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2017 Quantitative Science Forum

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2017

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Biostatistics Unit, Peking University First Hospital, China

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Senior Director, Biostatistics, CStone Pharmaceuticals Co., Ltd.

张玥
临智（上海）数据科技有限责任
公司总裁

Carrie ZHANG
CEO, eClinWise Co., Ltd.

张子豹 博士
生物统计与编程部高级总监
缔脉生物医药科技(上海)
有限公司

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Senior Director, Biostatistics and Programming, dMed Biopharmaceutical Co., Ltd.

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MSD R&D China

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

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

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August 21, 2017 | MONDAY			
08:30 – 10:00	Maqam Grand Ballroom A	**Opening & Plenary: Data Science in Regulatory Decision Making I**	
10:00 – 10:30	Tea Break		
10:30 – 12:00	Maqam Grand Ballroom A	**Opening & Plenary: Data Science in Regulatory Decision Making II**	
12:00 – 13:30	Lunch, Bazaar Fresh - Café, 1st Floor		
13:30 – 15:00	Maqam Grand Ballroom A	Parallel Session 1	Challenges and Solutions to Innovative Biotech Companies in China - from Regulatory, Study Design and Implementation Perspective
	Maqam Grand Ballroom B	Parallel Session 2	Pharmacometrics in Drug Development
	Function Room I	Parallel Session 3	Clinical Trials in New Data Management Regulations
15:00 – 15:30	Tea Break		
15:30 – 17:00	Maqam Grand Ballroom A	Parallel Session 4	The Design of Multi-Regional Clinical Trial: Case Examples
	Maqam Grand Ballroom B	Parallel Session 5	Early Phase Clinical Trials and Innovative Designs
	Function Room I	Parallel Session 6	Bayesian Statistics in Clinical Trials

August 22, 2017 | TUESDAY			
08:30 – 10:00	Maqam Grand Ballroom A	Parallel Session 7	Updates of CDISC Standard and Data Submission Requirements from USFDA, PMDA and CFDA
	Maqam Grand Ballroom B	Parallel Session 8	Novel Statistical Methods in Oncology Drug Development: Design, Development and Challenges
	Function Room I	Parallel Session 9	Safety Data Analysis Method
10:00 – 10:30	Tea Break		
10:30 – 12:00	Maqam Grand Ballroom A	Parallel Session 10	Recent Methodology in Oncology Drug Development
	Maqam Grand Ballroom B	Parallel Session 11	Risk Based Monitoring (RBM) and Site Inspection Readiness
	Function Room I	Parallel Session 12	Opportunity, Practice and Challenge of Real World Research in China
12:00 – 13:30	Lunch, Bazaar Fresh - Café, 1st Floor		
13:30 – 15:00	Maqam Grand Ballroom A	Parallel Session 13	Development and Evaluation in Biosimilar Products
	Maqam Grand Ballroom B	Parallel Session 14	Artificial Intelligence and Deep Learning in Clinical Research
	Function Room I	Parallel Session 15	Clinical Research Design and Evaluation for Medical Devices
15:00 – 15:30	Tea Break		
15:30 – 17:00	Maqam Grand Ballroom A	**Close & Plenary Session** **Statistical Considerations in MNC-Local Joint Drug Development and Opportunities and Challenges in China Innovative Drug Development**	

Opening & Plenary
Data Science in Regulatory Decision Making

Simultaneous Translation

August 21 | 08:30-12:00

Maqam Grand Ballroom A, 3rd Floor

Opening Address
Carol ZHU, MBA
Managing Director, DIA Greater China

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

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

Opening Remarks
Center for Drug Evaluation, CFDA

Keynote Speech Facilitator
William WANG, PhD
Executive Director, Clinical Safety Risk Management Statistics Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories

Keynote Speeches

Quantitative Science Initiatives in CDER, US FDA
Stephen WILSON, PhD
Former Director, Division of Biostatistics III, CDER, US FDA

Roles of Quantitative Sciences In Drug Development and Regulatory Review -- A perspective from Japan PMDA
Yuki ANDO, PhD
Senior Scientist for Biostatistics, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Quantitative Science Initiatives in CDE, CFDA
Head of Statistics and Clinical Pharmacology Department, CDE, CFDA

Opening Panel Discussion
Above Speakers and
Ning LI, MD, PhD
Vice President, Regulatory and Medical Policy - Asia, Sanofi-Aventis in sanofi Asia and China

Yaning WANG, PhD
Senior Expert in Pharmacometrics

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

Parallel Session 1
CHALLENGES AND SOLUTIONS TO INNOVATIVE BIOTECH COMPANIES IN CHINA - FROM REGULATORY, STUDY DESIGN AND IMPLEMENTATION PERSPECTIVE

August 21 | 13:30 – 15:00

Maqam Grand Ballroom A, 3rd Floor

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

Zibao ZHANG, PhD
Senior Director, Biostatistics and Programming, dMed Biopharmaceutical Co., Ltd

In last few years, China has made enormous efforts in reforming the regulatory policy and improving the regulatory environment in order to promote innovation, keep abreast with the present state of standard and streamline the regulatory application processes. These positive changes ignite the booming of the innovative biotech companies. And the traditional generic drug focused companies also take the opportunities to invest new drug development. Meanwhile, challenges come with the opportunities, for example, lack of talents with innovative drug development experience and knowledge will impact the drug development strategy, the quality of protocol development and clinical trial execution, etc. The speakers of this session will share the challenges and experience from the regulatory, different types of biotech companies and CRO's perspectives. We hope the audience can benefit from the experience sharing, discussion and find the appropriate solutions.

