2021 UCSF-Stanford CERSI Innovations in Regulatory Science Summit

Speaker/Panelist Biographies

Amy P. Abernethy, MD, PhD
Principal Deputy Commissioner, U.S. Food and Drug Administration

Amy P. Abernethy, M.D., Ph.D. is an oncologist and internationally recognized clinical data expert and clinical researcher. As the Principal Deputy Commissioner of Food and Drugs, Dr. Abernethy helps oversee FDA's day-to-day functioning and directs special and high-priority cross-cutting initiatives that impact the regulation of drugs, medical devices, tobacco and food. As acting Chief Information Officer, she oversees FDA's data and technical vision, and its execution. She has held multiple executive roles at Flatiron Health and was professor of medicine at Duke University School of Medicine, where she ran the Center for Learning Health Care and the Duke Cancer Care Research Program. Dr. Abernethy received her M.D. at Duke University, where she did her internal medicine residency, served as chief resident, and completed her hematology/oncology fellowship. She received her Ph.D. from Flinders University, her B.A. from the University of Pennsylvania and is boarded in palliative medicine.

Disclosures: None

Hal Barron, MD
Chief Scientific Officer and President, R&D, GlaxoSmithKline

Hal joined GSK as Chief Scientific Officer and President, R&D on 1 January 2018. He was also appointed to the GSK Board of Directors as an Executive Director and member of the Science Committee.
Hal is responsible for all research and development of our pipeline molecules as well as life-cycle management of the approved medicines. He is a member of the Corporate Executive Team.
Prior to joining GSK in 2018, Hal was President, R&D at Calico. Prior to this, he was Executive Vice President, Head of Global Product Development, and Chief Medical Officer of Roche, responsible for all the products in the combined portfolio of Roche and Genentech. At Genentech, he was Senior Vice President of Development and Chief Medical Officer.
Hal is an Associate Adjunct Professor, Epidemiology & Biostatistics, University of California, San Francisco. He is a Non-Executive Board Director of GRAIL, Inc, an early cancer detection healthcare company and a member of the Advisory Board of Verily Life Sciences, a subsidiary of Alphabet, Inc. Hal was a Non-Executive Director and Chair of the Science & Technology Committee at Juno Therapeutics until March 2018, when it was acquired by Celgene.
He holds a Bachelor of Science degree in Physics from Washington University in St Louis and a medical degree from Yale University. He completed his training in Cardiology and Internal Medicine at the University of California, San Francisco.
Hal has been issued several patents for his work in thrombosis and angiogenesis and has published more than 90 papers in peer-reviewed scientific journals.

Disclosures: None

Gideon Blumenthal, MD
Vice President of Global Regulatory Affairs for Oncology, Merck & Co.

Dr Gideon Blumenthal is a hematologist oncologist who is currently Vice President, Global Regulatory Affairs in Oncology, Merck. Prior to joining Merck, Dr Blumenthal spent over a decade at the US Food and Drug Administration Oncology office, taking on increasing leadership responsibilities during his time at the Agency. He initially served as a medical reviewer, then clinical team leader, followed by Acting Deputy Director in the Office of Hematology Oncology Products and Associate Director for Precision Oncology, and most recently

served as the Deputy Center Director of the Oncology Center for Excellence. Dr Blumenthal did his internal medicine training at the University of Maryland School of Medicine, followed by a hematology oncology fellowship at the National Cancer Institute. He was an attending physician in the NCI thoracic oncology clinic. He received numerous awards, including the 2018 American Society for Clinical Oncology Public Service Award. He has co-authored over 100 articles in the Oncology and Drug Development peer reviewed literature and has authored 3 book chapters.

Disclosures: Employee of Merck

Florence Bourgeois, MD, MPH
Associate Professor of Pediatrics, Harvard Medical School

Dr. Bourgeois, MD, MPH is Associate Professor of Pediatrics at Harvard Medical School and Co-Director of the Harvard-MIT Center for Regulatory Science. At Boston Children's Hospital, she directs the Initiative in Pediatric Therapeutics and Regulatory Science. Dr. Bourgeois' research is focused on applying clinical epidemiology and big data analytics to evaluate and inform evidence-based use of therapeutics in children. Her work examines the real-world use of therapeutic interventions across diverse patient populations, with major research contributions related to defining the evidence base underpinning regulatory approval of pediatric drug indications, assessing current policies aimed at increasing pediatric product labeling, and developing innovative trial designs to increase the efficiency of pediatric clinical trials and drug development. She is the recipient of an Innovation in Regulatory Science Award from the Burroughs Wellcome Fund to evaluate the epidemiology of off-label drug and biologic use in children and improve provider access to benefit-risk information on FDA-regulated products. Dr. Bourgeois has previously served as an Expert Visitor to the European Medicines Agency to analyze the EU's pediatric drug legislation. Her clinical training and experience are in pediatrics and pediatric emergency medicine.

