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

A March 29, 2021 Workshop to Inform the Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research

Speaker Biographies (in alphabetical order)

Jivan Achreja serves at the forefront of the intersection of technology and healthcare as a thought-expert, strategic innovator, and operational leader. His experience over the past ten years in the industry range in roles over entrepreneurship, technology, and healthcare. Jivan has served previously as CTO and President of Advarra, Principal of Platform at Medidata, and worked with companies across the life sciences and healthcare sphere globally. He currently serves on the Board of Mcginley Orthopedic Innovations, a cutting edge med-device company focused on innovative solutions. Diversity, Inclusion, and combating inequity has been a life-long career focus for Jivan.

Kirsten Bibbins-Domingo, PhD, MD, MAS is the Professor and Chair of the Department of Epidemiology and Biostatistics, and the Lee Goldman, MD Endowed Chair and Professor of Medicine at the University of California, San Francisco. She is the inaugural Vice Dean for Population Health and Health Equity in the UCSF School of Medicine. She co-founded the UCSF Center for Vulnerable Populations at Zuckerberg San Francisco General Hospital that focuses on actionable research to increase health equity and reduce health disparities in at-risk communities. She is one of the Principal Investigators for the UCSF Clinical and Translational Sciences Institute, and she leads the newly launched UCSF COVID Community Public Health Initiative. Dr. Bibbins-Domingo is a general internist and cardiovascular epidemiologist whose scholarship includes observational epidemiology, pragmatic trials, and simulation modeling to examine clinical and public health approaches to prevention in the US and globally. She previously served on and led the US Preventive Services Task Force from 2010-2017. She is an inducted member of the American Society for Clinical Investigation, the Association of American Physicians, and the National Academy of Medicine.

Robert M. Califf, MD, MACC, is the Head of Clinical Policy and Strategy for Verily and Google Health. Prior to this Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

Janine Austin Clayton, M.D., FARVO, was appointed Associate Director for Research on Women's Health and Director of the Office of Research on Women's Health at the National Institutes of Health (NIH) in 2012. Dr. Clayton has strengthened NIH support for research on diseases, disorders, and conditions that affect women. She is the architect of the NIH policy

requiring scientists to consider sex as a biological variable across the research spectrum, a part of NIH's initiative to enhance reproducibility, rigor, and transparency. As co-chair of the NIH Working Group on Women in Biomedical Careers with NIH Director Dr. Francis Collins, Dr. Clayton also leads NIH's efforts to advance women in science careers. Dr. Clayton was previously the Deputy Clinical Director of the National Eye Institute (NEI). A board-certified ophthalmologist, Dr. Clayton's research interests include autoimmune ocular diseases and the role of sex and gender in health and disease. Dr. Clayton has a particular interest in ocular surface disease and discovered a novel form of disease associated with premature ovarian insufficiency that affects young women, setting the stage for her commitment to rigorous, thoughtful exploration of the role of sex and gender in health and disease. She is the author of more than 120 scientific publications, journal articles, and book chapters. Her clinical research has ranged from randomized controlled trials of novel therapies for immune-mediated ocular diseases to studies on the development of digital imaging techniques for the anterior segment. Dr. Clayton, a native Washingtonian, received her undergraduate degree with honors from Johns Hopkins University and her medical degree from Howard University College of Medicine. She completed a residency in ophthalmology at the Medical College of Virginia. Dr. Clayton completed fellowship training in cornea and external disease at the Wilmer Eye Institute at Johns Hopkins Hospital and in uveitis and ocular immunology at NEI. Dr. Clayton has received several awards and has been recognized as a leader by her peers. She received the Senior Achievement Award from the Board of Trustees of the American Academy of Ophthalmology in 2008, was selected as a 2010 Silver Fellow by the Association for Research in Vision and Ophthalmology, and won the European Uveitis Patient Interest Association Clinical Uveitis Research Award in 2010. In 2015, she was awarded the American Medical Women's Association Lila A. Wallis Women's Health Award and the Wenger Award for Excellence in Public Service. Dr. Clayton was granted the Bernadine Healy Award for Visionary Leadership in Women's Health in 2016. She was also selected as an honoree for the Woman's Day Red Dress Awards and the American Medical Association's Dr. Nathan Davis Awards for Outstanding Government Service in 2017.

