## Participant List

**Meeting of Invited Experts**

### Developing Effective Quality Systems in Clinical Trials: An Enlightened Approach

A Clinical Trials Transformation Initiative (CTTI)-Sponsored Meeting

October 13–14, 2010

Bethesda Marriott Suites
6711 Democracy Boulevard, Bethesda, MD 20817

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brenda Aker</td>
<td>Biosense Webster</td>
</tr>
<tr>
<td>Landen Bain</td>
<td>CDISC</td>
</tr>
<tr>
<td>Leslie Ball</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Rachel Behrman</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Alex Boddy</td>
<td>Sanofi-Aventis</td>
</tr>
<tr>
<td>Jean Bolte</td>
<td>Clinical Trials Transformation Initiative</td>
</tr>
<tr>
<td>Richard Burlingame</td>
<td>Merck and Co., Inc.</td>
</tr>
<tr>
<td>Tomasz Burzykowski</td>
<td>International Drug Development Institute (IDDI)</td>
</tr>
<tr>
<td>Chrissy Cochran</td>
<td>Food and Drug Administration, CDRH</td>
</tr>
<tr>
<td>Rory Collins</td>
<td>University of Oxford</td>
</tr>
<tr>
<td>Karena Cooper</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Steve Cummings</td>
<td>San Francisco Coordinating Center</td>
</tr>
<tr>
<td>Michael Delahunty</td>
<td>St. Jude Medical</td>
</tr>
<tr>
<td>Fred Feldstein</td>
<td>Pfizer</td>
</tr>
</tbody>
</table>
Terry Ferguson  
Cheryl Grandinetti  
David Green  
Joseph Griffin  
Felix Gyi  
Ruyi He  
Jonathan Helfgott  
Ed Helton  
Debby Holmes  
Pat Holobaugh  
Grant Huang  
Cheri Janning  
Raffael Jovine  
Jonathan Kagan  
Michael Katz  
Cynthia Kleppinger  
Judith Kramer  
Martin Landray  
Mike Lauer  
Joanne Less  
Diane Maloney  
Eileen Magruder  
Jennifer Marsh  
Clare Matti

AstraZeneca  
Food and Drug Administration, CDER  
ACRO  
Food and Drug Administration, CDER  
Chesapeake Research Review  
Food and Drug Administration, CDER  
Food and Drug Administration, CDRH  
National Cancer Institute , NIH  
ICON  
Food and Drug Administration, CBER  
US Department of Veterans Affairs  
Clinical Trials Transformation Initiative  
International Institute for the Safety of Medicines  
National Institute of Allergy and Infectious Diseases, NIH  
International Myeloma Foundation  
Food and Drug Administration, CDER  
Clinical Trials Transformation Initiative  
University of Oxford  
National Heart, Lung, and Blood Institute, NIH  
FDA, Good Clinical Practice Program  
Food and Drug Administration, CBER  
Amgen  
Eli Lilly and Co.  
Duke Clinical Research Institute
Louise Mawer  Medicines and Healthcare Products Regulatory Agency

Robert McCormick  PPD

Amanda McMillan  Duke Clinical Research Institute

Ann Meeker O’Connell  Food and Drug Administration, CDER

Jerry Menikoff  Office of Human Research Protections

Briggs Morrison  Pfizer

Jean Mulinde  Food and Drug Administration, CDER

David Nickerson  Pfizer

Bob O’Neill  Food and Drug Administration, CDER

Paul Okwesili  Food and Drug Administration, CDER

Ray Policare  Amgen

Tejashri Purohit-Sheth  Food and Drug Administration, CDER

Andrea Rathe  Population Health Research Institute

Roland Rich  Novartis

Nancy Roach  Colorectal Cancer Coalition

Melissa Robb  Food and Drug Administration, CDER

David Rodin  Merck and Co., Inc.

Peter Schiemann  Hoffman La Roche LTD

Gabriele Schwarz  BfArM

John Simes  National Health and Medical Research Council

Grant Simmons  Novartis

Mark Stacy  Duke University

Norman Stockbridge  Food and Drug Administration, CDER

Linda Sullivan  Metrics Champion Consortium
<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fergus Sweeney</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>Barbara Tardiff</td>
<td>PAREXEL</td>
</tr>
<tr>
<td>Robert J. Temple</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Kathleen Uhl</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Janet Vargo</td>
<td>Johnson and Johnson Medical Devices and Diagnostics</td>
</tr>
<tr>
<td>Susan Vogel</td>
<td>National Institute of Allergy and Infectious Diseases, NIH</td>
</tr>
<tr>
<td>Lorraine Waring</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Beat Widler</td>
<td>Roche</td>
</tr>
<tr>
<td>Steve Wiviott</td>
<td>Brigham and Women's Hospital / Harvard Medical School</td>
</tr>
<tr>
<td>Janet Woodcock</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Craig Wozniak</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Larry Wright</td>
<td>National Cancer Institute, NIH</td>
</tr>
</tbody>
</table>