NATIONAL ACADEMIES Sciences Engineering Medicine

Toward a Framework to Improve Diversity and Inclusion in Clinical Trials: A Workshop

Forum on Drug Discovery, Development, and Translation
National Cancer Policy Forum

May 20, 2024

National Academy of Sciences Building
Lecture Hall
2101 Constitution Avenue NW
Washington, DC 20418

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Toward a Framework to Improve Diversity and Inclusion in Clinical Trials

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A Workshop

May 20, 2024 ▪ Washington, DC

In the United States, racial and ethnic minorities comprise 39% of the population yet only 2% to 16% of clinical trial participants[1]. There is a pressing need for increasing diversity and inclusion in clinical trial participation not only to earn and build trust, but also to promote fairness and generate biomedical knowledge[2]. Increasing clinical trial representativeness may also improve the generalizability of research findings, yield targeted therapeutic strategies, and discover new biologic insights[2]. And yet, over the past three decades, there has been little progress towards increasing clinical trial participation of racial and ethnic minority populations. Underrepresentation in clinical trials perpetuates long-lasting health disparities with severe consequences for underserved populations and the nation as a whole.

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize a public workshop to explore opportunities to improve racial and ethnic diversity in clinical trials with a focus on system-level change and collective efforts across organizations and sectors that no one entity can effectively take on alone. This workshop builds upon previous meetings hosted by the Clinical Trials Transformation Initiative in June 2023, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard in September 2023, and FasterCures, Milken Institute in November 2023.

The public workshop will feature invited presentations and discussions to:

- Explore strategies for equitable participation, including innovative trial designs and partnerships to support community investment, engagement, and workforce development.
- Highlight ways that stakeholders can contribute to sustainable and scalable public awareness campaigns.
- Discuss business plans and funding mechanisms to allocate financial resources to improve clinical trial diversity.
- Consider ways to enable established and developing sites to increase capacity to conduct more equitable and representative clinical trials.
- Examine components of national, interoperable, and accountable systems for collecting and sharing condition-specific demographic data.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

[1] Hopper, Leigh. USC Health Researchers Rise to the Challenge of Improving Diversity in Clinical Trials. October 2022. University of Southern California. https://today.usc.edu/usc-health-researchers-rise-to-the-challenge-of-improving-diversity-in-clinical-trials/.
[2] Schwartz et. Al. Why Diverse Clinical Trial Participation Matters. April 2023. The New England Journal of Medicine. https://www.nejm.org/doi/full/10.1056/NEJMp2215609

The National Academies of Sciences, Engineering, and Medicine are private, nonprofit institutions that provide expert advice on some of the most pressing challenges facing the nation and the world. Our work helps shape sound policies, inform public opinion, and advance the pursuit of science, engineering, and medicine. For more information about this workshop, contact Alex Helman (ahelman@nas.edu).

NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Drug Discovery, Development, and Translation
National Cancer Policy Forum

Toward a Framework to Improve Diversity and Inclusion in Clinical Trials – A Workshop

May 20, 2024, 8:30 am – 5:00 pm (ET)

National Academy of Sciences Building
2101 Constitution Avenue NW Washington, DC 20418

To watch an event livestream, please visit the workshop page here.

PURPOSE

This workshop, convened by the National Academies' Forum on Drug Discovery, Development, and Translation; and National Cancer Policy Forum; will provide a venue for stakeholders to explore opportunities to improve racial and ethnic diversity in clinical trials with a focus on system-level change and collective efforts across organizations and sectors that no one entity can effectively take on alone. This workshop builds upon previous meetings hosted by the Clinical Trials Transformation Initiative (CTTI) in June 2023, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT) in September 2023, and FasterCures, Milken Institute in November 2023.

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May 20, 2024

8:30 am WELCOME AND OPENING REMARKS

FREDA LEWIS-HALL, *Workshop Chair*
Former Executive Vice President and Chief Medical Officer (Retired)
Pfizer

VICTOR DZAU
President
National Academy of Medicine

8:40 am NATIONAL ACTION PLAN OVERVIEW

BARBARA BIERER
Faculty Director, Multi-Regional Clinical Trials Center
Professor of Medicine
Harvard Medical School and Bringham and Women's Hospital

MORGAN HANGER
Executive Director
Clinical Trials Transformation Initiative

9:00 am PANEL 1: STRATEGIES FOR EQUITABLE PARTICIPATION IN CLINICAL TRIALS

Session Objectives:

- Highlight strategies for equitable participation in clinical trials, including innovative trial designs and methodologies, nontraditional clinical trial sites, and community-based partnerships.
- Discuss collaborative approaches to increase relevance, impact, and ease of enrollment for clinical trial participants, while also minimizing the burden of engagement for those conducting the trials.
- Explore collective approaches to overcome barriers to equitable and representative clinical trial participation.

Panel Discussion with Audience Q&A

Moderator: Martin Mendoza, National Institutes of Health

QUITA HIGHSMITH
Vice President and Chief Diversity Officer
Genentech

BRIAN RIVERS
Director, Cancer Health Equity Institute
Morehouse School of Medicine

MATTHEW WATLEY
Senior Pastor
Kingdom Fellowship AME Church

KARRIEM WATSON
Chief Engagement Officer
All of Us Research Program`
National Institutes of Health

10:00 am **COFFEE BREAK (15 mins)**

10:15 am FIRESIDE CHAT: CENTERS FOR MEDICARE AND MEDICAID SERVICES

SHARI LING
Deputy Chief Medical Officer
Centers for Medicare and Medicaid Services

ESTHER KROFAH, *Moderator*
Executive Vice President, Health
Milken Institute

11:00 am PANEL 2: DEFINING, COLLECTING, AND SHARING DATA ON TRIAL DIVERSITY

Session Objectives:

- Highlight key components of national, interoperable, and accountable systems for collecting and sharing condition-specific demographic data.
- Explore collaborative approaches to collect and share clinical trial data across organizations and sectors to enable continuous learning and improvement in trial diversity.

Panel Discussion with Audience Q&A

Moderator: Jennifer Miller, Yale School of Medicine

JAMIE BREWER
Medical Oncologist and Clinical Team Lead
Office of Oncologic Diseases
Food and Drug Administration

U. MICHAEL CURRIE
Healthcare Consultant

STEPHEN KONYA
Senior Advisor to the Deputy National Coordinator
Innovation Portfolio Lead
Office of the National Coordinator for Health Information Technology

SARAH HUDSON SCHOLLE
Principal
Leavitt Partners

VINDELL WASHINGTON
Chief Clinical Officer
Director of Health Equity Center of Excellence
Verily

12:00 pm **LUNCH (45 mins)**

12:45 pm PANEL 3: CLINICAL TRIAL SITE ENABLEMENT

Session Objectives:

- Consider ways to enable established and developing sites – including community-based practices – to increase capacity to conduct more equitable and representative clinical trials.
- Explore business plans and funding mechanisms that promote site enablement and advance equity in clinical trials.
- Discuss cross-sector opportunities for workforce development to support clinical trial site development.

Panel Discussion with Audience Q&A

Moderator: Kathy Mickel, Society for Clinical Research Sites

MEGAN COYLEWRIGHT
Vice Chief of Cardiology
Erlanger Health System

AMY FLOWERS
Director of Policy Research
National Association of Community Health Centers

KRISTEN NWANYANWU
Associate Professor of Ophthalmology and Visual Science
Yale School of Medicine

JONI RUTTER
Director, National Center for Advancing Translational Sciences
National Institutes of Health

CHERYL WILLMAN
Executive Director, Cancer Programs
Director, Mayo Clinic Comprehensive Cancer Center
Mayo Clinic

1:45 pm FIRESIDE CHAT: FOOD AND DRUG ADMINISTRATION & NATIONAL INSTITUTES OF HEALTH

MONICA BERTAGNOLLI
Director
National Institutes of Health

ROBERT CALIFF
Commissioner of Food and Drugs
Food and Drug Administration

NAMANDJÉ BUMPUS
Principal Deputy Commissioner
Food and Drug Administration

FREDA LEWIS-HALL, *Workshop Chair*

2:45 pm **COFFEE BREAK (35 mins)**

3:20 pm PANEL 4: CHALLENGING THE CLINICAL TRIAL ECOSYSTEM

Session objectives:

- Explore practical and implementable approaches for collaboration across organizations and sectors to advance more equitable and representative participation in clinical trials.
- Consider collective strategies for scaling and sustaining proven approaches for enabling more diverse and inclusive clinical trials.
- Discuss collaborative opportunities for improving public awareness about the risks, benefits, and value of clinical trial participation.

Panel Discussion with Audience Q&A

Moderator: Michelle McMurry-Heath, BioTechquity Clinical

STACEY ADAM
Vice President, Science Partnerships
Foundation for the National Institutes of Health

MARIA APOSTOLAROS
Deputy Vice President, Science and Regulatory Advocacy
PhRMA

NATALIA CHALMERS
Chief Dental Officer
Centers for Medicare and Medicaid Services

GWEN DARIEN
Executive Vice President, Patient Advocacy, Engagement, and Education
National Patient Advocate Foundation

DECHANE DORSEY
Executive Director, AdvaMed Accel
AdvaMed

MARY THANH HAI
Deputy Director for Clinical, Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

4:40 pm CLOSING REMARKS

FREDA LEWIS-HALL, *Workshop Chair*

5:00 pm **ADJOURN WORKSHOP**

RECEPTION TO IMMEDIATELY FOLLOW (90 minutes)

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Planning Committee Biographies

FREDA LEWIS-HALL, M.D., (CHAIR) is the former executive vice president & chief medical officer at Pfizer. Trained as a psychiatrist, she has held leadership roles in academia, medical research, front-line patient care, and at global biopharmaceutical companies including Vertex, Bristol-Myers Squibb, and Eli Lilly. Prior to her work in industry, she led research projects for the National Institutes of Health and was vice chairperson of the Department of Psychiatry at Howard University College of Medicine. In 2010, Dr. Lewis-Hall was appointed by the Obama Administration to the inaugural Board of Governors for the Patient-Centered Outcomes Research Institute (PCORI) and, in 2012, she was appointed chair of the Cures Acceleration Network Review Board and a member of the National Center for Advancing Translational Sciences (NCATS) Advisory Council of the National Institutes of Health. She also serves on the executive committee of the Clinical Trials Transformation Initiative and on numerous other boards, including those of Harvard Medical School, The Institute of Medicine's Forum on Drug Discovery, Development, and Translation, and Save the Children. Dr. Lewis-Hall received a Bachelor of Arts and Sciences from Johns Hopkins University and her Medical Doctorate from Howard University Hospital and College of Medicine. Dr. Lewis-Hall was named one of Savoy's Top Influential Women in Corporate America in 2012, and was selected as the Healthcare Businesswomen's Association's 2011 "Woman of the Year."

BARBARA BIERER, M.D., is a hematologist-oncologist, is Professor of Medicine at Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH). Dr. Bierer is the Faculty Director of the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center), a collaborative effort to improve standards for the planning and conduct of international clinical trials. She is also the Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst, and PI and Director of SMART IRB. She serves as Faculty in the Center for Bioethics, HMS, and Affiliate Faculty in the Petrie-Flom Center for Health Law at Harvard Law School. She is a co-founder of COVID-19 Collaboration Platform and of the non-profit Vivli, a global clinical research data sharing platform. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research, BWH where she founded the Brigham Research Institute and the Brigham Innovation Hub. She is a past chair of SACHRP and has served or serves on the Board of Directors of AAHRPP, PRIMR, MSH, Vivli, North Star IRB, and the Edward P. Evans Foundation. She has authored over 275 publications. Dr. Bierer received her BS from Yale University and her MD from Harvard Medical School.

SILAS BUCHANAN is the Founder and CEO of the Institute for eHealth Equity, a social impact consulting firm. Silas is an experienced underserved community engagement strategist, dedicated to building equitable partnerships and crafting web-based ecosystems that solve for known, outreach and engagement failure points. Silas partnered with the AME Church (2000 congregations and 2 million members) to build and launch www.amechealth.org as their official health information sharing, and data collecting website. He then led the development of strategic partnerships with healthcare, wellness, and Pharma organizations. He is currently working with the start-up, OurHealthyCommunity.com, to redevelop the platform to better engage underserved communities both secularly and non-secularly. Silas has contributed thought leadership to the National Academies of Medicine, Milken Institute's FasterCures, the Clinical Trials Transformation Initiative, Morehouse School of Medicine, Duke Clinical Research Institute, HIMSS, Accenture, American Telemedicine Association, Digital Medicine Society, and the Kraft Precision Medicine Accelerator at Harvard Business School, among many others.

LUTHER CLARK, M.D., is Deputy Chief Patient Officer and Global Director, Scientific Medical and Patient Perspective in the Office of the Chief Patient Officer at Merck. In this role, he is responsible for (1) gathering internal and external scientific and medical information to assist with decision-making at the highest levels; (2) collaborating across Merck to increase the voice of patients, directly and indirectly in decision-making; (3) collaborating with key internal and external stakeholders in development of a systematized approach for collecting and incorporating patient insights across the patient journey and product lifecycle; and (4) representing Merck externally, expanding bi-directional exchange with key patient and professional leaders and organizations. Dr. Clark leads Merck's Patient Insights Team, is co-leader of the team that champions Health Care Equities (including promotion of health literacy and research diversity) and chairs the Patient Engagement, Health Literacy & Clinical Trials Diversity Investigator Initiated Studies Research Committee. Prior to joining Merck, Dr. Clark was Chief of the Division of Cardiovascular Medicine at the State University of New York Downstate Medical Center (SUNY Downstate) and founding Director of the NIH-funded Brooklyn Health Disparities Research Center. Dr. Clark earned his Bachelor of Arts degree from Harvard College and his Medical degree from Harvard Medical School. He is a Fellow of the American College of Cardiology and the American College of Physicians, and a past member of the Board of Directors of the Founders Affiliate of the American Heart Association. He is a nationally and internationally recognized leader in cardiovascular education, clinical investigation, cardiovascular disease prevention, and health equity. He has authored more than 100 publications and edited and was principal contributor to the textbook Cardiovascular Disease and Diabetes (McGraw-Hill). Dr. Clark has received numerous awards and honors, including the Harvard University Alumni Lifetime Achievement Award for Excellence in Medicine. He is the current President of the Health Science Center at Brooklyn Foundation, SUNY Downstate Medical Center.

MARIANNE HAMILTON LOPEZ, PH.D., M.P.A., is a Senior Research Director, Adjunct Associate Professor and Core Faculty at the Duke-Margolis Center for Health Policy at Duke University. Previously, Dr. Hamilton Lopez was a senior program officer at the National Academy of Medicine where she oversaw the Leadership Consortium for a Value & Science-Driven Health System's Science and Technology portfolio and directed the Clinical Effectiveness Research Collaborative and the Digital Health Collaborative. She held senior positions at Academy Health, the United States Cochrane Center, and the National Institutes of Health. Dr. Hamilton Lopez's work focuses on facilitating a more efficient, affordable, and equitable biomedical pathway. She leads the Duke-Margolis Biomedical Innovation program, which focuses on medical product development and regulation, clinical trials, real world evidence, digital health, payment and coverage, and drug pricing and competition. She recently oversaw the development of the Advancing Clinical Trials at the Point-of-Care coalition which aims to drive the implementation of representative clinical trial networks to support rapid evidence development. Dr. Hamilton Lopez earned a PhD from UMBC, an MPA from The George Washington University, and a BA from Earlham College. She is also a graduate of the Department of Health and Human Services' Emerging Leaders Program.

MORGAN HANGER, M.P.P., is the Executive Director of the Clinical Trials Transformational Initiative (CTTI), a public-private partnership between Duke University and the U.S. Food and Drug Administration. She has deep experience convening organizations to solve complex problems related to evidence generation and is passionate about data ethics and transparency. Prior to CTTI, Hanger worked at health technology companies focused on patients. Notably, Hanger served as vice president of the online patient research network PatientsLikeMe (PLM), where she led partnerships to utilize patient-generated health data in life sciences and regulatory settings. Prior to PLM, Hanger worked in advisory services for Avalere Health, where she helped pharma, biotech, and professional societies create more effective research strategies. She has also held positions within the Health Outcomes Group at Memorial Sloan Kettering Cancer Center and at the Congressional Budget Office. Ms. Hanger graduated summa cum laude from New York University with a BA in politics and holds a master's degree in public policy from the University of California, Berkeley.

ESTHER KROFAH, M.P.P., is the executive vice president of MI Health, leading FasterCures, Public Health, the Future of Aging and Feeding Change. She has extensive experience managing efforts to unite diverse stakeholders to solve critical issues and achieve shared goals that improve patients' lives. Most recently, Krofah was the director of public policy at GlaxoSmithKline (GSK), where she led engagement with the US Department of Health and Human Services (HHS) and relevant Executive Branch agencies on broad healthcare policy issues. Before GSK, Krofah was a deputy director of HHS' Office of Health Reform. She also served as program director at the National Governors Association healthcare division and worked in consulting at

Deloitte Consulting LLP. Krofah received a B.A. from Duke University and a Master of Public Policy from the Harvard University John F. Kennedy School of Government.

MARTIN MENDOZA, PH.D., serves as the Chief Health Equity Officer at the Centers for Medicare and Medicaid Services (CMS) and Director of the CMS Office of Minority Health (OMH). In this role, Dr. Mendoza leads OMH in its mission towards the advancement and integration of health equity in the development, evaluation, and implementation of CMS's policies, programs, and partnerships. Prior to CMS, Dr. Mendoza served as the first Director of Health Equity for the National Institutes of Health's (NIH) All of Us Research Program where he provided leadership and high-level expertise to improve inclusion and equity in precision medicine. Before joining All of Us, Dr. Mendoza led extramural research for minority health in the Office of the Commissioner at the U.S. Food and Drug Administration (FDA). He is a recognized expert in clinical trial diversity and has testified on it before Congress. He is also the primary author of the pivotal FDA guidance recommending that clinical trial sponsors submit a diversity action plan to FDA. Dr. Mendoza's original idea and recommendation became federal public law in December 2022. Dr. Mendoza has also served as director of the Division of Policy and Data in the Office of Minority Health in the U.S. Department of Health and Human Services Office of the Secretary, as well as in multiple NIH Institutes including the National Institute of Neurological Disorders and Stroke, the National Cancer Institute, and the National Human Genome Research Institute where he assisted in the genetic mapping of the Human Genome Project. Dr. Mendoza is a graduate of the University of Maryland, Baltimore County, and received his Ph.D. in cancer biology from Johns Hopkins University.

CARLA RODRIGUEZ-WATSON, PH.D., M.P.H., is the Director of Research for the Reagan-Udall Foundation for the FDA. Prior to this post, she was an investigator at Kaiser Permanente Mid-Atlantic Research and at the University of Washington. But her heart lies where it all began, in service of public health. Carla devoted over a decade to the service of public health in the New York City, San Francisco, and Seattle-King County Health departments in communicable disease and environmental epidemiology & surveillance. Her exposure and love for the complexity of real-world-data and its potential was born in public health. Today, Carla is focused on continuously developing and enhancing a portfolio of work to advance and leverage real-world data and experiences to inform and conduct clinical and post-market drug safety and effectiveness studies. This work includes: improving the quality and relevance of RWD (including data needed to advance health equity), developing and advancing frameworks and tools to systematically describe data sources and methods for use in pre and post-market studies of product safety and effectiveness; as well as the Innovation in Medical Evidence, Development and Surveillance (IMEDS) Program – where such tools can be leveraged and tested for regulatory and non-regulatory studies. Carla brings her extensive background in public health surveillance, health outcomes research, and pharmacoepidemiology to this work.

MICHELLE TARVER, M.D., PH.D., is a board-certified ophthalmologist and epidemiologist, serving as the Deputy Center Director for Transformation. In this role, Dr. Tarver facilitates the development, implementation, and direction of CDRH's transformative projects and initiatives. Under her leadership, CDRH is advancing efforts to include underserved and underrepresented populations in the evaluation of medical devices, including people across diverse age, sex, gender, racial, and ethnic backgrounds; those living with rare diseases and physical limitations; and those living in rural areas. Her CDRH career has included many leadership roles, most recently as the Deputy Director of the Office of Strategic Partnerships and Technology Innovation and the Program Director of Patient Science and Engagement. Over her career, she has received numerous awards, including the American Academy of Ophthalmology's Secretariat Award and is widely published in peer-reviewed journals. Dr. Tarver received a B.S. in Biochemistry from Spelman College in Atlanta, GA and completed the M.D./Ph.D. program at The Johns Hopkins University School of Medicine and Bloomberg School of Public Health. Following her internal medicine internship, she completed a residency in ophthalmology with fellowship training in ocular inflammation (uveitis) both at the Wilmer Eye Institute (Johns Hopkins). Board-certified in ophthalmology with an epidemiology doctorate, she has worked on laboratory-based and epidemiological studies, clinical trials, registries, developing patient-reported outcome measures as well as surveys to capture patient preferences. As a dedicated clinician, she continues to care for people living with eye disease.

ROBERT A. WINN., M.D., is the director of VCU Massey Comprehensive Cancer Center who oversees a cancer center designated by the National Cancer Institute that provides advanced cancer care, conducts groundbreaking research to discover new therapies for cancer, offers high-quality education and training, and engages with the community to make advancements in cancer treatment and prevention equally available to all. He is leading the nation in establishing a 21st-century model of equity for cancer science and care, in which the community is informing and partnering with Massey on its research to best address the cancer burden and disparities of those the cancer center serves, with a local focus but global impact. His current basic science research, which has been supported by multiple National Institutes of Health and Veterans Affairs Merit awards, focuses on the molecular mechanisms and novel therapeutic approaches for human models of lung cancer. He has authored or co-authored more than 80 published manuscripts in peer reviewed academic journals. As a pulmonologist, Winn is committed to community-engaged research centered on eliminating health disparities. He is a principal investigator on several community-based projects funded by the NIH and National Cancer Institute, including the All of Us Research Program, a NIH precision medicine initiative. Winn has nearly 20 years' commitment to Veterans Affairs health services and held appointments at the Denver VA and Jesse Brown VA in Chicago, where he established the first multidisciplinary pulmonary nodule clinic. Winn is the President of the Association of American Cancer Institutes (AACI); the Chair of the National Cancer Policy Forum of the National Academies of Sciences, Engineering, and Medicine; a Fellow of the American Association for Cancer Research (AACR) Academy; and a

member of the Board of Directors for the American Cancer Society and LUNGevity Foundation. The recipient of numerous awards and honors, Winn has received the National Cancer Institute Center to Reduce Cancer Health Disparities CURE Program Lifetime Achievement Award; the AACR-Minorities in Cancer Research Jane Cooke Wright Lectureship; the AACI Cancer Health Equity Award; and the Prevent Cancer Foundation Cancer Prevention and Early Detection Laurel Award for Increasing Health Equity. In 2022, the Bristol Myers Squibb Foundation Diversity in Clinical Trials Career Development Program was renamed the Robert A. Winn Diversity in Clinical Trials Award Program (Winn Award), which is committed to increasing diversity in clinical trials and training the new generation of community-oriented clinical researchers. Winn holds a B.A. from the University of Notre Dame and an M.D. from the University of Michigan Medical School in Ann Arbor. He completed an internship and residency in internal medicine at Rush-Presbyterian-St. Luke's Medical Center in Chicago and a fellowship in pulmonary and critical care medicine at the University of Colorado Health Sciences Center in Denver.

