protocols and government regulations continues to challenge the development of new drugs. Drug Development in the 21st Century requires a deep understanding of the changing trends in our industry and the ability to leverage our past experiences using data to better predict future success. We will review these industry trends and regulatory changes and demonstrate how Covance is leveraging data for a better and more cost effective future result.

Updates of Major Trends in Global Pharmaceutical Industry and Drug Development

**Eric LANG, MD**
Vice President and Global Head of Clinical Development Strategists

Recent China Regulatory Changes and the Opportunities for Global and Domestic Pharma/Biotech Industries

**Richard JIANG, MBA**
Senior Director, Head of Regulatory Affairs China

Clinical Trial Protocol Innovation and Patient Recruitment

**Bill HANLON, PhD**
Chief Development Officer and Head of Global Regulatory Affairs

Showcase of Patient Recruitment in China to Support a Global Study

**Liedong XU, MSE, MBA**
Head of Clinical Development Services China

**Zheng ZHU, MD**
Director of Customer Relationship Management, CDS China

*Panel Discussion: Question & Answer*
All Speakers

### Session 1305 | May 24, 2017

08:30-10:00 | 5th Floor, 5H

**BEIJING JINGWEI CHUANQI MEDICINE WHITE PAPER SHOWCASE**

**CLINICAL TRIAL QUALITY&RISK MANAGEMENT**
SESSION CHAIR

**Kitty JIN**
Deputy General Manager, Head of QC&Training, 3AUDIT Ltd.

With increasing awareness of the importance of quality in clinical trials and recent newly published regulations by CFDA, quality and risk management have reached a new level in the industry.

As a result, the fast GCP progress has left a gap between theory (what the regulations demand) and reality (what is actually implemented). Many stakeholders in clinical trials (sponsors, CROs, and investigators) are struggling catching up with those demands.

This gap can only be closed through the help of thought leaders who have a comprehensive understanding of the requirements and who can give guidance in establishing the new regulations in the clinical trial environment.

Employing a 3rd party audit- and quality management company would provide clinical trial stakeholders with a leading edge towards the competition and help them to understand better and implement faster any of the new regulations.

The following questions beckon: How to best deploy a 3rd party auditing and quality management service to receive the maximum benefit? How are 3rd party services used outside of China? What are the expectations by the stakeholders for 3rd party services?

Our session with representatives from the regulator, industry, CRO and GCP experts will answer the above questions.

3rd Party Audits in Clinical Trials - Their Added Value
-- A Report from Other Regions, i.e. Europe, US, Latin America & Australia

**Peter SCHIEMANN, PhD**
Managing Partner, Widler & Schiemann Ltd.

*Panel Discussion:*
Current Status of 3rd Party Audit Industry in China, and the Expectation from Regulatory Authority, Sponsor, CRO, and Hospital

**Xuliu CAI**
Founder & CEO, Beijing Jingwei Chuanqi Medicine Services Co., Ltd.

**Xiaoping YE**
Chairman of the board, Hangzhou Tigermed Consulting Co., Ltd.

**Qingyu XIU**
CFDI Inspection Specialist
Vice Chairman of Drug Clinical Trial Professional Committee of CPS
Chief of Respiration Department Affiliated Changzheng Hospital; The Second Military Medical University of PLA

**Heidi LIU**
Quality Assurance Lead, China, Pfizer (China) Research and Developmet Co., Ltd.
Chairperson, China QA Forum

**Ying SHAO, PhD**
Vice President and Director of R&D Center, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

**Yongqing ZHUO**
RDPAC Senior Advisor, Expert of Board 3rd Party Audits Expert Committee, Expert of Board, Chinese Pharmaceutical Enterprises Association

**Xiaona FAN**
Former Beijing FDA GMP Expert, Expert of Board 3rd Party Audits Expert Committee

The Introduction of "Total Process Control®" in Clinical Trial Quality Management

**Jialin SUN**
Deputy General Manager, Head of QC&Training, 3AUDIT Ltd.

## Session 1306 | May 24, 2017

10:30-12:00 | 5th Floor, 5H

**MOBILEMD SYSTEM WHITE PAPER SHOWCASE**

**UNCOVER THE NEW PERSPECTIVE OF CLINICAL TRIAL MANAGEMENT WITH INNOVATIVE CLINICAL TRIAL PLATFORM**

Are you looking for an effective approach to understand the process of clinical trial, ensure the quality and prevent the risk of clinical trial? The innovate clinical trial informationization platform, which covers every phases of clinical trial with complete product lines and solutions will bring you the answers.

