

Clinical Development and Innovation Forum 2021

临床开发与创新合作论坛 2021

Mar. 10-11, 2021

Crown Plaza Shanghai NOAH Square, PR. China



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 *partial*

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

Association Partners

Forum Partners | *partial*

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DELIVER | 迪易咨询
BioPharm Event Partner in Asia Pacific



Forum Speakers Committee | *partial*



Xingli Wang
Vice President
Novartis Global Drug
Development (China)



Johannes Nippgen
Head of R&D Biopharma
Merck Group (China)



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



Kai Wu
Co-CEO
Shanghai SIMR Bio



Bin Ye
Vice President, Clinical
Biomarkers and Precision
Medicine
Shenogen Pharma Group



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



Jerry Wang
Co-Founder and
Chief Executive Officer
AnHeart Therapeutics



Fugen Li
Senior Vice President,
Translational Medicine,
HaiHe Pharmaceuticals



Michael Lee
Vice President
Head of Biometrics
Harbour BioMed



Ye Hua
Founder and CEO
BioNova Pharmaceuticals



Rong Chen
Chief Medical Officer
Citrine (Shanghai)



Steve Chin
Chief Medical Officer
Elpiscience Biopharma



Barry Wang
Head of Medical Affairs
and Scientific Affairs
Servier (China)



Gary Tong
Co-Founder
and CMO
NeuroFront Therapeutics



Victoria Elegant⁺
Vice President,
Regional Medical Head,
JAPAC, Amgen



Victor Chen
Vice President, Head of
Early Development
Harbour BioMed



He Zhou
Executive Director, Asia Pacific
External Innovations
HiFiBio



Yizhong Ren
Medical Director
AnHeart Therapeutics



Yunxin Chen
Director of Clinical Biomarker,
Translational Medical
Oncology, Bayer Healthcare



Xiang Guo
Vice President and
Global Head of Statistics and
Data Science, Beigene



Haiyi Guo
Vice President, Head of
Clinical Development,
Hematology, China
Beigene



Derek Xu
Senior Medical Director,
Head of Clinical Scientist
Roche Innovation Center
Shanghai



Shuhong Liu
Head of Clinical Study Unit,
Greater China
Sanofi



Sean Cheng
Digital Trials Lead Asia
Boehringer Ingelheim



Jeffery Liu
Chief Scientific Officer
and President of
Huadong Global Development



Minnie Ke
Vice President, Clinical
Development and Medical Affairs
CANbridge Pharma



Hongwei Wang
Senior Director, Global Head
of Data Management
Beigene



Yanyan Zhang
Associate Director,
Translational Medicine and
Early Development, PKDM Asia
Pacific R&D, Sanofi (China)



Lobo Loo
Director, Clinical Data
Management
MSD R&D (China)



Irene Deng
Head of Regulatory Affairs,
China, Sanofi



Juan Pan
Head of Data Management
AnHeart Therapeutics



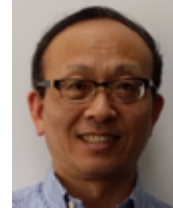
PJ Chen
Senior Vice President
APRINOIA Therapeutics



Jing Bao
Chief Medical Officer
Gmax Biopharm LLC



Cindy Ru⁺
Managing Director
CRC Oncology Corp



Hong Ling
SVP and CSO
Leads Biolabs



Qian Shi
General Manager and
Head of Science
Apollomics Inc.



Kenichi Nakano⁺
Asia Pacific Facilitator,
eClinical Forum



Linda Li
Director,
Translational Medicine Dept.
Merck Serono Beijing
R&D Centre



Archie Tse
CSO, SVP, Head of Research
and Early Clinical
Development
CStone Pharmaceuticals



Linglong Zou
Head of Bioanalytical and
Translational Sciences
Henlius Biotech



Jane Fang⁺
Founder and CEO
Polaris Strategic Partners



Ed Addison⁺
Chairman and CEO
Cloud Pharmaceuticals



Sarah Lu
Senior VP, President of Global
Development, VP of Research
Institute, Director of Clinical Center,
Shanghai Green Valley
Pharmaceutical



