

Preliminary Course Agenda

Friday, November 21, 2014 - Seaworld Grand Ballroom I

Time/Room	Subject	Speaker/Chair
07:00 – 07:50	Breakfast (OPEN Restaurant)	
Co-chairs: Prof. Yi-Long Wu and Prof. Jin Li		
08:00 – 08:15	Welcome and introduction	Yi-Long Wu, Jin Li
08:15–08:45	Introduction to the Characterization and Validation of Biomarkers	Jin Li
08:45–09:00	Q&A	
Phase II biomarker driven clinical trials		
09:00–09:30	Pharmacokinetics, drug-target interactions, and identifying adverse events in Phase II biomarker driven clinical trials	J. Jack Lee
09:30–09:45	Q&A	
09:45-10:00	Morning tea	
10:00–10:30	Phase II biomarker driven clinical trials: objectives, design and endpoints (what’s been done/issues)	Xiaodong Zhu
10:30–10:45	Q&A	
10:45–11:15	Phase II biomarker driven clinical trial development in Leukemia	Lin Qiu
11:15–11:30	Q&A	
11:30-12:00	Panel discussion: Phase II biomarker driven clinical trials, including DMCs and/or other clinical trial committees.	CSCO, Visiting Faculty, and Guest Commentators, Iordanis Gravanis, Max Ning
12:030–13:00	Lunch (Seaworld Grand Ballroom II)	
Co-chairs: Prof. Yi-Long Wu and Prof. Jin Li		
13:00–13:15	Welcome and housekeeping announcements	Yi-Long Wu
13:15–13:45	Development and validation of biomarkers as clinical tests (include genomic markers and companion diagnostics)	Monica Bertagnolli
13:45–14:00	Q&A	
14:00–14:30	Statistical considerations for Phase II biomarker driven trials and adaptive design	J. Jack Lee
14:30-14:45	Q&A	
14:45-15:00	Afternoon tea	
15:00–15:30	Master Protocol Design Considerations and endpoint selection for Phase II biomarker driven	Monica Bertagnolli

	clinical trials	
15:30–15:45	Q&A	
15:45-16:15	Do we need Phase II trial in biomarker driven study era?	Yi-Long Wu
16:15–16:30	Q&A	
16:30-17:00	Panel discussion: Use of Phase II clinical trials in the era of biomarker driven research	CSCO, Visiting Faculty and Guest Commentators
18:30 – 20:00	CSCO Gala Banquet (Seaworld Grand Ballroom II)	

Saturday, November 22, 2014
General Session - Seaworld Grand Ballroom I;
Simultaneous workshops – China Merchants Hall I - IV

08:00–08:15	Welcome and housekeeping announcements	Yi-Long Wu
8:15–10:15	Simultaneous workshops	
	1. Phase II biomarker driven clinical trial development – Breast Cancer	Ning LIAO
	2. Phase II biomarker driven clinical trial development in Lung cancer	Qing Zhou, Jack Lee
	3. Phase II biomarker driven clinical trial development – GI/Gastric Cancer	Jin LI, Max Ning
	4. Phase II biomarker driven clinical trial development – Other cancer	Lin Qiu, Monica Bertagnolli
10:15–10:45	Morning tea	
10:45 – 11:45	Reports from the Workshops (15 minutes each)	
11:45 – 12:00	Q&A	
12:00 – 13:00 Lunch (Seaworld Grand Ballroom II)		
13:00 – 13:30	“Lessons Learned” Session	CSCO and Visiting Faculty
Co-chairs and Moderators: Prof. Jin LI, Jack Lee		
	Phase III biomarker driven bridging clinical trials	
13:30–14:15	Phase III biomarker driven bridging clinical trials: design considerations and real world examples	J. Jack Lee
14:15–14:30	Q&A	
14:30-14:45	Afternoon tea	
14:45–15:45	Regulatory Issues -- EU regulatory tools for accelerated authorisation (I. Gravanis) -- Tricks and traps of Phase II design (M. Ning)	Max Ning, Iordanis Gravanis
15:45 -16:30	Panel discussion; additional topics of importance to Scholars: communication skills, manuscript preparation and manuscript review,	CSCO and Visiting Faculty

	English presentation skills, editorial writing	
16:30 – 16:45	Closing remarks and ACT China adjourned; Departures	Yi-Long Wu
18:00 – 20:00	Dinner (Seaworld Grand Ballroom II)	