



Participant List

Quality by Design Workshop A Clinical Trials Transformation Initiative (CTTI) Meeting September 20 - 21, 2012

Hyatt Regency Bethesda
One Bethesda Metro Center (7400 Wisconsin Avenue), Bethesda, MD 20814

Attendees

Name	Affiliation
John Alexander	Duke University
Jennifer Andree-Webb	Drug Information Association (DIA)
Patrick Archdeacon	Food and Drug Administration, CDER
Jeff Aycock	Amgen, Inc.
Lawrence Baizer	National Institutes of Health, NCI
Mark Behm	AstraZeneca
Brendon Binneman	Pfizer, Inc.
Louise Bowman	University of Oxford
Robert Califf	Duke Translational Medicine Institute (DTMI)
Lynda Chick	Bristol-Myers Squibb Pharmaceuticals
Christy Chuang-Stein	Pfizer, Inc.
Sabrina Comic-Savic	The Medicines Company
Diana Daly	Human Genome Sciences
Frances Degennaro-Culver	Merck
Fred Feldstein	Pfizer, Inc.
Marta Fields	Seattle Genetics
Patricia French	Left Lane Communications
David Fryrear	Eli Lilly and Company
Coleen Glessner	Pfizer, Inc.
Cheryl Grandinetti	Food and Drug Administration, CDER
Stephen Grant	Food and Drug Administration, Division of Cardiovascular & Renal Products, CDER
Jorge Guerra	Biogen Idec
Adam Haim	National Institutes of Health, NIMH
Grant Huang	US Department of Veterans Affairs

S. Percy Ivy	National Institutes of Health, NCI
Cheri Janning	Clinical Trials Transformation Initiative (CTTI)
LeeAnn Jensen	National Institutes of Health, NCI
Darlene Kalinowski	Bristol-Myers Squibb
Bob Kane (<i>teleconference</i>)	Food and Drug Administration, Office of Hematology and Oncology products, CDER
Jeffrey Kasher	Eli Lilly and Company
Cynthia Kleppinger	Food and Drug Administration, CDER
Kathy Kopnisky	National Institutes of Health
Judith Kramer	Duke Translational Medicine Institute (DTMI)
Martin Landray	University of Oxford
Lisa LaVange	Food and Drug Administration, CDER
Linda MacKeen	Seattle Genetics
Debra Madden	Breast Cancer Patient Representative / Research Advocate
Leanne Madre	Clinical Trials Transformation Initiative (CTTI)
Annie Marion	WomenHeart
Carol Matyka	National Breast Cancer Coalition
Gwen Mayes	WomenHeart/National Patient Advocate Foundation
Ann Meeker-O'Connell	Food and Drug Administration, CDER
Kunal Merchant	Clinical Trials Transformation Initiative (CTTI)
Jules Mitchel	Target Health
Briggs Morrison	AstraZeneca
Jean Mulinde	Food and Drug Administration, CDER
Tamara Navarro	Schizophrenia and Related Disorders Alliance of America (SARDAA)
David Nickerson	Pfizer, Inc.
Dan Odenheimer	Human Genome Sciences
Bray Patrick-Lake	Clinical Trials Transformation Initiative (CTTI)
Christine Pierre	RX Trials
Craig Reist	Duke Clinical Research Institute (DCRI)
Nancy Roach	Fight Colorectal Cancer
David Rodin	Pfizer, Inc.
Diane Ryan	Pfizer, Inc.
Ken Schiff	Quality Risk Management Associates, LLC
Stephanie Shapley	Food and Drug Administration, CDER
Jeffrey Skolnik	AstraZeneca
Gary Smith	National Institutes of Health, NCI-CTEP
Ken Sprenger	Pfizer, Inc.

Fergus Sweeney	European Medicines Agency (EMA)
Pamela Tenaerts	Clinical Trials Transformation Initiative (CTTI)
Cook Uhl	Food and Drug Administration, CDER
Beat Widler	Widler & Schiemann AG
Brett Wilson	Bristol-Myers Squibb / Hever
Craig Wozniak	GlaxoSmithKline
Vincent Yeung	Medicines and Healthcare Products Regulatory Agency (MHRA)