SCIENTIFIC COMPUTING + DIGITAL TRANSFORMATION SYMPOSIUM

Hosted by
FDA Office of Digital Transformation and the Scientific Computing Board.
In partnership with all FDA centers

November 4 – 6, 2024

FDA U.S. FOOD & DRUG ADMINISTRATION

Table of Contents

SPEAKERS AND BIOGRAPHIES

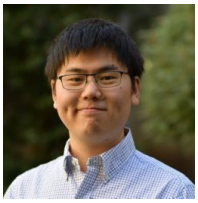
(Listed in alphabetical order by last name, by day of presentation)

Day 1: Monday, November 4, 2024

Venu Boppana

Senior Operations Research Analyst
Office of Strategic Programs (OSP)
FDA Center for Drug Evaluation and Research (CDER)

Venu Boppana is a Senior Operations Research Analyst in the Division of Business Management Service and Solution (DBMSS) Office of Business Informatics (OBI), Office of Strategic Programs (OSP) in the Center for Drug Evaluation and Research (CDER). DBMSS is leading the modernization and operations of work management, business intelligence and infrastructure support of the CDER Informatics Platform. Since joining the FDA in 2013, Mr. Boppana has led several critical programs including CDER Drug Supply Chain, COVID IT projects, CDEROne Analytics Platform and Mercado Enterprise Data Warehouse. He has over 20 years' experience in Augmented Analytics, Enterprise Architecture, Applications Development and System Integration. Venu received a BS from University of Mysore, India.



Qian Cao, PhD

Staff Fellow
FDA Center for Devices and Radiological Health (CDRH)

Qian Cao is a visiting scientist in the Division of Imaging, Diagnostics, and Software Reliability (DIDSR) in the Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration, where he contributes to regulatory review of AI-enabled medical devices. His current research involves developing quantitative imaging tools and models for predicting drug response in metastatic breast cancer and for evaluating uncertainty in AI systems. He holds a PhD in biomedical engineering from Johns Hopkins University.

Ethan Chen

Division Director
FDA Center for Drug Evaluation and Research (CDER)

Ethan Chen is the Director of the Division of Data Management Service and Solution (DDMSS), Office of Business Informatics (OBI), CDER. Under his leadership, DDMSS provides overall leadership in streamlining electronic and traditional submissions and delivering solutions to enable rapid adoption of emerging electronic data standards. Since joining the FDA in 2012, Mr. Chen has led several critical initiatives as the CDER Informatics Architect, including Data Management, Business Intelligence programs, and CDEROne Enterprise Data Analytics programs. He has over 20 years' experience in Data Management, Enterprise Architecture, Solution Development and System Integration. Ethan received a BS from Shanghai Jiao Tong University, an MSE from Temple University and MBA from University of Maryland at College Park.

Steve Condrey, MPS

Program Analyst
FDA Office of Inspections and Investigations (OII)

Steve Condrey has been with the FDA for 30 years, serving entirely in the former Office of Regulatory Affairs until October 1st of this year. Since 2010, he has been part of the FDA's internal Quality Management System, with responsibilities including data analysis across multiple platforms. In 2015, he was a co-recipient of the FDA Intercenter Scientific Collaboration Award for his contributions to a published paper on the FDA's use of data mining to promote public health. In 2022, he was co-chair of FDA Scientific Computing Days, where he helped highlight and promote the use of Big Data techniques in field operations. The presentation for this session is based on work done while he was part of ORA's Division of Quality Management Systems, developing a dashboard to display key performance indicators related to inspection operations.

Sujatha Dantuluri

Senior Solutions Architect
Amazon Web Services (AWS)

Sujatha Dantuluri is a Senior Solutions Architect in the US federal civilian team at AWS. She has over 20 years of experience supporting commercial and federal government. She works closely with customers in building and architecting mission-critical solutions. She has also contributed to the Institute of Electrical and Electronics Engineers (IEEE).

Vid Desai

Chief Information Officer
Director, Office of Digital Transformation (ODT)

Vid Desai is a seasoned technology leader who brings more than 30 years of experience in the information technology (IT) field, with over 26 years in the healthcare and life sciences industries. He has previous experience working for large Pharma, Clinical Research Organizations (CRO) and Medical Device companies. As the FDA's Chief Information Officer (CIO), Mr. Desai sets and leads the agency's IT strategy, as well as the agency's enterprise IT, data management, and cybersecurity in the Office of Digital Transformation (ODT). The ODT team oversees the overall FDA IT spend of more than $750M and a staff of around 2,500 employees and contractors. Prior to being named CIO, Mr. Desai served as the FDA's Chief Technology Officer, overseeing day-to-day technology operations as the leader of the Office of Information Management and Information Technology. Prior to joining the FDA, Vid held the Chief Information Officer (CIO) roles at Vyaire Medical, a Respiratory Medical Device company formed from a divestiture from Becton Dickinson. He was CIO at Endochoice, a GI device and services provider, and Lake Region Medical, which was acquired by Greatbach to form Integer, a medical device, outsource manufacturer.

Hesha Duggirala, PhD, MPH

Epidemiologist; Chair, FDA Data Science Council
FDA Center for Veterinary Medicine (CVM)

Hesha Duggirala, PhD, MPH is an epidemiologist at the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM). In CVM's Office of Surveillance and Compliance, she provides epidemiologic support to various groups across CVM. She is also the CVM Artificial Intelligence policy

lead, providing coordination of the Center's AI efforts and representing CVM on FDA level initiatives. She co-founded, and continues to chair, the FDA Data Science Council (formerly Data Mining Council). This group, a part of the FDA's Scientific Computing Board, advises and provides support to big data programs across the Agency.

Michael Gilbert
Senior Lead Scientist
Chief Technology Office, Artificial Intelligence Group
Booz Allen Hamilton

Michael Gilbert is a Senior Lead Scientist in Booz Allen Hamilton's Chief Technology Office with over 15 years of experience in the design, implementation and management of public health informatics technologies. Michael has led development of consumer facing decision support tools for potential poison exposures, experimental methods for generation and analysis of real-world evidence for pharmacovigilance, and methods for detection and characterization of emerging drug related trends and public health challenges. Michael currently supports the National Evaluation System for Health Technology in the implementation of the active surveillance system for medical devices.

Ram Iyer
Chief Data Officer
Director, Office of Data, Analytics, and Research (ODAR)
FDA Office of Digital Transformation (ODT)

As the FDA's Chief Data Officer, Ram C. Iyer directs the agency's data modernization strategy and oversees the FDA's use and governance of artificial intelligence. He focuses on building robust central and federated functions that support mission-critical work across the agency. Ram is a recognized data and technology professional with experience in the pharmaceutical, consulting, and Telecom industries as well as in international government organizations. He has fostered a thriving network of data scientists, data analysts, visual storytellers, and Agile specialists to address the FDA's urgent and complex challenges.