Challenges to Innovative Biotech Companies in China – Observations and Considerations from CDE, CFDA
Jun WANG, PhD
Deputy Director, Statistics and Clinical Pharmacology Department, CDE, CFDA

Innovate Partnership Model to Enable Collaborative Clinical Data Solutions
Roger ZHAO, PhD
Associate Director, Data Science, Hua Medicine

Drug-Development Challenges to Chinese Innovative Biotech Companies –From CRO's Perspective
Jack LI
Director of Biostatistics and Programming
dMed Biopharmaceutical Co., Ltd

Jonathan MA, PhD
Chief Data Scientist, Scientific Consulting, dMed Biopharmaceutical Co., Ltd

Panel Discussion
Above speakers and

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

Zhaohui WEI, PhD
Senior Director of Biometrics, Innovent Biologics

Anny-Yue YIN, PhD
Senior Director, Biostatistics, CStone Pharmaceuticals

Parallel Session 2
PHARMACOMETRICS IN DRUG DEVELOPMENT

August 21 | 13:30 – 15:00

Maqam Grand Ballroom B, 3rd Floor

Session Co-chairs

Qingshan ZHENG, PhD
Professor and Director, Center for Drug Clinical Research, Shanghai University of Traditional Chinese Medicine
President, Professional Committee of Pharmacometrics, Chinese Pharmacological Society

Jianing DI, PhD
Director and Head, Statistics & Decision Sciences, Janssen (China) R&D Center, Johnson & Johnson

Pharmacometrics is an emerging multi-disciplinary subject that quantifies drug, disease, and trial information to aid efficient drug development, therapeutic and regulatory decisions, and rational drug treatment in patients. This highly quantitative field consists of experts with backgrounds from clinical pharmacology, statistics, mathematics, engineering, etc, and focuses primarily on analysis of interactions between drugs and patients using advanced technics including modeling and simulation based on pharmacology, physiology, and disease. Over the years it has demonstrated the strength in integrating knowledge across the development program, compounds, and biology, accelerating drug development process, managing the risk, reducing the cost, and as a result been recognized by both pharmaceutical researchers and regulatory authorities.

This session aims to provide an overview of the most popular topics in pharmacometrics including dose finding, modeling & simulation, exposure-response, precision medicine, and model-based meta-analysis (MBMA). Overall framework will be introduced with case studies.

Population PK Modeling & Simulation Replacing Real Trial: Therapy and Practice
Qingshan ZHENG, PhD
Professor and Director, Center for Drug Clinical Research, Shanghai University of Traditional Chinese Medicine
President, Professional Committee of Pharmacometrics, Chinese Pharmacological Society

Exposure-Response Modeling and Precision Medicine
Peimin MA, PhD
Senior Director, China Head of Clinical Pharmacology, GSK

Model based Meta-Analysis Comparing Treated Chinese/Asian and Western Patients with Pain due to Knee Osteoarthritis-Enhanced Trial Design of China Methodology Study
Guangli MA, PhD
Associate Director, Pharmacometrics, Pfizer (China) Research & Development Co., Ltd.

Modeling-based Decision Making: A Case Sharing of Dose Selection of a Monoclonal Antibody in Oncology
Jia JI, PhD
Senior Manager, Clinical Pharmacology, Janssen (China) R&D Center, Johnson & Johnson

Parallel Session 3
CLINICAL TRIALS IN NEW DATA MANAGEMENT REGULATIONS

August 21 | 13:30 – 15:00 | Function Room I, 3rd Floor

Session Chair

Carrie ZHANG
CEO, eClinWise Co., Ltd.

Starting from the self-inspection request in year 2015, CFDA released multiple regulations regarding clinical data quality, electronic data capture platform and end to end management of entire clinical trial data. New regulations brought the requirement for clinical data management in China to the same level as international standard if not above. With the announcement that China joined ICH, reliable and high quality data management capability is keys to China pharmaceutical industry's success in international drug development. This session will focus on current situation in China clinical data management, and approach how to meet the goal for success.

Global NDA Submission: Challenges and Strategies in China Clinical Data Management
Carrie ZHANG
CEO, eClinWise Co., Ltd

New CFDA Regulations and Clinical Data Management Report
Anita SHEN
Director and Head, Clinical Data Management, Janssen (China) R&D Center, Johnson & Johnson

Apply Statistical Concept in Clinical Data Management
Hualong SUN, PhD
General Manager, Meta Clinical Technology Co. Ltd

Parallel Session 4
THE DESIGN OF MULTI-REGIONAL CLINICAL TRIAL: CASE EXAMPLES

August 21 | 15:30 – 17:00
Maqam Grand Ballroom A, 3rd Floor

Session Chair
Zhiwei JIANG, PhD
Senior Statistician, MSD (R&D) China Ltd.

