CHINATRIALS 16

CLINICAL DEVELOPMENT LEADERS' SUMMIT

Co-Organized By

Pharma 研发客

PROGRAM AGENDA

November 11-13, 2024

JW Marriott at Tomorrow Square, Shanghai

2024 Theme:

China Biopharma Innovation: Recalibrating Expectations and Moving the Industry Forward

www.chinatrials.com

CHINATRIALS 16
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Pharma 研发客

Workshop Day - Monday, November 11

Schedule-at-a-Glance

Please note that some workshops run simultaneously. Please check the schedule carefully so you may plan your attendance accordingly. The main session with exhibition runs on November 12-13; you may register on November 12 morning if you will not attend the Workshop Day.

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

9:00 am – 12:00 pm
Workshop 1: *Next-Gen Therapies: Global Development Landscape of Advanced Therapies & Strategic Approaches to Conducting Clinical Trials*

Featured Morning Workshop Organized By: NOVOTECH™ Biotech's Partner at Every Phase

***English-Chinese Simultaneous Translation Provided**

12:15 pm – 1:30 pm
Networking Lunch

1:30 pm – 6:00 pm
Workshop 2: *Fostering China-Global Clinical Development Success: Insights and Practices*

Featured Afternoon Workshop Organized By: ppd by Thermo Fisher Scientific

***English-Chinese Simultaneous Translation Provided**

1:30 pm – 3:30 pm
Workshop 3: *Going Global and Innovation: The Practice and Value of Endpoint Management of Oncology Clinical Trials*

Organized By: MERIT Your Clinical Endpoint Expert

***English-Chinese Simultaneous Translation NOT Provided**

4:00 pm – 6:00 pm
Workshop 4: *Crossroads of Innovation- Winning with Strategy & Science: How to Stand Out in the Next Wave of R&D*

Organized By: Tigermed

***English-Chinese Simultaneous Translation NOT Provided**

6:00 pm
End of Workshop Day

Morning Workshop - 9:00 am - 12:00 pm - November 11 (JW's Ballroom B, 5th Floor)

Next-Gen Therapies: Global Development Landscape of Advanced Therapies & Strategic Approaches to Conducting Clinical Trials

Featured Morning Workshop Organized by: NOVOTECH™ Biotech's Partner at Every Phase

Amid the rapid development of the global biopharmaceutical field, China is emerging as a key driving force for Advanced Therapies. With the rise of these therapies, issues such as regulatory affairs, global development, and clinical trial strategies also need to be addressed. How can biopharmaceutical companies seize opportunities in this expanding market and focus on strategic transformations from a global perspective? How to navigate the frontier amidst multiple challenges to find suitable clinical development paths? How to unlock the potential of Advanced Therapies?

This workshop will take a deep dive into cutting-edge therapies, including Radiopharmaceutical therapy, RNA, and Gene Therapies, while also expanding insights into AI-driven drug and BTDs. Together with leading experts, please join us in a dynamic exchange of ideas from multiple perspectives, to analyze the opportunities, challenges, and prospects of next-generation therapies.

9:00 am - 9:05 am
Opening Remarks
Andy Liu, Head of China, **NOVOTECH**

9:15 am - 9:45 am
Global Landscape and Regulatory Considerations for Advanced Therapies
Scott Schliebner, VP, Drug Development Consulting, **NOVOTECH**

9:45 am - 10:15 am
Best Practices for Conducting Radiopharmaceutical Therapy Trials
Jieli Hu, Associate Director, Project Management, **NOVOTECH**

10:15 am - 10:30 am
Tea Break

10:30 am - 11:00 am
Clinical Strategy for Oversea RNA Trials
Catherine Xu, Associate Director, Operational Strategy Lead, **NOVOTECH**

11:00 am - 11:30 am
Innovation and Future Directions in Gene Therapy
Bob Zhang, CEO, **EPIGENIC**

11:30 am - 12:00 pm
Panel Discussion: Overcoming Challenges in Advanced Therapy Development

Moderator:

Barry Murphy, Chief Commercial Officer, **NOVOTECH**

Panelists:

Scott Schliebner, VP, Drug Development Consulting, **NOVOTECH**
Bob Zhang, CEO, **EPIGENIC**
Xiao Li, Associate CDMD, **NOVARTIS**
Xurui Jin, Partner, **MINDRANK**
Andrew Lin, Founder & CEO, **LINGYI BIOTECH**
Nathan Chen, CEO, **HOPE MEDICINE**

