



## **FDA-AACR Workshop to Examine Under-representation of African Americans in Multiple Myeloma Clinical Trials**

February 13, 2020 | Washington, DC

---

### **Workshop Cochairs**

**Kenneth C. Anderson, MD, FAACR, *Dana-Farber Cancer Institute***



Dr. Anderson is the Kraft Family Professor of Medicine at Harvard Medical School as well as Director of the LeBow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center at Dana-Farber Cancer Institute. He is a Doris Duke Distinguished Clinical Research Scientist and American Cancer Society Clinical Research Professor. After graduating from Johns Hopkins Medical School, he trained in internal medicine at Johns Hopkins Hospital, and then completed hematology, medical oncology, and tumor immunology training at the Dana-Farber Cancer Institute. Over the last three decades, he has focused his laboratory and clinical research studies on multiple myeloma. He has developed laboratory and animal models of the tumor in its microenvironment which have

allowed for both identification of novel targets and validation of novel targeted therapies, and has then rapidly translated these studies to clinical trials culminating in FDA approval of novel targeted therapies. His paradigm for identifying and validating targets in the tumor cell and its milieu has transformed myeloma therapy and markedly improved patient outcome.

He is the recipient of many scientific and humanitarian awards including: the International Myeloma Workshop Waldenstrom's Award; the International Myeloma Foundation Robert A. Kyle Lifetime Achievement Award; the American Association for Cancer Research Joseph H. Burchenal Award; the American Society of Hematology William Dameshek Prize; the Johns Hopkins Society of Scholars; election to the Institute of Medicine of the National Academy of Sciences and the Royal Colleges of Physicians and of Pathologists (UK); the American Society of Clinical Oncology David A. Karnofsky Award; the Hope Funds for Cancer Research Award of Excellence in Clinical Research; the Ron Burton Humanitarian Award; the Harvard Medical School Warren Alpert Foundation Prize; the American Cancer Society Medal of Honor; the Leonard P. Zakim Patient Advocacy Award; the Samuel Waxman Research Foundation David Workman Memorial Award; and the University of Miami Sylvester Cancer Center Annual Zubrod Memorial Award. He is a Fellow of the American Association for Cancer Research and the American Society of Clinical Oncology, and has served as President of the International Myeloma Society and President of the American Society of Hematology. He also chairs the Regulatory Science and Policy Subcommittee of the American Association for Cancer Research and serves as founding editor-in-chief of Blood Cancer Discovery.



## **Lola A. Fashoyin-Aje, MD, MPH, U.S. Food and Drug Administration**



Lola A. Fashoyin-Aje, MD, MPH, is a medical oncologist and acting Deputy Division Directory in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Food and Drug Administration (FDA).

At the FDA, Dr. Fashoyin-Aje has served as clinical reviewer in the Gastrointestinal (GI) Malignancies team, and as team leader for the Breast Malignancies, Melanoma and Sarcoma, and Gastrointestinal Malignancies clinical teams. In her current role, she provides scientific and policy guidance and oversight to multidisciplinary teams reviewing drugs and biologics under development for the treatment of solid tumor (GI, sarcoma, melanoma) malignancies. She has also served as the Oncology Center of Excellence (OCE) Scientific Liaison for Cancer Disparities and in this role, has led the OCE's efforts to improve inclusion of diverse demographic subgroups in clinical trials and participates in several internal and external scientific and policy working groups. Dr. Fashoyin-Aje also serves on the ASCO Health Equity Committee, the AACR Science of Cancer Health Disparities Scientific Program and Scientific Review committees, and the ASCO Cancer Research Committee.

Prior to joining the FDA, Dr. Fashoyin-Aje completed her residency in internal medicine and fellowship in medical oncology at Johns Hopkins. She completed her undergraduate and graduate training at Columbia University and Yale University, respectively, and earned her medical degree from the University of Rochester.

## **Nicole Gormley, MD, U.S. Food and Drug Administration**



Nicole Gormley, MD, is the Acting Division Director for the Division of Hematologic Malignancies II at the U.S. Food and Drug Administration. Dr. Gormley joined the FDA in 2011 and previously served as a clinical reviewer and the Multiple Myeloma Clinical Team Lead. While in these roles, Dr. Gormley has actively engaged with the multiple myeloma community on the development of novel endpoints, including minimal residual disease, and methods to address racial disparities. Dr. Gormley completed fellowship training in hematology and critical care at the National Institutes of Health and served as the Deputy Clinical Director at the National Heart, Lung and Blood Institute prior to joining the Food and Drug Administration.

## **Paul Kluetz, MD, U.S. Food and Drug Administration**



Paul Kluetz is a medical oncologist and Deputy Director of the Oncology Center of Excellence (OCE) at the U.S. FDA. His interests include trial design and endpoint selection to expedite drug development and define clinical benefit in oncology trials. His work has included the initiation and direction of the OCE's patient-focused drug development program. This program has been instrumental in leading FDA's efforts to review, analyze and communicate clinical outcome information from patient reported outcomes (PRO), wearable technologies, and other methods to measure symptoms and function in both the clinical trial and "real-world" settings. He has also worked to advance patient-friendly trial designs including pragmatic and decentralized trials, as well as contributed to broader FDA efforts to expand trial eligibility criteria. In addition, Dr. Kluetz is leading Project Renewal, an OCE pilot project developing a systematic process to review accumulated evidence in order to update the product labels of longstanding cancer therapies. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