In the recent years, multi—regional clinical trial (MRCT) has been applied in China increasingly to accelerate registration and marketing. Some new MRCT designs are used in real trials, and the issues in the analyses of MRCT are also concerned. This session is to present the case examples of MRCT in practical, and brings some discussions.

Sample Size Considerations for Event Driven Trial When China Join MRCT
Wenfeng CHEN, PhD
Principal Biostatistician, Merck Serono R&D Beijing Hub

Fay GAO
Principal Biostatistician, Merck Serono R&D Beijing Hub

Jerry WANG, PhD
Head of GBEM, Merck Serono R&D Beijing Hub

Extension Designs in Oncology Trials with Combination Therapy
Xiongwen TANG, PhD
Statistical Scientist, PD Biometrics,
Roche (China) Holdings, Ltd.

Statistical Consideration in MRCT Extension for China Registration
Jingzhao WANG
Principal Statistician, Statistics & Decision Sciences, Janssen (China) R&D Center, Johnson & Johnson

Panel Discussion
All above speakers and
Panelist from Statistics and Clinical Pharmacology Department, CDE, CFDA Invited

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

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

William WANG, PhD
Executive Director, Clinical Safety Risk Management Statistics Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories

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

Parallel Session 5
EARLY PHASE CLINICAL TRIALS AND INNOVATIVE DESIGNS

August 21 | 15:30 – 17:00
Maqam Grand Ballroom B, 3rd Floor

Session Chair
Anny-Yue YIN, PhD
Senior Director, Biostatistics, CStone Pharmaceuticals

With the improved landscape for drug development in China, increased number of early phase clinical trials are being conducted. Early phase trials poses unique challenges, but also offers opportunities for innovative designs. In this session, we will discuss new designs such as umbrella trial and platform trial, as well as innovative designs that enables precision medicine.

Implementation of Bayesian Method in Dose-finding Trial Design
Jack LI
Director, Biostatistics & Programming, dMed Biopharmaceutical Co., Ltd

Bayesian Hierarchical Model for Dose Escalation
Yongjian SUN
Senior Principal Statistician, Translational Clinical Oncology, Novartis

Randomized Platform Basket Trial Design for Early Phase Oncology Development
Lilian BU
Statistical Scientist, Roche (China) Holding Ltd.

Parallel Session 6
BAYESIAN STATISTICS IN CLINICAL TRIALS

August 21 | 15:30 – 17:00 | Function Room I, 3rd Floor

Session Chair
Haige SHEN, PhD
Vice President, Statistical Science, Panacea Technology Co., Ltd.

The request of high-speed, effective drug development has significantly increased the complexity of clinical trials in the early phase. The complex clinical development strategies calls for innovation of statistical methods to balance statistical, clinical and operational considerations. How to integrate the existing information and adapt the statistical methods to the development strategy changes is challenging. Bayesian approaches have been applied in this setting and show advantages supporting more effective and efficient decision makings. In this session we will have a couple of examples that demonstrate the applications of Bayesian methods in clinical trial design.

Robust Exchangeability Design for Early Phase Clinical Trials, A Case Study
Xiaolei XUN, PHD
Statistical Methodologist, Novartis Pharmaceuticals (China)

Leveraging Historical Control for Single Arm Study Decision Making
Juan LIU, PhD
Statistical Scientist, Roche (China) Holding Ltd.

Prediction of Probability of Study Success and R Visual Analytics with Shiny Tool
Baoyue LI, PhD
Senior Manager Statistician, Lilly Suzhou Pharmaceutical Co. (Shanghai)

Parallel Session 7
UPDATES OF CDISC STANDARD AND DATA SUBMISSION REQUIREMENTS FROM USFDA, PMDA AND CFDA

August 22 | 08:30 – 10:00
Maqam Grand Ballroom A, 3rd Floor

Session Co-chairs
Zibao ZHANG, PhD
Senior Director, Biostatistics and Programming
dMed Biopharmaceutical Co., Ltd

Victor WU, PhD
Vice President, Beijing Data Science Express Consulting Co., Ltd.

Clinical Data Standards, mainly CDISC Standards, has been matured after 20 years development and enhancement. It is now mandatory or recommended as required by multiple regulatory agencies. In this session, global regulatory guidance and updates on CDISC Standard and Submission Data Requirements will be shared including the US FDA, Japan PMDA and China CFDA followed by panel discussion focused on data standards and its positive impacts on innovation and regulatory science in China.

