What: Issues and Case Studies in Clinical Trial Data Sharing: Lessons and Solutions

When: 17th May 2013, 7:30am – 5:00pm

Where: Wasserstein Hall, Milstein East (2nd Floor) 1585 Massachusetts Avenue, Cambridge, MA 02138

Who: MRCT Center and PFC Stakeholders

Objectives:

- To convene key global stakeholders on a neutral platform to review evidence from recent case studies in clinical trial data disclosure
- To discuss key areas of learning and potential solutions for clinical trial data sharing that may inform policy in this important area moving forward
- To discuss implications of data sharing initiatives for pharmaceutical, medical device and biotechnology regulation in the U.S. and other countries

Schedule:

7:30 – 8:00 am	Participants Arrive, Breakfast, and Registration	
8:00 – 8:15 am	Welcome Remarks	Barbara Bierer, MRCT Mark Barnes, MRCT

Keynote Speakers

8:15 – 8:35 am	Access to Patient-Level Data from Clinical Trials: What Data? For Whom? For What Reason? When?	Jeff Drazen, NEJM
8:35 – 8:55 am	Perspectives on Patient-Level Clinical Data Sharing From a Patient Advocate, Bioethicist, and Industry Physician	AJ Allen, Lilly
8:55 – 9:10 am	Q&A	Jeff Drazen AJ Allen

9:10 – 9:20 am	Introduction of Potential Data Sharing Models	Michelle Mello, HSPH

<u>Session I: Rationale for Increased Clinical Trial Data Sharing</u>

Moderator: Michelle Mello, HSPH

9:20 – 9:35 am	Case Study: Model of Data Sharing Among Multiple Stakeholders	Martha Brumfield, Critical Path Institute and Coalition Against Major Diseases
9:35 – 9:50 am	Case Study: A Review of Project Data Sphere	Robin Jenkins, Sanofi
9:50 – 10:05 am	• What are the specific rationales for data sharing? What public health benefits arise from being able to share and access data?	Patricia Teden, Teden Consulting

	• What kinds of data need to be shared to reach those goals, and in what format? • What conditions must be present to ensure that data sharing adequately achieves the identified goals?	
10:05 – 10:45 am	Discussion Panel / Q & A	AJ Allen, Lilly John Orloff, Novartis Martha Brumfield, CPI James Ware, NEJM, HSPH Patricia Teden, Teden Consulting Sally Okun, PatientsLikeMe Robin Jenkins, Sanofi
10:45 – 10:55 am	10 Minute Break	

Session II: Safeguarding Patient Privacy, Consent Principles, and the Integrity of Data Analyses

Moderator: Mark Barnes, MRCT

10:55– 11:10am	Case Study: GSK Data Sharing Initiative as One Model for Increasing Data Transparency and a First Step Toward a Broader Solution	Jessica Scott, GSK
11:10 – 11:25 am	Case Study: How Anonymous is Genetic Research Data?	Yaniv Erlich, Whitehead Institute
11:25 – 11:40 am	• What are the risks of clinical trial data sharing in regard to privacy protection, and how can they be balanced against the potential social benefits of data sharing? • Would privacy concerns related to clinical trial data sharing deter prospective subjects from participating in clinical trials? • Does de-identification of data solve the problem of risks to patient privacy and confidentiality? • Should research subject consent serve as a precondition for sharing of clinical trials data? • What should be the consequence (e.g., liability) if/when privacy is compromised as a result of increased clinical trial data sharing?	Mark Barnes, MRCT
11:40 – 12:20 pm	Discussion Panel / Q & A	Kristen Henderson, Quintiles Yaniv Erlich, Whitehead Jessica Scott, GSK Mark Lim, Faster Cures Claudia Emerson, Sandra Rotman Centre

12:20 – 12:40 pm	Lunch Served	
12:40 – 1:00 pm	Lessons Learned From the Implementation of FDAAA and the ClinicalTrials.gov Results Database	Deborah Zarin, NIH
1:00 – 1:10 pm	Q & A	

Session III: Balancing Companies' Intellectual Property Interests with Public Access to Data

Moderator: Justin McCarthy, Pfizer

1:10 – 1:40 pm	Case Study: Legal Issues Posed by the EMA Proposed Initiative (includes 10 min Q&A)	Richard Kingham, Covington
1:40 – 1:55 pm	• What intellectual property rights, proprietary interests, and competitive concerns do companies have that may be adversely affected by data sharing [by either voluntary or mandated clinical data disclosure policies]? • Would the impingement on these interests that could accompany data sharing likely affect public and private investments in R&D and, ultimately, innovation? • How should these concerns be balanced against the potential benefits of data sharing? • What strategies might effectively address companies' legitimate concerns while maximizing the public benefit of data sharing? • Is imposing a "learned intermediary" between those who seek access to data and the data sources a possible approach to ease competitive concerns while still allowing reasonable access for independent researchers?	Jeffrey Francer, PhRMA
1:55 – 2:35 pm	Discussion Panel / Q & A	Susan Forda, Lilly Ben Roin, HLS Richard Kingham, Covington Jeffrey Francer, PhRMA Ira Shoulson, Georgetown Aaron Kesselheim, HMS Sandra Morris, J&J

2:35 – 2:50 pm	Afternoon Break

Session IV: Assuming Research Participant Data is Shared in the Public Domain, What are the Ramifications?

Moderator: Marc Wilenzick, MRCT

2:50 – 3:20 pm	European Medicines Agency Update On Clinical Trial Data Transparency (includes 10 min Q&A)	Sabine Haubenreisser, EMA
3:20 – 3:45 pm	Anticipated Impact of BMJ's Data Sharing Policy on the Publications and Scientific Process	Elizabeth Loder, BMJ
3:45 – 4:00 pm	• What are the implications of public sharing of clinical trial data for regulatory processes? • Do the potential benefits of data sharing for regulatory processes outweigh the risks (e.g., second-guessing regulatory agencies, premature or incorrect conclusions on risk/benefit profile of medicines)? • Can a move toward increased public data sharing jeopardize ongoing efforts toward improved regulatory harmonization?	Jules Mitchel, Target Health
4:00 – 4:45 pm	Discussion Panel / Q & A	Robert O'Neill, FDA Sabine Haubenreisser, EMA Toshi Tominaga, PMDA Agnes Klein, Health Canada Deborah Zarin, NIH Elizabeth Loder, BMJ Jules Mitchel, Target Health Inc. Evgeny Rogoff, Russia

4:45 – 5:00 pm	Wrap Up Discussion	Mark Barnes, MRCT Barbara Bierer, MRCT Rebecca Li, MRCT Holly Lynch, PFC