What: MRCT at Harvard 2nd Annual Meeting

Theme: Clinical Trial Data Sharing

When: 4th December 2013 from 7:30 a.m. to 5:00 p.m.

(EC/SC Sponsor meeting 5:00-6:30 pm: 2014 MRCT project planning)

Where: Loeb House, Harvard University 17, 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. Discuss key initiatives in clinical trial data sharing including:
    a. Practical Implementation of clinical trial data sharing
    b. Return of individual results to patients

Schedule:

Registration and Breakfast

7:30 – 8:00 am	**Participants' Arrival, Registration, and Breakfast**

Welcome & Introductions

8:00 – 8:40 am	• **Agenda and Expectations** • **MRCT India Update**	**Rebecca Li (MRCT)** **Barbara Bierer (MRCT)** **Mark Barnes (MRCT)**

Keynote Speakers

8:40 -9:30 am	**EMA – Approach to Data Transparency** **GSK – Access to Patient-Level Data** **FDA – Perspective on Data Sharing**	**Hans Eichler (EMA)** **Perry Nisen (GSK)** **Richard Moscicki (FDA)**
9:30 – 10:25 am	**Moderated discussion of EMA, FDA and GSK approaches**	**Moderator:** **Mark Barnes/MRCT**

Break 10:25 – 10:40am

Data Sharing Implementation and Solutions

10:40 – 11:00 am	**MRCT Phase 2 Data Sharing Implementation Solutions :** ***Criteria, informed consent and commercial confidentiality***	**Barbara Bierer (MRCT)** **Jessica Scott (GSK)**
11:00 – 11:30 am	**Moderated discussion of strategies, approach and implementation**	**Participants: ALL**

11:30 – 12:00 pm	**Lunch**

Work Group Updates

12:00 – 12:45 pm	**Data Safety Monitoring Board**	**Joe Massaro (BU), Barbara Bierer**
	Protocol Ethics Guidance	**Susan D'Amico (Abbvie)**
	Investigator Competence & Training	**Rebecca Li (MRCT)**

Return of Results: Lessons Learned from Current Efforts

12:45 – 1:50 pm	**Moderated by Mary Ann Plummer (J&J)**	
	Pfizer Blue Button Initiative	**Craig Lipset (Pfizer)**
	Patient Perspective	**Cheryl Jernigan (Susan B. Komen)**
	Providing Research Results to Clinical Study Participants	**Sandy Prucka (Lilly)**
	CSCRP Return of Results	**Zach Hallinan (CSCRP)**

Return of Results: Next Steps

1:50-2:15 pm	**Framing the new initiative** - **pushing the envelope on returning results to patients** - **defining best practices** - **planned pilots and focus groups**	**Rebecca Li**

Return of Results: Panel Discussion

2:15 – 3:15pm	**Panel Discussants:** – **Holly Peay (Parent Project MD)** – **Cheryl Jernigan (Susan B. Komen)** – **Sandy Prucka (Lilly)** – **Zach Hallinan (CSCRP)** – **David Forster (Western IRB)** – **Ann Partridge (Dana Farber)**	**Moderators: Craig Lipset (Pfizer) and Mary Ann Plummer (J&J)**

Break 3:15 – 3:30 pm

Emerging Issues in Multi-Regional Clinical Trials

3:30 – 4:30 pm	**Panel Discussants:** – **Kris Joshi (Oracle)** – **Ed Silverman (Pharmalot)** – **Doug Peddicord (ACRO)** – **Christine Pierre (MYSCRS)** – **Walter Straus (Merck)**	**Moderator: Marc Wilenzick (MRCT)**

Conclusion

4:30 – 5:00 pm	**Wrap-up Discussion**	**Barbara Bierer (MRCT)** **Mark Barnes (MRCT)** **Rebecca Li (MRCT)**

Executive and Steering Committee (closed session) in Theatre Room, Harvard Faculty Club

5:00pm-6:30 pm	**2014 Budget** **Goals for 2014** **Review of Regulatory initiatives and planning for 2014**