FDA Broad Agency Announcement Day

October 25, 2023

Speaker Bios

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2023 BAA Day Presenters List:

(In order of appearance)

- Ms. Shaila Shaheed, Supervisory Program Manager, ORSI
- Ms. Vidya Vish, Supervisory Contract Specialist, OAGS
- Dr. Sameer Raney, CDER
- Dr. Jessie Floura, CDER
- Dr. Kimberly Maxfield, CDER
- Dr. Michele Lee, CDRH
- Dr. Julie Schneider, OCE
- Mr. Robert Orr, OCET
- CAPT Brianna Skinner, One Health
- Dr. Joyce Obidi, OWH
- Dr. Kinnera Chada, ORSI
- Mr. Ian Weiss, OAGS

Shaila Shaheed, MS, PM, COR II

OC/OCS/Office of Regulatory Science and Innovation (ORSI)

Shaila Shaheed joined ORSI in 2013, and serves as the leader for a regulatory science program focused on extramural research and development with an annual investment portfolio of 70+M. She is responsible for the scientific, administrative, and/or technical aspects of the program, including developing annual solicitation announcement, coordinating, and leading technical panel evaluation and signing off on panel recommendations and correspondences. Shaila provides programmatic technical assistance to various FDA subject matter experts (SMEs) interested in regulatory science research to fulfill an unmet area of need. She provides coordination and guidance for the centers, offices, and related programs agency-wide. She is well versed in FDA's Focus Area of Regulatory Science (FARS) report 2021, 2022 and the FDA Strategic Science Plan 2011. She works with FDA SMEs to identify regulatory science research gaps and science priorities to update the BAA solicitation announcement for research area of interest. She supervises a team of project managers and coordinators in ORSI. Shaila and her team manages the BAA SharePoint solution with data repositories and business process workflows.

Shaila is familiar with the OCS Challenge Grant and the Center of Excellence (CERSI) program at ORSI as she helped support these programs in the past. Before joining ORSI, Shaila worked as a Business Program Manager at ORA, FDA for three years. In this role, she led and managed the Laboratory Information Management System (LIMS), a large and complex scientific IT system related project for 13 field ORA labs, HQ and 2 mobile labs.

Before entering the regulatory agency, Shaila worked at a Contract Research Organization (CRO) for more than seven years. As an IT Quality Control, she assisted in implementing and validating 30+ local, global web and client-server computer applications in compliance with GLP, GCP, GMP, 21 CFR part 11. As a Research Assistant, Shaila performed various non-clinical genetic toxicology lab assays.

Shaila has been a Contracting Officer's Representative (COR) for over ten years and holds a Project Management Master Certificate from George Washington University. She has a M.S. in Biotechnology with a concentration in Regulatory Affairs from Johns Hopkins University and a Bachelor of Science in Biology degree from George Mason University.

Vidya Vish

Office of Finance, Budget, Acquisitions, and Planning/Office of Acquisitions and Grants Services

Vidya Vish serves as the Director of the Division of Acquisition Operations in FDA's Office of Acquisitions and Grants Services. In this capacity, she has the overall management and oversight of three branches and a division responsible for awarding approximately 1,800 contracts and Broad Agency Agreements. She is responsible for the oversight of her staff and the Federal Acquisition Certification in Contracting (FAC-C), FAC-COR, and FAC-P/PM programs. She began her civil service career as a Contract Specialist at the Department of Education. During her over 20 years of federal service, she has held various positions including Contracting Officer, Team Leader, Branch Chief, and Division Director. Before moving to the FDA eight years ago, she has more than 12 years of experience doing BAA actions.

Vidya is a Federal Acquisition Certification-Contracting (FAC-C) level III Certified Contracting Officer with an Unlimited Warrant. Vidya's dedication to service has garnered many awards over her career to include the 2023 Office of Operations Honor, Excellence in Awarding Contracts to Small Businesses, and many other Leadership Excellence awards.

Vidya is married, has two children, and resides in Potomac, Maryland.

