



## Participant List Meeting of Invited Experts

### Workshop: IND Safety Assessment and Communication A Clinical Trials Transformation Initiative (CTTI) Meeting

February 28 - 29, 2012

Hyatt Regency Bethesda  
One Bethesda Metro Center, Bethesda, MD 20814

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#### Attendees

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Name	Affiliation
John Alexander	Duke Clinical Research Institute
Patrick Archdeacon	Food and Drug Administration, CDER
David Balderson	Amgen, Inc.
Margaret Bash	Food and Drug Administration, CBER
Christopher Breder	Food and Drug Administration, CDER
Barbara Buch	Food and Drug Administration, CBER
Ramil Cabela	Celgene Corporation
Robert Califf	Duke Translational Medicine Institute
Aloka Chakravarty	Food and Drug Administration, CDER
Henry Che	Astellas Pharma Global Development
Christy Chuang-Stein	Pfizer, Inc.
Sabrina Comic-Savic	The Medicines Company
Brenda Crowe	Eli Lilly and Company
Milbhor D'Silva	Astellas Pharma Global Development
Diana Daly	Human Genome Sciences
Dave DeMets	University of Wisconsin
Rita Deng	Food and Drug Administration, CDER
Jethro Ekuta	Janssen Research & Development, LLC
Patricia French	Medical Writer
Cheryl Grandinetti	Food and Drug Administration, CDER
Achim Guettner	Novartis Pharma AG
Ruth Hager	Vertex Pharmaceuticals
David Hall	Boehringer Ingelheim
Diane Harrison	Janssen Research & Development, LLC
Grant Huang	US Department of Veterans Affairs
Cheri Janning	Clinical Trials Transformation Initiative

Qi Jiang	Amgen, Inc.
MaryAnn Karolchyk	Novartis Pharmaceuticals
Elias Kouchakji	Amgen, Inc.
Judith Kramer	Duke Translational Medicine Institute
Mike Lauer	National Heart, Lung and Blood Institute, NIH
Ron Leong	AstraZeneca
Joanne Less	Food and Drug Administration, OGCP
Elliott Levy	Bristol-Myers Squibb
Eric Lewis	GlaxoSmithKline
Debbie Lucas	Clinical Trials Transformation Initiative
Leanne Madre	Clinical Trials Transformation Initiative
Diane Maloney	Food and Drug Administration, CBER
Ann Meeker-O'Connell	Food and Drug Administration, CDER
Anthony Murgo	Food and Drug Administration, CDER
Janet Norden	Food and Drug Administration, CDER
Ann O'Brien	GlaxoSmithKline
Bob O'Neill	Food and Drug Administration, CDER
Dan Odenheimer	Human Genome Sciences
Jackie O'Shaughnessy	Food and Drug Administration, CDER
Bray Patrick-Lake	Patient Advocate
Richard Platt	Harvard Pilgrim Health Care Institute
Kamal Shah	Celgene Corporation
Stephanie Shapley	Food and Drug Administration, CDER
Steve Snapinn	Amgen, Inc.
Kathleen Swanson	US Department of Veterans Affairs
Bob Temple	Food and Drug Administration, CDER
Jose Vega	Amgen, Inc.
Stuart Warren	US Department of Veterans Affairs
Janice Wherry	Bristol-Myers Squibb
Leslie Williams	The Medicines Company
Janet Wittes	Statistics Collaborative, Inc.
Christopher Wohlberg	Pfizer, Inc.
Amy Xia	Amgen, Inc.