Disclosures: None

Diana Brainard, MD
Senior Vice President and Virology Therapeutic Area Head, Gilead Sciences

Diana Brainard, M.D., is senior vice president and head of the Virology therapeutic area at Gilead Sciences, Inc where she oversees the clinical development of novel therapeutic, preventative and curative approaches for HIV, hepatitis B and C, and emerging and respiratory viruses including SARS-CoV-2. Dr. Brainard began her industry career at Merck in 2007, working first in clinical pharmacology, then as infectious disease lead in experimental medicine. She joined Gilead in 2010 and led the clinical development of four therapies for hepatitis C, approved over four years; in 2020, she has led the company-wide initiative to rapidly develop and scale remdesivir. Dr. Brainard serves as an Independent Director on the board of Allovir as well as the Gilead Foundation and is a member of the TriNetX strategic advisory board.
Dr. Brainard performed her internal medicine and infectious diseases fellowship training at Massachusetts General Hospital and Brigham and Women's Hospital in Boston, Massachusetts. Following completion of her medical training, she was on faculty at Harvard Medical School where she conducted NIH-funded research on HIV immunology and T-cell trafficking. Dr. Brainard received a BA in comparative literature at Brown University and an MD at Tulane University School of Medicine.

Disclosures: Employee of and shareholder in Gilead Sciences, Inc.

Speaker/Panelist Biographies

Carolyn S. Calfee, MD
Professor of Medicine, University of California San Francisco

Carolyn S. Calfee, MD MAS is Professor of Medicine and Anesthesia at the University of California, San Francisco, where she attends in the intensive care units. Her primary academic focus is the pathogenesis and treatment of the acute respiratory distress syndrome (ARDS). Current research projects include: (1) molecular subphenotypes of ARDS and precision medicine in critical care; (2) the role of environmental exposures including smoking, air pollution, and novel tobacco products in susceptibility to lung injury; and (3) novel treatments for ARDS. During the COVID-19 pandemic, she has been the UCSF clinical lead and steering committee member for the NIAID-funded Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) study and she is one of the lead PI's for the ISPY COVID clinical trial, a Phase 2 adaptive platform clinical trial of novel treatments for COVID-19 associated ARDS.

Disclosures: Grant funding from: NIH, FDA, DOD, Roche/Genentech, Quantum Leap Healthcare Collaborative

---

Robert M. Califf, MD, MACC
Head of Clinical Policy and Strategy, Verily Life Sciences and Google Health

Robert M. Califf, MD, MACC, is the Head of Clinical Policy and Strategy for Verily and Google Health for Verily and Google Health. Prior to this Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

Disclosures: Verily – employee, Google Health – employee, Biogen - Advisory Panel member, Cytokinetics - Board Member, DIA Science and Policy - Advisory Council Member, ConcePTION - Advisory Board Member

---

Patrizia Cavazzoni, MD
Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Patrizia Cavazzoni, M.D., is the acting director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. The Center ensures that safe and effective drugs are available to improve the health of the people in the United States.
Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs, and safety surveillance.
Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, and she is a fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology, and recipient of the American College of Psychiatrists' Laughlin Fellowship."

Disclosures: None

Speaker/Panelist Biographies

Wilbur Chen, MD, MS
Professor of Medicine, University of Maryland

Dr. Chen is an adult infectious disease physician-scientist with a specific interest in clinical vaccinology. He is Professor of Medicine at the University of Maryland School of Medicine (UMSOM), Chief of the Adult Clinical Studies section within the Center for Vaccine Development and Global Health (CVD, an organized research center of UMSOM), and Director of the University of Maryland, Baltimore (UMB) Travel Medicine Practice. His research career has been focused on developing vaccines against pathogens of global health importance, especially those of resource poor or impoverished populations. Dr. Chen is active investigator within the NIAID-supported Vaccine and Treatment Evaluation Unit (VTEU) network, which is responsible for conducting high-priority vaccine trials for the government. He has been a principal investigator on a number of vaccine trials, spanning influenza viruses (Seasonal, Pandemic 2009 H1N1, Avian H5N1, and Avian H7N9 influenza), agents of bioterror (Tularemia and Staphylococcal enterotoxin B), and enteric pathogens (typhoid, cholera and enterotoxigenic E. coli). He has funding support from NIH, CDC, DARPA, the Bill & Melinda Gates Foundation, the Wellcome Trust, and PATH (an international nonprofit research organization).

Disclosures: Dr. Chen current has a research grant with Emergent Biosolutions, Inc. for the development of a Shigella-ETEC vaccine. He is receiving consulting fees with Leidos, ICON Clinical Research, Lumen Biosciences, and MassBiologics. He has previously received grant funding or fees from consulting with GSK, Seqirus, FluGen, MedImmune, Medicago, Valneva, Janssen, Watermark Research Partners, and the American Cleaning Institute.

