Innovations in Regulatory Science Summit

Sponsored by the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation

Mission Bay Conference Center, 1675 Owens St, San Francisco, CA
Sunday, January 12, 2020

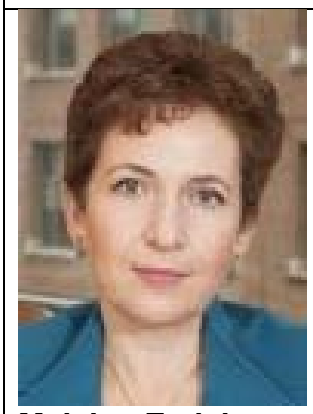
SPEAKER BIOGRAPHIES

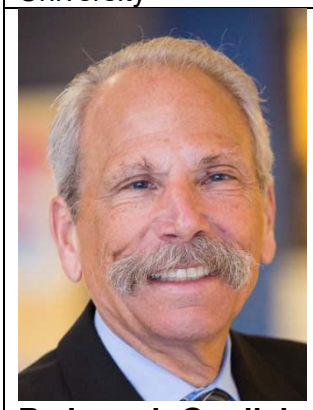
 **Amy Abernethy, MD, PhD** Principal Deputy Commissioner, U.S. Food and Drug Administration	As the Principal Deputy Commissioner of Food and Drugs, Dr. Amy P. Abernethy, M.D., Ph.D., helps oversee the agency's day-to-day functioning and directs special and high-priority initiatives that cut across offices overseeing FDA's regulation of drugs, medical devices, tobacco and food. Dr. Abernethy, a hematologist/oncologist and palliative medicine physician, is an internationally recognized clinical data expert and clinical researcher. Her areas of expertise include cancer data, real world evidence, clinical trials, health services research, patient reported outcomes (PROs), clinical informatics, and patient-centered care. Before coming to FDA, Dr. Abernethy served as chief medical officer, chief scientific officer, and senior vice president for oncology at Flatiron Health (a member of the Roche Group), where she led the research oncology, clinical operations and data science teams, and contributed to the overall strategic vision of the company, including directing their research vision on real world evidence. Prior to that, Dr. Abernethy was professor of medicine at Duke University School of Medicine, where she ran the Center for Learning Health Care in the Duke Clinical Research Institute and the Duke Cancer Care Research Program in the Duke Cancer Institute. At Duke, she pioneered the development of technology platforms to spur novel advancements in the care of people with cancer and other serious life-limiting illnesses. Dr. Abernethy was formerly an appointed member of the National Academy of Medicine's National Cancer Policy Forum, an elected member of the American Society for Clinical Investigation, and Past President of the American Academy of Hospice & Palliative Medicine. Dr. Abernethy received her M.D. at Duke University, where she also did her internal medicine residency, served as chief resident, and completed her hematology/oncology fellowship. She received her Ph.D. from Flinders University in Australia, with a focus on evidence-based medicine and clinical informatics, and her bachelor's degree from the University of Pennsylvania.
 **Russ Altman, MD, PhD**	Russ Biagio Altman is the Kenneth Fong Professor of Bioengineering, Genetics, Medicine, Biomedical Data Science and (by courtesy) Computer Science) and past chairman of the Bioengineering Department at Stanford University. His primary research interests are in the application of computing and informatics technologies to problems relevant to medicine. He is particularly interested in methods for understanding drug action at molecular, cellular, organism and population levels. His lab studies how human genetic variation impacts drug response (e.g., http://www.pharmgkb.org/). Other work focuses on the analysis of biological molecules to understand the actions, interactions and adverse events of drugs (e.g., http://feature.stanford.edu/). He helps lead an FDA-supported Center of Excellence in Regulatory Science & Innovation. Dr. Altman holds an AB from Harvard College, and an MD from Stanford Medical School, and a PhD in Medical Information Sciences from Stanford. He received the U.S. Presidential Early Career Award for Scientists and Engineers and a National Science Foundation CAREER Award. He is a fellow of the American College of Physicians (ACP), the American College of Medical