US FDA Data Submission Regulatory Requirements and Updates
Stephen WILSON, PhD
Former Director, Division of Biostatistics III, CDER, US FDA

Japan PMDA Data Submission Regulatory Requirements and Updates
Yuki ANDO, PhD
Senior Reviewer, PMDA, Japan

China CFDA Data Submission Regulatory Requirements and Updates
Head of Statistics and Clinical Pharmacology Department, CDE, CFDA

Yazhong DENG
General Manager, Beijing Trust Medicine Consulting Ltd.

Panel Discussion
Above Speakers

Parallel Session 8
NOVEL STATISTICAL METHODS IN ONCOLOGY DRUG DEVELOPMENT: DESIGN, DEVELOPMENT AND CHALLENGES

August 22 | 08:30 – 10:00
Maqam Grand Ballroom B, 3rd Floor

Session Chair
Ruixue WANG, PhD
Associate Principal Scientist, Biostatistics, MSD China R&D

With the rapid development of oncology area, especially immunotherapy, statistical assumption, methods and implementation are required to be improved synchronously. In this session, we will discuss new model such as cure rate model, as well as IRC audit methods and sub-group studies.

Design Considerations in Clinical Trials with Cure Rate Survival Data: a Case Study
Fubo (Bruce) XUE, PhD
Director, Statistics & Decision Sciences, Janssen (China) R&D Center, Johnson & Johnson

IRC Audit Methods for PFS
Fan WU
Statistical Scientist, Roche

A Simulation-based Approach in Sub-group Design of Multi-regional Oncology Trials
Panpan WANG, PhD
Senior Clinical Statistician, Pfizer China R&D

Multiplicity in Immuno-oncology Trials
Haiyan WU, PhD
Principal Scientist, Biostatistics, MSD China R&D

Parallel Session 9
SAFETY DATA ANALYSIS METHOD

August 22 | 08:30 – 10:00 | Function Room I, 3rd Floor

Session Chair
Ying ZHANG, PhD
Principal Scientist II, BARDS- AP, MSD China

Safety evaluation and monitoring is key essential part in drug development. Numerous regulatory guidance and industry standard practices call for systematic and timely review and evaluation of safety data during the entire product life cycle. Dedicated statistics expertise is required more and more often in recent years to help identify potential safety issues earlier and to help gain full lifecycle safety knowledge and insight. In this session, we are delighted to have renowned speakers from both industry and regulatory agency to share with us on statistical methodologies applied on safety data from different perspectives.

Likelihood Ratio Test on Safety Data Monitoring (Remote Presentation)
Yong MA, PhD
Mathematical Statistician, Office of Biostatistics, CDER, FDA

Scan Statistics in Public Health and Safety Areas
Lei YAN, PhD
Associate Principal Scientist, CORE Pharmacoepidemiology-AP, MSD (R&D) China

Cautionary Tales Regarding Collection of Safety Data
Jonathan HARTZEL, PhD
Executive Director, BARDS LDS, Merck & Co Inc.

Parallel Session 10
RECENT METHODOLOGY IN ONCOLOGY DRUG DEVELOPMENT

August 22 | 10:30 – 12:00

Maqam Grand Ballroom A, 3rd Floor

Session Chair

Nicole F. LI, PhD
Director and AP Site Head of Biostatistics, Roche (China) Holding Ltd.

Oncology drug development is increasingly challenging with rapid competition, and hence warrants innovative methodology in design and analysis. In this session, gating decision framework in an early phase study, a semiparametric approach for recurrent events in non-proportional hazard model, and the extension strategy in global trial will be discussed.

Two Analytical Frameworks of Treatment Selection and Efficacy Gating in an Early-Phase Oncology Study
Fan XIA, PhD
Statistical Scientist, Roche (China) Holding Ltd.

Semiparametric Estimation of Time-Varying Treatment Effect Using Recurrent Event Data
Jiajun XU, PhD
Statistician, Statistics & Decision Sciences, Janssen (China) R&D Center, Johnson & Johnson

Practical Consideration of Extension Strategy in Global Trials
Ruixue WANG, PhD
Associate Principal Scientist, Biostatistics, MSD China R&D

A Method to Simulate Rank Correlated Time-to-Event Variables and Its Application in Basket Trial
Jerry WU, PhD
Biostatistics Senior Manager, Amgen Biopharmaceutical R&D (Shanghai) Co., Ltd

Parallel Session 11
RISK BASED MONITORING (RBM) AND SITE INSPECTION READINESS

August 22 | 10:30 – 12:00

Maqam Grand Ballroom B, 3rd Floor

Session Co-chairs

Yazhong DENG
General Manager, Beijing Trust Medicine Consulting Ltd.

Zibao ZHANG, PhD
Senior Director, Biostatistics and Programming
dMed Biopharmaceutical Co., Ltd

Carrie ZHANG
CEO, eClinWise Co., Ltd.

In this session, global regulatory guidance about RBM and Data Inspection will be reviewed and updated, including RBM or centralized monitoring final guidance/guidelines released by US FDA and EU EMA in 2013. Then the recent updates from China on data quality, site inspection and RBM in 2015 and 2016 will be presented, and RBM implementation methodology and case studies in China will be shared followed by Panel discussion.