Melissa Gonzales, PhD is the Inclusion Principal, External Partnering within the Chief Diversity Office at Genentech. She received her PhD in Biochemistry from the University of Arizona. In 2006, she joined Genentech. During her 13 years with Genentech, Dr Gonzales has held a wide variety of positions including; Medical Science Liaison, Medical Science Director on HER2 Medical Teams, a Managed Care Liaison Field Manager, and most recently Inclusion Principal in the Chief Diversity Office. Dr. Gonzales is focused on developing external partnering strategies to address health equity issues and ensure patients of color have access to clinical trials and quality care by Advancing Inclusive Research.

Marsha B. Henderson served as the Associate Commissioner for Women's Health at the U.S. Food and Drug Administration (FDA). In this role, she led women's health research and outreach activities across the Agency. She was responsible for:

- Directing the Office of Women's Health at the FDA.
- Coordinating FDA policy, research, and outreach efforts to protect and advance the health of women.
- Advocating for the participation of women in clinical trials and for sex, gender, and subpopulation analyses.

Ms. Henderson is an expert in the development of public-private partnerships and culturally appropriate consumer information. She developed the Women's Health Take Time To Care Program which has reached over 120 million people with FDA consumer information in 18 languages, and received awards from more than 96 national organizations. In addition, her science-based but easy to read materials have been announced by Dear Abby, Parade

Magazine, Hints from Heloise, and the IRS and sponsored by external groups including the National Association of Chain Drug Stores, American Diabetes Association, YWCA, Ford Motor Company, Delta Airlines, American Medical Association, and even Las Vegas casinos. Ms. Henderson also leads new research collaborations with government, industry, and academia to promote best practices in the recruitment and retention of women in clinical trials and to advance the science of sex differences. Under her leadership, OWH released the first Women's' Health Research Roadmap at FDA which outlines seven priority areas for new or enhanced research including biomarkers, clinical trials design, nanotechnology, cardiovascular disease, and postmarket surveillance. Ms. Henderson is a nationally recognized leader, innovator, and change agent for the health of women and their families. She is the recipient of numerous awards from professional and consumer organizations, examples include the inaugural Dr. Estelle Ramey Award for Women's Health Leadership; the "HerMANA" Award for innovative outreach to Hispanic women, and the Pinnacle Award for exceptional leadership in enhancing health care quality and medication use for patients and caregivers. She was also the first non-pharmacist to receive the prestigious Jacob Miller Award from the American Pharmacists Association Foundation. Ms. Henderson's career in the federal government has spanned over 30 years. Prior to coming to FDA in 1996, Ms. Henderson served as the Director of Evaluation for the Interagency Council on the Homeless; Director of Placement for the National Health Service Corps, Chief of Analysis and Information for the Bureau of Maternal and Child Health, and Senior Advisor to the Director of the Women's Bureau at the Department of Labor**.** Ms. Henderson holds a graduate degree in Planning and Public Policy with a concentration in hospital administration from Rutgers University.

