Program Overview

China and Asia over the decades has been playing an increasingly important role in the context of clinical research activities due to the significant scientific investment by multinational companies as well as rapidly booming China domestic R&D programs. In past few years, the China regulatory agency has also issued several regulations and initiatives to accelerate the review and approval and improve the quality of new drugs and medical devices. With the joining of ICH in 2017, the government is continuing to improve the regulatory standards and systems to promote innovation, enhance the R&D ecosystem. However, the drug development is fraught with all kinds of challenges which needs innovation, efficiency and collaboration. In return, the Clinical Development and Innovation Forum will gather leaders and scientists across pharma, biotech and academia for discussions and cases studies on the major topics including: Robust Clinical and Regulatory Strategy, Clinical Biomarkers and CDx, Immuno-Oncology and Cell & Gene Therapies, Rare Disease, Data Sciences and Digital Innovation, AI and Machine Learning, China Domestic R&D Innovation, Clinical Operation and Patient Strategies etc, towards the Efficient and GCP-compliant Drug Development in the era of Precision Medicine.

2021 Conference Programs

• Clinical and Regulatory Strategy, Next Generation Clinical Trials
• Clinical Development for Biologics and Cell and Gene Therapies
• Orphan Drug Development and Patient Strategies
• Clinical Biomarkers and Companion Diagnostics
• Early Clinical Development and Precision Oncology Trials
• China-initiated New Drug Development: Opportunities and Challenges
• Clinical Data Management and eClinical Technologies
• Biostatistics and Innovative Clinical Design
• Clinical Safety and Pharmacovigilance
• Clinical Operation, Quality Management and Virtual Trials
• Clinical Outsourcing and Vendor Management
• Big Data Analytics, AI and Machine Learning in Clinical Trials

Who Would Attend

Approx. 450 senior R&D, Clinical, Medical and Regulatory executives and scientists are expected to attend the Clinical Development and Innovation Forum 2021. The participants will mainly come from the pharma/biotech, academia, investigational sites, regulatory agencies, CROs, technology and service providers with the main responsibilities including, but not limited to:

• Corporate Executives and Head of R&D
• Clinical and Regulatory Strategy
• Medical Sciences and Affairs
• Biomarkers, Companion Diagnostics and Translational Medicine
• Clinical Innovation and Strategy
• Clinical Data Sciences and Biostatistics
• Clinical Safety and Pharmacovigilance
• Clinical Operation and Quality Management
• Clinical Procurement and Sourcing
• Principal Investigators

2021 Speakers Committee

Hongjun Yang
Founder and Co-Director, The Committee of Precision Medicine, Chinese Society of Biotechnology

Xingli Wang
Vice President, Novartis Global Drug Development (China)

Yukun Wang
Head of Translational Medicine Oncology China, SBU Oncology China Site Head, Bayer Healthcare

Shuhong Liu
Head of Clinical Study Unit Greater China Sanofi

Victor Chen
Vice President, Head of Early Development Harbour BioMed

Rong Chen
Chief Medical Officer Citrine (Shanghai)

Ye Hua
Founder and CEO BioNova Pharmaceuticals

Gary Tong
Co-Founder and CMO NeuroFront Therapeutics

Junyuan Wang
Co-Founder and CEO AnHeart Therapeutics

Victoria Elegant
Vice President, Regional Medical Head, JAPAC, Amgen
Wednesday, Mar. 10, 2021

Clinical and Regulatory Strategy, Next Generation Clinical Trials

0730 Registration and Morning Coffee

0825 Chairperson Opening Remarks

0830 China and Asia’s Evolving Role in the Global Drug Development - an Industry Perspective
Xingli Wang
Vice President, Novartis Global Drug Development (China)

0900 From Precise Detection of SARS-CoV-2 to Cancer Precision Medicine (via remote presentation)
COVID-19 pandemic was a threat and challenge to human being and dramatically changed our lives. One of the key measures for prevention and control of the pandemic is the precise detection of the virus. This talk will cover all testing methods and analyze their pros and cons. Despite COVID-19 pandemic, the precision medicine for cancer treatment is still a big challenge in saving people’s lives. Two major breakthroughs of Tumor Mutant Burden (TMB) as a practical biomarker in I-O therapy and ctDNA for NGS applications will be addressed.
Hongjun Yang
Founder and Co-Director, The Committee of Precision Medicine, Chinese Society of Biotechnology

0930 Innovative Clinical Study Design: a Case Study of Phase 3 bridging study in China before Completion of the Global Phase 3 study
Qian Shi
General Manager and Head of Science, Apollomics Inc.

