Lychee Group

CHINATRIALS 11

CLINICAL DEVELOPMENT LEADERS' SUMMIT

November 7-9, Shanghai

JW Marriott Hotel at Tomorrow Square

2018's Theme:

Compete or Collaborate: How Will MNC and Domestic BioPharma Succeed in China's Fast-Changing Development Landscape?

PROGRAM AGENDA & SCHEDULE OF EVENTS

CHINATRIALS 11
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Workshop Day

Schedule-at-a-Glance

DAY 1: WEDNESDAY, NOVEMBER 7

Please note that some workshop times run simultaneously. Please check the schedule carefully so you may plan your attendance accordingly. The main session with exhibition runs from November 8-9 and you may also register on November 8 morning.

8:00 am – 9:00 am
Registration for Morning Workshop

9:00 am – 12:00 pm
Workshop 1
Current Trends for Conducting Clinical Trials in Asia Pacific

MORNING WORKSHOP ORGANIZED BY: PPC 佳生

1:00 pm – 5:30 pm
Workshop 2
From R&D to Commercialization: Value Creation Through Risk Mitigation

WORKSHOP ORGANIZED BY: IQVIA™

1:00 pm – 3:30 pm
Workshop 3
Innovative Trial Designs & Statistical Methods

1:00 pm – 3:30 pm
Workshop 4
Clinical Trial Safety Management

3:30 pm – 3:45 pm
Coffee & Tea Break

3:45 pm – 5:30 pm
Workshop 5
Current Status and Future Opportunities and Challenges of Chinese Antibody-Drug Conjugate (ADC) Trials

WORKSHOP ORGANIZED BY: prospwell® 春天医药 北京

5:30 pm – 6:30 pm
Welcome Cocktail Networking Reception

CHINATRIALS 11
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Special Morning Session Presented by: PPC 佳生

Workshop 1

Current Trends for Conducting Clinical Trials in Asia Pacific

DAY 1: WEDNESDAY, NOVEMBER 7

9:00 am – 12:00 pm

9:00 am – 9:25 am
Clinical Trials Industry in China: Trends, Challenges and Opportunities
Jason Zhu, M.D.
Chief Executive Officer, China
PPC GROUP

9:25 am – 9:50 am
Early Phase Clinical Development and Regulatory Environment in Korea
Sanghee Kim
Managing Director, PPC Korea
PPC

9:50 am – 10:15 am
Strategy and Considerations of New Drug Clinical Trials in Taiwan: From FIH to POC
Minhui Chen
Medical Affairs Director, PPC Taiwan
PPC

10:15 am – 10:30 am
Coffee & Tea Break

10:30 am – 10:55 am
Best Practices of Clinical Trials in CAR-T in China
Limin Wen
Head of Clinical Development
FOSUN KITE BIOTECHNOLOGY

10:55 am – 11:20 am
Australia's R&D Tax Incentive Policy
Michael Stibilj
Chief Executive Officer, PPC Group
PPC

11:20 am – 12:00 pm *Panel Discussion*
Future Drug Development in Asia Pacific
Moderator:
Jason Zhu, M.D.
Chief Executive Officer, China
PPC GROUP

Panelists:
Jason Yang
CMO & SVP, Clinical Development
CSTONE PHARMA

Yan Wu
VP, Head of Clinical Operations
HUTCHISON MEDIPHARMA

Helen Jiang
VP & CMO
QINGFENG MEDICINE

Yi Liu
CMO
KECHOW PHARMA

Workshop 2

From R&D to Commercialization: Value Creation Through Risk Mitigation

DAY 1: WEDNESDAY, NOVEMBER 7

1:00 pm – 5:30 pm

In this workshop, we will discuss what risks may exist from R&D to Commercial stage for new drug development and how to mitigate these risks to create commercial value by utilizing strategic thinking in Clinical Development for the new investigated drugs. The goal of this session is to share with the audience the latest and most current industry trends in drug development, upcoming new strategic investment directions and how to bridge the gap from the R&D mind-set to commercial value creation. The session is designed for attendees from various backgrounds, both general audience as well as those who are decision makers in the emerging biopharma companies. The workshop will be informative and interactive, so bring your questions and participate in the discussion!