Sharon K. Inouye, M.D., MPH is Professor of Medicine, Harvard Medical School, Milton and Shirley F. Levy Family Chair, and Director, Aging Brain Center, Marcus Institute for Aging Research, Hebrew SeniorLife. Dr. Inouye is an internationally recognized leader in aging, public health, epidemiology, clinical trials, health equity, and health policy. As a geriatrician, she maintains a clinical practice in geriatric and homeless populations, and currently mentors over 20 early stage investigators. She received her BA (1977, English Literature) from Pomona College; MD (1981) from UCSF School of Medicine; and MPH (1989) from Yale School of Public Health. She has served as a Health and Aging Policy Fellow (2016-2017) and American Political Science Association Congressional Fellow (2016-2017) and an Encore Public Voices Fellow (2019-2020). She is an elected member of the National Academy of Medicine (2011), who has served on the IOM Committee on Cognitive Aging, and the NAM Membership and Nominating Committees. She currently participates in the NASEM Health Care Services Board and NAM/APHA's Covid19Conversations.org Advisory Board, serves as a member of the President's Advisory Panel and Steering Committee for NAM's Healthy Longevity Roadmap Project, and served as former Chair of the NAM Interest Group on the Biology of Aging and Geriatrics (IG10), and Co-Chair of the Workshop on Health Care Systems and Public Health for Healthy Longevity for the NAM. Throughout the pandemic, Dr. Inouye has brought attention to vulnerable populations, including those based on age, race, socioeconomic status, disability, and homelessness, with many pertinent articles in biomedical journals (NEJM, Age & Aging), as well as the New York Times, NPR, BBC, and others related to equity issues surrounding COVID-19 treatment, enrollment into vaccine trials, equitable allocation of critical care resources, and other pressing issues.

Melanie Ivarsson, Ph.D. is Chief Development Officer at Moderna, a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients. Dr. Ivarsson comes to Moderna from Takeda Pharmaceuticals where she was Vice President, Head of Global Clinical Operations. Dr. Ivarsson has more than 20 years of experience in the pharmaceutical industry.

As Vice President, Head of Global Clinical Operations, at Takeda, she oversaw 130 clinical operations experts, with responsibility for the delivery of all clinical trials across oncology, neuroscience, rare disease, gastroenterology and plasma-derived therapies. She has also served as Senior Director, Head of Clinical Strategy and Operations, at Pfizer, where she led strategic and business operations for the clinical organization. Dr. Ivarsson also held roles within the early clinical development group at Eli Lilly. Dr. Ivarsson received her Ph.D. from University of Bristol and completed postdoctoral research at Lund University and New York University. She holds an Executive MBA from MIT Sloan School of Management.

Jonathan Jackson, PhD, is the executive director of the Community Access, Recruitment, and Engagement (CARE) Research Center at Massachusetts General Hospital and is an Assistant Professor of Neurology at Harvard Medical School. CARE investigates the impact of diversity and inclusion on the quality of human subjects research and leverages deep community entrenchment to build trust and overcome barriers to clinical trial participation. Jonathan's research focuses on inequities in clinical settings that affect underserved populations, and he has received generous funding for this work from the Michael J Fox Foundation for Parkinson's Research, Massachusetts General Hospital, and the National Institutes of Health, including a prestigious NIH Pioneer Award to advance this work. Dr. Jackson, who received his doctoral degree in Psychological and Brain Sciences in 2014, also conducts research as a cognitive neuroscientist investigating the early detection of Alzheimer's disease, particularly in the absence of overt memory problems. He has become a well-known representative to underserved communities and dozens of affiliated organizations, especially regarding participation in clinical research. Dr. Jackson serves in an advisory capacity for several organizations focused on equity in clinical research, and has written guidance for local, statewide, and national groups on research access, engagement, and recruitment.