Yutong Li, PhD
Principal Biostatistician
Novartis Pharmaceutical Corporation

Yutong obtained his PhD in Statistics from UIUC in 2021. His research focus is on developing novel machine learning methodologies for high-dimensional biomedical and bioinformatics applications. He joined Novartis after graduation and is currently a principal biostatistician in early development analytics, where he supports multiple oncology-related clinical trials that are in development. Additionally, he focuses on exploring and developing various statistical/machine learning methods in examining how biomarkers, especially ctDNA, can serve as effective surrogate endpoints for clinical trials.

Danica Marinac -Dabic, MD, PhD, MMSc, FISPE

Associate Director for Scientific Partnerships
Office of Clinical Evidence and Analysis
FDA Center for Devices and Radiological Health (CDRH)

Dr. Danica Marinac-Dabic is the Associate Director for Scientific Partnerships at the FDA's Office of Clinical Evidence and Analysis, CDRH. A physician and epidemiologist, she leads the development of methods for real-world evidence and the interoperability of diverse data sources to study health technologies. She previously directed the CDRH Division of Epidemiology. Before joining the FDA, she gained experience in obstetrics, gynecology, and epidemiology in both academic and clinical settings. Under her leadership, the FDA launched the Medical Device Epidemiology Network (MDEpiNet) to advance infrastructure and methods for studying devices throughout their life cycle. She also led an international group of experts at the IMDRF to establish principles for using registry-generated data and is spearheading coordinated registry networks. Dr. Marinac-Dabic is also the FDA lead on the Active Surveillance System for medical devices in collaboration with NESTcc.

Tina Morrison

Senior Science Advisor
FDA Office of the Commissioner (OC)

Tina Morrison serves as senior advisor to the FDA Chief Scientist, and formally directed the Office of Regulatory Science and Innovation in the Office of the Chief Scientist at FDA. She supports cross-agency projects on in silico alternative methods and complex in vitro test methods. She's a mechanical engineer with 20+ years of simulation experience and 16 years of regulatory experience.

Tom Osbourne, MD

Chief Medical Officer
Microsoft Federal

Dr. Thomas Osborne is the Chief Medical Officer for Microsoft, Federal Civilian. Before Microsoft, he held key leadership roles in both government and industry, using advanced technologies like AI, cloud computing, 5G, and wearables to transform healthcare. He has been recognized with numerous national awards for his work, which covers topics such as cancer, infectious diseases, surgery, elder care, and health tech. His research has been published in top medical journals and textbooks. Dr. Osborne earned his medical degree from Dartmouth Medical School and completed his residency and fellowship at Harvard hospitals.

Mark Palmer, PhD

Field CTO for Healthcare
Ansys

Dr. Palmer joined Ansys in April 2023 as their first Field Chief Technology Officer for Healthcare. Prior to Ansys, Dr. Palmer led the global modeling and simulation strategy team at Medtronic. He is a recognized expert in the field with more than 30 keyno te or invited lectures and over 40 journal publications and refereed conference papers that range from computational biotechnology to position papers on regulatory policy. Dr. Palmer's expertise includes fully coupled multiscale finite element methods, large deformation tissue mechanics and modeling, and clinical image-based modeling

techniques. He is passionate about advancing human simulation, virtual patient technologies, and digital evidence standards to improve product quality, safety, and patient outcomes in healthcare.

Rahul Paul

Bioinformatics Data Scientist
FDA Center for Biologics Evaluation & Research (CBER)

Rahul Paul is working as a Bioinformatics Data Scientist at the HIVE group in the office of Biostatistics and Pharmacovigilance of Center of Biologics Evaluation and Research. Rahul has more than 5 years of experience on machine learning and deep learning modelling experience to analyze imaging, omics, natural language processing and clinical data and has multiple patents.

Tyler Peryea

Cheminformatician, Health Informatics
FDA Office of Data, Analytics, and Research (ODAR)

Tyler Peryea is a cheminformatician currently serving as the Acting Director of Health Informatics Staff within the Office of Data, Analytics, & Research (ODAR). Tyler has over 15 years of experience developing open-source software tools that help computers deal with chemical data. These tools include MolVec: an AI tool for turning images of organic molecules into a format that computers can understand, and GSRS: an open-source chemical and biological database for capturing unique substances and tying them to regulatory, clinical and manufacturing data. Tyler leads an amazing team of scientists, data scientists and analysts on the Health Informatics Staff, working collaboratively to improve how the FDA accepts, organizes, and shares critical foundational data that affects public health.

Aidan Ricci

Solutions Architect
Amazon Web Services (AWS)

Aidan Ricci is a Solutions Architect at Amazon Web Services based in the Washington, D.C. area. In that role, he helps public sector customers achieve their mission objectives with well-architected solutions on AWS. He has 3 years of experience spanning nonprofit, healthcare, and government. His passion is using AI/ML and cloud solutions to help public sector customers achieve their business and technical goals.

Tara Ruttley, PhD

Chief Scientist
Orbital Reef

Dr. Tara Ruttley is the chief scientist for Orbital Reef, Blue Origin's upcoming commercial space station. Before joining Blue Origin, she managed engineering and science plans for the International Space Station (ISS) at NASA. From 2018-2022, she served as NASA's Associate Chief Scientist for Exploration and Applied Research, overseeing ISS science and Artemis lunar mission planning. Prior to this, she was Associate Chief Scientist for ISS at Johnson Space Center, where she spent a decade managing and communicating ISS science from its assembly completion to its peak utilization period.

Frank Samuelson, PhD

Physicist
FDA Center for Devices and Radiological Health (CDRH)

Frank Samuelson is a physicist in the Office of Science and Engineering Laboratories of the US Food and Drug Administration. His research includes methods of evaluating computational intelligence algorithms found in diagnostic medical imaging devices, including statistical methods and study designs. He studies signal detection in medical images with human observers, and he reviews regulatory studies for devices and algorithms for the FDA. Prior to the FDA, he received his Ph.D. in astrophysics from Iowa State University and completed a post-doc at Los Alamos National Laboratory.

Luis Santana -Quintero

Staff Fellow
FDA Center for Biologics Evaluation & Research (CBER)

Luis Santana-Quintero is leading the CBER's bioinformatics group (HIVE) in the Division of Analytics and Benefit Risk Assessment in the Office of Biostatistics and Epidemiology. His research focused on multiple fields of computational biology including immune informatics, as well as artificial intelligence, and machine learning. He has co-developed the CBER HIVE platform and numerous algorithms and bioinformatic tools for large datasets. Also, he is an Associate Editor of the "IEEE Transactions on Evolutionary Computation", a scientific journal in the area of evolutionary computation. Before joining CBER in 2012, Dr. Santana-Quintero was a Postdoctoral Fellow in the Krasnow Institute for Advanced Study at the George Mason University.