Professor of Bioengineering, Stanford University	Informatics (ACMI), the American Institute of Medical and Biological Engineering (AIMBE), and the American Association for the Advancement of Science (AAAS). He is a member of the National Academy of Medicine (formerly the Institute of Medicine, IOM). He is a past-president, founding board member, and a fellow of the International Society for Computational Biology (ISCB), and a past-president of the American Society for Clinical Pharmacology & Therapeutics (ASCPT). He has chaired the Science Board advising the FDA commissioner, currently serves on the NIH Director's Advisory Committee, and is cochair of the IOM Drug Forum. He is an organizer of the annual Pacific Symposium on Biocomputing, and a founder of Personalis, Inc. Dr. Altman is board certified in Internal Medicine and in Clinical Informatics. He received the Stanford Medical School graduate teaching award in 2000 and mentorship award in 2014.
 **Hal Barron, MD** Chief Scientific Officer, GlaxoSmithKline	Hal joined GSK in January 2018 as Chief Scientific Officer and President, R&D, responsible for all research and development of our pipeline molecules as well as life-cycle management of the approved medicines. He is an Executive Director of the GSK Board and a member of the Corporate Executive Team. His previous role was President, R&D at Calico (California Life Company). Prior to this, Hal 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 LLC, a subsidiary of Alphabet Inc. Hal was a Non-Executive Director and Chair of the Science & Technology Committee at Juno Therapeutics, Inc until March 2018, when it was acquired by Celgene Corporation. 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.
 **Howard Bauchner, MD** Editor in Chief, Journal of the American Medical Association	Howard Bauchner, MD was appointed the 16th Editor in Chief of JAMA and The JAMA Network in 2011. Prior to coming to JAMA, Howard was a Professor of Pediatrics and Public Health at Boston University School of Medicine and Editor in Chief of Archives of Disease in Childhood (2003-2011). At BUSM he was Vice-Chair of Research for the Department of Pediatrics and Chief, Division of General Pediatrics. He is a member of the National Academy of Medicine and an honorary fellow of the Royal College of Paediatrics and Child Health, United Kingdom. At JAMA Howard has focused on publishing important and novel research articles and special communications, improving and expanding clinical content, using electronic/digital approaches to enhance communication, and ensuring a commitment to innovation. Since his arrival in 2011 followers on social medical (twitter and Facebook) have increased from 13,000 to approximately 800,000 and the electronic table of contents is now distributed to close to 600,000 individuals each week. In print, via eTOC, and social media JAMA now reaches over 1.5M physicians each week worldwide. Views (PDF and HTML) have increased from 10M in 2011 to 31M in 2018 (50% from outside the U.S.), with an additional 17M views of the abstracts only. Podcast downloads have increased from 300,000 in 2014 to 2.3M in 2018. The print journal was redesigned for the first time in over 20 years and website has been updated twice. All 9 of the specialty journals were renamed (Archives of Pediatrics became JAMA Pediatrics), and 3 new journals have been launched – JAMA Oncology (2015), JAMA Cardiology (2016), and JAMA Network Open (2018).

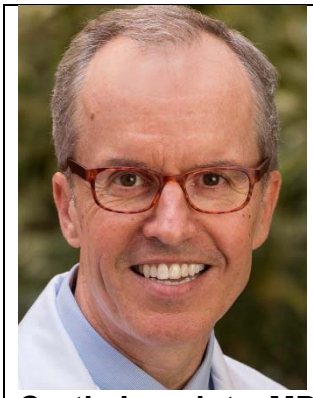
 **James Bradner, MD** President, Novartis Institutes for Biomedical Research	James (Jay) Bradner, M.D., joined Novartis on January 1, 2016 and became President of the Novartis Institutes for BioMedical Research (NIBR) on March 1, 2016. He is a member of the Executive Committee of Novartis. Prior to joining Novartis, Dr. Bradner was on the faculty of Harvard Medical School in the Department of Medical Oncology at the Dana-Farber Cancer Institute in the United States from 2005 through 2015. Dr. Bradner is a co-founder of five biotechnology companies and has authored more than 200 scientific publications and 30 US patent applications. Dr. Bradner is a graduate of Harvard University and the University of Chicago Medical School in the US. He completed his residency in medicine at Brigham and Women's Hospital and his fellowship in medical oncology and hematology at the Dana-Farber Cancer Institute. He has been honored with many awards and was elected into the American Society for Clinical Investigation in 2011 and the Alpha Omega Alpha Honor Medical Society in 2013.
 **Robert Califf, MD** Head of Health Policy and Strategy, Google Health and Verily Life Science (Alphabet)	Robert M. Califf, MD, MACC, is the Head of Medical Strategy and Policy 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.
 **Edward Chang, MD** Professor of Neurological Surgery, University of California San Francisco	Edward Chang is the Bowes Biomedical Investigator and Professor of Neurological Surgery at the University of California, San Francisco. Dr. Chang's clinical expertise is surgical therapies for epilepsy, pain, and brain tumors. He specializes in advanced neurophysiologic brain mapping methods, including awake speech and motor mapping, to safely perform neurosurgical procedures in eloquent areas of the brain.His research focuses on the discovery of cortical mechanisms of high-order neurological function in humans. Dr. Chang's laboratory has demonstrated the detailed functional organization of the human speech cortex. His clinical research focuses on outcomes related to epilepsy surgery and neuromodulation. Dr. Chang is Co-Director of the Center for Neural Engineering & Prostheses at UC Berkeley and UC San Francisco. He is principal investigator of the DARPA SUBNETS project to develop advanced therapies for neuropsychiatric conditions. Dr. Chang is the 2015 Blavatnik National Laureate in Life Sciences, and recipient of the NIH Director's New Innovator Award, and HHMI Faculty Scholars.