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Speaker and Moderator Biographies

STACEY J. ADAM, PH.D., is a Vice President, Science Partnerships at the Foundation for the National Institutes of Health (FNIH), leading many public-private partnerships, such as Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV); the Biomarkers Consortium (Cancer and Metabolic Disorders Steering Committees) and their projects; Accelerating Medicines Partnerships (AMPs)-Common Metabolic Diseases and Heart Failure, Partnership for Accelerating Cancer Therapies (PACT); Pediatric Medical Device Testing; and the Lung Master protocol (Lung-MAP) clinical trial.

Prior to FNIH, Dr. Adam was a Manager at Deloitte Consulting in the Federal Life Sciences and Healthcare Strategy practice where she supported many federal and non-profit client projects. Before Deloitte, Dr. Adam conducted her postdoctoral fellowship at Stanford University School of Medicine, where she was both an NIH and American Cancer Society supported fellow, and she earned her Ph.D. in Pharmacology with a Certificate in Mammalian Toxicology from Duke University.

MARIA APOSTOLAROS, PHARM.D., is currently a Deputy Vice President of Science and Regulatory Advocacy at PhRMA, the US industry association representing the country's leading innovative biopharmaceutical research companies devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. In this role, she currently leads PhRMA's regulatory policy initiatives on patient-focused drug development, clinical trial diversity, safety and pharmacovigilance, innovative clinical trials, clinical development, model informed drug development (MIDD), and drug development tools (DDTs). Maria has also led the pediatric, and rare disease portfolios. In addition to other committee efforts, Maria serves on the Equitable Breakthroughs in Medicine Development (EQBMED) Executive Committee. Prior to her time at PhRMA, Maria has spent many years in a variety of leadership positions in the biopharmaceutical industry. Maria completed her Juris Doctor at the University of Maryland Francis King Carey School of Law with a focus on health law, Doctor of Pharmacy at Temple University, Bachelor of Science in Pharmacy at Philadelphia College of Pharmacy and Science, Master of Science at Drexel University, and is a Certified Compliance and Ethics Professional (CCEP). She is based in the Washington DC metropolitan area.

MONICA M. BERTAGNOLLI, M.D., is the 17th director of the National Institutes of Health (NIH). She was nominated by President Joe Biden on May 15, 2023, confirmed by the U.S. Senate on November 7, 2023, and took office on November 9, 2023. She is the first surgeon and second woman to hold the position. As the NIH Director, Dr. Bertagnolli oversees the work of the largest funder of biomedical and behavioral research in the world. She previously served as the 16th director of the National Cancer Institute (NCI), the Richard E. Wilson Professor of Surgery in surgical oncology at Harvard Medical School, a surgeon at Brigham and Women's Hospital and a member of the Gastrointestinal Cancer Treatment and Sarcoma Centers at Dana-Farber Cancer Institute. Throughout her career, Dr. Bertagnolli has been at the forefront of the field of clinical oncology. Her laboratory focused on advancing our understanding of the genetic drivers of gastrointestinal cancer development and the role of inflammation as a promoter of cancer growth. As a physician–scientist, she led translational science initiatives from 1994 to 2011 within the NCI-funded Cooperative Groups Program (now known as NCI's National Clinical Trials Network), and from 2011–2022 served as group chair of the Alliance for Clinical Trials in Oncology, a National Clinical Trials Network member organization. In addition, from 2007–2018, she served as the chief of the division of Surgical Oncology for the Dana-Farber Brigham Cancer Center. Dr. Bertagnolli has championed collaborative initiatives to transform the data infrastructure for clinical research and is the founding chair of the minimal Common Oncology Data Elements (mCODE) executive committee. She also is a past president and chair of the board of directors of the American Society of Clinical Oncology and has served on the board of directors of the American Cancer Society and the Prevent Cancer Foundation. In 2021, she was elected to the National Academy of Medicine, having previously served on the National Academies National Cancer Policy Forum. The daughter of first-generation Italian and French Basque immigrants, Dr. Bertagnolli grew up on a ranch in southwestern Wyoming. She graduated from Princeton University with a Bachelor of Science in Engineering degree and attended medical school at the University of Utah. She trained in surgery at Brigham and Women's Hospital and was a research fellow in tumor immunology at the Dana-Farber Cancer Institute.

JAMIE BREWER, M.D., is a medical oncologist and Clinical Team Lead in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Food and Drug Administration (FDA). Dr. Brewer joined the FDA in 2018 and previously served as a clinical reviewer on the Genitourinary Cancer team. Dr. Brewer serves as the Oncology Center of Excellence (OCE) Scientific Liaison for Cancer Disparities for which she actively engages with FDA colleagues and external stakeholders to promote inclusion and representation of diverse patient populations in clinical trials. Dr. Brewer completed her medical training at The University of Illinois at Chicago. She completed her residency and a joint fellowship in Medical Oncology and Clinical Pharmacology and Pharmacogenomics at The University of Chicago.

NAMANDJÉ N. BUMPUS, PH.D., is the FDA's Principal Deputy Commissioner. Dr. Bumpus began her career at the FDA as Chief Scientist in August 2022, before becoming Principal Deputy Commissioner in February 2024. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and oversee the agency's day-to-day functions.

Before joining the FDA, Dr. Bumpus was on the faculty at Johns Hopkins for 12 years, where she quickly rose through the ranks to ultimately serve as the E.K. Marshall and Thomas H. Maren Professor and chair of the Department of Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. There she also served as associate dean for basic research. Dr. Bumpus is recognized as an international expert in pharmacology, and her research has expanded knowledge of drug metabolism, pharmacogenetics, bioanalytical chemistry, infectious disease pharmacology, and single cell biology. Prior to becoming a faculty member at Hopkins she completed a postdoctoral fellowship at The Scripps Research Institute in La Jolla, CA. Dr. Bumpus earned a Ph.D. in pharmacology from the University of Michigan and a bachelor's degree in biology from Occidental College.

Dr. Bumpus currently serves as president of the American Society for Pharmacology and Experimental Therapeutics, a 4000-member scientific society founded in 1908. She was elected by the membership to serve in this role. She previously served as chair of the NIH Xenobiotic and Nutrient Disposition and Action study section.

A lauded teacher and mentor, Dr. Bumpus was awarded the Johns Hopkins University Professor's Award for Excellence in Teaching Biomedical Sciences. Her scientific contributions and impact have been recognized through numerous national and international awards including the Presidential Early Career Award for Scientists and Engineers, the Leon I. Goldberg Award and the Abrams Award from the American Society for Clinical Pharmacology and Therapeutics, the James Gillette Award from the International Society for the Study of Xenobiotics, and the John J. Abel Award in Pharmacology from the American Society for Pharmacology and Experimental Therapeutics. In 2022, she was selected by the NIH to deliver the annual Rolla E. Dyer in Infectious Disease. Dr. Bumpus is an honorary member of the Society of Toxicology, an honor bestowed upon one scientist each year who embodies outstanding and sustained achievements in the field of toxicology. She has been elected by her peers as a fellow of the American Association for the Advancement of Science and a member of the National Academy of Medicine, which is one of the highest honors in the field of medicine.

ROBERT M. CALIFF, M.D., was confirmed as the 25th Commissioner of Food and Drugs. As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological

products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco.

Prior to rejoining the FDA in 2022, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and was the founding director of the Duke Clinical Research Institute.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

NATALIA CHALMERS, D.D.S., M.H.SC., PH.D., is a board-certified pediatric dentist, oral health policy expert, and public health advocate who brings more than 20 years of clinical, research, industry, and regulatory experience to CMS in her role as Chief Dental Officer in the Office of the Administrator. Previously, Dr. Chalmers served as a Dental Officer at the US Food and Drug Administration. Dr. Chalmers has devoted her career to transforming scientific and health care data and information into actionable insights to address equity, improve care, and better inform policy and funding. Chalmers completed her Doctor of Dental Surgery degree at the Faculty of Dental Medicine of the Medical University of Sofia, a residency in pediatric dentistry at the University of Maryland School of Dentistry, and a Ph.D. in oral microbiology from the Graduate Partnerships Program of the University of Maryland School of Dentistry and the National Institute for Dental and Craniofacial Research at the National Institutes of Health, Post-doctoral Fellowship at the Forsyth Institute, and Clinical Research Fellowship at the National Institute for Dental and Craniofacial Research, National Institutes of Health.

Dr. Chalmers holds a Master's degree in Clinical Research from Duke Medical University and a Certificate in Drug Development and Regulatory Science from the University of California San Francisco School of Pharmacy. Her research has translated into action, improving oral care and advocating for the role health policy can play across the lifespan—particularly when it embraces dental well-being as a facet of care for the whole person.

MEGAN COYLEWRIGHT, M.D., is a structural interventional cardiologist whose clinical practice includes minimally invasive options to treat congestive heart failure (through valve repair and replacement including TAVR and TEER) and prevent stroke (LAAO and PFO closure). She is a frequent lecturer on technical and procedural topics as well as the intersection of health policy and patient-centered shared decision making and is known for her advocacy to broaden access to cardiovascular therapies in clinical trials to women and patients of color. Dr. Coylewright is the Editor of the American College of Cardiology CardioSmart/Patient Voice Program and co-leads the Heart Valve Collaboratory Lifetime Management of Valvular Heart Disease task force. Dr. Coylewright's initial work as a middle school Teach for America teacher in the South Bronx continues to inform her perspectives on the intersections of sociodeterminants of health. She completed her medical school, residency, and Master of Public Health training at Johns Hopkins, and served as Health Disparities Coordinator at the Baltimore City Public Health Department. Five years of cardiovascular training were spent at the Mayo Clinic in her home state of Minnesota.

U. MICHAEL CURRIE, M.P.H., M.B.A., hails from Washington, D.C., and served as the Chief Health Equity Officer at UnitedHealth Group until Oct 2023. In this role, Michael led the coordination of health equity efforts across UnitedHealth Group since June of 2010. He was responsible for the development and execution of enterprise efforts, initiatives and interventions to identify health disparities, as well as the enhancement or implementation of programs, services and strategies to address identified health disparities. Michael has held roles in both the public and private sectors with responsibilities related to disease prevention, wellness and health benefits, and has spent nearly 30 years focused on population health management. Michael has contributed to numerous health equity and health disparities related articles and publications, been a guest lecturer at public and private organizations, as well as numerous academic institutions. He currently serves on various local and national boards and committees focused on addressing barriers to health care and improving health outcomes including the Maryland Department of Health Advisory Comm on Minority Health, American Telemedicine Association Advisory Board on Eliminating Health Disparities, the Health Care Payment Learning & Action Network Health Equity Advisory Team, the Howard Community College Educational Foundation Board, the Johns Hopkins Howard County Medical Center Foundation Board and the Creating Healthier Communities Board of Directors. Michael holds a bachelor's degree from

Morehouse College, a Master of Public Health degree from George Washington University and a Master of Business Administration degree from Johns Hopkins University.

GWEN DARIEN is a longtime patient advocate who has played leadership roles in some of the country's preeminent nonprofit organizations. As executive vice president for patient advocacy, engagement and education at Patient Advocate Foundation and National Patient Advocate Foundation, Gwen leads programs that link Patient Advocate Foundation's direct patient service programs to NPAF system change initiatives, with the goal of improving access to affordable, equitable quality health care.

Called "a bit of a renegade" by People magazine, Gwen has long insisted on pushing boundaries while maintaining a safe space for patients. As editor and publisher of Mamm, a magazine for women with breast or reproductive cancer, Gwen published features on previously taboo subjects, such as dating after a mastectomy, along with the more expected academic features on news and policy analysis. Her media leadership was recognized by the Avon Foundation, which honored her as one of "the most powerful women in breast cancer."

As a three-time cancer survivor herself, Gwen came into cancer advocacy expressly to change the experiences and outcomes for the patients who came after her and to change the public dialogue about cancer and other life-threatening illnesses. With these goals in mind, in 2005 she started the first stand-alone advocacy entity in a professional cancer research organization at the American Association for Cancer Research, causing outside observers to note the organization's "progressive commitment to patient advocacy." At AACR, she launched CR magazine – a magazine for people with cancer and those who care for them. Later, she served as the executive director of the Samuel Waxman Cancer Research Foundation; director of The Pathways Project; and executive vice president of programs and services at the Cancer Support Community. In each role, Gwen championed placing patients at the center of health system change, whether it is for research, public policy or direct services.

Gwen serves on a wide range of program committees and workshop faculties. She is the past Chair of PCORI's Patient Engagement Advisory Panel and founding Chair of Community Engagement in Genomics Working Group of the National Human Genome Research. Gwen serves on the Board of Trustees of the USP and is a member of the National Cancer Policy Forum. Gwen also writes about her experiences as an advocate and cancer survivor. A recent piece, Transformation: My Experience as a Patient and an Advocate in Three Chapters appeared in the National Academy of Medicine Perspectives. Gwen is a graduate of Sarah Lawrence College, where she also served as an advisor for their Health Advocacy program. She grew up in Milwaukee, but now lives in New York City, where she cooks Persian dishes, collects earrings and improves her friends' personal libraries, one book at a time.

DECHANE L. DORSEY, J.D., is the Executive Director of AdvaMed Accel, a division within the Advanced Medical Technology Association (AdvaMed). AdvaMed Accel represents small and mid-sized companies and works to address concerns specific to this group of companies that comprise more than 70% of AdvaMed's overall membership. She also leads AdvaMed's health equity and women's health workstreams. Prior to assuming her current role Dorsey was a Vice President in the Payment and Health Care Delivery Department at AdvaMed where her responsibilities included policy development and analysis of regulatory issues affecting the medical technology industry, including the Hospital Outpatient Prospective Payment System (OPPS), reimbursement for Ambulatory Surgical Centers (ASCs), advanced wound healing and tissue regeneration, coding, and physician payment issues. Prior to joining AdvaMed's staff in June 2006, Dorsey was the Director of Health Policy for the American Academy of Ophthalmology (AAO) where she managed issues affecting coverage and reimbursement for ophthalmology procedures. Before joining the AAO, Dorsey was a Senior Counsel with the U.S. Department of Health and Human Services' Office of Counsel to the Inspector General, where she worked as a litigator on a variety of fraud and abuse issues including enforcement of exclusion authorities, the Emergency Medical Treatment and Active Labor Act (EMTALA) statute, civil monetary penalties, and compliance monitoring. She holds a B.A. in Political Science from Syracuse University and a J.D. from the Georgetown University Law Center.

AMY FLOWERS, PH.D., is Director of Policy Research at the National Association of Community Health Centers (NACHC). She leads NACHC's policy research department, ensuring that it is informed by health centers' rapidly evolving policy and advocacy needs, and focused on health equity and the diverse communities served by community health centers. Dr. Flowers earned her Ph.D. from the University of Southern California and is a RIVA-trained focus group moderator. Her experience includes the development of both qualitative and quantitative research methodologies that address each arm of the quintuple aim: a focus on equity, patient and provider experience, cost efficiency and care quality. Prior to joining NACHC, she served as a consultant on hundreds of projects for government agencies at the federal, state, and local levels. Through these varied projects, she developed a sense for the importance of early stakeholder engagement, a deep understanding of the costs of health disparities and a sense of purpose for improving health equity and access to care.

QUITA HIGHSMITH, M.B.A., is Vice President and Chief Diversity Officer at Genentech, a member of the Roche Group. At Genentech, Highsmith was selected as the first Chief Diversity Officer in the 46- year history of the company and reports to the CEO. She is responsible for enterprise-wide strategic initiatives that drive business impact by: investing in commercial efforts, stakeholder engagement, research innovation and community relations.

Outside of D&I knowledge, Highsmith brings brand marketing, business development and a global leadership perspective. Prior to becoming the CDO, she held leadership roles in Commercial and Government Affairs of several companies (Genentech, Sanofi, Aventis) where she impacted and improved revenues. Because she recognized the need to diversify clinical research, she co-founded Advancing Inclusive Research® an initiative to embrace equitable access.

Highsmith is routinely requested to address members of Congress, speak at national and international forums, and give media interviews with both large and small outlets, such as WSJ, STAT, The Atlantic, and Essence Magazine. She has co-authored numerous publications regarding health disparities in peer reviewed journals. In 2024, she was chosen as a Top 15 Chief Diversity Officer by Diversity Global Magazine and selected by Savoy Magazine as one of the Most Influential Black Executives in Corporate America.

Highsmith is an advisor to Cerebral, a mental health startup company and Artis Ventures. She is also committed to community service by working with non- profit boards such as, Congressional Black Caucus Foundation, Northwest Kidney Centers, Delta San Francisco-Peninsula Scholarship Foundation and The Genentech Patient Foundation. Highsmith received both a Master of Business Administration Degree and an Advanced Diversity and Inclusion Certificate from Cornell University, as well as her undergraduate degree from the University of Kentucky.

STEPHEN KONYA serves as the Senior Advisor to the Deputy National Coordinator, and Innovation Portfolio Lead for the Office of the National Coordinator for Health IT (ONC), U.S. Department of Health and Human Services (HHS). In addition to shaping the Agency's long term strategy, he also serves as the primary liaison to the White House Office of Science and Technology Policy (OSTP) and the external healthcare startup and investor community. Furthermore, Mr. Konya also leads the Digital Health Innovation Workgroup under the Federal Health IT Coordinating Council, an interagency collaboration community comprised of innovation representatives from 40 other federal agencies. In addition to currently serving as the primary Federal Govt lead and Co-Founder for CancerX, Mr. Konya has previously led several other key federal projects, including the HHS PandemicX Innovation Accelerator, the national Health IT Playbook, the ONC Patient Engagement Playbook for Providers, the SMART App Gallery, the FHIR at Scale Taskforce (FAST) Initiative, and is a founding Co-Chair of the Together.Health Collaborative.

SHARI M. LING, M.D., currently serves as the Deputy Chief Medical Officer for the Centers for Medicare and Medicaid Services (CMS). Dr. Ling's committed focus is on the achievement of meaningful health out- comes for patients and families through the delivery of high quality, person-centered care, across all care settings. Her clinical focus and scientific interest is in the care of persons with dementia, multiple chronic conditions, and functional limitations.

Dr. Ling leads the CMS Behavioral Health Strategy implementation. She also represents CMS on several Health and Human Services (HHS) efforts. She represents CMS on the workgroups for the National Alzheimer's Project Plan, and workgroups to eliminate and prevent Healthcare Associated Infections (HAIs), the National Strategy to Combat Antimicrobial Resistance.

Dr. Ling earned a Master's in Gerontology in Direct Service at the Leonard Davis School of Gerontology, an MD degree at Georgetown University School of Medicine, completed a rheumatology fellowship at Georgetown University Hospital followed by a Geriatric Medicine fellowship at Johns Hopkins University School of Medicine. She continues her clinical work serving veterans as a volunteer dementia care provider, and has retained her appointment as part-time faculty in the Division of Geriatrics and Gerontology, Johns Hopkins University School of Medicine.

JENNIFER MILLER, PH.D., is Co-Director of the Program for Biomedical Ethics and an Associate Professor of Internal Medicine (primary) and Biomedical Informatics and Data Science (Secondary) in Yale School of Medicine. She is also President of the nonprofit Bioethics International, and Founding Director of the Good Pharma Scorecard, an index that ranks pharmaceutical companies on their social responsibility performance. Dr. Miller's current research centers on ethics, equity and governance in healthcare innovation. She specializes in developing accountability metrics for responsible, trustworthy, and equitable clinical research, healthcare data sharing, and use of AI in medicine. Her work is supported by numerous grants, including from the FDA and NIH. Prior to joining Yale's faculty, Dr. Miller was an Assistant Professor at NYU School of Medicine and completed her training in physics, bioethics, regulatory governance and ethics at Fordham University, Regina Apostolorum, Duke University, and Harvard University.

MICHELLE MCMURRY-HEATH, M.D., PH.D., is the Founder and CEO of BioTechquity Clinical, a novel clinical research organization designed to help drug and device innovators enroll and conduct diverse clinical trials. BioTechquity ends our conflation of race and poverty to find previously untapped diverse middle class patient partners. Partners better equipped to complete trials and lower the average 40% attrition rate seen in most modern trials. Before founding BioTechquity, she was the CEO of the Biotechnology Innovation Organization (BIO) where she launched the industry-wide BIOEquality Agenda. She is a former regulatory and clinical leader at both the US Food & Drug Administration (FDA) and Johnson&Johnson where she led a global team responsible for trials and regulatory approvals in 150 countries. She has experience on Capitol Hill and was the Founding Director of the Aspen Institute health program. Dr. McMurry-Heath has committed her career to the belief that medical innovation can improve lives and unlock opportunity for all people if inclusively conducted and equitably distributed. And that it will take market savvy innovations and breakthrough business models to achieve meaningful BioTech Equity.

KATHY MICKEL serves as the Learning Solutions Lead at the Society for Clinical Research Sites (SCRS), where she plays a pivotal role in shaping and executing SCRS events and educational programs. She spearheads initiatives such as the SCRS IncluDE (Inclusivity, Diversity & Equity) Program and the SCRS Oncology Program, contributing to the advancement of the clinical research community. With a rich background in the pharmaceutical industry, Mickel has excelled in Clinical Operations, demonstrating her expertise in site-facing roles across diverse therapeutic areas. Her adeptness in connecting with others, coaching, and leadership has been instrumental in her success, extending into impactful HR roles within pharmaceutical organizations. Drawing from her extensive experience across sites, CROs, and pharmaceutical companies, Mickel curates engaging learning experiences and fosters collaboration within the clinical research sphere. Beyond her commitments at SCRS, Mickel showcases her versatile leadership by actively supporting her family's industrial landscape business. Additionally, she serves as a Yoga Teacher Trainer, offering training, coaching, and mentorship to inspire personal and professional growth. Through her endeavors, Kathy instills a commitment to excellence and encourages individuals to pursue their talents and passions relentlessly.

KRISTEN NWANYANWU, M.D., M.B.A., M.H.S., is an NIH-funded, board-certified ophthalmologist and practicing vitreoretinal surgeon. She is an expert in health equity research and implementation science. She is currently the PI for the NIH-funded Sight-Saving Engagement and Evaluation in New Haven (SEEN) Program, a multi-method approach to identifying and addressing health disparities in diabetic retinopathy. She leads the implementation science team for the Equitable Breakthroughs in Medicine Development (EQBMED) pilot, the innovative collaboration to increase diversity in clinical trials. She lectures nationally on health equity, access to care, and the surgical management of diabetic retinopathy. She is the recipient of the National Eye Institute Director's Award and the Secretariat Award from the American Academy of Ophthalmology. She is proud to participate in the growing advocacy to advance diversity in clinical trials. She is the wife of a brilliant, patient husband and two dynamite daughters--her greatest achievements, by far.