Jennifer Cochran, PhD
Chair, Department of Bioengineering, Stanford University

Jennifer Cochran is the Shriram Chair of the Department of Bioengineering at Stanford University. She is a Professor of Bioengineering and, by courtesy, Chemical Engineering and a member of the Cancer Biology, Biophysics, and Immunology graduate programs. Dr. Cochran serves as the Director of the Stanford/NIH Biotechnology pre-doctoral training program. Her research group uses interdisciplinary approaches in chemistry, engineering, and biophysics to study complex biological systems and to develop new tools for basic science and biomedical applications. Dr. Cochran's translational interests span protein-based drug discovery and development for applications in oncology and regenerative medicine, and development of new technologies for high-throughput protein analysis and engineering. She and her research group have invented numerous therapeutic molecules that have been licensed to public and private biotech companies including an engineered protein currently in clinical trials for treating ovarian and kidney cancers. Dr. Cochran has also launched several companies in the drug discovery and development space. Leveraging this experience, she co-developed the Stanford Faculty Entrepreneurial Leadership Program and mentors Stanford faculty and students/postdocs on technology transfer and life science company formation.

Disclosures: Co-founder and shareholder: xCella Biosciences, Combangio, Inc, Trapeze Therapeutics. Shareholder: Aravive, Inc., Xyence Therapeutics.

Joe Derisi, PhD
Professor of Biochemistry and Biophysics, University of California San Francisco

Dr. Joe DeRisi is Co-President of the Chan Zuckerberg Biohub and a Professor in the Department of Biochemistry and Biophysics at UCSF. He employs an interdisciplinary approach combining genomics, bioinformatics, biochemistry, and bioengineering to study parasitic and viral infectious diseases in a wide range

of organisms, for the purpose of discovering and studying novel or unrecognized biothreats. Early work in his lab contributed to the identification of the SARS coronavirus in 2003. Dr. DeRisi was one of the early pioneers of DNA microarray technology and whole genome expression profiling and is nationally recognized for his efforts to make this technology accessible and freely available. He received a B.A. in Biochemistry and Molecular Biology (1992) from the UC Santa Cruz and a Ph.D. in Biochemistry (1999) from Stanford University prior to joining the UCSF faculty as a Sandler Fellow in 1999. Dr. DeRisi was a Howard Hughes Medical Investigator from 2006-2016, which he left to take on the role of Co-President of the Chan Zuckerberg Biohub, a non-profit medical research organization affiliated with UCSF, UC Berkeley, and Stanford University. More recently, through his role as Co-President of the Chan Zuckerberg Biohub, he has redirected his efforts to providing large-scale, rapid turnaround clinical COVID19 testing through a UCSF/Biohub collaboration called the "CLIAHUB." As of November, the CLIAHUB has returned over 155,000 clinical results to Californians.

Disclosures: None

Martha Donoghue, MD
Acting Deputy Director, Division of Oncology 2, Offices of Oncologic Diseases, U.S. Food and Drug Administration

Martha Donoghue is the Acting Deputy Director of the Division of Oncology 2 in the Office of Oncologic Diseases at the U.S. Food and Drug Administration (FDA). Dr. Donoghue provides regulatory oversight, engages in clinical review activities, and advises stakeholders regarding strategies for clinical development of drugs and therapeutic biologics for the diagnosis, prevention, and treatment of cancer. Dr. Donoghue also serves on several FDA and external working groups aimed at expediting development of treatments for pediatric and adult patients with cancer. Areas of special interest include development of treatments for rare cancers and the use of innovative designs and clinical outcome assessments in clinical trials to optimize drug development. Prior to joining FDA in 2009, Dr. Donoghue completed a fellowship in Pediatric Hematology and Oncology at the Children's National Medical Center after working for several years as a general pediatrician in private practice. She received her medical degree from Emory University and completed a residency in general pediatrics at the Georgetown University Medical Center.

Disclosures: None

Michael V. Drake, MD
President, University of California

Dr. Michael V. Drake was appointed the 21st president of the University of California in August 2020. He oversees UC's world-renowned system of 10 campuses, five medical centers, three nationally affiliated labs, more than 280,000 students and 230,000 faculty and staff.
Dr. Drake previously served as president of The Ohio State University from 2014 through June 2020. Prior to OSU, he served in several roles at the University of California including nine years as chancellor of UC Irvine and five years as the systemwide vice president for health affairs.
An ophthalmologist by training, Drake received his A.B. from Stanford University, his M.D. and residency from UCSF, and his fellowship training in ophthalmology at UCSF and the Massachusetts Eye and Ear Infirmary.