1015 Anticipating Changes in Clinical Trial Design and Execution Post Pandemic (via remote presentation)
Ken Getz
Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine

1040 Panel Discussion: Strategies for Asian Drug Development: An Integrated Approach
Moderator:
Gary Tong
Co-Founder and CMO, NeoFront Therapeutics
Panellists:
Victoria Elegant
Vice President, Regional Medical Head, JAPAC, Amgen
Yukun Wang
Head of Translational Medicine Oncology China, SBU Oncology China Site Head, Bayer Healthcare
Haiyi Guo
Vice President, Head of Clinical Development, Hematology (China), Beigene
Jeffrey Liu
Chief Scientific Officer and President of Huadong Global Development
Gloria Gong
China Development Unit Head, Novartis

1100 Coffee/Tea Break and Networking

1120 Panel Discussion: China-initiated Global Drug Development: Lessons Learned and Future Prospects
• Current Barriers and Opportunities for the Novel R&D programs from the China domestic companies
• Key points to consider for a successful development program
• Current obstacles for the trans-border Asian and Global studies initiated by the China domestic pharmaceutical company
• Navigating through the Regulatory Risks
• Optimal Partnership model to increase productivity and efficiency of clinical programs
Moderator:
Bin Peng
Chief Medical Officer, EpimAb Biotherapeutics
Panellists:
Junyuan Wang
Co-Founder and CEO, AnHeart Therapeutics
Kai Wu
Co-CEO, Shanghai SIMR Bio
PJ Chen
Senior Vice President, APRINOIA Therapeutics
Yan Wu
Senior Vice President, Head of Clinical Development and Medical Department, Ark Biosciences
Chih-Yi Hsieh
Chief Medical Officer, Impact Therapeutics
Xiaoning Guo
Vice President, Head of R&D and Chief Medical Officer, SciClone Pharmaceuticals

1205 Panel Discussion: Best Practice for Communication between Sponsors and Health Authorities
Panelists:
Irene Deng
Head of Regulatory Affairs, Sanofi (China)
A Speaker invited from Fresenius Kabi (China)

1230 Panel Discussion: Modernize Drug Development: Where are we now and where we are going?
Clinical development has evolved significantly due to the increased patient pools and complexity, new technologies available and new approaches to optimize and plan the clinical trials. In this session, we will discuss some of the important shifts, trends, regulations that affect on the clinical development in 2021 and beyond:
• Scientific Advancements
• Study Design and Study Conduct
• Technology and Data
• Policy and Regulatory Oversight
• The Impact of COVID19 on Trials Design and Conduct
Moderator:
Marion Martin
Head of Strategy and Technology Innovation, Pfizer R&D (China)
Panelists:
Gary Tong
Co-Founder and CMO, NeoFront Therapeutics
Xingli Wang
Vice President, Novartis Global Drug Development (China)
Xiang Guo
Vice President and Global Head of Statistics and Data Science, BeiGene
Juan Huang
Director for Development China Safety and Innovation Lead, Pfizer R&D (China)
Gloria Gong
China Development Unit Head, Novartis

1310 Networking Lunch
1400  Physiologically-Based Pharmacokinetics (PBPK) Modeling and Simulation in Drug Development
Yanyan Zhang
Associate Director, Translational Medicine and Early Development, PKDM Asia Pacific R&D, Sanofi (China)

1425  Accelerating Medicines to Patients worldwide through Model-Informed Drug Discovery and Development (via remote presentation)
Thomas Kerbusch
Chief Growth Officer Certara, Executive Director, Certara Shanghai

1450  Panel Discussion: Can China and Asia Lead the way for Early Drug Development?
- Is China and Asia ready to play a leading role in the early stage clinical trials
- Current landscape of early phase trials in Asia and the future prospect
- Gaps, country-specific challenges for early trials
- How Asian sites, academics shall work together for early clinical trials
- The impact to involve Asia into global early development on the late phase trials and registration
- Other key considerations
Moderator:
PJ Chen
Senior Vice President
APRINOIA Therapeutics
Panelists:
Yukun Wang
Head of Translational Medicine Oncology China, SBU Oncology China Site Head, Bayer Healthcare
Derek Xu
Senior Medical Director, Head of Clinical Scientist, Roche Innovation Center Shanghai
Helen Jiang
Senior Vice President, Chief Medical Officer, Qingfeng Medicine
Aik Han Goh
Vice President, Chief Medical Officer, Reistone Biopharma
Yongjiang Hei
Chief Executive Officer
Gloria Bioscience