RBM Practice Sharing -- From Risk To Monitoring
Weixing TAO
Senior Manager, Central Monitoring
Pfizer (China) Research and Development Co., Ltd.

The Role and Practice of Centralized Statistical Reviews in Clinical Trials to Enhance Data Integrity
Roger ZHAO, PhD
Associate Director, Data Science, Hua Medicine

Effective Preparation and Support for CFDA Self-Inspections and Onsite Inspections
Peng WAN
Manager, Statistical Programming, MSD R&D (China) Co., Ltd.

Panel Discussion
Above Speakers and
CFDA CFDI Panelist (Invited)

CFDI GCP Inspector (Invited)

Bob YAN, PhD
Head of Biostatistics and Programming, Sanofi China

Parallel Session 12
OPPORTUNITY, PRACTICE AND CHALLENGE OF REAL WORLD RESEARCH IN CHINA

August 22 | 10:30 – 12:00 | Function Room I, 3rd Floor

Session Co-chairs

Lian LIU, PhD
Associate Director, Statistics, GSK R&D China

Ting WU, MD, PhD
Manager, Biometrics and Real World Evidence, Shanghai Roche Pharmaceuticals Ltd.

While clinical trials remain the golden standard for evaluating efficacy and safety of medical product for registration, the need of real-world research and real-world evidence is continuously increasing with the rapid development of internet and electronic device. More and more data has been accumulated in real-world setting to make it possible to evaluate the effectiveness and safety of medical products, answer specific health economic questions and make informed decision with high quality. This session will offer a platform to discuss the opportunity, practice and challenge of real world research in China.

Real World Studies and Post-Market Drug Development: Practice, Challenges, and Strategies
Xin SUN, PhD, Professor
Director, Chinese Evidence-based Medicine Center, Sichuan University, West China Hospital
President, ISPOR West China Chapter

Exploratory Propensity Score Analysis in Non-randomized Clinical Trial Study
Yun LU, PhD
Associate Director Biostatistics, PPD

The Value of Real World Study in Post-Marketing Drug Development: Example Sharing
Na GUO, PhD
Principal Epidemiologist, GSK R&D China

Bingming YI, PhD
Cystic Fibrosis Statistics Leader, Vertex Pharmaceuticals

Big Data and Small Study
Yi WEN, MD, PhD
Medical Director, Medbanks Network Technology Co., Ltd.

Parallel Session 13
DEVELOPMENT AND EVALUATION IN BIOSIMILAR PRODUCTS

August 22 | 13:30 – 15:00 | Maqam Grand Ballroom A

Session Co-chairs

Jeannie QIU
Senior Biostatistician, Bayer Health Company

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

Biological products have been widely used in the treatment of various therapeutic areas. With the gradual expiration of patent and data protection, biosimilar products development has become a hot topic in the world. FDA, EMA and CFDA have issued corresponding guidelines, but many technical details of clinical research and regulatory review are still need be further explored. This session has invited experts with extensive experiences in this field to share and discuss their considerations and practices in the development and evaluation of biosimilar products in and out of China.

Considerations in Biosimilar Clinical Trials
CFDA CDE Speaker Invited

Equivalence and Non-Inferiority Tests
Jielai XIA, Prof.
Director, Department of Medical Statistics, the 4th Military Medical University

Statistical Considerations in Biosimilar Clinical Trials
Jia HE, Prof.
Director, Biostatistics Department, the Second Military Medical University

Panel Discussion
Above Speakers and
CFDA CDE Panelist Invited

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

Zhaohui WEI, PhD
Senior Director of Biometrics, Innovent Biologics

Parallel Session 14
ARTIFICIAL INTELLIGENCE AND DEEP LEARNING IN CLINICAL RESEARCH

August 22 | 13:30 – 15:00 | Maqam Grand Ballroom B, 3rd Floor

Session Co-chairs

Tong GUO, PhD
Vice President, Head of Sales, Greater China, Quintiles IMS

Ying ZHAO, PhD
Director, Statistical Services, Applied Statistics Methodology Quintiles IMS

This 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 Analytics to Historical Cancer Research Data: Project Data Sphere Oncology Data-Sharing Experiment
Chen YAO, Prof.
Vice Director, Peking University Clinical Research Institute
Professor and Head of Department of Biostatistics
Peking University First Hospital

The Challenges of Big Data and Artificial Intelligence in Clinical Research
Yiqing YIN, MD, PhD
General Manager, Shanghai Zhongshan Medical Technology
Director, Information Center, Shanghai Zhongshan Hospital

Data Operation Ecosystem in Clinical Development
Zhenglong TIAN
Director, Statistical Programming, APAC, PAREXEL International

Machine Learning in Big Data Application of Medical Research & Real World Data Analysis
Yan XUE
Senior Manager, Advanced Analytics, QuintilesIMS

Panel Discussion
Above Speakers and
Yang XIE, PhD
Principal, HEOR/RWE, QuintilesIMS