Mary Schwarz

Symposium Moderator
Managing Partner, Division Lead
ICF Next Government

Mary Schwarz, Managing Partner, ICF Next Government, is a digital strategist and marketing technologist with a comprehensive range of experience in direct marketing, web development, community outreach, and analytics. Mary leads ICF Next's Government, federal digital and engagement practices. She brings over 20 years of experience providing strategic guidance for health, education, and social programs. Mary helps clients define their objectives and business goals; map user journeys; and develop incremental and iterative development plans. She also helps clients evaluate the impact and efficiency of their programs and revise and optimize their digital programs for maximum impact. Mary has extensive experience crafting data-driven digital and engagement programs using a combination of on- and off-line tactics and strategies. Her work often calls upon deep data analytics to not only inform and tailor experiences, but to drive timing, frequency, and lasting behavior change.

Shanthi Vigneshwaran

Supervisory Operations Research Analyst, Data Governance
FDA Office of Data, Analytics, and Research (ODAR)

Shanthi Vigneshwaran has 20+ years extensive leadership and management experience in both the public and private sectors, delivering enterprise business process management, master data management and custom IT solutions. She currently serves as Supervisory Operations Research

Analyst of Office of Data Analytics and Research, which plays a lead role in many of the FDA's data strategic initiatives including enterprise data services, enterprise master data management, data standards, data analytics, health informatics, and governance.

Mark Walderhaug, PhD

Advisor, Scientific Computing Board
Associate Office Director, Office of Biostatistics and Pharmacovigilance
FDA Center for Biologics Evaluation & Research (CBER)

Mark Walderhaug is an Associate Office Director in the Office of Biostatistics and Pharmacovigilance in FDA's Center for Biologics Evaluation and Research. His expertise spans molecular biology, risk modeling-assessment, and information technology, including AI. His current goal is to get FDA "quantum ready" for the potential revolution to healthcare that quantum computing offers.

Tina Wang, MPH

Statistical Analyst
FDA Center for Drug Evaluation and Research (CDER)

Tina Wang is a statistical analyst in the Division of Analytics and Informatics. She joined office of Biostatistics in CDER at FDA in 2018. Her research interests include data science and data tools, statistical programming, data standard and central statistical monitoring.

Iwona Weidlich

Reviewer, Office of Pharmaceutical Manufacturing Assessment
FDA Center for Drug Evaluation and Research (CDER)

Dr. Iwona Weidlich serves as a reviewer in the Office of Pharmaceutical Manufacturing Assessment at CDER. Since joining the FDA in 2013 she contributed to the Substance Registration System, created the "AI for Regulatory Review" forum, and evaluated various drug dosage forms. Prior to the FDA, she worked at the NIH, and holds a Ph.D. in pharmaceutical sciences and an M.Sc. in chemical engineering. She has over 20 years of professional experience and believes that repetitive tasks could be better performed by robotic overlords.

Joshua Xu

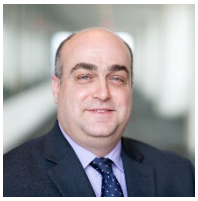
Branch Chief
FDA National Center for Toxicological Research (NCTR)

Dr. Joshua Xu is the Branch Chief of Research-to-Review and Return (R2R) at the Division of Bioinformatics and Biostatistics within FDA's National Center for Toxicological Research (NCTR). He has been (1) leading a community wide effort to assess the analytical performance of oncology panel sequencing technologies and develop best practice guidelines, (2) developing and adopting NLP methods for regulatory document review, (3) developing image analysis algorithms for digital pathology and food contamination detection.

Day 2: Tuesday, November 5, 2024

Nicole Barberis
Senior Director, Quantum Business Solutions
IonQ

Nicole and her global team collaborate with Westat to help our clients succeed on their journey to implementing quantum computing applications. She brings a strong technical background in classical and quantum machine learning that she uses to help clients choose the right quantum applications for their business. In collaboration with the client's domain experts, Westat's SMEs, and IonQ's quantum computing scientists, we prepare our clients for the quantum era. Prior to joining IonQ three years ago, she worked on the IBM Quantum team as a technical leader and quantum machine learning developer.



Tom Beach
Associate Director of Data Governance
FDA Office of Data, Analytics, and Research (ODAR)

Thomas is currently the Associate Director of Data Governance at the U.S. Food and Drug Administration (FDA), within the Office of Data, Analytics, and Research (ODAR) under the Office of Digital Transformation (ODT). In this role, he provides strategic leadership and expertise in deploying agency-wide data governance initiatives in collaboration with FDA Centers and offices. With over 10 years of experience, he has driven the adoption and implementation of data governance practices for data-intensive applications (AI/ML), during his tenure as Chief Data Officer (CDO) at the Department of Commerce and Chief Data Strategy Officer at the U.S. Patent and Trademark Office (USPTO). Thomas holds a degree in Engineering from the Georgia Institute of Technology and earned his master's degree from Georgetown University's McDonough School of Business.

Robert E. Bughman
Project Manager
FDA Office of Inspections and Investigations (OII)

Robert E. Bughman has worked at the FDA for the past 8 years as anOperations Research Analyst and Project Manager for the FDA Data Dashboard. Prior to joining the FDA, he spent 14 years working for the Department of Defense (DoD).

Kenny Cha
Assistant Division Director
FDA Center for Devices and Radiological Health (CDRH)

Kenny H. Cha is the Assistant Director for Software and High-Performance Computing in the Division of Imaging, Diagnostics, and Software Reliability within the U.S. Food and Drug Administration, Center for Devices and Radiological Health. He is the manager champion for the OSEL AI/ML research program and leads the CDRH HPC team. He earned his B.S.E, M.S.E, and Ph.D. degrees from the University of Michigan in Biomedical Engineering. His research interests include artificial intelligence, machine learning, and deep learning for medical data, computer-aided diagnosis, and radiomics, with a focus on performance assessment, and taking advantage of the HPC to enable these innovations.

Ashley Cook, PhD

Bioinformatics Reviewer
FDA Center for Veterinary Medicine (CVM)

Dr. Cook joined the FDA Center for Veterinary Medicine (CVM) as a bioinformatics reviewer in 2023. Prior to that, she completed her graduate degree in Cellular and Molecular Medicine at Johns Hopkins School of Medicine and her postdoctoral training at the University of Pennsylvania. At CVM, she evaluates data, including omics data, submitted to support new animal drug applications for intentional genomic alterations (IGAs) in animals. Dr. Cookis an active member in many scientific computing and data science groups and initiatives at the FDA.

