DAY 1 - OCTOBER 10, 2023

OPENING REMARKS

9:00AM – 9:20AM ET

Robert M. Califf, M.D.

Commissioner, US Food and Drug Administration

Dr. Robert M. Califf is the 25th Commissioner of Food and Drugs. He also served in 2016 as the 22nd Commissioner, and immediately prior to that as the FDA's Deputy Commissioner for Medical Products and Tobacco. He has spent a good portion of his career affiliated with Duke University, where he served as a professor of medicine and vice chancellor for clinical and translational research, director of the Duke Translational Medicine Institute, and was the founding director of the Duke Clinical Research Institute. He 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.

KEYNOTE SPEAKER

9:30AM – 10:20AM ET

Leveraging Multi-Omics Approaches to Uncover Novel Insights in Health and Disease

Temesgen D. Fufa, Ph.D.

Program Director, Division of Genome Sciences, National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH)

Dr. Temesgen D. Fufa is a program director at NHGRI in the Division of Genome Sciences, where he directs a portfolio of research grants focused on genome structure and function, including technology development for single-molecule sequencing and the application of multi-omics technologies. Dr. Fufa's portfolio also includes managing NHGRI's training grants as well as initiatives aimed at diversifying genomics and global health research such as through the Human Heredity and Health in Africa (H3Africa) program. Previously, Dr. Fufa was a staff scientist at the National Eye Institute where he led research focused on stem cells, functional genomics, and multi-omics to elucidate the mechanisms of developmental diseases. Dr. Fufa received a M.S. in biochemistry and molecular biology with a major in biotechnology from Georgetown University School of Medicine, and a Ph.D. in biochemistry and molecular biology from Howard University College of Medicine. He completed his dissertation research at NCI's Laboratory of Receptor Biology and Gene Expression and his postdoctoral research training at NHGRI in the Genetic Disease Research Branch.

BREAKOUT SESSION: ONE HEALTH OMICS

10:30AM – 12:00PM ET

Moderator

Carlo Mercado, Ph.D.

Biologist Reviewer, Division of Animal Bioengineering and Cellular Therapies, Office of New Animal Drug Evaluation, Center for Veterinary Medicine (CVM), US Food and Drug Administration

Dr. Carlo Mercado is a Biologist Reviewer on the Animal Biotechnology Team in the Division of Animal Bioengineering and Cellular Therapies. As a reviewer, Dr. Mercado evaluates applications that support the development of intentional genomic alterations in animals. After receiving a Bachelor of Science in Forensic Chemistry-DNA Analysis from Towson University, Dr. Mercado completed his Ph.D. in Human Genetics and Genomic Medicine from the University of Maryland School of Medicine, where he identified and characterized novel mRNA isoforms for hypertension-associated genes in the human kidney.

Omics Applications of One Health at the Center for Veterinary Medicine

Lucas Harrison, Ph.D.

Research Microbiologist, Division of Emerging Technologies, Office of Applied Science, Center for Veterinary Medicine (CVM), US Food and Drug Administration

Dr. Lucas Harrison joined CVM in 2019 as a Staff Fellow where he evaluated genomic markers for source attribution in foodborne pathogens such as Salmonella, Campylobacter and E. coli. In his current position, he investigates the application of long read sequencing technologies to evaluate the roles of antimicrobial resistance genes, virulence genes, and plasmid diversity in foodborne pathogens.

How Omics Technologies are Useful to the One Health Approach within Center for Food Safety and Applied Nutrition

Padmini Ramachandran, M.S.

Research Biologist, Division of Microbiology, Office Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN), US Food and Drug Administration

Dr. Padmini Ramachandran has been working on the application of metagenomics on food safety the past 13 years within FDA. She works on developing methods based on target and non-target metagenomic techniques to describe ecologies associated with metagenomic techniques to describe ecologies associated with complex environmental samples. She works with metagenomics team to develop precision analysis tools for the detection of outbreak strains from food matrices.

