Organized By

CHINATRIALS+US

PARALLEL CLINICAL DEVELOPMENT SUMMIT

July 30 - 31, 2019 - Boston, USA

2019 Theme:

Parallel Clinical Development in China + US:
Driving Global BioPharmaceutical Innovation Together

Co-Organized By:

2019 PROGRAM AGENDA

www.chinatrials.com/us_boston

Agenda & Schedule of Events

JULY 30

7:30 am – 8:15 am	**Main Conference Registration**
8:15 am – 8:30 am	Chairperson's Opening Remarks **After 11 Years, ChinaTrials Summit Comes to the US: Why Now?** **Frank Jiang** Chief Executive Officer **CSTONE PHARMACEUTICALS**
8:30 am – 9:00 am	Knowledge Insights Presentation **The New Normal: US + Chinese BioPharma to Drive the Next Generation of Innovative Medicines** **Ian Tzeng** Managing Director **LEK CONSULTING**
9:00 am – 10:00 am	Keynote Session **Clinical & Regulatory Overview of US + China: The Great Opportunity Emerging in the Current Landscape** **US:** The pressure is increasing in the US for biopharmaceutical companies to lower prices and this may bring a great opportunity for Chinese biotechs to bring their drugs to the US. The FDA has said on numerous occasions recently that they would welcome applications for approval of drugs with clinical data generated only in China, as long as high-quality level standards are met. **China:** In less than 24 months China has radically altered the global clinical development landscape, creating new pathways to commercialization. Since joining ICH as a full regulatory member in June 2017, the country has refocused its regulatory process on rapid approval of innovative therapies and devices, with non-Chinese biopharma firms emerging as the main beneficiaries. Speakers: **Barbara Weber** Chief Executive Officer **TANGO THERAPEUTICS** **Frank Jiang** Chief Executive Officer **CSTONE PHARMACEUTICALS**

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10:00 am – 10:30 am	**Networking Break**
10:30 am – 11:00 am	**Investor Perspective: Beginning With the End in Mind & Market Reaction to Clinical Data** Bihua Chen Chief Executive Officer & Portfolio Manager **CORMORANT ASSET MANAGEMENT**
11:00 am – 11:45 am	**The Next 10 Years: How Can/Will China's Innovation Push Dramatically Transform the Global Clinical Ecosystem for Advancing New Patient Therapies?** Through the macro-level strategic lens, MNC Pharma's view of China as a destination for drug development is still very much influenced by opportunities for labor arbitrage, treatment-naive patients, as well as a large population for clinical trial participation and a huge market. Over the past 10 years, a relatively short period, China's tremendous contributions to global biopharmaceutical development have not only realized these opportunities, but gone beyond to run the gamut from producing me-too, to me-better, to first-in-class therapies, while supporting innovation-based biotechnology advancement in key areas such as CAR-T, CRISPR, Big Data and A.I. In this exciting forward-looking session, we will discuss and debate what the global clinical ecosystem might look like 5-10 years from now, and what roles the US and China may both play. Moderator: Cory Williams Vice President, Global Product Development (Former) **PFIZER** Speakers: James Li Chief Executive Officer **JW THERAPEUTICS** Ryan Roller Director, Life Science & Healthcare **SILICON VALLEY BANK** Frank Jiang Chief Executive Officer **CSTONE PHARMACEUTICALS** Sean Zhang Chief Executive Officer **HENGRUI THERAPEUTICS**

Agenda & Schedule of Events

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11:45 am – 12:30 pm

Lessons Learned from Successful Clinical Development in China by Western Biotechs

- Attractions: Availability of subjects, speed of recruitment, patient costs, potential source of funding
- Getting over the hump: Where to start? What questions to ask?
- Do the benefits outweigh the complexity and management challenges
- How to ensure quality? Can manage from outside of China
- Using China data to support US/global registration

Moderator:
George Baeder
Senior Vice President, Strategy
DMED

Speakers:
Donnie McGrath
Chief of Corporate Strategy & Business Development
BIOHAVEN PHARMACEUTICALS

Qais Mekki
Head of Clinical Science (US), Marketed Products
TAKEDA PHARMACEUTICALS

Cory Williams
Vice President, Global Product Development (Former)
PFIZER

12:30 pm – 1:30 pm

Networking Lunch

1:30 pm – 3:00 pm

How to Navigate the Chinese Clinical and Regulatory Landscape: Challenges and Strategies for US Biotechs

- What advice would you give to other US biotechs?
- What are the most common pitfalls companies need to be aware of and how do you avoid them?

Workshop Leaders:
Min Irwin
Chief Executive Officer
REISTONE BIOPHARMA

Bin Peng
Chief Medical Officer
EPIMAB BIOTHERAPEUTICS

Susie Tan
Chief Medical Officer
HLT PHARMA

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JULY 30

3:00 pm – 5:00 pm

How to Navigate the US Clinical and Regulatory Landscape: Challenges and Strategies for Chinese Biotechs

- How did you approach clinical development and registration in the US?
- When is the best time to start? What infrastructure do you need to have in the US to make it work? What out side resources did you use and why?
- What are the biggest surprises or challenges in seeking drug registration in the US? How did you deal with these?

Workshop Leaders:

George Baeder
Senior Vice President, Strategy
DMED

Joan Shen
President of R&D
I-MAB BIOPHARMA

Jules Mitchel
Senior Vice President, Strategy
TARGETHEALTH

Eric Zhang
Vice President, Regulatory Affairs & Strategy
DMED

5:00 pm – 6:00 pm

Combining the US + China's Strengths for the Ultimate Global Development Strategy

Moderator:
Dan Zhang
Executive Chairman
FOUNTAIN MEDICAL DEVELOPMENT

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6:00 pm – 7:30 pm

"Meet & Greet Biotechs" Networking Cocktail Reception

This early evening cocktail reception is designed to faciliate networking and introductions to all attendees of the Summit. will feature 15 networking roundtables each hosted by up to 2 US or China-based biotechs. Any fully registered biotech company at the Summit may apply for a table; fulfilled on a first-come, first-serve basis so register early!