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Sammersingh Raney, PhD

Dr. Raney is the Associate Director for Science in the FDA's Office of Research and Standards where he oversees the research portfolio of FDA's generic drug science and research program. He also serves as the Chief Scientific Advisor for topical product bioequivalence issues in FDA's Office of Generic Drugs. Dr. Raney is a thought leader with over 30 years of experience in topical and transdermal drug products, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. He has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, and serves on multiple expert committees and panels for the U.S. Pharmacopeia. Dr. Raney holds a Bachelor's Degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Jasdeep (Jessie) Floura, PMP, FAC-COR III

Jessie Floura serves as Acting, Associate Director of Regulatory Affairs at the Office of Research and Standards (ORS), Office of Generic Drugs (OGD), CDER/FDA. Since joining OGD in 2018, she has held roles of various responsibilities, including Project Manager and Team Lead of the Research Management team. Prior to her OGD career, Jessie served as Branch Chief of Customer Relationship Management at the NIH's Electronic Research Administration within the Office of the Director. Jessie obtained her bachelor's in Economics and Mathematics from The University of Toronto and holds a certification in Project Management as well as a certification in Contractor Officer Representative Level III.

Kimberly Maxfield, PhD

Dr. Kimberly Maxfield is a PhD pharmacologist and regulatory scientist whose career focuses on the intersection between public health, drug development, policy, and regulation of therapeutic proteins. Currently, she serves as the scientific lead on the Biosimilar User Fee Act (BsUFA) III regulatory research pilot program in the U.S. Food and Drug Administration (FDA) Office of Therapeutic Biologics and Biosimilars (OTBB). Prior to OTBB, Dr. Maxfield led development of evidence-based guidance and policy in the FDA Office of Clinical Pharmacology (OCP). She also led the CDER Immunogenicity Review Committee (IRC) defining and leading multidisciplinary and integrated approaches to immunogenicity risk assessments. Additionally, Dr. Maxfield established and administered the CDER postgraduate fellowship program for training in policy development and regulatory science that aimed to promote therapeutic individualization through policy evaluation and development.

Dr. Maxfield received her PhD in Pharmacology from the School of Medicine at the University of North Carolina at Chapel Hill. Due to a laboratory relocation, she performed a half of her dissertation research at University of Texas Southwestern Medical Center (UTSW) in Dallas, Texas. Her doctorate focused on the systematic dissection of tumor cell biology through pan-genomic high throughput screening for the rational design of new therapeutic and dose combinations. Dr. Maxfield completed post-doctoral fellowships at the National Academies of Sciences, Engineering, and Medicine (NASEM) and at the FDA in health policy and regulatory science. The NASEM fellowship focused on the clinical implementation of immunotherapies and drug development paradigms in oncology. The FDA fellowship addressed the public health impact of FDA external engagement. Also, as a life-long learner, she is currently enrolled in a Master of Public Health with a Global Health Certificate program to focus on intersecting her scientific, technical, and regulatory experience with public health practice and policy.

Michele Lee, PhD

Dr. Michele Lee is a Regulatory Science Program Manager on the Partnerships to Advance Innovation and Regulatory Science (PAIRS) team in the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration. She coordinates CDRH's regulatory science research intramural and extramural funding programs and manages CDRH's public-private partnerships. She also serves on the Regulatory Science Workstream for CDRH's Advancing Health Equity Strategic Priority and the CDRH Critical Path Program Advisory Board. Dr. Lee began her time at the FDA in 2018 as a lead reviewer and materials chemistry consultant in Plastic Surgery Skin & Wound Healing Devices. Prior to joining the FDA, she completed her Ph.D. in Materials Science & Engineering at the University of Southern California. Her doctoral research focused on synthesis and characterization of novel stimuli-responsive polymers. Dr. Lee also holds a B.S. degree in Materials Science from Massachusetts Institute of Technology, where she conducted research in multifunctional coatings for nanoparticles.

Julie Schneider, PhD

Julie Schneider, Ph.D. is Associate Director for Research Strategy and Partnerships at the FDA Oncology Center of Excellence (OCE). In this role, she oversees the OCE Scientific Collaborative which supports applied research activities addressing topics identified during regulatory review of oncology products. She previously ran the HHS Entrepreneurs-in-Residence Program within the HHS IDEA Lab and worked in several roles at the National Cancer Institute (NCI) focused on developing new research funding opportunities. Julie initially joined the NCI as an AAAS Science and Technology Policy Fellow and obtained her doctoral degree in genetics from the University of Oxford and her bachelor's degree in biology from Yale.