Disclosures: None

Speaker/Panelist Biographies

Laura Esserman, MD, MBA
Professor of Surgery and Radiology, University of California San Francisco

Dr. Laura Esserman is Professor of Surgery and Radiology at the University of California, San Francisco (UCSF) and director of the UCSF Breast Care Clinic. Her work in breast cancer spans the spectrum from basic science to public policy issues, and the impact of both on the delivery of clinical care. Dr. Esserman is recognized as a thought leader in cancer screening and over-diagnosis, as well as innovative clinical trial design. She led the creation of the University of California-wide Athena Breast Health Network, a learning system designed to integrate clinical care and research as it follows 150,000 women from screening through treatment and outcomes. The Athena Network launched the PCORI-funded Wisdom Study, which tests a personalized approach to breast cancer screening in 100,000 women. She is also a leader of the innovative I-SPY TRIAL model, designed to accelerate the identification and approval of effective new agents for women with high risk breast cancers. She recently got FDA approval for an I-SPY Covid trial, designed to rapidly screen and confirm high impact treatments to reduce mortality and time on ventilators.

Disclosures: I am on the Blue Cross Medical Advisory Panel. I am an uncompensated board member of Quantum Leap Healthcare Collaborative and I have an Investigator initiated trial for high risk DCIS funded by MERCK

Kathleen M. Giacomini, PhD
Professor of Bioengineering and Therapeutic Sciences, University of California San Francisco

Kathy Giacomini, a professor in the School of Pharmacy at the University of California, San Francisco, is a leader in the field of membrane transporters with a focus on genetic polymorphisms. She cloned, characterized and discovered the endogenous role of the human xenobiotic transporter, OCT1 (SLC22A1), and recently de-orphaned SLC22A24, an anion exchanger that preferentially transports steroid glucuronide conjugates. Together with others, she co-founded the International Transporter Consortium, which has published highly impactful papers informing regulatory policy. She is the Co-Principal Investigator of the UCSF-Stanford Center of Excellence in Regulatory Sciences and Innovation and President of the Pharmacogenomics Research Network. She has received numerous awards and is an elected member of the National Academy of Medicine.

Disclosures: Co-founder of Apricity Therapeutics, Inc

Sam Hawgood, MD
Chancellor, University of California San Francisco

Sam Hawgood, MBBS, is currently the Chancellor and holds the Arthur and Toni Rembe Rock Distinguished Professor appointment at the University of California, San Francisco (UCSF). Dr. Hawgood graduated from the University of Queensland in Australia in 1975. After graduation, he trained in pediatrics with a sub-specialty interest in neonatology in Australia. Dr. Hawgood moved to the Cardiovascular Research Institute at UCSF in 1982 to work with Drs. Tooley and Clements, pioneers in the discovery and therapeutic uses of pulmonary surfactant in premature babies. Dr. Hawgood served as Division Chief of Neonatology from 1994 to 2006, Associate Director of the CVRI since 1997, and Chair of Pediatrics and Physician-in-Chief of the UCSF Children's Hospital from 2003-2009, and Dean of the School of Medicine from 2009-2014. He was the President of the Society for Pediatric Research in 1999 and is a member of the National Academy of Medicine.

Disclosures: None

RADM Denise Hinton, MS
Chief Scientist, U.S. Food and Drug Administration

Rear Admiral Denise Hinton has served as Chief Scientist at the US Food and Drug Administration since July 2017. She oversees the offices and centers that make up the Office of the Chief Scientist, Office of the Commissioner. Her responsibilities encompass interdisciplinary toxicology research, health informatics, technology transfer, scientific training and education, laboratory safety, as well as leadership, coordination, and oversight for FDA's national and global health security, counterterrorism, and emerging threats portfolios. RADM Hinton provides the strategic leadership, coordination, and expertise that support scientific excellence, innovation, and capacity to achieve FDA's public health mission.
Working closely with FDA center and field operations leadership, she promotes the adoption of cross-cutting, collaborative activities and initiatives, including One Health, a recently formalized FDA initiative that is leveraging innovative science and research to solve health problems resulting from the increasing interconnection between humans, animals, and their shared environments.
Before becoming Chief Scientist, RADM Hinton held multiple positions within FDA's Center for Drug Evaluation and Research, including Deputy Director of CDER's Office of Medical Policy. She is a Fellow of the American Academy of Nursing, earned her B.S. in Nursing from Florida State University, and M.S. from Boston University. She was an officer in the U.S. Air Force before joining FDA.

Disclosures: None

Peter S. Kim, PhD
Professor of Biochemistry, Stanford University

Peter S. Kim is the Virginia & D.K. Ludwig Professor of Biochemistry at Stanford University School of Medicine and an Institute Scholar of Stanford ChEM-H. He is also the Lead Investigator of the Infectious Disease Initiative at the Chan Zuckerberg Biohub. He was President of Merck Research Laboratories from 2003-2013 and oversaw development of more than 20 new medicines and vaccines, including JANUVIA, the first DPP 4 inhibitor for type 2 diabetes; GARDASIL, the first vaccine for the prevention of cervical cancer; ISENTRESS, the first HIV-1 integrase inhibitor; ZOSTAVAX, the first vaccine for the prevention of shingles; and KEYTRUDA, the first FDA approved PD-1 immune checkpoint inhibitor for the treatment of cancer. Earlier, he was Professor of Biology at MIT, Member of the Whitehead Institute and an HHMI Investigator, where he discovered a salient component of how proteins cause viral membranes to fuse with cells, designed novel compounds to stop membrane fusion by HIV-1, and pioneered efforts to create an AIDS vaccine based on similar principles. His current service includes the Medical Advisory Board of the Howard Hughes Medical Institute (HHMI); the Scientific Advisory Board of the NIH Vaccine Research Center; and the Biology Department Visiting Committee of the MIT Corporation. He is a member of the National Academy of Sciences, the National Academy of Medicine and the National Academy of Engineering.