1530  Coffee/Tea Break and Networking
### Wednesday, Mar.10, 2021

**Orphan Drug Development | Stream B**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1345</td>
<td>Challenges and Strategies for Orphan Drug Development in China</td>
<td>Rong Chen</td>
<td>Chief Medical Officer, Citrine (Shanghai)</td>
</tr>
<tr>
<td>1415</td>
<td>Current Status and Recent Advance of Gene Therapy in Rare Disease</td>
<td>Minnie Ke</td>
<td>Vice President, Clinical Development and Medical Affairs, CANbridge Pharma</td>
</tr>
<tr>
<td>1440</td>
<td>Q&amp;A and Panel Discussion: Strategies for ensuring Patient Access and the Role of Gene Therapy for Rare Diseases</td>
<td>Rong Chen</td>
<td>Chief Medical Officer, Citrine (Shanghai)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minnie Ke</td>
<td>Vice President, Clinical Development and Medical Affairs, CANbridge Pharma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Weiyi Zheng</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yong Xue</td>
<td>Senior Vice President</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sperogenix Therapeutics</td>
</tr>
</tbody>
</table>

**Development of Cell and Gene Therapies | Stream B**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1500</td>
<td>CAR-T Cell Therapy Development: Current Status and Future Prospectus (via remote presentation)</td>
<td>Cindy Ru</td>
<td>Managing Director</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CRC Oncology Corp</td>
<td></td>
</tr>
<tr>
<td>1525</td>
<td>The Clinical Progress of CAR-T Cell Therapy in China and International Outlook</td>
<td>Wen Wang</td>
<td>Chief Medical Officer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IASO Biotherapeutics</td>
<td></td>
</tr>
<tr>
<td>1555</td>
<td>Session Topic to be added</td>
<td>Qikuan Huang</td>
<td>General Manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acurant Biotech</td>
<td></td>
</tr>
<tr>
<td>1615</td>
<td>Biomarker and Translational Strategy for CAR-T Cell Therapy Development</td>
<td>Kathryn Liu</td>
<td>Director, Translational Sciences</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fosun Kite Biotechnology</td>
<td></td>
</tr>
<tr>
<td>1645</td>
<td>Strategies for building an innovative pipeline of Cellular Immunotherapy</td>
<td>Jinhua Lu</td>
<td>Co-Founder and Chief Scientific Officer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TriArm Therapeutics</td>
<td></td>
</tr>
</tbody>
</table>

**Immuno-Oncology Therapeutics Development | Stream B**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1715</td>
<td>Challenges and Opportunities for Immuno-Oncology Therapeutic Development</td>
<td>Steve Chin</td>
<td>Chief Medical Officer, Elpiscience Biopharma</td>
</tr>
<tr>
<td>1745</td>
<td>Panel Discussion: Challenges and Considerations in Designing and Conducting Immuno-Oncology Clinical Research</td>
<td>Archie Tse</td>
<td>CSO, SVP, Head of Research and Early Clinical Development, CStone Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Xiugao Yang</td>
<td>Medical Director, Clinical Development Division, CSPC Pharma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Haiyi Guo</td>
<td>Vice President, Head of Clinical Development, Hematology (China), Beigene</td>
</tr>
<tr>
<td>1830</td>
<td>Conference Day One Closure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Increasingly, biomarkers play a critical role in the pharmaceutical development and have shown to improve the drug approval success rates substantially. Also the Drug Development in many diseases is now moving towards the molecular-targeted treatment that often rely on the Biomarkers for their application. With the major breakthroughs towards precision medicine, the analytical and clinical validation of biomarkers and their subsequent registration as IVD and companion Diagnostics has received more attention recently and will likely to continue to rapidly increase in number and application to various disease areas. In this session, we will provide a discussion around the rapidly increase in number and application to various disease areas. In this session, we will provide a discussion around the Biomarker Research, the need for Integration of Biomarker and Companion Diagnostics.

