

Sunday, November 23, 2014 - China Merchants Hall

By Invitation only: 2nd Annual Roundtable: Biomarkers and their use in Targeted Drug Discovery

All ACT China faculty and guest commentators are invited to participate in this session.

Date	Subject	Speaker/Chair
07:00 - 07:45	Breakfast (OPEN Restaurant)	
Co-Chairs: Yilong Wu, Jin Li, Tony Mok		
07:45 - 08:00	Welcome and Overview	Tony Mok
08:00 - 08:30	Concepts of biomarker development and validation: their role in targeted drug development and biomarkers in clinical oncology	Monica Bertagnolli
08:30 - 09:15	Regulatory framework for molecular testing -- EU regulatory guidance on the use of biomarkers in oncology drug development (I. Gravanis) -- TBD (M. Ning)	Regulatory Guest Commentators
09:15 - 09:30	Current status of biomarker testing in China Adaptive design - 9291	Tony Mok Yilong Wu
09:30 - 10:15	Cancer biomarker tests available in China	10-15 minutes each
10:15 - 11:00	What are the biomarker testing needs in China?	Open discussion (all attendees)
11:00 - 11:45	Regulatory challenges	Open discussion (all attendees)
11:45 - 12:00	Next steps; adjourn	Jin Li
12:00 - 13:00	Lunch (OPEN Restaurant) and departures	