Workshop Chair:
Tong Guo
Vice President & Head of BD R&D Solutions
IQVIA GREATER CHINA

1:00 pm – 1:30 pm *Keynote Presentation*
Capturing the Best Chances of R&D and Commercial Success for New Drug Development in China
Brian Mi
President, Greater China
IQVIA GREATER CHINA

1:30 pm – 2:30 pm
Eyeing the End Game: The Importance of Strategic Clinical Development
Robert Gallagher
Head of Strategic Clinical Development Solutions
IQVIA SINGAPORE

Shu Lam
Senior Consultant
IQVIA AUSTRALIA

2:30 pm – 2:45 pm
Coffee & Tea Break

2:45 pm – 3:15 pm
The Disruptive Innovation on Portfolio Planning and Launch Excellence
Howard Chen
Principal, Management Consulting
IQVIA GREATER CHINA

3:15 pm – 5:00 pm *Panel Discussion*
Keeping a Commercial Mind in R&D
Session Chair:
Brian Mi
President
IQVIA GREATER CHINA

Panelists:
Joan Shen
Head of R&D
I-MAB BIOPHARMA

John Gong
Chief Executive Officer
3DMED

Ning Li
Chief Executive Officer
JUNSHI BIOSCIENCES

John Wan
Senior Vice President
BETTA PHARMA

Howard Chen
Principal, Management Consulting
IQVIA GREATER CHINA

5:00 pm – 5:30 pm
Q&A

CHINATRIALS 11
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Workshop 3

Innovative Trial Designs & Statistical Methods

DAY 1: WEDNESDAY, NOVEMBER 7

1:00 pm – 3:30 pm

In this workshop, we will discuss how to improve efficiency in new drug research, and bend the time and cost curve by utilizing innovative statistical methods and trial designs. The goal of this session is to share with general audiences the latest and most current industry trends in trial design, upcoming new concepts and how some of the new concepts are being used in the field. The session is designed for attendees from various backgrounds, both general audience as well as those with stats experience. The workshop will be informative and interactive, so bring your questions and participate in the discussion.

Key Topics Covered:

- Adaptive designs: concepts, applications and benefits in confirmatory and dose-finding trials
- Case study on Bayesian Logistic Regression Model (BLRM) use in dose-finding trials
- Cost/time reduction benefits from two-stage design in confirmatory trials
- The next frontier: virtual trials and synthetic-arm trials

Workshop Chairs:

Ping-Chung Chang
Asia-Pacific Region Head, Biostatistics and Programming
PPD

Susan Wang
Regional Head of Biostatistics & Data Sciences
BOEHRINGER-INGELHEIM

Speakers:

Julie Cong
Associate Director, Statistics
BOEHRINGER-INGELHEIM

Aileen Zhu
Senior Principal Biostatistician
CHINA NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH

Jerry Wang
Head of Global Biostatistics, Epidemiology and Medical Writing
MERCK SERONO

CHINATRIALS 11
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Workshop 4

Clinical Trial Safety Management

DAY 1: WEDNESDAY, NOVEMBER 7

1:00 pm – 3:30 pm

This pre-conference workshop is designed to assist Chinese pharmaceutical companies in implementing clinical trial safety data management that are specified by ICH E2A, E2B, E2E, E2F, and other safety regulations and standards around world. The workshop will focus on IND individual case safety reports, aggregated development safety update report, clinical trial safety monitoring, risk based clinical trial risk management and mitigations, as well as outsourcing strategy and information center support, which are suitable and scalable to clinical trial safety reporting.

- CFDA ICH implementation current status and future plan
- Development and updated Reference Safety Information (RSI)
- IND individual case safety reports (ICSR) related medical review: Expectedness Determination Rule and Causality Assessment
- Development safety update report (DSUR)
- Clinical trial safety signal identification, analysis, assessment, management, and mitigation
- Special safety considerations for gene-therapy, cell-therapy and other new modalities from study design to safety monitoring and assessment during clinical trials
- Clinical trial safety outsourcing

Workshop Leaders:

Sean Zhao
Head of US Patient Safety Surveillance
ASTRAZENECA

Helen Yu
Executive Director, Clinical Development
IONIS PHARMACEUTICALS

CHINATRIALS 11
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Workshop 5

Current Status and Future Opportunities and Challenges of Chinese Antibody-Drug Conjugate (ADC) Trials

DAY 1: WEDNESDAY, NOVEMBER 7

3:45 pm – 5:30 pm

Oncology is the most important area in clinical trials, but there are still many unmet medical needs. After the emergence of ADC drugs as an important branch in the oncology area, it has been one of the super stars in the industry. But due to its complex drug composition and clinical design, its development in the industry has progressed slowly. This workshop hopes to bring you a feast of the latest knowledge in the field of ADC from the perspectives of PIs, Sponsors, CROs and third-party testing. As more 1.1 new drugs get approved in China, the need for clinical trials of innovative drugs will increase. Post-Market Clinical Trials has become more and more important in the industry as it will help drug developers to distinguish their products from competitors, directly contributing to the profit of drug makers. In short, this exciting session will bring lots of value to the industry, by discussing how to leverage the best partnerships in clinical trials and assisting the innovative biopharma companies to achieve higher efficiency.