Molly Klote, MD, is Director, Office of Research Protections, Policy, and Education, Office of Research & Development at the US Department of Veteran Affairs. She is responsible for VHA human subjects research policy, education, and support to the VA central institutional review board (IRB). Prior to this, as an active duty Army Colonel with 30 years of service, she oversaw all human research policy and education for the United States Army through the office of the Army Surgeon General. She has 10 years of expanding responsibilities over research and human subjects protection policy. She is a leader in effective, efficient, and compliant policy and education in human subjects research. Dr. Klote was awarded the Legion of Merit, the Defense Meritorious Service Medal, the Parachutist Badge, and the Expert Field Medical Badge. Dr. Klote began her Army service through ROTC at James Madison University majoring in computer information systems and earned a regular Army commission in the Military Intelligence Corps upon graduation. She served as a Military Intelligence officer for five years with tours in Korea, Honduras, Fort Meade, MD, and as Detachment Commander, Rosman Research Station, NC. She was then accepted to the Uniformed Service University of the Health Sciences where she graduated with the Esprit de Corps award. She trained in Internal Medicine and Allergy Immunology at Walter Reed Army Medical Center. She holds a board certification in Allergy Immunology. She holds the Army's A designator for professional achievement, is a member of the Order of Military Medical Merit, and was awarded the Military Health System Leadership Award for junior officers. As a physician, Dr. Klote has worked at the Office of the Army Surgeon General, The Walter Reed National Military Medical Center, the US Army Medical Research and Materiel Command, and the Walter Reed Army Medical Center. She served one tour in Iraq in 2008. She has earned the Certificate for IRB Professionals (CIP).

Edith A. Perez, MD is an internationally recognized translational researcher and cancer specialist, Chief Medical Officer of Bolt Therapeutics, Inc., Professor of Medicine at Mayo Clinic, and Director of the Mayo Clinic Breast Cancer Translational Genomics Program. Dr. Perez is known for her strategic vision in designing innovative clinical trials, her passion for patient care, and her strong team leadership. Her experience includes leadership in academic and biopharmaceutical environments, as well as focused philanthropic endeavors. Her academic work has been extensive, including chairing the NCCTG Breast Committee, serving in multiple committees with the NCI (such as the Board of Scientific Advisors, Clinical Trials and Translational Advisory Committee, amongst others), grant reviewer for the NIH, extensive editorial board and reviewer for multiple journals, participation, and leadership in Independent Data Monitoring Committees, leading the Publication Committee for the Alliance for Clinical Trials in Oncology, membership in Institute of Medicine Committees including the most recent one Use of Biomarkers for Selection of Molecularly Targeted Therapies. Dr. Perez earned her medical degree from the University of Puerto Rico School of Medicine in San Juan and completed her residency in internal medicine at the Loma Linda University Medical Center in California. She served as a general internist in the Division of National Health Services Corps, LA, and completed her Hematology/Oncology fellowship at the University of California, Davis School of Medicine. Dr. Perez also pursued additional leadership, management, and executive development at The Wharton School of the University of Pennsylvania and Harvard Kennedy School in Boston. Dr. Perez is board certified in internal medicine, medical oncology, and hematology.

Alonzo L. Plough is Vice President, Research-Evaluation-Learning and Chief Science Officer at the Robert Wood Johnson Foundation. in January 2014. He is responsible for aligning all of the Foundation's work with the best evidence from research and practice and incorporating program evaluations into organizational learning. He also oversees the two grantmaking portfolios focused on innovation and emerging issues: Pioneer and Global Ideas for U.S. solutions. Plough has been a national leader in public health practice for over 25 years. He came to the Foundation from the Los Angeles County Department of Public Health, where he served as director of emergency preparedness and response from 2009–2013. In that role, he was responsible for the leadership and management of activities protecting the 10 million residents of Los Angeles County from natural disasters and threats related to disease outbreaks and other public health emergencies. He coordinated activities in emergency operations, infectious disease control, risk communication, planning, and community engagement.
Prior to this position, Plough served as vice president of strategy, planning and evaluation for The California Endowment from 2005–2009. Before this, he served 10 years as director and health officer for the Seattle and King County Department of Public Health and previously served as director of public health in Boston for eight years. Plough earned his PhD and MA at Cornell University, and his MPH at Yale University School of Medicine's Department of Epidemiology and Public Health. He has held academic appointments at Harvard University School of Public Health, Tufts University Department of Community Medicine, and Boston University School of Management. He is currently clinical professor of health services at the University of Washington School of Public Health in Seattle. He has been the recipient of numerous awards for public service and leadership and is the author of an extensive body of scholarly articles, books, and book chapters. Plough lives in Princeton and Los Angeles, and is married with two adult sons and two granddaughters. He is a jazz guitarist and vocalist.