Wenfeng Chen
Head of Biostatistics
AnHeart Therapeutics



Xia Wang⁺
Director, Health Informatics
Data Science and Artificial
Intelligence, R&D
AstraZeneca Pharmaceuticals



Wen Wang
Chief Medical Officer
IASO Biotherapeutics



Jinhua Lu
Co-Founder and CSO
TriArm Therapeutics



Weiye Zheng
Chief Executive Officer
Innov Pharma



Simon Zhang
General Manager, China
OncXerna Therapeutics



Yabing Mai
Regional Head of Biostatistics
Asia, Boehringer
Ingelheim (China)



Amy Jiang
Head of Quality
Harbour BioMed



Ruixin Zhu
Vice President
Glorious Med



Helen Jiang
Senior Vice President,
Chief Medical Officer
Qingfeng Medicine Group



Yao Yao
Vice President, Biology
EOC Pharma



Gloria Gong
China Development Unit
Head, Novartis



Thomas Kerbusch⁺
Chief Growth Officer Certara
& Executive Director
Certara Shanghai



Ken Getz⁺
Director and Professor,
Tufts Center for the Study
of Drug Development



Chih-Yi Hsieh
Chief Medical Officer
Impact Therapeutics



Chunhua Wu
Head of Pharmacovigilance
Jixing Pharmaceuticals



Ming Yao
Senior Manager,
Clinical Biomarker & CDx,
AP CoE-TS, Janssen (China)
Research & Development Center



Xiugao Yang
Medical Director
Clinical Development Division,
CSPC Pharmaceutical Group



Qikuan Huang
General Manager, China
Accurant Biotech



Ernest Su
Senior Vice President
Yucebio,
General Manager, YTNeoAG



Hualong Sun
Chief Operational Officer
Beijing Clinical Service Center



David Lu
Head of Digital Strategy
and Innovation
Brii Biosciences



James Pan
Senior Director, China Head of
Statistic and Decision Sciences
Janssen China R&D



Howe Li
Founder and CEO
DeltaMed



Matt Jones⁺
Managing Director,
Digital Quality Associates



Bin Peng
Chief Medical Officer
EpimAb Biotherapeutics



Kathryn Liu
Director, Translational Sciences
Fosun Kite Biotechnology



Xiaoning Guo
Vice President,
Head of R&D and
Chief Medical Officer
SciClone Pharmaceuticals



Chen Huang
Associate Director
Medical Director
Roche Product Development
Safety Risk Management



Yan Wu
Senior Vice President,
Head of Clinical Development
and Medical Dept.
Ark Biosciences



Aik Han Goh
Vice President,
Chief Medical Officer
Reistone Biopharma



Yong-Jiang Hei
Chief Executive Officer
Gloria Bioscience

⁺ indicates the speaker will give the presentation remotely

Wednesday, Mar.10, 2021

Clinical and Regulatory Strategy,
Next Generation Clinical Trials

0730 **Registration and Morning Coffee**

0825 **Chairperson Opening Remarks**

0830 **China and Asian'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 threaten 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.

1000 **Coffee/Tea Break and Networking**

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, NeuroFront Therapeutics

Panelists:

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

1120 **Panel Discussion: China-initiated Global Drug Development: Lessons Learned and Future Prospectus**

- 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

Panelists:

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, NeuroFront 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**

