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Overcoming Barriers to Diversifying Clinical Trials: Lessons Learned from Regulatory Agencies, Industry, and Federal and Private Funders

A Workshop to Inform the Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research

Monday, March 29, 2021

10:00 am – 10:15 am EST Welcome Remarks and Background on the Study

Kirsten Bibbins-Domingo, **PhD**, **MD**, **MAS**, *Committee Chair*, *University of California San Francisco*

10:15 am – 11:15 am Regulatory Challenges to Diversifying Clinical Trials: A Conversation with former FDA officials and a former ORISE fellow

Janice Schwartz, MD, Professor of Medicine, UCSF Robert Califf, MD, MACC, Head of Clinical Policy and Strategy, Verily and Google Health Marsha Henderson, Associate Commissioner for Women's Health, FDA (retired)

Moderator: Sharon Inouye, MD, MPH, Professor of Medicine, Harvard Medical School

11:15 am – 12:15 pm Diversifying Clinical Trials and Clinical Research: The Industry Perspective

Melissa Gonzales, Ph.D, Inclusion Principal, External Partnering, Genentech Jivan Achreja, Life Science Executive Melanie Ivarsson, Ph.D., MBA, Chief Development Officer, Moderna

Moderator: Edith Perez, MD, Chief Medical Officer, Bolt Biotherapeutics

12:15 pm – 1:15 pm Lunch Break

1:15 pm - 2:00 pmThe Role of Funders in Diversifying Clinical Trials and Clinical Research: How
Foundations are Taking Action

Alonzo Plough, PhD, MPH, MA, Vice President for Research and Chief Science Officer, Robert Wood Johnson Foundation Bernadette Siddiqi, MA, Senior Associate Director, Michael J Fox Foundation

Sung Poblete, PhD, RN, Chief Executive Officer, Stand Up To Cancer

Moderator: Jonathan Jackson, PhD, Executive Director, CARE Research Center, Massachusetts General Hospital

2:00 pm – 2:45 pm The Role of Funders in Diversifying Clinical Trials and Clinical Research: Federal Funders Driving Change

Janine Clayton, MD, Director, Office of Research on Women's Health, NIH Molly Klote, MD, Director, Office of Research Protections, Policy, and Education, Office of Research & Development, US Department of Veteran Affairs Gayle Vaday, PhD, Deputy Director, Congressionally Directed Medical Research Programs, U.S. Army Medical Research and Development Command

Moderator: Jason Resendez, Executive Director, UsAgainstAlzheimer's Center for Brain Health Equity

- 2:45 pm Workshop Adjourns
- 2:45 pm 3:15 pm Committee Break
- 3:15 pm 4:00 pm Committee Discussion on workshop