FDA Broad Agency Announcement Day

November 14, 2024

Speaker Bios

Quick links:

Agenda

2024 BAA Day Presenters List:

(In order of appearance)

- Ms. Shaila Shaheed, ORES
- Mr. Ian Weiss, OAGS
- Dr. Darlese Solorzano, CDER
- Dr. Bridget Nugent, CDER
- Dr. Michele Lee, CDRH
- Mr. Robert Orr, ORES
- Dr. Rebekah Zinn, OCE
- Ms.Sara Sklenka, MPH, CVM
- CAPT Brianna Skinner, ORES
- Dr. Joyce Obidi, OWH
- Dr. Kinnera Chada, ORES

Shaila Shaheed, M.S.

Office of Regulatory and Emerging Science (ORES)/ Office of The Chief Scientist (OCS)/ Office of The Commissioner (OC)

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.

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.

Darlese Solorzano, MS, MBA

Darlese Solorzano is the Senior Program Manager for the BsUFA III Regulatory Science Pilot Program in the FDA's Center for Drug Evaluation and Research where she is responsible for the operational leadership of the program and executing programmatic goals in alignment with the strategic objectives of BsUFA III. She has expertise in program infrastructure development and overseeing multi-level research projects through experience in the clinical research sector and in her current role at FDA. Darlese has two advanced degrees: M.S. in Biotechnology with a subspeciality in Regulatory Affairs and an M.B.A.

Bridget Nugent, PhD

Bridget Nugent, PhD, is a Science Policy Analyst who leads regulatory science initiatives for FDA CDER's Rare Diseases Team (RDT). Dr. Nugent is a neuroscientist with over 16 years of research and mentorship experience. Prior to joining RDT, she was the Research Program Lead in the FDA Office of Women's Health, where she oversaw OWH's Intramural and Extramural Research Programs and served on several FDA and inter-Agency committees and working groups. Dr. Nugent received her PhD in Neuroscience from the University of Maryland School of Medicine (UMSOM) and completed postdoctoral fellowships at Yale University and the University of Pennsylvania. Prior to joining FDA in 2018, she was an Assistant Professor in the Department of Pharmacology at University of Maryland School of Medicine and the Associate Director for Research Analyses in the Center for Epigenetic Research in Child Health and Brain Development.

Michele Lee, PhD

Dr. Michele Lee is the Team Lead for Regulatory Science Programs in the Division of Partnerships & Innovation, Office of Equity & Innovative Development 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 relationships with 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.

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 ORES 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.

Rebekah Zinn, PhD

Rebekah is a Senior Advisor for Research Strategy and External Partnerships in the Oncology Center of Excellence (OCE) at FDA. Prior to joining the OCE, she managed regulatory science research collaborations and training activities in the Office of the Chief Scientist, Office of Regulatory Science and Innovation (OCS/ORSI) and served as the Program Leader for the Centers of Excellence in Regulatory Science and Innovation (CERSI). Rebekah has over 10 years of research experience in cancer biology and epigenetics. She earned a PhD from the Cellular & Molecular Medicine program at Johns Hopkins University School of Medicine and completed five years of postdoctoral research at JHU with a focus on lung cancer therapeutics.

Sara Sklenka, MPH

Sara Sklenka is a Consumer Safety Officer on the Science Policy Branch in OSC. She has the privilege to work alongside dedicated and talented scientists in tackling known and emerging animal food contaminants that are physical, chemical, or biological in nature. Her role involves coordinating annual animal food sampling and analysis plans under FDA's Animal Food Contaminants Program and the Laboratory Flexible Funding Model, and managing projects relating to contaminants in animal foods.

Sara began her career at CVM in 2013 as a chemist in the Office of Research (now Office of Applied Science) working on analytical method development and validation of veterinary drug residues in food of animal origin. She has also held positions as a medicated animal feed program manager in OSC and policy and regulations staff project manager in the Office of the Director.

Sara holds a Master Certificate in Project Management from George Washington University. She also has a Master of Public Health degree with a concentration in Veterinary Public Health and a Bachelor of Science in Pharmaceutical Sciences, both from The Ohio State University.

CAPT Brianna Skinner

CAPT Brianna Skinner has a veterinary career that spans over 28 years. She is a graduate of Tuskegee University, College of Veterinary Medicine where she received her veterinary medical degree and a graduate of Benedictine University where she received a Master of Public Health with certifications in epidemiology and health education and promotion. She is a diplomate in the American College of Laboratory Animal Medicine and an honorary diplomate in the American Veterinary One Health Society.

CAPT Skinner began her veterinary career in the U.S. Army Veterinary Corps before her interservice transfer into the U.S. Public Health Service. She has served her country proudly in leadership and supporting roles for humanitarian and disaster response missions such as Hurricane Katrina, Operation Continue Promise on the U.S. Mercy, Haiti Earthquake Response, remote area medical deployments, Hurricane Maria, the 2014 -2015 Ebola Outbreak Response in West Africa, Hurricane Maria, and the COVID-19 Pandemic.

CAPT Skinner is currently assigned to the U.S. Food and Drug Administration within the Office of Regulatory and Emerging Science where she is a senior advisor and veterinary expert responsible for crosscutting policies on One Health, animal welfare, medical countermeasures, and pandemic preparedness. She regularly interfaces with interagency stakeholders and partners from various federal agencies and nongovernmental institutions on several national initiatives related to One Health, pandemic preparedness and response, climate change, and environmental justice.

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 and Emerging Science (ORES), FDA. Prior to working on the BAA Program, 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). 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.