Key Topics Covered:

- Global development of ADC clinical trials
- Key considerations for ADC clinical design
- Key technologies of biosimilars research
- Post-Marketing clinical strategy and PV case studies
- Challenges and practice of ADC bioanalysis

Workshop Chair:

Yi Fang
Director, Phase I Clinical Trials Institute
PEKING UNIVERSITY PEOPLE'S HOSPITAL

Speakers:

Guanghao Wu
Vice President
SHANGHAI JIAOLIAN MEDICINE R&D

Xichun Hu
Director, Medical Oncology
SHANGHAI CANCER CENTER
FUDAN UNIVERSITY

Fiona Chen
Senior Director of Bioanalysis Department
UNITED-POWER PHARMA TECH

Sean Zhao
Head of US Patient Safety Surveillance
ASTRAZENECA

DAY 2: THURSDAY, NOVEMBER 8

COMPETE OR COLLABORATE: WHAT ROLES WILL MNC PHARMA & DOMESTIC BIOPHARMA PLAY IN CHINA?

7:30 am - 8:20 am

Main Registration

8:20 am - 8:30 am

Opening Remarks
Min Irwin
Chief Executive Officer
REISTONE BIOPHARMA

8:30 am - 8:45 am

Industry Overview
Global Perspectives on the New Drug Innovation Landscape- What Is China's Role?
Fangning Zhang
Partner
MCKINSEY & COMPANY

8:45 am - 9:45 am

Opening Keynote Session
Compete or Collaborate: How Will MNC Pharma, Domestic Pharma and the New Wave of Domestic Biotechs Succeed in China's New Drug Development Landscape?

- If MNC's successfully bring their first-in-class therapies to China and price aggressively, how will domestic innovative biotechs survive?
- Is "me-too / me-better" still a viable strategy?
- What is the right strategy needed to succeed in this fast-changing environment?

Moderator:
Lianshan Zhang
Senior Vice President & Global R&D President
JIANGSU HENGRUI MEDICINE

Speakers:
Shirley Zhao
General Manager & President, China & HK
BRISTOL-MYERS SQUIBB

Zhenping Zhu
CSO & President of R&D
3SBIO

Yimin Mao
Professor of Gastroenterology
CEO, State Institution for Drug Clinical Research
RENJI HOSPITAL

Min Irwin
Chief Executive Officer
REISTONE BIOPHARMA

Fangning Zhang
Partner
MCKINSEY & COMPANY

DAY 2: THURSDAY, NOVEMBER 8

9:45 am - 10:35 am

MNC Pharma Spotlight Session

Registering Imported Drugs: What Strategies Should MNC's Employ to Leverage Global Data for China Approval?

When the CFDA introduced new rules that allowed foreign data to be used for regulatory filings in China in 2017, no one expected the speed at which the process would be implemented. Fast forward to 2018 and we've already seen a number of high-profile drugs approved in China through this strategy. This session will bring together experts from top MNC's in China to discuss the impact of the new policies and highlight the new strategic challenges that come along with this great new opportunity.

- What are the requirements, what data can be used and which situations call for which data to be used?
- How do you ensure clear communication and strategy alignment with global HQ for your submission?
- How can MNC's adapt previous strategies to fully leverage the new rules and compete against the crop of new domestic biotechs?

Moderator:

Heidi Wang
VP & Head, Global Regulatory Science, China & HK
BRISTOL-MYERS SQUIBB

Speakers:

Yue Kang
China Development Director
ABBVIE

Minnie Ke
Country Medical Head
SHIRE PHARMACEUTICALS

Lin Wang
Head of Takeda Development Center, Asia VP
TAKEDA PHARMACEUTICALS

10:35 am - 11:00 am

Networking Break

11:00 am - 11:55 am

Risk Management Session

When Something Goes Wrong in a Clinical Trial- Who's Liable?