One Health Approach to Tackle Cyclosporiasis: Cyclospora Genomics and Genotyping Method Development for Food and Environmental Samples

Hediye Nese Cinar, Ph.D.

Research Biologist, Division of Virulence Assessment, Office of Applied Research and Safety Assessment, Center for Food Safety and Applied Nutrition (CFSAN), US Food and Drug Administration

Dr. Hediye Nese Cinar is a Research Biologist at CFSAN. Her areas of research include bacterial virulence mechanisms, genome-wide responses to bacteria and heavy metals in the model organism Caenorhabditis elegans; developmental genetics and neurobiology of this organism; and genomics of foodborne parasite Cyclospora cayetanensis. Since 2014, she has been leading genomics and method development projects to obtain near complete genome assemblies of foodborne parasite Cyclospora cayetanensis and developing genotyping and in vitro culture methodologies for this parasite.

Adverse Outcome Pathways and One Health: Improving Predictive Toxicology and Toxicological Risk Analysis

Anwar Husain, Ph.D.

Toxicologist, Division of Nonclinical Science, Office of Science, Center for Tobacco Products (CTP), US Food and Drug Administration

Dr. Anwar Husain joined CTP in October 2020. As part of his regulatory duties, Anwar's interests are in the implementation and use of applied computational toxicology for data associated with tobacco product

applications. Anwar previously worked as a Research Scientist at Johns Hopkins University School of Medicine, Department of Oncology. Anwar received his M.D. and Ph.D. in Pharmacology and Toxicology from the University of Louisville School of Medicine, his Master of Science in Computer Science from Hood College, and his Bachelor of Science in Computer Science and his Bachelor of Science in Biochemistry from the University of Maryland, College Park. Anwar also enjoys outdoor activities, playing tennis, basketball, swimming, and astronomy.

BREAKOUT SESSION: GENOMICS, TRANSCRIPTOMICS, AND METAGENOMICS

14:00PM-15:30PM ET

Moderator

Cinque Soto, Ph.D.

Biologist, Division of Cell Therapy, Office of Cellular Therapy and Human Tissues, Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration

Dr. Cinque Soto received his PhD in molecular biophysics from Columbia University's School of Medicine. After receiving his PhD, Cinque went on to carry out postdoctoral studies at the University of Pennsylvania's School of Medicine. Following his postdoctoral studies, Cinque moved into the software industry where he worked on molecular force field development and small-molecule docking protocols at SCHRODINGER. In 2013, Cinque left the software industry to become co-head of the structural bioinformatics core section (SBIS) at NIAID's Vaccine Research Center (VRC). In 2016, Cinque moved to Vanderbilt University Medical Center (VUMC) as a research associate professor where he developed NGS methods for the longitudinal analysis of antibody repertories. In 2021, Cinque joined CBER in the Office of Tissues and Advanced Therapies (OTAT) as a bioinformatics reviewer. Cinque continues to serve as a lead bioinformatics reviewer for neoantigen discovery products and gene editing products in CBER's Office of Therapeutic Products (OTP).

Finding Pathogen Needle in the Metagenomic Haystack

Sandip De, Ph.D.

Senior Staff Fellow, Division of Cell Therapy, Office of Cellular Therapy and Human Tissues, Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration

Dr. Sandip De completed his PhD in molecular and cellular biology at University of Birmingham (UK). During his PhD, he got very interested in next-generation sequencing and epigenetic regulation of gene expression. After graduating in 2011, Dr. De joined the NICHD/NIH to work on understanding how epigenetics control organism development and cancer. In 2019, he started as an assistant research professor at University of Maryland, College Park and used his NGS expertise to understand the ticks and tick-borne disease pathogenesis. In September 2021, Dr. De joined as a senior staff fellow/principal investigator at CBER. He and his team are working on developing NGS/metabolomics-based pathogen detection assays and is exploring the mechanisms of host-pathogen interactions for safe use of cells and tissues for therapy.

