PUBLIC ENGAGEMENT AND CLINICAL TRIALS: NEW MODELS AND DISRUPTIVE TECHNOLOGIES

June 27-28, 2011
Conduits and Department of Health Evidence & Policy
Mount Sinai School of Medicine
Goldwurm Auditorium
Icahn Medical Institute, 1st Floor
1425 Madison Ave. (at the NE corner of East 98th St)
New York, NY 10029

Background:
Rapid advances in biomedical research have drawn attention to the critical need for an effective clinical trials system that can generate the evidence needed to translate discoveries into improved patient care, and illuminate targets for further innovation. There is growing recognition, however, that the U.S. clinical trials enterprise is unable to keep pace with the national demand for actionable research results, and inefficiencies in the clinical trials enterprise limit our ability to realize the clinical benefits of scientific discovery. Many clinical trials never meet their recruitment goals and others are accruing patients far too slowly. In addition, the divide between clinical research and clinical practice is growing wider—physicians working in real world clinical care settings are removed from the clinical trials on which medical evidence and care choices are ideally made. Successfully engaging the broader public (including patients and communities) and medical professionals (e.g., community physicians and those practicing in academic medical centers) in the clinical trials enterprise is a significant challenge.

In light of these current challenges to clinical trials in the United States, this collaboration between the IOM Forum on Drug Discovery, Development, and Translation and Mount Sinai School of Medicine seeks to engage stakeholders and experts in an open discussion of current challenges and potential solutions to improving the capacity for efficiently conducting clinical trials in the United States by enhancing public engagement.

Meeting Objectives:
• Define and discuss the problem of inadequate public engagement in clinical trials.
• Identify the structures and culture of health care systems and delivery organizations that fail to support or engage with the clinical trial enterprise and suggest potential solutions for how health centers can be engaged to support the clinical trial enterprise.
• Discuss how academic medical centers can create successful community partnerships to improve public engagement in clinical trials.
• Highlight and discuss models/methods, both proven and yet to be tried, of public engagement. Address the media’s role in public engagement.
• Describe novel clinical trial designs (such as adaptive clinical trial designs) that minimize enrollment needs and address treatment assignment concerns of physicians and their patients.
• Involve stakeholders in a discussion of moving forward to create a comprehensive strategy for enhanced public engagement in clinical trials.
SESSION I: FRAMING THE PROBLEM

Moderator: Jeffrey Drazen, Co-Chair, Forum on Drug Discovery, Development and Translation, New England Journal of Medicine

Session Objectives:
- Provide a definition of “engagement,” both public and professional, in clinical trials.
- Survey the current landscape in terms of deficiencies in public and professional engagement, and discuss consequences of this lack of engagement.
- Identify gaps/areas of particular need, desired outcomes of enhanced engagement, and the challenges facing this progress.

12:00 – 12:10 PM Welcome
Dennis Charney, Dean, Mount Sinai School of Medicine
Jeffrey Drazen, Co-Chair Forum on Drug Discovery, Development and Translation, New England Journal of Medicine

12:10 – 12:25 PM Shaping an Effective and Efficient Clinical Trials Enterprise: What are the Challenges?
Annetine Gelijns and Deborah Ascheim, Mount Sinai School of Medicine

12:25 – 12:45 PM An Effective Clinical Trials System: A perspective from the NIH Clinical Center
Juan Lertora, National Institutes of Health

12:45 – 1:30 PM Panel Discussion: A Perspective from Industry, Patient Advocates, Payors and Regulatory Agencies
Leslie Ball, FDA
Joan Finnegan Brooks, Patient-Focused Market Research
Angela Geiger, Alzheimer’s Association
Richard Murray, Merck
Greg Simon, Pfizer
Bruce Vladeck, Senior Advisor, Nexera

SESSION II: MODELS AND METHODS FOR PUBLIC ENGAGEMENT

Moderator: Nancy Sung, Burroughs Wellcome Fund, Drug Forum

Session Objectives:
- Through case examples, discuss various stakeholder perspectives and efforts focused on public engagement. In case studies identify primary audiences, key messages, and success or lack of success in engaging the public.
- Present strategies that foster research interest and participation in diverse populations through innovative community partnerships.

1:35 – 1:50 PM Recruitment Challenges in Cardiothoracic Surgical Trials
Robert Michler, Montefiore-Einstein Heart Center

1:50 – 2:05 PM Diabetes, Clinical Trials and Innovative Community Partnerships
Carol Horowitz and Nina Bickell, Mount Sinai School of Medicine

2:05 – 2:20 PM Clinical Trials in Mental Health
Wayne Goodman, Mount Sinai School of Medicine
2:20 – 2:35 PM  Recruitment in Breast Cancer Trials, A New Approach:  
*The Love/Avon Army of Women*  
Marc Hurlbert, Avon Foundation Breast Cancer Crusade

2:35 – 2:55 PM  Panel Discussion  
Kenneth Davis, President and CEO, Mount Sinai Medical Center  
Robert Michler, Carol Horowitz, Nina Bickell, Wayne Goodman, Marc Hurlbert

2:55 – 3:20 PM  COFFEE BREAK

### SESSION III: TECHNOLOGIES AND NOVEL COMMUNICATION APPROACHES

**Moderator:** Janet Tobias, Mount Sinai School of Medicine  
**Session Objectives:**
- Present innovative technologies/platforms that hold promise for achieving higher levels of public awareness (e.g., clinical trial matching; increasing adherence, online information efforts).