Danita Dixon, MS

Associate Director for Information Management
FDA Office of the Commissioner (OC)

Danita Dixon, M.S., is the Associate Director for Information Management at the US-FDA Office of the Chief Medical Officer (OCMO). She leads a team with an emphasis on developing and implementing informatics capabilities related to key strategic priorities for the FDA medical product centers and the Chief Medical Officer. During her 8 years working in the Office of the Commissioner, she implemented the Salesforce Intercenter Consult Request (ICCR) System, which supports efficient cross-Agency collaboration for medical product reviews. In her current role in the OCMO, her informatics portfolio includes strategic planning for the ICCR program, among other initiatives.

Tomas Drgon, PhD

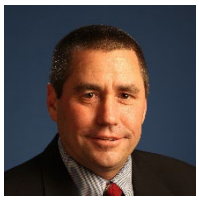
Dataforward Program Lead
FDA Office of Digital Transformation (ODT)

Tomas Drgon earned his MSc in Food Technology from Slovak Technical University and a PhD in biochemistry and molecular biology from Comenius University. He completed postdoc work at NIH and the University of Maryland before joining NIH as a staff researcher and later transitioning to science administration. In 2015, he joined the FDA as a Program Analyst, focusing on program evaluation, modeling, and simulation in regulatory science. Dr. Drgon leads the ODT/ODAR Dataforward program, has co-authored over 50 scientific articles, and serves as an NIH grant reviewer and guest lecturer at Georgetown University.

Michael Dubbin

Data Scientist, Data Analytics as a Service
FDA Office of Data, Analytics, and Research (ODAR)

Michael Dubbin is a Biologist in the Office of New Animal Product Evaluation in CVM. He has supported Data Analytics as a Service (DAaaS) in ODAR since February 2024 as a Data Scientist. He enjoys sharing a ballpark frank with his DAaaS coworker, Greg Pishko, eating Chili's wings with Sachin Shah, and petting baby farm animals with Meghan Mariman.



Thomas Farrell

Supervisory Information Technical Specialist
FDA Human Foods Program (HFP)

Thomas Farrell has over 30 years of leadership and technical experience providing information technology (IT) services to the Federal Government and possesses a comprehensive understanding of IT systems. He is a seasoned executive experienced in all aspects of project management, customer relationship management, human resources, contract management, business development, and finance. Thomas served as a Vice President and Program Manager for HHS Accounts at both large and small businesses overseeing various IT programs at the NIH, FDA, HHS, MHS, and USCG and worked for the Federal Government overseeing data center operations for FDA, US Patent and Trademark Office and the IRS.

Lauren Hines

Data Management Lead
FDA Human Foods Program (HFP)

Lauren Hines is the Data Management Lead for the FDA Human Foods Program (HFP). In this role, she is responsible for overseeing the centralization and organization of HFP data assets with the goals of improving data accessibility, quality, and interoperability. She manages the Human Foods Data Platform (HFDP) as well as teams responsible for development of end-user analytics products. Prior to her work in this role, she spent five years leading key IT modernization initiatives in support of the Food Safety Modernization Act (FSMA). Ms. Hines holds a B.A. from The Ohio State University and is a certified Project Management Professional (PMP).

Lara Jehi, MD, MHCDS

Professor of Neurology
Chief Research Information Officer
Chair, Center of Computational Life Sciences, Cleveland Clinic

Dr. Jehi is a professor of neurology at Cleveland Clinic Lerner College of Medicine and the Chief Research Information Officer for the Cleveland Clinic Health System. She leads the clinic's digital infrastructure and research strategy, aiming to enhance research and accelerate treatments. As the principal investigator of the Biorepository and Executive Program Lead for the Discovery Accelerator, she drives innovation with IBM using high-performance computing, AI, and quantum computing. She chairs the Cleveland Clinic Center for Computational Life Sciences and the Data Advisory Council and leads key commissions in professional societies. With over 200 peer-reviewed publications and 12 book chapters, she is also a regular NIH study section reviewer.

Duncan MacCannell, PhD, MBT

Director, Office of Advanced Molecular Detection
Division of Infectious Disease Readiness and Innovation
National Center for Emerging and Zoonotic Infectious Diseases
US Centers for Disease Control and Prevention

Duncan MacCannell is the Director of the Office of Advanced Molecular Detection (OAMD) at the CDC, where he drives innovation in pathogen genomics, molecular epidemiology, and bioinformatics. OAMD collaborates with CDC's infectious disease programs, state and local health departments, and

global partners. MacCannell promotes open science, accessible bioinformatics tools, and swift exchange of public health data. His background includes public health microbiology and molecular epidemiology, contributing to the PulseNet program and leading surveillance for antimicrobial-resistant and healthcare-associated pathogens.

Mike Mikailov, PhD, MBA
Computer Scientist
FDA Center for Devices and Radiological Health (CDRH)

Dr. Mikailov, a seasoned software development leader, transitioned from L-3 Communications, where he served as Director of Software Development from 2004 to 2009, to the U.S. Food & Drug Administration's Center for Devices and Radiological Health in 2009. Since then, he has been a key contributor to one of the most powerful HPC centers in the federal government. As a Computer Scientist, Dr. Mikailov has pioneered innovative software scaling techniques on HPC clusters and has published his research in prestigious peer-reviewed journals, including IEEE Transactions on Artificial Intelligence.

Alexis Norris
Biologist
FDA Center for Veterinary Medicine (CVM)

Alexis Norris joined CVM as a bioinformatics reviewer in 2018. Prior to that, she completed her PhD and postdoctoral training at Johns Hopkins School of Medicine where she used genomics, transcriptomics, proteomics, and metabolomics to study human cancer and psychiatric disorders. At CVM, Alexis evaluates next generation sequencing (NGS) data submitted to support new animal drug applications for genome edited animals, through an independent analysis of the raw NGS data. For the analysis, Alexis uses multiple bioinformatics platforms (precisionFDA, CDRH Betsy HPC, and Galaxy), and codes primarily in Linux/bash scripting and R. Alexis is actively involved in multiple omics and data science working groups at the FDA and currently co-chairs the FDA Omics Working Group.

Jamie Pettengill
Director, Division of Surveillance and Data Integration
FDA Human Foods Program (HFP)

Jamie Pettengill is currently a co-chair of the FDA Scientific Computing Board. He is also the Director of the Division of Surveillance and Data Integration within the Human Foods Program. The division is responsible for managing large inventories of data, surveilling and analyzing genomic data from foodborne pathogens, and providing statistical expertise in support of applied research and regulatory activities.

Greg Pishko
Data Scientist, Data Analytics as a Service
FDA Office of Data, Analytics, and Research (ODAR)

Greg Pishko is lead data scientist at OC/ODT/ODAR Data Analytics as a Service. He believes that improvement and innovation are keys to delivering excellent value to the U.S. public. Prior to joining

ODAR, Greg spent 9 years at the Center for Devices and Radiological Health serving as a reviewer, policy analyst, assistant director and data scientist.