Wednesday, Mar.10, 2021

Early and Model-based Drug
Development | Stream A

- 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

China Domestic New Drug Development and
Progress Update | Stream A

- 1545 **Chairperson Opening Remarks**
Junyuan Wang
Co-Founder and Chief Executive Officer
AnHeart Therapeutics
-
- 1550 **Clinical Development of Innovative Pharmaceutical Products for Neurodegenerative Diseases - a case study from APRINOIA Therapeutics**
PJ Chen
Senior Vice President
APRINOIA Therapeutics
-
- 1615 **New Considerations for License-in Model in Today's Biotech Industry in China**
Ye Hua
Chairman and CEO, BioNova Pharmaceuticals
-
- 1645 **Clinical safety and efficacy of the first-in-class APC activator EOC202**
Yao Yao
Vice President, Biology
EOC Pharma
-
- 1710 **Targeting Undruggable Oncogene Targets, A Global Effort for Cancer Patients with Unmet Medical Need**
Liandong Ma
Vice President and President of R&D,
Kintor Pharmaceuticals
-
- 1735 **Case Study on Global Drug Development of First-in-Class Therapies for Neurodegenerative Diseases**
Sarah Lu
Senior VP, President of Global Development, VP of Research Institute, Director of Clinical Center, Shanghai Green Valley Pharmaceutical
-
- 1805 **Q&A and Discussions**
-
- 1820 **Day One Closure**

Wednesday, Mar.10, 2021

Orphan Drug Development | Stream B

- 1345 **Challenges and Strategies for Orphan Drug Development in China**
Rong Chen
Chief Medical Officer, Citrine (Shanghai)
-
- 1415 **Current Status and Recent Advance of Gene Therapy in Rare Disease**
Minnie Ke
Vice President, Clinical Development and Medical Affairs, CANbridge Pharma
-
- 1440 **Q&A and Panel Discussion: Strategies for ensuring Patient Access and the Role of Gene Therapy for Rare Diseases**
Panelists:
Rong Chen
Chief Medical Officer, Citrine (Shanghai)
Minnie Ke
Vice President, Clinical Development and Medical Affairs, CANbridge Pharma
Weiyi Zheng
Chief Executive Officer
Innov Pharma
Yong Xue
Former Chief Medical Officer, Senior Vice President
Sperogenix Therapeutics

Development of Cell and Gene Therapies | Stream B

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

Wednesday, Mar.10, 2021

Immuno-Oncology Therapeutics Development | Stream B

- 1715 **Challenges and Opportunities for Immuno-Oncology Therapeutic Development**
Steve Chin
Chief Medical Officer, Elpiscience Biopharma
-
- 1745 **Panel Discussion: Challenges and Considerations in Designing and Conducting Immuno-Oncology Clinical Research**
 - IO Biomarker Development
 - Imaging Considerations
 - Toxicity Grading
 - Operational Challenges and Best Practices**Panelists:**
Archie Tse
CSO, SVP, Head of Research and Early Clinical Development, CStone Pharmaceuticals
Xiugao Yang
Medical Director, Clinical Development Division, CSPC Pharma
Haiyi Guo
Vice President, Head of Clinical Development, Hematology (China), Beigene
-
- 1830 **Conference Day One Closure**

Thursday, Mar. 11, 2021

Biomarkers, Companion Diagnostics and Translational Medicine | Special Focus

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 Biomarker Research, the need for Integration of Biomarker and IVD Validation in Clinical Development with a focus on Oncology and Companion Diagnostics.

- 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, Shenogen 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, Henlius 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 Nippgen
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

0700 Registration and Morning Coffee

0835 Chairperson Opening Remarks

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)

Panelists:

Ang Main Fong
Regional Head, Trial Monitoring Organization, China,
Global Development Operations, Global Drug
Development, Novartis

Marion Martin
Head of Strategy and Technology Innovation,
Pfizer R&D (China)

Sean Cheng
Digital Trials Lead Asia, Boehringer Ingelheim

Shenglong Dai
Director for Development China Safety and Innovation
Lead, Pfizer R&D (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)

David Lu
Executive Director
Head of Digital Strategy and Innovation,
Brii Biosciences

Yong Xue
Former Chief Medical Officer, Senior Vice President
Sperogenix Therapeutics

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

Panelists

Sunny Zhu
Chief Medical Officer, Everest Medicines

Yan Wu
Senior Vice President, Head of Clinical Development
and Medical Department, Ark Biosciences

Amy Jiang
Head of Quality, Harbour BioMed

Yong Xue
Former Chief Medical Officer, Senior Vice President
Sperogenix Therapeutics

1300 Networking Lunch

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**