Disclosures: None

Nevan Krogan, PhD
Professor of Cellular and Molecular Pharmacology University of California San Francisco

Nevan Krogan, PhD, is a molecular biologist, UC San Francisco professor, and director of the intensely interdisciplinary Quantitative Biosciences Institute (QBI) under the UCSF School of Pharmacy. He is also a senior investigator at the Gladstone Institutes.

He led the work to create the SARS-CoV-2 interactome and assembled the QBI Coronavirus Research Group (QCRG), which includes hundreds of scientists from around the world. His research focuses on developing and using unbiased, quantitative systems approaches to study a wide variety of diseases with the ultimate goal of developing new therapeutics.
Nevan serves as Director of The HARC Center, an NIH-funded collaborative group that focuses on the structural characterization of HIV-human protein complexes. Dr. Krogan is also the co-Director of three Cell Mapping initiatives, the Cancer Cell Mapping Initiative (CCMI), the Host Pathogen Map Initiative (HPMI) and the Psychiatric Cell Map Initiative (PCMI). These initiatives map the gene and protein networks in healthy and diseased cells with these maps being used to better understand disease and provide novel therapies to fight them.
He has authored over 250 papers in the fields of genetics and molecular biology and has given over 350 lectures and seminars around the world. He is a Searle Scholar, a Keck Distinguished Scholar and was recently awarded the Roddenberry Prize for Biomedical Research.

Disclosures: Consultant and Shareholder in Maze Therapeutics. Consultant to Interline Therapeutics. Consultant and Shareholder in Tenaya Therapeutics.

Mathai Mammen, MD, PhD
Global Head of Research and Development, Janssen Pharmaceutical Companies of Johnson & Johnson

As Global Head of R&D at the Janssen Pharmaceutical Companies of Johnson & Johnson, Mathai's mission is to focus the energy of the best research and development teams in the world at the intersection of profound unmet medical need and actionable breakthroughs in science and technology to make medicines of unequivocal benefit for humanity. The team works across a wide range of therapeutic areas and biological pathways. Janssen's approach to medicines is patient-focused, agnostic to both source of the idea and the treatment modality. The team is invested deeply in data sciences in every aspect of R&D. Janssen R&D has fueled the growth of Janssen to be the largest pharmaceutical company in the United States, and the fourth largest in the world.
Prior to Janssen, Mathai was SVP at Merck Research Laboratories, and with his team he initiated numerous new programs and progressed eight into early clinical development. At Theravance, a company he co-founded in 1997 based on his work at Harvard University, his talented team nominated 31 development candidates and created five approved products.
Mathai has more than 150 peer-reviewed publications and patents and serves on various boards and advisory committees. He received his M.D. from Harvard Medical School/Massachusetts Institute of Technology (HST program) and his Ph.D. in Chemistry from Harvard University's Department of Chemistry. "

Disclosures: None

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Dr. Peter Marks is Director of the Center for Biologics Evaluation and Research (CBER) at FDA. He received his graduate and medical degrees from New York University. Following this, he completed an Internal Medicine residency and Hematology/Medical Oncology fellowship at Brigham and Women's Hospital in Boston, where he subsequently joined the attending staff as a clinician-scientist and eventually served as Clinical Director of Hematology. He then moved on to work for several years in the pharmaceutical industry prior to returning to academic medicine at Yale University where he served as Chief Clinical Officer of Smilow Cancer Hospital. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

Disclosures: None

Mark McClellan, MD, PhD
Professor of Business, Medicine and Health Policy, Duke University

Mark McClellan, MD, PhD, is Director and Robert J. Margolis, M.D., Professor of Business, Medicine and Policy at the Margolis Center for Health Policy at Duke University. He is a physician-economist who focuses on quality and value in health care, including payment reform, real-world evidence and more effective drug and device innovation. Dr. McClellan is at the center of the nation's efforts to combat the pandemic and the author of a roadmap that details the steps needed for a comprehensive COVID-19 response and safe reopening of our country. He is former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and serves as an advisor for Arsenal Capital Group, Blackstone Life Sciences, and MITRE.