3:25 – 3:40 PM  23 and Me  
Brian Naughton, Chief Scientist, 23 and Me

3:40 – 3:55 PM  Social Networks and Public Engagement in Clinical Trials  
Bernadette Boden-Albala, Columbia University

3:55 – 4:15 PM  Panel Discussion

### SESSION IV: MEDIA AND PUBLIC ENGAGEMENT IN CLINICAL TRIALS

**Moderator:** Paul Costello, Stanford School of Medicine  
**Session Objectives:**
- Discuss the role in public engagement of media, healthcare information portals, and public advocates.

4:20 – 4:35 PM  Survey of the Public Perception and Media Landscape  
Christina Zarcadoolas, CUNY and Mount Sinai School of Medicine  
Janet Tobias, Mount Sinai School of Medicine

4:35 – 4:55 PM  A Recent Trial of Pediatric Fluid Resuscitation and Novel Methods for Physician Engagement  
Kathryn Maitland, Imperial College

4:55 – 5:40 PM  Panel Discussion: Public Information and Public Advocacy  
Joan Finnegan Brooks, Patient-Focused Market Research  
Cornelia Dean, *The New York Times*  
Peggy Peck, *MedPage Today*  
Roger Sergel, ABC  
Heather Won Tesoriero, CBS

5:40 PM  RECEPTION  
*The Plaque Room*  
Guggenheim Pavilion, 1190 Fifth Avenue @ 101st Street
JUNE 28  SESSION V: NOVEL CLINICAL TRIAL DESIGN
Moderator: Michael Krams, Johnson & Johnson
Session Objectives:

- Present novel clinical trial designs currently in use (e.g., adaptive trial designs), their strengths and weaknesses, and the desirability and/or feasibility of scaling up the widespread use of such designs.
- Discuss the ways in which novel clinical trial designs can enhance public engagement in clinical research and address treatment assignment concerns of physicians and their patients.

8:05 – 8:20 AM  The Promise of Novel Trial Designs  
Michael Parides, Mount Sinai School of Medicine

8:20 – 8:35 AM  Trial Designs Addressing Treatment Assignment Concerns  
Louis Fiore, VA Boston Healthcare System

8:35 – 8:55 AM  Perspective of the Food and Drug Administration (FDA)  
Bram Zuckerman, Center for Devices and Radiological Health, FDA  
Douglas C. Throckmorton, Center for Drug Evaluation & Research, FDA

8:55 – 9:15 AM  Panel Discussion

SESSION VI: HEALTH SYSTEM STRUCTURES AND CULTURE
Moderator: Harry Greenberg, Stanford University
Session Objectives:

- Present case studies that include a health system perspective on public and professional engagement methods and approaches and address broader culture and infrastructure/systemic issues.
- How can health systems develop a culture conducive to conducting clinical trials, including incentives for the careers of health professionals, systems approaches to better identify potential enrollees, engagement of referring physician community?
- For a health care delivery system, what are the suggested messages/approaches to enhance public support, understanding, buy-in, and ultimately participation in clinical trials? What organizations at the local level can be leveraged to achieve this?
- How can academic medical centers create effective community partnerships to improve public engagement in clinical trials?

9:20 – 9:35 AM  Building a Clinical Trials Culture in Academia  
Eric Rose, Mount Sinai School of Medicine

9:35 – 9:50 AM  Exploring Novel Institutional Models in Cancer  
George Demetri, Dana-Farber Cancer Institute and Harvard Medical School

9:50 – 10:05 AM  New Organizational Models in Rheumatoid Arthritis Trials  
James O'Dell, Rheumatoid Arthritis Investigational Network (RAIN), University of Nebraska

10:05 – 10:20 AM  ResearchMatch.org and Other IT Solutions  
Paul Harris, Vanderbilt University
10:20 – 10:40 AM  Panel Discussion

10:40 – 11:00 AM  COFFEE BREAK

11:00 – 11:45 AM  Building Connections Between Community Physicians and Academic Medicine: The Challenges

Panel Moderated by: Hugh Sampson, Mount Sinai School of Medicine
Sanford Friedman, Mount Sinai Hospital
Rafat Abonour, Indiana University Simon Cancer Center
Ramon Murphy, Mount Sinai School of Medicine

SESSION VII: BUILDING A COMPREHENSIVE STRATEGY

Session Objectives:
- What are the most promising methods and messages for public and professional engagement that you heard during this meeting? What is the likelihood of action? How can they be prioritized?
- What would be the ideal technology to enhance public and professional engagement?
- What are the most pressing structural and cultural needs for a local health care system to enhance promotion of public and professional engagement and participation in clinical trials?
- What efforts aimed at physicians, researchers, patients, and the broader public will facilitate closing the gap between clinical researchers and clinical practitioners?

11:45 – 12:05 PM  The Changing Politics of Clinical Trial Engagement
Larry Brown, Columbia University

12:05 – 12:15 PM  Building a Comprehensive Strategy: A Summary of the Meeting
Jeffrey Drazen, New England Journal of Medicine

12:15 - 12:30 PM  Summary Discussion
Jeffrey Drazen, New England Journal of Medicine
Juan Lertora, National Institutes of Health
Greg Simon, Pfizer
Nancy Sung, Burroughs Wellcome Fund

12:30 PM  Adjourn