Benchmarks for Diversity in Oncology Clinical Trials

An FDA-ACS Hybrid Symposium
October 16, 2024

Biographies

Welcome

William Dahut, MD
Chief Scientific Officer
American Cancer Society, Inc.

William L. Dahut, MD, serves as chief scientific officer for the American Cancer Society (ACS). In this role, he oversees the strategic direction of both intramural and extramural research for the largest nonprofit funder of cancer research. Dr. Dahut manages all pieces of the organization's discovery work, including surveillance and health equity science, population science, cancer screening guidelines, and extramural discovery science. He serves as the scientific voice of the organization, advises key discovery positions, and manages more than $400 million in research funding. Dr. Dahut guides efforts to enhance and focus the American Cancer Society's research program, concentrating priorities where they will be most effective and working with key partners and supporters to further progress.

An internationally recognized physician-investigator, Dr. Dahut is known for his thoughtful and determined leadership in cancer research. Before joining ACS, Dr. Dahut held leading roles at the National Cancer Institute (NCI), where he served as scientific director for clinical research at the NCI's Center for Cancer Research, head of the agency's prostate cancer clinical research section, and NCI clinical director. Dr. Dahut led the revitalization of NCI's clinical research program, growing the number and caliber of senior, tenure-track, and physician-scientist early investigators and staff clinicians, reorganizing clinical research, and increasing regulatory support and facilities for cell therapies.

Karen Knudsen, MBA, PhD
Chief Executive Officeer
American Cancer Society, Inc.
American Cancer Society Cancer Action Network

Dr. Karen E. Knudsen, MBA PhD, is CEO of both the American Cancer Society (ACS, a 501c3) and its advocacy affiliate ACS CAN (a 501c4). An internationally recognized oncology leader and healthcare executive, Dr. Knudsen guides both organizations toward the goal of ending cancer as we know it, for everyone. Her expertise in merger and acquisition was leveraged to successfully transform and grow ACS from a federated model into a thriving single enterprise.

ACS acts to improve the lives of cancer patients and their families through a tripartite strategy of cancer discovery, advocacy and direct patient support, touching >55 million lives each year. ACS is the largest nonprofit funder of cancer research outside the US government, generating breakthroughs that reduced cancer mortality. The ACS advocacy arm functions at the state and federal level to increase access to these breakthroughs through legislation and policy change. ACS patient support teams work in >5,000 communities across the country to provide patient education, navigation, transportation, and lodging near cancer care. Finally, under Dr. Knudsen, ACS has also lifted up 3 mission

aligned businesses, including a joint venture with Color Health, a patient navigator training and certification program (ACS LION) and an impact investment arm (BrightEdge).

Prior to leading ACS and ACS CAN, Dr. Knudsen was the EVP of Oncology Services for Jefferson Health and the NCI-designated Sidney Kimmel Cancer Center, leading oncology for a 16 hospital system across 2 states. She is known for her practice-changing discoveries in prostate cancer, and holds thought leadership roles on advisory boards in the healthcare and biopharma industries. She has chaired or served on numerous Boards (including the Association of American Cancer Institutes, and the American Association for Cancer Research) and currently serves on the Board of Directors for Research!America. She also served on the Board of Advisors for the National Cancer Institute. Dr. Knudsen has received numerous awards for her contributions to cancer research and as a result of her healthcare leadership. She was recently honored by Forbes as one of "50 over 50" Women of Impact, is a CNBC "Changemaker", and QVC Quintessential Q50".

Tamy Kim, PharmD
Director for Regulatory Affairs and Regulatory Policy, Oncology Center of Excellence
U.S. Food and Drug Administration

Tamy Kim is the Director for Regulatory Affairs and Policy in the Oncology Center of Excellence (OCE) at the FDA. Dr. Kim is responsible for developing policies and procedures affecting the review of products under the OCE across CDER, CBER and CDRH. She is also responsible for providing guidance to oncology review divisions and sponsors for complex regulatory issues. During her time with FDA Oncology, Dr. Kim helped established the OCE and formed policy and procedures for Breakthrough Therapy, Accelerated approval, Real-Time Oncology Review (RTOR), expanded access, master protocols, seamless trials designs and more.