Genome-Wide Detection of Mutations Induced by Chemicals and Genome Editing by HiFi Sequencing

Javier Revollo, Ph.D.

Research Biologist, Division of Genetic and Molecular Toxicity, National Center for Toxicological Research (NCTR), US Food and Drug Administration

Dr. Javier Revollo obtained a Ph.D. in Molecular Cell Biology from Washington University in St. Louis and completed his postdoctoral training at the NIEHS/NIH. He has been in the FDA for 10 years leading efforts for the direct detection of somatic mutations by DNA sequencing. Somatic mutations are genetic alterations that increase cancer risk. They can occur spontaneously but also result from DNA damage induced by the environment (*e.g.*, sunlight) or genotoxic compounds (*e.g.*, carcinogens). Current genetic toxicology assays can only estimate somatic mutation rates by assaying the function of certain reporter genes or transgenes. Dr. Revollo has developed several sequencing methods capable of directly and efficiently identifying somatic mutations in the whole genomes. These methods could facilitate the risk assessments of chemicals and genome editing therapies.

The Quartet Project for Quality Control and Data Integration of Multi-Omics Profiling

Leming Shi, Ph.D.
Professor, School of Life Sciences and Shanghai Cancer Center, Fudan University
Director, International Human Phenome Institutes, Shanghai, China

Dr. Leming Shi is a professor at the School of Life Sciences and Shanghai Cancer Center of Fudan University and serves as the director of the International Human Phenome Institutes (Shanghai), China. Dr. Shi received his PhD in computational chemistry from the Chinese Academy of Sciences, MSc in computational chemistry from the University of Science and Technology of China, and BSc in analytical chemistry from Hunan University, China. Dr. Shi's research aims to improve the success rate of drug discovery and development and to promote precision medicine by generating and integrating high-quality multiomic data. While working at the FDA/NCTR, Dr. Shi conceived and led the MicroArray and Sequencing Quality Control (MAQC/SEQC) consortia, publishing four special issues in *Nature Biotechnology*. Dr. Shi was a co-founder of Chipscreen Biosciences and co-developed a chemogenomics-based drug discovery platform, resulting in the marketing approvals of one novel HDAC inhibitor (Chidamide) for treating cancers, and one novel PPARα/γ/δ pan-agonist (Chiglitazar) for treating type 2 diabetes.

Harnessing Multi-Omic Data for Exploratory Health Insights: Lessons from the SpaceX Inspiration4 Mission

Eliah G. Overbey, Ph.D.
Research Associate, Mason Lab, Institute for Computational Biomedicine,
Department of Physiology and Biophysics, Weill Cornell Medicine

Dr. Eliah G. Overbey is a former NASA Fellow and current Research Associate at Weill Cornell School of Medicine and Chief Scientific Officer at BioAstra. Dr. Overbey received her PhD from the University of Washington. She has pioneered genomic health research for numerous missions including Inspiration4, Polaris, and Axiom2.

KEYNOTE SPEAKER

15:45 PM – 16:45PM ET

Assembling the Perfect Bacterial Genome

Ryan Wick, Ph.D.
Department of Microbiology and Immunology, University of Melbourne at the Peter Doherty Institute for Infection and Immunity, Melbourne, Australia

Dr. Ryan Wick is a bioinformatician with a focus on bacterial genome assembly, specializing in long-read assembly and hybrid assembly techniques. Throughout his career, Ryan has developed numerous bioinformatics tools that have significantly advanced the field, including Bandage, Unicycler, Porechop, Filtlong, Badread, Trycycler, and Polypolish. Collectively, his publications have been cited over 10000 times. Ryan earned his PhD from Monash University under the supervision of Professor Kathryn Holt, for which the Australian Bioinformatics and Computational Biology Society awarded him the Outstanding PhD Thesis Award. Currently, Ryan is a postdoctoral researcher in Tim Stinear's group at the University of Melbourne's Peter Doherty Institute for Infection and Immunity, where he continues to work on developing novel assembly algorithms for bacterial genomes and metagenomes.