Sung Poblete, PhD, RN has made it her life's work to fight cancer from all angles: galvanizing awareness, improving patient outcomes, and enabling cutting-edge research. Today, she is chief executive officer of Stand Up To Cancer (SU2C). A common thread throughout Poblete's career has been her dedication to cutting-edge innovation on the research front, paired with a

steadfast focus on improving nonprofit and corporate healthcare. Previously, Poblete was director of clinical and translational programs at the American Association for Cancer Research (AACR), the scientific partner of SU2C, where she spearheaded the organization's scientific review, oversaw grants administration and management, and served as the primary liaison for scientific communications and general administration. Pivotal to the organization's collaborations, she was liaison to the Clinical and Translational Committee, the Pediatric Cancer Working Group, the Task Force on Survivorship Research, the Oncology Nursing Society, and the American Society of Clinical Oncology, all while leading AACR's continuing medical education program. Poblete has also held senior-level positions focused on patient outcomes and disease management. Notably, as vice president of clinical operations for a subsidiary of Fresenius Medical Care North America, she developed and ran national chronic kidney disease management programs. As executive director of the Oxford Health Plans Foundation, she facilitated grants that furthered research and programs aimed at improving health care delivery. Poblete has received grants from the Centers for Disease Control and Prevention, National Institutes of Health, National Science Foundation, and private foundations. She also served as a Centers for Disease Control and Prevention–UC Health Systems Public Scholar from 1999 to 2000. She currently serves on the Executive Board of the Osteosarcoma Institute and on the Stand Up To Cancer – Canada Board of Directors. She earned her bachelor of science degree, master of science degree, and PhD in nursing from Rutgers, where she also began her teaching career 20 years ago. She continues to serve Rutgers as a visiting professor at the School of Nursing. In 2016, Dr. Poblete was inducted into Rutgers Hall of Distinguished Alumni.

Jason Resendez currently serves as the Executive Director of the UsAgainstAlzheimer's Center for Brain Health Equity—partially funded by the Centers for Disease Control and Prevention's (CDC) Healthy Brain Initiative—which focuses on advancing health equity in brain health education and research. In 2020, Resendez was recognized as one of America's top 20 "Influencers in Aging" by PBS Next Avenue. Jason has helped establish UsAgainstAlzheimer's as a hub for driving health equity in brain research and care through patient-centered public health strategies and research collaborations in partnership with academic medical centers, industry leaders, and community-based organizations serving multicultural communities. From 2016 to 2018, he was a co-principal investigator with Dr. Goldie Byrd, Professor of Public Health Sciences at Wake Forest, on a Patient Centered Outcomes Research Institute (PCORI) Patient Engagement Award to establish the Alzheimer's Disease Disparities Engagement Network, a platform for connecting researchers, patients, caregivers and community leaders to share insights and establish collaborative partnerships to address disparities in Alzheimer's research engagement. Jason is currently a co-principal investigator of the Foundations of Representative Engagement, Valid & Effective Recruitment in Alzheimer's Research study (FOREVER) (NIH/NIA- 1DP1AG069873-01) with Dr. Jonathan Jackson of Massachusetts General Hospital. The project will operationalize the science of engagement, recruitment, and retention by developing a data-based framework directed at, and informed by, lay communities, research communities, and their intersection.

Janice B. Schwartz, MD, a Professor of Medicine in Geriatrics and Clinical Pharmacology at the University of California, San Francisco, is a board-certified internist and cardiologist with a distinguished record of leadership and research in clinical pharmacology and geriatric medicine. Dr. Schwartz received her medical degree from Tulane University School of Medicine and completed an internship in internal medicine at LAC/USC Medical Center and internal medicine residency training at Cedar Sinai Medical Center, Los Angeles. She began cardiology training at Cedar Sinai followed by a combined clinical and research cardiology fellowship at Stanford University, where she focused on evaluation of new cardiovascular drugs in clinical populations.