Session 1: The Role of Epidemiology and Design in Enhancing Diversity: Approaches to Data Sources, Statistical Approaches, and Design to Achieve Clinical Trial Enrollment Goals

Nicole Gormley, MD (Moderator)
Division Director, Office of Oncologic Diseases, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Nicole Gormley, MD, is the Division Director for the Division of Hematologic Malignancies II at the U.S. Food and Drug Administration and serves as the Associate Director for Oncology Endpoint Development in the Oncology Center of Excellence. The Division of Hematologic Malignancies II oversees the drug development of products for the treatment of multiple myeloma, lymphomas, and chronic lymphocytic leukemia. In her role as the Associate Director of Oncology Endpoint Development, Dr. Gormley provides direction, coordination and oversight for scientific and policy efforts related to early endpoint development in oncology. Dr. Gormley also serves as the co-lead for the Oncology Center of Excellence's Equity Program, which seeks to advance equitable access to clinical trials for all patients with cancer through policy, research, and education.

Session 1 Presenters:

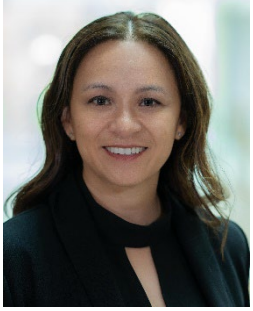
Cleo Ryals, PhD
Senior Director and Head of Health Equity Research
Flatiron Health

Dr. Cleo A. Ryals is the Head of Health Equity Research at Flatiron Health, where she is tasked with developing and executing Flatiron's company-wide health equity strategy with the goal of advancing cancer health equity through real-world evidence generation. Dr. Ryals is a health services researcher by training with expertise in cancer health equity, real-world data and evidence generation, health equity research methodology and data analytics, clinical trial diversity, and community engagement. She is a nationally recognized and highly sought after health equity researcher and leader with several publications on topics related to health equity and oncology care.

Prior to joining Flatiron Health, Dr. Ryals was a tenured Associate Professor of Health Policy and Management at the UNC Chapel Gillings School of Global Public Health, where she built substantial health equity research and training programs and was the Founding Director of the Centering Racial Equity in Data Science (CREDS) Initiative at the UNC Lineberger Comprehensive Cancer Center. Dr. Ryals has also held positions within multiple federal offices/agencies, including the former United States Senate Office of Barack Obama, the Office of the National Coordinator for Health Information Technology, and the Government Accountability Office. In 2019, Dr. Ryals was recognized as a *'40 Under 40' Leader in Minority Health* by the National Minority Quality Forum and Congressional Black Caucus. Dr. Ryals holds a PhD in Health Policy from Harvard University.

Mary Redman, PhD
Professor, Clinical Research Division
Fred Hutchinson Cancer Center

Mary Redman is a Professor and biostatistician in the Clinical Research Division at the Fred Hutchinson Cancer Center (FHCC). She has extensive experience in the design, conduct, analysis and reporting of phase II and III clinical trials, with a particular focus on lung cancer and incorporation of biomarkers. She has been the Statistical Chair of the Lung Cancer Committee within the SWOG Cancer Research Network since 2005; she is co-lead of the Biostatistics and Data Science Core of the Fred Hutch Lung SPORE; and she is the Statistical Chair of the Lung-MAP Master Protocol which just celebrated its 10th anniversary of being open to accrual. Lung-MAP is conducted via a Public-Private Partnership with all four National Clinical Trials Network Groups, the National Cancer Institute, Foundation for the NIH, and Friends of Cancer Research with a special collaboration with the FDA. Finally, Mary is the Statistical Chair of the Pragmatica Lung Study (SWOG S2302) which was the first trial launched as part of the FDA's Project Pragmatica. The Pragmatica Lung seeks to confirm the positive overall survival results from S1800A, a randomized phase II trial conducted within Lung-MAP.



