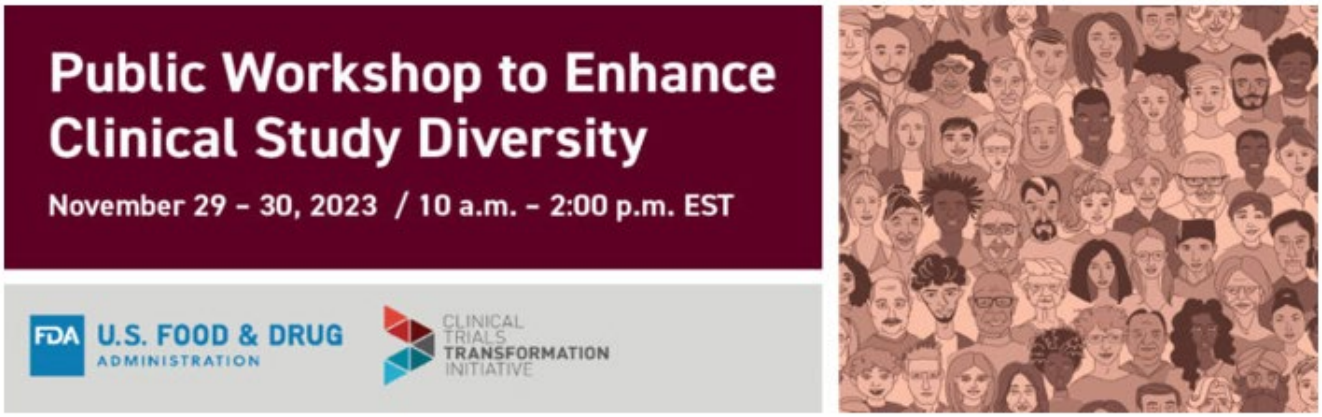

2-Day Virtual Public Workshop to Enhance Clinical Study Diversity

The U.S. Food and Drug Administration, in collaboration with the Clinical Trials Transformation Initiative, is convening a public workshop to solicit input on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups. This workshop fulfills a requirement under Section 3603 of the Food and Drug Omnibus Reform Act of 2022 (FDORA).

Workshop Agenda Day 1
November 29, 2023
10:00AM - 2:00PM (EST)

10:00 a.m.	**Welcome and Opening Remarks**
10:00 a.m.	Welcome and Opening Remarks **Karen Hicks**, *Deputy Director, Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), United States Food and Drug Administration (FDA)*
10: 05 a.m.	Keynote Speaker **Patrizia Cavazzoni**, *Director, CDER, FDA*
10: 15 a.m.	**Session 1: Clinical Study Diversity – A Brief Overview: Where are we now?**
	Session Objective: • Discuss the current status of clinical study diversity regarding increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the U.S. prevalence or incidence of the disease or condition among demographic subgroups from FDA, industry, academia, and patient viewpoints. **Moderator: Richardae Araojo**, *Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity, FDA*

	Speaker/Panelists: **Lola Fashoyin-Aje**, *Deputy Division Director & Associate Director, Oncology Center for Excellence (OCE), FDA* **Eldrin Lewis**, *Simon H. Stertzer Professor of Cardiovascular Medicine, Stanford Medicine* **Laura Mauri**, *Senior Vice President (VP), Chief Scientific, Medical and Regulatory Officer, Medtronic* **Allison Cuff Shimooka**, *Chief Operating Officer (COO), TransCelerate BioPharma, Inc.* **Ricki Fairley**, *Chief Executive Officer (CEO), Touch, the Black Breast Cancer Alliance*
11:15 a.m.	**Session 2: Establishment of Clinical Study Enrollment Goals & Use of Disease Prevalence or Incidence Data**
	Session Objectives: • Discuss how and when to collect and present the prevalence or incidence data on a disease or condition by demographic subgroup, including possible sources for such data and methodologies for assessing such data. • Discuss the establishment of goals for enrollment in clinical trials, including the relevance of the estimated U.S. prevalence or incidence of the disease or condition for which the drug or device is being developed. **Moderator**: **Dionne Price**, *Deputy Director, Office of Biostatistics, CDER, FDA* **Speakers/Panelists:** **Scott Halpern**, *John M. Eisenberg Professor of Medicine, Epidemiology, and Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania* **Dooti Roy**, *Director, Global Biostatistics & Data Sciences, Boehringer Ingelheim Inc* **Bobbi Bogaev Chapman**, *Vice President (VP), Heart Failure, Abiomed* **Tom Fleming**, *Professor of Statistics and Biostatistics, University of Washington* **Michel Reid**, *Senior Director and Head, Global Demographics and Diversity, GlaxoSmithKline*
12:35 p.m.	**BREAK**
12:45 p.m.	**Session 3A: Approaches to Support the Inclusion of Underrepresented Populations and to Encourage Clinical Study Participation – Age, Race, Ethnicity, Sex, Pregnancy and Lactation**
	Session Objectives: • Discuss approaches to support inclusion of historically underrepresented populations in clinical studies and to encourage clinical study participation that reflects the population expected to use the drug or device under study, including with respect to age, race, ethnicity, sex, pregnancy and lactation.