Afternoon Workshop - 1:30 pm - 6:00 pm - November 11 (JW's Ballroom B, 5th Floor)

Fostering China-Global Clinical Development Success: Insights & Practices

Featured Afternoon Workshop Organized by: ppd by Thermo Fisher Scientific

1:30 pm - 1:45 pm
Partnering for Success: Empowering Clinical Development from China to the World
Miguel Faustino, President, **THERMO FISHER CHINA**

Session 1: Leverage Effective Solutions for Your China - Global Clinical Development Success

1:45 pm - 2:10 pm
How to More Efficiently Meet Your Timelines Using FSP Engagements
Les Enterline, SVP, Global Head, Functional Service Partnership Solutions, **PPD**

2:10 pm - 2:35 pm
Operational and Regulatory Considerations in Early Phase Development
Trang Gisler, VP, Early Development CRO Segment, **PPD**

2:35 pm - 3:00 pm
Regulatory Considerations and Successful Experiences in the Development of Multi-regional Clinical Trials (MRCT) in Europe
Guoliang Liu, Director, Regulatory Affairs, **PPD**

3:00 pm - 3:15 pm
Case Study-Support China Biotech in FDA NDA Approval
Xianyi Kong, Biostatistics Director, **PPD**

3:15 am - 3:45 pm *Panel Discussion*
How To Leverage Effective Solutions for China-Global Clinical Development Success
Moderator: **Dongning Zang**, VP & Head of China Clinical Development, **PPD**
Panelists:
Xiaoxiang Chen, CEO, **TENACIA**
Stella Shi, Founder, CEO and Chairman of the Board, **RONA THERAPEUTICS**
Samantha L. Hadfield, VP, Business Segment Lead – FSP Operational Delivery, **PPD**
Trang Gisler, VP, Early Development CRO Segment, **PPD**
Valerie Brown, VP, Quality, Enterprise Learning & EHS, **PPD**
Guoliang Liu, Director, Regulatory Affairs, **PPD**
Xianyi Kong, Biostatistics Director, **PPD**

3:45 pm - 3:50 pm **Tea Break**

Session 2: Key Considerations in China - Global Clinical Development Operational Excellence

3:50 pm - 4:15 pm
Inspection Support for Addressing Global Regulatory Updates: Strategies and Implementation
Valerie Brown, VP, Quality, Enterprise Learning & EHS, **PPD**

4:15 pm - 4:40 pm
From Benchtop to Bedside – Practical Applications for Early Development Success
Darin Brimhall, VP, Strategic Medical, Early Development, **PPD**

4:40 pm - 5:05 pm
Solutions for Successfully Delivering in MRCT
Rania Laguel, VP, Pillar Head for Rare Diseases and Benign Hematology, EMEA and APAC Biotech Business Segment Lead, **PPD**
David Dai, Director, Project Management, **PPD**

5:05 pm - 5:20 pm
Laboratory Partnership Perspective: Key Success Factors in MRCT Clinical Development
Xibin Yang, Account Director, Business Development, **PPD**

5:20 pm - 5:55 pm *Panel Discussion*
Key Considerations in China - Global Clinical Development Operational Excellence
Moderator: **Grace Geng**, VP and Head of Commercial, China, **PPD**
Panelists:
Anbo Xiang, President, Clinical Business Unit and CMO for Non-Oncology, **CSPC**
Yonghong Zhu, CMO, **EPIMAB BIOTHERAPEUTICS**
Valerie Brown, VP, Quality, Enterprise Learning & EHS, **PPD**
Darin Brimhall, VP, Strategic Medical, Early Development, **PPD**
Rania Laguel, VP, Pillar Head for Rare Diseases and Benign Hematology, EMEA and APAC Biotech Business Segment Lead, **PPD**

5:50 pm - 6:00 pm **Wrap Up**
Ming Ding, SVP and General Manager, China Operations, **PPD**

Workshop 3 - 1:30 pm - 3:30pm - November 11

Going Global and Innovation: The Practice and Value of Endpoint Management of Oncology Clinical Trials

Organized by: MERIT — Your Clinical Endpoint Expert

With the rapid development of the global pharmaceutical industry and continuous innovation in new drug research and development, clinical research on oncology drugs has become a focal point in the industry. Endpoint management in clinical trials, as a key factor in assessing efficacy and safety, directly impacts the speed of drug approval and market entry. However, endpoint management faces not only stringent regulatory requirements but also the complexity and diversity of clinical practice. Particularly in oncology drug development, the challenge of balancing quality and efficiency has become a widely discussed topic within the industry.

