2-Day Virtual Public Meeting:

Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies

October 18 – 19, 2023 / 10 a.m. – 1:30 p.m. EDT

U.S. FOOD & DRUG ADMINISTRATION

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies (PHEs)

A public meeting to fulfill FDORA Section 3605 requirements and to address the need for advanced planning for clinical study disruptions

Meeting Agenda Day 1
October 18, 2023
10:00AM - 1:30PM (EDT)

10:00 a.m.	**Welcome and FDA Overview**
10:00 a.m.	Welcome, FDA overview on the Agency's activities and responses to address COVID-19 public health emergency and clinical trial conduct disruptions Speaker: *Jacqueline Corrigan-Curay, Principal Deputy Center Director, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)*
10:20 a.m.	Opening Remarks, Meeting Overview Speaker: *Janet Woodcock, Principal Deputy Commissioner, FDA*
10:30 a.m.	**Session I Cross-cutting Industry Perspectives**
	Session Facilitator/Moderator: *John Farley, CDER, FDA* Session Objectives: Discuss characteristics of clinical studies, sponsors, and patients affected by COVID-19 pandemic and how recommendations from FDA's guidance entitled ''Conduct of Clinical Trials of Medical Products During the COVID–19 Public Health Emergency," were leveraged to address and mitigate study disruptions. Speakers and Panelists: **Anina Adelfio**, Chief Operating Officer, Association of Clinical Research Organizations (ACRO) **David Borasky**, Vice President, Compliance Review Solutions, WCG **Janice Chang**, Chief Executive Officer, TransCelerate

	Karla Childers, Head, Bioethics-based Science & Technology Policy, Office of the Chief Medical Officer, Johnson & Johnson **Janet Vessotskie**, Deputy Vice President of Science and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)
11:20 a.m.	**Break**
11:35 a.m.	**Session II Patient Experience and Perspectives**
	Session Facilitator/Moderator: *Captain Julienne Vaillancourt, Center for Biologics Evaluation and Research (CBER), FDA* Session Objectives: Discuss patient experiences in clinical studies during the COVID-19 pandemic, including barriers and needs for safe enrollment and ongoing participation. Panelists: **Karin Hoelzer**, Director of Policy and Regulatory Affairs, National Organization for Rare Disorders (NORD) **Valen Keefer**, Patient Advocate, Educator, Consultant, Thermo Fisher Scientific and Otsuka America Pharmaceutical **Neena Nizar**, Executive Director, Founder, Jansen's Foundation
12:15 p.m.	**Session III Drugs, Biologics, and Device Sponsors' and Investigators' Perspectives**
	Session Facilitator/Moderator: *Harpreet Singh, CDER, FDA* Session Objectives: Discuss sponsors' and investigators' organizational level practices related to clinical study disruptions during the COVID-19 pandemic and effective mitigation strategies adopted. Speakers and Panelists: **Lisa Bennett**, Principal Quality Lead, Roche **Kenneth Getz**, Executive Director, Tufts Center for the Study of Drug Development; Professor, Tufts University School of Medicine **Chris Labaki**, Post-doctoral Research Fellow, Dana-Farber Cancer Institute (DFCI), Broad Institute of MIT, Harvard **Vinod (Vinny) Parthasarathy**, Senior Clinical Monitoring Director, Medtronic **Joanne (Jo) Spallone**, Clinical Quality Consultant (JS GCP Clinical Consulting Services, LLC); Retired from Novartis Pharmaceuticals
1:25 p.m.	**Concluding Remarks**
	Speaker: *Sally Okun, Executive Director, Clinical Trials Transformation Initiative (CTTI)*
1:30 p.m.	**Adjourn Day 1**

Meeting Agenda Day 2
October 19, 2023
10:00AM - 1:30PM (EDT)