Jimmy Sanders, MS
Principal Solutions Architect
Digitrix, LLC

Jimmy is a principal co-owner and Chief Technology Officer of Digitrix, LLC, a small business focused on providing modern software and cloud solutions to public sector government agencies. Jimmy has supported the Food and Drug Administration since 2008 and began working with the Human Foods Program (prior CFSAN) since 2016 as a solutions architect. He has been the technical lead and software developer for many data sharing and access implementation projects since 2016. Most notably his leadership in the design of GalaxyTrakr, FoodTrak, Analytical Product Survey (CAPS) and the Product Label Analysis and Text Extraction System (PLATES) have transformed how various stakeholders access, process and analyze data within the FDA.

Saul Sarria, PhD
Microbiologist
FDA Center for Veterinary Medicine (CVM)

Saul was born in Colombia, where he earned a bachelor's degree in biology-genetics. After his graduation, he moved to the U.S.A, where he earned a master's degree in biotechnology from Johns Hopkins University, and PhD from the University of Maryland, Biological Science Program (BISI). Saul has worked at J. Craig Venter Institute, where he acquired experience on genomics and proteomics. He has worked at The Department of Defense (DoD), Wright Patterson Air Force Base, Dayton, Ohio, where he earned experience in DNA/RNA Next Generation Sequencing Technology. He is currently working at the Center for Veterinary Medicine (CVM), Office of Applied Science (OAS). At OAS, his work focused on studying the effect of antimicrobials and mapping microbiomes and resistom es of food animals.

Fatih Selekler
Vice President, Health IT
Westat

Mr. Selekler has been designing and implementing complex IT solutions for the federal agencies for over 33 years. As the Executive FDA Account Manager for Westat, he is focusing on bioinformatics solutions for advancing biomedical and regulatory science interests, particularly in the areas of advanced AI and quantum computing solutions.

Charles Strittmatter
Infrastructure Project Manager, Science Application Architect
FDA Human Foods Program (HFP)

Charles Strittmatter brings over 16 years of experience managing complex projects in areas such as Project Management, Cloud Computing, Bioinformatics, Data Science, Machine Learning, Security, ERP, and Collaboration Software. For the past 4 years, he has served as a Project Manager for HFP under the OM/DITM/SIB (Business Innovation Branch), overseeing HFP's Scientific Computing

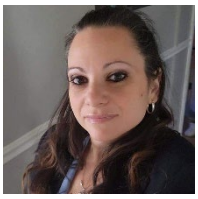
Infrastructure. His role includes managing physical networks, data storage, and on-premise and cloud computing services. Charles coordinates program goals, processes, and administrative operations while negotiating with stakeholders. Notable projects under his management include GalaxyTrakr, WILEE Datacenter Operations,HFP Splunk Implementation, and the WDC to White Oak Data Center Move.

Day 3: Wednesday, November 6, 2024

Kathleen Abt
IT Specialist
FDA Office of Digital Transformation (ODT)

Casi Alexander
Portfolio and Relationship Management Team (PRMT) Lead
FDA Office of Digital Transformation (ODT)

Casi Alexander is an accomplished IT leader with over 23 years of expertise in IT governance, strategic planning, enterprise architecture, and program and project management. She currently leads the Portfolio Relationship Management Team within the FDA's Office of Digital Transformation. In this role, Casi is responsible for policy and performance management, overseeing the IT governance framework, and guiding the strategic planning and monitoring the execution of the FDA IT Strategy and Operating Plan. Throughout her career, Casi has successfully led large-scale, enterprise-wide initiatives, demonstrating strong leadership and the ability to manage complex projects that deliver significant value to the agency. She holds a master's degree from Webster University and a bachelor's degree from Bennett College and is a certified Project Management Professional (PMP).



Jessica Bernhardt
IT Program Manager
FDA Office of Digital Transformation (ODT)

Jessica Bernhardt is the ESG Program Manager at the U.S. Food & Drug Administration (FDA) where she manages the existing electronic submission gateway and oversees its modernization, known as ESG NextGen. Jessica has a Bachelor of Science in Information Systems Management and Master of Science in Information Systems Management with a concentration in Project Management.

Jessica Berrellez
Executive Officer, ODT
FDA Office of Digital Transformation (ODT)

Jessica "Jess" N. Berrellez is the Executive Officer for the Office of Digital Transformation at the U.S. Food and Drug Administration. Jess has broad leadership experience in a variety of areas and currently oversees strategic initiatives, organizational effectiveness, strategic communications, high priority change initiatives, events and engagement, human capital management, learning and development, and administrative operations. She was previously ODT's Executive Director for Strategy and Operations, Senior Advisor to the Chief Information Officer, Senior Advisor to the Principal Deputy Commissioner, and Director for Program Evaluation and Process Improvement. Jess is the recipient of agency, federal, and industry honors and has received national recognition for her

volunteer work. She is a graduate of the Senior Executive Fellows Program at Harvard University's Kennedy School of Government and earned an Executive Certificate in Public Leadership. Jess holds a Master of Arts and Master of Science from the University of Arizona and earned a Bachelor of Arts from Indiana University.

Beau Brooks
Internet/Intranet Branch Chief
FDA Office of Digital Transformation (ODT)

Beau Brooks has been the Internet/Intranet Branch Chief in ODT over the last 10 years managing IT services like Office365, www.fda.gov, and the intranet. He's come up through the ranks in ODT and really enjoys solving problems, getting things done and challenging ideas about what and how we can do things at FDA.

Leah Buckley
Deputy Chief Information Security Officer, Cybersecurity Operations, Counterintelligence, and Insider Threat
Office of Information Security (OIS)
FDA Office of Digital Transformation (ODT)

Ms. Leah Buckley serves as the Deputy Chief Information Security Officer for Cybersecurity Operations, Counterintelligence, and Insider Threat at the FDA. Previously, Ms. Buckley retired from the U.S. Air Force as a Lieutenant Colonel and Special Agent in the Office of Special Investigations and served as a consultant supporting the government and private sectors. She graduated from the U.S. Air Force Academy with a Bachelor of Science in Foreign Area Studies and the U.S. Naval Postgraduate School with a Master of Arts in National Security Affairs.

