

**Improving Productivity in Pharmaceutical Research and Development:
The Role of Clinical Pharmacology and Experimental Medicine**

The Embassy Row Hotel • Washington, DC

July 28, 2015

8:30 a.m. Registration

9:00 a.m. Welcome, Overview, and Meeting Objectives

- Mark McClellan, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution
- Gregory Daniel, Managing Director for Evidence Development & Innovation, Center for Health Policy and Fellow, Economic Studies, The Brookings Institution

9:10 a.m. Introductory Keynotes: Framing the Issues

Regulatory Perspective:

- Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Industry Perspective:

- Mark Rogge, Global Head of Clinical Pharmacology, Early Clinical Development, Biogen

9:40 a.m. Session I: Optimizing Target and Compound Selection to Enhance Early Stage Decision-Making

Lead Presentations:

- Paul Morgan, Head of Translational Safety, AstraZeneca
- James Barrett, Professor and Chair, Department of Pharmacology & Physiology, Drexel University

Perspectives:

- Karen Davis-Bruno, Acting Associate Director Pharmacology/Toxicology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Volker Fischer, Vice President, Drug Metabolism and Pharmacokinetics, AbbVie
- Piet Hein van der Graaf, Director of Research, Academic Center for Drug Research, Leiden University
- Christopher Austin, Director, National Center for Advancing Translational Sciences, National Institutes of Health

11:00 a.m. Break

11:10 a.m. Session II: The Right Dose for the Right Patient: Challenges and Opportunities in Dose Optimization

Lead Presentation:

- Vikram Sinha, Director, Division of Pharmacometrics, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Case Studies:

- Amita Joshi, Senior Director, Clinical Pharmacology, Genentech
- Brenda Cirincione, Group Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb

Perspectives:

- Sandra Allerheiligen, Vice President, Pharmacokinetics Pharmacometrics Drug Metabolism, Quantitative Pharmacology & Pharmacometrics, Merck Research Laboratories
- Lisa LaVange, Director, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Michael Maitland, Assistant Professor of Medicine, The University of Chicago Medicine

12:30 p.m. Lunch

1:45 p.m. Session III: Precision Medicine: Trial Enrichment, Biomarker Science, and Mechanistic Reasoning to Optimize Patient Selection

Lead Presentation:

- Michael Pacanowski, Associate Director for Genomics and Targeted Therapy, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Case Studies:

- Vissia Viglietta, Director Medical Research, Biogen
- James Sullivan, Director, Clinical Biomarkers, Vertex Pharmaceuticals

Perspectives:

- Richard Moscicki, Deputy Center Director for Science Operations, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Alice Chen, Head, Early Clinical Trials Development Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute
- Stephen Friend, President and Co-Founder, Sage Bionetworks

3:15 p.m. Break

3:25 p.m. Session IV: Applications of Clinical Pharmacology to Support Demonstration of Efficacy

Lead Presentation:

- Robert Temple, Deputy Director for Clinical Science, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Perspectives:

- Jack Cook, Vice President, Clinical Pharmacology, Pfizer
- Steve Ryder, Senior Vice President and Chief Development Officer, Alexion Pharmaceuticals
- Carl Peck, Adjunct Professor, Center for Drug Development Science, Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California San Francisco
- Alasdair Breckenridge, Partner, NDA Partners LLC
- Issam Zineh, Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

4:45 p.m. Recap and Closing Remarks

- Mark McClellan, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution

5:00 p.m. Adjournment

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Biographies



Sandra Allerheiligen is vice president of Quantitative Pharmacology & Pharmacometrics at Merck Research Laboratories and previously led the Modeling and Simulation department at Merck. Prior to joining Merck in 2010, she held positions at Eli Lilly & Company including Global Senior Director Pharmacokinetics, Pharmacodynamics (PK/PD) & Trial Simulation, Senior Director Drug Disposition, and Distinguished Fellow & Chief Scientific Officer of Quantitative Pharmacology. Her research focuses on study design and application of mathematical methods to enable quantitative decisions for nonclinical and clinical development. She has applied PK/PD modeling to oncolytic and endocrine agents. Her recent work is on the integration of biomarkers, PK/PD modeling and trial simulation

in non-clinical and clinical drug development, drug disease models and utilization of quantitative and systems pharmacology approaches. Dr. Allerheiligen received a doctorate in PKPD from the University of Texas, Austin (1985); completed postdoctoral fellowships at the University of Texas Health Center - San Antonio (1986); and clinical assistant professor of Clinical Pharmacology (1986-1990). Through her involvement in American Association of Pharmaceutical Scientists, American Association of Clinical Pharmacology and Therapeutics, International Society of Pharmacometrics, and NIH Working Groups, she has worked to expand the use of PK/PD Modeling and Quantitative & Systems Pharmacology methodologies in academia, regulatory agencies, and across the industry. She is a Fellow of the American Association of Pharmaceutical Sciences and frequently lectures on modeling and simulation topics.