Conducting human clinical trials involves many different parties including CRO, Investigator, Regulatory Agency and Sponsor. But if something goes wrong during the trial, with whom does the liability lie with and who is responsible to pay damages? This session aims to discuss the possibility of mitigating risk by captive or commercial insurance and will feature perspectives and experiences from HCT parties including Sponsor, CRO, PI, regulations/guideline from regulator and expert commentary from a top lawyer who has experience in litigating such cases.

DAY 2: THURSDAY, NOVEMBER 8

By the end of this session, attendees will learn:

- Liability Risk of Human Clinical Trials- Global Trends
- What to be aware of in terms of their liability
- How to best manage the risk when conducting clinical trials

Moderators:

Alex Forrest
Head of Life Science, COG
CHUBB

Cece Liu
Underwriting Manager of Life Sciences- Asia
CHUBB

Speakers:

Yong Li
Chief Physician, Cardiology
HUASHAN HOSPITAL OF FUDAN UNIVERSITY

David Fuller
Senior Vice President, Clinical Development, Oncology
SYNEOS HEALTH

Demi Liu
Clinical Project Director
ZAI LAB

Mark Zhang
Partner
KING & WOOD MALLESONS

Gang Liu
Vice General Manager
Vice President & Secretary General
ZHANGJIANG BIOTECH & PHARMACEUTICAL BASE
SHANGHAI PUDONG BIOINDUSTRY ASSOCIATION

11:55 am - 12:55 pm **Networking Lunch**

THE ROAD TO EXECUTING WORLD-CLASS CLINICAL TRIALS IN CHINA

12:55 pm - 1:55 pm

Landmark Clinical Trials Case Studies

Case Study 1: Rydapt (Midostaurin): Its Odyssey from Discovery to Approval for Treating Acute Myeloid Leukemia and Advanced Systemic Mastocytosis

The successful development of midostaurin provides several lessons for clinical trialists, in general and specifically in AML. Although they were not successful in terms of clinical outcomes in solid tumors, CLL, or diabetic retinopathy, the first 2 stages were crucial for having identified tolerable dosing, characterizing pharmacokinetics, and establishing the safety profile of midostaurin.

This "early" work enabled investigators to efficiently design trials once AML was selected as a potential indication. This journey shows the feasibility of conducting a large, international phase 3 trial in a sub set of patients molecularly defined using a well-validated test before chemotherapy is initiated. Extensive coordination between clinical trial cooperative groups, the pharmaceutical industry, and governmental agencies united in a common goal enabled the successful completion of the RATIFY study.

Case Study 2: Panobinostat (LBH-589): Development of the Pan-DAC inhibitor

Moderators:

Bin Peng
Chief Medical Officer
EPIMAB BIOTHERAPEUTICS

Yongjiang Hei
Chief Medical Officer
ZAI LAB

Rydapt Case Study Expert:

Paul Manley
Executive Director
NOVARTIS PHARMA AG

Panobinostat Case Study Expert:

Peter Atadja
Executive Director, Head, Oncology Drug Discovery
CHINA NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH

1:55 pm - 2:35 pm

Going Global: What To Be Aware of When Conducting Clinical Development Globally

This session will gather some of the leading domestic biotechs who are pioneering global trials and will share their experiences and "battle stories" in conducting their trials outside of China in the US, EU and Australia.

By the end of this session, attendees will:

- Gain honest insights through critical analysis of the process of going international
- Where have things gone right? Wrong?
- What are your options for going global and what are some common mistakes you can easily avoid?

Moderator:

Michael Winlo
Chief Executive Officer
LINEAR CLINICAL RESEARCH

DAY 2: THURSDAY, NOVEMBER 8

Speakers:

Jianwen Chen
Vice President, Medical Department
JIANGSU HENGRUI MEDICINE

Xiaowei Shi
Executive Director, Clinical Operations, Asia Pacific
BEIGENE

Yan Wu
Vice President, Head of Clinical Operations
HUTCHISON MEDIPHARMA

Jason Yang
Chief Medical Officer & SVP Clinical
CSTONE PHARMA

2:35 pm - 3:45 pm

Debate Forum

Medical vs. Biostatistics Teams: How Do We Work Together for Truly Innovative Trial Design?

As Chinese biotechs move from "copycat" trials and classic domestic bioequivalence studies into a truly adaptive design era, the need for medical and statistics teams to work closely together has become increasingly more important. This exciting session will bring together Medical and Statistics teams from some of China's top innovative biotechs to openly discuss how medical and statistics could and should work together for innovative trial design.