Dr. Namandjé N. Bumpus
Principal Deputy Commissioner
Food and Drug Administration

Dr. Namandjé N. Bumpus became the FDA's Principal Deputy Commissioner on Feb. 1, 2024. In this role, she collaborates with FDA leadership to advance public health initiatives and oversee the agency's operations, including a reorganization of the Human Foods Program and enhancements to the Office of Regulatory Affairs. Previously, as Chief Scientist since August 2022, Dr. Bumpus elevated the research foundation, science and innovation that provides vital support for the FDA's public health mission. A respected advocate for plain language and public health transparency, Dr. Bumpus has raised FDA's profile in regulatory science. Before joining the FDA, she was a professor at Johns Hopkins University School of Medicine, where she chaired the Department of Pharmacology and Molecular Sciences. Dr. Bumpus is recognized as an international expert in pharmacology, and her research has expanded knowledge of drug metabolism, pharmacogenetics, bioanalytical chemistry, infectious disease pharmacology, and single cell biology.

Robert M. Califf M.D. , MACC
Commissioner of Food and Drugs
Food and Drug Administration

Dr. Robert M. Califf was confirmed in 2022 as the 25th Commissioner of Food and Drugs. As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products. Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

Mohammed Sohail Chaudhry
Chief Technology Officer
Director, Office of Information Management and Technology (OIMT)
FDA Office of Digital Transformation (ODT)

Mohammed Sohail Chaudhry is a strategic leader with progressive and vibrant ideology of transformative change in the delivery of technology and information management processes. Mr. Chaudhry has a proven record of saving millions in information technology (IT) expenses by leveraging secure innovation and business transformation. Currently serving as the Chief Technology Officer (CTO) at the United States Food and Drug Administration (FDA), he is responsible for the standardization and modernization of IT. Mr. Chaudhry is accomplishing this by leading the development of enterprise solutions that enables the Office of Information Management and Technology (OIMT) to align and integrate with the strategic business objectives of the agency. Prior to serving as the CTO, Mr. Chaudhry served as the Chief Technology Architect (CTA) and as the Director of the Division of Infrastructure Operations (DIO) leading the implementation, operations, and maintenance of enterprise IT.

Mahesh Kanubhai Choksi
Director, Division of Acquisitions Innovation
Office of Digital Transformation (ODT)

Mr. Mahesh Choksi is the Director of the Acquisition Strategies and Partnership (ASAP) Division, within the Office of Digital Transformation (ODT) at the Food and Drug Administration (FDA). He leads ODT-wide acquisitions support, including the development and implementation of ODT's Acquisition-as-a-Service (AaaS) model, vendor management program, small business participation support services, business process improvement, and CORs workforce development in overall acquisitions management. Mr. Choksi began his 14-year career with FDA as a deputy branch chief in Division of Application Services (DAS), supporting IT solutions for multiple FDA centers. He then moved on to the role of Director in the Division of Infrastructure Operations (DIO) with a focus on infrastructure management services. In 2024, Mr. Choksi was the recipient of the HHS Acquisition Excellence Award: Category Management Superior Achievement.

Sophia Donaldson

Associate Deputy Chief Information Officer
FDA Center for Tobacco Products (CTP)

Sophia Donaldson, MBA, Associate Deputy Chief Information Officer (ADCIO) and IT Director of Information Technology Staff, Office of Management (OM), Center for Tobacco Products (CTP), Food and Drug Administration (FDA). She has contributed to FDA's public health mission for over 13 years. She joined CTP in 2011 and was instrumental in leading various innovative technology implementation to support the new Family Smoking Prevention and Tobacco Control Act. Prior to joining CTP, Sophia worked in the private sector where she supported public sector customers on various public health initiatives. She has a Master of Business Administration (MBA) with a specialization in Leadership from Champlain College and a Bachelor of Arts (BA) in Communication from Marymount University.

Julie Donnell , MBA

Director, Management Strategy
ICF

Julie Donnell, MBA,
Julie Donnell is the Director of Management Strategy at ICF bringing 15 years of expertise in organizational transformation, process improvement, and employee experience. She has supported the Office of Digital Transformation for four years helping with organizational development and change management activities including the Digital Leadership Program. Ms. Donnell has partnered with many federal agencies including the FDA, Veterans Health Administration, Centers for Disease Control and Prevention, as well as with non-profit and private sector organizations. She holds an MBA, Graduate Certificate in Strategic Innovation and Entrepreneurship, and a Lean Six Sigma Green Belt.

Allison Ford

Business Informatics Specialist
FDA Center for Drug Evaluation and Research (CDER)

Allison R. Ford is a Business Informatics Specialist in the Office of Business Informatics (OBI), Office of Strategic Programs (OSP), CDER. Since joining OBI in 2016, Ms. Ford has played key roles in all stages of the software development lifecycle process in support of all CDER offices. Presently, she is focused on a modernization effort aim to transition CDER's siloed legacy systems to a single enterprise cloud-based workflow management system with the goal to help CDER make better data-driven decisions.

Jaimee Friend

Director, Employee Resource & Information Center (ERIC)
FDA Office of Digital Transformation (ODT)

Jaimee Friend serves as the Branch Chief for the Employee Resource & Information Center (ERIC) within the Office of Digital Transformation (ODT). His branch serves as the "front door" Service Desk supporting all FDA employees on a myriad of administrative services including: finance and travel, building and facilities, human resources, contracts and grants, safety services, and other employee support services. ERIC also provides certain services to contractors and the external public.

Saumyendu Ghosh, PhD

Director, Office of Business Informatics and Solutions Management (OBISM)
FDA Office of Inspections and Investigations (OII)

Saum Ghosh, Ph.D., is director of the Office of Business Informatics and Solutions Management (OBISM) in the FDA's Office of Inspections and Investigations (OII). In this role, he leads OII-wide information technology activities to optimize systems and data for operational work and decision-making in support of public health. His executive leadership experience in enterprise software and services has focused on relationship building and process improvement. Dr. Ghosh earned his Ph.D. and Master of Engineering in project management from the University of Maryland, College Park, and Master of Statistics from the Indian Statistical Institute in Kolkata, India.

John Andrew Johnson , MPA, PMP

Director, Fiscal Services and Operations (FSO)
FDA Office of Finance, Budget, and Acquisitions

John Andrew Johnson serves as the Director of Fiscal Services and Operations within the Office of Operations at the Food and Drug Administration. 0078Currently he is responsible for managing the FDA's Working Capital Fund, valued at over $800 million dollars. John has been with the FDA since 2008 and with the Federal government since 2005. Prior to that he spent 8 years working at the New York State Division of Budget. John was born in Queens New York and attended the State University of New York college system where he received his Bachelor's in Political Science and Master's in Public Administration. John is an avid music lover, is married to his high school sweetheart and has two kids; John and Gabrielle, 14-year-old fraternal twins.

Lana Kostecka

Supervisory IT Specialist
FDA Office of Digital Transformation (ODT)

Lana Kostecka has worked at the FDA for 29 years. She currently supervises the Office of Digital Transformation's Administrative Services Team which provides cost-effective IT training to Agency staff and focuses on providing IT training to the office. She is excited about the new technology that ODT is supporting and is eager to incorporate the changing technology into a more robust training program.