 **Mildred Cho, PhD** Professor of Pediatrics, Stanford University	Mildred Cho is a Professor in the Division of Medical Genetics of the Department of Pediatrics and in the Division of General Medical Disciplines in the Department of Medicine at Stanford University. She is also Associate Director of the Stanford Center for Biomedical Ethics. She received her B.S. in Biology in 1984 from the Massachusetts Institute of Technology and her Ph.D. in 1992 from the Stanford University Department of Pharmacology. Her post-doctoral training was in Health Policy as a Pew Fellow at the Institute for Health Policy Studies at the University of California, San Francisco and at the Palo Alto VA Center for Health Care Evaluation. Dr. Cho's major areas of interest are the ethical and social impacts of genetic research and its applications, ethical issues raised by artificial intelligence in health care, how conflicts of interest affect the conduct of academic biomedical research, and ethical issues in synthetic biology, gene therapy and genome editing. She established the Benchside Ethics Consultation Service at Stanford University in 2005.
 **Arthur Ciociola, PhD** Vice President and Head Regulatory Affairs, Global Drug Development Ophthalmology, Novartis	Arthur (Art) Ciociola, Ph.D., is Vice President and Head Regulatory Affairs, Global Drug Development Ophthalmology for Novartis Pharmaceuticals Corporation based in Fort Worth TX. He is responsible for the global regulatory strategies for all ophthalmic drugs and medical devices under development in the retinal, rare genetic diseases, glaucoma, presbyopia and dry eye disease therapeutic areas at Novartis. He has been responsible for directing the global regulatory activities for several drug and medical device approvals while at Novartis including, Beovu that was recently approved for the treatment of neovascular age-related macular degeneration. Prior to joining Novartis, Art was the Head of Global Regulatory Affairs at Alcon Labs and his regulatory teams were responsible for the approval of a variety of global pharmaceutical, vision care and surgical device products. Prior to joining Alcon, he held positions of increasing responsibility while at Bausch & Lomb, Abbott Laboratories, Pfizer and GlaxoSmithKline in the Regulatory and Clinical Development areas. Art earned his Ph.D. in Pharmacology from Temple University and is a Fellow of the American College of Gastroenterology.
 **Tejal Desai, PhD** Chair, Dept. of Bioengineering and Therapeutic Sciences, University of California San Francisco	Tejal Desai, PhD, is the Ernest L Prien Endowed Professor and Chair of the Department of Bioengineering & Therapeutic Sciences, Schools of Pharmacy and Medicine at University of California, San Francisco (UCSF), director of the NIH training grant for the Joint Graduate Program in Bioengineering at the University of California, Berkeley (UCB) and UCSF, and founding director of the UCSF/UC Berkeley Masters Program in Translational Medicine. Dr. Desai's research spans multiple disciplines including materials engineering, cell biology, tissue engineering, and pharmacological delivery systems to address issues concerning disease and clinical translation. She has published over 200 peer-reviewed articles. Her research is at the cutting-edge in precision medicine, enabled by advancements in micro and nanotechnology, engineering, and cell biology directed to clinical challenges in disease treatment. She seeks to design new platforms to overcome existing challenges in therapeutic delivery. Her research efforts have earned recognition including Technology Review's "Top 100 Young Innovators," Popular Science's Brilliant 10, and NSF's New Century Scholar. She is Chair of the American Institute for Medical and Biological Engineering College of Fellows. In 2015, she was elected to the National Academy of Medicine.