**Thursday, Mar. 11, 2021**

**Biomarkers, Companion Diagnostics and Translational Medicine | Special Focus**

- **0815 Chairperson Opening Remarks**
  Ye Hua
  Chairman and CEO, BioNova Pharmaceuticals

- **0820 The Evolving Biomarker and Companion Diagnostic Landscape: Key Factors that Impact the Delivery of Precision Medicine**
  Yizhong Ren
  Medical Director, AnHeart Therapeutics

- **0850 Translational Medicine Accelerates Innovative Drug Development**
  Victor Chen
  Vice President, Head of Early Development, Harbour Biomed

- **0920 Biomarker Discovery using Single Cell Technology**
  He Zhou
  Executive Director, Asia Pacific External Innovations HiFiBio

- **0950 Single Cell and Spatial Multi-omics Technology for Basic and Translational Oncology Research**
  Linlin Zhao
  Regional Marketing Manager, China 10x Genomics

- **1015 Session Reserved by Genetron Health**

- **1040 Session Topic to be added**
  Ruixin Zhu
  Vice President, GloriousMed

- **1105 Coffee/Tea Break and Networking**

- **1120 The Progress of Artificial Intelligence in Biomarker Research of Cancer**
  Yunxin Chen
  Director of Clinical Biomarker, Translation Medical Oncology, Bayer

- **1150 Multi-omics translation platform for research and development of new drugs for tumor Immunotherapies**
  Ernest Su
  Senior Vice President of Yucebio and General Manager of YTNeoAG

- **1215 Clinical Biomarkers empower the First-in-Class Immune Oncology Phase I/II Trials and for Successful Publication**
  Bin Ye
  Vice President, Clinical Biomarker and Precision Medicine, Shengone Pharma Group

- **1245 Networking Lunch**

- **1330 Strategic planning and implementation of Biomarkers/CDx in Oncology/Immuno-Oncology Clinical Trials**
  Linda Li
  Director, Translational Medicine Dept. Merck Serono Beijing R&D Centre

- **1400 Drug-diagnostic co-development for the first-in-class KRAS G12C inhibitor**
  Hong Yin
  China Head of Clinical Biomarkers and Diagnostics, Amgen Biopharmaceutical R&D

- **1430 Streamlining co-development of Drug-Dx in the Clinic**
  Fugen Li
  Senior Vice President, Translational Medicine, HaiHe Pharmaceuticals

- **1500 Key roles of Biomarker Research in Pre- and Clinical Development**
  Hong Ling
  Senior Vice President and CSO, Leads Biolabs

- **1525 Clinical Biomarkers and Companion Diagnostics in Immuno-oncology (Tentative)**
  Archie Tse
  CSO, SVP Head of Research and Early Clinical Development, CStone Pharmaceuticals

- **1555 Session Available**

- **1615 Clinical Biomarker Research Provides Novel Insights to Drug Discovery and Development**
  Yiling Yu
  Director, Clinical Biomarker, Beigene

- **1640 Delivering Next-Generation Precision Medicine for a larger group of Cancer Patients by leveraging proprietary RNA biomarker platform**
  Simon Zhang
  General Manager, China OncXerna Therapeutics

- **1700 Panel Discussion: Challenges and Opportunities to Execute the Biomarker-Driven and Diagnostic-enabled Clinical Trials**
  - Clinical Operations to adapt to the Concept of Precision Medicine
  - Logistical and Clinical Informatics Considerations
  - Design Strategies and Analysis of Biomarker-driven Clinical Trials
  - Latest Diagnostics Advances
  - Collaboration between CRO, Laboratory and Sponsor to Support the Biomarker-driven Clinical Trials

  **Panelists:**
  Yukun Wang
  Head of Translational Medicine Oncology China, SBU Oncology China Site Head, Bayer Healthcare
  Linglong Zou
  Head of Bioanalytical and Translational Sciences, Henglius Biotech
  Chih-Yi Hsieh
  Chief Medical Officer, Impact Therapeutics
  Jingyu Zhang
  Site Head, Oncology Biomarker Development, Roche (China)
  Ming Yao
  Janssen (China) Research & Development Center Sr. Manager, Clinical Biomarker & CDx, AP Coe-TS

- **1730 Panel Discussion: Precision Oncology Trials: Learnings, Barriers and Enablers**
  - Current State of Precision Medicine in Oncology
  - Elements in Precision Medicine Trial Design
  - The Good, The Bad and the Future of Tumor Profiling
  - Liquid biopsy Technology
  - Scientific Collaborations for Precision Oncology Trials

  **Panelists:**
  Johannes Nippen
  Head of R&D Biopharma, China, Merck Group
  Helen Jiang
  Senior Vice President, Chief Medical Officer Qingfeng Medicine
  Jingyu Zhang
  Site Head, Oncology Biomarker Development, Roche (China)