Business Intelligence under Clinical Trial Informationization——Understand the whole picture of Clinical Research and make accurate commercial decision
- Apply informationization technology approach to ensure the quality of clinical research and risk control
- Apply informationIzation management approach to optimize human resource management and personnel training capability

**Gary MA**
Vice President, Clinical Research Business Department, Taimei Medical Technology

Launch of eCollege, an Online Training System by Taimei Medical Technology

**Lu ZHAO**
CEO, Tiamei Medical Technology

Apply CDISC Standard in EDC to Enhance Data Standardization

**Yuhuang SHI**
Director, Data Management, Taimei Medical Technology

Launch of Medical Image Review System by Taimei Medical Technology.

**Wenchun WU**
Deputy Director, Clinical Research Business Department, Taimei Medical Technology

## Session 1307 | May 24, 2017

13:30-15:00 | 5th Floor, 5H

**DXC WHITE PAPER SHOWCASE**

**ECTD DOSSIER PUBLISHING & CDISC COMPLIANCE**
SESSION CHAIR

**Winnie YANG**
eCTD Consultant, DXC Technology

Part 1
As the expert of eCTD, we will help you to understand the concept of eCTD, dossier publishing process, submitting channel, various solutions (DIY with professional software or Outsourcing), and related strategy preparation.

Part 2
Introduction to CDISC and some specific requirements on standard format and submission package. Preparation from data collection to SDTM, ADaM, TLF, and final package.

Get Ready for eSubmission – eCTD Dossier Publishing

**Winnie YANG**
eCTD Consultant, DXC Technology

**Cherry YAO**
Senior Trainer,Life Science, DXC Technology

The Path from Raw Data to Submission – CDISC Compliance

**Han ZOU**
Global Head of Biometrics Practice, DXC Technology

## Innovation Hub 10 Minutes Presentation

### May 23rd, 2017 | 10:00-10:10 | 1st Floor, Century Hall

**PAREXEL INTERNATIONAL CORPORATION**
SPEAKER

**Mr. Kieran CONNOLLY**
Senior Director, APAC Operations, PAREXEL Informatics

Improving site and patient centricity with clinical supply innovations

- Challenges in clinical trial supply chain design and management
- Technologies to streamline medication management to reduce burden on sites and enhance patient safety
- Innovation in clinical supply management- Active Tracking

### May 23rd, 2017 | 10:10-10:20 | 1st Floor, Century Hall

**BEIJING JINGWEI CHUANQI MEDICINE SERVICES CO., LTD.**
SPEAKER

**Kitty JIN**
Deputy General Manager, Head of QC&Training, 3AUDIT Ltd.

Value added by 3rd party audits in clinical trial ecosystem, create confidence to new drug R&D

With increasing awareness of the importance of quality in clinical trials and recent newly published regulations by CFDA, quality and risk management have reached a new level in the industry.

As a result, the fast GCP progress has left a gap between theory (what the regulations demand) and reality (what is actually implemented). Many stakeholders in clinical trials (sponsors, CROs, and investigators) are struggling catching up with those demands.

Employing a 3rd party audit- and quality management company would provide clinical trial stakeholders with a leading edge towards the competition and help them to understand better and implement faster any of the new regulations. This presentation will introduce how 3rd party audits to advocate the value in clinical trial ecosystem, and how to create confidence to new drug R&D for all the stakeholders.

### May 23rd, 2017 | 10:20-10:30 | 1st Floor, Century Hall

**GUANGZHOU HEALGOO INTERACTIVE MEDICAL TECHNOLOGY CO., LTD.**
SPEAKER

**Chengyan LV**
Marketing Director

Magic "box": Intelligent System Helps Clinical Data Collection

Data collection plays important role in clinical trials. Accurate, prompt and normalized data collection can significantly improve the quality of clinical trials and shorten the research cycle. Healgoo Box is an intelligent data acquisition and analysis system. It can collect the examination data in the equipment automatically in real-time, and fill in the Electronic Clinical Research Form in the same time, which will highly improve the work efficiency and data accuracy. Healgoo Box's principle and application in clinical trial will be detailed introduced in the talk.

### May 23rd, 2017 | 17:15-17:25 | 1st Floor, Century Hall

**CHINESE ORGANIZATION FOR RARE DISORDERS**
SPEAKER

**Kevin Rufang HUANG**
President of Chinese Organization for Rare Disorders, China

How far away is the rare disease?