DAY 2 - OCTOBER 11, 2023

OPENING REMARKS

9:00AM – 9:20AM ET

Namandjé N. Bumpus, Ph.D.

Chief Scientist, US Food and Drug Administration

Dr. Namandjé N. Bumpus was named as the FDA's Chief Scientist on June 30, 2022. Before joining the FDA, Dr. Bumpus was the E.K. Marshall and Thomas H. Maren Professor and chair of the Department of Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. She served previously as associate dean for basic research in the Johns Hopkins University School of Medicine. Dr. Bumpus' research has focused on drug metabolism, pharmacogenetics, bioanalytical chemistry, and infectious disease pharmacology. Dr. Bumpus joined the faculty at Johns Hopkins in 2010 as an assistant professor. She earned a bachelor's degree in biology at Occidental College in 2003, a doctorate in pharmacology at the University of Michigan in 2007 and completed a postdoctoral fellowship in molecular and experimental medicine at The Scripps Research Institute in La Jolla, CA in 2010. Her many honors include the Leon I. Goldberg Award from the American Society for Clinical Pharmacology and Therapeutics, the James Gillette Award from the International Society for the Study of Xenobiotics, the John J. Abel Award in Pharmacology from the American Society for Pharmacology and Experimental Therapeutics and the Presidential Early Career Award for Scientists and Engineers, which is the highest honor bestowed by the United States government on early career scientists and engineers. Dr. Bumpus is an elected fellow of the American Association for the Advancement of Science. She became a Member of the National Academy of Medicine, Class of 2022, one of the highest honors in the fields of health, science, and medicine.

KEYNOTE SPEAKER

9:30AM – 10:30AM ET

Metabolomic Characterization of the Pathophysiology and Treatment Response of Major Depressive Disorder

Sudeepa Bhattacharyya, Ph.D.

Associate Professor, Arkansas State University

Dr. Sudeepa Bhattacharyya is an associate professor of Bioinformatics and Data Science in the College of Sciences and Mathematics at Arkansas State University since Fall, 2019. She also has a secondary appointment in the Department of Biomedical Informatics, University of Arkansas for Medical Sciences, Little Rock, AR where she had remained an assistant professor and a tenured associate professor for seven years (2012 – 2019). Her interest and experience span a broad spectrum of research domains, from multi-omics and multi-modal data integration for understanding disease pathobiology, particularly in neuropsychiatric disorders, to developing deep learning algorithms for healthcare applications such as risk predictions, mapping social determinants of health at individual level, missing value imputation for electronic health records data and addressing bias in healthcare. Additionally, her lab is developing spatial machine learning models to identify high-risk clusters of diseases like cancer. She is an active member of two large, NIH-funded, international consortia on neuropsychiatric disorders. She serves in leadership roles in several premier societies like American Public health Association, American Statistical Association, and the JEDI task force of ASA. She has co-facilitated think-tank sessions at NIH, served in NSF and OAH review panels, serves in editorial board of multiple journals, filed two US/international patent applications, and have remained funded in multiple NIH, NSF and USDA grants.

BREAKOUT SESSION: PROTEOMICS AND METABOLOMICS

10:30AM – 12:00PM ET

Moderator

Matt Hartog, Ph.D.