This forum focuses on " Going Global and Innovation: The Practice and Value of Endpoint Management of Oncology Clinical Trials," inviting multiple experts and scholars to discuss innovative practices in endpoint management, share successful experiences, and look ahead to future development trends.

1:30 pm - 1:35 pm
Welcome Remarks
David Huang, China GM, **MERIT**

1:35 pm - 1:50 pm
Who Protects My Study Endpoint: How to Avoid Bias in Medical Monitoring
Chengyu Lin, Associate Medical Director, **MERIT**

1:50 pm - 2:05 pm
Protecting the Study Endpoint, Starting from the Sponsor's Interest: Aiming for the End, Balancing Quality and Speed
Alex Wang, Director, Project Management, **MERIT**

2:05 pm - 2:25 pm
Key ADC - Global Perspective on Clinical Development and Strategic Considerations
Steve Chin, CMO, **MEDILINK THERAPEUTICS**

2:25 pm - 2:45 pm
Suggestions on the Value of Using IRC in Clinical Trials for Chinese Oncology Drugs
Jian Peng, Executive Vice President, Clinical Development & Regulatory, **ZELGEN BIOPHARMA**

2:45 pm - 3:30 pm
Panel Discussion: New Challenges and Future Developments in Clinical Trials
Moderator:
Ming Zhou, CMO, **BOAN BIOTECH**

Panelists:
Yuan Lu, Head of Clinical Strategy and Operation, **ABBISKO THERAPEUTICS**
Yehua Zhu, Head of Clinical Science, **ELPISCIENCE BIOPHARMA**
Jian Peng, Executive Vice President, Clinical Development & Regulatory, **ZELGEN BIOPHARMA**
Steve Chin, CMO, **MEDILINK THERAPEUTICS**
David Huang, China GM, **MERIT**

Workshop 4 - 4:00 pm - 6:00pm - November 11

Crossroads of Innovation - Winning With Strategy & Science: How to Stand Out in the Next Wave of R&D

Organized by: Tigermed

Moderator: **Yueqin Ding**, E-site Regional Director, **TIGERMED**

4:00 pm - 4:30 pm
The Future Path of Cancer Drug Development
Hongxia Wang, Director of General Medicine, **FUDAN UNIVERSITY SHANGHAI CANCER HOSPITAL**

4:30 pm - 5:00 pm
Case Analysis and Strategic Considerations for Patient Selection in Early-Stage Research
Xia Chen, Senior Vice President and Chief Medical Officer, **TIGERMED**

5:00 pm - 5:30 pm
The Future of Clinical Trials - Reshaping Possibilities
Jiaojiao Yu, Vice President,Head of DCT Business, **TIGERMED**

5:30 pm - 6:00 pm
Analysis of Investment and Development Trends in Conjugated Drugs
Linjie Zhang, Senior Consultant, Investment Data, **PHARMCUBE**

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MAIN PROGRAM

November 12-13, 2024

CHINATRIALS 16
CLINICAL DEVELOPMENT LEADERS' SUMMIT

Pharma 研发客

Main Program: Tuesday, November 12
(JW Ballroom, 5th Floor)

7:45 am - 8:30 am

Main Registration

8:30 am - 8:45 am

Opening Remarks

Frank Jiang
Chief Strategy Officer
HENGRUI PHARMA

Jialing Dai
President & Publisher
PHARMADJ

8:45 am - 9:15 am

China Biotech: Innovation Upgrade and Going Global

Fangning Zhang
Partner
MCKINSEY & COMPANY

9:15 am - 10:15 am

Opening Keynote Session

China Biopharma Innovation: Recalibrating Expectations and Moving the Industry Forward

Moderator:
Frank Jiang
Chief Strategy Officer
HENGRUI PHARMA

Panelists:
Jian Zhang
Director of Phase I Clinical Trial Center
FUDAN UNIVERSITY SHANGHAI CANCER CENTER

Darren Ji
Chief Executive Officer
ELPISCIENCE

Weikang Tao
Corporate VP & General Manager
Global R&D of Innovative Medicines
QILU PHARMACEUTICALS