Disclosures: Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Clive Meanwell, MD, PhD
Executive Chairman, Population Health Partners

Clive is Executive Chairman of Population Health Partners, a global investment firm deploying capital, ideas and labor into companies pursuing innovative therapeutics which have the potential to transform health outcomes among people with prevalent conditions. He is also Chief Executive of Population Health Investment Corporation, Vice Chairman of BB Biotech the large Swiss investor in biotechnology, and Chairman of its four investing subsidiaries. Previously, Clive was the founder, Chairman and Chief Executive Officer of The Medicines Company. He began his industrial career at Roche, with leadership roles in marketing, medical affairs, research and development, regulatory affairs, and pharmacovigilance. Clive is a physician who trained in medical oncology, and performed research in the role of human papillomaviruses in cervical cancer.

Disclosures: I manage and hold investments in a range of biopharmaceutical companies which may be discussed during the conference. Should I make any remarks about any of the technologies or businesses concerned, I will make specific reference to the investment as disclosure.

Andy Plump, MD, PhD
President, Research & Development, Takeda Pharmaceutical

Andrew Plump, M.D., Ph.D., is the President, Research & Development of Takeda Pharmaceutical and serves as a member of the company's Board of Directors. His career spans nearly 30 years in the pharmaceutical industry and academia and his experience encompasses early research through regulatory approval and patient access. Dr. Plump's approach toward drug research and development is reflected in a virtuous cycle of â€œbench to bedside to benchâ€• learning. He is a true translational physician-scientist, with deep

knowledge in biomedical research, experimental medicine, early development, genomics and biomarkers and a history of scientific contributions in neuroscience, cardiovascular and metabolic diseases
Dr. Plump received his M.D. from the University of California, San Francisco (UCSF), his Ph.D. in cardiovascular genetics with Dr. Jan Breslow at Rockefeller University and his B.S. from the Massachusetts Institute of Technology (MIT). He completed a residency in Internal Medicine and a fellowship in Medical Genetics at UCSF. Following his clinical training, Dr. Plump trained as a Howard Hughes and Stanley J. Sarnoff postdoctoral fellow with Dr. Marc Tessier-Lavigne at UCSF, concurrently assuming faculty responsibilities as an Adjunct Clinical Instructor in the Department of Medical Genetics.

Disclosures: None

Michael Rosenblum, PhD
Associate Professor of Biostatistics, Johns Hopkins University

Michael Rosenblum is an Associate Professor of Biostatistics at Johns Hopkins Bloomberg School of Public Health. He received his Ph.D. in Applied Math from MIT, followed by a postdoc in Biostatistics at the University of California, Berkeley and the Center for AIDS Prevention Studies (CAPS) at the University of California, San Francisco. His research is in causal inference and experimental design with a focus on developing new statistical methods and software for the design and analysis of randomized trials, with clinical applications in HIV, Alzheimer's disease, stroke, and cardiac resynchronization devices. He received a 2017 Burroughs Wellcome Fund (BWF) Innovation in Regulatory Science Award that provides funding for his project to develop new methods and software to characterize how robust a proposed design is to violations of an investigator's assumptions. He is funded by the Johns Hopkins Center for Excellence in Regulatory Science and Innovation (CERSI) for the project: "Statistical methods to improve precision and reduce the required sample size in many phase 2 and 3 clinical trials, including COVID-19 trials, by covariate adjustment".
https://mrosenblumbiostat.wordpress.com/

Disclosures: None

George Scangos, PhD
President and Chief Executive Officer, Vir Biotechnology

George Scangos, Ph.D., has served as Vir's President and Chief Executive Officer and as a member of Vir's board of directors since January 2017. From July 2010 to December 2016, Dr. Scangos served as Chief Executive Officer and as a member of the board of directors of Biogen Inc., a publicly traded biopharmaceutical company focused on the treatment of serious diseases. From October 1996 to July 2010, Dr. Scangos served as President and Chief Executive Officer at Exelixis, Inc., a drug discovery and development company. From 1993 to 1996, Dr. Scangos served as President of Bayer Biotechnology, where he was responsible for research, business development, process development, manufacturing, engineering and quality assurance of Bayer Biotechnology's biological products. Before joining Bayer Biotechnology in 1987, Dr. Scangos was a Professor of Biology at Johns Hopkins University.
Dr. Scangos received his B.A. in Biology from Cornell University and a Ph.D. in Microbiology from the University of Massachusetts.

Disclosures: None

Speaker/Panelist Biographies

Jason K. Sello, PhD
Professor of Pharmaceutical Chemistry, University of California San Francisco

Jason K. Sello is a full professor in the Department of Pharmaceutical Chemistry at the University of California, San Francisco (UCSF). Prior to his appointment at UCSF, Prof. Sello was a professor in the department of chemistry at Brown University. Before his first faculty appointment, he investigated RNA processing in Streptomyces bacteria using genetic tools as a visiting scientist at the John Innes Centre in Norwich, England and studied enzymes catalyzing antibiotic biosynthesis as a post-doctoral research fellow at Harvard Medical School in the laboratories of Prof. Christopher T. Walsh. He earned a Ph.D. in biophysics from Harvard University in 2002 for work in diversity-oriented chemical synthesis under the supervision of Prof. Stuart L. Schreiber and a B.S. in biology, magna cum laude, from Morehouse College in 1997. In his independent career, Prof. Sello has been synergistically using experimental methods from chemistry, biophysics, biochemistry, and genetics to study biological phenomena and to develop new therapeutics for infections, cancer, and neurological disorders.