Use this opportunity to stop by the tables to informally meet with the CEOs/CMOs of these companies and learn more about what technologies and treatments each company is developing, make new friends and potentially begin your next partnership. These tables will be informal in nature and are designed to help promote networking between all biotech participants.

Enjoy drinks and finger foods served around while you network!

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JULY 31

8:00 am – 8:10 am	**Opening Remarks** Wenru Song President, Head of R&D / Board Director **KIRA PHARMACEUTICALS / CAHON**
8:10 am – 9:30 am	**East to West & West to East: The PI / Clinician's Perspective on Conducting Clinical Trials in the US and China** Moderator: Wenru Song President, Head of R&D / Board Director **KIRA PHARMACEUTICALS / CAHON** Panelists: **Delong Liu** Professor of Medicine **NEW YORK MEDICAL COLLEGE / CAHON** **Zhen Su** Senior Vice Presidenbt, Global Head of Oncology Unit **EMD SERONO / CAHON** **Jiping Wang** Associate Director, Hepatobiliary Cancer, Division of Surgical Oncology **BRIGHAM & WOMEN'S HOSPITAL / CAHON** **Ruirong Yuan** President, Chief Medical Officer / Department of Medicine **ADLAI NORTYE BIOPHARMA** **NEW JERSEY MEDICAL COLLEGE / VA HOSPITAL / CAHON** **Lei Zheng** Associate Professor **BLOOMBERG-KIMMEL INSTITUTE FOR CANCER IMMUNOTHERAPY** **JOHNS HOPKINS MEDICINE / CAHON** **Tony Ho** Executive Vice President, Head of R&D **CRISPR THERAPEUTICS / CAHON**

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9:30 am – 10:15 am

How China Can Support Global Drug Development

Clinical development for new and innovative new pipeline products have become more complex and competitive, particularly with pipeline products close to each other in the R&D stage. Clinical development in China has evolved for the last 15 years. This session will focus on the following areas:

- What are the advantage and disadvantage to include China in the global development?
- When is the best time to include China in the development?
- How to engage in China in the global development?

Moderator:
Min Irwin
Chief Executive Officer
REISTONE BIOPHARMA

Speakers:
William Wang
Executive Director, Clinical Safety Statistics
MERCK RESEARCH LABORATORIES

Yaping Shou
Chief Medical Officer
TRILLIUM THERAPEUTICS

Sean Zhang
Chief Executive Officer
HENGRUI THERAPEUTICS

Yong Yue
Chief Medical Officer
LAEKNA THERAPEUTICS

10:15 am – 11:00 am

Sailing West: How Chinese Companies Can Navigate a Changing US Clinical Trials Landscape

With perspectives from Chinese and U.S. biotech executives, this panel will delve deep into the challenges and opportunities for Chinese companies as they build global drug development programs. The discussion will focus on U.S. FDA's push to modernize drug R&D and how companies in the US/China can or are rethinking how they develop drugs, including, novel trial designs, the establishment of new surrogate endpoints and the sources of data used to support regulatory filings.

Moderator:
Erin McCallister
Senior Editor & Head, Clinical Development & Market Access
BIOCENTURY

JULY 31

Speakers:

Eric Rubin
Senior Vice President, Clinical Oncology
MERCK & CO.

Sanjeev Redkar
President
APOLLOMICS

Yuri Maricich
Chief Medical Officer & Head of Clinical Development
PEAR THERAPEUTICS

11:00 am – 11:30 am

Networking Break

11:30 am – 12:15 pm

How to File IND in Both China + US Simultaneously: Lessons Learned from Leading Chinese Biotechs

This session will bring together leading Chinese biotechs that are following a strategy to file IND in both China + US. They will share their key learnings and challenges to consider when implementing such a strategy.

- Best practices case studies when planning simultaneous trials in China + US
- Biomarkers Hurdle: shipment of samples between China + US is challenging
- Managing the risks: different medical practice, different regulatory systems

Moderator:

Bin Peng
Chief Medical Officer
EPIMAB BIOTHERAPEUTICS

Speakers:

Chris Lu
Chief Executive Officer
LAEKNA THERAPEUTICS

Joan Shen
President of R&D
I-MAB BIOPHARMA

Naiqi Ya
President
EVENUS PHARMACEUTICAL LABORATORIES

JULY 31

12:15 pm – 1:00 pm	**Utilizing US Data for China Submission** Moderator: Sanjeev Redkar President **APOLLOMICS** Speakers: Jonathan Wang Senior Vice President, Business Development **ZAI LAB** Minori Koshiji Rosales Vice President, Clinical Development **MACROGENICS** Anna Vardanyan Executive Director, BD & Alliance Management **EVEREST MEDICINES**
1:00 pm – 2:00 pm	**Networking Lunch & ChinaTrials+US Summit Conclusion**
2:00 pm – 4:00 pm	**"Chinese Biotech Company Showcase" Networking Tables** The second afternoon of the Summit will feature 10 networking roundtables each hosted by a China-based biotech. Any fully registered biotech company at the Summit may apply for a table; fulfilled on a first-come, first-serve basis so register early!
4:00 pm	**ChinaTrials+US Summit Concludes**

For more information or to register, please visit: www.chinatrials.com/us_boston