Neo Zhang
Managing Director
CBC GROUP

Fangning Zhang
Partner
MCKINSEY & COMPANY

10:15 am - 10:40 am

Networking Break

10:40 am - 11:30 am

MNC Perspectives: The Evolving Role of Big Pharma in China

Moderator:
Donglei Mao
Editor-in-Chief
PHARMADJ

Panelists:
Wei Zhang
SVP, Head of Medicine, Greater China
BOEHRINGER INGELHEIM

Xingli Wang
Executive President, Co-CEO of Innovative Medicines Division, CEO of Global R&D Center
FOSUN PHARMA

Yu Chen
China Development Head
AMGEN

Jing He
SVP, Head of China R&D
ASTRAZENECA

Gary Tong
VP of Research and Development, Head of TDC Asia
TAKEDA

11:30 am - 12:20 pm

New Trends in Clinical Trial Design from the FDA ODAC Meeting

Moderator:
Feng Chen
Professor of Statistics
NANJING MEDICAL UNIVERSITY

Panelists:
Gang Chen
CSO
R&G PHARMASTUDIES

Xing Sun
Vice President of Biostatistics & Information Science
INNOVENT BIOLOGICS

Jie Chen
Chairman and Chief Scientific Officer
ECR GLOBAL

Jingjun (Jeannie) Qiu
VP of Global R&D Center
GM of Biometrics and Data Science
FOSUN PHARMA

Chao Zhu
Head of Medical Science, Drug Development & Medical Affairs Center
LILLY CHINA

12:20 pm - 1:10 pm **Networking Lunch**

1:10 pm - 2:00 pm **Current Status for Conducting Clinical Trials at China's Top Sites: Investigators' Perspectives**

Moderator:
Helen Jiang
Chief Medical Officer
SHANGHAI BEST-LINK BIOSCIENCE

Panelists:
Jing Zhang
Pharmacist
HUASHAN HOSPITAL FUDAN UNIVERSITY

Shuhang Wang
Associate Chief Physician
CANCER HOSPITAL CHINESE ACADEMY OF SCIENCES

Jennifer Hou
Director, Clinical Research Center / CMO
GOBROAD HEALTHCARE GROUP

2:00 pm - 2:50 pm **Innovative Practices and Prospect of DCT in China**

Moderator:
Kevin Lin
Chief Executive Officer
XINCERE MEDICAL

Panelists:
Weian Yuan
Vice President
SHUGUANG HOSPITAL

Mia Sun
Senior Manager
PFIZER

Zhihong Lu
Chief Medical Officer
ZHIMENG BIOPHARMA

Vela Shi
Head of Quality, China Pharma Service Group
PATHEON

Parvin Wang
CNS Clinical Development Head
HENGRUI MEDICINE

2:50 pm - 3:20 pm **Networking Break**

Main Program: Tuesday, November 12
(JW Ballroom, 5th Floor)

3:20 pm - 4:10 pm

Opportunities for China Biopharma Clinical Development in Japan and Asia

Moderator:

Helen Chen
Global Sector Co-Head for Healthcare
Greater China Managing Partner
L.E.K. CONSULTING

Panelists:

Yiming Du
Senior Vice President
HAIHE BIOPHARMA

Jin Li
General Manager, Regulatory Affairs
HENLIUS BIOTECH

Tetsuomi Takano
Founder and Chief Executive Officer
T2T HEALTHCARE

Yuta Inokuchi
Representative Director, Partner Tokyo
L.E.K. CONSULTING

4:10 pm - 5:10 pm

The Future of CNS Drug Development in China

Moderators:

PJ Chen
Chief Executive Officer
CALI BIOSCIENCES

Xianbo Zhou
Founder & Chief Executive Officer
ASTRANEURA

Panelists:

Yelin Chen
Researcher
INTERDISCIPLINARY RESEARCH CENTER ON BIOLOGY & CHEMISTRY (IRCBC)

Joan Shen
Chief Executive Officer
NEUSHEN THERAPEUTICS

Yan Cheng
Executive Medical Director, CNS
ELI LILLY & COMPANY

5:10 pm - 5:40 pm

Current Status and Future Trends of Lung Cancer Drug Research from the Perspective of Chinese PI

Caicun Zhou
Directory, Oncology
EAST HOSPITAL AFFILIATED TO TONGJI UNIVERSITY

5:40 pm

End of Day

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CHINATRIALS 16
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Main Program: Wednesday, November 13