## Workshop Speakers and Panelists

### **Sikander Ailawadhi, MD, *Mayo Clinic Cancer Center Jacksonville***



Dr. Ailawadhi is an Associate Professor with the Division of Hematology-Oncology at Mayo Clinic in Jacksonville and joined the Division in 2014 when he moved from the University of Southern California, Los Angeles where he was an academic faculty with Hematology. His career focus has been on treatment of plasma cell disorders, namely multiple myeloma and Waldenström's macroglobulinemia. His research has focused on understanding the epidemiology and pathophysiology of these disorders, evaluating the benefit of various therapeutic strategies in different populations based on racial-ethnic and socioeconomic diversity, as well as developing novel therapeutics by means of conducting several regional and national clinical trials. Some of these research projects have included comparison of various epidemiological and disease-related characteristics in patients with multiple myeloma, Waldenström's macroglobulinemia and chronic lymphocytic leukemia in various ethnic subgroups of the population, exploring molecular variations in multiple myeloma patients from different age groups and ethnic backgrounds, patient knowledge, compliance and psychosocial distress analyses in hematological malignancies, investigator-initiated and cooperative group clinical trials of novel therapeutic regimens in patients with these diagnoses, and secondary analyses of large databases e.g., SEER, SEER-Medicare and NCDB to understand practice patterns and outcomes across United States.

### **Daniel Auclair, PhD, *Multiple Myeloma Research Foundation***



Dr. Auclair has been with the Multiple Myeloma Research Foundation (MMRF) for over a decade (2007-2010, and 2013-now) where he is now Chief Scientific Officer. In addition to being responsible for all of MMRF preclinical and translational activities, Dr. Auclair is also deeply involved in the Multiple Myeloma Research Consortium (MMRC), a network of 25 multiple myeloma (MM) centers of excellence through which 82 MM clinic trials have been run to date. Dr. Auclair is a lead Investigator on MMRF/C MyDRUG (NCT03732703) and MyCheckpoint (NCT04150965) studies as well as on the CureCloud Research Initiative longitudinal study (NCT03657251) and a co-investigator on MMRF CoMMpass study (NCT01454297).

After completing his graduate studies in Montreal and postdoctoral fellowship at Dana-Farber Cancer Institute/Harvard Cancer Center where he conducted some of the original multiple myeloma genomic work, Dr. Auclair then spent a decade in early cancer drug discovery in biotech/pharma, mostly at Bayer where he worked, among others, on overseeing the Bayer-Millennium cancer genomics drug collaboration as well as on Nexavar and Stivarga. Dr. Auclair also worked at the Broad Institute of MIT and Harvard where as a senior manager in the Cancer Program he was involved in a wide range of academic and industry collaborations centered around cancer genomics and precision medicine initiatives. Dr. Auclair was selected by PharmaVoice in 2017 as one of the 100 Most Inspiring People in the life-sciences industry.

### **Vishal Bhatnagar, MD, *U.S. Food and Drug Administration***



Vishal Bhatnagar, MD, is a medical oncologist/hematologist and the Associate Director for Patient Outcomes in the OCE. His interests include patient reported outcomes, patient preference and incorporation of patient experience in oncology trials. His work focuses on the operational management of the OCE's Patient-Focused Drug Development program. Additionally, Dr. Bhatnagar has a strong clinical interest in multiple myeloma and has previously served as an Office of Hematology and Oncology multiple myeloma scientific liaison. Dr. Bhatnagar received his BA in Political Science and his medical degree at the George Washington University. He completed his internal medicine residency and hematology/oncology fellowship at the University of Maryland.

## **Ruemu E. Birhiray, MD, Hematology-Oncology of Indiana**



Ruemu E. Birhiray, MD is an attending physician in medical oncology, hematology, and hematopoietic stem cell transplantation at Hematology-Oncology of Indiana, and at St. Vincent Hospital in Indianapolis, Indiana. He attended medical School at the University of Benin, Benin City, Nigeria, and completed his internal medicine residency at Columbus Hospital in Chicago where he also served as Chief Medical Resident in 1994, he was a postgraduate fellow in bone marrow transplant at Johns Hopkins University in Baltimore and in medical oncology at the National Cancer Institute, National Institutes of Health in Bethesda, Maryland where his research included gene therapy and adoptive cellular immunotherapy strategies in bone marrow transplantation.

Dr. Birhiray's professional experience has also included serving as an attending physician, and Director of bone marrow transplantation and a member of Marshfield Clinic, Wisconsin and a Clinical Assistant Professor at the University of Wisconsin from 1998 to 2001. Additionally, Dr. Birhiray was appointed an Associate Professor of bone marrow transplantation at Rush University, Chicago, Illinois in 2001, prior to joining Hematology Oncology of Indiana.

Subsequently, Dr. Birhiray, served as and director of Bone Marrow Transplantation and Institutional Principal Investigator for the National Surgical Adjuvant Breast and Bowel Project of the National Cancer Institute at St. Vincent's Hospital, Indianapolis. Currently, he is also, Clinical Associate Professor, Marion University School of Osteopathic Medicine, Indianapolis, Indiana, and an Editorial Board Member of The Journal of Blood Transfusion and Hematopathology.

Projects for which Dr. Birhiray is principal investigator include reduced intensity allogeneic transplantation in hematologic malignancies, and a trial of Interferon A, CHOP, and rituximab therapy in advanced-stage follicular lymphoma, and neoadjuvant chemotherapy for breast cancer. Additional collaborations have included major phase III clinical trials. Additionally, Dr. Birhiray founded the Clinical research program at Hematology Oncology of Indiana. His awards include, "Intern of the year" from Columbus Hospital, Hope award from the Indiana Wellness community and named "best physician" by the Indianapolis monthly magazine and "top doctor" by Castle Connelly.