Robert "Bobby" Orr

Robert "Bobby" Orr is a biologist and project manager for the MCMi extramural Regulatory Science Program. He currently serves as a contracting officer representative (COR) and technical point of contact for both OCET and OCS contracts and grants. Prior to joining FDA, Bobby consulted on the Agricultural Defense portfolio in the Department of Homeland Security, Chemical & Biological Defense Division. Bobby earned a BS in biology from James Madison University and an MS in biodefense from George Mason University.

CAPT Brianna Skinner

CAPT Brianna Skinner is a Commissioned Corps officer in the U.S. Public Health Service who has also served in the U.S. Army Veterinary Corps. As a uniformed service officer, she has proudly served her country within the continental United States and abroad on several humanitarian and disaster response missions. She is currently assigned to the Office of Countermeasures and Emerging Threats (OCET), Office of the Chief Scientist at the U.S. Food and Drug Administration (FDA) where she currently serves as a Senior Regulatory Veterinarian and animal model expert for the administration of policies to facilitate the availability of safe and effective medical countermeasures against chemical, biological, radiological, nuclear agents and emerging threats. CAPT Skinner is the Chair for FDA's Animal Welfare Council and serves as the Co-Lead of FDA's One Health Steering Committee's operational activities and is the OCS One Health representative. Prior to transferring to the FDA, she worked at the Centers for Disease Control and Prevention for over eleven years leading clinical operations within the vivarium, consulting with principal investigators on animal care and use with infectious disease research from biosafety levels 1 – 4, and training laboratory animal veterinarians. She earned her Doctor of Veterinary Medicine degree from Tuskegee University, her Master's in Public Health from Benedictine University, and is board certified in laboratory animal medicine with the American College of Laboratory Animal Medicine.

Joyce Obidi, PhD

Joyce Obidi is the Health Programs Coordinator in the Office of Women's Health. She leads the Extramural Research Program for OWH. Her research background is in translational oncology research. In 2012, Dr. Obidi graduated from Johns Hopkins University School of Medicine with a doctoral degree in Cellular and Molecular Medicine. After completing her dissertation, Dr. Obidi completed her post-doctoral research at MedImmune, the global biologics R&D arm of AstraZeneca. She worked on developing assays that could be used to optimize new therapeutic strategies and personalized medicine which could aid in the stratification of cancer patients. Dr. Obidi joined FDA in 2016 as a recipient of the FDA Commissioner's Fellowship. She focused on understanding how to harness electronic health records to complement FDA's post market surveillance activities.

Kinnera Chada, PhD

Dr. Kinnera Chada is the Broad Agency Announcement (BAA) Program Lead at the Office of Regulatory Science and Innovation (ORSI), FDA. She has served as the Program Official for two of the FDA's Centers of Excellence in Regulatory Science and Innovation (CERSIs): Johns Hopkins University (2019-2023) and University of California at San Francisco in a joint effort with Stanford University (2021-2023). Prior to joining ORSI/FDA, she has worked with Center for Biologics Evaluation and Research (2011-2019) on developing mathematical models for antigen dose sparing for adjuvanted influenza vaccines, benefit-risk assessment of blood donation policies, and active surveillance of biologics through the Sentinel and Biologics Effectiveness and Safety (BEST) Initiatives. Dr. Chada completed her Ph.D. and Master's in biomedical engineering at the University of Kentucky. Her doctoral research focused on optimization of treatment regimens for carbonmonoxide poisoning using physiological systems modeling.

Ian Weiss

Ian Weiss is the Branch Chief for the Scientific Support Branch (SSB) of the Office of Acquisitions and Grants Services (OAGS) and is the Contracting Lead for the Broad Agency Announcement (BAA) program. Mr. Weiss has over 14 years of Contracting experience, and has served on both the Contracting and Programmatic sides of the contracting table. He has a passion for finding common ground and innovative solutions to contracting issues that benefit all parties.

Ian brings 20 years of active duty Coast Guard experience to the table, both as an enlisted member and a Warrant Officer. In addition, his civilian experience includes time with the US Army Corps of Engineers (USACE), The US Coast Guard (USCG) and the Food and Drug Administration. Mr. Weiss has lead several high profile contracting efforts over his career, such the Next Generation HURREVAC – Hurricane Decision Support platform with FEMA, DHS and USACE, The refit of the Coast Guard Cutter Healy and updates to the century old Washington Aqueduct. Ian is proud to now serve the FDA and to help guide the evolution of the FDA BAA program.