Toxicologist, Division of Nonclinical Science, Office of Science, Center for Tobacco Products (CTP), US Food and Drug Administration

Dr. Matt Hartog is a toxicologist within the Division of Nonclinical Science, Office of Science, at the Center for Tobacco Products. Matt joined CTP and the FDA in 2020 and is involved in the review of tobacco product applications and researching the toxicological properties of tobacco products. He has extensive experience in studying the toxicological mechanisms of inhaled chemicals and in using computational methods to identify susceptible groups and evaluate the human health risks associated with chemical exposures. Prior to joining the FDA, he completed his post-doctoral training at the United States Army Medical Research Institute of Chemical Defense where he used omics-based technology and computational methods to characterize the toxicity of inhaled chemicals and identify potential medical countermeasures for exposure.

Non-Targeted Analysis using LC/HR-MS for Food Safety: Data Collection/Processing Strategies and Quality Controls

Ann Knolholf, Ph.D.

Chief, Spectroscopy and Mass Spectrometry Branch, Office Regulatory Science
Center for Food Safety and Applied Nutrition (CFSAN), US Food and Drug Administration

Dr. Ann Knolhoff is the Branch Chief for the Spectroscopy and Mass Spectrometry Branch (SMSB) at the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition. She received her B.Sc. in Chemistry at Truman State University and her Ph.D. in Chemistry at the University of Illinois at Urbana-Champaign under the direction of Professor Jonathan Sweedler. Dr. Knolhoff has been at the FDA since 2011, first as a post-doctoral fellow under the direction of Dr. Tim Croley and then transitioning to a Research Chemist in SMSB. Her research primarily focused on the development of non-targeted analysis approaches using liquid chromatography and high-resolution mass spectrometry for food safety applications. The goal of this work was to determine best practices for non-targeted analysis so that these methods could be applied to a variety of different sample types, were capable of detecting and identifying broad molecular species, and yielded reliable and reproducible results. As Branch Chief, she directs SMSB researchers working on diverse applications and projects, including food additives, allergens, protein toxins, plant-incorporated protectants, species identification, nanomaterials, economic adulteration, and non-targeted analysis in CFSAN-regulated food, packaging, and cosmetic products.

Metabolomics Evaluation of the Impact of Violet-Blue Light (405 nm) on Platelet Concentrate

Richard D. Beger, Ph.D.

Director, Biomarkers and Division of Systems Biology, National Center for Toxicological Research (NCTR), US Food and Drug Administration

Dr. Richard Beger received a Ph.D. from Purdue University and completed postdoctoral training at Wesleyan University and Johns Hopkins University Medical School. His Ph.D. research focused on normal mode analysis of DNA under a variety of conditions. His postdoctoral appointments concentrated on using homonuclear and heteronuclear nuclear magnetic resonance (NMR) spectroscopy to solve NMR spectroscopy solution structures of zinc fingers, damaged DNA, and protein-protein complexes. During his second postdoctoral appointment, he developed an *in silico* method to use 1H, 13C, and 15N NMR assigned chemical shifts of the protein backbone atoms to form dihedral constraints on the backbone of proteins. This method increased the accuracy of the protein structures and permitted larger proteins to be solved by NMR spectroscopic methods. Dr. Beger is currently the branch chief of the Omics, Models, Imaging and Chemistry (OMIC) Branch in the Division of Systems Biology at NCTR. OMIC consists of a metabolomics team, proteomics team, tissue imaging, alternative methods team, and chemical modeling of toxicological endpoints.

Application of Proteomics for the Identification of Circulating Pharmacodynamic Biomarkers of IFNβ-1a Biologics

Paula Hyland, D. Phil., M.P.H.

Senior Staff Fellow and Genomics Lead, Division of Applied Regulatory Science, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), US Food and Drug Administration

Dr. Paula Hyland was trained in molecular biology and molecular epidemiology in the UK. She is currently a Senior Staff Fellow and Genomics Lead in the Division of Applied Regulatory Science, OCP, FDA. Her job functions include genomics support for reviews in rare diseases and research focusing on the identification of biomarkers of drug response and toxicity. Before joining the FDA in September 2017, Paula worked at the National Cancer Institute, NIH, in the Division of Cancer Prevention from 2009 to 2011, and in the Genetic Epidemiology, and the Integrative Tumor Epidemiology Branches in the Division of Cancer Epidemiology and Genetics from 2021 to 2017. Her work experience extends from in vivo and in vitro molecular projects evaluating the efficacy and adverse effects of drugs to omics discovery research in cancer susceptibility and etiology.