### May 23rd, 2017 | 17:25-17:35 | 1st Floor, Century Hall

**SHANGHAI I-HYGEIA INFORMATION TECHNOLOGY CO. LTD.**
SPEAKER

**Zen WANG**
CEO

Big data and scientific research : Highly efficient application of intelligent patient follow up.

There are always some problems of clinical trial patient follow-up in the process of implementation. For example, patient recruitment and follow up work are time-consuming, and patients are easy to lose. Mobile healthcare tools and clinical application of big data, will bring clear benefits to scientific research projects and build up new research methods.

Shanghai I-hygeia company developed patient follow up platform "Askdr", which is helpful for clinical trial patient follow-up. For example, the benefits are reduction of manpower cost, improvement of data integrity and authenticity, and effective application of retrospective data analysis...etc. We will further introduce with the real cases.

### May 23rd, 2017 | 17:35-17:45 | 1st floor, Century Hall

**SHANGHAI ZHANGJIANG BIOTECH&PHARMACEUTICAL BASE DEVELOPMENT CO.,LTD.**

**Ji LIU**

Vice General Manager, Shanghai Pharma Engine Co., Ltd.
Manager, Business Promotion & Incubator Management Department, Shanghai Zhangjiang Biotech & Pharmaceutical Base Development Co., Ltd.

Zhangjiang Pharma Valley-China's Own Boston

## TUESDAY, 23 MAY | WEDNESDAY, 24 MAY — INNOVATION HUB

### May 24th, 2017 | 10:00-10:10 | 1st Floor, Century Hall

**UNIMED SCIENTIFIC CORPORATION**
SPEAKER

**Andy ZHAI**
Deputy General Manager.

Clinical data capture, processing and analysis techniques for the big data era
Introduction of Clinical data capture, processing and analysis technology in the mobile Internet and big data era , focusing on the function and characteristics of the big data technology developed by UNIMEDSCI, combined with the explanation of the application on clinical research area.

### May 24th, 2017 | 10:10-10:20 | 1st Floor, Century Hall

**DMED BIOPHARMACEUTICAL CO., LTD.**
SPEAKER

**Zibao ZHANG**
Senior Director, Biostatistics & Programming

New Mission for CRO in the Clinical Development Ecosystem (Alternative: How CRO leverage the expertise to commit to the new mission in clinical development)
With the evolving clinical development ecosystem and more stringent regulatory environment, there are new requirements to biopharmaceutical companies in clinical development process. From service offering to collaboration model provided by CRO, the goal is to increase the probability of product success and reduce risks. In the new era, CRO has the new mission to leverage expertise and experience, to be able to support client development strategy, provide study design, conduct Risk Based Monitoring, apply global data standards, and provide high efficiency and professional biometrics service. It is also important to establish innovative service model with the agility and strong sense of ownership to meet the new requirements. With such new mission, CRO can play unique role and provide differentiated service to better serve the clients.

### May 24th, 2017 | 10:20-10:30 | 1st Floor, Century Hall

**BGI**
SPEAKER

**Jiong ZHANG**
Director of Pharma Department, BGI Genomics Co. LTD. Mr. Zhang has finished his Master of Microbiology in Sun Yat-sen University, and MBA in The Chinese University of Hong Kong. He has been working at BGI for seven years, during this period he committed to applied research in research and development for drugs by using high throughput sequencing, as well as, using high throughput sequencing in molecular biomarkers found, pharmacogenomics studies, screening and screening patients by clinical trials and other relevant area to collaborate with global pharmaceutical industry. His current working field is take charge of multidimensional high quality precision medical special project, to build digital innovation platform in drug research and development under the big sample data.)

Innovation on drugs R&D in real world study, RWS
The weakness of new drug Research & Development are high cost, long period, and high risk, traditional pharmaceutical industry takes around 0.5-1 billion dollars, at least 10-15 years to developed a new drug. BGI as a leader company of high throughput sequencing utilize digital technology to established government, hospital and pharmaceutical industry collaboration precision medical chain. Not only can change patients' data collecting method in medical healthcare area, but also change clinical trials data collecting way. In order to using real world evidence to improve precision medical research and development, along with to accelerate pharmaceutical industry research process.