Shan HE, PhD
Chief Business Officer, LinkDoc

Parallel Session 15
CLINICAL RESEARCH DESIGN AND EVALUATION FOR MEDICAL DEVICES

August 22 | 13:30 – 15:00 | Function Room I, 3rd Floor

Session Chair

Wei LI, Prof.
Director, Medical Research & Biometrics Center, National Center for Cardiovascular Diseases

Because of its characteristics, mechanism, life cycle and performance, medical devices have a huge difference from the drugs. Therefore, national and international regulatory administration have very different requirements for the design and evaluation of the medical device clinical trials from drug clinical trials, especially for clinical trials of innovative medical devices. Due to lack of routine products as controls, it is hard for designing and evaluation. It is concerned how to conduct clinical trials of medical device per the latest version of the "Specification for Quality Management for Clinical Trials of Medical Devices" and "Regulations on the Supervision and Administration of Medical Devices" issued by the State Food and Drug Administration (CFDA), which is a new challenge faced by enterprises under the new situation. This session is to provide a comprehensive explanation for the designing and evaluation of medical device clinical trials from the angle of biostatistics.

Statistical Consideration for Clinical Trials of Innovational Medical Devices
Wei LI, Prof.
Director, Medical Research & Biometrics Center, National Center for Cardiovascular Diseases

Application of Bayes Approach in Clinical Trials of Innovational Medical Devices
Yang WANG, Associate Professor
Senior Director of Statistics, Medical Research & Biometrics Center, National Center for Cardiovascular Diseases

Statistical Consideration for Clinical Trial Design and Evaluation of Innovational Diagnostic Medical Devices
Songbai WANG, PhD
Senior Director of Statistics, Johnson & Johnson, USA

Common Statistical Mistakes for Clinical Evaluation Of Medical Devices
Lu YIN, PhD
Director for Medical Affairs, Medical Research & Biometrics Center, National Center for Cardiovascular Diseases

Plenary and Closing Session
STATISTICAL CONSIDERATIONS IN MNC-LOCAL JOINT DRUG DEVELOPMENT AND OPPORTUNITIES AND CHALLENGES IN CHINA INNOVATIVE DRUG DEVELOPMENT

August 22 | 15:30 – 17:00

Maqam Grand Ballroom A, 3rd Floor

Closing Session Co-organizers

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

Zhaohui WEI, PhD
Senior Director of Biometrics, Innovent Biologics

Jack PENG, PhD
Senior Director of Biometrics, Hutchison MediPharma

Tao WANG, PhD
Director and Head of Biostatistics and Programming, Jiangsu Hengrui Medicine

Closing Session Co-chairs

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

Tao WANG, PhD
Director and Head of Biostatistics and Programming, Jiangsu Hengrui Medicine

In recent years, China has been in a fast-track lane for innovative drug development in both MNCs and local companies. One option to accelerate the innovative drug development in China is to build a partnership model between two parties. In this session, we will share some experiences on joint drug development using such a model from statistical perspectives. In addition, unique opportunities and challenges will be discussed for local innovative drug development. Statistical leaders and experts from academia, pharmaceutical industry and regulatory agency will also share their experiences, insights and visions on these topics.

Statistical Issues and Roles of Statisticians in MNC-Local Joint Drug Development.

Xin WANG, PhD
Associate Director of Statistics, Eli Lilly and Company China

Opportunities and Challenges in China Innovative Drug Development--Statistician's Perspective

Jack PENG, PhD
Senior Director of Biometrics, Hutchison MediPharma

Panel Discussion
Panelist from Statistics and Clinical Pharmacology Department, CDE, CFDA Invited

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

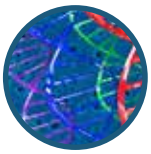
Ning LI, MD, PhD
Vice President, Regulatory and Medical Policy - Asia, Sanofi-Aventis in sanofi Asia and China

William WANG, PhD
Executive Director, Clinical Safety Risk Management Statistics, Biostatistics and Research Decision Sciences, (BARDS), Merck Research Laboratories

Jianjun ZOU, MD, PhD
Vice President & CMO, Jiangsu Hengrui Medicine, Co., Ltd.

DIA CHINA 2017 PROGRAMS

September



MedDRA Coding and Adverse Event Reporting
September 1-2
Shanghai Qilu Courtyard Hotel