(JW Ballroom, 5th Floor)

8:45 am - 9:00 am

Opening Remarks

9:00 am - 9:30 am

Trends and the Application of AI in R&D

Tingting Wu
Director
DELOITTE

9:30 am - 10:20 am
Keynote Panel

Annual China Leaders' Roundtable: New Strategy in the Era of Licensing

Moderator:
Jason Yang
Chief Executive Officer & Executive Director
CSTONE PHARMA

Panelists:

Jing Li
Head of Global Product Development
HENLIUS BIOTECH

Bin Peng
Medical Advisor
ENNOVABIO / CYTOSINLAB

Michael Shi
Chief Medical Officer
HUTCHMED

Ye Hua
Chief Executive Officer
BIONOVA PHARMA

10:20 am - 10:45 am

Networking Break

10:45 am - 11:35 am

M&A and Deal-Making in the Current Environment

Moderator:
Wenseng "Wendy" Pan
Partner, Head of Life Sciences Asia
GOODWIN

Panelists:

Jonathan Wang
Chief Business Officer
ZAI LAB

Dongxu Shu
Chief Executive Officer
ARGO BIOPHARMA

Albert Ren
VP, Strategy & Business Development
PFIZER

Zhaoyu Jin
Chairman & CEO
FUTUREGEN

Yu Qi
Associate Director, Pacific BD & Licensing
MSD

Min Zhong
Chief Operating Officer
REGOR THERAPEUTICS

Main Program: Wednesday, November 13

(JW Ballroom, 5th Floor)

11:35 am - 12:25 pm

How to Leverage AI to Improve the Efficiency and Quality of Clinical Development

Moderator:
Dong Ma
SVP and Head of Systems Division
TAIMEI TECHNOLOGY

Panelists:
Cynthia Liu
Data Management Director
SIMCERE PHARMACEUTICAL

Jie Chen
Chairman & CSO
ECR GLOBAL

Mengying Xia
Senior Director, Clinical Operations
AKESO BIO

Chris Wang
Head, Enterprise Solutions Team,
Alibaba Cloud Intelligence Group, Shanghai
ALIBABA CLOUD COMPUTING

12:25 pm - 1:15 pm

Networking Lunch

1:15 pm - 2:00 pm

Radionuclide Drug Conjugates (RDCs) for Next Generation Therapeutics

Moderator:
Shirley Xu
Chief Executive Officer
TEDDY CLINICAL RESEARCH LAB

Panelists:
Ziwen Wang
Head of RLT Franchise
NOVARTIS CHINA

Amy Tang
President
SINOTAU

Daisy Zhang
VP, Medical
SMARTNUCLIDE

2:00 pm - 3:00 pm

Former FDA Experts Analyze a Virtual Case of an SiRNA New Drug from IND to NDA

Moderator:
Donglei Mao
Editor-in-Chief
PHARMADJ

Panelists:
Yaning Wang
Founder & Chief Executive Officer
RUI NING KANG PHARMA

Shen Xiao
Chief Medical Officer
HASTEN BIOPHARMACEUTICAL

Gang Wang
Deputy General Manager
JUNSHI BIOSCIENCES

Gang Chen
Chief Scientific Officer
R&G PHARMASTUDIES

3:00 pm - 3:30 pm

How To Develop Lung Cancer Drugs Based on Clinical Needs To Ensure Approval by the CDE

Shun Lu
Director, Oncology Department &
Deputy Director, Clinical Trial Institution
SHANGHAI CHEST HOSPITAL

Main Program: Wednesday, November 13

(JW Ballroom, 5th Floor)

3:30 pm - 4:30 pm

IND Pilot from 60 to 30 Working Days: Opportunities and Challenges for Registration and Trial Initiation

Moderator:
Jianqing Chang
VP, Drug Regulatory Policy
TIGERMED

Panelists:
Yanfei Liu
Director, Clinical Institute
FUDAN UNIVERSITY SHANGHAI CANCER CENTER

Julia Wang
VP, Clinical Development
ELI LILLY & CO.

Fang Xiao
Strategy, Policy & Intelligence Lead
J&J INNOVATIVE MEDICINE

Angela Jiang
Senior Vice General Manager, Regulatory Affairs
HENGRUI

Tracy Gong
Regulatory Affairs Director
ROCHE

4:30 pm

CHINATRIALS 16 Concludes