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

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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*

Featured Afternoon Workshop Organized By: MERIT Your Clinical Endpoint Expert

***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 blue ocean and focus on strategic transformations from a global perspective? How to explore 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 radiotherapy, RNA, and gene therapies. In collaboration with leading experts, we encourage all attendees to join us in exploring insights and engaging 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 Radiotherapy 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**

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**
Jian Peng, Executive Vice President, Clinical Development & Regulatory, **ZELGEN BIOPHARMA**
Steve Chin, CMO, **MEDILINK THERAPEUTICS**
David Huang, China GM, **MERIT**

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MAIN PROGRAM

November 12-13, 2024

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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

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

10:40 am - 11:30 am

MNC Perspectives: The Evolving Role of Big Pharma in China

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

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

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

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

Jie Chen
Chairman and Chief Scientific Officer
ECR GLOBAL

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

Xiaoni Liu
Head of Biostatistics Department, China
NOVARTIS

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

Nanya Wang
Deputy Director, Oncology
THE FIRST BETHUNE HOSPITAL JILIN UNIVERSITY

Shuhang Wang
Associate Chief Physician
CANCER HOSPITAL CHINESE ACADEMY OF SCIENCES

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

Zhihong Lu
Chief Medical Officer
ZHIMENG BIOPHARMA

Xinning Wang
Medical Director
HENGRUI MEDICINE

Xiaojing Sun
Senior Manager
PFIZER

Vela Shi
Head of Quality, China Pharma Service Group
PATHEON

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 Biotech Clinical Development in Asia

Moderator:

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

Panelists:

Ruiping Dong
Chief Executive Officer
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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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

David Xie
Partner, China Life Sciences & Healthcare
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:

Jason Zhu
Executive Director & CEO
HENLIUS BIOTECH

Bin Peng
Medical Advisor
ENNOVABIO

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

Zhihong Chen
Chief Executive Officer
CURON

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:
Li Liu
Director, Data Management
SIMCERE

Jie Chen
Chairman & CSO
ECR GLOBAL

Mengying Xia
Director, Clinical Operation
AKESO BIO

Jieping Ye
Head of Technology for Large Models
ALIBABA

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

How Can a Company's Asset Successfully Proceed from IND to NDA: A Hypothetical Case Study From a Panel of Former U.S. FDA Reviewers

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

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