



Clinical Trials Transformation Initiative (CTTI)
Quality By Design Meeting
January 29 - 30, 2014
DoubleTree by Hilton Bethesda - Washington DC, Bethesda, MD

Participant List

<u>Name</u>	<u>Affiliation</u>	<u>Location</u>
Alexander, John	Duke University	Durham, NC
Alonso Garcia, Angeles	St. George's University of London; EMA	London, United Kingdom
Ashar, Binita	Food and Drug Administration / CDRH	Silver Spring, MD
Baldwin, Tim	National Institutes of Health / NHLBI	Bethesda, MD
Behm, Mark	AstraZeneca	Wilmington, DE
Breiter, David	Covidien Vascular Therapies	Plymouth, MN
Brescher, Jessica	C.R. Bard, Inc.	Murray Hill, NJ
Bulbulia, Richard	University of Oxford	Oxford, United Kingdom
Campbell, Robert	Children's Hospital of Philadelphia	Philadelphia, PA
Colder Carras, Michelle	Mental Health America	Ellicott City, MD
Collins, Doreen	RTI International	Research Triangle Park, NC
Connor, Jason	Berry Consultants	Orlando, FL
Diaz, Roni	St. Jude Medical	Plano, TX
Dorman, Diane	National Organization for Rare Diseases	Washington, DC
Foreman, Christy	Food and Drug Administration / CDRH	Silver Spring, MD
Gordon, Mary Jo	Spaulding Clinical	Seymour, WI
Guidry, Cyrus	Johnson & Johnson Global Surgery Group	Somerville, NJ
Harper, Patricia	Becton Dickinson	Franklin Lakes, NJ
Heller, Allen	Pharma Study Design, LLC	Woodbridge, CT
Hieshetter, Janet	Dystonia Medical Research Foundation	Chicago, IL
Jacques, Louis	Centers for Medicare & Medicaid Services	Baltimore, MD
Jolly, Sanjit	Hamilton Health Sciences, McMaster University	Hamilton, Ontario, Canada
Kurpanek, Katharina	The QM Company	Brussels, Belgium
Lam, Peter	Boston Scientific	Natick, MA
Landray, Martin	University of Oxford	Oxford, United Kingdom
Laschinger, John	Food and Drug Administration / CDRH	Silver Spring, MD
Leitner, Angela	Regulatory & Clinical Research Institute, Inc.	Mendota Heights, MN
Less, Joanne	Food and Drug Administration / OGCP	Silver Spring, MD
Lystig, Ted	Medtronic	Minneapolis, MN
Marinac-Dabic, Danica	Food and Drug Administration / CDRH	Silver Spring, MD
Mauri, Laura	Brigham and Women's Hospital	Boston, MA
Meeker-O'Connell, Ann	Janssen, Pharmaceutical Companies of Johnson & Johnson	Raritan, NJ
Mehran, Roxanna	Mount Sinai Medical Center	New York, NY
Miller, Marissa	National Institutes of Health / NHLBI	Bethesda, MD
Mulinde, Jean	Food and Drug Administration / CDER	Silver Spring, MD
O'Callaghan, Katie	Food and Drug Administration / CDRH	Silver Spring, MD
Panhuis, Janette	Population Health Research Institute	Hamilton, Ontario, Canada
Pina, Ileana	Montefiore Medical Center	Bronx, NY
Pinnow, Ellen	Food and Drug Administration / CDRH	Silver Spring, MD
Pocock, Stuart	London School of Hygiene and Tropical Medicine	London, United Kingdom
Purohit-Sheth, Tejashri	Food and Drug Administration / CDRH	Silver Spring, MD
Rao, Sunil	Duke University	Durham, NC
Reist, Craig	Duke Clinical Research Institute	Durham, NC
Richardson, Eric	Food and Drug Administration / CDRH	Silver Spring, MD
Robb, Melissa	Food and Drug Administration / CDER	Silver Spring, MD
Rose, Daniel	Pulmonary Fibrosis Foundation	Truckee, CA

Saviola, James	Food and Drug Administration / CDRH	Silver Spring, MD
Shipman, Tamara	St Jude Medical	Sunnyvale, CA
Smith, Karen	Parkinson's Disease Foundation	Evansville, IN
Stephenson, Betty	Becton Dickinson	Franklin Lakes, NJ
Tcheng, Jimmy	Health Disparities Research Consortium; Duke Clinical Research Institute	Durham, NC
Themeles, Ellison	Population Health Research Institute	Hamilton, Ontario, Canada
Toth-Allen, Jean	Food and Drug Administration / OGCP	Silver Spring, MD
Wu, Winifred	Strategic Regulatory Partners, LLC	Minneapolis, MN
Zuckerman, Bram	Food and Drug Administration / CDRH	Silver Spring, MD

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<u>Name</u>	<u>Affiliation</u>	<u>Location</u>
Forrest, Annemarie	Clinical Trials Transformation Initiative	Durham, NC
Janning, Cheri	Clinical Trials Transformation Initiative	Durham, NC
Madre, Leanne	Clinical Trials Transformation Initiative	Durham, NC
Mencini, MariJo	Clinical Trials Transformation Initiative	Durham, NC
Patrick-Lake, Bray	Clinical Trials Transformation Initiative	Durham, NC
Tenaerts, Pamela	Clinical Trials Transformation Initiative	Durham, NC