

MRCT Center 2017 Annual Meeting: AGENDA

Tuesday, December 5, 2017

Benedetto Restaurant, Charles Hotel, 1 Bennett Street, Cambridge, MA

6:00-8:30 PM	<p>Conference Dinner</p> <p>For Executive and Steering Committee, Conference Speakers and Panelists</p>
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Wednesday, December 6, 2017

Loeb House at Harvard University, 17 Quincy Street, Cambridge, MA

7:30 – 8:00	Breakfast & Registration
8:00 – 8:15	<p>Welcome & Introductions</p> <p>Moderator: Barbara Bierer and Mark Barnes</p>
8:15 – 8:45	<p>Keynote</p> <p>Alison Cave (European Medicines Agency):</p> <p style="padding-left: 40px;">EMA's Perspective on Real World Evidence and Regulatory Decision-Making</p> <p>Moderator: Mark Barnes</p>
8:45 – 9:45	<p>Real World Evidence</p> <p>Panel Discussion:</p> <ul style="list-style-type: none"> • William Crown (OptumLabs) • Sebastian Schneeweiss (Brigham and Women's Hospital) • Cathy Critchlow (Amgen) • David Martin (USFDA) <p>Moderator: Barbara Bierer Followed by group discussion and Q&A</p>

9:45 – 10:30	<p>Core Competencies for Clinical Research Professionals</p> <p>Framework Version 2.0 and expectations of professional competencies for advancement</p> <ul style="list-style-type: none"> • Steve Sonstein (Eastern Michigan University and MRCT Center Senior Advisor) <p>Panel:</p> <ul style="list-style-type: none"> • Rebecca Brouwer (Duke University) • William Gluck (Durham Technical Community College) • Robert Kolb (University of Florida) •Carolynn Thomas-Jones (Ohio State University) <p>Moderator: Steve Sonstein Followed by group discussion and Q&A</p>
10:30 – 10:45	<p>Break</p>
10:45 – 11:45	<p>Return of Individual Results: Genomics and Axes of Communication in Results Return</p> <p>Presentation Sandra Prucka (Indiana University)</p> <p>Panel Discussion:</p> <ul style="list-style-type: none"> • Elizabeth Cahn (Patient and Research Advocate) • Robert Green (Brigham and Women's Hospital) • Scott Kennedy (Novartis) • Carol Weil (National Institutes of Health) <p>Moderator: Mark Barnes Followed by group discussion and Q&A</p>

11:45 – 12:45	<p>Vivli: Global Clinical Trial Data Sharing Platform Public Preview</p> <p>Presentation:</p> <ul style="list-style-type: none"> • Rebecca Li (Vivli) <p>Panel Discussion:</p> <ul style="list-style-type: none"> • Pablo Gazmuri (BlueMetal) • Ida Sim (UCSF) • Paul Slater (Microsoft) <p>Moderator: Barbara Bierer Followed by group discussion and Q&A</p>
12:45 – 1:00	<p>Closing Remarks</p> <p>Moderators: Barbara Bierer & Mark Barnes</p>

Meeting of the Executive and Steering Committee

Please note: This is a closed meeting for EC/SC Sponsors and External Advisory Board members.

1:00 – 5:00	<p>Discussion with Alison Cave (EMA) and David Martin (FDA) over Lunch</p> <p>Update and discussion of ongoing MRCT Center projects</p> <ul style="list-style-type: none"> • Update on 2017 initiatives • Discussion of new projects • Discussion of current/emerging issues • Administrative Update
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