

Harvard MRCT 3rd Annual Meeting and Dinner

- *Dinner*- 2nd December 2014 from 6:00-8:00 pm, Henrietta’s Table, 1 Bennett St, Cambridge, MA
- *Annual Meeting*- 3rd December 2014 from 7:30 am-5:00 pm, Loeb House, 17 Quincy Street, Cambridge, MA

Participants: MRCT Executive Committee, Steering Committee and Interested Stakeholders

2nd December 2014, Dinner PART ONE (for Executive Committee, Steering Committee, & Conference Speakers)

6:00 – 8:00 pm	Dinner at <u>Henrietta’s Table</u> ; welcoming Harvard MRCT Executive and Steering Committee members and conference speakers
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3rd December 2014, Annual Meeting

PART TWO (Open to all registered participants)

7:30 – 8:00 am	Participants’ Arrival, Registration, and Breakfast
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Welcome

8:00 – 8:30 am	<ul style="list-style-type: none"> • Welcome • Introduction to Harvard MRCT and the Return of Results Guidance Document 	<ul style="list-style-type: none"> • Barbara Bierer, M.D. • Mark Barnes, J.D.
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Invited Speakers Perspectives on Returning Aggregate Results to Study Participants

8:30 – 8:50 am	<ul style="list-style-type: none"> • Regulatory perspective, EMA 	<ul style="list-style-type: none"> • Anabela Marcal, PharmD
8:50 – 9:05 am	<ul style="list-style-type: none"> • Regulatory perspective, FDA 	<ul style="list-style-type: none"> • Richard Moscicki, M.D.
9:05 – 9:20 am	<ul style="list-style-type: none"> • OHRP perspective 	<ul style="list-style-type: none"> • Jerry Menikoff, M.D., J.D.
9:20 – 9:35 am	<ul style="list-style-type: none"> • NEJM perspective 	<ul style="list-style-type: none"> • Jeffrey Drazen, M.D.
9:35 – 9:50 am	<ul style="list-style-type: none"> • Industry perspective, Merck 	<ul style="list-style-type: none"> • Michael Rosenblatt, M.D.
9:50 – 10:05 am	<ul style="list-style-type: none"> • PhRMA perspective 	<ul style="list-style-type: none"> • Jocelyn Ulrich
10:05 – 10:20 am	<ul style="list-style-type: none"> • Patient perspective, Dana-Farber 	<ul style="list-style-type: none"> • Elizabeth Frank
10:20 – 10:30 am	<ul style="list-style-type: none"> • NIH perspective 	<ul style="list-style-type: none"> • David Gordon, M.D., MPH, PhD
10:30 – 11:00 am	<ul style="list-style-type: none"> • Panel Discussion 	<ul style="list-style-type: none"> • Mark Barnes, J.D. (Moderator)

Break 11:00 – 11:20 am

11:20 – 12:00 pm	<ul style="list-style-type: none"> • India Regulatory • Trial Causality and Compensation Program 	<ul style="list-style-type: none"> • Barbara Bierer, M.D. • Mark Barnes, J.D.
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PART THREE

12:00 – 4:00 pm	Closed Meeting for Executive and Steering Committees <ul style="list-style-type: none"> • Lunch for Executive/Steering Committees and Speakers served
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PART FOUR

4:00 – 5:00 pm	Executive Committee Session
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