BRIAN RIVERS, PH.D., M.P.H., is Professor and Director of the Cancer Health Equity Institute at Morehouse School of Medicine (MSM). Dr. Rivers is nationally and internationally recognized as a thought leader in health disparities research and a retired appointed member of the National Institutes of Health (NIH) National Advisory Council on Minority Health and Health Disparities (NACMHD). Dr. Rivers is an active member in the American Association for Cancer Research (AACR) community and has served in several leadership capacities, such as the steering committee for the inaugural AACR Cancer Disparities Progress Report, Chairperson for AACR Minorities in Cancer Research Council, Conference Co-Chair for the 11th AACR Conference on Cancer Health Disparities, and Co-Chair for the AACR Think Tank on Cancer Health Disparities. Currently, Dr. Rivers serves as chair of the Science Education and Career

Advancement Committee. Rivers also serves as Co-Chair for the Georgia Cancer Control Consortium (GC3), a state-funded entity responsible for developing the state's cancer plan and maintaining the cancer prevention and control infrastructure. Dr. Rivers research portfolio has endeavored to expand the application of population-based intervention/implementation/dissemination science to address cancer health disparities and advance cancer health equity in clinical and community-based settings, utilizing multi-level/multi-domain/multi-sectoral approaches, such as novel technological platforms and iterations of the Patient Navigation model. Dr. Rivers has and is leading several large randomized controlled trials, funded by NIH National Institute on Minority Health and Health Disparities (NIMHD) (R01), to evaluate and characterize the impact of multi-level, digital health psychosocial interventions, targeting African American men diagnosed with prostate cancer, and the National Cancer Institute (NCI) (R01), to examine the interplay of social and molecular determinants in lung cancer disparities. Dr. Rivers is lead Multiple-Principal Investigator (MPI) for the NIH National Cancer Institute (NCI) funded Partnerships to Advance Cancer Health Equity (PACHE) U54 Cancer Research Partnership between MSM, Tuskegee University, and the University of Alabama-Birmingham O'Neil Comprehensive Cancer Center (UAB OCCC). Rivers serves as MPI of the inaugural NIH Faculty Institutional Recruitment for Sustainable Transformation Coordination and Evaluation Center (FIRST CEC). Lastly, Rivers is the Principal Investigator of two American Cancer Society recently launched initiatives, Diversity in Cancer Research Institutional Development Program (Health Equity Research Career Advancement Program) and Cancer Health Equity Research Centers (Georgia Cancer Health Equity Research Center). Dr. Rivers has presented his novel and innovative research findings in diverse settings including the First Congress on Oncology Clinical Trials (Lagos, Nigeria); Movember International Prostate Cancer Consortium (Queensland, Australia); The Atlantic Magazine, The People vs Cancer; South by Southwest (SXSW) conferences; and the National Press Foundation.

JONI RUTTER, PH.D., is the acting director of the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH). Dr. Rutter oversees the planning and execution of the Center’s complex, multifaceted programs that aim to overcome scientific and operational barriers impeding the development and delivery of new treatments and other health solutions. Under her direction, NCATS supports innovative tools and strategies to make each step in the translational process more effective and efficient, thus speeding research across a range of diseases, with a particular focus on rare diseases. By advancing the science of translation, NCATS helps turn promising research discoveries into real-world applications that improve people’s health. In her previous role as the NCATS deputy director, Dr. Rutter collaborated with colleagues from government, academia, industry and nonprofit patient organizations to establish robust interactions with NCATS programs. Prior to joining NCATS, Dr. Rutter served as the director of scientific programs within the All of Us Research Program, where she led the scientific programmatic development and implementation efforts to build a

national research cohort of at least 1 million U.S. participants to advance precision medicine. During her time at NIH, she also has led the Division of Neuroscience and Behavior at the National Institute on Drug Abuse (NIDA). In this role, she developed and coordinated research on basic and clinical neuroscience, brain and behavioral development, genetics, epigenetics, computational neuroscience, bioinformatics, and drug discovery. Dr. Rutter also coordinated the NIDA Genetics Consortium and biospecimen repository. Throughout her career, Dr. Rutter has earned a national and international reputation for her diverse and unique expertise via more than 50 publications in journals, and she has received several scientific achievement awards, including a SmithKline Beecham Student Award in Pharmacology, a Janssen Research Foundation Young Investigator Award, and a Fellowship Achievement Award from the National Cancer Institute (NCI). Dr. Rutter received her Ph.D. from the Department of Pharmacology and Toxicology, Dartmouth Medical School, Hanover, New Hampshire, and completed a fellowship at NCI within the Division of Cancer Epidemiology and Genetics.

SARAH HUDSON SCHOLLE, PH.D., M.P.H., is a principal at Leavitt Partners, an HMA Company based in Washington, D.C., specializing in supporting multisector alliances to promote improvement in quality, equity, and person-centered health care. Prior to joining Leavitt Partners, Dr. Scholle was vice president of research and analysis at the National Committee for Quality Assurance (NCQA). She led a portfolio of quantitative and qualitative research that contributed to national thought leadership in quality and equity, contributed to program development and policy action, and resulted in numerous peer-reviewed studies. Specifically, she led projects to develop and test quality measures, including those subsequently adopted into national programs. Her content expertise includes mental health, substance use, child health, care coordination and patient-reported outcomes. Scholle has served on national panels for the National Academy of Sciences, Engineering, and Medicine; the Centers for Medicare and Medicaid Services; and the National Quality Forum. Prior to NCQA, she was an associate professor at the University of Pittsburgh School of Medicine and an assistant professor at the University of Arkansas. Dr. Scholle earned a B.A. in history and an M.P.H. from Yale University, and a Ph.D. in public health from the Johns Hopkins Bloomberg School of Public Health.

MARY T. THANH HAI, M.D., is an internist/endocrinologist receiving her medical degree from Georgetown University. She has been with the FDA since 1998 and is currently the Deputy Director for Clinical Science in the Office of New Drugs/CDER. She directly oversees the Office of Drug Evaluation Sciences responsible for the drug development tool qualification programs, OND's research program, clinical outcomes assessment program and more recently, the Drug Trials Snapshot program. Her prior positions include Director of the Division of Metabolism and Endocrinology Products (DMEP) from 2006-2013, Deputy Office Director for the Office of Drug Evaluation 2 from 2013-2018, and acting director for this office before

moving into her current position. Over her 26+ years at the Food and Drug Administration (FDA), Dr. Thanh Hai has served on several internal and external committees on a wide range of issues, including serving as rapporteur for an ICH expert work group, participating in Prescription Drug User Fee Act (PDUFA) VI and VII reauthorization negotiations, and representing CDER in several tobacco cessation initiatives.

VINDELL WASHINGTON, M.D., M.S., is the Chief Clinical Officer and Head of Health Equity Center of Excellence at Verily. In his role, he leads clinical and data innovation teams across Verily's care delivery and research solutions; he also leads cross-functional teams focused on advancing health equity through Verily's people and products. He previously served as Chief Medical Officer and EVP at Blue Cross Blue Shield of Louisiana where he oversaw network operations and contracting, medical policy and quality, disease management, and pharmacy benefits. Prior to that, he was National Coordinator for Health Information Technology (ONC), where he provided high-level executive direction and leadership for ONC programs, operations, and policies. He received his medical degree from the University of Virginia and his MS in healthcare management from the Harvard University School of Public Health.

MATTHEW WATLEY, M.DIV., M.A., is a dynamic and dedicated pastor, renowned speaker, author, professor, entrepreneur, leadership consultant, and visionary ‘kingdom builder '.
As the founder and Senior Pastor of Kingdom Fellowship AME Church, Reverend Watley leads and spiritually guides a thriving community of over 7,000 members. In a remarkable testament to his leadership, the church recently transitioned to a cutting-edge facility, the Kingdom Worship Center, valued at $45,000,000.

Reverend Watley's community involvement extends beyond the church. As the Chair of The Black IDEA Coalition, he is dedicated to achieving black parity in employment, investment, and contracting. He also leads the Kingdom Global Community Development Corporation, which provides comprehensive support services to address food insecurity, health, and outreach to those in various communities.

Rev. Watley frequently speaks on issues of economy, culture, leadership, and health equity. He has spoken for Ch2Mhill, The Prudential, Industrial Bank, The American Institute of CPAs, the US Department of Transportation, and the Milken Institute. Rev. Watley founded The Kingdom Network (TKN), a leadership program that supports national clergy development. Rev. Watley is a member of the Board of Trustees of Wiley University, the Advisory Board of the Museum of the Bible, the Board of Visitors of the Howard University School of Divinity, the Sub-Saharan Africa Advisory Committee of EXIM, and an at-large member of the General Board of the African Methodist Episcopal Church. He has served as an adjunct professor at Georgetown University and lectured at various higher-learning institutions, including Howard University,

Alabama State University, Cornell University, Wesley Theological Seminary, and Wilberforce University.

Pastor Watley also has a B.A. in Political Science and a Master of Divinity from Howard University, an Executive Master's in Leadership from Georgetown University, and a Master of Arts in Education and Human Development from George Washington University. In May of 2021, Pastor Watley was awarded an Honorary Doctorate of Humane Letters from Wiley College, where he delivered the commencement address to the graduating class of 2021. Rev. Watley is currently a doctoral candidate at Fuller Theological Seminary. He also received a Lifetime Achievement Award from President Joseph R. Biden, Jr., for his commitment to building a stronger nation through volunteer service. Pastor Watley is the author of several books and articles; Ignite is his most recent book.

Pastor Watley professes that among his most significant roles are husband, father, and son. He is married to Shawna Francis Watley, Senior Policy Advisor with Holland and Knight LLC, and has one daughter, Alexandra Elizabeth Watley. The Watley family resides in the Metropolitan Washington Area.

KARRIEM S. WATSON, D.H.SC., M.S., M.P.H., is the Chief Engagement Officer for the National Institutes of Health's All of Us Research Program. He leads the All of Us Research Programs efforts to foster relationships with participants, communities, researchers and providers across the United States and territories through equitable engagement to help build one of the largest and most diverse health datasets of its kind to advance precision medicine research.

Prior to joining the NIH, Dr. Watson spent over 15 years conducting cancer disparities research. He completed his post-doctoral training in cancer center leadership under Dr. Robert A. Winn at the University of Illinois at Chicago Cancer Center and went on to become an independent funded researcher with funding from the NCI, NIMHD and NHLBI. Dr. Watson's work spans across community engaged research, CBPR, and implementation and dissemination science including engaging community members as Citizen Scientists to improve diversity, equity, and inclusion in clinical trials. In addition to his research, Dr. Watson also served as a health care administrator overseeing community-based research and serving as the Associate Executive Director for a network of Federally Qualified Health Centers (FQHCs). Dr. Watson has been recognized by many organizations for his commitment to training and education including being awarded an Innovator in STEM award by the Chicago Urban League.

CHERYL L. WILLMAN, M.D., serves as the Enterprise Executive Director of Mayo Clinic Cancer Programs and Director of the Mayo Clinic Comprehensive Cancer Center. She also holds the rank of Professor and Consultant of Laboratory Medicine and Pathology in the Mayo Clinic College of Medicine and Science. An internationally renowned physician scientist and cancer

center leader, Dr. Willman leads the National Cancer Institute (NCI)-Designated Mayo Clinic Comprehensive Cancer Center across three national sites: Rochester, Minnesota and the Mayo Clinic Health System, a rural health care delivery system across the Upper Midwest; Phoenix and Scottsdale, Arizona; and Jacksonville, Florida. In 2023, these sites together provided care for greater than 130,000 unique, diverse cancer patients. Dr. Willman is a pioneer in the field of cancer genomics and cancer precision medicine with a track record of innovation and successful translation of discoveries to clinical trials. She previously served as the director of the University of New Mexico Comprehensive Cancer Center, which under her leadership developed into one of the nation's preeminent NCI-designated Cancer Centers serving the region's diverse, underserved, and underrepresented patients. She has led or co-led several key National Cancer Institute initiatives that are improving the lives of patients with cancer and addressing disparities in cancer care as well as cancer incidence and mortality among diverse and underserved populations. She currently serves as Principal Investigator of one of the nation's 5 NCI-funded *Participant Engagement-Cancer Genome Sequencing Centers: Engagement of American Indians of Southwestern Tribal Nations in Cancer Genome Sequencing*. This program is deeply engaging Tribal leaders, communities, and cancer patients to deliver state of the art comprehensive clinical genomic sequencing, cancer genetic counseling, and navigation to care for tribal cancer patients. The overall goal is to identify the spectrum of cancer-associated genomic mutations and mutational signatures in this understudied population, enhance access to state-of-the-art diagnostics and care, and drive cancer health equity. Dr. Willman has been continuously funded by the National Institutes of Health, the National Cancer Institute, and the Leukemia & Lymphoma Society for more than 35 years. She is a highly cited physician-scientist who has published over 290 papers, reporting her work in the highest-quality medical and scientific journals. She also holds 11 patents or patents pending. Dr. Willman has served in many leadership roles at NCI, including the Board of Scientific Advisors and the Scientific Advisory Board of the NCI Frederick National Laboratory for Cancer Research, overseeing NCI science and investments in cancer genomics, drug discovery, nanotechnologies, computing and large-scale data analysis, and relationships and collaborations between NCI and the nation's Department of Energy (DOE) laboratories. She also has held many national leadership positions in professional organizations, including the American Association of Cancer Research, the American Society of Hematology, and the Leukemia and Lymphoma Society. She was a founder of the field of Molecular Diagnostic Pathology and President of the Association of Molecular Pathologists. She is an elected fellow of the National Academy of Inventors. Dr. Willman received her medical degree at Mayo Medical School, now Mayo Clinic Alix School of Medicine, which included a medical student fellowship in immunology at the National Institutes of Health. She completed her residency and postdoctoral training in pathology and cancer research at Mayo Clinic, University of New Mexico, and University of Washington.

NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Drug Discovery, Development, and Translation
National Cancer Policy Forum

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- Filing a complaint with the Office of Human Resources at 202-334-3400, or
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Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

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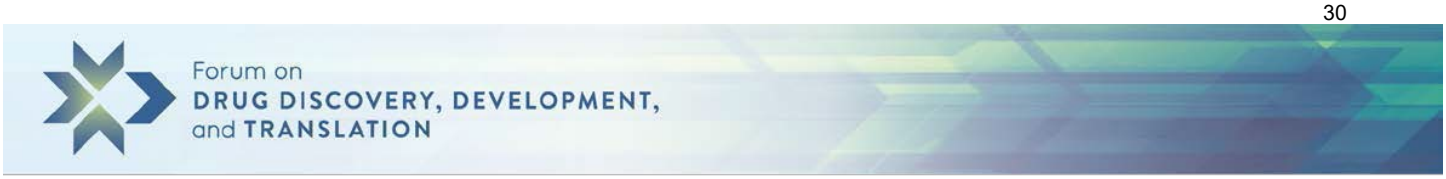
Updated June 7, 2018



ABOUT THE FORUM

The Forum on Drug Discovery, Development, and Translation (the forum) of the National Academies of Sciences, Engineering, and Medicine (the National Academies) was created in 2005 by the National Academies Board on Health Sciences Policy to foster communication, collaboration, and action in a neutral setting on issues of mutual interest across the drug research and development lifecycle. The forum membership includes leadership from the National Institutes of Health, the U.S. Food and Drug Administration, industry, academia, consortia, foundations, journals, and patient-focused and disease advocacy organizations.

Through the forum's activities, participants have been better able to bring attention and visibility to important issues, explore new approaches for resolving problem areas, share information and find common ground, and work together to develop ideas into concrete actions and new collaborations.

Forum work is based on four thematic priorities:

Spurring INNOVATION and IMPLEMENTATION

Revolutionary advances in biomedical research and technology present new and exciting opportunities for the discovery and development (R&D) of new therapies for patients. The evolution of health care is expanding possibilities for integration of clinical research into the continuum of clinical care and new approaches are enabling the collection of data in real-world settings. Innovative modalities, such as digital health technologies and artificial intelligence applications, can now be leveraged to overcome challenges and advance clinical research. The forum unites key stakeholders to identify opportunities, address bottlenecks, and spur innovation in drug discovery, development, and translation.

Increasing PERSON-CENTEREDNESS and EQUITY

There is much greater awareness around the need for more person-centered and inclusive approaches that prioritize lived experience, equity, and justice in the discovery, development, and translation of new treatments. The forum seeks to center priorities of people living with disease and those who have been traditionally under-represented or excluded from the clinical trials enterprise, advance the science of patient input, and help bring to fruition innovations that better address the needs of patients.

Promoting COLLABORATION and HARMONIZATION

The forum provides a neutral platform for communication and collaboration across sectors and disciplines to better harmonize efforts throughout the drug R&D life cycle. It does this by convening a broad and evolving set of stakeholders to help integrate patients, caregivers, researchers, trialists, community practitioners, sponsors, regulators, payers, patient and disease advocacy groups, and others into the continuum of research and clinical care. The forum also strives to enable shared decision-making and ensure that patients have input into research questions, researchers have insight into clinical practice, and practitioners are engaged in the clinical trials enterprise.

Enhancing the WORKFORCE and INFRASTRUCTURE

The forum has fostered the development of strategies to improve the discipline of innovative regulatory science and continues to focus on building a workforce that is diverse, adaptable, and resilient. Considerable opportunities remain to improve and expand the evolving clinical trials workforce and infrastructure, integrate community-based practices, and engage early-career scientists and clinicians in drug discovery, development, and translation. The forum will continue to anticipate and promote adaptation to changes in the infrastructure of health care delivery.

For more information about the Forum on Drug Discovery, Development, and Translation, please visit at:

NATIONALACADEMIES.ORG/DRUGFORUM

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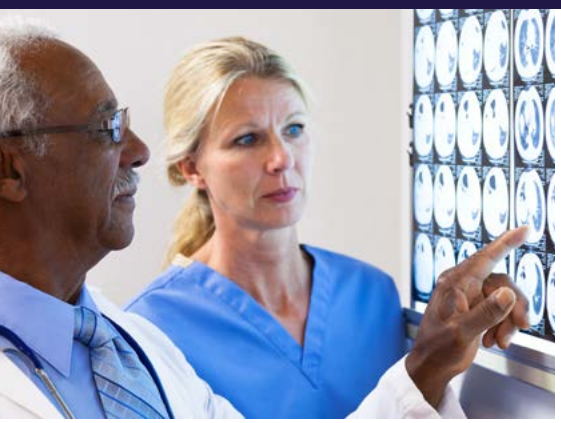

National Cancer Policy Forum

The National Cancer Policy Forum serves as a trusted venue in which experts can identify emerging high-priority policy issues in cancer research and cancer care and work collaboratively to examine those issues through convening activities focused on opportunities for action. The forum provides a continual focus within the National Academies on cancer, addressing issues in science, clinical medicine, public health, and public policy that are relevant to the goal of reducing the cancer burden through prevention and by improving the care and outcomes for those diagnosed with cancer. Forum activities inform the cancer community and the public about critical policy issues through workshops and published reports. The forum has members with a broad range of expertise in cancer, including patient advocates, clinicians, and basic, translational, and clinical scientists. Forum members represent patients, federal agencies, academia, professional organizations, nonprofits, and industry.

The forum has addressed a wide array of topics, including

- enhancing collaborations to accelerate research and development;
- improving the quality and value of care for patients who have been diagnosed with or are at risk for cancer;
- developing tools and technologies to enhance cancer research and care; and
- examining factors that influence cancer incidence, mortality, and disparities.

NATIONAL CANCER POLICY FORUM

Upcoming and Recent Workshops

Opportunities and Challenges for the Development and Adoption of Multicancer Detection Tests

October 28-29, 2024

Cancer screening is considered a key cancer control strategy because patients who are diagnosed with earlier stages of disease often have better treatment options and improved health outcomes. However, effective screening tests are lacking for most cancers. The development of minimally invasive approaches to screen for multiple tumor types at once could address this unmet need, but the clinical utility of multicancer detection (MCD) testing has yet to be established.

Learn more and register here

Enabling 21st Century Applications for Cancer Surveillance Through Enhanced Registries and Beyond

July 29–30, 2024

Population-based cancer surveillance has a pivotal role in assessing the nation's progress in cancer control. Cancer surveillance helps inform research and care interventions aimed at reducing the burden of cancer on patients and communities, including the ability to identify health disparities in cancer outcomes. Surveillance data are crucial for identifying emerging trends in health outcomes and opportunities to improve the quality of cancer care. However, challenges with the current approach to cancer surveillance in the United States include delays and gaps in data collection, as well as inadequate infrastructure and workforce to keep pace with the informatics and treatment-related advances in cancer. The National Cancer Policy Forum will convene a public workshop to examine opportunities to enhance and modernize cancer surveillance in order to improve cancer research, care, and outcomes for all patients.

Learn more and register here

Toward a Framework to Improve Diversity and Inclusion in Clinical Trials

Collaborative workshop convened by:
Forum on Drug Discovery, Development, and Translation
National Cancer Policy Forum

May 20, 2024

This workshop aims to explore opportunities to improve racial and ethnic diversity in clinical trials with a focus on system-level change and collective efforts across organizations and sectors that no one entity can effectively take on alone.

Learn more and register here

Biological Effectors of Social Determinants of Health in Cancer: Identification and Mitigation

March 20–21, 2024

Biological effectors of social determinants of health (SDOH) interact and impact cancer risk, treatment outcomes, and health equity. Workshop presentations and discussions will consider opportunities to advance health equity in cancer by identifying promising avenues for future research, as well as policies and interventions aimed at mitigating the negative impacts of the SDOH in cancer.

Learn more and register here

Optimizing Public–Private Partnerships for Clinical Cancer Research

Collaborative workshop convened by:
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation

October 17–18, 2023

Public–private partnerships (PPPs) have the potential to more effectively leverage public funding and resources, increase the breadth and depth of research, and affect a more rapid translation from basic discoveries to public health applications. Industry, government, nonprofit, and academic organizations could each make important and unique contributions to this endeavor. This workshop examined opportunities to enhance and foster PPPs for clinical cancer research and considered lessons learned from examples of public–private collaborations in oncology or other fields that have helped to advance clinical research and improve patient outcomes.

Workshop videos and presentations

Assessing and Advancing Progress in the Delivery of High-Quality Cancer Care

Collaborative workshop co-hosted by:
National Cancer Policy Forum
American Society of Clinical Oncology

October 5–6, 2023

2023 marked the 10-year anniversary of the Institute of Medicine report *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis* and the ability of the cancer care delivery system to provide high-quality cancer care to all patients remains elusive. This workshop provided an opportunity for the cancer care community to discuss persistent barriers to achieving excellent and equitable cancer care for all and additional actions that could be taken to implement the 2013 recommendations. Workshop presentations and discussions also identified aspects of cancer care that have changed over the past decade and where new strategies are needed to improve the quality of care.

Workshop videos and presentations

Recent Workshops

Developing a Multidisciplinary and Multispecialty Workforce for Patients with Cancer, from Diagnosis to Survivorship

Collaborative workshop convened by:
National Cancer Policy Forum
Global Forum on Innovation in Health Professional Education

July 17–18, 2023

Patients living with and beyond cancer often require care from a wide range of clinicians as they navigate cancer diagnosis, treatment, and survivorship care. A multispecialty and multidisciplinary workforce is critical to ensuring that all patients with cancer receive high-quality care. This workshop examined opportunities to improve equitable access to multispecialty, multidisciplinary care for patients living with and beyond cancer.

Workshop videos and presentations

The Impact of the Dobbs Decision on Cancer Care Webinar Series

The National Cancer Policy Forum hosted a webinar series to discuss the downstream effects of the U.S. Supreme Court ruling *Dobbs v. Jackson Women's Health Organization* on access to reproductive health care in the context of cancer care.

- **How Abortion Restrictions Affect Patients and Care Delivery, July 11, 2023**
- **Health System and Workforce Effects, July 25, 2023**
- **Ethical, Legal, and Social Implications, August 31, 2023**

Webinar series website

The Potential Contribution of Cancer Genomics Information to Community Investigations of Unusual Patterns of Cancer

Collaborative workshop convened by:
National Cancer Policy Forum
Roundtable on Genomics and Precision Health

April 13, 2023

This workshop examined the opportunities to apply genomic and epigenomic biomarkers of environmental exposures associated with unusual patterns of cancer, particularly in pediatric populations. The workshop was sponsored by the Division of Environmental Health Science and Practice in the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC) and was convened to provide background information to assist the CDC in revising its *Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns*.

Workshop videos and presentations

Proceedings

Incorporating Integrated Diagnostics into Precision Oncology Care

Collaborative workshop convened by:
National Cancer Policy Forum
Computer Science and Telecommunications Board
Board on Human-Systems Integration

March 6–7, 2023

Innovations in the diagnostic specialties have the potential to reshape cancer diagnosis and enable precision therapy. Spurred by advances in informatics, there are opportunities to combine information from imaging, pathology, and molecular testing. Multidisciplinary collaboration among pathologists, radiologists, and oncologists supplemented by machine learning-based tools could facilitate a more precise understanding of a patient's diagnosis and what treatment strategies may be most effective to improve outcomes. Integrated diagnostics may also improve patient access to subspecialty expertise, particularly in community-based settings of cancer care. This workshop convened members of the cancer community to better define the purpose, goals, and components of integrated diagnostics.

