CHINATRIALS
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Lychee Group

November 8-10 - JW Marriott Hotel at Tomorrow Square - Shanghai

2017's Theme:

"Entering the New Era of China Clinical Development- Are We Ready?"

AGENDA & SCHEDULE OF EVENTS

CHINATRIALS
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Special Morning Workshop Presented by: PPC 佳生

Early Clinical Development Workshop

WEDNESDAY, NOVEMBER 8

Ballroom A, 5th Floor- 9:00 am – 12:00 pm

9:00 am – 9:30 am
Regulatory Considerations on the Phase I Trial Design for the Development of Biosimilars in EU and US

Kamali Chance
CEO / Executive Consultant
KC BIOPHARMA CONSULTING / PPC CHINA GROUP

9:30 am – 10:00 am
How to Improve Your Success Rate in Bioequivalence Studies

Yanan Chen
Director, Clinical Research Division
PPC CHINA GROUP

10:00 am – 10:30 am
Early Clinical Development: Strategy, Design and Quality

Yan Wu
VP, Clinical Operations
HUTCHISON MEDIPHARMA

10:30 am – 10:50 am
Coffee & Tea Break

10:50 am – 11:20 am
World-Class Clinical Pharmacology Unit (CPU): PPC Case Study

Fu Mei Hung
Director, Quality Assurance Division
PPC CHINA GROUP

Calvin Tzeng
Director, Clinical Resource Management Division
PPC CHINA GROUP

11:20 am – 12:00 pm
Panel Discussion:
Examining Outsourcing Models in Early Clinical Development: What Are the Challenges and Opportunities?

Moderator:
Jason Zhu
CEO
PPC CHINA GROUP

Panelists:
Jessie Zou
Chief Medical Officer
HENGRUI MEDICINE

Yan Wu
VP, Clinical Operations
HUTCHISON MEDIPHARMA

Helen Jiang
SVP & Chief Medical Officer
QINGFENG MEDICINE

Carrie Duan
Head of Clinical Project Management & Operations
BAXTER CHINA

研发客
新药 · 法规 · 双语

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Workshop 1: An Executive Workshop for CEO's of BioPharmaceutical Companies

New Product Clinical Development: What You Must Know to Succeed

WEDNESDAY, NOVEMBER 8

VIP Holding Room, 5th Floor - 1:00 pm – 7:00 pm

1:00 pm – 1:10 pm
Opening Remarks

Min Irwin
Venture Partner
QIMING VENTURES

1:10 pm – 2:30 pm
Part 1: Designing Clinical Development Programs

- The objectives of clinical development and target product profile
- The phases and milestones of clinical development
- Local, regional and global development plans and strategies
- The organization, teams and decision-making

Simon Li
SVP & CMO
CSPC PHARMA

2:30 pm – 4:00 pm
Part 2: Moving from Preclinical to Clinical Development

- Preparing IND/CTA applications
- Preparing Investigator Brochure (IB)
- The protocol and clinical trials methodology
- Regulatory interactions
- Phase I trial and data interpretation

Min Irwin
Venture Partner
QIMING VENTURES

Simon Li
SVP & CMO
CSPC PHARMA

Jiansong Yang
CEO
MOSIM

4:00 pm – 4:15 pm
Coffee & Tea Break

4:15 pm – 5:35 pm
Part 3: Proof-of-Concept (POC) and Transition to Phase III

- POC design
- Regulatory interactions before and after phase II
- Oncology product specific path in FDA and global strategies
- How to combine the needs of science and market

Ye Hua
SVP, Head of Clinical & RA
HUTCHISON MEDIPHARMA

Jonathan Ma
Chief Data Scientist
DMED

5:35 pm – 6:40 pm
Part 4: The Standards of Conducting Clinical Development

- Quality management
- Risk management
- Stakeholders management (investors, partners, and contractors)
- GCP principles and regulatory guidelines

Frank Fan
Consultant on Pharmaceutical Medicine

6:40 pm – 7:00 pm
Closing Q&A

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Workshop 2

New Developments & Challenges in Design & Analysis of I/O Trials

WEDNESDAY, NOVEMBER 8

Ballroom B, 5th Floor - 1:00 pm – 5:30 pm

- Differences in Efficacy Endpoints Between I/O and Non-I/O Therapy from the Statistical Perspective
- Using Critical Success Factor (CSF) and Probability of Study Success (PrSS) to Facilitate Decision Making and Study Design for IO Combination Therapies
- Strategic Thinking of IO Study Design from Asian Perspective
- Debate: MNC's vs. Domestic Companies: What are the Advantages and Disadvantages?