Disclosures: None

Jeffrey Shuren, MD, JD
Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration

JEFFREY SHUREN, MD, JD is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.

Disclosures: None

Kuldev Singh, MD, MPH
Professor of Ophthalmology, Stanford University

Kuldev Singh is Professor of Ophthalmology at the Stanford University School of Medicine. His research interests include the epidemiology and genetics of eye diseases, as well as patient reported outcomes in clinical trials. His clinical practice focuses on the medical, laser and surgical management of glaucoma and cataract. Dr. Singh has served as a member of the FDA Advisory Committee on Ophthalmic Devices and as an advisor to the UCSF/Stanford CERSI. He is funded by CERSI to study patient reported outcomes with minimally invasive glaucoma surgery in collaboration with the FDA and other stakeholders. Dr. Singh received a Bachelor of Science degree from McGill University, MD and MPH degrees from the Johns Hopkins University and was a Dana Foundation Fellow at the Wilmer Eye Institute, Johns Hopkins Hospital. His residency training was at the Casey Eye Institute, OHSU followed by subspecialty fellowship training in glaucoma at the Bascom Palmer Eye Institute, University of Miami. Dr. Singh received the Lifetime Achievement Award from the

American Academy of Ophthalmology and was inducted into the Delta Omega Public Health Honor Society at the Johns Hopkins Bloomberg School of Public Health as a distinguished alumnus.

Disclosures: Consultant: Johnson & Johnson and Novartis

Marc Tessier-Lavigne, PhD
President, Stanford University

Pioneering neuroscientist and former biotechnology leader Marc Tessier-Lavigne became Stanford University's 11th president on September 1, 2016. He returned to Stanford after serving as president of The Rockefeller University, a graduate biomedical research university in New York city. From 2001 to 2005, he was professor of biological sciences at Stanford, where he held the Susan B. Ford Professorship in the Humanities and Sciences; he previously held faculty positions at the University of California, San Francisco. He also served as executive vice president for research and chief scientific officer at biotechnology firm Genentech Inc., where he directed disease research and drug discovery, and helped oversee the development of eight FDA-approved drugs for cancer and immune disorders.
Dr. Tessier-Lavigne and his colleagues have performed pioneering work on the mechanisms that direct the wiring up of the brain during embryonic development. He has also helped elucidate mechanisms of neurodegeneration. He is the recipient of numerous awards for his scientific contributions, including the 2020 Gruber Neuroscience Prize, and he has been elected to several learned societies, including the National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences and the American Philosophical Society.

Disclosures: Dr. Tessier-Lavigne serves on the board of directors of Denali Therapeutics and of Regeneron Pharmaceuticals, and is a member of the scientific advisory board of Agios Pharmaceuticals.

Gita Thanarajasingham, MD
Assistant Professor of Medicine, Mayo Clinic

Dr. Gita Thanarajasingam is an Assistant Professor of Medicine and consultant in the Division of Hematology at Mayo Clinic in Rochester, Minnesota. She is a graduate of Yale University and Mayo Clinic School of Medicine, and completed her internal medicine residency at the Brigham and Women's Hospital at Harvard Medical School. She completed her Hematology/Oncology Fellowship and Advanced Lymphoma Fellowship at Mayo Clinic Rochester before joining the faculty of the Mayo Clinic Lymphoma disease-oriented group. Her clinical practice as an oncologist is focused on Hodgkin and non-Hodgkin lymphoma, and she performs health outcomes research in lymphoma and other cancers. As a clinical investigator, her work focuses on improving the evaluation of adverse events (AEs) of treatment and measuring their impact on cancer patients. She developed the Toxicity over Time (ToxT), a longitudinal patient-focused approach to AE evaluation. She is active in the implementation of patient-reported outcomes to better understand treatment toxicity and tolerability. She serves of as vice co-chair of the Alliance for Clinical Trials in Oncology Health Outcomes Committee and is the recipient of K and U01 grants from the U.S. National Institutes of Health in support of her work. Her research program endeavors to improve the accuracy and patient-centeredness of AE evaluation and better understand cancer treatment tolerability from the patient's perspective.