She began her faculty career in the Department of Medicine at Baylor College of Medicine in the Divisions of Cardiology and Clinical Pharmacology. It was here that she received her first research funding from the AHA and a faculty development funding grant from the PhRMA Foundation, allowing her to combine her clinical research with training in clinical pharmacology and laboratory procedures to pursue her goal of understanding alterations in drug responses in older patients. Following three years at Baylor, she became a faculty member at the University of California, San Francisco with joint appointments in the Schools of Medicine and Pharmacy. She spent her Assistant Professor through Associate Professor years at the University of California, where she was a core faculty member for the clinical pharmacology fellowship training program throughout. She completed mid-career training in geriatrics at UCLA in 1990, led the UCSF Gerontology and Geriatric Medicine Training Program from 1991-1995 and served on the Scientific Advisory Committee to the General Clinical Research Center. In 1995, she became Professor of Medicine and Chief of Geriatrics and Chief of Clinical Pharmacology at Northwestern University Medical School and Professor of Molecular Pharmacology and Biological Chemistry. She was also Chair of the Northwestern Hospital Pharmacy and Therapeutics Committee and Director of the Drug Assay laboratory and Associate Director, Buehler Center on Aging, McGaw Medical Center and Director, Geriatric Medicine Fellowship Program.

Bernadette Siddiqi joined The Michael J. Foundation in 2016. As a Research Programs Officer, Ms Siddiqi is responsible for contracting and managing the Foundation's motor and non-motor therapeutics and clinical trial grants. Ms Siddiqi focuses on developing and implementing strategies to grow the pool of eligible study volunteers and improve recruitment and retention to Parkinson's trials. She designs studies to understand barriers and motivations to research participation and test solutions to facilitate study enrollment. She is particularly passionate about engaging diverse populations in research to improve the generalizability of study results and the optimal development of next generation therapies for all those who could benefit. Ms Siddiqi also consults research teams on strategies to engage volunteers in their Parkinson's studies. Ms Siddiqi is passionate about the mission of the Foundation to find a cure for Parkinson's disease. Prior to joining MJFF, Bernadette worked at Penguin Random House where she contracted translation, audio, and periodical excerpt licenses for the company's collection of published books. Bernadette graduated from New York University with a B.A. in History and a M.A. in French Studies.

Gayle Vaday, PhD, is currently the Deputy Director of the Congressionally Directed Medical Research Programs (CDMRP). She also serves as a Deputy Director for Program Management, and previously served as the Program Manager of Breast Cancer Research Program at CDMRP for 14 years. Dr. Vaday provides senior leadership support for medical research programs totaling over $1.5 billion per year, through strategic planning, process development and improvement, and coordination with DoD and external stakeholders. She leads scientific staff to execute the acquisition program cycle and provides senior technical support to CDMRP administrative areas. Dr. Vaday graduated with a B.A. in Biology from Whittier College. She received her Ph.D. in Microbiology and Immunology from the University of Rochester School of Medicine and Dentistry. She completed postdoctoral training at the Weizmann Institute of Science. Prior to joining the CDMRP in January 2006, Dr. Vaday was a Research Assistant Professor at Stony Brook University and a Research Scientist at the Northport Veterans Affairs Medical Center. Dr. Vaday has represented the CDMRP at diverse forums including national conferences, advocacy groups, the National Academy of Medicine, and Congressional and VIP visits. She served as a member of the Interagency Breast Cancer and Environmental Research Coordinating Committee, Advisory Committee for Breast Cancer in Young Women, and Metastatic Cancer Research Task Force, and she will serve as a federal liaison to the NIH

Office of Research on Women's Health, 5th Annual Vivian Pinn Symposium in May 2021. Dr. Vaday is currently a member of the Army Acquisition Corps, Level III Science and Technology Management. She served on the working group that developed CDMRP's policy on Inclusion of Women and Minorities in Clinical Research.