3rd DIA China Drug Discovery Innovation Conference

September 26-28
Four Points by Sheraton Suzhou

November

Vaccine Development and GCP Inspection Workshop
Beijing

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December

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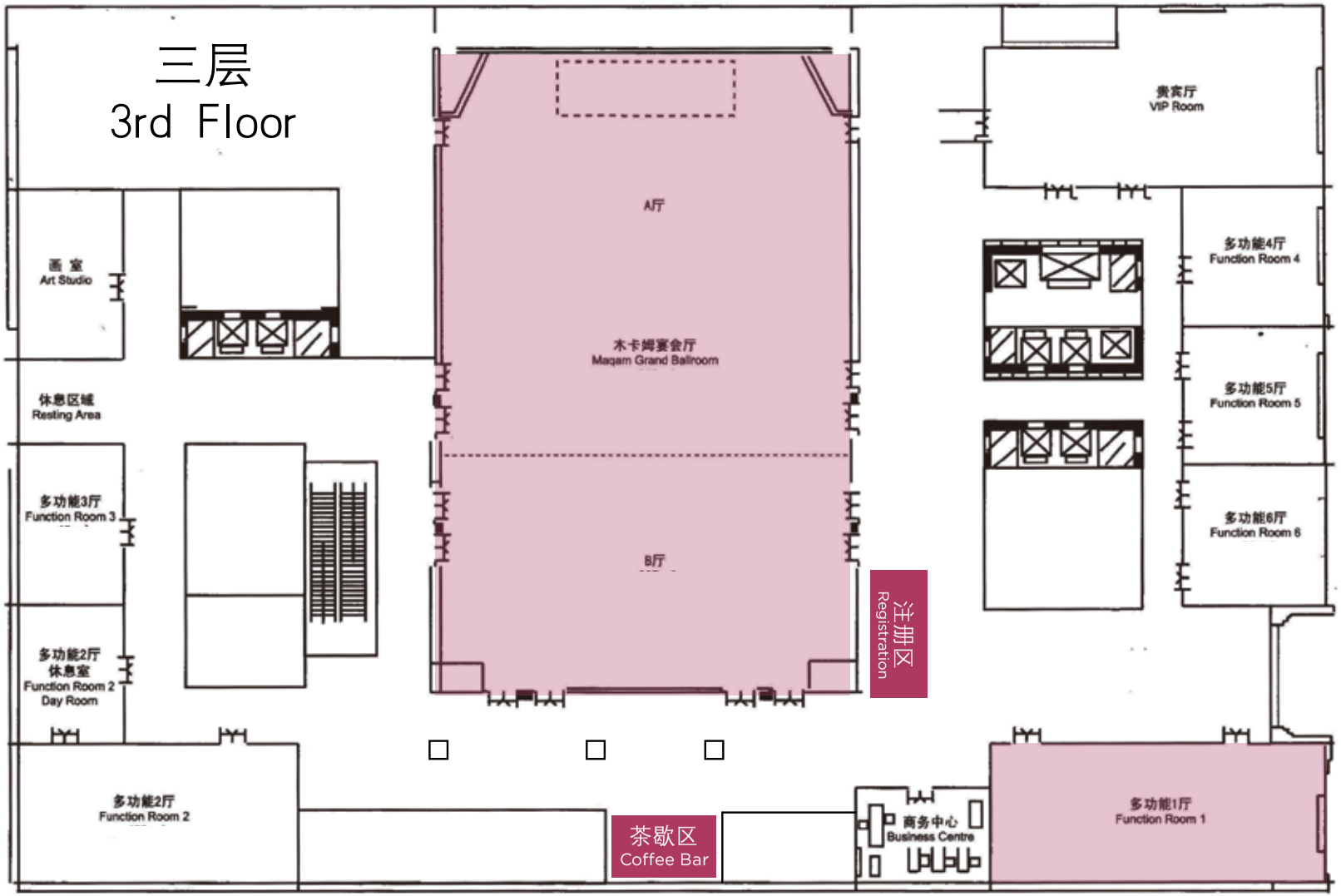

北京|新疆大厦
Beijing Xinjiang Plaza

新疆大厦

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Note: It is suggested that you bring the printed hotel address in Chinese, together with the hotel phone number for reference purpose.

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Contact: Tony Guo
Mobile: +86-13811039073