 **Laura Esserman, MD, MBA** Professor of Surgery, 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.
 **Malvina Eydelman, MD** Director, Office of Health Technology 1, U.S. Food and Drug Administration	Dr. Eydelman is the Director of the Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices at the FDA. She leads a large, multidisciplinary staff in the development, implementation, execution and management of the premarket, postmarket, compliance and quality programs. Dr. Eydelman received her M.D. degree from Harvard Medical School and a Doctorate in Health Sciences and Technology from Massachusetts Institute of Technology. Dr. Eydelman originated numerous symposia and workshops to facilitate medical device innovation and has been instrumental in expediting development of novel endpoints for clinical trials of pioneering technologies. She organized multi-stakeholder public-private partnerships; oversaw development of regulations, standards and guidance for industry. Dr. Eydelman has spearheaded numerous clinical and laboratory studies designed to improve the safety and effectiveness of medical devices. Dr. Eydelman has been granted a U.S. patent, published nearly 100 peer-reviewed articles, book chapters, and monographs, and presented over 250 lectures worldwide.
 **Adam Gazzaley, MD, PhD** Professor of Neurology, Physiology and Psychiatry, University of California San Francisco	Adam Gazzaley, M.D., Ph.D. is Professor in Neurology, Physiology and Psychiatry at UC San Francisco and the Founder & Executive Director of Neuroscape, a translational neuroscience center engaged in technology creation and scientific research of novel brain assessment and optimization approaches. Dr. Gazzaley is co-founder and Chief Science Advisor of Akili Interactive Labs, a company developing therapeutic video games, and co-founder and Chief Scientist of JAZZ Venture Partners, a venture capital firm investing in experiential technology to improve human performance. Additionally, he is a scientific advisor for over a dozen technology companies including Apple, GE, Magic Leap and The VOID. He has filed multiple patents, authored over 125 scientific articles, and delivered over 540 invited presentations around the world. He wrote and hosted the nationally-televised PBS special The Distracted Mind with Dr. Adam Gazzaley, and co-authored the 2016 MIT Press book The Distracted Mind: Ancient Brains in a High-Tech World, winner of the 2017 PROSE Award. Dr. Gazzaley has received many awards and honors, including the 2015 Society for Neuroscience – Science Educator Award.

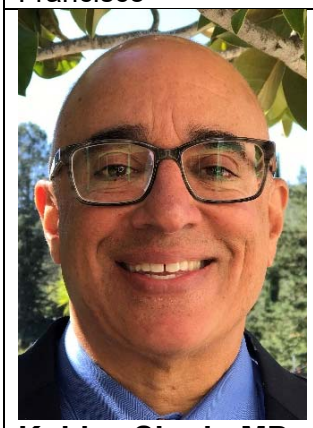
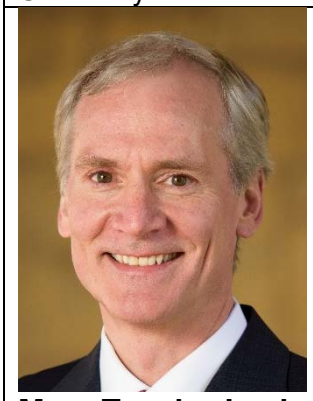
 **Kathy Giacomini, PhD** Professor of Bioengineering and Therapeutic Sciences, University of California San Francisco	Kathy Giacomini, a professor in the School of Pharmacy at the University of California, San Francisco, is a leader in the field of membrane transporters with a focus on genetic polymorphisms. In genomewide association studies she and her team discovered genetic variants in transporters associated with response to the anti-diabetic drug, metformin and the anti-gout medication, allopurinol. 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 of the NIH's Pharmacogenomics Research Network hub, PGRN-Hub. She has received numerous awards and is an elected member of the National Academy of Medicine.
 **Steve Goodman, MD, MHS, PhD** Associate Dean for Clinical and Translational Research, Stanford University	Steve Goodman, MD, MHS, PhD, is Associate Dean for Clinical and Translational Research and Professor of Epidemiology & Population Health and of Medicine at the Stanford University School of Medicine. He is co-founder and co-director of the Meta-research Innovation Center at Stanford (METRICS), a group dedicated to studying and improving the reproducibility and efficiency of biomedical research. His expertise is in the proper measurement and use of research evidence, with particular emphasis on Bayesian approaches. He currently serves as chair of the PCORI Methodology Committee, senior statistical editor at the Annals of Internal Medicine, and is scientific advisor to the national Blue Cross-Blue Shield technology assessment program. He co-chaired a 2012 IOM committee on drug safety. He was awarded the 2016 Spinoza Chair in Medicine from the University of Amsterdam for his work in inference and the 2019 Lilienfeld award from the American College of Epidemiology for his contributions in research and teaching to the field of epidemiology. From 1989-2011 he was on the faculties of the Johns Hopkins Schools of Medicine and Public Health.
 **B. Joseph Guglielmo, PharmD** Dean, School of Pharmacy, University of California San Francisco	B. Joseph Guglielmo, PharmD, is a pharmacist, clinical scientist, teacher, and international expert in the evidence-based use of antimicrobials to treat infections. He has served as interim dean, then as dean of the UCSF School of Pharmacy, since 2012 and holds the Troy C. Daniels Distinguished Professorship in Pharmaceutical Sciences. He is widely known as an advocate for therapeutics-related research, from basic science to health policy research. As chair of the School's Department of Clinical Pharmacy, Guglielmo oversaw a 40 percent increase in the Department of Clinical Pharmacy's faculty research funding from 2006 to 2012, including grants from the National Institutes of Health. During that period an increasing number of the department's clinical faculty members received National Institutes of Health "K" awards, designed to develop clinical research scientists as independent investigators, as well as "R" awards that fund specific research projects.