Disclosures: None

Speaker/Panelist Biographies

John Tsai, MD
Head of Global Drug Development and Chief Medical Officer, Novartis

John Tsai, M.D., has been Head of Global Drug Development and Chief Medical Officer for Novartis since 2018. He is a member of the Executive Committee of Novartis.
Dr. Tsai joined Novartis from Amgen Inc., where he was chief medical officer and senior vice president of Global Medical from 2017 to 2018, overseeing all clinical and medical functions across multiple sites worldwide. Before joining Amgen in 2017, he spent 11 years at Bristol-Myers Squibb Co. (BMS), most recently as global head of clinical development for marketed products from 2016 to 2017. During his time at BMS, Dr. Tsai also served as a full development team leader in oncology from 2015 to 2016, head of Worldwide Medical from 2014 to 2015, chief medical officer for Europe from 2012 to 2014, vice president of US Medical from 2010 to 2012, and vice president of Cardiovascular Medical from 2006 to 2010.
Dr. Tsai holds a doctor of medicine from the University of Louisville School of Medicine in the United States. He received a Bachelor of Science in electrical engineering from Washington University in St. Louis, also in the US.

Disclosures: None

Leslie Wilson, PhD
Professor of Clinical Pharmacy, University of California San Francisco

Leslie Wilson, PhD, is a Professor of Health Policy and Economics in the Departments of Medicine and Clinical Pharmacy at the University of California, San Francisco. Her current research focuses on understanding the patients view point by developing behavioral economics methods to understand how they trade off the risks and benefits when making difficult treatment decisions. As one of the founding members of the International Association of Health Preference Research (IAHPR) and other groups developing and validating health preference methods, years of experience in the pharmaceutical industry examining the economic value of drugs, combined with her collaborations with the FDA, has given her the ideal combination of skills to advance patient preference in the regulatory environment. Leslie is currently leading two patient preference projects using quantitative discrete choice conjoint analysis in collaboration with the FDA with the goal of incorporating the results into regulatory decisions for innovative devices and biologics. She is a member of the UCSF/Stanford Center for Excellence in Regulatory Science and Innovation (CERSI) which is acting as the flashpoint for FDA collaborations around developing patient preference methodology, workforce development, and gaining pre-submission guidance for patient preference evidence to ensure quality and usefulness to the FDA.

Anne Wojcicki
CEO and Co-Founder, 23andMe

Anne co-founded 23andMe in 2006, three years after the first human genome was sequenced. Her goal was audacious: to help people access, understand, and benefit from the human genome and fundamentally change healthcare in the process. Prior to founding 23andMe, Anne spent a decade on Wall Street investing in healthcare and felt frustrated by a system built around monetizing illness instead of incentivizing prevention. She wanted to flip that model on its head and build a business that helps people prevent illness rather than profit from it. Anne focused on empowering people with direct access to genetic information so that they could use their data to make decisions that could lower their risks for disease. Under her leadership, 23andMe now provides the only personal genetic test with FDA authorization to deliver health information directly to consumers. Along with empowering consumers with health information, Anne wanted 23andMe to transform

how research discoveries are made and revolutionize the development of treatments for disease. By inviting people to participate in research, 23andMe is able to crowdsource billions of data points resulting in the world's largest resource for genetic research. This novel, web-based approach has already resulted in thousands of new genetic insights. This approach to research powers 23andMe Therapeutics, the goal of which is to translate genetic insights into new treatments for serious unmet medical needs.

Disclosures: I am the co-founder and CEO of 23andMe, Inc., a commercial entity.

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research on detail to Operation Warp Speed and Principal Medical Advisor to the Commissioner, U.S. Food and Drug Administration

Janet Woodcock is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). In 2015, Dr. Woodcock also assumed the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality, (OPQ). Dr. Woodcock first joined CDER in 1994. For three years, from 2005 until 2008, she served FDA's Commissioner, holding several positions, including as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities involved oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

Disclosures: None

George Yancopoulos, MD, PhD
Co-Founder, President and Chief Scientific Officer, Regeneron Pharmaceuticals

George D. Yancopoulos, M.D., Ph.D., has built leading-biotechnology company Regeneron alongside Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer, over the past 30 years. Regeneron invents life-transforming medicines for people with serious diseases. Its unique ability to repeatedly and consistently translate science into medicine has led to eight FDA-approved treatments and numerous product candidates in development, all of which were homegrown in its laboratories, for a range of diseases, including cancer, vision-threatening eye diseases, asthma, pain and infectious diseases. George is a principal inventor of Regeneron's FDA-approved medicines and foundational technologies. He is the key driver of Regeneron's unique science-driven culture and successful drug discovery and development engine, which is currently hard at work investigating an antibody medicine to combat COVID-19. After graduating as valedictorian at both Bronx High and Columbia University, George received his M.D. and Ph.D. in Biochemistry and Molecular Biophysics from Columbia University. George was the 11th most highly cited scientist in the world in the 1990s, in 2004 was elected to both the National Academy of Sciences and the American Academy of Sciences, and in 2014 was elected as a Fellow by American Association for the Advancement of Science (AAAS).

Disclosures: None