Bea Lavery, MS
Vice President, Portfolio Strategy Lead, Product Development Regulatory
Genentech, a member of the Roche Group

Bea Lavery is the Vice President, Portfolio Strategy Lead in Product Development Regulatory at Genentech, a member of the Roche Group. In her current role, Bea oversees Roche's global regulatory development strategies and execution for the pharmaceutical portfolio, across all disease areas and platforms. Bea joined Genentech in 2001 in the immunology research department, and transitioned to oncology regulatory affairs in 2005. Bea has held a number of

leadership positions over the years in regulatory affairs, including Global Head of Oncology Regulatory Affairs. Originally from Canada, Bea received her Bachelors and Masters Degrees from the University of Calgary, specializing in Microbiology and Infectious Disease research. Bea is currently based in Basel, Switzerland.

Session 1 Panelists:

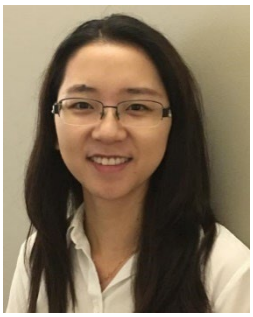
Craig L. Tendler, MD
Vice President, Oncology Clinical Development, Diagnostics, and Global Medical Affairs, Johnson & Johnson Innovative Medicine Research & Development, LLC

Craig Tendler, M.D. is Vice President and Global Head of Clinical Development, Diagnostics, and Medical Affairs for the Oncology Therapeutic Area at Johnson & Johnson Innovative Medicine. In this position, he is responsible for creating and overseeing robust development plans, including optimal integration of biomarkers and diagnostics, and comprehensive data generation activities for all products in the oncology portfolio, from proof of concept through registration and lifecycle management. He works closely with teams in early development and the disease areas of focus to implement a seamless end-to-end oncology clinical research strategy that incorporates compelling science, broad clinical trial access to diverse populations, and addresses areas of high unmet medical need.

Craig has overseen and coordinated > 30 major drug approvals by national regulatory agencies, including at least ten NDAs by the US Food and Drug Administration (FDA). He and his have team worked in collaboration with the FDA and the European Medicines Agency to secure the worldwide approvals of J&J's treatments in prostate cancer (ZYTIGA, AKEEGA, and ERLEADA), hematologic malignancies (DARZALEX, CARVYKTI, TECVAYLI, TALVEY, IMBRUVICA), as well as for lung (RYBREVANT) and bladder cancer (BALVERSA). Craig has played a key role in achieving 13 FDA breakthrough designations for accelerating the early development of promising investigational medicines intended for the treatment of serious oncology conditions.

Prior to joining Johnson & Johnson Innovative Medicine, Craig served as the Vice President of Oncology Clinical Research and Chair of the Oncology Licensing Committee at the Schering-Plough Research Institute. In addition to his pharmaceutical industry experience, he has served as Assistant Professor of Pediatrics/Hematology-Oncology at the Mount Sinai School of Medicine in New York City and as a NIH physician-scientist grant recipient and research fellow at the National Cancer Institute in Bethesda, Maryland.

Craig earned his undergraduate degree from Cornell University, and graduated from the Mount Sinai School of Medicine with high honors and induction into the Alpha Omega Alpha Medical Society.



Jianjin Xu, PhD
Statistical Reviewer, Department of Biometrics V, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Jianjin Xu is a statistical reviewer from DBV/CDER/FDA. She got a Ph.D degree in Applied Mathematics and Statistics and a master's degree in biomedical engineering from Stony Brook University. Her work is focused on reviewing regulatory submissions for breast, gynecologic, and genitourinary cancers. Her research interests include statistical method development on safety signal detection and Bayesian adaptive design by leveraging real world data. She has been with FDA since 2017.

Catherine Lerro, PhD, MPH
Senior Epidemiologist, Oncology Center of Excellence
U.S. Food and Drug Administration

Dr. Catherine Lerro, Ph.D., M.P.H. is a Senior Epidemiologist in the Oncology Center of Excellence (OCE) at the US Food and Drug Administration (FDA). In this role, Dr. Lerro reviews clinical studies intending to support oncology applications that incorporate real-world data, supports collaborative regulatory science research related to real-world data, and provides education, training, and outreach. Prior to joining the OCE, Dr. Lerro was an epidemiology reviewer and team lead in the Office of Surveillance and Epidemiology in the FDA's Center for Drug Evaluation and Research.