Workshop videos and presentations

Addressing Treatment Resistance in the Development of Cancer Immune Modulator Therapeutics

Collaborative workshop convened by:
National Cancer Policy Forum
Forum on Drug Discovery, Development, and Translation

November 14–15, 2022

Many patients who initially respond to immunotherapy treatment may develop resistance to treatment over time. The reasons for the development of resistance are not fully understood, and resistance continues to pose a major threat to further advances in the field of immunotherapy for cancer treatment. This workshop gave participants in cancer research and cancer care an opportunity to examine the current challenges related to resistance to immunotherapies and to discuss potential policy options that could help overcome these challenges.

Workshop videos and presentations

Proceedings

Advancing Progress in Cancer Prevention and Risk Reduction

June 27–28, 2022

This workshop considered the current state of knowledge on risk factors for cancer and best practices for cancer prevention and risk reduction. Workshop sessions focused on strategies to implement population-based and clinic-based prevention, with exemplar programs in both settings. Participants also examined opportunities to spur progress in cancer prevention and risk reduction.

Workshop videos and presentations

Proceedings

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National Cancer Institute

S. Gail Eckhardt, M.D., FASCO
Baylor College of Medicine

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Case Western Reserve University

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University of California, San Francisco

Julie R. Gralow, M.D., FACP, FASCO
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Yale University

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Georgetown University; Society for Immunotherapy of Cancer

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Program Coordinator

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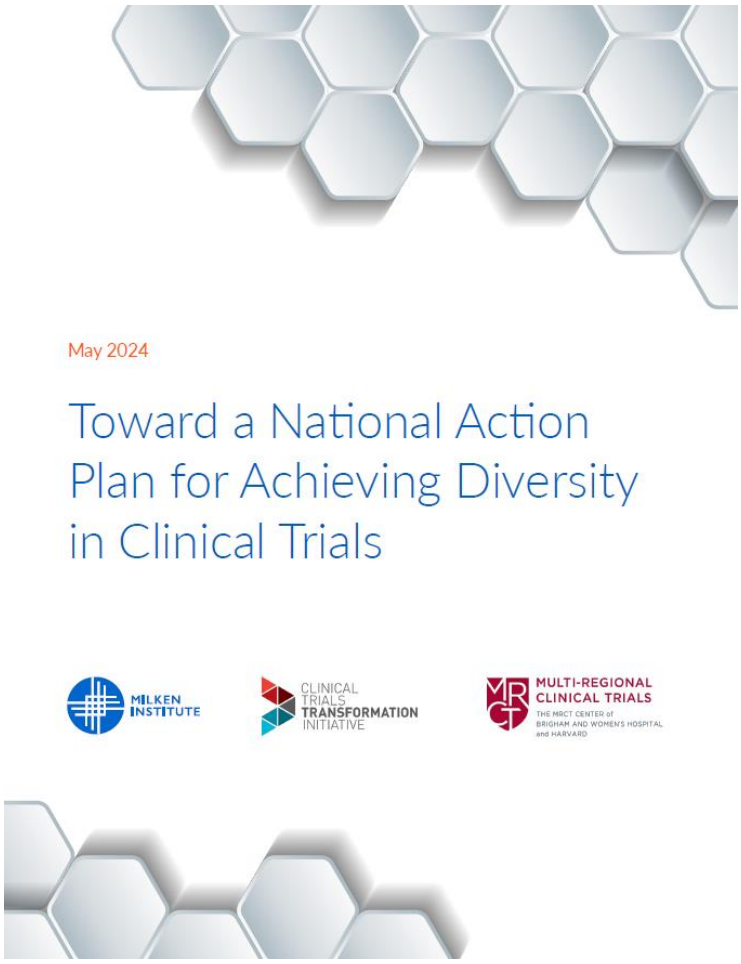


[CLICK HERE TO VIEW THE REPORT]

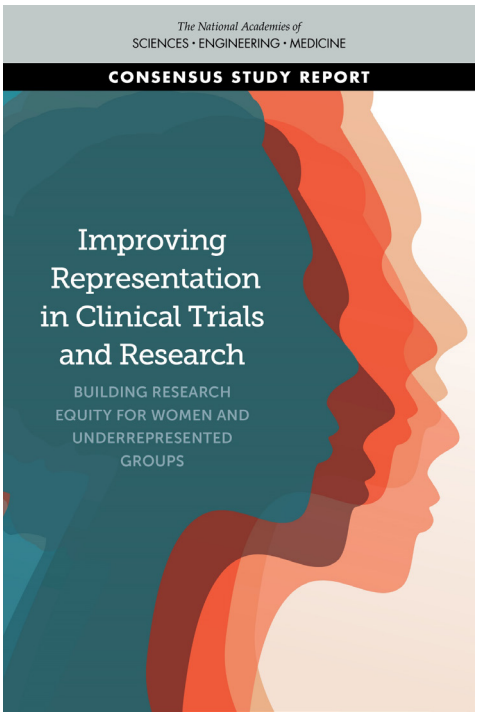
Participation in clinical research among racial and ethnic minorities remains low, even though such groups now represent nearly 40 percent of the US population. Health disparities were laid bare during the COVID-19 pandemic, with ethnic and racial minorities significantly underrepresented in early vaccine trials despite being disproportionally impacted by the disease. As a 2022 National Academies report stated, “The lack of equitable representation in clinical trials compounds disparities in health and will cost the United States hundreds of billions of dollars.

Despite decades of work and recent progress—including passage of the Food and Drug Omnibus Reform Act of 2023, which established legislative mandates for increasing clinical trial diversity—there remains a need for collective action across sectors and organizations to align on goals for system-wide, sustainable change. To that end, members of the four organizations with established leadership in advancing diversity in clinical trials—the Clinical Trials Transformation Initiative (CTTI), FasterCures, the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center), and the National Academies Forum on Drug Discovery, Development, and Translation—coordinated a series of convenings in 2023 to establish a path toward increased diversity in clinical trials.

This report details the actions organizations and sectors from across the enterprise can take to create a clinical trials enterprise that is diverse, equitable, inclusive, and accessible to all.

Improving Representation in Clinical Trials and Research

Building Research Equity for Women and Underrepresented Groups



The United States has long made substantial investments in clinical research with the goal of improving the health and well-being of our nation. There is no doubt that these investments have contributed significantly to treating and preventing disease and extending human life. Nevertheless, clinical research faces a critical shortcoming. Currently, large swaths of the U.S. population, and those that often face the greatest health challenges, are less able to benefit from these discoveries because they are not adequately represented in clinical research studies. While progress has been made with representation of white women in clinical trials and clinical research, there has been little progress in the last three decades to increase participation of racial and ethnic minority population groups. This underrepresentation is compounding health disparities, with serious consequences for underrepresented groups and for the nation.

At the request of Congress, the National Academies appointed the Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research for the purpose making recommendations for improving representation of underrepresented and excluded populations in clinical trials and clinical research and creating lasting change. The committee's report, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*,[1] identifies policies, procedures, programs, or projects aimed at increasing the inclusion of these groups in clinical research and the specific strategies used by those conducting clinical trials and clinical and translational research to improve diversity and inclusion. The report models the potential economic benefits of full inclusion of men, women, and racial and ethnic groups in clinical research, as well as highlights new programs and interventions in medical centers and other clinical settings designed to increase participation.

[1] To view the full report, visit: https://nap.nationalacademies.org/catalog/26479/improving-representation-in-clinical-trials-and-research-building-research-equity.

DIVERSE REPRESENTATION IN CLINICAL RESEARCH MATTERS

By failing to achieve a more diverse clinical trial and clinical research enterprise, the nation suffers serious costs and consequences, including the following:

- Lack of representation compromises generalizability of clinical research findings to the U.S. population.
- Lack of representation costs hundreds of billions of dollars.[2]
- Lack of representation may hinder innovation.
- Lack of representation may compound low accrual that causes many trials to fail.
- Lack of representation may lead to lack of access to effective medical interventions.
- Lack of representation may undermine trust.
- Lack of representation compounds health disparities in the populations currently underrepresented in clinical trials and clinical research.

[2] The committee used the Future Elderly Model to value how chronic conditions differentially affect the lives of older Americans.

BARRIERS TO REPRESENTATION OF UNDERREPRESENTED AND EXCLUDED POPULATIONS

INDIVIDUAL AND COMMUNITY FACTORS These factors are often cited as reasons for lack of participation in clinical trials, but the evidence is clear: Asian, Black, Latinx Americans, and American Indian/Alaskan Native individuals are no less likely, and in some cases are more likely, to participate in research if asked. Distrust and mistrust exist but they are not shown to be associated with willingness to participate in medical research. The evidence suggests these concerns misrepresent barriers to participation in research or are surmountable with effort from research teams, funders, and policymakers.

INDIVIDUAL RESEARCH STUDIES Factors leading to the underrepresentation and exclusion of certain populations in clinical trials and research begin with and follow the life cycle of a project. This requires examining practices at every level of the research process, including: the development of research questions; the composition, training, and attitudes of the research team; research site selection; participant selection, including sampling and recruitment methods and inclusion and exclusion criteria.

INSTITUTIONAL STRUCTURES Medical institutions of different types face structural barriers to inclusion in clinical trials. Although academic medical centers conduct most medical research funded by the federal government, engaging underrepresented populations in research and building relationships with communities does not align with traditional paradigms of promotion and tenure at these institutions. Many academic medical centers also struggle to recruit and retain diverse investigators and staff and often lack trust with their surrounding communities. Community Health Centers serve a more diverse population, but face challenges including with the electronic health record (EHR) infrastructure that can limit providers' ability to query the EHR using study inclusion and exclusion criteria.

INSTITUTIONAL REVIEW BOARDS IRBs can also present barriers to diverse participation in clinical trials by limiting the types and amount of compensation given to research participants to avoid the impression of coercion or undue influence. However, limiting incentives may ultimately compromise beneficence and justice, two of the ethical principles for research with human subjects detailed in the Belmont Report.

RESEARCH FUNDERS Research funders can influence the diversity of clinical trials in the following ways: setting funding priorities, deciding which projects ultimately get funded, providing adequate funding to recruit and retain participants, requiring transparent reporting, and evaluating research outputs. Industry trials often face pressure to gather data quickly and the selection of easy-to-recruit samples is often incentivized.

MEDICAL JOURNALS Peer-reviewed medical journals, which serve as the gatekeepers to scientific advancements in clinical practice and health, have responsibility for what is, and is not, published in their pages. Lack of representation on editorial boards and other journal leadership positions may contribute to biases in publication.

FACILITATORS TO SUCCESSFUL INCLUSION IN RESEARCH

There is a dearth of critical qualitative data about facilitators of successful inclusion in clinical research. The study committee supplemented existing literature with commissioned research with 20 researchers who worked on trials that met criteria for diverse trial enrollment. The following eight major themes emerged from this research, they are actions that serve as key facilitators to inclusion.

- Starting with Intention and Agency to Achieve Representativeness
- Establishing a Foundation of Trust with Participants and the Community at Large
- Anticipating and Removing Barriers to Study Participation
- Adopting a Flexible Approach to Recruitment and Data Collection
- Building a Robust Network by Identifying All Relevant Stakeholders
- Navigating Scientific, Professional Peer, and Societal Expectations
- Optimizing the Study Team to Ensure Alignment with Research Goals
- Attaining Resources and Support to Achieve Representativeness

STATUS OF CLINICAL TRIAL PARTICIPATION

The study committee commissioned an analysis to examine available data from the FDA and NIH, which found that women now represent more than 50 percent of clinical trial participants in the United States, particularly for white women. However, pregnant and lactating individuals, sexual- and gender-minority populations, and racial and ethnic subgroups of women remain underrepresented in clinical trials. The analysis also revealed that the racial and ethnic diversity of clinical trials is largely stagnant, with little changes in diversity over time.

IMPROVING REPRESENTATION IN CLINICAL RESEARCH

1. IMPROVING REPRESENTATION IN CLINICAL RESEARCH IS URGENT

Despite greater diversity in the United States today, deep disparities in health are persistent, pervasive, and costly. Failing to reach these growing communities will only prove more costly over time and prevent meaningful reductions in disparities in chronic diseases.

2. IMPROVING REPRESENTATION IN CLINICAL RESEARCH REQUIRES INVESTMENT

In order to better address health disparities, our workforce should look more like our nation. Building trust with local communities cannot be episodic or transactional and pursued only to meet the goals of specific studies; it requires sustained presence, commitment, and investment.

3. IMPROVING REPRESENTATION REQUIRES TRANSPARENCY AND ACCOUNTABILITY

Transparency and accountability throughout the entire research enterprise must be present at all points in the research lifecycle – from the questions being addressed, to ensuring the populations most affected by the health problems are engaged in the design of the study, to recruitment and retention of study participants, to analysis and reporting of results.

4. IMPROVING REPRESENTATION IN CLINICAL RESEARCH IS THE RESPONSIBILITY OF EVERYONE INVOLVED.

The clinical research landscape involves multiple stakeholders— participants, communities, investigators, IRBs, industry sponsors, institutions, funders, regulators, journals, and policy-makers. The responsibility (and cost) will be borne to some extent by all stakeholders in the larger research ecosystem, acting in consort to improve representation.

5. CREATING A MORE EQUITABLE FUTURE ENTAILS A PARADIGM SHIFT

The clinical research field must embrace a paradigm shift that moves the balance of power from institutions and puts at the center the priorities, interests, and voices of the community. An ideal clinical trial and research enterprise pursues justice in the science of inclusion through scalable frameworks, expects transparency and accountability, invests more in people, institutions and communities to drive equity, and invests in the science of community engagement and empowerment.

RECOMMENDATIONS

The Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research developed 17 recommendations to improve the representation of underrepresented and excluded populations in clinical trials and clinical research and create lasting change. The committee focused on system-level recommendations to drive change on a broader scale. The recommendations focus on tangible actions that must urgently be taken within the context of the existing structures of the clinical research ecosystem to achieve the goals of representation and inclusion.

REPORTING

- The Department of Health and Human Services (HHS) should establish an intradepartmental task force on research equity charged with coordinating data collection and developing better accrual tracking systems across federal agencies.
- The NIH should standardize the submission of demographic characteristics for trials to ClinicalTrials.gov beyond existing guidelines so that trial characteristics are labeled uniformly across the database and can be easily disaggregated, exported, and analyzed by the public.
- Journal editors, publishers, and the International Committee on Medical Journal Editors should require information on the representativeness of trials and studies for submissions to their journals.

ACCOUNTABILITY

- The Food and Drug Administration should require study sponsors to submit a detailed recruitment plan no later than at the time of Investigational New Drug and Investigational Device Exemption application submission that explains how they will ensure that the trial population appropriately reflects the demographics of the disease or condition under study.
- In grant proposal review, the NIH should formally incorporate considerations of participant representativeness in the score-driving criteria that assess the scientific integrity and overall impact of a grant proposal.
- The Office of Human Research Protections (OHRP) and the FDA should direct local institutional review boards (IRBs) to assess and report the representativeness of clinical trials as one measure of sound research design that it requires for the protection of human subjects.
- The CMS should amend its guidance for coverage with evidence development to require that study protocols include a plan for recruiting and retaining participants who are representative of the affected beneficiary population and a plan for monitoring achievement of representativeness and a process for remediation if CED studies are not meeting goals for representativeness.

FEDERAL INCENTIVES

- Congress should direct the FDA to enforce existing accountability measures, as well as establish a taskforce to study new incentives for new drug and device for trials that achieve representative enrollment.
- The CMS should expedite coverage decisions for drugs and devices that have been approved based on clinical development programs that are representative of the populations most affected by the treatable condition.
- CMS should incentivize community providers to enroll and retain participants in clinical trials by reimbursing for the time and infrastructure that is required.
- The Government Accountability Office (GAO) should assess the impact of reimbursing routine care costs associated with clinical trial participation for both Medicare (enacted in 2000) and Medicaid (enacted in 2020).

REMUNERATION

- Federal regulatory agencies, including OHRP, NIH, and

FDA, should develop explicit guidance to direct local IRBs on equitable compensation to research participants and their caregivers.

- All sponsors of clinical trials and clinical research (e.g., federal, foundation, private and/or industry) should ensure that trials provide adequate compensation for research participants.

EDUCATION, WORKFORCE, AND PARTNERSHIPS

- All entities involved in the conduct of clinical trials and clinical research should ensure a diverse and inclusive workforce, especially in leadership positions.
- Leaders and faculty of academic medical centers and large health systems should recognize research and professional efforts to advance community-engaged scholarship and other research to enhance the representativeness of clinical trials as areas of excellence for promotion or tenure.
- Leaders of academic medical centers and large health systems should provide training in community engagement and in principles of diversity, equity, and inclusion for all study investigators, research grants administration, and IRB staff as a part of the required training for any persons engaging in research involving human subjects.
- HHS should substantially invest in community research infrastructure that will improve representation in clinical trials and clinical research.

COMMITTEE ON IMPROVING THE REPRESENTATION OF WOMEN AND UNDERREPRESENTED MINORITIES IN CLINICAL TRIALS AND RESEARCH

Kirsten Bibbins-Domingo (*Chair*)
Editor in Chief, Journal of the American Medical Association; MD Endowed Chair and Professor of Medicine, University of California, San Francisco

Marcella Alsan
Professor of Public Policy, Harvard Kennedy School; Co-Director of Health Care Delivery Initiative Abdul Latif Jameel Poverty Action Lab, Massachusetts Institute of Technology

Arleen Brown
Professor of Medicine, University of California, Los Angeles; Chief of General Internal Medicine and Health Services Research, Olive View-UCLA Medical Center

Gloria Coronado
Epidemiologist and Mitch Greenlick Endowed Distinguished Investigator in Health Disparities Research, Kaiser Permanente Center for Health Research

Carlos del Rio
Distinguished Professor of Medicine, Emory University School of Medicine; Professor of Epidemiology and Global Health, Rollins School of Public Health, Emory University; Executive Associate Dean for Emory University School of Medicine, Grady Health System

XinQi Dong
Director of the Institute for Health, Health Care Policy, and Aging Research (IFH) and Inaugural Henry Rutgers Professor of Population Health Sciences, Rutgers University

Dana Goldman
Dean of the Sol Price School of Public Policy, C. Erwin and Ione L. Piper Chair, and Leonard D. Schaeffer Director's Chair, Schaeffer Center for Health Policy & Economics, University of Southern California

Sharon Inouye
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

Amelia Knopf
Assistant Professor of Nursing, Indiana University

Edith A. Perez
Chief Medical Officer of Bolt Therapeutics, Inc.; Professor of Medicine, Mayo Clinic; Director of the Mayo Clinic Breast Cancer Translational Genomics Program

Phyllis Pettit Nassi
Associate Director for Research and Science, Special Populations, American Indian Program, Huntsman Cancer Institute, University of Utah

Jason Resendez
President and CEO, National Alliance for Caregiving

Susan Schaeffer
Founder, President, and CEO of The Patients' Academy for Research Advocacy

STUDY STAFF

Alex Helman
Study Director and Program Officer, Committee on Women in Science, Engineering, and Medicine

Ashley Bear
Director, Committee on Women in Science, Engineering, and Medicine

Laura Aiuppa
Senior Program Officer, Board on Health Care Services

Austen Applegate
Research Associate, Committee on Women in Science, Engineering, and Medicine

John Veras
Senior Program Assistant, Committee on Women in Science, Engineering, and Medicine

Abigail Harless
Senior Program Assistant, Committee on Women in Science, Engineering, and Medicine

Mollie Marr
Mirzayan Fellow, Committee on Women in Science, Engineering, and Medicine

Anne Marie Houppert
Senior Librarian

FOR MORE INFORMATION

This Consensus Study Report Highlights is prepared by the Committee on Women in Science, Enginieering, and Medicine, based on the Consensus Study Report, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*. (2022).

The study was sponsored by the the National Institutes of Health. Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.

This Consensus Study Report is available from the National Academies Press
(800) 624-6242 | http://www.nap.edu | http://www.nationalacademies.org

CMS Framework for Health Equity 2022–2032

GO.CMS.GOV/OMH

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Contents

CMS Office of Minority Health Director's Foreword

"As the nation's largest health insurer, the Centers for Medicare & Medicaid Services has a critical role to play in driving the next decade of health equity for people who are underserved. Our unwavering commitment to advancing health equity will help foster a health care system that benefits all for generations to come."

Dr. LaShawn McIver, Director, CMS Office of Minority Health

The *CMS Framework for Health Equity* provides a strong foundation for our work as a leader and trusted partner dedicated to advancing health equity, expanding coverage, and improving health outcomes. This includes strengthening our infrastructure for assessment, creating synergies across the health care system to drive structural change, and identifying and working together to eliminate barriers to CMS-supported benefits, services, and coverage for individuals and communities who are underserved or disadvantaged and those who support them.

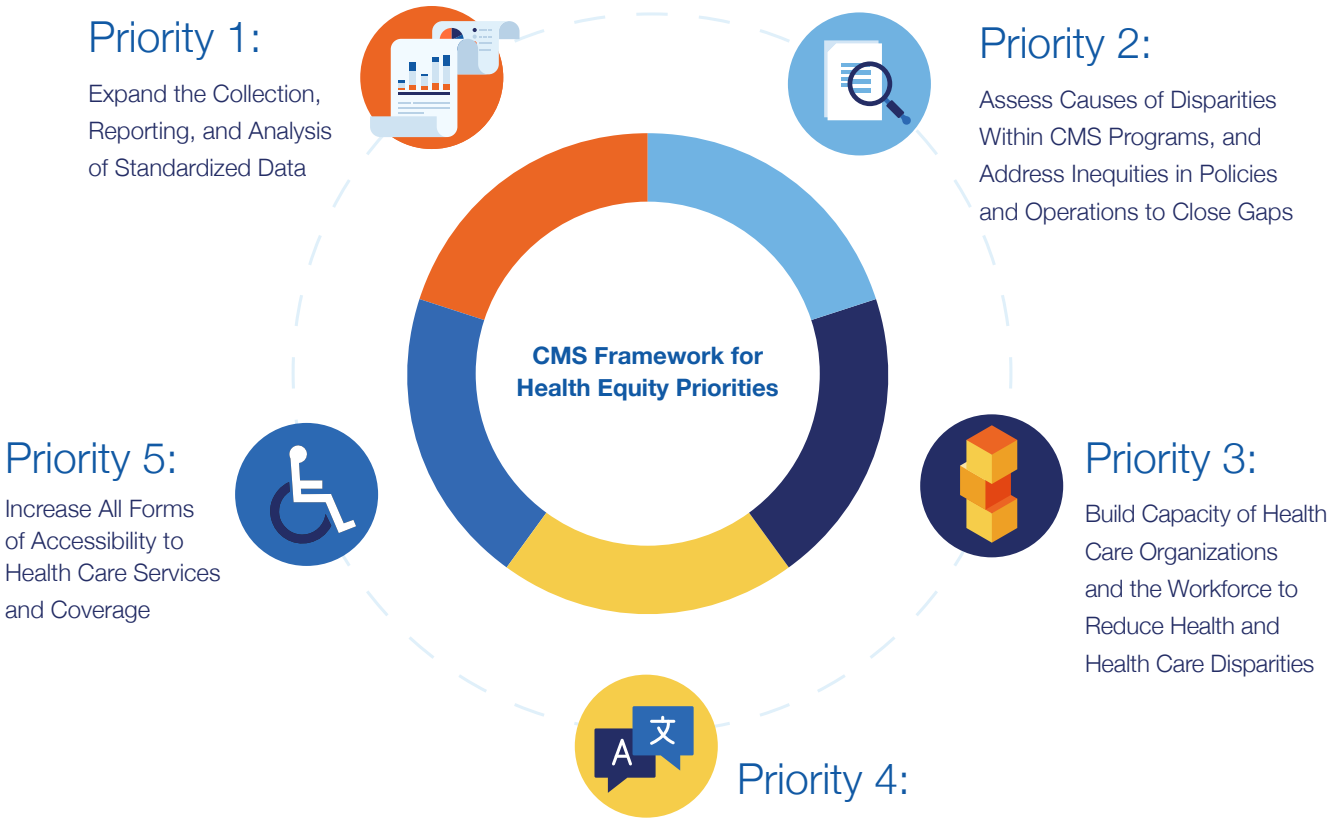
Across our Centers and Offices, we are committing to taking an integrated, action-oriented approach to advance health equity among members of communities, providers, plans, and other organizations serving such communities, who are underserved or disadvantaged.