10:00 a.m.	**Welcome and FDA Overview**
10:00 a.m.	Welcome, Day 2 Overview, and Opening Remarks Speaker: *Celia Witten, Deputy Center Director, CBER, FDA*
10:05 a.m.	**Session IV Federal Partners Perspectives**
	Session Facilitator/Moderator: *Bray Patrick-Lake, Center for Devices and Radiological Health (CDRH), FDA* Session Objectives: Discuss federal experiences on disruption of clinical studies, focusing on multi-center/multi-region clinical studies funded/conducted during COVID-19 pandemic including access to underrepresented populations. Speakers: **John Beigel**, Associate Director for Clinical Research, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIH) **Margaret Mooney**, Associate Director, Chief, Clinical Investigations Branch (CIB), Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) **Salina Waddy**, Associate Director, CTSA Program Clinical Affairs, Chief, CTSA Program Clinical Affairs Branch, Division of Clinical Innovation, Clinical Affairs Branch, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)
10:50 a.m.	**Session V Creating Resilience in Clinical Studies Through Advanced Planning for Disruptive Emergencies**
10:50 a.m.	Introduction to Panel Discussions
10:55 a.m.	**Panel Discussion #1 - Emergency Preparedness in Clinical Studies**
	Panel Moderator: *Paul Kluetz, Deputy Director, Oncology Center for Excellence (OCE), FDA* Panel Discussion Objectives: - Discuss factors for when and how to build emergency preparedness into clinical studies - Discuss maintaining data quality during disruptive emergencies - Discuss regulatory considerations and communications with FDA related to disruptive emergencies Panelists:

	John H. Alexander, Professor of Medicine/Cardiology, Duke Clinical Research Institute, Duke University; Co-Chair, CTTI **Jeffrey Blank**, Adult Patient with Cystic Fibrosis **Marianne Chase**, Senior Director of Clinical Trial Operations, Neurological Clinical Research Institute/ Healey & AMG Center for ALS at Mass General Hospital **Hassan Kadhim**, Director, Head of Clinical Trial Business Capabilities, Global Development Operations, Bristol-Myers Squibb **Nina Movsesyan**, Manager, Clinical Research Programs, Metabolic Disorders Division, CHOC Children's Hospital Orange County **Veronica Suarez**, Global Product Leader, Vaccines Innovation Unit, CSL
11:55 a.m.	**Break**
12:05 p.m.	**Panel Discussion #2 - Digital Health Technologies (DHT) and Study Monitoring during Disruptive Emergencies**
	Panel Moderator: *Kassa Ayalew, CDER, FDA* Panel Discussion Objectives: - Discuss off-site data collection and acquisition tools, including broadband access, the use of technology/digital platforms such as DHT, electronic consent platforms, virtual patient reported outcomes, electronic clinical outcome assessments, and telehealth. - Discuss off-site study monitoring, including remote site monitoring by teleconference, remote review of study documents and source records, and centralized monitoring methods Panelists: **Cindy Geoghegan**, Patient Advocate, Advisor, and Activist **Catherine Gregor**, Chief Clinical Trial Officer, Florence Healthcare **Patrick Naldony**, Global Head, Clinical Data Management, Clinical Sciences & Operations, Sanofi **Pamela Tenaerts**, Chief Scientific Officer, Medable **Ramya Thota**, Investigator, Intermountain Health **Marion Wolfs**, Head, Risk Management and Central Monitoring Oncology, Johnson & Johnson Innovative Medicine
1:05 p.m.	**Wrap-up of Panel Discussions #1 and #2**
	Panel Moderators Objective: Summarize proposed strategies for mitigating clinical study disruptions during disasters and PHEs
1:15 p.m.	**Concluding Remarks**
	Speaker: *M. Khair ElZarrad, Director, Office of Medical Policy, CDER, FDA*
1:30 p.m.	**Adjourn Day 2**

CTTI and FDA Scientific Planning Committee

Clinical Trials Transformation Initiative

Sally Okun	Sara Calvert	Summer Starling	Morgan Hanger	Sabrena Mervin-Blake
Lindsay Kehoe	Rae Holliday	Kristi Geercken	Susan Morris	Damon Williams

U.S. Food and Drug Administration

Linda Akunne	Victor Crentsil	Paul Kluetz	Stephanie O. Omokaro	Yvonne Santiago
Cecilia Almeida	Dat Doan	Stefanie Kraus	Timil Patel	Mona Shing
Kassa Ayalew	M. Khair ElZarrad	Christine Lee	Jennifer Pippins	Anne Talley
Bryce Bennett	Mathilda Fienkeng	Peter Lenahan	Atasi Poddar	Hong Vu
Sanjeev Bhavnani	Andrea Furia-Helms	Mark Levenson	Kevin Prohaska	Dorothy West
Karen Bleich	Emily Gebbia	Diane Maloney	Ryan Robinson	Lori Wiggins
Raymond Chiang	Stephen Hansen	Kristen Miller	Ouided Rouabhi	Susan Wollersheim
David Cho	Karen Hicks	Jean Mulinde	Leonard Sacks	
John Concato	Alyson Karesh	Bindi Nikhar	Anindita Saha	