- **1800 Conference Day Two Closure**
**Thursday, Mar.11, 2021**

**Clinical Operation, Quality Management and Virtual Trials | Stream A**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>0700</td>
<td>Registration and Morning Coffee</td>
</tr>
<tr>
<td>0835</td>
<td>Chairperson Opening Remarks</td>
</tr>
</tbody>
</table>
| 0840  | How to Save Time, Reduce Cost, and Increase Efficiency for Multi-centre Clinical Trials?  
       Jing Bao  
       Chief Medical Officer,  
       Gmax BioPharm LLC   |
| 0910  | Risk-based Clinical Quality Management: Opportunities and Challenge  
       Lobo Loo  
       Director, Clinical Data Management  
       MSD R&D (China)   |
| 0940  | Patient-centric Trial Feasibility and Recruitment powered by Real-World Data Analytics and Digital Innovation  
       (via remote presentation)  
       Jane Fang  
       Founder and CEO, Polaris Strategic Partners Inc.   |
| 1005  | Digital Solution - Key to Clinical Trial Acceleration and Quality Optimization  
       David Lu  
       Executive Director,  
       Head of Digital Strategy and Innovation  
       Brii Biosciences   |
| 1035  | Panel Discussion: Virtual Trials: Moving towards Patient-Centric, Site-Less Trials  
       • Barriers and Challenges  
       • Technology Advance  
       • Patient Experience with Virtual Trials  
       • What does this mean for the future of clinical trials  
       Moderator:  
       Barry Wang  
       Dept. Head of Medical Affairs and Scientific Affairs,  
       Servier (China)   |
| 1115  | Coffee/Tea Break and Networking                                       |
| 1130  | A Presentation on GCP and cQMS  
       Amy Jiang  
       Head of Quality, Harbour BioMed   |
| 1200  | Panel Discussion: Digital Solutions for Patient Engagement and Retention  
       • What are the challenges with current clinical trial patient engagement and how can be filled by emerging health solutions  
       • How are these technologies being applied to patient engagement  
       • Industry best practices and case studies  
       • Strategies and Imperatives for future success  
       Panelists:  
       Shuhong Liu  
       Head of Clinical Study Unit, Greater China, Sanofi  
       Marion Martin  
       Head of Strategy and Technology Innovation,  
       Pfizer R&D (China)   |
| 1230  | Panel Discussion: Considerations for Choosing and Implementing an Outsourcing Strategy  
       Choosing, Updating and Implementing an outsourcing strategy is a daunting task with so many methodologies, business needs and resource needs to consider. Stakeholders in outsourcing will discuss key considerations to define outsourcing needs, choosing an effective outsourcing and implementing the strategy across the organization.  
       Moderator:  
       Helen Jiang  
       Senior Vice President, Chief Medicine Officer,  
       Qingfeng Medicine   |
| 1300  | Networking Lunch                                                      |

Tel: 86-21-6034-0229 | Email: wzhang@deliver-consulting.com | Website: www.clinicaldev-innovation.com
Thursday, Mar.11, 2021

Clinical Data Management, Big Data, AI and Blockchain in Clinical Trials | Stream A

1355 Chairperson Opening Remarks

1400 Big Data Analytics in Healthcare and Opportunities of Applied AI (via remote presentation)  
Xia Wang  
Director, Health Informatics, Data Science and Artificial Intelligence R&D  
AstraZeneca Pharmaceuticals

1430 AI Assisted Precision Drug Development (via remote presentation)  
- AI Benefits All Phases of Drug Development  
- Identifying Targets from Patient Data  
- Identifying Leads from Targets  
- Using AI to Guide Development  
- Interpreting Clinical Data with AI  
- The Product is the Drug, not the AI  
- Point Solutions are Insufficient  
Ed Addison  
Chairman and CEO, Cloud Pharmaceuticals

1500 Session Available

1530 Assessment of EHR Systems that May Originate eSource for Clinical Trials (via remote presentation)  
- Sponsor's responsibility regarding using data from EHR systems  
- Regulations and guidelines on clinical trials  
- eClinical Forum's assessment tool: eSRA  
- Incorporating eSRA into Site's Processes  
- Incorporating eSRA into Sponsor's Processes  
Kenichi Nakano  
Asia Pacific Facilitator  
eClinical Forum

