

DEPARTMENT of

BIOSTATISTICS

INFORMATICS

EPIDEMIOLOGY &

Optimizing Dose Selection Across the Clinical Trials Spectrum

8:15am-8:45am	Check-in and breakfast for in-person attendees
8:45am-9:00am	Opening/Logistics – Mary Putt, PhD, ScD, University of Pennsylvania Welcome – Emma Meagher, MD, Senior Vice Dean for Clinical and Translation Research, University of Pennsylvania Perelman School of Medicine
Morning Session: M	oderator - Yimei Li, PhD, University of Pennsylvania
9:00am-9:30am	Overview: Dose-Response Characterization: A Key to Success in Drug Development Frank Bretz, PhD, <i>Novartis AG</i>
9:30am	Joyce Cheng, PhD, Food and Drug Administration Regulatory Perspectives on Dosage Optimization for Oncology Drugs
9:55am	Ying Yuan, PhD, UT MD Anderson Cancer Center Statistical Designs and Strategies for Dose Optimization
10:20am	Man (Mandy) Jin, PhD, <i>Abbvie, Inc.</i> Comparison of Adaptive Seamless Phase 2/3 Designs with Dose Selection and Multiple Endpoints
10:45am-11:15am	Break
11:15am-11:45am	Panel Discussion: (Pamela Shaw, PhD, Kaiser Permanente WHRI – AM Online Facilitator) Elizabeth Garrett-Mayer, PhD, American Society of Clinical Oncology Ken Cheung, PhD, Columbia University Mailman School of Public Health
11:45am-12:15pm	Audience Discussion/Q&A Session
12:15pm-1:10pm	Lunch
Afternoon Session:	Moderator Devan Mehrotra, PhD, <i>Merck & Co., Inc.</i>
1:10pm-1:15pm	Welcome back for PM session – Devan Mehrotra, PhD
1:15pm	Weng Kee Wong, PhD, UCLA Fielding School of Public Health Nature-Inspired Meta-Heuristic Algorithms for Constructing Efficient Designs for Clinical Trials
1:40pm	Pavel Mozgunov, PhD, MRC Biostatistics Unit, University of Cambridge Practical Implementation of a Model-based Design in a Phase I Combination-schedule Dose- finding Trial
2:05pm	Michael Kosorok, PhD, UNC Gillings School of Global Public Health A SMART Clinical Trial for Chronic Lower Back Pain
2:30pm	Yunda Huang, PhD, Fred Hutch Cancer Center Dose Finding in HIV-1 Preventive Vaccine and Monoclonal Antibody Trials
2:55pm-3:30pm	Break
3:30pm-4:00pm	Panel Discussion: (Mary Putt, PhD, ScD, University of Pennsylvania – PM Online Facilitator) Anna Heath, PhD, SickKids Research Institute Kelley Kidwell, PhD, University of Michigan School of Public Health
4:00pm-4:15pm	Audience Discussion/Q&A Session