Distinct Proteomes and Allergen Profiles Appear Across the Life Cycle Stages of Alternaria alternata

Michael Strader, Ph.D.

Biologist, Laboratory of Immunobiochemistry, Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration

Dr. Michael Strader received his Master of Science in 1998 and Doctor of Philosophy in 2003 from the University of Tennessee with an emphasis on enzymology and protein structure-function. Afterward, he received extensive post-doctoral training in biological mass spectrometry at Oak Ridge National Laboratory (ORNL) and the National Institutes of Health (NIH). In 2011, he joined the Food and Drug Administration (FDA) serving as a research scientist in Dr. Abdu Alayash's laboratory at the Office of Blood Research and Review (OBRR). His work at OBRR resulted in 17 peer-reviewed publications and culminated in the 2017 FDA Excellence in Laboratory Science award for his development of a quantitative mass spectrometry method for studying hemoglobin exposed to oxidative stress. In 2020, he joined Dr. Jay Slater's laboratory at the Office of Vaccines Research and Review (OVRR) where he currently applies quantitative proteomic strategies for improving the quality of allergen extracts used to treat allergy patients. Dr. Strader has published 36 peer-reviewed journals and has been an invited speaker and presenter at national and international conferences.

KEYNOTE SPEAKER

13:45PM – 14:45PM ET

Getting the Best Out of -Omics Data – An Overview with Specific Examples

Wendell Jones, Ph.D.

Principal Bioinformaticist and Scientific Advisor, Q^2 Solutions Genomics

Dr. Wendell Jones is Principal Bioinformaticist and Scientific Advisor at Q2 Solutions Genomics. He conducts collaborative scientific research in multiple areas, including immuno-oncology and autoimmune disorders. His background includes analysis, development, and validation of the bioinformatic systems that process complex genomic assays, including next generation sequencing assays, evaluating new and emerging genomic technologies, and developing bioinformatic and biomarker implementation strategies. Dr. Jones received his BS in Mathematics at Furman University and his MS and PhD in Math Sciences (emphasis in Statistics) at Clemson University. He has over 20 years of experience in advanced genomic technologies and biomarker development and 25 years of experience in scientific and technology leadership positions. In addition to his duties at Q2 Solutions Genomics, Dr. Jones is currently Chair and founding member of the Board of Directors of the MAQC Society, a relatively new society devoted to enhancing reproducibility in scientific methods, especially in "Big Data" areas such as genomic science. He is author or co-author of over 75 peer-reviewed publications in genomics and engineering.

BREAKOUT SESSION: DATA INTEGRATION AND DATA MANAGEMENT

15:00PM – 16:30PM ET

Moderator

Samir Lababidi, Ph.D.

Statistician, Office of Data Analytics & Research, Office of Data Transformation (ODT), US Food and Drug Administration

Dr. Samir Lababidi is a Mathematical Statistician and a Bioinformatician, working on further development of the health informatics platforms, precisionFDA, and the Global Substance Registration System (GSRS). He is also co-leading the Data Integration and Data Management subgroup in the Omics Working Group. Previously, Dr. Lababidi worked in the Center for Biologics Evaluation and Research (CBER), where he was involved in several research studies for genomics risk factors associated with vaccines utilizing NGS technology. Prior to CBER, he served as a statistical reviewer at the Center of Devices and Radiological Health (CDRH), where he worked on diagnostic clinical studies and genomic research studies. Before joining the FDA, he was a research fellow in the Genomics and Bioinformatics Group at the National Cancer Institute/NIH. Dr. Lababidi served on several NIH panels, has a patent, and authored/co-authored over 60 publications in peer-reviewed journals including Nature Biotechnology, Cell, PNAS, and Cancer Research.

