

2016 BBA-BBF Joint Symposium

Global Simultaneous Drug Development

May 21st, 2016 • Beijing

To facilitate discussion on acceleration of simultaneous drug development around the world, Beijing Biometrics Association (BBA) - Beijing Biometrics Forum (BBF) organized this joint symposium on recent advances in the design and conduct Multi-Regional Clinical Trials (MRCTs).

We invite you to participate in the discussion and share with others your ideas and valuable experience. Please find below details of the symposium and register as requested if you are interested.

To ensure the efficiency and productiveness of the symposium, total number of participants will be limited to no more than 120.

MRCT: A multiregional trial conducted in more than one region under a common protocol

Co-organizers

BBA, BBF

Sponsorship

Statistical Consulting Center, Renmin University of China

MRCT Center of Brigham and Women's Hospital and Harvard University

J&J China R&D

Merck Sharp & Dohme, MSD

Ipsen(Beijing)Pharmaceutical Science and Technology Development Co.,Ltd



Theme: Simultaneous Drug Development using MRCT approach

Who should attend: Biostatistician, Regulatory personnel, and other clinical research-related staff in pharmaceutical industry, academia and regulatory agency

Date: May. 21st, 2016 (Saturday)

Moderator: Gang Chen (J&J) / Rebecca Li (MRCT Center of Brigham and Women's Hospital and Harvard University)

Venue: Renaissance Beijing Wangfujing Hotel (北京金茂万丽酒店)

Venue transportation: Located in Wangfujing Street, near subway Line 5 and Line 6

Agenda	Presenter	Time
Registration		8:00~8:30
Greetings and opening remarks	Gang Chen / Rebecca Li	8:30~8:40
Morning session - Overview, Current Regulations and Practice Chair: Gang Chen		8:40~12:00
• MRCT : Overall introduction and ICH E17 update	Rebecca Li (MRCT center)	8:40~9:25
• MRCT: Legal issues affecting globalization in China	Mark Barnes (MRCT center)	9:25~9:55
Coffee break		9:55~10:15
• MRCT: Considerations on consistency	Feng Chen (Nanjing Medical University)	10:15-10:45
• Panel Discussion	Panel Members	10:45~11:45
Luncheon		11:45~13:30
Afternoon session – Design strategies, stat methods and case studies Chair: Rebecca Li		13:30~17:30
• Type I error control in MRCT Consistency Test	Jielai Xia (FMMU)	13:30~14:00
• Assessment of Statistical methods for level 3 consistency	Justin Li/Fei Chen (J&J)	14:00~14:30
• Consistency evaluation in MRCT non-inferiority trials	Xiang Guo (MSD)	14:30~ 15:00
Coffee break		15:00~15:20
• MRCT: DMC monitoring statistical and other indicators of differences or non-compliance in MRCT trials	Robert Makuch (Yale University)	15:20~15:50
• MRCT – Statistical considerations fits into the landscape of regulatory sciences in Asia	Luyan Dai (BI)	15:50-16:20
• Panel Discussion	Panel Members	16:30~17:25
Closing remarks	Rebecca Li / Gang Chen	17:25~17:30

Panel list (listed alphabetically):

CDE

Mark Barnes

Feng Chen

Fei Chen

Gang Chen

Yao Chen

Luyan Dai

Xiang Guo

Justin Li

Rebecca Li

Robert Makuch

Jielai Xia

Registration:

Registration fee will be 1200RMB/person (**Free for presenters**). You can pay with your credit/debit cards or cash at reception desk on the day of symposium.

Please send email with registration form to the registration contact person below before April 15th (those without registration will not be allowed to enter the meeting venue given the limitation of accommodation capacity).

Yongji Wang J&J

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Venue transportation:

Located in Wang fujing Street, near subway Line 5 and Line 6

Location Map of : Renaissance Beijing Wangfujing Hotel