We strive to identify and remedy systemic barriers to equity so that every one of the people we serve has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.

This Framework challenges us to incorporate health equity and efforts to address health disparities as a foundational element across all our work, in every program, across every community. We are designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive.

Executive Summary

CMS is the largest provider of health insurance in the United States, responsible for ensuring that more than 170 million individuals supported by CMS programs (i.e., Medicare, Medicaid, Children's Health Insurance Program (CHIP), and the Health Insurance Marketplaces) are able to get the care and health coverage they need and deserve.[1] Consistent with the Department of Health and Human Services' Healthy People 2030 Framework,[2] CMS recognizes that addressing health and health care disparities and achieving health equity should underpin efforts to focus attention and drive action on our nation's top health priorities. CMS defines health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[3]



The *CMS Framework for Health Equity* is consistent with the Healthy People 2000 Framework which first incorporated health equity as a guiding objective as well as other efforts undertaken across HHS to address health equity and disparities reduction as a critical aspect of health and health care. The Framework is also consistent with the bold goals CMS Centers and Offices have articulated in our program areas, including Medicaid and CHIP and the CMS Innovation Center.[4, 5] This Framework reinforces the concept that in order to attain the highest level of health for all people, we must give our focused and ongoing attention to address avoidable inequalities and eliminate health and health care disparities.[6]

Consistent with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, the term "underserved communities" refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified in the definition of "equity."[7] This includes members of racial and ethnic communities, people with disabilities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, individuals with limited English proficiency, members of rural communities*, and persons otherwise adversely affected by persistent poverty or inequality.[8, 9]

This plan focuses on people who experience, or serve those who experience, disproportionately high burdens of disease, worse quality of care and outcomes, and barriers to accessing care. The *CMS Framework for Health Equity* was developed with particular attention to disparities in chronic and infectious diseases such as diabetes, chronic kidney disease, cancer, dementia, cardiovascular disease, maternal and infant health, behavioral health, as well as HIV/AIDS, and COVID-19, which disproportionately impact members of underserved communities due to prevalence, complexity, and social risk factors.[10, 11, 12, 13, 14, 15, 16] This plan also considers the impacts natural disasters (e.g., earthquakes, fires, viral outbreaks) and manmade disasters (e.g., oil spills, lead poisoning, climate change) have on specific communities — both during an event and in response and recovery — as health and social risk factors may work together to cause or worsen existing health and health care disparities.[17, 18, 19, 20, 21]

This *CMS Framework for Health Equity* updates the previous Medicare-focused *CMS Equity Plan for Improving Quality in Medicare* [22] with an enhanced and more comprehensive 10-year approach to further embed health equity across all CMS programs including Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces.

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* In referencing members of rural communities, we are inclusive of individuals in frontier areas, tribal lands, and those residing in the U.S. territories.

The updated *CMS Framework for Health Equity* also brings focus to CMS's work supporting health care organizations, health care professionals and partners — providers, health plans, federal, state, and local partners, tribal nations, individuals and families, quality improvement partners, researchers, policymakers, and other stakeholders — in activities to achieve health equity. The initial *CMS Equity Plan for Improving Quality in Medicare* identified high-impact priorities based on stakeholder engagement, a review of the evidence base, and discussions across HHS, CMS, and among federal partners. This enhanced and expanded *CMS Framework for Health Equity* refines CMS's health equity priorities and broadens our focus beyond Medicare. It is informed by the seven interim years of stakeholder input, evidence review, and knowledge and understanding gained through the Agency's work. The five priorities of this new, enhanced, and comprehensive *CMS Framework for Health Equity* are described in detail throughout this plan. These priorities encompass both system and community-level approaches to achieve equity across CMS programs. Each of the priorities are complementary, and their integrated adoption and implementation is central to the elimination of barriers to health equity for all Americans.

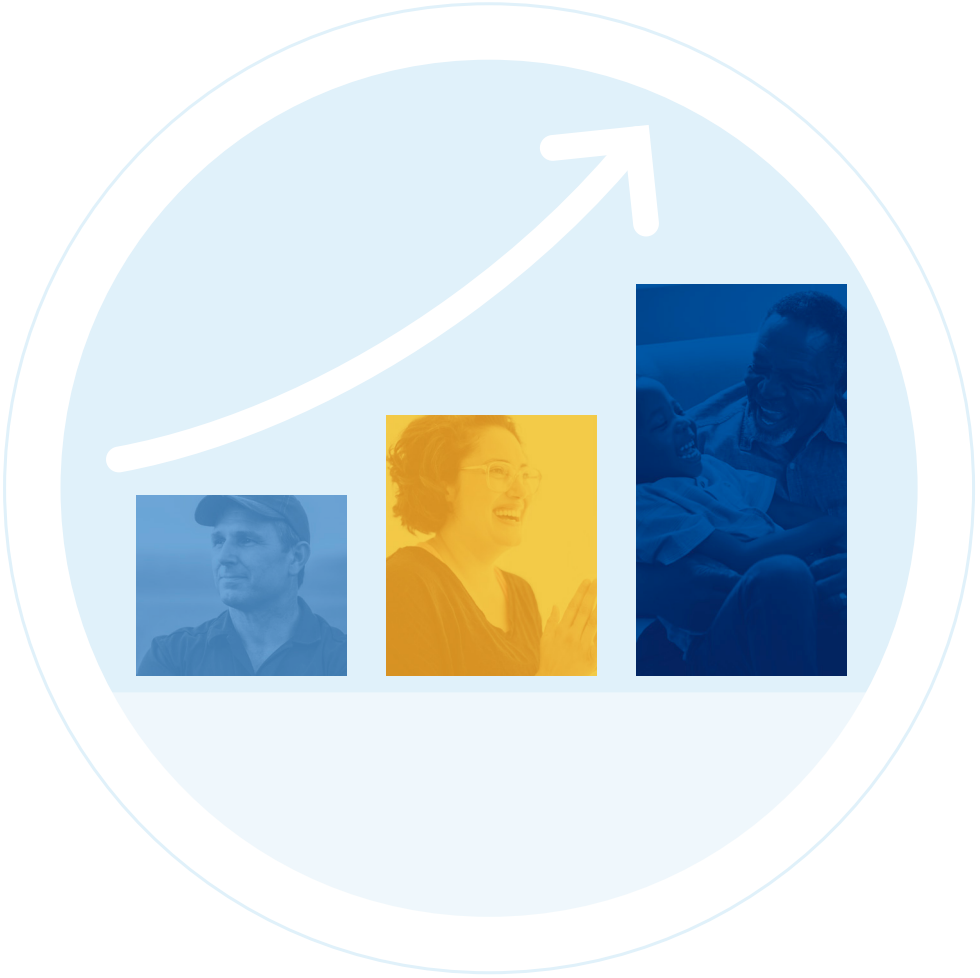
This plan aligns with the federal government's goal in advancing equity, which is to provide everyone with the opportunity to reach their full potential.[23] Consistent with this aim, the *CMS Framework for Health Equity* supports CMS's ability to assess whether, and to what extent, its programs and policies perpetuate or exacerbate systemic barriers to opportunities and benefits for the communities referenced above. This includes understanding and addressing the ways in which Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces (Marketplaces) meet the needs of those we serve, particularly underserved communities and individuals.

CMS will identify, establish, and monitor progress of our efforts across the Agency. We will draw on CMS data and other available sources to monitor and assess whether disparities in health and health care quality, access, and outcomes are improving across CMS programs and among the individuals we serve. Our progress in advancing health equity will reflect our commitment to continuous quality improvement for all individuals, and we will incorporate ongoing input from those that participate in CMS programs — our communities, providers, plans, and other partners — to help us innovate and improve over time. True success will be realized only when all those served by CMS have achieved their highest level of health and well-being, and that we have eliminated disparities in health care quality and access. While this vision may not be fully attainable in the ten-year horizon of this plan, we will report on our progress and continuously identify opportunities to improve.

Aligning with CMS and HHS

The United States has made progress towards improving health care quality, but well-documented disparities persist for members of racial and ethnic communities, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, members of rural communities, and persons otherwise adversely affected by persistent poverty or inequality.[24, 25, 26, 27] CMS promotes health equity by using policy levers and program authorities and engaging health care stakeholders across settings and communities. We consistently identify and disseminate new and promising practices and embed health equity into CMS programs to better meet the needs of all communities — particularly underserved communities. In addition, we facilitate knowledge sharing and collaboration among stakeholders and engage with new audiences to expand and extend efforts to achieve equity. In particular, CMS leverages existing and new quality improvement initiatives to support and amplify best practices that are proven to address social risk factors and unmet social needs and reduce disparities.

The *CMS Framework for Health Equity* is structured to align with HHS initiatives that seek to achieve health equity and reduce disparities among minority and underserved populations. This includes the Healthy People 2030 Framework,[28] which establishes the foundational principle that "achieving health and well-being requires eliminating health disparities, achieving health equity, and attaining health literacy."[29] This also includes but is not limited to Department-wide strategies and approaches to embedding health equity across our program — for example, the HHS Rural Action Plan,[30] the HHS Maternal Health Action Plan,[31] the HHS National Standards for Culturally and Linguistically Appropriate Standards (CLAS) in Health and Health Care,[32] the HHS National Quality Strategy,[33] and the IHS Strategic Plan which ensures that across HHS we are providing federal health services to American Indian and Alaska Native people.[34] Healthy People 2030 also outlines a Social Determinants of Health (SDOH) Framework[35] with five domains including economic stability, education access and quality, health care access and quality, neighborhood and built environment, and social and community context. Healthy People 2030 and related work across HHS underscores that social risk factors and unmet social needs contribute to wide health and health care disparities and inequities. Stakeholders across the health care spectrum have a role to play in addressing social determinants of health.[36]



Of primary and critical importance, the *CMS Framework for Health Equity* aligns across CMS initiatives and other existing strategy documents such as the Administrator's Strategic Vision for CMS,[37] the CMS Rural Health Strategy,[38] the CMS Quality Strategy,[39] the CMS Innovation Center's Strategy Refresh,[40] and CMS's Strategic Vision for Medicare and CHIP.[41] These strategies focus on eliminating disparities as a cross-cutting criteria to be applied throughout the Agency's work. The *CMS Framework for Health Equity* also aligns with other Agency-wide efforts, particularly strengthening infrastructure and data systems, empowering individuals, families, and caregivers as partners in their health care, and addressing the need for measures for population-based payment through alternative payment models. Work across these areas supports the Agency in monitoring trends in quality of care and health outcomes, learning directly from the communities and families CMS serves, and incorporating population health improvement activities into measurement and payment. All of these activities are essential to achieving health equity across care settings and health conditions.

Priorities for the 2022–2032 *CMS Framework for Health Equity*

The next section of the *CMS Framework for Health Equity* outlines five priorities that inform CMS's efforts for the next ten years and how the Agency may operationalize each priority to achieve health equity and eliminate disparities. Each priority area reflects a key area in which CMS stakeholders from communities that are underserved and disadvantaged express that CMS action is needed and critical to advancing health equity. Together, the five priorities provide an integrated approach to build health equity into existing and new efforts by CMS and our stakeholders.

Priority 1: Expand the Collection, Reporting, and Analysis of Standardized Data

CMS strives to improve our collection and use of comprehensive, interoperable, standardized individual-level demographic and SDOH data, including race, ethnicity, language, gender identity, sex, sexual orientation, disability status, and SDOH. By increasing our understanding of the needs of those we serve, including social risk factors and changes in communities' needs over time, CMS can leverage quality improvement and other tools to ensure all individuals have access to equitable care and coverage.

Priority 2: Assess Causes of Disparities Within CMS Programs, and Address Inequities in Policies and Operations to Close Gaps

CMS is committed to move beyond observation and into action, assessing our programs and policies for unintended consequences and making concrete, actionable decisions about our policies, investments, and resource allocations. Our goals are to explicitly measure the impact of our policies on health equity, to develop sustainable solutions that close gaps in health and health care access, quality, and outcomes, and to invest in solutions that address health disparities.

Priority 3: Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities

CMS has a commitment to support health care providers, plans, and other organizations who ensure individuals and families receive the highest quality care and services. Health care professionals, particularly those serving minority and underserved communities, have a direct link to individuals and families and can address disparities at the point of care. CMS policy, program, and resource allocation decisions must build capacity among providers, plans, and other organizations to enable stakeholders to meet the needs of the communities they serve.

Priority 4: Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services

CMS must ensure that all individuals we serve, including members of communities that are underserved, can equitably access all CMS benefits, services and other supports, and coverage. Language access, health literacy, and the provision of culturally tailored services play a critical role in health care quality, patient safety and experience, and can impact health outcomes. CMS has opportunities across our operations, direct communication and outreach to enrollees and consumers, and guidance to plans, providers, and other partners to improve health care quality, patient safety, and the experience individuals have within the health care system.

Priority 5: Increase All Forms of Accessibility to Health Care Services and Coverage

CMS has a responsibility to ensure that individuals and families can access health care services when and where they need them, in a way that is responsive to their needs and preferences. CMS must seek direct feedback from individuals with disabilities, including physical, sensory and communication, intellectual disabilities, and other forms of disability, to understand their experiences navigating CMS-supported benefits, services, and coverage and tailor our programs and policies to ensure equitable access and quality.

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/Medical

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials
Guidance for Industry

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Silver Spring, MD 20993-0002
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Office of the Center Director
Guidance and Policy Development
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Food and Drug Administration
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Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The purpose of this guidance is to provide recommendations to sponsors developing medical products[2] on the approach for developing a Race and Ethnicity Diversity Plan (henceforth referred to as the "Plan") to enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States, such as Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific Islanders, and other persons of color, in clinical trials.[3] Individuals from these populations are frequently underrepresented in biomedical research despite having a disproportionate disease burden for certain diseases relative to their proportional representation in the general population. Adequate representation of these populations in clinical trials and studies supporting regulatory submissions helps ensure that the data generated in the development program reflect the racial and ethnic diversity of the population expected to use the medical product if approved, and may

[1] This guidance has been prepared by the Oncology Center of Excellence (OCE) in collaboration with the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Office of Minority Health and Health Equity (OMHHE) at the Food and Drug Administration.

[2] For the purposes of this guidance, medical product is used to refer to human drugs (including human biological products that are regulated as drugs) and medical devices.

[3] FDA follows the Office of Management and Budget's definitions of race and ethnicity. *See* Office of Management and Budget (OMB) Directive No. 15 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (October 30, 1997), available at https://www.whitehouse.gov/wp-content/uploads/2017/11/Revisions-to-the-Standards-for-the-Classification-of-Federal-Data-on-Race-and-Ethnicity-October30-1997.pdf. Consistent with OMB Policy Directive 15, the categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. Ethnicity is comprised of two categories: Hispanic/Latino or not Hispanic/Latino. Race is comprised of five minimum categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. In certain situations, as recommended in OMB Policy Directive 15, more detailed race and ethnicity information may be desired. OMB standards do not designate underrepresented populations, thus FDA's recommendations regarding race and ethnicity data in clinical trials provide additional guidance, see the guidance for industry *Collection of Race and Ethnicity Data in Clinical Trials* (October 2016). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

potentially identify effects on safety or efficacy outcomes that may be associated with, or occur more frequently within these populations.

As discussed below, this guidance focuses specifically on racial and ethnic demographic characteristics of study populations, recognizing the broader issues regarding health disparities and differential access to health care in certain racial and ethnic populations, many of whom are part of underserved communities. However, FDA advises sponsors to seek diversity in clinical trial enrollment beyond populations defined by race and ethnicity, including other underrepresented populations defined by demographics such as sex, gender identity[4], age, socioeconomic status, disability, pregnancy status, lactation status, and co-morbidity. FDA encourages sponsors to also submit plans that help ensure the adequate participation of relevant and underrepresented populations and analyses of data collected from clinically relevant subpopulations.[5]

This guidance expands on FDA's guidance, *Collection of Race and Ethnicity Data in Clinical Trials* (October 2016), which outlines how to collect and present race and ethnicity data in submissions to the FDA and recommends that sponsors develop and submit a plan to address inclusion of clinically relevant populations, for discussion to the Agency. Given the importance of increasing enrollment from historically underrepresented racial and ethnic populations, FDA is publishing this guidance to provide detail on what sponsors should include in a Race and Ethnicity Diversity Plan. As described in further detail below, FDA recommends that a Plan to enroll representative numbers of participants from historically underrepresented racial and ethnic populations be submitted to the investigational new drug (IND) application, for a drug, including biological products regulated as drugs, or the investigational device exemption (IDE) application, for a device. This Plan should be discussed with the FDA as soon as practicable during medical product development. For drugs, this should occur no later than when a sponsor is seeking feedback regarding the applicable pivotal trial(s) for the drug (often during the End of Phase 2 (EOP2) meeting). The current guidance provides general considerations for the content and format of the Plan. This guidance is not intended to address all issues related to the clinical development of medical products such as the design of studies, trial endpoints, or the data package necessary to support a marketing application; sponsors should refer to the appropriate FDA guidance documents for FDA recommendations on these matters.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is

[4] See *National Strategy on Gender Equity and Equality*. https://www.whitehouse.gov/wp-content/uploads/2021/10/National-Strategy-on-Gender-Equity-and-Equality.pdf.

[5] Adequate participation and analyses of data collected from clinically relevant subpopulations may provide important information pertaining to medical product safety and effectiveness for product labeling. Additional patient characteristics such as age, sex, gender, geographic location (e.g., rural), emotional, physical, sensory, and cognitive capabilities can often be important variables when evaluating medical product safety and efficacy. While these additional characteristics are not addressed in this guidance, FDA encourages sponsors to consider broadening their diversity plans to include all clinically relevant populations as appropriate. FDA guidance on *Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices, and Trial Designs* encourages the inclusion of persons with disabilities in clinical trials including during the study design phase. For example, FDA guidance recommends that sponsors consider the recruitment challenges that may occur because of the planned visit schedule and difficulties with accessibility. FDA also has guidance on inclusion of older adults in clinical trials.

intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

Clinical trials are used to characterize the safety and effectiveness of medical products intended for the prevention, treatment, or diagnosis of many diseases, including those that are serious and life-threatening. Across many therapeutic areas, participation in clinical trials may be an important component of a participant's clinical care.

FDA regulations require IND holders to include in their annual reports, among other things, the total number of subjects initially planned for inclusion in a clinical study and the number entered into the study to date, tabulated by age group, race, and gender.[6] In addition, a new drug application (NDA) must present effectiveness and safety data by gender, age, and race and must identify any modifications of dose or dose interval needed for a specific subgroup.[7]

Medical product development programs should consider the clinical and demographic factors that impact the generalizability of study results with respect to the patient population that will use the medical product once it is approved. Diverse populations as defined by race and ethnicity are relevant to the evaluation of medical products and there have been some observed correlations between self-reported race, ancestry, genetic variations or ethnicity, and response.[8]

FDA has issued several sets of recommendations to improve clinical trial diversity.[9,10] These recommendations address a range of topics, including: the collection and analysis of racial and ethnic data; measures that enhance diversity in clinical trials; and the broadening of eligibility criteria when scientifically appropriate to improve clinical trial participation. Stakeholders have also recommended that sponsors develop a plan that outlines the operational measures that will be implemented to ensure diverse clinical trial participation to improve the generation of evidence regarding safety and effectiveness across the entire population.[11] Such measures could include but are not limited to offering financial reimbursement for expenses incurred by

[6] See 21 CFR 312.33(a)(2).
[7] See 21 CFR 314.50(d)(5)(v and vi).
[8] Burchard EG et al., The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice. N Engl J Med 2003; 348(12):1170-1175.
[9] See FDASIA Section 907: Inclusion of Demographic Subgroups in Clinical Trials available at https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-section-907-inclusion-demographic-subgroups-clinical-trials. See also FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data available at https://www.fda.gov/media/89307/download.
[10] See the following three guidances for industry: *Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs* (November 2020); *Collection of Race and Ethnicity Data in Clinical Trials* (October 2016); and *Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies* (September 2017).
[11] See Cancer Disparities Progress Report 2020: Achieving the bold vision of health equity for racial and ethnic minorities and other underserved populations. American Association for Cancer Research; ©2020. Available at https://cancerprogressreport.aacr.org/disparities/.

participation in a clinical trial or study (e.g., travel or lodging)[12], providing language access to participants with limited English language proficiency, and partnering with community-based organizations to provide support to study or trial participants. FDA guidance documents define a diverse population, when applicable, to be inclusive of all populations as defined by demographic factors such as race, ethnicity, sex, gender identity, age, pregnancy status, lactation status[13], and by the presence of certain clinical characteristics such as multiple comorbidities. Some individuals from these groups have often been underrepresented in medical product development and FDA considers their representation in clinical trials and studies to be a priority. FDA has, for some of these populations, already published specific guidance (e.g., enrollment of women, including pregnant and lactating women, and older adults).[14,15] However, FDA is focusing this guidance on diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations because the lack of representation of these populations in clinical research reflects, in part, a broader issue regarding differential access to health care[16], including access to centers that conduct clinical research programs for new therapies and awareness of clinical trials conducted there. In addition, mistrust of the clinical research system may stem from historical events that adversely impacted racial and ethnic minorities, such as the unethical Tuskegee experiments.[17] Clinical trials designed to include pediatric participants should also take into account adequate representation of children from racial and ethnic minority backgrounds.[18]

Swift development and approval of medical products is a highly desirable goal for the public, sponsors, and the FDA. There has been increasing reliance on relatively small studies, intermediate endpoints, and innovative study designs to expedite development and approval of

[12] FDA does not consider reimbursement for reasonable travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. Similarly, consideration may be given to paying participants in exchange for their participation in research. FDA recognizes, however, that payment for participation may raise difficult questions that should be addressed by the Institutional Review Board (IRB), such as how much money participants should receive, and for what participants should receive payment, such as their time, inconvenience, discomfort, or some other consideration. See Information Sheet "Payment and Reimbursement to Research Subjects" (January 2018) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects

[13] See the draft guidance for industry *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials* (April 2018)). When final, this guidance will represent the FDA's current thinking on this topic. See also the guidance for industry *Evaluation of Sex-Specific Data in Medical Device Clinical Studies* (August 2014).

[14] See the guidance for industry *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs* (July 1993). See the following two draft guidances for industry: *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials* (April 2018) and *Clinical Lactation Studies: Considerations for Study Design Guidance for Industry* (May 2019). When final, these guidances will represent the FDA's current thinking on these topics.

[15] See the following guidances for industry: *Guideline for the Study of Drugs Likely to be Used in the Elderly* (November 1989) and *E7 Studies in Support of Special Populations: Geriatrics Questions and Answers* (February 2012).