In 2002, Dr. Birhiray founded and has served as Chair of the annual "Indy Hematology Review", a nationally respected program providing education for hematologists and oncologists nationally and regionally, and he is also President and CEO of Indy Hematology Education, Inc.

A member of the American Society of Clinical Oncology, the American Society of Hematology, and the American Medical Association, Dr Birhiray has published in the Journal of Clinical Oncology, Leukemia, Gene Therapy and Therapeutic Apheresis, Journal of Blood Transfusion and Hematopathology, Human Immunology, Familial Cancer, Annals of Pharmacotherapy, American Journal of Health System Pharmacists, Pharmacotherapy, Journal of Oncology Practice, in addition to multiple abstracts.

Dr. Birhiray is married to Donna Marie (nee Baynard) since 1995, and they are blessed with 3 children, a daughter, Maya, born in 1999, and a son, Dirin, born in 2003, and an older daughter Meaghan who was born in 1990.


## **Yelak Biru, Patient Advocate**



Diagnosed at a young age of 25 with stage III Myeloma, Yelak is a patient turned Myeloma research advocate and has been able to successfully integrate Myeloma into his life for almost a quarter of a century. Yelak is a member of the International Myeloma Foundation board of directors, ECOG's patient advocate and myeloma committees, NCI's Myeloma Steering Committee (MYSC), various pharma patient leadership councils, and is active on tweeter under the handle @NorthTxMsg. He was a featured presenter at the 2015 and 2017 European Hematology Associate satellite symposiums on Relapsed and Refractory Myeloma, IMWG's conference series on drug prices and access to therapies. He speaks frequently at IMF patient and family seminars, a two-day educational emersion program for myeloma patients and their families, on the topic of "Living Well Successfully." His areas of

@FDAOncology

@AACR

 Join the conversation with #MyelomaDiversity

advocacy interest include, patient education, clinical trial design, quality of life improvements, drug accessibility, minority engagement, access disparities and global capacity building of patient organizations. Yelak has a master's degree in computer science and leads data and analytics initiatives for a fortune 50 company.

### **Kunthel By, PhD, U.S. Food and Drug Administration**



Kunthel By is a statistical reviewer in the Office of Biostatistics (OB) at the Center for Drug Evaluation and Research at FDA. He supports both malignant and benign hematology, including myeloma, lymphoma, and leukemia. Prior to oncology, Dr. By was a safety reviewer in OB, supporting the Office of Surveillance and Epidemiology at FDA. He has extensive experience designing and analyzing post-market observational studies using VA and CMS claims data to assess drug safety. He was also involved with FDA's efforts to assess whether prescription opioids formulated with abuse-deterrent properties are effective at reducing abuse and abuse-related outcomes in the community and was instrumental to the understanding of the limitations of data used for such assessments.

### **Craig E. Cole, MD, Michigan State University Breslin Cancer Center**



Dr. Craig Cole is a board-certified hematologist who received his Bachelor of Science degree in physiology at Michigan State University and the School of Lyman Briggs. Dr. Cole went on to receive his doctoral degree at the Ohio State University College of Medicine and completed his Internal Medicine Residency and Hematology Fellowship at the University of Michigan. He has had an opportunity to do post-fellowship laboratory research at the Jerome Lipper Multiple Myeloma Center of Medicine at the Dana Farber Cancer Institute. He subsequently an attending hematologist at Gundersen Health System in La Crosse, Wisconsin; the western campus of the University of Wisconsin School of Medicine and Public Health. Dr. Cole then returned as a Clinical Assistant Professor at the

University of Michigan in the Division of Hematology/Oncology where he continued his focus on clinical research in multiple myeloma. In May of 2019 he returned to Michigan State University College of Human Medicine at Breslin Cancer Center as the director of the clinical research in hematology and multiple myeloma. Dr. Cole has participated in over 50 clinical trials in multiple myeloma and malignant hematology.

### **Ruthanna Davi, PhD, Acorn AI**



Ruthie Davi is a Statistician and Vice President, Data Science at Acorn AI, a Medidata company, and has a background in pharmaceutical clinical trials with more than 20 years working as a Statistical Reviewer, Team Leader, and Deputy Division Director in the Office of Biostatistics in CDER at FDA. At Acorn AI Ruthie is part of a team creating analytical tools to improve the efficiency and rigor of clinical trials, an example of which is her Synthetic Control Arm work. Ruthie holds a PhD in Biostatistics from George Washington University.

### **Laura Fernandes, PhD, U.S. Food and Drug Administration**



Dr. Laura Fernandes is a statistical reviewer in the Office of Biostatistics at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). She received her PhD in biostatistics from the University of Michigan, Ann Arbor. Prior to joining the FDA, she worked as a research analyst supporting the cancer center at University of Michigan. She also held positions as a statistical programmer at GlaxoSmithKline (GSK) prior to her PhD. At the FDA she supports the division of oncology products in hematology and solid tumors in the division of oncology. Her research focusses on clinical trials, adaptive dose-finding designs and disparities in clinical trials in oncology.

## Margaret Foti, PhD, MD (hc), American Association for Cancer Research



Margaret Foti, PhD, MD (hc), is the chief executive officer of the American Association for Cancer Research (AACR), the first and largest cancer research organization in the world. Under her visionary leadership, membership has grown from about 3,000 members to over 40,000 in 120 countries, and the AACR's portfolio of peer-reviewed scientific journals has increased from one to eight.

