2012 MRCT Annual Meeting Agenda

What: MRCT Annual Meeting

When: 28th November, 2012 from 8:00 a.m. to 4:30 p.m. (EC/SC meeting 4:30-6:00 pm)

Where: Harvard Faculty Club, Theatre Room, 20 Quincy Street, Cambridge, MA

Who: MRCT Executive Committee, Steering Committee and Stakeholders

Objectives:

1. Provide an update to all stakeholders regarding current initiatives and progress
2. Engage regulators in the MRCT initiatives and mission
3. Obtain feedback from regulators and stakeholders on MRCT ongoing and planned initiatives
4. 2013 Budget and Proposed Goals (EC/SC meeting)

Schedule:

Registration and Breakfast

8:00 am – 8:30 am	**Participants Arrival and Registration**

Welcome

8:30 am – 9:15 am	**– MRCT Welcome & Introductions** **– Agenda and Expectations** **– Overview of Current MRCT Initiatives**	**– Barbara Bierer (MRCT)** **– Mark Barnes (MRCT)** **– Rebecca Li (MRCT)**

Keynote Speaker

9:15-10:00 am	**Keynote Speaker** **Regulatory Perspective on MRCT Issues and Potential Strategies**	**– Dr. Robert O'Neill (FDA)**

Keynote Speaker *- Dr. Robert O'Neill is currently the Senior Statistical Advisor to CDER in the Office of Translational Sciences in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration. Up until June, 2011 , Dr. O'Neill was the Director of the Office of Biostatistics which provides biostatistical and scientific computational leadership and support to all programs of CDER. Prior to October 1998 he was Director of the Office of Epidemiology and Biostatistics, responsible also for the post-market safety surveillance of new drugs. In 1989-1990, Dr. O'Neill was a visiting professor at the Department of Research, University Medical School, Basel, Switzerland, where he developed and presented numerous lectures and created a course series Topics in Therapy Evaluation and Review (TITER) for European pharmaceutical scientists, which was the model for the European Course In Pharmaceutical Medicine (ECPM), a degree granting graduate program. He is a fellow of the American Statistical Association (1985), a member of several professional societies, a past Member of the Board of Directors of the Society for Clinical Trials, the 2002 recipient of the Marvin Zelen Leadership Award in Statistical Science, and the 2004 Lowell Reed Lecture Awardee from the American Public Health Association.*

Roadmap of Clinical Trial Initiatives / MRCT Initiatives

10:00-10:30 am	Roadmap Project of Ongoing Clinical Trial Initiatives by Consortia and Collaborative Groups (15 min presentation, 15 min discussion)	– Pete Lyons (Deloitte) – Rohin Rajan (Deloitte)
10:30-11:00	MRCT Protocol Ethics Initiative	– Susan D'Amico (Reata Pharma) – David Forster (WIRB)
11:00-11:30	PANEL DISCUSSION MRCT Protocol Ethics Initiative focused on: – Specific needs by region – Feedback on webtool – Other suggested areas of focus – Pilot approaches	– ALL Speakers

Regulatory and Key Stakeholder Perspectives on MRCT

11:30-2:00pm (Working Lunch)	Global Regulatory Authority and Regional Stakeholder Presentations (15 min each), 45 minute discussion – Needs and priorities with respect to Multi-Regional Clinical Trial issues (region specific)	– Health Canada (Agnes Klein) – India (Sonali Kochhar) – India (Vijai Kumar) – Korea (Ock Joo Kim) – Russia (Evgeny Rogoff) – EMA (Sabine Haubenreisser) – FDA (Ann Meeker-O'Connell)

Break

2:00-2:15pm	Break

2:15-2:45pm	MRCT DMC/DSMB Initiative	– Chuck Knirsch (Pfizer)
2:45-3:15 pm	PANEL DISCUSSION MRCT DMC/DSMB Initiative – Specific needs by region – Suggested opportunities for training and apprenticeships	– ALL Speakers

3:15-3:45 pm	**MRCT TRAINING Initiative**	**– Natalie Rossignol (Gates Foundation)**
3:45-4:30 pm	**Wrap-up Discussion Steps for moving forward**	**– Barbara Bierer (MRCT) – Mark Barnes (MRCT) – Rebecca Li (MRCT)**

Executive Committee and Steering Committee (closed session)

4:30-6:00 pm	**2013 Budget Goals for 2013 Review of Progress and New Initiatives**