[16] Cooper Lisa A., Health Inequity and Racism Affect Patients and Health Care Workers Alike Vol. 2 No. 3 March 2021 NEJM Catalyst Innovations in Care Delivery, 2021; 03. doi:10.1056/CAT.21.0033.

[17] Shariff et al., More than Tuskegee: Understanding Mistrust about Research Participation J Health Care Poor Underserved. 2010 August; 21(3): 879–897. doi:10.1353/hpu.0.0323.

[18] For further considerations regarding the inclusion of pediatric participants in clinical investigations, see the guidances for industry *E11 Clinical Investigation of Medicinal Products in the Pediatric Population* (December 2000) and *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans* (July 2020).

medical products, notably for rare diseases and for serious and life-threatening conditions. Specific approaches are needed to both obtain data in diverse populations and facilitate efficient medical product development and approval. This underscores the importance of prospectively defining the approach to generating data for a broader and more diverse population early in the development program. Consistent implementation of actions to improve racial and ethnic diversity in clinical trials and studies can support early access to medical discoveries and innovations, improve the generalizability of results across all patient populations, improve our understanding of the disease and/or medical product under study, and inform the safe and effective use of the medical product for all patients who are expected to use the medical product if approved.

III. WHEN A RACE AND ETHNICITY DIVERSITY PLAN IS RECOMMENDED

FDA recommends a Plan be submitted for medical products for which an IND submission is required and/or for which clinical studies are intended to support a marketing submission under section 351(a) of the Public Health Service Act for a standalone Biologics License Application (BLA), or under 505(b)(1) or 505(b)(2)[19] of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) for an NDA. A Plan is also recommended for medical products for which an IDE is required and/or for which clinical studies are intended to support a device marketing submission, whether a premarket notification (510(k))[20], premarket approval (PMA) application[21], a De Novo classification request[22], or a humanitarian device exemption (HDE) application.[23] FDA will evaluate the Race and Ethnicity Diversity Plan as an important part of the sponsor's development program.

IV. TIMELINES AND PROCESS FOR SUBMITTING RACE AND ETHNICITY DIVERSITY PLANS

Sponsors may discuss their strategy to enroll a diverse study population at any time throughout the medical product's development.[24]

A. For drugs, sponsors should submit the Plan to the relevant IND application as soon as practicable during drug development but no later than when a sponsor is seeking feedback regarding the applicable pivotal trial(s) for the drug (often at the EOP2 meeting). The Plan can be submitted to the IND as part of a milestone meeting package,

[19] To the extent that the submission will include clinical studies that are sponsored by the applicant.
[20] See 21 CFR 807
[21] See 21 CFR 814.20
[22] See section 513(f)(2) of the FD&C Act
[23] See 21 CFR 814.104
[24] The plan should emphasize the enrollment of participants from underrepresented racial and ethnic populations early and throughout medical product development to ensure the availability of sufficient data about the safety and effectiveness of the product in diverse populations. In the event that recruitment goals are not met despite best efforts, sponsors should discuss with FDA a plan to collect this data in the post-marketing setting.

or on its own. Sponsors should request FDA feedback on the Plan by including specific questions in a formal milestone meeting request and Meeting Package.[25]

B. For devices, sponsors should submit their Plan as part of the investigational plan included in the IDE application. To discuss a proposed enrollment strategy before submitting the Plan to the IDE or for clinical studies not conducted under an IDE, a sponsor should follow the Q-submission process for obtaining feedback or requesting a meeting with FDA.

C. For IND, IDE, or Q submissions containing a Plan, sponsors should alert the FDA by marking the submission with "**RACE AND ETHNICITY DIVERSITY PLAN**" in large, bolded type in the cover letter. FDA may request that sponsors provide periodic updates to specific components of the Plan throughout medical product development.

D. Sponsors should include the Plan in the marketing application for the medical product as well as a description of the successes and challenges in implementing it.

V. CONTENT OF THE RACE AND ETHNICITY DIVERSITY PLAN (THE PLAN)

- Sponsors should define enrollment goals for underrepresented racial and ethnic participants as early as practicable in clinical development for a given indication. These enrollment goals should be based in part on the pre-specified protocol objectives of the investigation. While in many cases race- and/or ethnicity- defined populations may be genetically heterogenous such that analyses to characterize differential effects due to pharmacogenomic variability may be difficult to discern, the Plan should begin with an assessment of any data that may indicate the potential for a medical product to have differential safety or effectiveness associated with race or ethnicity. For drug development, as applicable to the particular drug, the collection of sufficient pharmacokinetic (PK), pharmacodynamic (PD), and pharmacogenomic data from a diverse population is strongly encouraged to inform analyses of drug exposure and response.[26] For devices, data on the relevant factors for device performance (e.g., phenotypic, anatomical, or biological) should be collected to inform any differential effects across a diverse population. For example, variations in skin pigmentation exist across diverse populations and it is known that skin pigmentation can affect the performance of certain devices. For studies of such devices (e.g., pulse oximeters), skin pigmentation data in a diverse population would be a relevant attribute to collect to inform the assessment of any differential effects.

[25] See draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (December 2017). When final, this guidance will represent the FDA's current thinking on this topic.
[26] See guidance for industry *Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications* (May 2003) and draft guidance for industry *Population Pharmacokinetics* (July 2019). When final, this guidance will represent the FDA's current thinking on this topic.

- The Plan should describe the planned assessment of race and ethnicity in addition to other covariates with known potential to affect the safety and effectiveness of the medical product. In particular, for drugs, covariates with known potential to affect PK and PD should be assessed in order to facilitate exposure-response analyses and to inform safe and effective dosing regimens across the intended patient population, as applicable. For devices, device performance may be impacted by factors associated with race (e.g., the ability of a device to detect skin cancer based on skin pigmentation).

- When there are data that indicate that the medical product may perform differentially across the population based on factors associated with race or ethnicity, the Plan should specify the study design features that will support analyses that will inform the safety and effectiveness of the medical product in the relevant racial and ethnic populations. In some cases, increased (i.e., greater than proportional) enrollment of certain populations may be needed to elucidate potential important differences. When there are no data that indicate that race or ethnicity will impact safety or effectiveness, it is nonetheless appropriate that enrollment reflects the epidemiology of the disease. FDA recognizes that enrollment based on epidemiology alone may not be sufficient to detect any differences in safety and effectiveness or make such inferences; however, consistent representative enrollment may provide opportunities for pooling data to evaluate outcomes by race and ethnicity.

- The Plan should outline the sponsor's plan to collect data to explore the potential for differences in safety and/or effectiveness associated with race and ethnicity throughout the entire development life-cycle of the medical product and not just during the pivotal trial(s) or studies.

- In certain situations, it may be challenging to set an enrollment goal based on the epidemiology of the disease due to limited data to characterize the incidence and/or prevalence of the disease across diverse racial/ethnic populations (e.g., diseases that are defined by the presence of a rare molecular aberration). FDA encourages sponsors to leverage various data sources (e.g., published literature and real-world data) to set enrollment goals; if this is not feasible, it may be appropriate to set the enrollment goal based on demographics in the overall population with the disease or condition.

- The Plan should include the clinical pediatric studies that are planned for inclusion as part of the pediatric development of the medical product.

- The table below outlines the recommended elements of the Plan. Note that the examples provided in the table are intended to illustrate the type of information that should be included in the Plan and are not meant to be an exhaustive list of the measures that may be undertaken to improve diversity in clinical trials or studies.

Category	Recommended Scope
1. Overview of the disease/condition	A. Describe available data on the pathophysiology of the disease or condition in underrepresented racial and ethnic populations. As appropriate, describe

Category	Recommended Scope
	any differential application or use of currently available prevention, screening or diagnostic strategies and treatments, across racial and ethnic populations. B. Discuss the current understanding of and available evidence supporting any similarities and/or differences in the disease or condition under study that are associated with the underrepresented racial and ethnic populations in the United States.
2. Scope of medical product development program	Briefly describe the planned trials or studies that will support the medical product's safety, effectiveness and, if a drug, dosage in a future marketing submission. Outline the following: A. Study design, study population (including study eligibility criteria), endpoints and, the expected geographic locations of the trials or studies and how these aspects of the trial or study may specifically address inclusion of underrepresented racial and ethnic populations. B. As applicable, summarize any differential findings from clinical pharmacology studies (PK /PD data, pharmacogenomics) that may be associated with certain racial and ethnic populations and/or other relevant information.
3. Goals for enrollment of underrepresented racial and ethnic participants	Define and provide justification for the planned enrollment of participants from underrepresented racial and ethnic populations. A. Specify underrepresented racial and ethnic populations based on assessment in Category #1. B. Specify goals for enrollment of underrepresented racial and ethnic participants (e.g., based on the epidemiology of the disease and/or based on *a priori* information that may impact outcomes across racial and ethnic groups; and where appropriate, leverage pooled data sources or use demographic data in general population). In some cases, increased (i.e., greater than proportional) enrollment of certain populations may be needed to elucidate potential important differences.

Category		Recommended Scope
4.	Specific plan of action to enroll and retain diverse participants	A. Describe in detail the operational measures that will be implemented to enroll and retain underrepresented racial and ethnic participants in the planned trial(s) or studies, and the planned use of data to characterize safety, efficacy, and optimal dosage in these participants, when applicable. B. Describe specific trial enrollment and retention strategies, including but not limited to: i. site location and access (e.g., language assistance for persons with limited English proficiency, reasonable modifications for persons with disabilities, and other issues such as transportation); ii. sustained community engagement (e.g., community advisory boards and navigators, community health workers, patient advocacy groups, local healthcare providers, etc.); iii. reducing burdens due to trial/study design/conduct (e.g., number/frequency of study-related procedures, use of local laboratory/imaging, telehealth); C. Describe metrics to ensure that diverse participant enrollment goals are achieved and specify actions to be implemented during the conduct of the trial(s) or studies if planned enrollment goals are not met.
5.	Status of meeting enrollment goals (as applicable)	A. As the diversity plan is updated (when applicable), discuss the status of meeting enrollment goals. If the sponsor is not able to achieve enrollment goals despite best efforts, discuss a plan and justification for collecting data in the post-marketing setting.

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Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) CDEROMP@fda.hhs.gov, 301-796-2500; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (OMHHE) Office of Minority Health and Health Equity, healthequity@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Office of Minority Health and Health Equity (OMHHE)
Office of Women's Health (OWH)
Office of Clinical Policy (OCLiP)
Office of Pediatric Therapeutics (OPT)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)
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Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products Guidance for Industry

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Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
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Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
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Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The purpose of this guidance is to provide FDA's expectations for, and recommendations on, use of a standardized approach for collecting and reporting race and ethnicity data in submissions including information collected and reported from clinical trials and clinical studies[2] for FDA-regulated medical products.[3,4] Using standard terminology for race and ethnicity helps ensure that data are collected and reported consistently in submissions to FDA. FDA's recommended approach is based on the Office of Management and Budget (OMB) Statistical Policy Directive No. 15 (Policy Directive 15)[5] and was developed in accordance with section 4302 of the Affordable Care Act;[6] the Health and Human Services (HHS) Implementation Guidance on Data

[1]This guidance has been developed by the Office of the Commissioner, the Office of Minority Heath and Health Equity, the Office of Women's Health, the Office of Clinical Policy, the Office of Pediatric Therapeutics, the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Oncology Center of Excellence at the Food and Drug Administration.

[2] Going forward in this guidance, we use the term *clinical studies* to refer broadly to research that evaluates human health outcomes associated with the use of medical products. We use the term clinical studies to include interventional (clinical trial) and non-interventional (observational) designs. Some recommendations in this guidance are specific to clinical trials and are identified as such when relevant.

[3] See the guidance for industry *Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies* (September 2017). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[4] For the purposes of this guidance, the term *medical products* refers to drugs, including biological products, and devices as defined by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301–392) unless otherwise specified.

[5] OMB Statistical Policy Directive No. 15, Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Policy Directive 15) (October 30, 1997), available at https://obamawhitehouse.archives.gov/omb/fedreg_1997standards.

[6] Patient Protection and Affordable Care Act, Public Law 111–148, section 4302 (42 U.S.C. 300kk) (March 23, 2010), available at https://www.gpo.gov/fdsys/pkg/CREC-2009-11-19/pdf/CREC-2009-11-19-pt1-PgS11607-3.pdf#page=127.

Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status;[7] and the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 Action Plan.[8] This guidance revises the guidance for industry and FDA staff *Collection of Race and Ethnicity Data in Clinical Trials* issued in October 2016. When finalized, this guidance will replace the October 2016 guidance.

Current OMB standards for the classification of Federal data on race and ethnicity were developed to provide a common framework for uniformity and consistency in the collection and use of data on race and ethnicity by Federal Agencies.

On January 27, 2023, OMB announced a formal review of OMB Policy Directive 15 and requested public comments on initial proposals to revise the directive to account for large societal, political, and economic demographic shifts in the United States over the 25 years since its publication.[9] FDA began the process to update this guidance before the OMB announcement. FDA continued the process to update this guidance, including updating references and contact information for FDA and revising the title, to ensure the appropriate collection and reporting of race and ethnicity data in submissions from clinical studies and clinical trials for FDA-regulated medical products. FDA will update this guidance as appropriate if OMB revises Policy Directive 15.

This guidance provides recommendations on:

1. Meeting the requirements set forth in the 1998 final rule[10] regarding presentation of demographic data in investigational new drug applications (INDs) and new drug applications (NDAs) (known as the Demographic Rule)

2. Collection of race and ethnicity data in biologics license applications (BLAs) and medical device applications[11]

3. Addressing the FDASIA Section 907 Action Plan to improve the completeness and quality of demographic data collection and reporting

[7] HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status (October 31, 2011), available at https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.

[8] See the FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (FDASIA Section 907 Action Plan), August 2014, available at https://www.fda.gov/media/89307/download.

[9] See OMB *Federal Register* notice (88 FR 5375), https://www.federalregister.gov/documents/2023/01/27/2023-01635/initial-proposals-for-updating-ombs-race-and-ethnicity-statistical-standards.

[10] 1998 final rule, "Investigational New Drug Applications and New Drug Applications" (the Demographic Rule), see 63 FR 6854 (February 11, 1998) (codified at 21 CFR 312.33(a)(2) and 21 CFR 314.50(d)(5)), available at https://www.gpo.gov/fdsys/pkg/FR-1998-02-11/pdf/98-3422.pdf.

[11] For medical devices, see also the guidance for industry and FDA staff *Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies*.

For drugs, the Demographic Rule requires the sponsor of an IND to tabulate in an IND annual report the number of participants enrolled in the clinical trial by certain demographic subgroups including race and requires NDA submissions to include summaries of effectiveness and safety data for demographic subgroups, including racial subgroups.[12] FDA also strongly recommends the collection and reporting of ethnicity data (Hispanic or Latino or not Hispanic or Latino) consistent with OMB standards.[13]

This guidance is also intended to help an applicant preparing a BLA or a device premarket submission, which should be done in accordance with the OMB standards regarding collection and reporting of race and ethnicity data described herein.[14]

This guidance also recommends the use of the OMB race and ethnicity categories in proposed medical product labeling.

Sponsors of investigational new drugs and investigational devices should enroll participants who reflect the population that will use the medical product if approved.[15] Sections 505(z) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as amended by section 3601 of the Food and Drug Omnibus Reform Act of 2022 (FDORA) require that such sponsors submit a diversity action plan outlining (1) the sponsor's goals for enrollment in the clinical trial, (2) the sponsor's rationale for such goals, and (3) an explanation of how the sponsor intends to meet such goals. As described in section 3602 of FDORA, this requirement will apply with respect to clinical trials for medical products for which enrollment commences 180 days after the publication of a final guidance on diversity action plans.[16] This guidance does not address diversity action plans or the appropriate population for a clinical study. For questions related to enrollment of clinically relevant demographic subpopulations in clinical trials, sponsors should consult with the review division of the appropriate centers and offices.[17]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[12] See footnote 10.

[13] See footnote 5.

[14] Ibid.

[15] See also the guidance for industry *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs* (November 2020).

[16] See Food and Drug Omnibus Reform Act of 2022 (FDORA) available at https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf.

[17] See also the draft guidance for industry *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials* (April 2022). When final, this guidance will represent FDA's current thinking on this topic.

II. BACKGROUND

Although uncommon, differences in response to medical products have been observed in racially and ethnically distinct populations in the United States.[18] In some cases, differences in the pharmacokinetics, efficacy, or safety of medical products that lead to these different responses may be attributable to intrinsic factors (e.g., genetics, metabolism, elimination, skin pigmentation), extrinsic factors (e.g., diet, environmental exposure, socioeconomic status, culture), or interactions between these factors.[19] Collecting data on race and ethnicity is critical to identifying population-specific signals.

In 1997, OMB issued its revised recommendations for the collection and use of race and ethnicity data by Federal Agencies (Policy Directive 15).[20] OMB stated that the recommended race and ethnicity categories were not anthropologically or scientifically based designations, but instead are categories that describe the sociocultural construct of our society.

In 1999, HHS issued the report *Improving the Collection and Use of Racial and Ethnic Data in HHS*.[21] The report describes HHS policy on collecting and reporting data on race and ethnicity for HHS programs. The report recommends inclusion of race and ethnicity categories in HHS-funded and sponsored data collection and reporting systems in all HHS programs to (1) help monitor HHS programs, (2) determine whether Federal funds are being used in a nondiscriminatory manner, and (3) promote the availability of standard race and ethnicity data across various agencies to facilitate HHS responses to major health and human services issues. This policy, updated in 2011,[22] states that the minimum standard categories in OMB Policy Directive 15 should be used when collecting and reporting data in HHS data systems or when reporting HHS-funded statistics. On September 21, 2016, HHS issued the final rule, "Clinical Trials Registration and Results Information Submission" (81 FR 64982) (42 CFR part 11). The final rule requires the submission of race and ethnicity information with summary results information if it is collected during the trial.

[18] For example, in 2005, FDA approved BiDil (isosorbide dinitrate and hydralazine hydrochloride tablets), the first drug approved by the Agency to treat a disease only in patients who identified by a specific racial subgroup. BiDil is approved for the treatment of heart failure as an adjunct to standard therapy in self-identified Black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status. Although the sponsor's initial two trials in certain patients with heart failure failed to show a benefit in the overall population (sum of all racial groups), there was a suggestion of benefit of BiDil in one racial subgroup (i.e., Black patients). In a subsequent study in 1,050 self-identified Black patients with a certain type of heart failure, BiDil was shown to be safe and effective for the treatment of heart failure as an adjunct to standard therapy.

[19] Ramamoorthy A, MA Pacanowski, J Bull, L Zhang, 2015, Racial/Ethnic Differences in Drug Disposition and Response: Review of Recently Approved Drugs, Clin Pharmacol Ther, Mar;97(3):263–273.

[20] See footnote 5.

[21] Improving the Collection and Use of Racial and Ethnic Data in HHS (December 1, 1999), available at https://aspe.hhs.gov/report/improving-collection-and-use-racial-and-ethnic-data-hhs.

[22] See footnote 7.

III. COLLECTING RACE AND ETHNICITY DATA IN CLINICAL TRIALS AND CLINICAL STUDIES[23]

OMB Policy Directive 15 provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for Federal reporting purposes. As previously stated, the categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. OMB recommends a two-question format to provide flexibility and ensure data quality for reporting race and ethnicity as described below.

A. Two-Question Format

To remain consistent with OMB Policy Directive 15, FDA recommends using the two-question format for requesting race and ethnicity information, with the ethnicity question preceding the question about race.[24] For example:

Question 1 (answer first): Are you Hispanic/Latino or not Hispanic/Latino?

Question 2 (answer second): What is your race?[25] More than one choice is acceptable.

B. Self-Reporting

Consistent with best practices, FDA recommends that trial participants self-report race and ethnicity information and that those individuals be permitted to designate a multiracial identity. When the collection of self-reported designations is not feasible (e.g., because of the participant's inability to respond), FDA recommends requesting information from a first-degree relative or other knowledgeable representative. Race and ethnicity should not be assigned by the study team conducting the trial. While data on race and ethnicity may be available in a patient's medical record, FDA recommends that investigators and/or other clinical study staff verify the accuracy of the information provided in the medical record with the study participant.

C. Ethnicity

For ethnicity, we recommend the following minimum choices be offered:

- **Hispanic or Latino**
- **Not Hispanic or Latino**

[23] FDA recognizes that the collection of race and ethnicity data in clinical practice may vary considerably and impact demographic data available for analysis in non-interventional studies. Sponsors seeking to conduct non-interventional studies to support regulatory decision-making should discuss the availability of race and ethnicity data with the relevant review division.

[24] For more information on the basic racial and ethnic categories for Federal statistics and program reporting, see OMB Policy Directive 15, described in footnote 5.

[25] Note: Please see racial designations in section III.D of this guidance.

D. Race

For race, we recommend the following minimum choices[26] be offered:

- **American Indian or Alaska Native**
- **Asian**
- **Black or African American**
- **Native Hawaiian or Other Pacific Islander**
- **White**

FDA recommends offering an option of selecting one or more racial designations or additional subgroup designations. Recommended forms for the instruction accompanying the multiple response questions are "Mark one or more" and "Select one or more."

Sponsors should report the number of respondents in each racial category who self-reported as Hispanic or Latino. When aggregate data are presented, data producers should provide the number of respondents who marked (or selected) only one category, separately for each of the five racial categories. In addition to these numbers, sponsors are encouraged to provide the detailed distributions, including all possible combinations of multiple responses to the race question. If data on multiple responses are condensed, at a minimum the total number of respondents reporting "more than one race" should be reported.

E. Use of More-Detailed Racial and Ethnic Categories

In certain situations, as recommended in OMB Policy Directive 15, more-detailed race and/or ethnicity information may be desired. For example, for clinical trials enrolling participants outside the United States, FDA recognizes that the recommended categories for race and ethnicity were developed in the United States and that these categories may not adequately describe racial and ethnic groups in other countries.

Where appropriate, FDA recommends using more-detailed categories by geographic region to provide sponsors flexibility in characterizing race and ethnicity. FDA recommends that these characterizations be aligned with the five minimum designations for race and the two designations for ethnicity listed previously in subsections D and C, respectively. If additional granularity or more-detailed characterizations of race or ethnicity are collected to enhance understanding of the trial participants, FDA recommends following the 2011 HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status,[27] as described below.

[26] As explained in the next section of this guidance (section III.E), sponsors may include more-detailed categories, and doing so is recommended where appropriate.
[27] See footnote 7.

Ethnicity Data Standard

Are you Hispanic or Latino? (One or more categories may be selected.)

a. No, not Hispanic or Latino
b. Yes, Mexican, Mexican American, Chicano
c. Yes, Puerto Rican
d. Yes, Cuban
e. Yes, Other Hispanic or Latino

These categories are part of the Hispanic or Latino category of the OMB standard

Race Data Standard

What is your race? (One or more categories may be selected.)

a. White
b. Black or African American
c. American Indian or Alaska Native

These categories are part of the OMB standard

d. Asian Indian
e. Chinese
f. Filipino
g. Japanese
h. Korean
i. Vietnamese
j. Other Asian

These categories are part of the Asian category of the OMB standard

k. Native Hawaiian
l. Guamanian or Chamorro
m. Samoan
n. Other Pacific Islander

These categories are part of the Native Hawaiian or Other Pacific Islander category of the OMB standard

OMB Policy Directive 15 states that the term *nonwhite* is not acceptable for use in the presentation of Federal Government data. It should not be used in publication or text of any report. If there are questions or concerns regarding the collection of race or ethnicity categories, sponsors are encouraged to discuss the matter with the appropriate review division.