Foti progressed through several key editorial and management roles in scientific publishing to become chief executive officer. She launched seven major peer-reviewed scientific journals: *Cancer Epidemiology, Biomarkers & Prevention*; *Clinical Cancer Research*; *Molecular Cancer Therapeutics*; *Molecular Cancer Research*; *Cancer Prevention Research*; *Cancer Discovery*; and *Cancer Immunology Research*. She also helped launch *Cancer Today*, a magazine for cancer patients, survivors, and their families and caregivers, as well as a new AACR publication, titled *Leading Discoveries*.

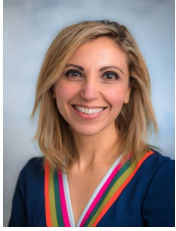
A graduate of Temple University, Foti is one of the most influential voices in advancing the field of cancer research, both in the United States and abroad. She was elected president of three professional societies in scholarly publishing and in cancer research. She has also served as a board member, committee member, and consultant to a number of other nonprofit organizations. There is a legacy of young women, minority scientists, and investigators-in-training whose careers have been advanced as a result of her mentorship and support.

Under Foti's leadership, the AACR has served with distinction as the Scientific Partner of Stand Up To Cancer (SU2C). In this capacity, Foti and the AACR staff have brought significant expertise to their work with SU2C, especially in the scientific peer review of projects, scientific project management, grants administration, communications, and science policy.

Foti's leadership was instrumental in the production of the first landmark AACR Cancer Progress Report in 2011 and the equally important subsequent annual reports which celebrate advances in basic, translational, and clinical cancer research, all of which has had a major impact on therapeutic development and improved patient care.

Foti's contributions have been widely recognized by numerous awards from organizations around the world. Her lengthy list of formal recognitions includes honorary degrees in medicine and surgery from the University of Rome La Sapienza and the University of Catania in Sicily, and an honorary degree in medicine from the University CEU of San Pablo in Madrid. She was recognized with the 2018 Women for Oncology Award from the European Society for Medical Oncology, the 2016 PHL Life Sciences Ultimate Solution Award, the Ovarcome Excellence 2016 Award, the 2016 James Ewing Layperson's Award from the Society of Surgical Oncology, the 2016 Honorary Member Award from the Oncology Nursing Society, and as a 2015 honoree of "the one hundred" by Massachusetts General Hospital Cancer Center. Additionally, she received the 2015 Children's Champion Award from the Children's Hospital of Philadelphia, the 2014 Ellen V. Sigal Advocacy Leadership Award from Friends of Cancer Research, the 2014 Morton M. Kligerman Visiting Professorship Award from the University of Pennsylvania, the 2013 Stanley P. Reimann Honor Award from Fox Chase Cancer Center, and the 2013 Distinguished Partner in Hope Award during the Annual Colorectal Cancer Conference hosted by the Abramson Cancer Center of the University of Pennsylvania. In 2007, the AACR established the first AACR Margaret Foti Award for Leadership and Extraordinary Achievements in Cancer Research, which is given annually in her name. Her visionary leadership, combined with her steadfast focus on the AACR's mission, continues to drive the field forward towards the vital goal of preventing and curing all cancers.

## **Irene M. Ghobrial, MD, *Dana-Farber Cancer Institute***



Dr. Irene Ghobrial is a Professor at Dana-Farber Cancer Institute (DFCI), Harvard Medical School, Boston, MA and an Associate member of the Broad Institute, Cambridge, MA. She is the Director of the Clinical Investigator research program at Dana-Farber Cancer Institute, co-director of the Center for Prevention of Progression (CPOP) and co-leader of the Blood Cancer Research Partnership (BCRP). She is also the director of the Michele & Stephen Kirsch Laboratory.

She received her medical degree from Cairo University School of Medicine, Egypt. She completed her internal medicine training at Wayne State University, MI, and her Hematology/Oncology subspecialty training at Mayo Clinic College of Medicine, MN.

Her research focuses on understanding mechanisms of tumor progression from early precursor conditions such as monoclonal gammopathy of undetermined significance (MGUS) and Smoldering disease to symptomatic Multiple Myeloma (MM) and Waldenstrom Macroglobulinemia (WM). She specifically focuses on the role of the malignant bone marrow niche in regulating disease progression. She is interested in the development of new molecular/genomic markers that predict progression in precursor conditions which can identify patients who should be eligible for therapeutic interventions to prevent progression or potentially cure the disease at the early stages of the disease before clonal evolution occurs.

She authored or co-authored over 250 publications and book chapters and has received funding support from the National Cancer Institute as well as multiple foundations including Stand Up-to Cancer, Leukemia and Lymphoma Society, Multiple Myeloma Research Foundation and International Myeloma Foundation. She has received multiple awards including the Ken Anderson Young Investigator Award, Robert A. Kyle Award for Research in Waldenstrom Macroglobulinemia, and Mentor of the Year Award at DFCI.

## **Wan-Jen Hong, MD, *Genentech***



Dr. Wan-Jen Hong is a Senior Medical Director at Genentech focusing on clinical development of novel agents in hematologic malignancies. Dr. Hong received her MD from Stanford University School of Medicine and completed her residency and fellowship in hematology/oncology at Stanford. After completing her clinical training, she did her post-doctoral research in leukemia stem cells in myeloid malignancies. She then decided to pursue a career in industry and joined Genentech in 2014 and is now a global development lead focusing on myeloma and myeloid malignancies. She also continues to hold an adjunct clinical faculty position at Stanford.