Session Chair:
Tong Guo
VP, Head of Business Development- Greater China
IQVIA

Regulatory Agency Perspective:
Jun Wang
Vice Director, Department of Statistics & Clinical Pharmacology
CDE

Stats Heads from MNC's:
Dong Xu
Director, Lead Statistician for China/Japan
BRISTOL-MYERS SQUIBB

Chao Zhu
Director and Head of Statistics and Statistical Computation
ELI LILLY CHINA

Helen Wu
Principal Statistician
MSD CHINA

Stats Heads from Domestic Companies:
Tony Guo
Executive Director, Head of Biometrics China
BEIGENE

Tao Wang
Director, Head of Biostatistics and Programming
HENGRUI PHARMACEUTICALS

Anny-Yue Yin
Senior Director, Biostatistics
CSTONE PHARMA

Yuntao Wan
VP, Clinical Development & Operations
MABSPACE BIOSCIENCES

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Workshop 3

Key Factors for Successful Global NDA/BLA Filing & Final Approval

WEDNESDAY, NOVEMBER 8

Ballroom A, 5th Floor - 1:00 pm – 3:30 pm

- How to design one protocol to fit global needs
- How to prepare a comprehensive clinical submission dossier
- How to manage all these puzzles (project management role on timeline and resource management)

Session Chairs:

Michael Song
Medical Director- Immunology
JANSSEN

Cindy Ru
EVP & Chief Scientific Officer
CARSGEN THERAPEUTICS

Carrie Duan
Head of Clinical Project Management & Operations
BAXTER CHINA

Workshop 4

Clinical Quality: Are You Ready for CFDA and FDA Inspections?

WEDNESDAY, NOVEMBER 8

Ballroom A, 5th Floor - 3:45 pm – 6:00 pm

- FDA inspection outline and preparation strategy
- CFDA self-examination regulations and its implementation
- Road map of CFDA inspection – sponsor and site readiness
- Panel Discussion: QA/QC activities in line with readiness of US, EMEA and China inspection

Session Chairs:

Yan Wu
VP, Head of Clinical Operations
HUTCHISON MEDIPHARMA

Stephen Gilbride
President
SG RESEARCH

Yvonne Chen
GM & QA Consultant
STREAMLINE MEDTECH

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Workshop 5
Medical Devices (MedTech): Clinical & Regulatory Development

WEDNESDAY, NOVEMBER 8

Ballroom C, 5th Floor - 1:00 pm – 6:00 pm

Session Co-Chairs:

Joalin Lim
Managing Director
AGAPE-LIFE

Annie Yin
Regulatory Affairs Leader, China
JOHNSON & JOHNSON

How to Interpret and Apply Current Medical Device 2.7.1 (rev 4) for CE Mark?
Robin Stephens
Chief Executive Officer
PSEPHOS BIOMEDICA

EU Medical Device Regulation: How Does It Impact the MedTech Industry?
Chenchuan Weng
IVD Med Dev Section Manager, GC
TÜV SÜD

EU Medical Device Regulation: How to Implement Clinical Trials/CER Regulation
Jan-Paul Van Loon
Senior Consultant
QSERVE

Notified Body Perspective: How to Prepare an Effective Audit Under the New EU Medical Device Regulation?
Roger Chen
Director of Medical/Healthcare
DEKRA CERTIFICATION

How Easy Is It To Register China Medical Device in ASEAN?
Joalin Lim
Managing Director
AGAPE-LIFE

How to Raise the Quality of Regulatory Documentation?
Peter Muller
Managing Director
SCHLAFENDER HASE GMBH

The Importance of UDI in Medical Device Tracking
Flora Sue
Director of Healthcare
GS1 CHINA

UDI in China
Yan Liang
Chairman, MDTA Association
MDTA

Applicable Medical Device Standards of China
Jiahua Huang
Head of Shanghai Testing Center
SHANGHAI TESTING CENTER

Good Regulatory Practice in China
Davey Han
President / Partner
BIOHAN / AGAPE-LIFE

CER Latest Updates in China
Lin Feng
Director of Registration Department
SHANGHAI FDA

CER Corporate Perspectives
Xiaojing Chen
VP, Clinical & Medical
MEDTRONIC

Medical Device GCP Corporate Perspectives
Jane Lin
VP, Strategic Medical Affairs
JOHNSON & JOHNSON MEDICAL