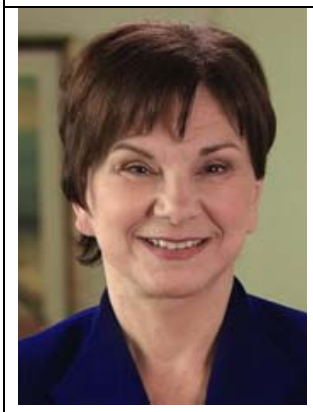
 **Sam Hawgood, MBBS** Chancellor, University of California San Francisco	Sam Hawgood, MBBS, is currently the Chancellor and holds the Arthur and Toni Rembe Rock Distinguished Professor appointment at the University of California, San Francisco (UCSF). Dr. Hawgood graduated from the University of Queensland 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 currently is a trustee of the International Pediatric Research Foundation.
 **Sandra Horning, MD** Former Chief Medical Officer, Genentech/Roche	Sandra J. Horning, M.D., FACP, FASCO, was appointed Chief Medical Officer and Head of Global Product Development for Roche/Genentech in January 2014. She leads employees in the Product Development organization across the globe, oversees all aspects of late stage clinical development, and co-chairs the Late Stage Portfolio Committee that invests in pivotal registrational trials. During her tenure, she has received recognition for her industry contributions and overseen the successful development of 14 new molecular entities and numerous line extension in oncology, hematology, neuroscience, ophthalmology, immunology and infectious disease. Sandra joined Roche in late 2009 as Senior Vice President, Global Head of Clinical Science/Oncology and Hematology in the Product Development organization. Prior to that, she served as a tenured professor, practicing oncologist and investigator, and held multiple leadership positions including Vice-Chair of the Department of Medicine at Stanford University, where she is an Emerita Professor of Medicine (Oncology and Blood and Bone Marrow Transplantation).Sandra has authored more than 300 peer-reviewed journal articles, book chapters, reviews and editorials, and has served on the editorial boards of multiple peer-reviewed medical journals. She was named a Best Doctor in America consecutively from 1992-2008 and served as Chairman of the Eastern Cooperative Oncology Group lymphoma committee and 2005-6 President of the American Society of Clinical Oncology. Sandra received Bachelor of Arts and Doctor of Medicine degrees at the University of Iowa and completed post-doctoral training in internal medicine at the University of Rochester and in medical oncology at Stanford University.
 **Daphne Koller, PhD** Founder and CEO, Insitro	Daphne Koller is the CEO and Founder of insitro, a startup company that aims to rethink drug development using machine learning. Daphne was the Rajeev Motwani Professor of Computer Science at Stanford University, where she served on the faculty for 18 years. She was the co-founder, co-CEO and President of Coursera for 5 years, and the Chief Computing Officer of Calico, an Alphabet company in the healthcare space. She is the author of over 200 refereed publications appearing in venues such as Science, Cell, and Nature Genetics. Daphne was recognized as one of TIME Magazine's 100 most influential people in 2012. She received the MacArthur Foundation Fellowship in 2004 and the ACM Prize in Computing in 2008. She was inducted into the National Academy of Engineering in 2011 and elected a fellow of the American Academy of Arts and Sciences in 2014 and of the International Society of Computational Biology in 2017.