Moderator:

Tong Guo
Vice President & Head of BD R&D Solutions, Greater China
IQVIA

Opening Statements:

Jason Yang
Chief Medical Officer & SVP Clinical
CSTONE PHARMA

Tony Guo
Executive Director, Head of Biostatistic
BEIGENE

Panelists:

Xiaoxiang Chen
EVP, Head of Clinical Development
HARBOUR BIOMED

Luyan Dai
Head of Biostatistics
HARBOUR BIOMED

Tony Guo
Executive Director, Head of Biostatistics
BEIGENE

Jin Wang
Senior Director, Clinical Development
BEIGENE

3:45 pm - 4:05 pm

Networking Break

DAY 2: THURSDAY, NOVEMBER 8

4:05 pm - 4:55 pm

Cell Therapy Clinical Development: What Are the Critical Factors to Consider When Conducting Trials in China?

Moderator:
Gloria Wang
Chief Medical Officer
TASLY BIOPHARMACEUTICALS

Speakers:
Yang Shen
Professor, Department of Hematology
RUIJIN HOSPITAL
SHANGHAI JIAOTONG UNIVERSITY

Sophia Yang
Senior Director of Clinical Research Operations
JW THERAPEUTICS

Limin Wen
Head of Clinical Development
FOSUN KITE BIOTECHNOLOGY

4:55 pm - 5:30 pm

ICH Insights Session

Implementing ICH E17 Guideline for Multi-Regional Clinical Trials (MRCTs): The Pathway for Domestic Chinese Biotechs to Succeed?

- Is conducting simultaneous trials in US/EU/Japan/China through ICH E17 the only way Chinese companies will be able to compete globally?
- What advantages do Chinese biotechs have vs. other countries?

Moderator:
Dan Zhang
Executive Chairman
FOUNTAIN MEDICAL DEVELOPMENT

Speakers:
Hesheng Zhang
Chief Executive Officer
HEMAY PHARMACEUTICALS

Luana Pesco Koplowitz
Chief Medical & Scientific Officer
DUCK FLATS PHARMA

Zhihong Li
VP of International Regulatory Affairs
FOUNTAIN MEDICAL DEVELOPMENT

CHINATRIALS 11
CLINICAL DEVELOPMENT LEADERS' SUMMIT

DAY 2: THURSDAY, NOVEMBER 8

5:30 pm - 6:30 pm

Standards for Electronic Medical Record Capture for China Clinical Trials

- Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions

Moderator:
Jennifer Hou
Head of Phase I Clinical Center
PKUCARE LUZHONG HOSPITAL

Speakers:

Carrie Zhang
Chief Executive Officer
ECLINWISE

Bitao Zhao
Chief Operating Officer
ESTARTMED

Jing Zhang
Director, Ministry Key Laboratory on Clinical Antibiotic Pharmacology/Director Phase I Clinical Trial Unit
NATIONAL HEALTH & FAMILY PLANNING COMMISSION / HUASHAN HOSPITAL

Helen Jiang
SVP & Chief Medical Officer
QINGFENG MEDICINE

Kevin Lin
Chief Executive Officer & GM
JSURE HEALTH

6:30 pm

End of General Session Day 2

DAY 3: FRIDAY, NOVEMBER 9

DOMESTIC BIOTECHS: DEVELOPMENT PATHWAYS & PREPARATION FOR SUCCESS

8:00 am - 8:05 am

Opening Remarks

8:05 am - 8:55 am

IRB Before CTA Approval: The New Bottleneck?

Moderator:
Helen Jiang
SVP & Chief Medical Officer
QINGFENG MEDICINE

Speakers:
Hua Bai
Director, Clinical Pharmacology Research Center
PEKING UNION MEDICAL COLLEGE HOSPITAL

Jennifer Hou
Head of Phase I Clinical Center
PKUCARE LUZHONG HOSPITAL

Xuening Li
Director, Medical Institution for Conducting Human Clinical Trials for Drugs
ZHONGSHAN HOSPITAL OF FUDAN UNIVERSITY

8:55 am - 9:35 am

China Clinical Research Innovation Keynote Session

Elevated Global Clinical Research Driven by Chinese Innovation: The New Normal

Impressive clinical trial data from Chinese innovative biotechs published in the world's top journals has elevated the new normal for global clinical research. The reality of local-to-local data; clinical trials results led by domestic principal investigators for domestic biopharmas, has finally arrived.

This exciting session will examine the journey here and what to expect in the near future.