She earned her Ph.D. from Yale in cancer epidemiology and completed a post-doctoral fellowship at the National Cancer Institute in the Division of Cancer Epidemiology and Genetics. Dr. Lerro has authored over 50 peer-reviewed publications, editorials, and book chapters. Her research interests include enhancing real-world data quality, epidemiologic methods and design, and descriptive epidemiology.

Jamie Brewer, MD
Medical Oncologist & Clinical Team Lead, Division of Oncology 3, Office of Oncologic Diseases (OOD), Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Jamie Brewer, MD 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. In her current role as Clinical Team Lead, Dr. Brewer participates in the review of cancer drugs intended to treat patients with melanoma and gastrointestinal malignancies. Dr. Brewer completed her internal medicine residency and hematology/oncology fellowship training at The University of Chicago Medical Center. During her hematology/oncology training she also completed a Clinical Pharmacology and Pharmacogenomics fellowship at The University of Chicago.

Presentation: OCE Relevant Projects

Bindu Kanapuru, MD
Supervisory Associated Director of Therapeutic Review, Divison of Hematologic Malignancies II, Office of Oncologic Diseases
U.S. Food and Drug Administration

Dr. Bindu Kanapuru is a hematologist-oncologist in the Office of Oncologic Diseases (OOD) at the U.S. Food and Drug Administration. Dr. Kanapuru serves as the Supervisory Associate Director of Therapeutic Review in the Division of Hematologic Malignancies II, that oversees development of therapies for the treatment of multiple myeloma and lymphomas. She joined the FDA in 2015. Her areas of interest include geriatric oncology, real world evidence, and novel trial designs. Dr.

Kanapuru completed her fellowship in hematologic and oncology at the University of Maryland Medica Center in Baltimore.

Session 2: Patient-Centric Approaches to Enhance Diversity

Donna Rivera, PharmD, MS (Moderator)
Associate Director, Pharmacoepidemiology and Oncology RWE, Oncology Center of Excellence
U.S. Food and Drug Administration

Donna R. Rivera, PharmD., MSc., is the Associate Director for Pharmacoepidemiology in the Oncology Center of Excellence at the U.S. Food and Drug Administration. She leads the Oncology Real World Evidence (RWE) Program, focused on the use of Real World Data (RWD) and RWE for regulatory purposes, as well as management of the RWD research portfolio strategy and development of regulatory policy to support the OCE mission.

As a pharmacist and pharmacoepidemiologist, Dr. Rivera has interests in the use of RWD to advance health equity, observational study designs and methodological approaches, and appropriate uses of RWD for drug development to increase access of effective therapies to patients.

In her previous role at the National Cancer Institute (NCI), she led a strategic RWD initiative to facilitate large scale, longitudinal treatment data linkages with SEER through collaborative public private partnerships.

Session 2 Presenters:

Electra D. Paskett, PhD
Professor and Director
The Ohio State University

Electra D. Paskett, Ph.D., became the Marion N. Rowley Professor of Cancer Research at The Ohio State University in 2002. She is the Director of the Division of Cancer Prevention and Control in the College of Medicine, a professor in the Division of Epidemiology in the College of Public Health, Deputy Director for Population Sciences and Community Outreach and Founding Director of the Center for Cancer Health Equity at the James Cancer Hospital. Dr. Paskett's 500+ peer-reviewed publications showcase her work in intervention research directed at cancer prevention, early detection and survivorship issues. Her studies use multi-level interventions in transdisciplinary teams with community-based participatory research to identify and intervene on factors causing disparities among underserved populations such as social and ethnic minority groups and rural/underserved populations. Dr. Paskett was the Principal Investigator of the Ohio Patient Navigator Research Program and has received funding from the Breast Cancer Research Foundation since 2001. She continues to work with the Women's Health Initiative (WHI) and is one of the multiple PIs of the WHI Cancer Survivor Cohort, and currently is the PI of the WHI Midwest Regional Coordinating Center. She has funding for a UG3 to improve colorectal cancer screening through implementation science and a P01 that is looking to improve cervical cancer prevention services in Appalachia.