1600 Considerations to Accelerate e-Source Adoption in Clinical Research  
Hualong Sun  
Chief Operating Officer, Beijing Clinical Service Center  
General Manager, Meta Clinical Technology

Thursday, Mar.11, 2021

Clinical Data Management, Big Data, AI and Blockchain in Clinical Trials | Stream A

1630 Panel Discussion: Challenges in the Clinical Data Management for China Domestic Pharmaceuticals in the era of Globalization  
Panelists:  
Tim Wang  
Senior Director, Global Head of Data Management, Statistics and Data Science, Beigene  
Juan Pan  
Head of Data Management, Anheart Therapeutics  
Hualong Sun  
Chief Operating Officer, Beijing Clinical Service Center  
General Manager, Meta Clinical Technology

1700 Utilization of Blockchain for a unified medical lexicon- Navigating the void of patient records (via remote presentation)  
Matt Jones  
Managing Director, Digital Quality Associates

1730 Panel Discussion: Emerging Trends of Efficient Clinical Data Management  
- Barriers and Opportunities to Implement eSource from regulatory, operational and financial perspectives  
- Efficient data acquisition and integration from difference platforms  
- Challenges in Clinical Data Management for Increasingly Complex Trials and Precision Medicine Development  
- Virtual Trials and Patient Centricity  
- Big Data Analytics and Artificial Intelligence  
- Blockchain Technologies  
Panelists to be updated

1800 Conference Day Two Closure
Thursday, Mar.11, 2021

Biostatistics and Innovative Clinical Design | Stream B

0820 Chairperson Opening Remarks
James Pan
Senior Director, China Head of Statistics and Decision Sciences, Janssen China R&D

0825 Innovative Clinical Trial Designs: Opportunities and Challenge
Michael Lee
Vice President, Head of Biometrics
Harbour BioMed

0855 Interim Analysis result: should we trust it or not?
Wenfeng Chen
Head of Biostatistics
AnHeart Therapeutics

0925 Evidentiary Standards for Drug Development and Approval
- Understanding of regulatory requirement from statistical perspective, for instance two pivotal study vs. one pivot study
- Implementing it in clinical development plan
- Accelerate drug development using adaptive design, real world evidence, synthetic control, et al
Alex Shen
Vice President, Head of Biometrics
Jixing Pharmaceuticals

0950 Lead and Impact: Turning Statistical Innovation into Practice
Yabing Mai
Regional Head of Biostatistics Asia
Biostatistics and Data Sciences, Boehringer Ingelheim (China) Investment

1020 Promising Zone Design and Its Applications: A few Case Studies
Fan Xia
Head of Biostatistics,
Zai Laboratory

1045 Q&A and Panel Discussion: Statistical Considerations in Multi-regional Clinical Trials
Panelists:
James Pan
Senior Director, China Head of Statistics and Decision Sciences, Janssen China R&D
Xiang Guo
Vice President and Global Head of Statistics and Data Science, BeiGene
Other Session Speakers

1110 Coffee/Tea Break and Networking

Thursday, Mar.11, 2021

Clinical Safety and Pharmacovigilance Stream B

1125 Designing a Risk Management Plan to Effectively Monitor Drug Safety
Chen Huang
Associate Medical Group Director, Portfolio Clinical Safety, Roche (China)

1150 Complying with Multiple Pharmacovigilance Regulations: Recent and Impending Regulatory Changes
Sally Chen
Senior Director, Head of Pharmacovigilance
Genor Bio

1215 Post-marketing Studies
Howe Li
Founder and CEO, DeltaMed

1240 Panel Discussion: Meeting the Challenges of Safety Monitoring and Reporting in Asia
Drug Safety is the most critical component of drug development programs and which is also increasingly recognized and regulated by regulators, drug developers and the public alike in China and Asia Pacific. However, a couple of challenges still exist mainly as of the less harmonized pharmacovigilance regulations among Asia countries and for this speech, we will review and discuss:
- The challenges to comply with the ever-changing and progressing safety regulations in China and Asian countries
- Complying with the various countries regulations while meet up global safety requirements
- Effectively and proactively manage drug safety aspects during new drug development
Moderator:
Chunhua Wu
Head of Pharmacovigilance
Jixing Pharmaceuticals
Panelists:
Chen Huang
Associate Medical Group Director, Portfolio Clinical Safety, Roche (China)
Sally Chen
Senior Director, Head of Pharmacovigilance
Genor Bio
Howe Li
Founder and CEO, DeltaMed

1310 Networking Lunch