 **Curtis Langlotz, MD, PhD** Professor of Radiology, Stanford University	Curtis P. Langlotz, MD, PhD is Professor of Radiology and Biomedical Informatics and Director of the Center for Artificial Intelligence in Medicine and Imaging (AIMI Center) at Stanford University. As Associate Chair for Information Systems and a Medical Informatics Director for Stanford Health Care, he is responsible for the computer technology that supports the Stanford Radiology practice. The AIMI Center develops artificial intelligence methods that enable computer systems to draw inferences directly from image information and associated clinical data, augmenting the skills of human imaging professionals. Dr. Langlotz has authored over 100 scholarly publications and the book, “The Radiology Report: A Guide to Thoughtful Communication for Radiologists and Other Medical Professionals”. He led the development of the RadLex standard terminology for radiology report information, a national standard for imaging exam codes, and a library of radiology report templates that have been downloaded over 5 million times. Dr. Langlotz is a past president of the Radiology Alliance for Health Services Research (RAHSR), the College of SIIM Fellows, and the Society for Imaging Informatics in Medicine (SIIM), and a former board member of the Association of University Radiologists (AUR), the American Medical Informatics Association (AMIA) and the Society for Medical Decision Making (SMDM). He currently serves on the Board of Directors of the Radiological Society of North America (RSNA). Dr. Langlotz has founded 3 health care information technology companies, the most recent of which was acquired by Nuance Communications in 2016.
 **Carol Linden, PhD** Director, Office of Regulatory Science and Innovation, U.S. Food and Drug Administration	Dr. Linden is the Director, Office of Regulatory Science and Innovation at U.S. Food and Drug Administration. She oversees a broad array of both intramural and extramural programs focused on bringing understanding of the latest in scientific and technological advances to the process of regulating products that support the health of the American public. Prior to assuming this position, Dr. Linden was the Principal Deputy Director of the Office of the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Her duties included oversight of advanced development and acquisition programs for Project BioShield medical countermeasures for CBRN threats as well as pandemic influenza vaccines, drugs, diagnostics and infrastructure. In 2009, Dr. Linden co-chaired with the Department of Defense the Working Group on Strengthening the Biosecurity of the United States, which was mandated by an Executive Order, and produced a report with recommendations submitted to the White House. Dr. Linden obtained her bachelor’s degree in biology from Bryn Mawr College, and a Ph.D. from the University of California Los Angeles in molecular biology. She conducted postdoctoral research at the California Institute of Technology and University of Maryland prior to joining the research staff at the U.S. Army Medical Research Institute of Infectious Diseases, where she subsequently served as the Chief, Research Plans and Programs.
 **Mathai Mammen, MD, PhD**	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.