DAY 2: THURSDAY, NOVEMBER 9

THE IMPACT OF NEW POLICIES ON CLINICAL DEVELOPMENT IN CHINA

7:30 am - 8:20 am	**Main Registration** *Ballroom Foyer, 5th Floor*
8:20 am - 8:30 am	**Opening Remarks** Frank Jiang Chief Executive Officer **CSTONE PHARMA** *Ballroom, 5th Floor*
8:30 am - 8:45 am	**China Drug Innovation Enters the Golden Age of Development** Fangning Zhang Partner **MCKINSEY & COMPANY**
8:45 am - 9:45 am	**What a Difference 10 Years Makes! 10 Years of Progress and What Will the Next 10 Years Bring?** This session will feature commentary from China development veterans who have seen the dramatic progress and made it through all the ups and downs of the past 10 years of China drug development. They will reflect on the past 10 years of China's development progression and share their thoughts and insights on what the next 10 years will bring. *Moderator:* Frank Jiang Chief Executive Officer **CSTONE PHARMA** *Speakers:* James Li Chief Executive Officer **JW THERAPEUTICS** Dayao Zhao VP and Head of Development China **PFIZER CHINA** Ling Zhen SVP & Head of R&D- Greater China **IQVIA** Ye Hua SVP, Head Clinical Development & Regulatory Affairs **HUTCHISON MEDIPHARMA** Fangning Zhang Partner **MCKINSEY & COMPANY**

DAY 2: THURSDAY, NOVEMBER 9

9:45 am - 10:40 am

The Future vs. Actuality: Identifying and Bridging the Gap Between Policy Intentions and Current Development Capabilities

Moderator:
Jingsong Wang
Chief Executive Officer
HARBOUR BIOMED

Speaker:
Xiaoping Ye
Founder & President
TIGERMED

Lin Shen
Vice President
PEKING UNIVERSITY CANCER HOSPITAL

Huafang Li
Chief Psychiatrist
SHANGHAI MENTAL HEALTH CENTER

Ruiping Dong
Chief Executive Officer
RBX BIOPHARMA

Jay Mei
Chief Executive Officer
ANTENGENE

Ling Su
Venture Partner
LILLY ASIA VENTURES

10:40 am - 11:00 am

Networking Break

Ballroom Foyer, 5th Floor

11:00 am - 11:45 am

How Should MNC's Respond to CFDA Articles 52-55?

- How will MNC's catch the opportunity to bring innovative new medicines to China faster?
- Perspectives on the impact felt by different clinical job functions at MNC's

Moderator:
Tong Li
Senior Director, Head of Clinical Development
JANSSEN

Speakers:
Yue Kang
China Development Director
ABBVIE

Zig Lang
Vice President- Medical Director
BAYER HEALTHCARE

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

Dennis Wong
Associate VP, Head of Development, Asia Pacific
SANOFI

Ballroom, 5th Floor

DAY 2: THURSDAY, NOVEMBER 9

STRATEGIC CONSIDERATIONS FOR ONCOLOGY DEVELOPMENT IN CHINA

11:45 am - 12:45 pm

Considerations for Early Oncology Drug Development

The goal of this session is to highlight the general strategic considerations to address the most relevant issues during early oncology drug development in order to obtain sufficient information to make the critical "Go-No-Go" decision.

- General considerations of early clinical program for oncology drug development
- Supportive non-clinical and clinical trials for oncology drug development
- Regulatory considerations for early oncology drug development: clinical pharmacology perspectives

Moderator:
Simon Li
SVP & CMO
CSPC PHARMA

Speakers:
Luana Pesco Koplowitz
President & Chief Medical & Scientific Officer
DUCK FLATS PHARMA

Derek Zhang
President
ALAVANDA REGULATORY & DRUG DEVELOPMENT

12:45 pm - 1:45 pm

Networking Lunch

Wanhao Xuan Restaurant, 39th Floor

1:45 pm - 2:45 pm

Why Are We Running So Many PD-1 / PD-L1 Clinical Trials?

- Overview of the PD-1/PD-L1 status globally including China
- What should your development strategy in China look like?
- Patient perspectives on competition for recruitment and trials
- With so many PD-1/PD-L1 inhibitors in China how are you going to position your pipeline?

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

Speakers:
Hongfei
Founder
FAMILY OF LYMPHOMA PATIENTS

Jessie Zou
CMO & VP, Clinical R&D
HENGRUI PHARMACEUTICALS

Ballroom, 5th Floor

DAY 2: THURSDAY, NOVEMBER 9

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

Yuntao Wan
VP, Clinical Development & Operations
MABSPACE BIOSCIENCES

Kevin Lin
Chief Executive Officer
JSURE HEALTH

PRINCIPAL INVESTIGATORS + PATIENTS FORUM: IMPROVING ENGAGEMENT BETWEEN SPONSORS, SITES AND PATIENTS

2:45 pm - 3:45 pm

An Interview with Top Principal Investigators and Patients in China

- Are PI's excited or concerned about the pending regulatory changes?
- How can we expand the pool of high-quality investigators and prepare to be clinically capable?
- How do patients view these changes?
- How can industry collaborate better with patients?

