



HARVARD Global Health Institute

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

Session I: Rationale for Increased Clinical Trial Data Sharing

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	<ul style="list-style-type: none"> • What rationales exist for increased public sharing of clinical trial data? • What types of data and how much data should be shared (e.g., pre-registration, post-registration, etc.)? • Who stands to benefit from sharing more clinical trial data? 	Patricia Teden, Teden Consulting



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10:05 – 10:45 am	Discussion Panel / Q & A	AJ Allen, Lilly John Orloff, Novartis Martha Brumfield, CPI James Ware, NEJM 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	<ul style="list-style-type: none"> • 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 trials data sharing constitute a barrier to participation to clinical trials? • Does de-identification of data solve the problem of risks to patient privacy and confidentiality? • Should research participant consent be a precondition for sharing of clinical trials data? • What could be the consequences (e.g., liability) if/when privacy is compromised as the result of increased clinical trial data sharing? 	Mark Barnes, MRCT
11:40 – 12:20 am	Discussion Panel / Q & A	Kristen Henderson, Quintiles Yaniv Erlich, Whitehead Jessica Scott, GSK Mark Lim, Faster Cures Claudia Emerson, Sandra Rotman Centre



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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	<ul style="list-style-type: none"> • What intellectual property rights, proprietary interests, and competitive concerns do pharmaceutical companies have that might be adversely affected by data sharing? • 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	
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Session IV: Assuming patient-level 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	<ul style="list-style-type: none"> • 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 Inc.
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