	• Discuss the establishment of inclusion and exclusion criteria for pregnant and lactating women. **Moderator**: **Larissa Aviles-Santa**, *Director, Division of Clinical and Health Services Research, National Institute on Minority Health and Health Disparity (NIMHD), National Institutes of Health (NIH)* **Speakers/Panelists**: **Rose Blackburne**, *VP, Global Therapeutic Area Head, General Medicine & Women's Health, Medical Science & Strategy (MSS), PPD, Thermo Fisher Scientific Company* **Anne Lyerly**, *Professor of Social Medicine, The University of North Carolina at Chapel Hill* **Michele Kipke**, *Professor of Pediatrics, Associate Vice President for Strategic Health Initiatives, Keck School of Medicine, University of Southern California* **Jennifer Jones-McMeans**, *Divisional VP of Global Clinical Affairs, Abbott* **Dawn Corbett**, *Inclusion Policy Officer, Office of Extramural Research, NIH*
1:25 p.m.	**Session 3B: Approaches to Support the Inclusion and Clinical Study Participation of Individuals with Disabilities Including Intellectual or Developmental Disabilities**
	Session Objectives: • Discuss approaches to support inclusion of historically underrepresented populations in clinical studies and to encourage clinical study participation that reflects the population expected to use the drug or device under study, including the establishment of inclusion and exclusion criteria for individuals with disabilities, including intellectual or developmental disabilities. • Discuss considerations regarding informed consent with respect to individuals with intellectual or developmental disabilities, including ethical and scientific considerations. • Discuss practices for overcoming barriers to participation of individuals with intellectual or developmental disabilities. **Moderator**: **David Resnik**, *Bioethicist, National Institute of Environmental Health Sciences, NIH* **Speaker/Panelists**: **Willyanne Decormier Plosky**, *Program Director, Multi-Regional Clinical Trials Center, Harvard University* **Kellie Malloy Foerter**, *VP, Global Trial Management, Immunology, Cardiovascular and Neuroscience, Bristol Myers Squibb* **Ari Ne'eman**, *PhD Candidate, Harvard University*

	Alison Barkoff, *Performing the duties of the ACL Administrator and Assistant Secretary for Aging*
1:55 p.m.	**Concluding Remarks**
	Sally Okun, *Executive Director, Clinical Trials Transformation Initiative (CTTI)*
2:00 p.m.	**Adjourn Day 1**

Workshop Agenda Day 2
November 30, 2023
10:00AM – 2:00PM (EST)

10:00 a.m.	**Welcome and Opening Remarks**
10:00 a.m.	Overview and Opening Remarks **Mathilda Fienkeng**, *Director, Division of Medical Policy Development, OMP, CDER, FDA*
10: 05 a.m.	**Session 3C: Approaches to Support the Inclusion and Clinical Study Participation of Individuals with Mental Illness**
	Session Objectives: • Discuss approaches to support inclusion of historically underrepresented populations in clinical studies and to encourage clinical study participation that reflects the population expected to use the drug or device under study, including the establishment of inclusion and exclusion criteria for individuals with mental illness. • Discuss considerations regarding informed consent with respect to individuals with mental illness, including ethical and scientific considerations. • Discuss practices for overcoming barriers to participation of individuals with mental illness. **Moderator**: **Paul Appelbaum**, *Professor of Psychiatry, Medicine & Law, Columbia University* **Speakers/Panelists:** **Patricia Areán**, *Director, Division of Services and Intervention Research, National Institute of Mental Health, NIH* **Allissa Torres**, *Director of Mental Health Equity, Mental Health America* **Scott Kim**, *Senior Investigator, Department of Bioethics, NIH Clinical Center* **Eric Lenze**, *Professor and Head, Department of Psychiatry, Washington University School of Medicine*
10: 35 a.m.	**Session 4: Appropriate Use of Decentralized Studies, Digital Health Tools, and Other Trial Elements to Support the Inclusion of Underrepresented Populations in Clinical Studies**
	Session Objectives: • Discuss approaches to support inclusion of underrepresented populations and to encourage clinical study participation that reflects the population expected to use the drug or device under study, including with respect to:

	○ the appropriate use of decentralized trials or digital health tools; ○ clinical endpoints; ○ biomarker selection; and ○ analysis of study results **Moderator**: **Craig Tendler**, *VP, Oncology Clinical Development, Diagnostics & Global Medical Affairs, Janssen, Pharmaceutical Companies of Johnson and Johnson* **Speakers/Panelists:** **Craig Lipset**, *Co-Founder and Co-Chair, Decentralized Trials and Research Alliance* **Laura Esserman**, *Professor of Surgery & Radiology, School of Medicine, University of California, San Francisco* **Luther T. Clark**, *Deputy Chief Patient Officer, Merck* **Alanna Morris**, *Associate Professor, Department of Medicine, Emory University School of Medicine* **Ivor Horn**, *Director of Health Equity and Product Inclusion, Google*
11:35 a.m.	**BREAK**
11:45 a.m.	**Session 5A: Post-Approval Dissemination of Clinical Study Enrollment Demographic Data to the Public**
	Session Objective: • Discuss considerations for public dissemination as appropriate, of clinical study enrollment demographic data after drug or device approval. **Moderator**: **James Hildreth**, *President and CEO, Meharry Medical College* **Speakers and Panelists**: **Paula Boyles**, *External Clinical Trial Data Sharing Program Lead, Pfizer* **Cynthia Chauhan**, *Heart Failure Collaborative* **Tarek Hammad**, *VP, Head of Medical Safety, Marketed Products, Global Patient Safety Evaluation, Takeda* **Barbara Bierer**, *Professor of Medicine, Center for Bioethics, Harvard Medical School*
12:20 p.m.	**Session 5B: Community Engagement**
	Session Objective: • Discuss community engagement as it relates to approaches to support inclusion of historically underrepresented populations in clinical studies and to encourage clinical study participation that reflects the population expected to use the drug or device after approval.

	Moderator: **Tesheia Johnson**, *Deputy Director and COO, Yale Center for Clinical Investigation* **Speakers and Panelists:** **Ileana Pina**, *Professor of Medicine, Thomas Jefferson University* **Angeloe Burch, Sr**, *African American Community Collaborative, Inc* **Reed Tuckson**, *Managing Director, Tuckson Health Connections, LLC* **Perla Nunes**, *Perla Nunes, Consulting* **Billy Caceres**, *Assistant Professor, Columbia University School of Nursing* **Kali Zhou**, *Assistant Professor of Clinical Medicine, Keck School of Medicine, University of Southern California*
1:15 p.m.	**Session 6: Moving Forward**
	Session Objectives: • Discuss key elements of enhancing clinical study diversity in the context of FDA's overall mission. **Moderator**: **Nakela Cook**, *Executive Director, Patient-Centered Outcomes Research Institute* **Panelists:** **Peter Marks**, *Director, Center for Biologics Evaluation and Research, FDA* **Jeff Shuren**, *Director, Center for Devices and Radiological Health, FDA* **Peter Stein**, *Director, Office of New Drugs, CDER, FDA* **Marc Theoret**, *Deputy Director, OCE, FDA* **Meghan McKenzie**, *Principal, Patient Inclusion and Health Equity, Chief Diversity Office, Genentech*
1:50 p.m.	**Concluding Remarks**
	Karen Hicks, *Deputy Director, OMP, CDER, FDA*
2:00 p.m.	**Adjourn**

Public Docket Information:
A docket is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. We encourage you to submit your comments to the docket by the comment period close date, January 29, 2024: https://www.federalregister.gov/documents/2023/08/23/2023-18149/workshop-to-enhance-clinical-study-diversity-public-workshop-request-for-comments or go to www.regulations.gov and search for docket number FDA-2023-N-2462.

CTTI and FDA Scientific Planning Committee

Clinical Trials Transformation Initiative

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

U.S. Food and Drug Administration

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Joshua Chetta	Raymond Chiang	Jacqueline Corrigan-Curay	Victor Crentsil	Asha Das
Dat Doan	M. Khair ElZarrad	Roselyn Epps	Tala Fakhouri	Tiffany Farchione
Lola Fashoyin-Aje	Mathilda Fienkeng	Karen Fikes	Kemba Ford	Jamie Gamerman
Karen Hicks	Andrea Hulse	Sarah Ibrahim	Stefanie Kraus	Christine Lee
Samantha LohCollado	Diane Maloney	Carmen Matos	Kristen Miller	Rihana Miller
Yeruk Mulugeta	Stephanie Omokaro	Bryon Pearsall	Kevin Prohaska	Anuradha Ramamoorthy
Anuja Rastogi	Mark Rothman	Leonard Sacks	Leyla Sahin	Yvonne Santiago
Mignon Schley	Jennifer Shepherd	Michelle Tarver	Mary Thanh Hai	Julienne Vaillancourt
Kaveeta Vasisht	Keith Verrett	Dorothy West	Lori Wiggins	Christina Williams
Alicia Witters	Lynne Yao			