

FDA ACS Symposium: Benchmarks for Diversity in Oncology Clinical Trials October 16, 2024 Omni Shoreham Hotel Washington, D.C. Agenda	
Meeting Objectives <ul style="list-style-type: none"> • Address strategies to develop enrollment goals that are relevant to a U.S. patient population, considering the global conduct of clinical trials. • Explore innovative approaches to enhance enrollment of diverse clinical trial population 	
8:30 am – 9:30 am	Networking Breakfast
9:30 am – 10:00 am	Welcome <ul style="list-style-type: none"> • ACS Welcome Bill Dahut, MD <i>American Cancer Society</i> Karen Knudson, MBA, PhD <i>American Cancer Society</i> • FDA Welcome & Introductory Presentation Tamy Kim, PharmD <i>U.S. Food and Drug Administration</i>
10:00 am – 11:45 am	Session 1: The Role of Epidemiology and Design in Enhancing Diversity: Approaches to Data Sources, Statistical Approaches, and Design to Achieve Clinical Trial Enrollment Goals Moderator: Nicole Gormley, MD <i>U.S. Food and Drug Administration</i> Presentations: <ul style="list-style-type: none"> • Epidemiologic Approaches Cleo Ryals, PhD <i>Flatiron Health</i> • Statistical Considerations and Clinical Trial Design Mary Redman, PhD <i>Fred Hutchinson Cancer Center</i> • Considerations for Global Enrollment Bea Lavery, MS <i>Genentech/Roche</i> Panel Discussion <ul style="list-style-type: none"> • Presenters and Panelists: Cleo Ryals, PhD <i>Flatiron Health</i> Mary Redman, PhD

	<p><i>Fred Hutchinson Cancer Center</i> Bea Lavery, MS <i>Genentech/Roche</i> Craig Tendler MD <i>Janssen Pharmaceutical Companies of Johnson & Johnson</i> Jianjin Xu, PhD <i>U.S. Food and Drug Administration</i> Cathy Lerro, PhD, MPH <i>U.S. Food and Drug Administration</i> Jamie Brewer, MD <i>U.S. Food and Drug Administration</i></p>
11:45 am – 12:30 pm	Lunch
12:30 pm – 12:45 pm	<p>OCE Relevant Projects Bindu Kanapuru, MD <i>U.S. Food and Drug Administration</i></p>
12:45 pm – 2:15 pm	<p>Session 2: Patient-Centric Approaches to Enhance Diversity</p> <p>Moderator: Donna Rivera <i>U.S. Food and Drug Administration</i></p> <p>Presentations:</p> <ul style="list-style-type: none"> • Rural Health Considerations Electra Paskett, PhD <i>Ohio State University College of Medicine</i> • Decentralized Trials Lesley Curtis, PhD <i>U.S. Food and Drug Administration</i> • Digital Health L. Johnetta Blakely, MD, MS, MMHC <i>Tennessee Oncology</i> <p>Panel Discussion</p> <ul style="list-style-type: none"> • Presenters and Panelists <p>Bindu Kanapuru, MD, <i>U.S. Food and Drug Administration</i> Electra Paskett, PhD, <i>Ohio State University College of Medicine</i> Lesley Curtis, PhD, <i>U.S. Food and Drug Administration</i> L. Johnetta Blakely, MD, MS, MMHC, <i>Tennessee Oncology</i> Josh Chetta, PhD <i>U.S. Food and Drug Administration</i> Stephanie Walker, RN</p>

	<p><i>Patient Advocate</i> Timil Patel, MD <i>U.S. Food and Drug Administration</i> Karen Noonan, MA <i>Association of Clinical Research Organizations (ACRO)</i></p>
2:15 pm – 2:30 pm	<p>Closing Remarks & Adjournment Christina Annunziata, MD American Cancer Society Nicole Gormley, MD, U.S. Food and Drug Administration</p>