### May 24th, 2017 | 15:00-15:10 | 1st Floor, Century Hall

**QIAGEN (SUZHOU) TRANSLATIONAL MEDICINE CO., LTD**
SPEAKER

**Wei ZHANG, PhD**
Director of Business Development

QIAGEN's Growing Immuno-Oncology Testing Portfolio
Currently, Immunotherapy(PD-1, PD-L1, CTLA4 antibodies etc)is the most attractive and potential anti-cancer therapy, however, predictive biomarkers of immunotherapy outcome (IO) are still under investigation. The well-known PD-L1 protein expression testing by IHC is not well associated with the drug efficacy, also the assay cut-off is intriguing. The tumor mutation burden (TMB) is recently shown to differentiate the patients well during the retrospective analysis of BMS CHECKMATE-026 Trial, thus emerging as a potential new biomarker of IO. Besides, other biomarkers such as microsatellite instability (MSI), mismatch–repair deficiency (MMR) and cancer immune response profiling (CIRP) are under rapid development. We, QIAGEN(Suzhou) Translational Medicine Co.Ltd, will introduce recent advance in above field and our solutions of IO biomarker.

# DIA中国区顾问委员会 (2015–2017)　ADVISORY COUNCIL OF CHINA (ACC)

## Overview

中国区顾问委员会(ACC)由企业、学术界、医疗机构和政府部门的专家组成。委员会为DIA中国区开展学术交流活动、建立战略伙伴、发展会员等提供战略指导和支持 。

The Advisory Council of China (ACC) consists of regional industry and academic leaders, regulators and researchers who are responsible for creating a sense of community among those who support the DIA vision to provide a global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.

## Chair

**王劲松 医学博士**
和铂医药首席执行官

**Jingsong WANG, MD, PhD**
CEO, Harbour BioMed

## Vice Chair

**吕玉真**
罗氏(中国)投资有限公司亚太区
法规部门负责人

**Janet LU**
Head of Regulatory, Asia Pacific,
Roche (China), Ltd.

## Members

中国区顾问委员会成员
Members of Advisory Council of China

| | |
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| 赵大尧 | Dayao ZHAO |
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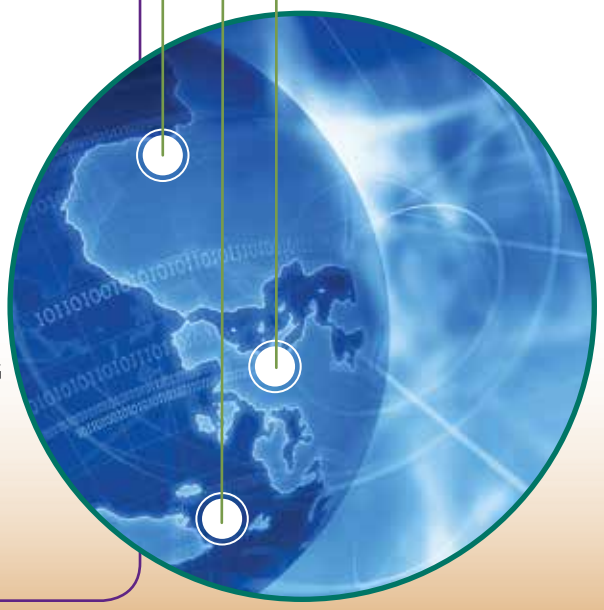
| 朱煦 | Sunny ZHU |
| 朱向阳 | Xiangyang ZHU |

Making Connections
建立联系

Fostering Relationships
增进了解

Advancing Innovation
推进创新



10th Years Anniversary

DIA

# 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

2018年5月22-25日 | 北京国际会议中心

May 22-25, 2018

Beijing International Convention Center

# DIA CHINA 2017 PROGRAMS


## July

### Ethics Issues and the Governance of Innovative Clinical Research
July 7-8 | Nanjing

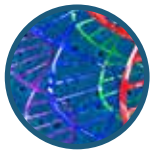
### Safety Management Plan Workshop
July 10-11 | Beijing Xinjiang Plaza

## August

### DIA China Medical Devices Clinical Trial Workshop
August 3-4 | Beijing Vision Hotel

### 2017 Quantitative Science Forum
August 21-22 | Beijing Xinjiang Plaza

## September



### MedDRA Coding and Adverse Event Reporting
September 7-8 | Shanghai

### 2017 DIA GCP Inspection and Data Integrity Workshop
Beijing / Shanghai

### 3rd DIA China Drug Discovery Innovation Conference
September 26-28
Four Points by Sheraton Suzhou

## October

### Vaccine Development and GCP Inspection Workshop
Beijing

## November

### 2017 DIA China Clinical Project Management Workshop 101
November 20-22 | Beijing

### 2017 DIA China Medical Affairs Workshop
Shanghai

## December

### 2017 Vendor Selection, Qualification and Management Workshop
Shanghai

DIA CHINA Wechat Subscription

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