Global Head of Research and Development, Janssen	
 **Peter Marks, MD, PhD** Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration	Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.
 **Carl Peck, MD** Chairman, NDA Partners	Dr. Peck (BA mathematics, chemistry; MD University of Kansas 1968; internal medicine 1969-72; clinical pharmacology UCSF 1972-74) headed the Army Blood Preservation Research Program, LAIR (1994-80). During 1980-87, Dr. Peck was Professor (Medicine, Pharmacology), Director, USUHS Clinical Pharmacology Division. During 1987-93, he directed FDA CDER and was Assistant Surgeon General, PHS (1990-93). Dr. Peck taught as "Boerhaave" Professor at Leiden University, Netherlands (1993-94), then founded the Georgetown University Center for Drug Development Science, and NDA Partners LLC in 2003. Among many awards, he has received the FDA Distinguished Alumnus Award (2000), Honorary Doctorate for "outstanding contributions to the science of drug development" (Uppsala University 2002), ASCPT Gary Neal Prize for Innovation in Drug Development (2012), 2017 ASCPT Sheiner-Beal Pharmacometrics Award and the 2018 Gary Levy Memorial Lectureship. Dr. Peck has mentored more than 40 postdoctoral fellows and co-founded the American and Chinese Courses in Drug Development and Regulatory Science. Dr. Peck's research interests center on optimizing informativeness, efficiency, speed and economy of drug development and regulation using advanced concepts and techniques of clinical pharmacology, trial designs, and pharmaco-statistical modeling and simulation to generate causal evidence of effectiveness and safety. He is an author of more than 175 original research papers, chapters and books.
 **Lee Sanders, MD, MPH**	Lee M. Sanders, MD, MPH is Associate Professor of Pediatrics, Co-Director of the Center for Policy, Outcomes and Prevention (CPOP), and Chief of the Division of General Pediatrics at Stanford University. Dr. Sanders is a national expert in the fields of health literacy and health disparities. He is a graduate of the Robert Wood Johnson Foundation Generalist Physician Scholars Program. Dr. Sanders is PI on several federally-funded studies examining the impact of parent health literacy on child obesity, on the management of child chronic illness, and on appropriate medication labeling. At Stanford, he leads a multi-disciplinary research team that provides analytic guidance to public policy affecting children in California with chronic conditions, including epidemiologic analyses linking health data with school data. Dr. Sanders has served as an advisor to several national agencies, including the American Academy of Pediatrics, the American Cancer Society, the Institute of Medicine, the CDC, and the FDA. As a general pediatrician, he provides primary care for low-income families and for children with complex chronic conditions.

Associate Professor of Pediatrics, Stanford University	
 **Alfred Sandrock, MD, PhD** Chief Medical Officer, Biogen	Alfred W. Sandrock Jr. is the Executive Vice President, Research and Development and Chief Medical Officer at Biogen, Inc. Dr. Sandrock has served as Chief Medical Officer since November 2015 and was recently named Head of R&D in October 2019. Since joining Biogen in 1998, Dr. Sandrock has held several senior executive positions including Group Senior Vice President of Development Sciences, Senior Vice President of Neurology Research and Development, and Vice President of Clinical Development, Neurology. Prior to joining Biogen, Dr. Sandrock was an Assistant Professor of Neurology at Harvard Medical School and an Assistant in Neurology at Massachusetts General Hospital. Dr. Sandrock received a B.A. in Human Biology from Stanford University, an M.D. from Harvard Medical School, and a Ph.D. in Neurobiology from Harvard University. He completed an internship in medicine, a residency and chief residency in neurology, and a clinical fellowship in neuromuscular disease and clinical neurophysiology (electromyography) at Massachusetts General Hospital in Boston, MA. Dr. Sandrock is also a Director at Neurocrine Biosciences, Inc, Praxis Precision Medicines, Inc., and Disarm Therapeutics Inc., and is a member of the Partners Healthcare Innovation Advisory Board. He serves as Chairman of the Board of the PhRMA Foundation.
 **George Scangos, PhD** CEO,Vir Biotechnology	George Scangos, Ph.D., has served as our President and Chief Executive Officer and as a member of our 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 has served as a member of the board of directors of various publicly traded companies, including: Exelixis, Inc., since 1996; Agilent Technologies, Inc., a life sciences, diagnostics and applied chemical analysis company, since 2014; and Anadys Pharmaceuticals, Inc., a biopharmaceutical company, from 2003 to 2010. Dr. Scangos served as Chair of PhRMA in 2016, and as the Chair of the California Healthcare Institute in 2010. He was a member of the board of directors of the Global Alliance for TB Drug Development from 2006 until 2010. Dr. Scangos currently serves on the Board of Trustees of Cornell University and the Board of Overseers of the University of California, San Francisco. Dr. Scangos received his B.A. in Biology from Cornell University and a Ph.D. in Microbiology from the University of Massachusetts.
 **Brian Shoichet, PhD**	Brian Shoichet is a Professor of Pharmaceutical Chemistry at UCSF. His lab focuses on novel ligand discovery and optimization using both structure-based and chemoinformatic approaches, in a cycle of prediction and experimental testing.