Moderators:

Gloria Wang
Executive Director, Clinical Development
JUST BIOTHERAPEUTICS

Meiju Lin
Lead of Patient Strategy, Commercial Strategy Excellence
ASTRAZENECA CHINA

Investigators:

Prof. Xichun Hu
Director, Department of Medical Oncology
SHANGHAI CANCER CENTER
FUDAN UNIVERSITY

Prof. Tianshu Liu
Director, Department of Medical Oncology
ZHONGSHAN HOSPITAL
FUDAN UNIVERSITY

Patient:

Hongfei
Founder
FAMILY OF LYMPHOMA PATIENTS

Patient Advocacy Group:

Steven Liu
Founder & CEO
MIJIAN

3:45 pm - 4:05 pm **Networking Break** *Ballroom Foyer, 5th Floor*

DAY 2: THURSDAY, NOVEMBER 9

NEW REGIONAL & GLOBAL DEVELOPMENT OPPORTUNITIES

4:05 pm - 4:30 pm

Pilot of the MAH Pilot: A Case Study of Fruquintinib New Drug Registration in Advanced Colorectal Cancer

Ye Hua
SVP, Head Clinical Development& Regulatory Affairs
HUTCHISON MEDIPHARMA

Ballroom, 5th Floor

4:30 pm - 4:55 pm

Future Perspectives on MRCT and NDA Strategies in East Asia (China, Korea, Taiwan and Japan) Including Updates on ICH Reform and E17 MRCT Guideline

Tetsuomi Takano
Senior Strategy Director, Operational Strategy & Planning Clinical Development
COVANCE JAPAN

4:55 pm - 5:45 pm

Simultaneous Early Development in China: How Will it Work and What's the Best Strategy for Global BioPharma Companies?

- What's the pathway for MNC biopharma companies to do early development in China?
- What should smaller foreign biotech companies' early development strategy in China look like?
- What is the early development strategy for China biotech? What would the decision-making process be?
- What is the role of contract manufacturing organization (CMO) in the early development strategy?
- What is the impact of the new regulation reform – where the line between imported and domestic products is blurred?

Moderator:
PJ Chen
VP, Head of Clinical & Medical Affairs Center & President
UNITED BIOPHARMA CHINA

Speakers:
Gang Chen
Senior Medical/Clinical Development Director
HENGRUI MEDICINE

George Liu
Head of Early Development
HARBOUR BIOMED

DAY 2: THURSDAY, NOVEMBER 9

	Victor Chen Site Head, Early Development Lab **COVANCE** James Pang VP, Clinical Development **DMED**	Jennifer Hou Phase I Clinical Center **PKUCARE LUZHONG HOSPITAL**
6:00 pm - 7:00 pm	**Networking Cocktail Reception** *Ballroom Foyer, 5th Floor*	

DAY 3: FRIDAY, NOVEMBER 10

WHAT ARE THE KEYS FOR LONG-TERM SUCCESS FOR CHINA'S CLINICAL-STAGE COMPANIES?

8:30 am - 8:45 am	**Opening Remarks** Dan Zhang Executive Chairman **FOUNTAIN MEDICAL DEVELOPMENT** *Ballroom, 5th Floor*	
8:45 am - 9:20 am	**Fireside Chat on New Policy Insights** **China's Historic Regulatory Policy Changes and ICH Entry: How Should Your Clinical and Regulatory Strategy Adapt for the Short and Long Term?**	
	Dan Zhang Executive Chairman **FOUNTAIN MEDICAL DEVELOPMENT**	Gongshu Li Senior Vice President & Chief Medical Officer **FOUNTAIN MEDICAL DEVELOPMENT**

DAY 3: FRIDAY, NOVEMBER 10

9:20 am - 10:20 am

China Against the World: How Do Clinical-Stage Companies in China Compare to the Rest of the World?

This exciting session will approach the outlook for China development from a variety of angles not often discussed at ChinaTrials or other R&D-focused events.