## **Bindu Kanapuru, MD, *U.S. Food and Drug Administration***

Dr. Kanapuru is the Acting Clinical Team Lead for the Multiple Myeloma team in the Division of Hematologic Malignancies 2 (DHM2) in the Office of Oncologic Diseases (OOD) at the FDA. Her areas of interest include: the treatment of hematological malignancies, geriatric oncology and novel trial designs. She also serves as the scientific liaison for geriatric hematology.

Dr. Kanapuru joined the FDA in 2015. She is a board-certified hematologist-oncologist. Dr. Kanapuru completed her fellowship in hematology and oncology at the University of Maryland Medical Center in Baltimore. During her fellowship she did her research at the National Institute on Aging on mechanisms of unexplained anemia and cancer incidence in older adults, and co-authored multiple publications and book chapters.

**Rachel Kobos, MD, *Janssen Pharmaceuticals***



Dr. Kobos is an Executive Medical Director at Janssen Pharmaceuticals. She has been part of the daratumumab clinical team at Janssen since 2016 and involved in the development and implementation of clinical trials in multiple myeloma during this time. Prior to joining Janssen she was an assistant professor at Memorial Sloan Kettering Cancer Center in the pediatric leukemia and stem cell transplant services.

**Shaji K. Kumar, MD, *Mayo Clinic Cancer Center***



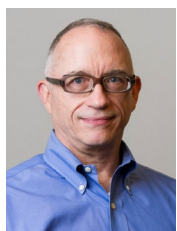
Shaji K. Kumar, MD, is Consultant in the Division of Hematology and Professor of Medicine at Mayo Clinic Cancer Center in Rochester, Minnesota. He serves as Medical Director for the Mayo Clinic Cancer Center Clinical Research Office and Vice Chair for research in the Department of Medicine, Mayo Clinic.

Dr. Kumar received his medical degree from the All India Institute of Medical Sciences in New Delhi, India. His postdoctoral training included a residency in internal medicine from the All India Institute of Medical Sciences, followed by an internal medicine residency and a hematology/oncology fellowship at the Mayo Graduate School of Medicine in Rochester, Minnesota.

Dr. Kumar's research focuses on the development of novel drugs and drug combinations for the treatment of myeloma. His laboratory focuses on understanding the role of bone marrow microenvironment in the development and progression of myeloma.

Dr. Kumar serves as Co-Chair of the NCI Myeloma Steering Committee as Chair of the NCCN Multiple Myeloma Guidelines Panel.

**Richard F. Little, MD, *National Cancer Institute***



Dr. Little is a Senior Investigator and Head of the Blood and HIV-related Cancer Therapeutics section in the Clinical Investigations Branch of the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, at the National Institutes of Health. Dr. Little is also an adjunct investigator in the HIV and AIDS Malignancy Branch of the National Cancer Institute.

**Kathleen Maignan, MSN, NP, *Flatiron Health***



Kathleen Maignan, AGPCNP-BC, MSN, OCN is a Sr. Clinical Director at Flatiron Health, focused on supporting their hematology portfolio. She comes with an extensive background centered in oncology nursing and clinical research, and has a special interest in investigating health disparities. She received her MSN from CUNY Hunter, and continues to serve as a Nurse Practitioner focused on Bone Marrow and Stem Cell transplantation at Weill Cornell Medicine.



## **Mihaela Popa McKiver, MD, PhD, *Bristol-Myers Squibb***



Mihaela Popa McKiver, currently Hematology Clinical Program Lead at BMS, completed her medical and residency training in Geriatrics in Romania. During her doctoral studies at the University of South Florida, School of Aging Studies, she developed a research agenda focused on health disparities in older adults. She continued and expanded this research agenda in older cancer patients during her post-doctoral fellowship at Moffit Cancer Center. With over 10 years of clinical trials experience in hematological malignancies and immunotherapies, in her current role she is leading the clinical development of elotuzumab and nivolumab in multiple myeloma.

## **Khalid Mezzi, MD, *Amgen***



Khalid received his MD from Faculty of Medicine in Rabat, Morocco, focusing his areas of research in nephrology and pediatric nephrology. He also earned his Executive Master of Business Administration (EMBA) from University of Quebec in Montreal, Canada.

Throughout his 25 years career in the Pharmaceutical Industry, Khalid has worked within the clinical, medical affairs and commercial functions, on the development and the delivery of new treatments to patients in a variety of cancers, and across different regions throughout the world (Europe, Africa, and North America)

Prior to joining Amgen, Khalid was the US Medical Director for the Oncology Franchise at Onyx Pharmaceuticals, the Amgen subsidiary where he led the Medical activities for Nexavar in Liver and Thyroid cancer. Prior to that, Khalid served as the Medical Affairs Lead at OTSUKA Canada Pharmaceutical Inc. where he oversaw the Field Medical and Medical Advisors teams, led the medical prelaunch activities for the CNS and the cardio-renal products. Khalid has also served as the Oncology Medical Lead where he played a key role in launching the OTSUKA Oncology Franchise in Canada. Khalid has joined AMGEN as of June 1st, 2015 and he is currently serving as the Medical Affairs, Global Multiple Myeloma Platform Lead.

## **Joseph Mikhael, MD, Med, FRCPC, FACP, *International Myeloma Foundation | TGen***



Dr. Mikhael is a Professor in the Applied Cancer Research and Drug Discovery Division at the Translational Genomics Research Institute (TGen), an affiliate of City of Hope Cancer Center. He is also the Chief Medical Officer of the International Myeloma Foundation (IMF). He facilitates and promotes myeloma research worldwide, especially in underprivileged countries.