- Experience Sharing: How do PI's feel when working with domestic companies vs. MNC's?
- What are the remaining the challenges that we need to overcome to take us to the next level?

Co-Presenters:
Xiaoxiang Chen
EVP, Head of Clinical Development
HARBOUR BIOMED

Ye Hua
Chairman & Chief Executive Officer
BIONOVA PHARMACEUTICALS

DAY 3: FRIDAY, NOVEMBER 9

9:35 am - 10:05 am

Networking Break

10:05 am - 11:05 am

Investor Outlook Session

Cash Winter Is Coming... What To Do If "The Bubble" Bursts

Numerous recent events in the industry are signaling the potential popping of the Chinese biotech "bubble" that has been building over the past couple of years. Financing is beginning to get tight. Some recent IPO's have underperformed against high anticipation. Some investors are being "more careful" (AKA scared).

This forward-looking session will focus on how Chinese biotechs should prepare for a cash winter if it does come:

- How to raise financing?
- How do you manage your cash flow for drug development?
- Which assets to "kill" if you don't have enough funding to do all?
- Where to IPO?
- Should you partner or sell the assets you can't afford to bring through clinical trials?

Moderator:

Jonathan Wang
Partner
ORBIMED

Speakers:

Guoliang Yu
Global CEO & Venture Partner
APOLLOMICS PHARMACEUTICALS
ORBIMED

Scott Liu
President & Chief Executive Officer
HENLIUS BIOTECH

Chris Lu
Chief Executive Officer
LAEKNA THERAPEUTICS

Xiaolin Zhang
Chief Executive Officer
DIZAL PHARMA

DAY 3: FRIDAY, NOVEMBER 9

11:05 am - 11:35 am

Regulatory Impact Session

Accelerated Approval Strategies: Which Regulatory Path Should You Select for Your New Drug Registration?

Ye Hua
Chairman & Chief Executive Officer
BIONOVA PHARMACEUTICALS

11:35 am - 12:15 pm

Combination Trials of Novel/Novel Drugs: Conducting Successful Trials Globally and China Outlook

Speakers:

Sanjeev Redkar
President & Chief Executive Officer
CBT PHARMA

Yong Yue
Chief Medical Officer
LAEKNA THERAPEUTICS

12:15 pm - 1:15 pm

Networking Lunch

1:15 pm - 2:05 pm

What's the Best Development Model Biotechs in China Should Follow?

- How do we determine which core development aspects to run internally vs. outsource?
- What should our early development strategy look like in China?
- How do we manage external environmental factors (eg. talent, trade war, etc.)?

Moderator:

PJ Chen
President
UNITED BIOPHARMA CHINA

Speakers:

Xiaoxiang Chen
EVP, Head of Clinical Development
HARBOUR BIOMED

Ye Hua
Chairman & Chief Executive Officer
BIONOVA PHARMACEUTICALS

Maggie Gu
Vice President, Clinical Research & Operations
JUNSHI BIOSCIENCES

Helen Jiang
SVP & Chief Medical Officer
QINGFENG MEDICINE

DAY 3: FRIDAY, NOVEMBER 9

PATIENT SAFETY IN CHINA'S AGE OF INNOVATIVE DRUG DEVELOPMENT

2:05 pm - 4:05 pm

Protecting the Rights, Safety and Welfare of Study Subjects in Clinical Trials

- Proactive safety monitoring for clinical trials to protect rights, safety, and welfare of study subjects and to ensure clinical trial data integrity
- Impact of ICH standards implementation in China on IRB/IEC's responsibilities before, during and after a Trial
- Active safety surveillance and management for clinical trials
- Data and Safety Monitoring (DSM) Plan and Board establishment and execution for clinical trials
- What are new accountabilities and responsibilities for CRO's in conducting clinical trial after implementation of ICH standards in China?
- Risk assessment based on SUSARs submitted from clinical trial for single or multiple product development programs

Session Chair & Co-China Chair:

Sean Zhao
Head of US Patient Safety Surveillance
ASTRAZENECA

Howe Li
Chairman & Chief Executive Officer
DELTAMED

Speakers:

Tianshu Liu
Director, Medical Oncology
ZHONGSHAN HOSPITAL

Joan Shen
Head of R&D
I-MAB BIOPHARMA

Yan Wu
Vice President, Head of Clinical Operations
HUTCHISON MEDIPHARMA

4:05 pm

CHINATRIALS 11 Concludes- See you next year!