Dr. Paskett was elected as a Fellow to the American Association for the Advancement of Science in 2004. She is a past-President of the American Society of Preventive Oncology, a past Deputy Editor of the journal *Cancer, Epidemiology, Biomarkers & Prevention*, and Section Editor of the journal, *Cancer*, and currently serves as Editor in

Chief of the journal *Preventive Oncology and Epidemiology.* She is Director of the Cancer Control Program in Alliance. She has numerous awards such as the American Society of Preventive Oncology Distinguished Achievement Award, The Alliance for Clinical Trials in Oncology Jimmie Holland Award, the American Association for Cancer Research (AACR) Distinguished Lecture Award on the Science of Cancer Health Disparities and the AACR Team Science Award for her long-standing role in the WHI. In 2016, she became a member of the National Cancer Institute's National Cancer Advisory Board. Dr. Paskett became a member of the Ohio Commission on Minority Health (OCMH) in 2020 and was appointed Chair in 2023. In 2024, Dr. Paskett was elected to a 3year term of the Board of Directors of AACR (American Association for Cancer Research).

Lesley Curtis, PhD
Senior Policy Advisor, U.S. Food and Drug Administration
U.S. Food and Drug Administration

Lesley H. Curtis is Professor in the Departments of Population Health Sciences and Medicine in the Duke School of Medicine. A health services researcher by training, Dr. Curtis is an expert in the use of health care and Medicare claims data for health services and clinical outcomes research, and a leader in national data quality efforts. Dr. Curtis currently serves as a senior policy advisor at the Food and Drug Administration, supporting the Agency's evidence generation initiative, and is co-PI of the NIH Pragmatic Trials Collaboratory, an NIH initiative to strengthen the national capacity for large-scale research studies embedded in health care delivery.

L. Johnetta Blakely, MD, MS, MHHC
Medical Oncologist and Hematologist
Executive Vice President of Quality and Clinic Operations
Tennessee Oncology

Johnetta Blakely is a medical oncologist and hematologist practicing at Tennessee Oncology the largest provider of oncology care in Tennessee. In April 2024, Dr. Blakely was appointed Executive Vice President of Quality and Clinic Operations, where she oversees clinical programs across nearly 40 sites, focusing on delivering high-quality, innovative, and patient-centered care. In this leadership role, she also spearheads value-based care initiatives and drives quality improvement efforts throughout the practice. Alongside her executive responsibilities, she has maintained a thriving Hematology-Oncology practice for over two decades, with a clinical focus on breast and lung cancers.

She earned her medical degree from the University of Tennessee in Memphis, completed her Internal Medicine residency at the University of Texas in Houston, and pursued a fellowship in Medical Oncology at the University of Texas MD Anderson Cancer Center. Dr. Blakely also holds a Master of Science in Clinical Research from the University of Texas Health Science Center at Houston and a Master of Management in Healthcare from Vanderbilt University.

Living in Nashville for over 13 years with her husband, Dr. Blakely is an active member of the community. She recently served as Executive Chair for Nashville's Light the Night annual fundraiser. The couple has two grown daughters.

Session 2 Panelists:

Josh Chetta, PhD
Deputy Division Director, Division of Clinical Policy and Quality, Center for Devices and Radiological Health
U.S. Food and Drug Administration

Josh Chetta serves as the Deputy Division Director in CDRH's Division of Clinical Policy and Quality, overseeing policy development and implementation of program areas including Investigational Device Exemptions (IDEs), Breakthrough Devices, the Safer Technologies Program (STeP), Real-World Evidence (RWE), expanded access, and postmarketing studies. Before assuming this role, he worked as a Policy Advisor in CDRH's Office of Policy, where he helped develop CDRH policy and drafted policy documents including guidances, discussion papers, and Federal Register documents. Previously, he worked as a lead premarket reviewer and in the Clinical Trials Program in the Office of Device Evaluation (ODE). Josh earned his undergraduate degree in Biology from the University of Chicago and a doctorate in Bioengineering from the University of Maryland. He spent three years as a post-doctoral fellow at the NIH's Clinical Center before joining CDRH in 2014.