Dr. Mikhael is a consultant hematologist and Director of Myeloma Research at the HonorHealth Research Institute where he conducts phase 1 clinical trials. He also serves as a Councilor on the Executive of the American Society of Hematology. He also recently led the ASCO guidelines for multiple myeloma.

Dr. Mikhael was recently a hematologist at Mayo Clinic Arizona where he served as a Professor at the Mayo College of Medicine, Associate Dean of Graduate Medical Education and Deputy Director - Education of the Mayo Clinic Cancer Center. He has been recognized with numerous awards in education including being in the Mayo Clinic Resident and Fellow Association Hall of Fame as Educator of the Year. He was also recently named in the Top 100 Doctors in the United States.

He specializes clinically in plasma cell disorders, namely multiple myeloma, amyloidosis and Waldenstrom's macroglobulinemia. Dr. Mikhael is currently the principal investigator of many clinical trials, primarily in multiple myeloma. His other clinical research interests also include pharmaco-economics, communication skills and media relations. He has published over 150 peer reviewed articles in these fields. He lectures internationally on a regular basis. He is an active

member of the International Myeloma Working Group, and serves on the editorial board of the Journal of Clinical Oncology.

Dr. Mikhael is leading the IMF African American initiative which seeks to improve the care delivered to African Americans with myeloma – a disease with double the incidence in African Americans than Caucasians. Dr. Mikhael also spends about 20% of his time in the third world seeking ways to enhance access to myeloma therapies in underprivileged countries.

### **Edith P. Mitchell, MD, MACP, FCPP, Sidney Kimmel Cancer Center at Thomas Jefferson University**



Edith Peterson Mitchell, MD, MACP, FCPP, is Board Certified in Internal Medicine and Medical Oncology and is Clinical Professor, Department of Medicine and Medical Oncology at Sidney Kimmel Medical College at Thomas Jefferson University and Associate Director for Diversity Programs and Director of the Center to Eliminate Cancer Disparities for the Sidney Kimmel Cancer Center at Thomas Jefferson University.

Dr. Mitchell has spent her medical career helping individuals in medically underserved areas to realize that simple changes in lifestyle can have a dramatic impact on cancer care. Through her work, Dr. Mitchell has demonstrated the importance of community service and outreach especially to those individuals who may not have the means to seek out more conventional medical advice.

Dr. Mitchell received a bachelor of science in Biochemistry “with distinction” from Tennessee State University and her medical degree from the Medical College of Virginia in Richmond. In 1973, while attending medical school, Dr. Mitchell entered the Air Force and received a commission through the Health Professions Scholarship Program. She entered active duty after completion of her internship and residency in Internal Medicine at Meharry Medical College and a fellowship in Medical Oncology at Georgetown University.

Dr. Mitchell’s research in breast, colorectal, and pancreatic cancers and other GI malignancies involves new drug evaluation and chemotherapy, development of new therapeutic regimens, chemoradiation strategies for combined modality therapy, patient selection criteria and supportive care for patients with gastrointestinal cancer. She travels nationally and internationally teaching and lecturing on the treatment of gastrointestinal malignancies.


Dr. Mitchell has authored and co-authored more than 100 articles and book chapters as well as many abstracts on cancer treatment, prevention, and cancer control. As a distinguished researcher, she has received many Cancer Research and Principal Investigator Awards including a recent Promise Grant from the Susan G. Komen Foundation. She serves on the National Cancer Institute Review Panel and the Cancer Investigations Review Committee, the Clinical Trials and Translational Research Advisory Committee, serves as Co-Chair of the NCI Disparities Committee, and is a member of the NIH Council of Councils. Because of her experience in the cancer research community Dr. Mitchell was selected to serve as a member of the NCI’s Blue Ribbon Panel convened to advise the National Cancer Advisory Board on Vice President Biden’s National Cancer Moonshot Initiative.

Dr. Mitchell holds leadership positions in the American Society of Clinical Oncology and served as the 116th President of the National Medical Association serving from August 2015 to August 2016. She also serves on the editorial board of the Journal of the National Medical Association and on the Board of Trustees for Geisinger Commonwealth Medical College and Tennessee State University.

Among her many honors, Dr. Mitchell has received The ‘Tree of Life’ Award which recognizes health professionals who have made extraordinary contributions to health management in both the local and global community. Dr. Mitchell was awarded the American Cancer Society’s Cancer Control Award for her significant commitment to research, education, and diversity and Research Award by the Council of Women Physicians of The National Medical Association. In 2010 she received the National Cancer Care Physician of the Year Award in recognition of her outstanding contribution of time and talent. Other awards for Dr. Mitchell include the 2009 Looking Glass Award presented by the Living With Cancer

**@FDAOncology**

**@AACR**

 Join the conversation with #MyelomaDiversity

Foundation and the Women in Medicine Research Award from the National Medical Association. She received the 2011 Practitioner of the Year Award by the Philadelphia County Medical Society and the 2012 Humanitarian Practitioner of the Year Award by the American Society of Clinical Oncology. In 2013 she received the Lifetime Achievement Award from Alpha Kappa Alpha Sorority, Inc., was inducted into the National Historical Black College Hall of Fame and also received the Octavius Valentine Catto Award for community service in the City of Philadelphia from the Mann Center. In 2015 she received the Medical Tree of Life Award from Debbie's Dream Foundation: Curing Stomach Cancer. In 2016, Dr. Mitchell was selected as the Historically Black College Alumnus of the Year. In 2017, Dr. Mitchell was inducted as an Honorary Member of the American Society for Radiation Oncology. In 2018, she received the Edith P. Wright Breast Cancer Foundation Eydie's Angels Loving Hands Service Award and the Jefferson Health Achievement Award in Medicine. Most recently, she received the 2019 Ultimate Solution Award from Philadelphia Life Sciences, the Distinguished Citizen Award from Kappa Alpha Psi Fraternity, Inc., and was honored by the Geisinger Commonwealth School of Medicine with their Well-Being Award.