Steven Kozlowski, M.D

Acting Chief Scientist
Office of the Chief Scientist

Steven Kozlowski, M.D., is the FDA's Acting Chief Scientist. The Chief Scientist promotes, leverages, and leads cross-cutting, collaborative activities and initiatives that catalyze FDA science, innovation, and research to help the agency address its most pressing regulatory and public health questions and respond to emerging issues. Prior to assuming the role of Acting Chief Scientist, Dr. Kozlowski was responsible for ensuring the quality of all the active ingredients and biological products overseen by CDER in the Office of Pharmaceutical Quality. Dr. Kozlowski holds a bachelor's and a medical degree from Northwestern University and trained in pediatrics at the University of Illinois. He has published in a wide range of scientific areas relevant to the FDA mission from in vivo models for drug development to vaccine safety and from biosimilar uptake to epidemiology.

Karen Ledden

Business Informatics Specialist
FDA Center for Drug Evaluation and Research (CDER)

Kara Ledden is a Business Informatics Specialist in the Office of Business Informatics (OBI), Office of Strategic Programs (OSP), CDER. Since joining OBI in 2016, Ms. Ledden has been involved in modernizing IT solutions across several CDER offices, including the Offices of New Drugs, Generic Drugs, and Pharmaceutical Quality. Currently, she is the Product Manager for CDER's transition from siloed legacy systems to a single CDER-wide cloud-based workflow management system.

General Lee

Senior IT Program Manager
Office of Enterprise Portfolio Management (OEPM)
FDA Office of Digital Transformation (ODT)

General serves as the Food and Drug Administration Agency Lead for Technology Business Management within the Office of Enterprise Portfolio Management, providing governance oversight, strategic planning, and performance analysis expertise for all IT investments, projects, contracts, applications, and systems across FDA. He has been an FDA government employee for nearly 7 years, serving in various IT and regulatory science roles across FDA such as solutions architect, technical lead, project manager, health scientist, regulatory informatics specialist, Scientific Computing Board member, Big Data Interest Group Leader, and contracting officer's representative. General is dedicated to providing FDA staff involved in digital transformation with the right data to improve mission and business outcomes.

Josh Lehman

Director, Office of Business and Customer Assurance (OBCA)
Office of Information Management and Technology (OIMT)
FDA Office of Digital Transformation (ODT)

Joshua Lehman, PMP, is the Director, Office of Business and Customer Assurance (OBCA) and the Division of Business Partnership and Support (DBPS) in the Office of Information Management and Technology (OIMT) at the Food and Drug Administration. He is responsible for the Agency's collaboration services, FDA.gov, operational support, and end user IT equipment. Mr. Lehman is also the sponsor of FDA's User Experience Project Portfolio, which consists of 20+ information technology modernization projects to improve the day-to-day IT collaboration end user experience in a heightened telework environment. With over 23 years of extensive IT experience, Mr. Lehman excels in managing and developing information technology program solutions, project management, search engine optimization, web development as well as personnel management and mentoring.

Michael Phillips

MLaaS/RPAaaSIT Project Manager
Office of Information Management and Technology (OIMT)
FDA Office of Digital Transformation (ODT)

Michael Phillips has several years of experience managing large-scale project teams in both public and private sector organizations. He holds a Master of Business Administration and a bachelor's degree in healthcare administration and information systems. His duties as a member of the Division of Application Services within OIMT has allowed for several major accomplishments in the area of

Project Management. This work includes projects in the CDER IT portfolio and more recently as the Program Manager for the ML/RPA Enterprise Platform. The ML/RPA Program supports ODT's Strategic Priorities by Improving the alignment and management of lifecycle costs and IT investments and establishes a framework for best practices, controls, process improvement and stakeholder engagement agency wide.

Ajay Phogat
Senior Advisor to CIO
Customs and Border Protection

Mr. Phogat has decades of technical, managerial, and executive leadership experience in private industry. He has been a valued member of Customs and Border Protection for the past 18 years in Office of Information and Technology (OIT), first as a contractor since 2005 and then as a government employee since 2018. With his knowledge of both Legacy Automated Commercial Environment (ACE) and modernized ACE, he was responsible for Disaster Recovery and Resiliency of these critical systems. In the area of applications development, he led the creation of a standardized DevSecOps pipeline for applications move to the Cloud using Gitlab, led Robotic Process Automation (RPA) bot innovation among others and led multiple application development teams. Most recently, he led the successful modernization of the ACE Portal to a Cloud platform.

Anne Redding , PMP, CXPA
Director, ICF Digital Delivery
ICF

Anne Redding is a senior digital transformation strategist and certified Customer Experience (CX) professional with over 25 years of communications and project management experience. As a senior leader in ICF's Digital Delivery practice, Anne oversees a portfolio of digital health IT teams across HHS and has led ICF's Change Management Center of Excellence team at FDA since 2020. Anne and her team were instrumental in the establishment of FDA's Office of Digital Transformation as well as the development of ODT's Leadership Modernization Action Plan (LMAP) and the Digital Leadership Program (DLP). She holds a certificate in leadership from the University of Oxford and a degree in Journalism specializing in Government and Public Relations from the University of Maryland. Anne uses her multi-disciplinary expertise to design dynamic solutions that bridge people, processes, and technology to increase operational efficiency and improve customer/employee experience.

Eugene Reilly
Director, Division of Enforcement Systems Solutions
FDA Office of Inspections and Investigations (OII)

Eugene Reilly is the Director of the Division of Enforcement Systems which manages several systems that support operational staff conducting inspections, pursuing compliance actions, conducting sample collections and analysis, and managing recalls as well supporting systems involved with FDA's exchange of information with State, Local, Tribal, and Territorial (SLTT) regulatory partners. The Division also contains subject matter experts on the data from the systems the Division supports.

Lilliam Rosario

Senior IT Solutions Advisor
FDA Office of Digital Transformation (ODT)

Dr. Lilliam Rosario is the Director of the Office of Computational Science, Office of Translation Science, CDER, FDA. Dr.Rosario has been with the Agency for over 20 years. For the last 10 years, she has led the Office of Computational Science in its mission to provide CDER reviewers innovative and reliable solutions that improve and strengthen the scientific review process. Dr. Rosario drives the implementation of effective tools, technologies, and services that enable regulatory reviewers to apply their expertise to information. In OCS, she prioritizes innovation and collaboration with a mantra to “keep it small, keep it focused, and keep it moving”. In recognition of the Office’s accomplishments, Dr. Rosario received an Innovation Award during the 6th annual FedHealthIT in 2020. Dr. Rosario has a B.S. in Chemistry from the University of Puerto Rico and doctorate in Neuroscience from Rutgers University.