IV. PRESENTATION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS AND CLINICAL STUDIES

For INDs, NDAs, and BLAs, we recommend that the submission of demographic data for all new clinical trials and clinical studies be tabulated using the characterizations of race and ethnicity described in this guidance. For medical device submissions, see also the guidance for industry *Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies* (September 2017)

The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) require marketing applications to be submitted electronically.[28] CDER and CBER use the electronic common technical document (eCTD) as the standard for their electronic applications. When submitting an electronic application, presentation of demographic data is described in the ICH guidance for industry *M4E(R2): The CTD – Efficacy* (July 2017), which suggests a tabular display of demographic characteristics, including race, by treatment group (e.g., active drug, placebo).[29]

FDA recommends that applicants include race and ethnicity information (using the categories described in section III of this guidance) in their proposed product labeling. For example, the CLINICAL STUDIES section of drug and biological product labeling should include the baseline demographics (including racial and ethnic characteristics) of the studied population.[30] The ADVERSE REACTIONS section of drug and biological product labeling should include the baseline demographics of the safety population.[31] If the baseline demographics in the safety and efficacy populations are generally the same and the description of the baseline demographics are included in the CLINICAL STUDIES section, instead of repeating the same baseline demographics in the ADVERSE REACTIONS section, the ADVERSE REACTIONS section can cross-reference the CLINICAL STUDIES section. OMB Policy Directive 15 states that the term *nonwhite* is not acceptable for use in the presentation of Federal Government data. It should not be used in publication or text of any report. If there are questions or concerns regarding the collection of race or ethnicity categories, sponsors are encouraged to discuss the matter with the appropriate review division.[32]

[28] See the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020).

[29] See the revision of M4E Guideline on Enhancing the Format and Structure of Benefit-Risk Information in the International Council for Harmonisation (ICH) guidance for industry *M4E(R2): The CTD – Efficacy* (July 2017).

[30] See section III.B.4 in the guidance for industry *Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* (January 2006).

[31] See the guidance for industry *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* (January 2006).

[32] See section III.E of this guidance.

National Institutes of Health

Minority Health and Health Disparities Strategic Plan 2021–2025

Taking the Next Steps

National Institutes of Health
Turning Discovery Into Health

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NIH Director's Foreword

"Advancing the science of understanding the causes of health disparities and of developing effective interventions to reduce health disparities and improve minority health is one of my personal priorities. NIH has a major role in identifying interventions and causes of health disparities. If we can chip away at health disparities, everyone can experience the better health they deserve. Using the tools of research and our creativity to address our task, we have a moral responsibility to address health disparities. What a privilege to be engaged in this noble enterprise that has real promise to give every person the opportunity to have better health."

— Francis S. Collins, M.D., Ph.D., Director of NIH

"As health disparities remain a potentially preventable burden, public health is impacted unnecessarily."

— Eliseo J. Pérez-Stable, M.D., Director of the National Institute on Minority Health and Health Disparities, NIH

The publication of the Institute of Medicine report on unequal treatment, ***Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care***, summarized a legacy of unequal health care and differential health outcomes for most leading causes of disability and death in the United States among African Americans compared with Whites, with selected available data on other racial and ethnic minority groups. Since then, sources of data dramatically have improved while scientific advances in basic mechanisms have strengthened our understanding of etiological pathways and potential intervention points to improve minority health, reduce health disparities, and promote health equity. The need for rigorous scientific approaches to minority health and health disparities—building on decades of studies addressing social inequality and health, behavioral epidemiology, and access to quality health care—is now increasingly being met by an expanding array of biological and data science tools that help us understand health and disease mechanisms.

The Office of Minority Health Research was founded at NIH in 1990 to provide a focus for research questions that addressed racial/ethnic minority populations. Through congressional legislation, the Office was upgraded to the National Center on Minority Health and Health Disparities in 2000 and to the National Institute on Minority Health and Health Disparities (NIMHD) in 2010. NIMHD is charged with coordinating and leading NIH's vision and programs on minority health and health disparities research. The topics are broad and include health determinants pertaining to the entire life course, including all populations, diseases, prevention, and health care. Research that advances understanding and improvement of health and disease in minority racial/ethnic groups in the United States requires a basic understanding of the construct of race and ethnicity, incorporating the social determinants of health in the context of science. Research to understand the causes of and define mechanisms leading to interventions to reduce health disparities is a parallel mandate, incorporating socioeconomic, geographic, and cultural factors to address conditions with negative outcomes in specific populations. NIMHD envisions an America in which all populations will have an equal opportunity to live long, healthy, and productive lives.

Introduction

Medical advances and new technologies have allowed Americans to live longer and healthier lives for the past century. These advances, however, have not helped all Americans equally, and health disparities persist, disproportionately affecting racial and ethnic minority populations, individuals of less privileged socioeconomic status (SES), underserved rural residents, sexual and gender minorities (SGMs),[1] and any subpopulations that can be characterized by two or more of these descriptions. In October 2016, SGMs were formally designated as a health disparity population for research purposes.

In the 35 years since the Heckler report was published,[2] pioneering researchers studying health disparities and minority health have worked to reduce the burden of premature illness and death experienced by many people from minority racial and ethnic backgrounds, SGMs, rural residents, and individuals of less privileged SES. For example, thanks to the efforts of researchers, advocates, and other stakeholders, the gap in mortality between Blacks and Whites was reduced by about half from 1999 to 2015, narrowing from 33 percent to 16 percent.[3] Not all health outcomes are worse for disparity populations; in selected conditions, racial and ethnic minorities of less privileged SES have better health.[4] However, the individuals comprising these groups still face considerable health disparities in most conditions. These disparities include shorter life expectancy; higher rates of cardiovascular disease, cancer, diabetes, infant mortality, stroke, cognitive impairment, asthma, sexually transmitted infections, and dental diseases; and differences in prevalence and outcomes of mental illness.

Health disparities are the result of differences in and interplay among numerous determinants of health, including biological factors, the environment, health behaviors, sociocultural factors, and the way health care systems interact through complex multilevel pathways. These dynamic and complex interactions lead to poor health outcomes and challenge researchers to identify mechanistic pathways to develop interventions that may lead to reductions in health disparities and improvements in minority health that promote health equity with a systematic applied approach.

Section 10334 of **P.L. 111-148** tasks NIMHD with coordinating NIH's research related to minority health and health disparities: "The Director of the Institute, as the primary Federal official with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities, shall plan, coordinate, review, and evaluate research and other activities conducted or supported by the Institutes and Centers of the National Institutes of Health." In addition, Section 2038 of P.L. 114-255 (21st Century Cures Act) tasks NIMHD with fostering partnerships and collaborative projects relating to minority health and health disparities: "The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities." As part of all strategic planning processes across NIH, Institutes and Centers (ICs) are tasked with coordinating with the Directors of NIMHD and the Office for Research on Women's Health to ensure that the plans account for the unique perspectives, strengths, and challenges facing minorities and women, as described in Section 2031 of P.L. 114-255. Furthermore, section 404N of the Public Health Service Act encourages increased research with SGM populations as a response to the mounting evidence of the health disparities experienced by SGM populations, as well as an acknowledgment of unique

1 Sexual & Gender Minority Research Office (SGMRO). **Strategic Plan to Advance Research on the Health and Well-being of Sexual & Gender Minorities: Fiscal Years 2021–2025.**

2 Heckler MM. **Report of the Secretary's Task Force on Black and Minority Health.** U.S. Department of Health and Human Services.

3 Cunningham TJ, Croft JB, Liu Y, Lu H, Eke PI, Giles WH. **Vital Signs: Racial Disparities in Age-Specific Mortality Among Blacks or African Americans — United States, 1999–2015**. MMWR Morb Mortal Wkly Rep 2017;66:444–456.

4 Franzini L, Ribble JC, Keddie AM. **Understanding the Hispanic Paradox.** Ethn Dis. 2001;11(3):496-518.

health challenges faced by SGM individuals who may be affected by a socially disadvantaged position. The plan will guide NIH in setting scientific goals, such as advancing the scientific understanding of health disparities, and research-related activity goals, such as strengthening the national research capacity to address minority health and health disparities.

Research supported by NIH has worked to reduce these disparities and improve minority health across all diseases, disorders, and conditions. As a result, all ICs contribute to the science and support activities. NIH also supports training, workforce development, capacity building, and other activities that work to reduce health disparities. This NIH strategic plan demonstrates ICs' commitment to research that improves minority health and reduces health disparities and to activities like training and capacity building that enhance the ability to reveal the new scientific knowledge needed to improve health for all Americans.

The scientific information discovered in basic research proposes to move along a continuum through clinical sciences until a practice or procedure that improves individual and population health can be implemented. Minority health and health disparities research can be viewed in a similar framework. Information about a racial or ethnic minority group—such as behavioral, biological, sociocultural, socio-ecological, and environmental characteristics and attributes—placed within a health care or public health setting provides the basis for understanding minority health. Once these basic factors are identified, similarities and differences between population groups may become apparent. These population differences may or may not constitute a health disparity, since the outcome for some conditions may be better for the population presumed to be disadvantaged, such as in the Hispanic Paradox.[5]

Understanding why a racial or ethnic minority group has a specific health outcome is at the core of minority health science. Minority health research intends to identify factors contributing to health conditions, independent of whether a health disparity exists or is identified. When investigations of differences in health between diverse groups exist, where the disadvantaged population group has a worse health outcome, this defines one aspect of health disparity research. Health disparity research then strives to understand mechanisms as to why a racial or ethnic minority group has a worse health outcome compared to a reference group.

Clarifying the difference between minority health and health disparities research prompted NIMHD to develop revised definitions for the biomedical research field. These distinct definitions provide justification for a new approach for the next generation of knowledge discovery to improve minority health and reduce health disparities.

5 Ruiz JM, Steffen P, Smith TB. **Hispanic mortality paradox: a systematic review and meta-analysis of the longitudinal literature.** Am J Public Health. 2013;103(3):e52-e60.

Minority Health and Health Disparities: Definitions and Parameters

Definitions of the terms "minority health" and "health disparities" have evolved as the research fields have grown and interacted with the full spectrum of scientists. Initially, the definitions were intertwined, as the researchers doing this important work have bridged both fields, and the assumption was made that minority populations always had health disparities. For NIH, this plan underscores the need to separate the science of minority health, which focuses on the health of racial and ethnic minority communities, and the science of health disparities, which focuses on differences in health outcomes for defined disadvantaged populations that are worse than the White reference population. There is clear overlap, since for many conditions, minority populations have well-defined health disparities compared with the White population in the United States. However, creating some separation of these disciplines may prove beneficial in enabling each field to make greater independent strides. Over the course of fiscal years (FYs) 2015 and 2016, NIMHD undertook a process across NIH to revise the definitions for minority health and health disparities.[6]

Minority Health Definition

Minority health (MH) refers to the distinctive health characteristics and attributes of racial and/or ethnic minority groups, as defined by the U.S. Office of Management and Budget (OMB), that can be socially disadvantaged due in part to being subject to potential discriminatory acts.

Minority Health Populations

NIH uses the racial and ethnic group classifications determined by OMB in the Revisions to Directive 15, titled ***Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity***. The minority racial and ethnic groups defined by OMB are American Indian or Alaska Native, Asian, Black or African American, and Native Hawaiian or other Pacific Islander. The ethnicity used is Latino or Hispanic.

Although these five categories are minimally required, the mixed or multiple race category should be considered in analyses and reporting, when available.

Other NIH efforts that support Tribal Nations can be found in the ***NIH Strategic Plan for Tribal Health Research FY 2019–2023***.

Self-identification is the preferred means of obtaining race and ethnic identity.

Minority Health Research

Minority health research is the scientific investigation of distinctive health characteristics and attributes of minority racial and/or ethnic groups who are usually underrepresented in biomedical research to understand health outcomes in these populations.

Health Disparity Definition

A health disparity (HD) is a health difference that adversely affects disadvantaged populations, based on one or more of the following health outcomes:

- Higher incidence and/or prevalence and earlier onset of disease
- Higher prevalence of risk factors, unhealthy behaviors, or clinical measures in the causal pathway of a disease outcome
- Higher rates of condition-specific symptoms, reduced global daily functioning, or self-reported health-related quality of life using standardized measures
- Premature and/or excessive mortality from diseases where population rates differ
- Greater global burden of disease using a standardized metric

6 **AJPH Supplement: New Perspectives to Advance Minority Health and Health Disparities Research.** Am J Public Health. 2019;109(S1).

Health Disparity Populations

NIH defines health disparity populations as racial and ethnic minority populations (see above OMB directive), less privileged socioeconomic status (SES) populations, underserved rural populations, sexual and gender minorities (SGM), and any subpopulations that can be characterized by two or more of these descriptions.

Other NIH efforts that support SGMs can be found in the ***NIH FY 2016–2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities***.

Health Determinants

There are many factors that impact an individual's health and the risk of experiencing health disparities. These domains of influence have been expanded into "health determinants" in order to capture areas that go beyond the social determinants and that include factors, such as individual behaviors, lifestyles, and social responses to stress; biological processes, genetics, and epigenetics; the physical environment; the sociocultural environment; social determinants; and clinical events and interactions with the health care and other systems. Each of these health determinants plays an important role in health disparities and interacts in complex ways to affect an individual's health. For example, African American/Black women and Latinas experience lower survival rates from triple-negative breast cancer than White women with the same disease—even with similar access to care, screening mammography, and insurance coverage—due to the lack of specialized screening and lack of viable treatment options available for this form of breast cancer.[7]

7 Ko NY, Hong S, Winn RA, Calip GS. **Association of Insurance Status and Racial Disparities With the Detection of Early-Stage Breast Cancer.** JAMA Oncol. 2020;6(3):385–392.

NIH and HHS Commitment

Healthy People 2020 envisions a society in which all people live long, healthy lives. The U.S. Department of Health and Human Services (HHS) aims to enhance the health and well-being of all Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. In April 2011, HHS released the ***HHS Action Plan to Reduce Racial and Ethnic Health Disparities*** (*HHS Disparities Action Plan*), a comprehensive national strategy to reduce health disparities. The HHS Disparities Action Plan sets out five goals to help achieve the vision of a nation free of disparities in health and health care.

The mission of NIH, as part of HHS, is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In 2015, NIH released the ***NIH-Wide Strategic Plan, Fiscal Years 2016–2020***, outlining a vision for biomedical research that capitalizes on new opportunities for scientific exploration and addresses new challenges for human health. The *NIH Minority Health and Health Disparities Strategic Plan* also aligns with the health promotion and disease prevention objective of the *NIH-Wide Strategic Plan* by advancing opportunities in biomedical research through evidence-based reduction of health disparities.

The *NIH Minority Health and Health Disparities Strategic Plan* follows the missions and goals outlined in these plans and addresses the current insufficient progress in improving MH and reducing HDs in the United States. The plan integrates NIMHD's vision of an America in which all populations have equal opportunity to live long, healthy, and productive lives with NIH's mission to seek fundamental knowledge of the nature and behavior of living systems and apply new knowledge to enhance health, lengthen life, and reduce illness and disability.

The *NIH Minority Health and Health Disparities Strategic Plan* represents a commitment by NIH to support research aimed at addressing the risk and protective factors that operate and interact on multiple levels to impact the well-being of HD populations. NIH is also committed to supporting research-sustaining activities—such as research capacity building, workforce development, outreach, and inclusion of minorities in clinical trials—that improve MH and reduce HDs, as well as activities that promote collaboration and dissemination in different fields.

The *NIH Minority Health and Health Disparities Strategic Plan* aligns NIH's efforts to address MH and HDs with advancing scientific knowledge and innovation in the HHS Disparities Action Plan.

Foundation for Planning

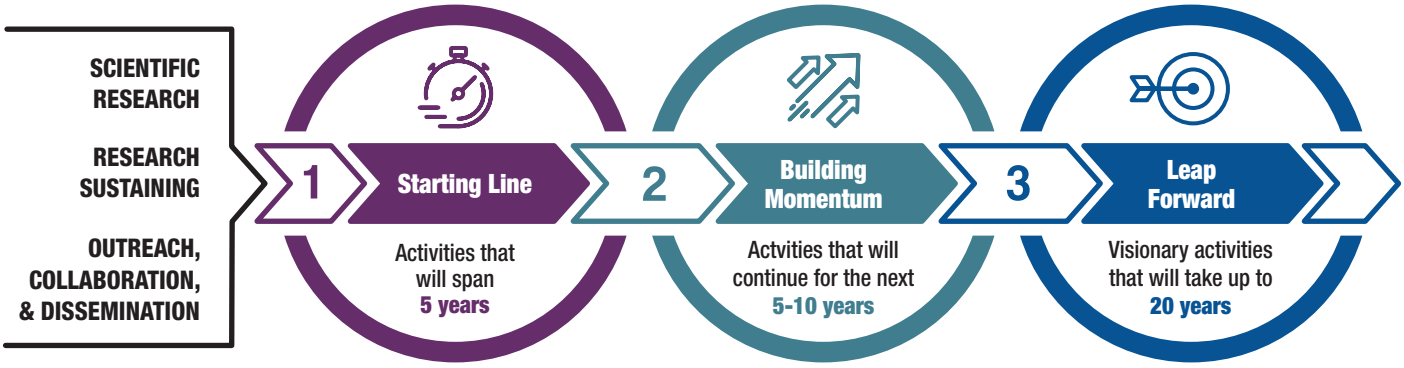
This strategic plan was created with the input of several NIH working groups, including teams of staff and researchers. To ensure that stakeholders at multiple levels were involved in this strategic planning process, NIMHD gathered input from experts within and outside of NIH. A few of these foundational activities are described below.

- In FY 2012, during the Science of Eliminating Health Disparities summit, NIMHD conducted town hall meetings to collect data on critical minority health and health disparity research issues.
- In FY 2015, NIMHD led an analysis of NIH's portfolio of minority health and health disparities research to survey the status of both fields, analyze investments, and gauge gaps in the science or supporting structures.
- During FY 2015 and FY 2016, NIMHD undertook a science visioning process to produce recommendations for advancing the fields of minority health and health disparities. Participating NIH staff and outside stakeholders suggested 10 priority recommendations each in defining etiologies and mechanisms, developing and evaluating interventions, and identifying innovative methods from a wide range of needs, to reduce disparities and improve minority health. After review by the National Advisory Council on Minority Health and Health Disparities (NACMHD), the relevant recommendations were woven into the current strategic planning efforts, which include strategies beyond the visioning process and the Minority Health and Health Disparities Research Framework. Details are available in the *American Journal of Public Health (AJPH)* supplement ***New Perspectives to Advance Minority Health and Health Disparities Research***.
- During FY 2018, NIMHD held three virtual sessions and four listening sessions across the country to collect community-level input for the *NIH Minority Health and Health Disparities Strategic Plan*.

These activities—in coordination with NIH working groups and input from a range of NIH Institutes, Centers, and Offices—were reviewed by the National Advisory Council on Minority Health and Health Disparities (NACMHD) and provide the foundation for the *NIH Minority Health and Health Disparities Strategic Plan*.

Structure of This Plan

FIGURE 1: NIH MH and HD Research Strategic Plan Priority Areas Framework



The NIH Minority Health and Health Disparities Strategic Plan 2021–2025 has been designed with three categories to represent a long-term framework: scientific research; research-sustaining activities; and outreach, collaboration, and dissemination to encompass the range of NIH's MH- and HD-related work. Embedded in each category are goals that encompass up to 10 years of expected research. There are four research goals; three research-sustaining activities goals; and two outreach, collaboration, and dissemination goals.

This plan describes scientific goals with related research strategies and priority areas that represent key opportunities and needs to advance MH and HD research. Rather than reflecting a comprehensive listing of all relevant NIH activities, this plan describes how NIH can best advance minority health and health disparities research. Each goal is divided into strategies that are intended to capture strategic ways in which NIH can advance the sciences of MH and HD or develop key supporting structures. The priority areas consist of Starting Line and Building Momentum research efforts and activities that encompass MH and HD efforts across NIH. This plan includes 48 Starting Line activities that will span 5 years and 56 Building Momentum activities that will continue for the next 5 to 10 years (see **Figure 1**).

Eliminating health disparities is an indefinite priority for NIH, and NIH's efforts in this space will continue well into the future. This plan lays out a focused vision for the next 10 years, specifying short-, intermediate-, and long-range research strategies and activities that will facilitate progress toward long-term goals.

These priority areas are described below:

- **Starting Line** priority areas represent concrete, current efforts and initiatives aimed at improving minority health and/or reducing health disparities that are underway at NIH or with NIH partners.
- **Building Momentum** priority areas represent concepts and potential initiatives for advancing the sciences of minority health and health disparities. These concepts include early ideas and initiatives being developed and considered for potential implementation.
- **Leap Forward** priorities represent trans-NIH visionary goals that can have a significant impact on improving minority health or reducing health disparities in disease and disorders.

The *NIH Minority Health and Health Disparities Strategic Plan 2021–2025* includes performance tracking and evaluation components to meet federal requirements. Most importantly, the plan aims to advance the science of minority health and health disparities and produce meaningful, measurable improvements in minority health and reductions in health disparities through the dissemination and implementation of both existing and novel scientific breakthroughs over the duration of the strategic plan and beyond.

Strategic Plan Categories

Scientific Research

Scientific research encompasses the continuum of research activities, from basic through applied research. Research is systematic study directed toward advancing scientific knowledge and/or gaining understanding of etiology and interventions to improve minority health and/or to reduce health disparities. This section also focuses on the need to strengthen and promote analytic methods that will enable a better understanding of the indicators and underlying causes of health disparities and facilitate ongoing monitoring.

Research Sustaining

Beyond conducting research, NIH also promotes the strengthening and expansion of structures that support research throughout the scientific process. NIH supports a variety of training programs, including those that work to promote diversity of the national biomedical workforce and those that work to increase the number of scientists studying minority health and health disparities. NIH also supports strengthening the national research capacity for minority health and health disparities research, capacity building for institutions that offer doctoral degrees in the health professions or the sciences related to health and have a historical and current commitment to educating underrepresented students, and programs to facilitate their inclusion in biomedical research. These activities are essential components of NIH's minority health and health disparities research-sustaining activities.

- **Biomedical Workforce Diversity**
  The overall composition of the biomedical workforce—not just individuals' skills—plays a role in its effectiveness. The Notice of NIH's Interest in Diversity (**NOT-OD-20-031**) states, "Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in and benefit from health research, and enhancing public trust."

- **Minority Health and Health Disparities Scientific Workforce**
  As the sciences of minority health and health disparities become more complex, the need for scientists with expertise in minority health and health disparities issues and for collaboration in a multidisciplinary team must be addressed. Recruitment, training, and retention of investigators with state-of-the-art skill sets in minority health and health disparities science are essential, throughout all stages of career development.

- **Research Capacity Building**
  The fields of minority health and health disparities research are growing, requiring greater academic infrastructure. NIH continues to strengthen programs and initiatives aimed at building scientific infrastructure and capacity at academic institutions and other organizations to support research in minority health and health disparities. These activities will help to develop vibrant communities of researchers to move both fields forward.

- **Including Racial and Ethnic Minorities and SGM Populations in Clinical Research Involving Human Participants**
  NIH is committed to ensuring that individuals who identify as racial and ethnic minorities, SGMs, and women are included in clinical research. This plan suggests additional actions intended to ensure that appropriate and meaningful representation occurs in NIH-funded research.

Identifying and addressing the barriers to inclusion of minorities (i.e., racial and ethnic and other HD populations, such as SGMs) in clinical research and developing tools to help researchers enhance minority recruitment should facilitate efforts to promote minority health and reduce health disparities. Furthermore, NIH-funded investigators need to be held accountable for proposed recruitment targets when launching research studies with human participants. Including minority populations in clinical studies and data sets is critical to ensure that people from all racial and ethnic backgrounds and other HD populations share in the benefits of new scientific discoveries.

