Agenda

What: "Standardizing and Measuring PI and Site Qualifications for Conducting Clinical Trials"

When: 18th September, 2012 from 8:00 a.m. to 4:00 p.m.

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

Objectives:

1. Provide a forum for those working in this area to collaborate with others
2. Derive a consensus list of "key selection standards or criteria for sites and PIs"
3. Proposed methods to quantify the importance of these criteria
4. Discuss issues and guidance for Regional Ethics Committees

Schedule:

1. Registration and Breakfast

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

2. Welcome and Introduction to MRCT

8:30 am – 9:00 am	**MRCT Background and Objectives**	**– Rebecca Li (MRCT)**

3. Meeting Outline and Objectives

9:00 am – 9:15 am	**Agenda and Expectations**	**– Barbara Bierer (MRCT)**

4. Panel # 1: Summary of Current Initiatives in PI standards and Certification External to MRCT

9:15 am – 10:10 am	**Overview of Initiatives Presentations (5 min each speaker)**	**– Justin McCarthy (Pfizer)** **– Greg Koski (ACRES)** **– Marjorie Spears (AAHRPP)** **– David Vulcano (ACRP)** **– Peter Goldschmidt (HII)**
	Panel Discussion (30 min) • Perceived gaps and overlaps of initiatives • Areas of collaboration	**– Moderator Adrian Otte (Amgen)**

5. Panel # 2: PI and site requirements in emerging vs. developed markets

10:10 am – 11:40 am	**Presentations (10 min each speaker)**	**– Helmut Wolf (Novartis)** **– Dana Niedzielska (August Res)** **– John Oidtman (Pfizer)** **– Fabio Thiers (ViS)** **– Sonali Kochhar (PATH)** **– Richard Peters (Sanofi)**
	Panel Discussion (30 min) • Which requirements are testable/measurable and how? • Which requirements are high impact? • How can we assist sites in developing countries meet requirements?	**– Co-Moderators Helmut Wolf & Richard Peters**

6. Lunch Break

11:40 am – 12:20pm	**Lunch**

7. Speaker Series: Regulatory considerations in foreign site selection

12:20 pm – 1:15 pm	**Session 1 (20 min)**	**– Ann Meeker-O'Connell (FDA)**
	Session 2 (20 min)	**– Fergus Sweeney (EMA)**
	Panel Discussion (15 min) • Current challenges in this area • How can we best collaborate to assist sites?	**– All**

8. Panel # 3: Building the Infrastructure for Trialists – A focus on Regional Ethics Committees

1:15pm – 2:05 pm	**Presentations (10 min each)**	**– Marjorie Speers (AAHRPP)** **– Delia Wolf (HSPH)** **– Nicholas Slack (WIRB)**
	Panel Discussion (20 min) • Current challenges in emerging markets? • What high-impact opportunities exist for MRCT to guide and assist in this space?	**– Moderator- Debasish Roychowdury (Sanofi)**

9. Break

2:05 pm – 2:15 pm	**Coffee/ Tea**	

10. Panel # 4 Training challenges in emerging markets and potential solutions

2:15 pm – 3:35 pm	**Presentations (10 min each speaker)**	**– Trudie Lang (Global Health)** **– Anna Ravdel (Synergy)** **– Glenn Wise (PPD-TIPS)** **– Shelia Clapp (fhi360)** **– Kim Havens (PPD)** **– Paul Pomerantz (DIA)**
	Panel Discussion (20 min) • What high-impact opportunities do we have in the pre-competitive collaboration space?	**– Moderator- Craig Eslinger (PPD)**

11. Wrap-up

3:35 pm – 3:45 pm	**Consensus & Discussion on Next Steps for MRCT**	**– Rebecca Li (MRCT)**

12. Closing Remarks

3:45 pm – 4:00 pm	**Wrap-up**	**– Mark Barnes (MRCT)**