Christopher P. Austin is director of the National Center for Advancing Translational Sciences (NCATS) at the U.S. National Institutes of Health (NIH). Austin leads the Center's work to improve the translation of observations in the laboratory, clinic and community into interventions that reach and benefit patients—from diagnostics and therapeutics to medical procedures and behavioral changes. Under his direction, NCATS researchers and collaborators are developing new technologies, resources and collaborative research models; demonstrating their usefulness; and disseminating the data, analysis and methodologies for use by the worldwide research community. Austin's career has spanned the spectrum of translational research, in the public and private sectors. Austin

joined NIH in 2002 as the senior advisor to the director for translational research at the National Human Genome Research Institute, where he was responsible for conceptualizing and implementing research programs to derive scientific insights and therapeutic benefit from the newly completed Human Genome Project. While at NHGRI, he founded and directed the NIH Chemical Genomics Center, Therapeutics for Rare and Neglected Diseases program, Toxicology in the 21st Century initiative, and NIH Center for Translational Therapeutics. Upon creation of NCATS in 2011, he became the inaugural director of the NCATS Division of Pre-Clinical Innovation, and was appointed NCATS director in 2012. Prior to joining NIH, Austin worked at the pharmaceutical company Merck, where he directed programs on genome-based discovery of novel targets and drugs, with a particular focus on schizophrenia and Alzheimer's disease. Austin is trained as a clinician and geneticist. He trained in internal medicine and neurology at the Massachusetts General Hospital in Boston, and practiced medicine in academic and community hospital settings as well as in urban primary care and in rural Alaska and Africa. He completed a research fellowship in developmental neurogenetics at Harvard, studying

genetic and environmental influences on stem cell fate determination. Austin earned an M.D. from Harvard Medical School and A.B. summa cum laude in biology from Princeton University.



James E. Barrett is Professor and Chair of Pharmacology and Physiology and Founding Director of the Drug Discovery and Development Program at Drexel University College of Medicine and of the Clinical and Translational Research Institute, Drexel University. He received his Ph.D. from Pennsylvania State University followed by postdoctoral training in neuropsychopharmacology at the Worcester Foundation for Experimental Biology. He has served on the faculty at the University of Maryland and the Uniformed Services University of the Health Sciences (USUHS) where he was Professor in the Departments of Psychiatry, Pharmacology and Medical Psychology. Dr. Barrett joined Wyeth as Vice President of Neuroscience Discovery Research following the merger with Lederle Laboratories where he had been Director of Central Nervous System Research. Prior to his current position at Drexel University College of Medicine, he was Senior Vice President, Chief Scientific Officer, and President, Research at Adolor Corporation, a company focused on pain pharmaceuticals. He moved to Adolor after serving as President of Research and Development at Memory Pharmaceuticals, a biopharmaceutical company dedicated to the development of drugs for the treatment of debilitating central nervous system (CNS) disorders. He has published more than 300 scientific articles, books and abstracts in the areas of neuropharmacology, neurobiology, behavioral pharmacology, translational research and neuroscience and serves on several editorial boards. He has served as President of the Behavioral Pharmacology Society and of the American Society for Pharmacology and Experimental Therapeutics (ASPET). He served as the Chair of the Board of Publication Trustees for ASPET and has served on the Board of Directors for the Federation of American Societies for Experimental Biology (FASEB), where he was a member of the Science Policy Committee and the Public Affairs Committee as well as Chair of the “Breakthrough Series in Science” and “Horizons in Bioscience” Series. Dr. Barrett recently joined the Board as Series Editor for the Handbook of Experimental Pharmacology. He has received the Solvay-Duphar Award for Research on Affective Disorders, the George B. Koelle Award from the Mid-Atlantic Pharmacology Society for contributions to teaching and research and, most recently, the P.B. Dews Lifetime Achievement Award for Research in Behavioral Pharmacology. He is also the recipient of the Torald Sollmann Award in Pharmacology for significant contributions to the advancement and extension of knowledge in the field of pharmacology. Dr. Barrett is currently a member of the External Scientific Advisory Board, Preclinical Autism Consortium for Therapeutics. He is also the President of the Association of Medical School Pharmacology Chairs and was recently elected to the Executive Committee of the International Union of Basic and Clinical Pharmacology. In addition to being a member of ASPET, he is also a member of AAAS, the American Pain Society and a Fellow of the American College of Neuropsychopharmacology. His current research emphasis is in the area of pain, its co-morbid pathologies, and on basic mechanisms, biomarkers and on the development of new therapeutics emerging from academic research.