In addition to her medical achievements, Dr. Mitchell is a retired United States Air Force Brigadier General, having served as the Air National Guard Assistant to the Command Surgeon for US Transportation command and headquarters Air Mobility Command (AMC) based at the Scott Air Force Base in Illinois. General Mitchell has been awarded over 15 military service medals and ribbons including the Legion of Merit, Meritorious Service Medal, Air Force Achievement and Commendation Medals, National Defense Service Medal, and Humanitarian Service Medal. Dr. Mitchell was selected for inclusion in America's Top Oncologists. Dr. Mitchell is a Fellow of the American College of Physicians; member of our Society; also the American Medical Association, the National Medical Association, Aerospace Medical Association, Association of Military Surgeons, the Medical Society of Eastern Pennsylvania, the Eastern Cooperative Oncology Group, Radiation Therapy Oncology Group, and the National Surgical Adjuvant Breast and Bowel Project.

On a personal note, Dr. Mitchell enjoys gardening, quilting, listening to jazz and rock music, and spending time with her family. She and husband Delmar have been married for forty-nine years and have two daughters, Dale and DeAnna, one granddaughter, Gabriella, and two grandsons, Jude and Luke.

### **Nikhil C. Munshi, MD, *Dana-Farber Cancer Institute***




Nikhil C. Munshi, MD, is the Kraft Family Chair and Professor of Medicine at the Harvard Medical School and the Director of Basic and Correlative Science, and Associate Director of the Jerome Lipper Myeloma Center at the Dana Farber Cancer Institute. He is an attending physician at the Brigham and Women's Hospital, Harvard Medical School. Dr. Munshi received his medical degree from the S.S.G. Hospital and M.S. University, Baroda India. He completed a Research Fellowship in Medical Oncology at the Johns Hopkins Oncology Center in Baltimore, Maryland, and a clinical fellowship in hematology/oncology at the Indiana University Medical Center. Prior to joining Dana Farber, Dr. Munshi was Professor of Medicine and Director of the Clinical Gene Transduction Laboratory at the University of Arkansas.

Dr. Munshi's research focus spans both basic sciences to understand genomic changes in myeloma and elucidate molecular mechanisms driving the genomic instability in cancer, to translational approaches directed at improving diagnosis and prognosis as well as therapeutics. Dr. Munshi's clinical interests include CAR T-cell therapy in multiple myeloma and developing novel targeted therapeutics including novel antigen-directed and immune effector cell therapy/vaccine approaches.

He has over 500 peer-reviewed publications and book chapters. Dr. Munshi has mentored over 70 junior faculty, post-doctoral fellows, medical residents, as well as medical and undergraduate students. A number of them are now independent scientists, physicians, and professionals. His grant support has included Program Project and SPORE grants from National Institutes of Health, and VA Research grants. He is the current President of the International Myeloma Society. He has received number of Awards including a Leukemia Society of America Scholar in Translational Research Award, the Dr. B.C. Roy National Award by the president of India in 2016 and the prestigious "Waldenstrom's Award" for Most Distinguished Lifetime Achievement in Myeloma Research in 2013.

**@FDAOncology**

**@AACR**

 Join the conversation with #MyelomaDiversity

## Ajay K. Nooka, MD, *Winship Cancer Institute of Emory University*



Dr. Ajay Nooka is an Associate Professor in the Department of Hematology and Medical Oncology at the Winship Cancer Institute of Emory University. He earned his medical degree from Andhra Medical College in India before relocating to the United States. He received a Masters' in Public Health from the University of Texas School of Public Health in Houston, Texas and then completed his internship and residency at the Northeastern Ohio University College of Medicine, Ohio. He pursued a fellowship in Hematology and Oncology at Emory University School of Medicine in Atlanta, Georgia where he also served as Chief Fellow before he joined faculty.

Board certified in Hematology and Medical oncology, Dr. Nooka primarily focuses on multiple myeloma treatment and research. He is involved in numerous professional organizations, including the American Society of Clinical Oncology, the American Society of Hematology, and the American Society for Blood and Marrow Transplantation.

Dr. Nooka's interests as a clinical investigator focuses on multiple myeloma and bone marrow transplant. His research interests include integrating genomic and clinical data on a uniform platform to risk-stratify myeloma; and evaluate newer myeloma therapeutic strategies aimed at prolonging survival in myeloma patients. In addition to leading several investigator-initiated and industry-sponsored clinical trials, he is a recipient of several awards and grants including the Multiple Myeloma Research Foundation Accelerator Award and the International Myeloma Foundation Research Grants. He has published more than 200 articles and abstracts in high quality peer-reviewed journals including New England Journal of Medicine, Journal of Clinical Oncology, Blood, Leukemia, Lancet Oncology, Cancer. In addition, he serves on the editorial board of the American Journal of Clinical Oncology and as an invited or ad hoc reviewer for several prestigious journals including Lancet Oncology, Journal of Clinical Oncology, Cancer, Bone Marrow Transplantation and Biology of Blood and Marrow Transplantation.