CellMinerCDB Cancer Cell Pharmacogenomic Databases

Sudhir Varma, Ph.D.

Genomics and Bioinformatics Branch, National Cancer Institute (NCI), National Institutes of Health (NIH)

Dr. Sudhir Varma has been deeply interested in the challenges and promise of integrated analysis of genomic data for the past 15 years. He is currently the lead bioinformatician at the Genomics and Bioinformatics Branch of the National Cancer Institute. There, his work has focused on the integromic analysis of data for the NCI-60 cancer cell line panel, on multiple mRNA, DNA, miRNA, and protein platforms combined with one of the most comprehensive drug response datasets in the world, to support the development of CellminerCDB, a web tool used by more than 1500 researchers world-wide. Previously he has worked at NIAID as a bioinformatician and as a data scientist with various pharmaceutical and digital health companies.

Visualization Approaches for Facilitation Omics Data Analysis

Wenjun Bao, Ph.D.

Chief Scientist and Director of Advanced Analytics, JMP statistical Discovery, SAS Institute Inc.

Dr. Wenjun Bao is a Chief Scientist and Director of advanced analytics for JMP statistical Discovery, SAS Institute Inc. Before joining SAS, she was an Intramural Research Training Award (IRTA)Fellow at NIH (National Institutes of Health), a professor at Duke University, and a scientist at the US EPA (Environmental Protection Agency). She has rich experiences in clinical, bioinformatics, biochemistry, and molecular biology research. She has expertise in variety data analysis including AI/ML models in clinical trial and genomics data analysis and text mining with multiple publications in peer-reviewed journals. Dr. Bao has been a research grant review committee member for NIH since 2005 and a research adviser for scientists at universities and government agencies. Dr. Bao is a Board of Director for CDISC and an adjunct professor at Fudan University.

Efficient Data Management with HIVE: Accelerating Genomic and Machine Learning Workflows

Luis Santana-Quintero, Ph.D.

Staff Fellow, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration

Dr. 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, transcriptomics, metagenomics, and single cell omics. As well as evolutionary computation, 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. He received his M.Sc. and Ph.D. in Computer Science from the "Center for Research and Advanced Studies" in Mexico in the area of nonlinear optimization using Evolutionary Algorithms.

Data Science for Omics

Vikrant Vijay, Ph.D.

Staff Fellow (Pharmacologist/Data Scientist), Division of Systems Biology, National Center for Toxicological Research (NCTR), US Food and Drug Administration

Dr. Vikrant Vijay received his initial training in veterinary medicine and subsequently earned a master's and Ph.D. degree in pharmacology. After a brief work at the NIEHS/NTP following his doctorate, Dr. Vijay accepted an ORISE fellow position at FDA's National Center for Toxicology Research (NCTR) in 2009. Since 2012, Dr. Vijay has worked in the capacity of staff fellow (pharmacologist/Data Scientist) in the NCTR's Division of Systems Biology. For more than a decade, his research has focused on advancing predictive-toxicology and precision-medicine efforts. Dr. Vijay is an expert in developing and utilizing diverse computational approaches to integrate, analyze, and interpret toxicological and omics data. Dr. Vijay has received numerous awards for his outstanding achievements and contributions to promote public health, which include FDA's "Outstanding Service Award" (2014 and 2017), NCTR's "Outstanding Service Group Award" (2014), NCTR's "Special Act Award" (2014, 2017, 2019, and 2021), NCTR's "Outstanding Junior Investigator Award" (2016), and Excellence in Laboratory Science (2020). In addition, Dr. Vijay has served as chair in several platform and poster sessions as well as mentor for the Society of Toxicology's undergraduate education program, NCTR's summer student research program, FDA's mentoring program and FDA's Applied Learning Track program.