



**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

<u>Name</u>	<u>Organization</u>
Brenda Aker	Biosense Webster
Landen Bain	CDISC
Leslie Ball	Food and Drug Administration, CDER
Rachel Behrman	Food and Drug Administration, CDER
Alex Boddy	Sanofi-Aventis
Jean Bolte	Clinical Trials Transformation Initiative
Richard Burlingame	Merck and Co., Inc.
Tomasz Burzykowski	International Drug Development Institute (IDDI)
Chrissy Cochran	Food and Drug Administration, CDRH
Rory Collins	University of Oxford
Karena Cooper	Food and Drug Administration, CDER
Steve Cummings	San Francisco Coordinating Center
Michael Delahunty	St. Jude Medical
Fred Feldstein	Pfizer

Terry Ferguson	AstraZeneca
Cheryl Grandinetti	Food and Drug Administration, CDER
David Green	ACRO
Joseph Griffin	Food and Drug Administration, CDER
Felix Gyi	Chesapeake Research Review
Ruyi He	Food and Drug Administration, CDER
Jonathan Helfgott	Food and Drug Administration, CDRH
Ed Helton	National Cancer Institute , NIH
Debby Holmes	ICON
Pat Holobaugh	Food and Drug Administration, CBER
Grant Huang	US Department of Veterans Affairs
Cheri Janning	Clinical Trials Transformation Initiative
Raffael Jovine	International Institute for the Safety of Medicines
Jonathan Kagan	National Institute of Allergy and Infectious Diseases, NIH
Michael Katz	International Myeloma Foundation
Cynthia Kleppinger	Food and Drug Administration, CDER
Judith Kramer	Clinical Trials Transformation Initiative
Martin Landray	University of Oxford
Mike Lauer	National Heart, Lung, and Blood Institute, NIH
Joanne Less	FDA, Good Clinical Practice Program
Diane Maloney	Food and Drug Administration, CBER
Eileen Magruder	Amgen
Jennifer Marsh	Eli Lilly and Co.
Clare Matti	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

Fergus Sweeney	European Medicines Agency
Barbara Tardiff	PAREXEL
Robert J. Temple	Food and Drug Administration, CDER
Kathleen Uhl	Food and Drug Administration, CDER
Janet Vargo	Johnson and Johnson Medical Devices and Diagnostics
Susan Vogel	National Institute of Allergy and Infectious Diseases, NIH
Lorraine Waring	Pfizer
Beat Widler	Roche
Steve Wiviott	Brigham and Women's Hospital / Harvard Medical School
Janet Woodcock	Food and Drug Administration, CDER
Craig Wozniak	GlaxoSmithKline
Larry Wright	National Cancer Institute, NIH