

MRCT Center 2016 Annual Meeting: Data Sharing for the Public Good

Wednesday, December 7, 2016

Loeb House, 17 Quincy Street, Cambridge, MA

7:30 – 8:00	Breakfast & Registration
8:00 – 8:15	Welcome & Introductions
8:15 – 9:15	<p>Discussion of the Impact of Draft ICH E17 Guidelines</p> <ul style="list-style-type: none"> • Laurie Letvak, Head of Clinical Policy and Medical Ethics, Chief Medical Office, Novartis Pharmaceuticals Corporation • William Wang, Executive Director, Biostatistics and Research Decision Sciences, Merck & Co., Inc. <p>Moderator: Mark Barnes, Faculty Co-Director, MRCT Center; Partner, Ropes & Gray LLP Followed by group discussion and Q&A</p>
9:15 – 10:45	<p>Data Sharing and Data Transparency</p> <p>Keynote: Data transparency today and tomorrow: current state, issues, and vision</p> <ul style="list-style-type: none"> • Murray Stewart, Chief Medical Officer, GlaxoSmithKline <p>Progress in 2016 and outlook to 2017</p> <ul style="list-style-type: none"> • Rebecca Li, Executive Director, MRCT Center; Instructor in Medicine, Center for Bioethics, Harvard Medical School <p>Responses from key stakeholders</p> <ul style="list-style-type: none"> • Jeffrey Drazen, Editor-in-Chief, <i>New England Journal of Medicine</i> • Amita Gupta, Associate Professor of Medicine and International Health, Center for Clinical Global Health Education, Johns Hopkins University • Murray Stewart, Chief Medical Officer, GlaxoSmithKline <p>Moderator: Rebecca Li, Executive Director, MRCT Center; Instructor in Medicine, Center for Bioethics, Harvard Medical School Followed by group discussion and Q&A</p>

10:45 – 11:00	Break
11:00 – 12:30	<p>Individual Return of Results Working Group</p> <p>Remit of the Working Group and Overview of IRR Principles</p> <ul style="list-style-type: none"> • Debra JH Mathews, Assistant Director for Science Programs, Berman Institute of Bioethics, Johns Hopkins University • David Pulford, Genetics TA Head Rare Diseases, GlaxoSmithKline • Sandra Prucka, Innovation Lead, Clinical Innovation, Eli Lilly and Co. <p>Responses from key stakeholders</p> <ul style="list-style-type: none"> • Atul Gawande, Director, Ariadne Labs; Professor, Harvard T.H. Chan School of Public Health; Professor of Surgery, Harvard Medical School • Barbara LeStage, Steering Committee Member, Clinical Trials Transformation Initiative • Alvaro Pascual-Leone, Director, Berenson-Allen Center for Noninvasive Brain Stimulation, Beth Israel Deaconess Medical Center; Professor of Neurology, Harvard Medical School • Holly Taylor, Core Faculty Member, Berman Institute of Bioethics, Johns Hopkins University; Associate Professor, Department of Health Policy and Management, Bloomberg School of Public Health <p>Moderator: Barbara Bierer, Faculty Co-Director, MRCT Center; Professor of Medicine, Harvard Medical School Followed by group discussion and Q&A</p>
12:30 – 12:45	Closing Remarks
12:45 – 1:15	Lunch

Meeting of the Executive and Steering Committee

Please note: This is a closed meeting, however participants from sponsors attending the Annual Meeting are welcome.

1:15 – 5:00	<p>Update and discussion of ongoing MRCT projects</p> <ul style="list-style-type: none"> • Update on 2016 initiatives • Discussion of new projects
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