Promoting Clinical Trial Data Transparency Conference

When: March 30 & 31, 2015

Where: Harvard Faculty Club, 20 Quincy Street, Cambridge, Massachusetts

Who: Data generators and data users, academic and government agencies, journal leadership, and other stakeholders (by invitation only)

Conference Objectives

- To discuss high-level principles with the explicit goal of developing an approach whereby participant level clinical trial data could be integrated, enabling researchers to access and combine data across the various platforms and sponsors.
- To present and deliberate centrally managed and federated models.
- To discuss implementable solutions to realize harmonization and enable broader data sharing across platforms.

Agenda

Day 1 To introduce current approaches, lessons learned and criteria for harmonizing data sharing platforms

Time	Topic	Speakers
7:30-8:00	Registration and Breakfast	
8:00-8:45	Welcome Remarks Introduction: The Potential Scope of the Data Sharing Issue Summary of pre-conference survey: commonalities, limitations, and gaps of current data sharing approaches	MRCT Center at Harvard: Barbara Bierer, Mark Barnes Deloitte Consulting

Session I: Lessons Learned and Current Needs

Time	Topic	Speakers
8:45- 9:20 (6-7min each)	Session #1A: Experiences & best practices from current initiatives: • Clinical Study Data Request platform • Duke Clinical Research Institute (DCRI) • Merck • Pfizer • Yale University Open Data Access Project (YODA)	 • Frank Rockhold (GSK) • Eric Peterson (Duke) • Barbara Kress (Merck) • Justin McCarthy (Pfizer) • Joseph Ross (Yale)

9:20 – 9:50	Moderated Panel discussion of key stakeholders from Session #1A: What are the key principles and best practices that can be harmonized and agreed upon? Questions from the audience	Speakers from Session #1A Moderators: Barbara Bierer & Mark Barnes (MRCT Center at Harvard)
9:50 – 10:25 (6-7 min each)	Session #1B: Forward looking strategies and initiatives: • CDISC: role of data standards in harmonization • National Institutes of Health (NIH) • Patient-Centered Outcomes Research Institute (PCORI) • University of Pittsburgh • Wellcome Trust	 • Rebecca Kush (CDISC) • Kathy Hudson (NIH) • Steven Goodman (Stanford) • Ronald Krall (Univ. Pittsburgh) • Nicola Perrin (Wellcome Trust)
10:25-10:55	Moderated Panel discussion of key stakeholders from Session #1B: What are the key principles and strategies that can be harmonized and agreed upon? Questions from the audience	Speakers from Session #1B Moderators: Barbara Bierer & Mark Barnes (MRCT Center at Harvard)
10:55-11:15	BREAK	
11:15 – 12:30 (10-15 min each)	Case Studies: history, lessons learned, best practices • Global Alliance for Genomics & Health • Working group on data sharing of the European Federation of Statisticians in the Pharmaceutical Industry • Laboratory of Neuro Imaging (LONI) • The NHLBI BioLINCC Program Questions from the audience	 • Peter Goodhand (Global Alliance) • Christoph Gerlinger (Bayer) • Arthur Toga (University of Southern California) • Michael Lauer National Heart, Lung, and Blood Institute (NIH/NHLBI)
12:30 – 1:15	LUNCH	

Session II: The Way Forward

Objective: To devise and agree on common standards, criteria, approaches and harmonization of data platforms for the sharing of clinical trials data.

1:15 – 1:45	Implications of the IOM Report *Sharing Clinical Trial Data*, including proposed sustainability models	Bernard Lo (Greenwall Foundation)
1:45 – 2:00	Introduction to breakout sessions: All groups discuss all topics, facilitator reports back in plenary. Topics: 1. Vision of ideal platform 2. Barriers and incentives 3. Characteristics of platform 4. Getting data into common platform and accessing data from common platform	MRCT Center at Harvard
2:00 – 4:00	Breakout Groups convene	Deloitte and MRCT Center moderators
4:00 – 4:15	BREAK	
4:15 – 5:15	Facilitators report back from each group (10-15 min per group)	Deloitte and MRCT Center moderators
5:15 – 5:30	Closing of Day 1	MRCT Center at Harvard
6:00 – 8:30	Conference Dinner	Adolphus Busch Hall, Harvard Art Museums, 27 Kirkland Street, Cambridge

Day 2 **<u>Session III: Commitments and Next Steps</u>**

<u>Objective:</u> To delineate solutions, next steps and commitments

8:00–8:30 Breakfast

Time	Topic	Respondents
8:30-9:20	**Developing a new model for data sharing** Response from key stakeholders to Topic 1 (Vision of ideal platform) • Academic vs commercial • Disease specific • Portal vs repository • Federated vs centralized • Learned Intermediary (Review Board) vs Data Generator vs Open Access Model • Downloadable vs non-downloadable • Sharing with general public vs approved researchers Discussion: Questions from audience Commitments of stakeholders	Deloitte / MRCT Center at Harvard • Joseph Ross (Yale) • Jessica Scott (GSK) • Deborah Zarin (NIH) • Thomas Peppard (Gates) • Julie Ingelfinger (NEJM) • Kay Dickersin (JHU)
9:20-10:10	Response from key stakeholders to Topic 2 (Incentives to address barriers and gaps) • Incentives for expanded data sharing for non-adopters • Harmonization of standards • Privacy concerns • Criteria to use data • Standards for de-identification of data • Accountability toward research participants Discussion: Questions from audience Commitments of stakeholders	Deloitte / MRCT Center at Harvard • Pamela Gavin (NORD) • Benjamin Rotz (Lilly) • Frances Rawle (Medical Research Council, UK) • Heather Pierce (AAMC) • Elizabeth Loder (BMJ) • Stuart Buck (Arnold)

10:10 – 10:30	BREAK	
10:30-11:20	Response from key stakeholders to Topic 3 (Characteristics of platform) • Business model and governance • Involvement of stakeholders: existing vs new group to review and assess standards • Assessing compliance & adherence to standards • Global or regional • Equitable distribution of costs of data sharing across both data generators and users Discussion: Questions from audience Commitments of stakeholders	Deloitte / MRCT Center at Harvard • Daniel Moreira (Mayo) • Jennifer Miller (Harvard) • Laurie Letvak (Novartis) • Hanns-Georg Leimer (BI) • Kathy Hudson (NIH) • Davina Ghersi (Natl Health & Medical Research Council, Australia)
11:20-12:10	Response from key stakeholders to Topic 4 (Getting data into common platform and accessing data from common platform) • Access mechanism • Protection of personally identifiable information • Independent review • Data Use Agreements • Appropriate data availability standard defined • Pre-uploaded vs as-needed Discussion: Questions from audience Commitments of stakeholders	Deloitte / MRCT Center at Harvard • Catrin Tudur Smith (University of Liverpool) • Sandra Morris (J & J) • Caroline Stockwell (Pfizer) • Martha Brumfield (Critical Path Institute)
12:10 – 12:30	Wrap Up & Next Steps: Summary of proposed new model for data sharing and key commitments of stakeholders	MRCT Center at Harvard

12:30-1:30 LUNCH