## Angela X. Qu, MD, PhD, *Parexel*



Dr. Qu, Vice President of Translational Medicine at Parexel, is an innovative subject matter expert and team leader in Genomic Medicine and Clinical Research. She has 20 years of experience working in pharmaceutical R&D and CRO clinical development. At Parexel, she is leading therapeutic strategy development and implementation of genomics and biomarker studies, provision of scientific guidance, and consulting on partnerships with sponsors across broad therapeutic areas with a focus in Oncology and Immuno-oncology.


Dr. Qu has drug development experience spanning from discovery to clinical development. Prior to joining Parexel, Dr. Qu served in increasingly senior roles in large pharma including GSK, P&G Pharmaceutical, where she has led many complex multi-omics, disease pathway modeling, and biomarker development projects across broad therapeutic areas. Dr. Qu also has extensive clinical development experience via serving as medical director to design clinical trials, monitor and assess safety, co-author and signoff study reports. Prior to joining pharmaceutical industry, Dr. Qu held research faculty position at Columbia Medical Center of Columbia University.

Throughout her career she has been engaged in leading and applying scientific innovation to translational medicine. In addition to invited book chapters and conference speakers, she has authored over 40 publications in peer-reviewed journals including *Science* and *Nature* for her work in translating complex genomics and clinical data in precision medicine and accelerated therapy development.

Dr. Qu earned her MS & PhD in Biomedical Informatics from Columbia University, University of Cincinnati /Cincinnati Children's Hospital Medical Center. She received her medical degree and completed her residency training from Shandong Medical University and Peking Union Medical College, followed by Postdoctoral training in Genomics and Cancer Genetics at Columbia University Medical Center.

@FDAOncology

@AACR

 Join the conversation with #MyelomaDiversity

## **Joseph M. Unger, PhD, MS, *Fred Hutchinson Cancer Research Center***



Dr. Joseph Unger is a health services researcher and biostatistician and a faculty member at the Fred Hutchinson Cancer Research Center. He has developed innovative strategies to the application of big data strategies and data linkages to better understand cancer patients' treatment outcomes and disparities, especially as they pertain to disparities in access and outcomes in clinical trials. He has been at the forefront of efforts to link Medicare claims data to clinical-trial records to address novel research questions. Dr. Unger also has extensive expertise in the design and analysis of prospective clinical trials that examine disease symptoms and treatment side effects, patient quality of life and delivery of cancer care. His research has revealed that factors such as annual household income and

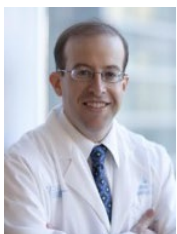
having multiple simultaneous health conditions, or comorbidities, can affect patients' participation in clinical trials, as can structural and logistical issues such as the availability of a trial at the center where the patient is receiving treatment. Dr. Unger is a member of the SWOG Cancer Research Network at SWOG's Statistics and Data Management Center (SDMC), where he serves as the SWOG SDMC NCORP Vice-Chair and is the Principal Investigator for the SDMC Cancer Care Delivery Program Project. He also serves the National Cancer Institute's Symptom Management and Quality of Life Steering Committee and the Cancer Care Delivery Research Steering Committee.

## **Tiffany H. Williams, *Patient Advocate***



Tiffany H. Williams was diagnosis with multiple myeloma in November 2013. The life changing treatment and remission process led her to transforming her life's purpose as a myeloma advocate focused on increasing awareness and improving outcomes. Locally, she co-founded the Charleston Area Multiple Myeloma Network Group, Charleston, SC, and founded the Orangeburg Myeloma Network Group, Orangeburg, SC. Tiffany has been a speaker at multiple MM awareness meetings, she works with the International Myeloma Foundation (IMF) Diversity Council, and several industry and pharmaceutical companies. She shares her experiences as a myeloma cancer survivor to speak truth to those experiences in her community and beyond.

## **William A. Wood, MD, *University of North Carolina, Lineberger Comprehensive Cancer Center***




Dr. Bill Wood is a hematologist and oncologist and focuses on blood cancers, hematopoietic cell transplantation and cellular therapy. His research looks at measuring and intervening upon physical function during and after cancer treatment. As part of this, he is doing work on digital biomarker development, physiologic sensor integration, home-based functional assessments, patient reported outcomes implementation, and health coaching. His health coaching program, "HealthScore," will soon be available to both transplant and non-transplant cancer patients through the UNC Comprehensive Cancer Support Program, where he is the medical director of health coaching and physical activity. Dr. Wood is interested in using new technologies to improve the cancer patient experience.

Dr. Wood is involved in a number of local, state-wide, national and international digital medicine collaborations and research initiatives. He is the current chair of the American Society of Hematology Research Collaborative's Data Hub Oversight Group. The ASH Research Collaborative Data Hub aims to become one of the world's largest repositories of research grade clinical data in benign and malignant hematologic diseases, starting with sickle cell disease and multiple myeloma, with expansion to other diseases over the next several years.

Dr. Wood obtained his undergraduate degree in government from Harvard, his medical degree at Duke, his Master's in Public Health from UNC, and did his residency training in the Harvard internal medicine and pediatrics program before coming to UNC for his adult hematology/oncology fellowship where he has remained on faculty since finishing training.

@FDAOncology

@AACR

 Join the conversation with #MyelomaDiversity