Outreach, Collaboration, and Dissemination

NIH supports outreach, collaboration, and dissemination efforts that are needed to ensure that key MH and HD research findings are shared with the people and communities that need them. This plan focuses on expanding community outreach and enhancing dissemination efforts, as well as building community to enhance networks of MH and HD researchers and stakeholders across the nation and within NIH.

- **Outreach and Dissemination**
  Promoting the capacity to translate research findings into recommendations to be implemented in clinical and public health practice is essential for reducing health disparities. NIH can support appropriate stewardship by considering factors related to dissemination of MH and HD research at every stage of the research process. These efforts are needed to ensure that evidence-based interventions become part of established, everyday practice and integrated into the public health process.

- **Community Engagement and Building**
  As part of the outreach and dissemination process, broadening and strengthening the community of minority health and health disparities stakeholders—including health disparity communities, researchers, clinicians, advocacy groups, government employees, and policy makers—expands the potential avenues for collaboration and progress toward evidence-based practice and policy. This plan offers strategies for engaging and enhancing MH and other HD communities at multiple levels to help support the research of both fields.

Leap Forward Research Challenge

Leap Forward priority areas are expected to have a significant impact on advancing the field of minority health and health disparities research over the next 10 to 15 years. NIH challenged itself and the research community to be bold and strive for transformational progress across the continuum of research in minority health and health disparities. Leap Forward priority areas represent aspirational activities that NIH hopes to embark upon to improve minority health or to reduce a health disparity in scientific research and in research-sustaining activities.

Summary of Categories and Goals

Scientific Research: Goals and Strategies

Goal 1: Promote research to understand and to improve the health of racial/ethnic minority populations

- **Strategy 1.1:** Examine health determinants that underlie resilience or susceptibility to diseases and conditions experienced by minority populations.
- **Strategy 1.2:** Develop and assess interventions to improve the health status of minority populations.

Goal 2: Advance scientific understanding of the causes of health disparities

- **Strategy 2.1:** Investigate health determinants through basic, behavioral, clinical, and applied research to better understand the contributions to health disparity outcomes.
- **Strategy 2.2:** Support research to explore multilevel pathways and dynamic interrelationships of health determinants that affect health disparity outcomes over the life course and across generations.
- **Strategy 2.3:** Identify relevant critical periods and feasible targets for health disparity interventions.

Goal 3: Develop and test interventions to reduce health disparities

- **Strategy 3.1:** Design and test interventions that target known health determinants within the context of specific populations and appropriate life course time points to influence specific health disparity outcomes.
- **Strategy 3.2:** Embed implementation science within intervention studies to inform efforts to scale, sustain, and translate efficacious interventions within and across populations and settings.
- **Strategy 3.3:** Promote prevention and evaluate the impact of upstream interventions on distal health disparity outcomes across the lifespan and across generations.

Goal 4: Create and improve scientific methods, metrics, measures, and tools that support health disparities research

- **Strategy 4.1:** Identify and test the adoption of common indicators to quantify the status of health disparities across different diseases/conditions and populations.
- **Strategy 4.2:** Define the continuum from health differences to health disparities, both qualitatively and quantitatively across multiple dimensions, as well as develop contextually informed clinical and statistical measures of disparities reductions.
- **Strategy 4.3:** Apply complex systems modeling approaches, including biological models, to identify and predict relationships between health determinants and health disparity outcome measures.
- **Strategy 4.4:** Support movement toward standardization, collection, reporting, and leveraging of measures of health determinants in both existing and emerging data sources, including administrative clinical data, to foster linkages between health, sex and gender, and relevant health determinants data for use in identifying health disparities and underlying causes through emerging techniques found in data science.
- **Strategy 4.5:** Identify and strengthen rigorous quantitative and qualitative methods to enable analysis on small populations and subpopulations.
- **Strategy 4.6:** Evaluate minority health and health disparities proposals, programs, and policies to assess the effectiveness in improving minority health and/or reducing health disparities.

Research-Sustaining Activities: Goals and Strategies

Goal 5: Support training to enhance diversity and to promote training and career advancement of minority health and health disparities researchers

Workforce Diversity

- **Strategy 5.1:** Support individual-level programs to train individuals from health disparity populations in the biomedical sciences.
- **Strategy 5.2:** Support current and novel institution-level programs at institutions that have a historical and current commitment to educating underrepresented students and at less research-intensive institutions to enhance the ability of these programs to recruit, train, and retain a diverse biomedical research workforce.
- **Strategy 5.3:** Promote diversity-supporting recruiting programs at research-intensive institutions to expand the pool of applicants from health disparity groups underrepresented in biomedical research.

Minority Health and Health Disparities Scientific Workforce

- **Strategy 5.4:** Support training and mentorship programs for minority health and health disparities researchers at all stages of career development and leadership development.
- **Strategy 5.5:** Incorporate development of specialized research skills into health disparities training programs, including core and emerging skills that are important for measuring, understanding, and identifying solutions to address minority health and health disparities complexities.

Goal 6: Strengthen the national capacity to conduct minority health and health disparities research

- **Strategy 6.1:** Support programs to enhance capacity for minority health and health disparities research at institutions of all sizes.
- **Strategy 6.2:** Develop and test methods to foster, coordinate, and promote the field of health disparities among research institutions and organizations.

Goal 7: Ensure appropriate representation of minority and other health disparity populations in NIH-funded research

- **Strategy 7.1:** Provide guidance, recommendations, and technical assistance for NIH-funded researchers in appropriate study design and best practices for recruitment to ensure compliance with laws, regulations, and policies regarding the inclusion of minorities and other health disparity populations in research.
- **Strategy 7.2:** Promote and enforce accountability for inclusion of diverse populations by tracking originally proposed recruitment strategies and objectives to ensure sufficient samples for analyses of subpopulation data.
- **Strategy 7.3:** Promote inclusion of minorities and other health disparity populations in big data sets, clinical research, and future big science initiatives.

Outreach, Collaboration, and Dissemination: Goals and Strategies

Goal 8: Promote evidence-based community engagement, dissemination, and implementation of minority health and health disparities research best practices

- **Strategy 8.1:** Develop and test best practices for dissemination and implementation of minority health and health disparities research discoveries into different settings and with different populations.
- **Strategy 8.2:** Conduct studies to determine strategies for effective population-specific communication and outreach to inform recruitment and retention into clinical research studies and databases, design of culturally tailored health interventions, and community engagement and participation in research.
- **Strategy 8.3:** Generate strategies and tools to transform minority health and health disparities best practices into policies.

Goal 9: Cultivate and expand a community of minority health and health disparities researchers and advocates

- **Strategy 9.1:** Build an NIH interdisciplinary community of scholars around minority health and health disparities research to coordinate disparities science and to foster accountability and integration of minority health and health disparities science within NIH research activities.
- **Strategy 9.2:** Promote interagency collaboration and coordination with federal departments and agencies, including use of common data elements (CDEs) and data sharing relevant to minority health and health disparities research.
- **Strategy 9.3:** Establish partnerships with nongovernmental groups (e.g., mentoring networks, advocacy groups, industry and private groups, science communities, grantees) to advance the development, improvement, and utilization of minority health and health disparities definitions, methods, measures, metrics, interventions, and best practices.

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Revisions to Federal Standards for Collecting and Reporting Data on Race and Ethnicity: What are They and Why do They Matter?

Drishti Pillai (https://www.kff.org/person/drishti-pillai/) **and**

Samantha Artiga (https://www.kff.org/person/samantha-artiga/)

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Data are a cornerstone for efforts to advance health equity. How we ask for, analyze, and report information on race and ethnicity affects our ability to understand the racial and ethnic composition of our nation's population and our ability to identify and address racial disparities in health and health care. The accuracy and precision of such data have important implications for identifying needs and directing resources and efforts to address those needs.

On March 29, 2024, the Office of Management and Budget (OMB) announced revisions to Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf), which apply to federal data collection and reporting. The revisions include using a single combined question for race and ethnicity, adding Middle Eastern or North African (MENA) as a minimum category, clarifying instructions for individuals to select multiple racial and ethnic categories that represent their identity, and requiring collection of more detail beyond the minimum categories. In addition, the Standards require that data tabulation procedures result in the production of as much information on race and/or ethnicity as possible, including data for people reporting multiple racial and/or ethnic categories.

The updated standards are effective for all new federal racial and ethnic data collection and reporting as of March 28, 2024, and existing racial and ethnic data must be updated as soon as possible but no later than March 28, 2029. OMB indicates that these revisions are intended

to result in more accurate and useful race and ethnicity data across the federal government and are the first revisions that have been made since the last directive was issued in 1997. This brief provides an overview of these changes and their implications.

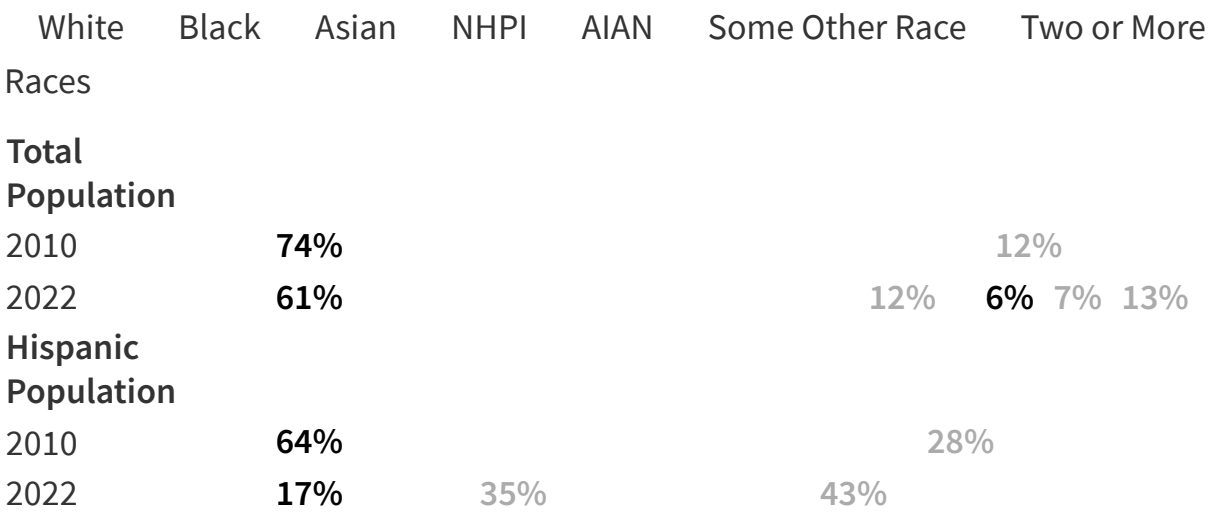
Why Were the Standards Revised?

Data and research (https://www.census.gov/about/our-research/race-ethnicity.html) **show that a growing number of people do not identify with the previously used OMB race and ethnicity categories.** These standards were last updated in 1997 (https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf), with subsequent guidance (https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0) provided by the Department of Health and Human Services (HHS) in 2011, which called for additional granularity in the collection and reporting of racial and ethnic data where possible for surveys conducted by HHS. The diversity of the U.S. population has grown significantly since the standards were last updated in 1997, as the share of people identifying as multiracial has increased and immigration patterns have evolved. Research suggests that under the previous standards, some people with Hispanic (https://www.npr.org/2021/09/30/1037352177/2020-census-results-by-race-some-other-latino-ethnicity-hispanic) ethnicity and people from the Middle East and North Africa (https://www2.census.gov/programs-surveys/decennial/2020/program-management/final-analysis-reports/2015nct-race-ethnicity-analysis.pdf) selected other race because they did not identify with the available categories. Moreover, recent refinements (https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html) to how the Census and other national surveys ask about race and ethnicity within the previous standards resulted in increased measures of population diversity, largely due to increases in the shares of people reported as some other race or multiracial, particularly among the Hispanic population.

Specifically, data from the American Community Survey show that between 2010 and 2022, the share of people identifying as some other race grew from 5% to 7%, while the share reporting two or more races increased from 3% to 13% (Figure 1). Among the Hispanic population, the share who identified as some other race grew from 28% to 35% between 2010 and 2022, and there was a ten-fold jump in the share reporting as multiracial, from 4% to 43%. During this period, the share of Hispanic people identifying as White plummeted from 64% to 17%. The Census Bureau indicates that many of these differences were largely due to changes (https://www.census.gov/newsroom/blogs/random-samplings/2021/08/improvements-to-2020-census-race-hispanic-origin-question-designs.html) in the design, data processing, and coding of the race and ethnicity questions over this period (including write-in responses), highlighting the powerful impact of these decisions. The process changes also make it challenging to identify how much of the observed change is due to actual demographic shifts.

Figure 1

Distribution of the Total Population and Hispanic Population by Race, 2010 to 2022



What was the Process for Updating these Standards?

In June 2022, OMB established a Federal Interagency Technical Working Group on Race and Ethnicity Standards (https://spd15revision.gov/content/spd15revision/en/about.html) **to review the racial and ethnic data collection and reporting standards with a goal of updating them to better reflect the diversity of the nation.** At that time, there were growing calls (https://www.gih.org/publication/federal-action-is-needed-to-improve-race-and-ethnicity-data-in-health-programs/) among federal, state, and local health agencies (https://www.gih.org/wp-content/uploads/2021/12/GIH-Commonwealth-Fund-federal-data-report-part-2.pdf); health systems; health information technology experts, and commercial health insurance plans to revisit and revise the standards. The Working Group developed initial proposals and questions, which were published in a Federal Register notice (https://www.govinfo.gov/content/pkg/FR-2023-01-27/pdf/2023-01635.pdf) in January 2023 to provide the opportunity for public input. In developing the new standards, the Working Group examined existing research (https://www2.census.gov/about/ombraceethnicityitwg/final-recommendations-for-csotus.pdf) and evidence, reviewed public comments (https://www.whitehouse.gov/omb/briefing-room/2024/03/28/omb-publishes-revisions-to-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and-presenting-federal-data-on-race-and-ethnicity/) submitted in response to the notice, and conducted listening sessions (https://www.whitehouse.gov/omb/briefing-room/2022/08/30/omb-launches-new-public-listening-sessions-on-federal-race-and-ethnicity-standards-revision/) and town halls with stakeholders and members of the public. Based on this process, the Working Group outlined final recommendations (https://www2.census.gov/about/ombraceethnicityitwg/final-recommendations-for-csotus.pdf) to OMB, which informed OMB's final decisions.

How Have the Standards Been Revised?

In March 2024, OMB announced revisions (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf) to the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity that reflect the recommendations of the Working Group. Examples of how race and/or ethnicity data would be collected under these new standards are included in Appendix A. Key changes from the previous standards include:

- **Moving to a single combined race and ethnicity question.** Under the previous standards, there were separate questions for individuals to identify race and Hispanic or Latino ethnicity. Research (https://www2.census.gov/about/ombraceethnicityitwg/final-recommendations-for-csotus.pdf) suggests that having separate questions for race and ethnicity confused some respondents who may not view the two concepts as distinct. Studies (https://www.jstor.org/stable/26582324) have found that many Hispanic or Latino individuals view their Hispanic or Latino identity as their race and do not identify with the race categories provided in a separate question. Many commenters expressed that moving to a single race and ethnicity question would help provide a more accurate count of the Hispanic or Latino population by reducing the number of blank responses or those classified as "some other race." In the 2020 Census, four in ten (44%) individuals who selected Hispanic or Latino as their ethnicity did not report a race or were classified as some other race. Some commenters expressed concern that a combined race and ethnicity question may contribute to a loss of data for Afro-Latino individuals, as respondents may solely select Hispanic or Latino. However, Census Bureau research did not find that use of a single combined question led to a significant difference in estimates of the Afro-Latino population.
- **Adding MENA as a new minimum category.** Prior to the 2024 update, the "White" racial category included people with European, Middle Eastern, or North African origins. However, there have been longstanding calls (https://www.census.gov/content/dam/Census/library/working-papers/2015/demo/MENA-Forum-Summary-and-Appendices.pdf.) by the MENA community and the public to provide MENA as a separate category since most people of Middle Eastern or North African origin do not view themselves as White. Consistent with these perspectives, prior research (https://www2.census.gov/programs-surveys/decennial/2020/program-management/final-analysis-reports/2015nct-race-ethnicity-analysis.pdf) shows a significant reduction in the share of people reporting some other race and White when a separate MENA category is offered compared to when there is no separate MENA category.
- **Requiring detailed collection of racial and ethnic categories as the default.** Under the revisions, agencies are required to collect the detailed categories outlined in the standards by default. These detailed categories represent the largest population groups within the broader minimum racial and/or ethnic categories. An agency may request an exemption to the requirement to collect more detailed data if it determines that the potential benefit would not justify the additional burden to the agency and the public or the additional risk to privacy or confidentiality. Under the prior standards, detailed racial and ethnic data collection was encouraged but not required. Overall, the majority of commenters supported the collection of more detailed data beyond the minimum categories as a default, citing the diverse experiences of groups within the broader categories and the importance of having detailed data to measure differences in health

care outcomes. Some commenters expressed concern regarding privacy risks, respondent burden, and the burden on agencies.

- **Modifying question instructions to encourage respondents to select all categories that reflect their identity.** Specifically, question instructions must explicitly state that respondents should, "Select all that apply." In cases in which detailed categories are collected with write-in responses, instructions must further encourage respondents to enter additional details, with instructions to, "Select all that apply and enter additional details in the spaces below."

The revisions also make updates to terminology (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf) including removing use of "majority" and "minority" terminology (except when statistically accurate or when legal requirements call for use of those terms) and removing "Other" from the "Native Hawaiian and Other Pacific Islander" category title. They also make some revisions to definitions for the categories, including but not limited to removing "Negro" from the Black or African American definition, replacing "Far East" with "Central or East Asia" in the Asian definition, and removing the phrase "who maintains tribal affiliation or community attachment" from the American Indian or Alaksa Native definition.

Consistent with recommendations from the Working Group, OMB refrained from establishing requirements regarding a specific order for presenting racial and/or ethnic categories, continuing to leave this to agencies' discretion. It notes that agencies generally order the categories alphabetically or by population size and that future research may help inform the best approach for ordering response options.

What are the Standards for Presenting Data on Race and/or Ethnicity?

OMB further specifies that agencies must use procedures that result in the production of as much information on race and/or ethnicity as possible, including for people reporting multiple categories, while still maintaining data quality and privacy. It encourages agencies to use one of three approaches for presenting data, including:

- **Alone or in combination.** This approach groups all individuals belonging to a racial or ethnic group, whether alone or in combination with another racial or ethnic group. For example, an individual who reports their identity as both White and Black would be included in both the "White alone or in combination category" and the "Black alone or in combination" category.
- **Most frequent multiple responses.** Under this approach, information is reported for as many race and ethnicity combinations as possible. In addition to the seven minimum race and/or ethnicity categories alone, the agency would report data for all combinations of racial and ethnic groups (e.g., American Indian or Alaska Native *and* Hispanic or Latino) that meet sufficient response thresholds or are of specific interest.
- **Combined Multiracial and/or Multiethnic category.** This approach presents data for the seven minimum race and/or ethnicity categories and groups all other respondents who identify multiple race and/or ethnicity categories into a single Multiracial and/or Multiethnic category. Since this approach provides limited understanding of the diversity

of the population, OMB indicates that agencies should use this approach in combination with one of the alternative approaches above to meet the overarching requirement to provide as much race and/or ethnicity information as possible, including for people who report more than one category.

Looking Ahead

The updated guidelines issued by OMB are effective (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf) for all new data collection that includes race and/or ethnicity questions as of March 28, 2024, and all existing data must be updated to the new standards "as soon as possible but, no later than March 28, 2029." Each agency must develop an Action Plan on Race and Ethnicity Data within 18 months of the notice of the revised standards and make them publicly available upon submission to OMB.

Bridging challenges are expected as the implementation of these guidelines takes effect, with agencies expressing via public input the importance of "tools to support bridging" (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf) to compare race and ethnicity data collected under the 2024 guidelines and the 1997 guidelines. To address these concerns, the OMB Working Group has provided bridging guidelines (https://www2.census.gov/about/ombraceethnicityitwg/annex-6-itwg-bridging-team-methods-report.pdf) for federal agencies. Some commenters have also expressed concern regarding the tabulation (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf) of different racial and/or ethnic categories including how to tabulate responses for individuals who select multiple race and ethnicity categories and whether Hispanic or Latino responses will be presented separately from other racial categories in civil rights reporting.

OMB has also identified areas of future research (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf), which include, among others, how to encourage respondents to select multiple race and/or ethnicity categories by enhancing question design, how to collect high quality and useful data related to descent from people who were enslaved in the United States, the optimal order for presenting the minimum categories, and how to collect race and/or ethnicity data consistently across different languages. OMB also indicates it will establish an Interagency Committee on Race and Ethnicity Statistical Standards, that will undertake regular reviews of the standards on a ten-year cycle and provide an opportunity for public input. It also may conduct a review at any time outside of those regular review periods.

Appendix: Examples of Race and/or Ethnicity Questions Consistent with Revised OMB Standards

What is your race and/or ethnicity?
Select all that apply.

☐ **American Indian or Alaska Native**
For example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.

☐ **Asian**
For example, Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese, etc.

☐ **Black or African American**
For example, African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali, etc.

☐ **Hispanic or Latino**
For example, Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, etc.

☐ **Middle Eastern or North African**
For example, Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli, etc.

☐ **Native Hawaiian or Pacific Islander**
For example, Native Hawaiian, Samoan, Chamorro, Tongan, Fijian, Marshallese, etc.

☐ **White**
For example, English, German, Irish, Italian, Polish, Scottish, etc.

(https://www.kff.org/wp-content/uploads/2024/04/10368-Appendix-Figure-1.png)Source: Office of Management and Budget, Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity

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(https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf)

What is your race and/or ethnicity?

Select all that apply and enter additional details in the spaces below.

☐ **American Indian or Alaska Native** – *Enter, for example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.*

☐ **Asian** – *Provide details below.*

☐ Chinese ☐ Asian Indian ☐ Filipino
☐ Vietnamese ☐ Korean ☐ Japanese

Enter, for example, Pakistani, Hmong, Afghan, etc.

☐ **Black or African American** – *Provide details below.*

☐ African American ☐ Jamaican ☐ Haitian
☐ Nigerian ☐ Ethiopian ☐ Somali

Enter, for example, Trinidadian and Tobagonian, Ghanaian, Congolese, etc.

☐ **Hispanic or Latino** – *Provide details below.*

☐ Mexican ☐ Puerto Rican ☐ Salvadoran
☐ Cuban ☐ Dominican ☐ Guatemalan

Enter, for example, Colombian, Honduran, Spaniard, etc.

☐ **Middle Eastern or North African** – *Provide details below.*

☐ Lebanese ☐ Iranian ☐ Egyptian
☐ Syrian ☐ Iraqi ☐ Israeli

Enter, for example, Moroccan, Yemeni, Kurdish, etc.

☐ **Native Hawaiian or Pacific Islander** – *Provide details below.*

☐ Native Hawaiian ☐ Samoan ☐ Chamorro
☐ Tongan ☐ Fijian ☐ Marshallese

Enter, for example, Chuukese, Palauan, Tahitian, etc.

☐ **White** – *Provide details below.*

☐ English ☐ German ☐ Irish
☐ Italian ☐ Polish ☐ Scottish

Enter, for example, French, Swedish, Norwegian, etc.

(https://www.kff.org/wp-content/uploads/2024/04/10368-Appendix-Figure-2.png)Source: Office of Management and Budget, Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf)

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