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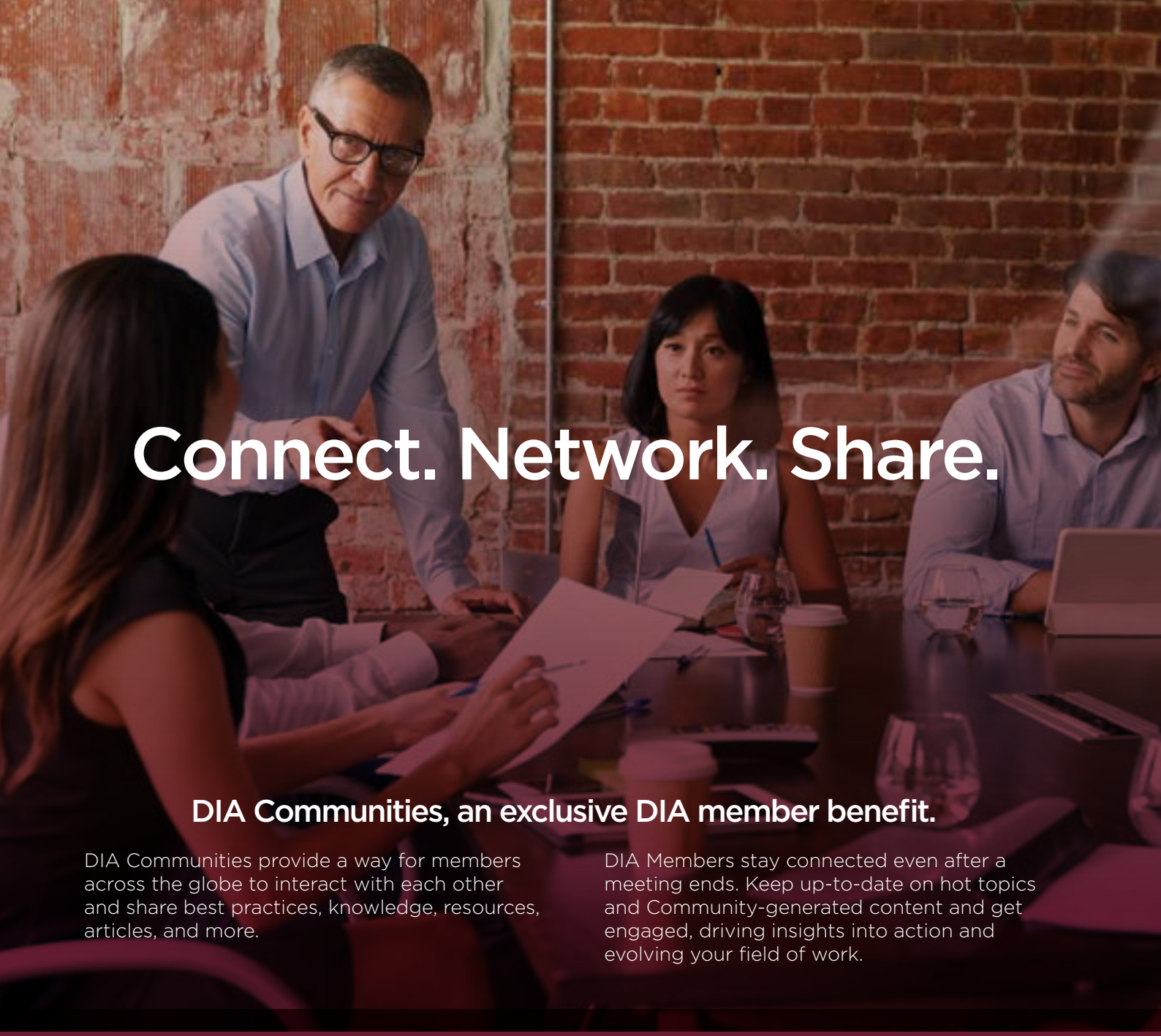

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Honorary Professor, Tokyo Institute of Technology
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- 医药早期研发科学家，研究所和大学的教授，学者
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王劲松 医学博士
和铂医药首席执行官

中国新药研发在资本的助力下如火如荼。如何将基础研究与解决患者实际需求结合起来，将基础研究的成果“转化”到临床实践，用于疾病预防、诊断、治疗及预后评估，转化为临床实际应用的理论、技术、方法和药物，在实验室到病房（Bench To Bedside）之间架起一条快速通道，这是最近几年转化医学研究的方向。转化医学越来越受到世界的关注，已经成为世界医学研究的一个新的起步点和着力点，转化医学的研究成果正成为新药研发的引擎。

今天的中国医药产业已经发生了非常重大的转折。单纯追求生产规模、漠视临床需求、通过非规范手段人为制造需求，不重视询证医学证据、缺乏科学理论支持的药物开发模式已经穷途末路。药政科学管理无论在以满足国人临床需求上、更细致的技术规范与指南上， 还是公开透明，以科学为指引，数据为基础的评审原则上，支持创新、支持真实、支持完整、支持科学已经迈出了巨大而坚定的步伐。这无疑将过去劣币驱良币的行业潜规则颠覆回来，使得我们创新开发者有了政策的保障。在全球生物医学日新月异进展带来的对疾病发病机理的深入理解的同时，如何让最新的创新科学研究成果转化为治病救人的利器，并通过我们的努力使这些创新研究结果服务于世界，是中国医药行业未来的发展之路。而在实现这个未来发展之路时，如何更科学地进行创新药物的早期研究、评价和确定？如何将早期研发结果能够成功地转化为可批准上市的药品？如何将早期研发的成果以合适的商业模式进行实施？

DIA作为一个全球性、公益性的学术组织，在推动科学研究者、临床医生、创新药物开发者及药政科学管理者的相互交流、共同促进行业健康发展以能更好地满足患者的临床需求方面，作出了杰出的贡献。正是这种基于科学、客观、透明、平等的交流氛围使得业内很多的专家学者积极自愿参与到DIA创新大会的组织工作并希望通过大家的努力能带给参会者一定的收获。

即将于2017年9月26-28日在苏州举办的DIA中国第三届药物研究创新大会将在延续前两届大会优良传统的基础上，结合中国药物研发现状，围绕转化医学过程中大家最关心的早期研究创新、人才教育体系规划、重点疾病领域进展、早期临床研究设计、创新审评、MAH实施以及本土创新如何联盟等热点问题进行深入探讨。

会议联系人: **林云**
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