Stephanie Walker, RN
Patient Advocate

Stephanie Walker believes in helping those in need.
After a 40-year career as a nurse in critical care, pediatric intensive care, critical care transport, and hospice/end-of-life, Walker continues to help, but on a different path.

Diagnosed with metastatic breast cancer in July 2015, Walker now advocates for other Black Americans with cancer and those living in rural America — historically our most medically underserved populations.

Stephanie is a member of the MBC Alliance, as a co-chair of the Clinical Care working group, patient lead on a project called BECOME and Black W0(men) Speak. She is a member of patient leadership with Living Beyond Breast Cancer organization by completing Hear My Voice Advocacy training and a helpline volunteer ; an Advocate in Science member with SG Komen; a Project Lead grad; she leads peer to peer support groups and volunteers many hours in her community with the Pilot Club and on a community board that supports the elderly population. She wants to be a voice for the underserved, underrepresented and dismissed men and women with MBC and early stage breast cancer. No one should be alone.

Timil Patel, MD
Medical Oncologist, Acting Clinical Team Leader, Division of Oncology 2, Office of Oncologic Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Timil Patel is a medical oncologist and an acting clinical team leader in the Division of Oncology 2 at the U.S. Food and Drug Administration. In this role, he leads a team of oncologists and scientists who evaluate drug development programs for thoracic and head and neck cancers, from first-in-human trials to approval. His research focuses on modernizing cancer trials, particularly through

decentralized and pragmatic approaches. Dr. Patel serves on the White House Cancer Moonshot's Data and Innovation Task Force and was part of the FDA's Decentralized Trials Guidance Working Group. He completed hematology/oncology fellowship at Yale before joining the FDA.

Karen Noonan, MD
Senior Vice President, Global Regulatory Policy
Association of Clinical Research Organizations (ACRO)

Karen joined ACRO in 2014 and leads ACRO's global regulatory advocacy, engaging with regulators and other policymakers on issues impacting clinical research. She manages ACRO's US and European regulatory committees and led the ACRO DCT Working Party in the development of the DCT Toolkit. She also leads ACRO engagement with colleague associations such as EFPIA, ABPI, and BIA. Karen has an MA in political science and a BA in French.

Closing Remarks & Adjournment

Christina Annunziata, MD
Senior Vice President, Extramural Discovery Science
American Cancer Society

As Senior Vice President of Extramural Discovery Science at the American Cancer Society, Dr. Annunziata leads a team of scientific directors and staff to identify the most innovative and promising research to end cancer as we know it for everyone. In addition to leading the grant review process at the American Cancer Society, Dr. Annunziata builds and fosters critical relationships with cancer researchers across the nation and with international scientific communities.

Dr. Annunziata received her MD and PhD degrees from Georgetown University and completed Medical Oncology Fellowship training at the National Cancer Institute, where she then attained the position of tenured Senior Investigator before joining the American Cancer Society. At NCI, Dr. Annunziata was a leader in innovative cancer research in both the laboratory and in clinical trials. Her laboratory established the NF-kappB signaling pathway as important for ovarian cancer stem cells and their progression. She also developed the field of intraperitoneal cellular immunotherapy, using autologous monocytes or engineered CAR-T cells administered directly to the abdominal cavity. Her work in both areas led to investigator-initiated clinical trials and multi-center trials to test novel treatments for patients with chemo-refractory recurrent ovarian cancer.

In addition to her research, Dr. Annunziata has chaired scientific review committees for both laboratory and clinical research proposals. These include committees across NIH, ASCO, and the Department of Defense.

Nicole Gormley, MD (Moderator)
Division Director, Office of Oncologic Diseases, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

See above entry