- Innovation: In-Licensing vs. Developed In-House
- Valuation: China Deals vs. US Deals
- Exit Strategies: Asia Markets vs. Nasdaq
- Talent: Local Talent vs. Returnees
- Market Opportunity: China Disease Profiles vs. US/EU Disease Profiles

Moderator:

Jonathan Wang
Senior Managing Director
ORBIMED ASIA

Speakers:

Sanjeev Redkar
Chief Executive Officer
CBT PHARMA

Yaolin Wang
Chief Executive Officer
INVENTISBIO

Dajun Yang
Chief Executive Officer
ASCENTAGE PHARMA

Yi Shi
Managing Director
LILLY ASIA VENTURES

Xiaoqiang Yan
Chief Executive Officer
GENERON

10:20 am - 10:45 am

Networking Break

Ballroom Foyer, 5th Floor

10:45 am - 11:45 am

Hot Topic: CAR-T Clinical Development in China: Experiences and Learnings

This session will feature top KOLs in China who have first-hand experience on running CAR-T trials in China. Our moderator will also review the latest data and learnings from high profile trials recently completed in the US.

Key points of discussion will include:

- Summary of global progress in CAR-T clinical development: what have we learned?
- Achievements of CAR-T in hematology cancers
- Challenges of CAR-T clinical development in solid tumors
- Critical factors to consider when designing and implementing CAR-T trials

DAY 3: FRIDAY, NOVEMBER 10

Moderator:
Cindy Ru
EVP & Chief Scientific Officer
CARSGEN THERAPEUTICS

Speakers:
Xianbao Zhan
Deputy Director, Dept. of Gastroenterology
CHANGHAI HOSPITAL

Bo Zhai
Department of Interventional Oncology
RENJI HOSPITAL

Lei Yu
Chief Executive Officer/Director of The Institute of Biomedical Engineering & Technology
UNICAR THERAPY / EAST CHINA NORMAL UNIVERSITY

Ballroom, 5th Floor

11:45 am - 12:45 pm

Central Labs vs Local Hospital Labs: What Benefits and Challenges Come with Each?

- Why was the concept of central laboratory developed and implemented by big pharma companies?
- What are the benefits and risks of using the central laboratory system?
- How to protect patient's rights by using central laboratory?

Moderator:
Helen Jiang
SVP & Chief Medical Officer
QINGFENG MEDICINE

Speakers:
Yi Zhang
VP, Clinical Research & Development
HUA MEDICINE

Qingyu Xiu
Director, Respiratory Department
SHANGHAI CHANGZHENG HOSPITAL

Hansong Andy Liu
General Manager- China
COVANCE CENTRAL LABS

Yanfei Liu
Director, Clinical Trial Institution
FUDAN UNIVERSITY SHANGHAI CANCER CENTER

Luxia Liang
VP & General Manager
FANTASTIC BIOIMAGING

12:45 pm - 1:45 pm

Networking Lunch

Wanhao Xuan Restaurant, 39th Floor

DAY 3: FRIDAY, NOVEMBER 10

PATIENT SAFETY IN THE NEW INNOVATIVE DRUG DEVELOPMENT ENVIRONMENT

1:45 pm - 5:00 pm

Strengthening Your Company's Pharmacovigilance Capabilities to Meet the Spring of Innovative Drug Development in China

The many recent encouraging CFDA policy proposals while groundbreaking, will introduce significant challenges, i.e., even greater competition from MNC's, significantly increased post marketing research requirements, and great enhancement needs of safety surveillance system to protect safety of patient in post marketing setting. Further, as we step into the space of first and or best in class products, for which no previous safety information is wildly available, what kind safety system and processes should be setup during clinical development to protect subject's right, welfare, and safety?

The session will share some global and local considerations and experiences in protecting human subjects throughout a product's clinical development program and focused on the following areas:

- Safety readiness for initialing a clinical trial: Establishing a strong safety system that includes safety organization, processes, and database is a fundamental basis of safety surveillance in clinical trials
- Risk management during clinical trials: Identification, assessment, mitigation of risks for study subjects in clinical trials
- Reference Safety Information (RSI): Best practice and challenges in developing, updating, and using RSI for clinical studies.
- Accelerated approval related post marketing research: Strategies, practice considerations and experiences for products with breakthrough status in regulatory approval and post marketing research.
- Active post marketing safety surveillance: Regular periodic collection of adverse drug reaction from healthcare providers or facilities to allow collection of more complete data for identifying drug safety signal and validating drug safety signal identified through passive surveillance.

Session Leaders:

Sean Zhao
Head of US Patient Safety Surveillance
ASTRAZENECA

Joan Shen
Head of Discovery & Clinical Development
I-MAB BIOPHARMA

Songlin Xue
EVP & Global Head of Pharmacovigilance
ASTELLAS PHARMA

Howe Li
Chief Medical Officer
TIGERMED-INTELLIPV

Conny Xiaoyao Mo
Medical Safety Advisor
BEIJING RHGT INFO

Ballroom, 5th Floor

5:00 pm

Conference Concludes