



**Participant List
Meeting of Invited Experts**

**Findings and Implications of a Project Sponsored by the
Clinical Trials Transformation Initiative (CTTI):**

*“Improving the System of Reporting and Interpreting Unexpected Serious Adverse Events to
Investigators Conducting Research Under an Investigational New Drug Application”*

October 3 and 4, 2010

Marriott Inn & Conference Center, University of Maryland University College.
3501 University Blvd. East, Hyattsville, MD, 20783

<u>NAME</u>	<u>ORGANIZATION</u>
Jeff Abrams	National Cancer Institute, NIH
Priscilla Adler	Medstar Health Research Institute
John Alexander	Duke Clinical Research Institute
Leslie Ball	Food and Drug Administration, CDER
Rachel Behrman	Food and Drug Administration, CDER
Fred Bloom	Centers for Disease Control and Prevention
M. Luisa Bonura	Pfizer, Inc.
Grendel Burrell	Duke Translational Medicine Institute
Kelly Cahill	National Institute of Allergy and Infectious Diseases, NIH
Robert Califf	Duke Translational Medicine Institute
Kay Dickersin	Johns Hopkins University
Susan Ellenberg	University of Pennsylvania

Kathryn Flynn	Duke Clinical Research Institute
Bridget Foltz	Food and Drug Administration, Office of Good Clinical Practice
John Fredenburg	Eli Lilly and Co.
Suzanne Gagnon	ICON
Cheryl Grandinetti	Food and Drug Administration, CDER
Christopher Granger	Duke Clinical Research Institute
Howard Greenberg	American College of Clinical Pharmacology (ACCP)
Steve Hirschfeld	National Institute of Child Health and Human Development
Patricia Holobaugh	Food and Drug Administration, CBER
Peter Honig	AstraZeneca
Grant Huang	US Department of Veterans Affairs
Percy Ivy	National Cancer Institute, NIH
Cheri Janning	Duke Translational Medicine Institute
Jonathan Kagan	National Institute of Allergy and Infectious Diseases, NIH
MaryAnn Karolchyk	Novartis
Judith Kramer	Duke Translational Medicine Institute
Mike Lauer	National Heart Lung and Blood Institute, NIH
Michael Lincoff	The Cleveland Clinic Foundation
Diane Maloney	Food and Drug Administration, CBER

Amanda McMillan	Duke Clinical Research Institute
Ann Meeker-O'Connell	Food and Drug Administration, CDER
Margaret Mooney	National Cancer Institute, NIH
Van Moore	US Department of Veterans Affairs
Jean Mulinde	Food and Drug Administration, CDER
Greg Nadzan	Amgen
Janet Norden	Food and Drug Administration, CDER
Nancy Roach	Colorectal Cancer Coalition
Fabienne Santel	Food and Drug Administration, CDRH
Sundeep Sethi	Amgen
Lynda Szczech	Duke Clinical Research Institute
Barbara Tardiff	Parexel
Robert Temple	Food and Drug Administration, CDER
Kathleen Uhl	Food and Drug Administration, CDER
Jose Vega	Amgen
David Vock	Duke University
Kevin Weinfurt	Duke Clinical Research Institute
Janet Woodcock	Food and Drug Administration, CDER
Salim Yusuf	Population Health Research Institute, McMaster University
Deborah Zarin	National Library of Medicine, NIH