Professor of Pharmaceutical Chemistry, University of California San Francisco	
 **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 clinical 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.
 **Marc Tessier-Lavigne, PhD** President, Stanford University	Dr. Marc Tessier-Lavigne, a neuroscientist, is President of Stanford University, where he is also Professor of Biology. He studied physics as an undergraduate at McGill University and then earned his second BA in philosophy and physiology as a Rhodes scholar at Oxford. He earned a PhD in physiology from University College London and did postdoctoral work at Columbia University. He was a member of the faculty of the University of California, San Francisco, from 1991 until 2001, when he moved his laboratory to Stanford. In 2003 he joined Genentech, where he led research and drug discovery, eventually serving as the Chief Scientific Officer and Executive Vice President for Research. In 2011 he became President of Rockefeller University. In 2016 he was appointed to his current position at Stanford. Dr. Tessier-Lavigne and his colleagues have done pioneering work on axon guidance, identifying molecules and mechanisms that direct the formation of neuronal projections in the mammalian nervous system. He has also helped elucidate mechanisms of neurodegeneration. Dr. Tessier-Lavigne 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 in the US; the Royal Society and the Academy of Medical Sciences in the UK; and the Royal Society of Canada.
 **Andrew Weber, MS**	Andrew Weber is a Research Director with the ATOM Consortium, a public-private consortium developing accelerated workflows for the discovery of small molecule cancer therapeutics. His current research focus areas are on generative networks for optimization of chemical structure in high performance compute workflows, predictive pharmacokinetics, and drug induced liver injury. Andrew has over 10 years of drug discovery and development experience at GlaxoSmithKline, deploying computational modelling techniques applied to pharmacokinetics (including physiologically based pharmacokinetics), pharmacodynamics, translational medicine, systems toxicology, route of delivery, and manufacturing throughput and cost of goods. Andrew has a M.S. in Chemical Engineering from Villanova University and a B.S. in Chemical Engineering from Bucknell University.

Research Director, ATOM Consortium (GlaxoSmithKline)	
 **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.
 **Janet Woodcock, MD** Director, Center for Drug Evaluation and Research, 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.
 **Anne Wojcicki** CEO, 23andMe	Anne co-founded 23andMe in 2006 after a decade spent in healthcare investing, focused primarily on biotechnology companies. Her hope was to empower consumers with access to their own genetic information and to create a way to generate more personalized information so that commercial and academic researchers could better understand and develop new drugs and diagnostics. Presently, 23andMe has built one of the world's largest databases of individual genetic information. Its novel, web-based research approach allows for the rapid recruitment of participants to many genome-wide association studies at once, reducing the time and money needed to make new discoveries, and the company has created a proven and standardized resource for finding new genetic association and confirming genetic loci discovered by others. Under Anne's leadership 23andMe has made significant advances in bringing personalized medicine directly to the public. Anne graduated from Yale University with a BS in Biology. Getting access to and understanding her own genetic information had always been one of her ambitions.

 **Joseph Wu, MD, PhD** Director, Stanford Cardiovascular Institute	Joseph C. Wu, MD, PhD is Director of the Stanford Cardiovascular Institute and Simon H. Stertzer, MD, Professor of Medicine and Radiology at the Stanford School of Medicine. His lab works on biological mechanisms of patient-specific and disease-specific induced pluripotent stem cells (iPSCs). The main goals are to (i) understand basic cardiovascular disease mechanisms, (ii) accelerate drug discovery and screening, (iii) develop “clinical trial in a dish” concept, and (iv) implement precision cardiovascular medicine for prevention and treatment of patients. Dr. Wu has received numerous awards, including National Institutes of Health (NIH) Director’s New Innovator Award, NIH Roadmap Transformative Award, American Heart Association (AHA) Innovative Research Award, Presidential Early Career Award for Scientists and Engineers given out by President Obama, AHA Established Investigator Award, Burroughs Wellcome Foundation Innovation in Regulatory Science Award, AHA Merit Award, and AHA Distinguished Scientist Award. Dr. Wu serves on the Scientific Advisory Board for the Keystone Symposia, FDA Cellular, Tissue, and Gene Therapies Advisory Committee, AHA National Board of Directors, Chair of the AHA Basic Cardiovascular Science Council, and Chair of the AHA National Research Committee. Dr. Wu is an elected member of American Society of Clinical Investigators (ASCI), Association of University Cardiologists (AUC), American Institute for Medical and Biological Engineering (AIMBE), American Association of Physicians (AAP), American Academy of Arts & Sciences (AAAS), and National Academy of Medicine (NAM).