

## MRCT Center 2017 Annual Meeting: DRAFT AGENDA

**Tuesday, December 5, 2017**

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

6:00-8:30 PM	<p><b>Conference Dinner</b></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><b>Welcome &amp; Introductions</b></p> <p>Moderator: Barbara Bierer and Mark Barnes</p>
8:15 – 8:45	<p><b>Keynote</b></p> <p><b>Alison Cave (European Medicines Agency):</b></p> <p style="padding-left: 40px;">EMA’s Perspective on Real World Evidence and Regulatory Decision-Making</p> <p>Moderator: Barbara Bierer</p>
8:45 – 9:45	<p><b>Real World Evidence</b></p> <p>Panel Discussion:</p> <ul style="list-style-type: none"> <li>• William Crown (OptumLabs)</li> <li>• Sebastian Schneeweiss (Brigham and Women’s Hospital)</li> <li>• Cathy Critchlow (Amgen)</li> <li>• David Martin (USFDA)</li> </ul> <p>Moderator: Barbara Bierer Followed by group discussion and Q&amp;A</p>

9:45 – 10:45	<p><b>Vivli: Global Clinical Trial Data Sharing Platform</b></p> <p><b>Vivli – Current progress, opportunities and timeline to launch Vivli public preview – Live Demonstration</b></p> <p><b>Panel Discussion</b></p> <ul style="list-style-type: none"> <li>• Rebecca Li (Vivli)</li> <li>• Paul Slater (Microsoft)</li> <li>• Ida Sim (UCSF)</li> <li>• Pablo Gazmuri (BlueMetal)</li> <li>• Julie Wood (Vivli)</li> </ul> <p>Moderator: Barbara Bierer Followed by group discussion and Q&amp;A</p>
10:45 – 11:00	<p><b>Break</b></p>
11:00 – 11:45	<p><b>Core Competencies for Clinical Research Professionals</b></p> <p>Framework Version 2.0 and expectations of professional competencies for advancement</p> <ul style="list-style-type: none"> <li>• Steve Sonstein (Eastern Michigan University and MRCT Center Senior Advisor)</li> </ul> <p>Panel Discussion:</p> <ul style="list-style-type: none"> <li>• Rebecca Brouwer (Duke University)</li> <li>• William Gluck (Durham Technical Community College)</li> <li>• H. Robert Kolb (University of Florida)</li> <li>•Carolynn Thomas-Jones (The Ohio State University)</li> </ul> <p>Moderator: Steve Sonstein Followed by group discussion and Q&amp;A</p>
11:45 – 12:45	<p><b>Return of Individual Results: Genomics and Axes of Communication in Results Return</b></p> <p>Presentation:</p> <ul style="list-style-type: none"> <li>• Sandra Prucka (Indiana University)</li> </ul>

	<ul style="list-style-type: none"> <li>• Joan Chambers (SCORR Marketing, formerly CenterWatch)</li> <li>• Jessica Scott (GSK)</li> </ul> <p>Panel Discussion:</p> <ul style="list-style-type: none"> <li>• Elizabeth Cahn (Cancer Connection)</li> <li>• Robert Green (Brigham and Women's Hospital)</li> <li>• Scott Kennedy (Novartis)</li> <li>• Carol Weil (National Institutes of Health)</li> </ul> <p>Moderator: Mark Barnes Followed by group discussion and Q&amp;A</p>
12:45 – 1:00	<p><b>Closing Remarks</b> Moderators: Barbara Bierer &amp; 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 – 4:30	<p><b>Discussion with Alison Cave (EMA) and David Martin (FDA) over Lunch</b></p> <p><b>Update and discussion of ongoing MRCT Center projects</b></p> <ul style="list-style-type: none"> <li>• Update on 2017 initiatives</li> <li>• Discussion of new projects</li> <li>• Discussion of current/emerging issues</li> <li>• Administrative Update</li> </ul>
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