Steven Schecter

Senior IT Solutions Advisor
FDA Office of Digital Transformation (ODT)

Steve Schecter serves as a Senior IT Solutions Advisor within the Office of Information Management and Technology where he is responsible for providing overall project management, contract management, integration, and deployment services in support of FDA infrastructure, data centers, and service deliveries. In this role, Steve evaluates engineering technologies and their potential benefit and overall impact on the FDA IT infrastructure. Steve is also responsible for supporting enterprise IT modernization efforts for the agency focused on End-of-Life remediation activities and advises the Chief Technology Officer on Enterprise Risk.

Maria Shams-Ramsey

Senior Advisor
Office of Enterprise Portfolio Management (OEPM),
Office of Digital Transformation (ODT)

Maria Shams-Ramsey currently serves as a Senior Adviser within the Office of the Commissioner in support of the Office of Enterprise Portfolio Management (OEPM). In her role Maria leads enterprise-level initiatives and special projects in the areas of Portfolio Management, Financial Management, and enterprise governance. Maria provides FDA leadership with strategic and tactical guidance ensuring FDA’s $1B technology investment portfolio is in compliance with federal policies and enterprise-wide portfolio optimization efforts. In her current role, Maria serves as a strategic thought partner, spearheading innovative initiatives that drive positive outcomes for the FDA. Maria has supported various federal agencies as a consultant for much of her career. She began her federal consulting career at the Pentagon within the Office of the Secretary of Defense (OSD) where she specialized in strategy and public affairs for high-visibility technology initiatives. Maria obtained a Bachelor of Science from Indiana University and progressed her professional competencies at Georgetown University.

Kevin Snyder

Associate Director of Nonclinical Informatics
FDA Center for Drug Evaluation and Research (CDER)

Dr. Snyder received his bachelor's degree in biochemistry from the University of Maryland in 2008 and his PhD in neuroscience from the University of Pennsylvania School of Medicine in 2013. He currently serves as the Associate Director of Nonclinical Informatics in the Office of New Drugs in the Center for Drug Evaluation and Research at the US FDA where he manages data science and informatics initiatives to support the pharmacology/toxicology r eview program. These initiatives include research efforts to develop methods to optimize the regulatory use of standardized electronic CDISC-SEND-formatted toxicology study data as well as internal informatics projects to promote the development of scientifically sound, data-driven regulatory policies. Dr. Snyder also leads an agency-wide Data Science and Software Development working group that is focused on building out the internal infrastructure necessary to support the work of data scientists across the agency and is an active collaborator with several consortia efforts, e.g. CDISC, PHUSE, and BioCelerate, toimprove the implementation and use of the SEND data standard.

Nakia Stewart

Senior Director
FDA Office of Digital Transformation (ODT)

Karen Stokes -Lockhart

Senior Director
Gartner

Ms. Karen Stokes Lockhart is a Senior Director with Gartner where she guides public sector organizations through complex challenges spanning areas from strategic planning to portfolio and project management to talent development. She also hosts ThinkCast, a Gartner podcast with insights at the intersection of business and technology. Karen holds a Master of Science from George Mason University and a Bachelor of Science from University of Connecticut.

Craig Taylor

Chief Information Security Officer (CISO)
Director, Office of Information Security (OIS)
FDA Office of Digital Transformation (ODT)

Mr. Craig Taylor serves as the FDA's Chief Information Security Officer, leading the Cybersecurity, Counterintelligence, and Insider Threat Program. He ensures the confidentiality, integrity, and availability of information while protecting IT infrastructure, data, systems, and applications. After retiring as a Master Chief Petty Officer from the U.S. Navy, Mr. Taylor also served multiple Intelligence Community agencies. He holds an M.S. from George Mason University and B.S. from University of Maryland.

Nihar Thadani

Associate Director
Gartner

Ms. Nihar Thadani is an Associate Director with Gartner where she manages and delivers public sector consulting engagements. Her experience spans multiple IT capabilities including strategic planning, governance, talent and organization design, and data & analytics. Nihar holds an MBA and B.A. from Emory University.

Sandra Tibbs, PhD

Director, Organizational Performance and Leadership
ICF

Dr. Sandra Tibbs is the Director of Organizational Performance and Leadership at ICF, bringing over 20 years of expertise in leadership, organizational development, and transformation. She serves as the ICF lead and a primary facilitator for the FDA's Digital Leadership Program, supporting the FDA's Office of Digital Transformation (ODT) project team in its design, development, and execution. Dr. Tibbs has a strong background across government and corporate sectors, having collaborated with organizations such as the FDA, CDC, NIH, Microsoft, Inova, BP and Medtronic. She holds a Ph.D. in Organizational Leadership and is a Professional Certified Coach, leveraging her extensive experience to drive strategic initiatives and support impactful leaders.

Lewis Watson

Deputy Chief Information Security Officer
Cybersecurity Capabilities, Risk Management and Compliance
Office of Information Security (OIS)
FDA Office of Digital Transformation (ODT)

Mr. Lewis Watson serves as FDA's Deputy Chief Information Security Officer for Cybersecurity Capabilities, Risk Management and Compliance. Previously, Mr. Watson filled multiple senior leadership roles, including Director of Risk and Compliance and Director of Cybersecurity Capabilities and Integrations. Mr. Watson also served as a private sector consultant providing cybersecurity advice to industry clients and government agencies. Lewis earned his Bachelor of Science and Master of Science in Information Technology from Virginia Tech.

Jennifer Wendel

Acting Chief Information Officer (CIO)
U.S. Department of Health and Human Services (HHS)

Jennifer Wendel was appointed Acting Chief Information Officer (CIO) for the U.S. Department of Health and Human Services (HHS) on December 4, 2023. Prior to her Acting CIO appointment, Jennifer served as Deputy Chief Information Officer (DCIO) for HHS since January 2023. Jennifer provides leadership and oversight of the information technology (IT) systems and security activities for a workforce of over 83,000. As the head of the Office of the Chief Information Officer (OCIO), she leads the Department's efforts in developing and implementing IT policies, managing high priority projects, and planning strategic IT investments. As the Acting CIO, Jennifer also provides leadership and oversight of the Department's $7B IT portfolio in support of its expansive mission to enhance the health and well-being of Americans.

Margaret Zabriski
Business Informatics Advisor
FDA Center of Veterinary Medicine (CVM)

Margaret Zabriski is a Business Informatics Advisor in the Office of Management (OM) at the Center of Veterinary Medicine (CVM). Dr. Zabriski leads CVM's IT Modernization Initiative, in which CVM re-imagining a data-first approach to provide real-time, comprehensive, situational awareness to predict, protect, and promote global human and animal health. Prior to her current role, Dr. Zabriski served as the Director of OM's Business Informatics Staff, providing oversight and leadership of the IT, property and AV support for CVM.