Alasdair Breckenridge, CBE, was Chairman of the Medicines and Healthcare products Regulatory Agency which was formed in April 2003 by the merger of the Medicines Control Agency and the Medical Devices Agency. Previously he was Chairman of the Committee on Safety of Medicines and Professor of Clinical Pharmacology in the University of Liverpool. He was knighted in 2004.



Alice Chen is the acting head of the Early Clinical Trials Development Program, DCTD, NCI. She received her Medical Oncology training at Baylor College of Medicine and completed a Clinical Oncology and Regulatory Sciences fellowship with FDA and NCI. She is board certified in Internal Medicine and Medical Oncology. Dr. Chen had served for 10 years as a medical officer in the Cancer Therapy Evaluation Program, NCI specializing in HSP 90 inhibitors, PARP inhibitors and other agents in the DNA damage and repair process. She has served as a primary and associate investigator in a broad spectrum of clinical trials ranging from phase 0 through phase 4. She directs the NCI's Developmental Therapeutics Clinic which focuses on determining proof of concept, biomarkers and experimental trial

designs in early drug development working toward more successful confirmatory late phase trials. She is the primary investigator for two of the NCI sponsored Precision Medicine Initiative trials: Molecular Analysis for Therapy Choice (NCI MATCH) and Molecular Profiling based Assignment of Cancer Therapeutics (MPACT). She is the recipient of 6 NIH Awards of Merit for her contribution to international relationships, adverse event reporting, CTCAE, PRO-CTCAE, and NCI-MATCH.



Brenda Cirincione is Group Director, Clinical Pharmacology & Pharmacometrics, at Bristol-Myers Squibb. Her primary professional goal is to support and expand the use of pharmacometrics in drug development. She has over 18 years of research experience in Pharmacometrics. Brenda received a PhD in pharmaceutical sciences and a MA in statistics from the University of Buffalo, State University of New York, and has experience working in businesses across the pharmacometrics continuum: starting in a CRO (Cognigen), then a biotech (Amylin), and now in a large biopharma (Bristol-Myers Squibb). Currently, as a Gr. Director within clinical pharmacology and pharmacometrics at Bristol-Myers Squibb, Brenda directs a talented team to develop and apply innovative

mechanism-based clinical pharmacology models to optimize drug development and support approval for multiple therapeutic areas, including cardiovascular, immunosciences, virology and metabolic disorders. She has been very involved in the pharmacometrics community. Since transitioning back to the east coast Brenda has been co-chairing the local ISO-P chapter, helping to organize meetings and engaging our local pharmacometrics community. Besides ACoP, she has presented many PK and PK/PD research projects at prominent international meetings, such as AAPS and ICAAC. Brenda has published several papers in peer-reviewed journals. In 2010, she was a founding committee member of PaSiPhIC, with the mission of creating a platform for bringing statisticians and pharmacometricians together.



Jack Cook is a Vice President in the Clinical Pharmacology Department for the Global Innovative Pharma Business Unit at Pfizer, Inc., in Groton, CT. He also holds adjunct faculty positions at the Universities of Michigan and Florida in their respective Colleges of Pharmacy. He received an A.A.S degree in Industrial Chemistry Technology, and B.S. degrees in Applied Mathematics and Pharmacy from Ferris State College, and his Ph.D. in Pharmaceutics from the University of Michigan. Dr. Cook has authored/co-authored 50 peer-reviewed publications as well as 3 book chapters. He is a fellow of the American Association of Pharmaceutical Scientists and a member of the Board of Directors of the Drug Delivery Foundation. His current interests include improving therapy by optimizing

drug delivery and the use of modeling and simulation to make rational decisions in the development of drugs.



Gregory Daniel is a Fellow in Economic Studies and Managing Director for Evidence Development and Innovation in the Center for Health Policy at the Brookings Institution. In this position, Dr. Daniel leads the Center's pharmaceutical and medical device policy portfolio that includes developing strategies for better post-market safety surveillance and comparative effectiveness research, improving regulatory science, fostering practical steps for implementing expedited drug development and review tools, improving biomedical innovation, and supporting payment reform. Dr. Daniel is also a senior advisor to the Reagan-Udall Foundation for the FDA. Prior to joining Brookings, Dr. Daniel was the Vice President of Government and Academic Research at HealthCore, Inc., a research

subsidiary of Anthem, Inc. At HealthCore, he led a division responsible for research in the areas of pharmacoepidemiology, drug, vaccine, and biologic safety evaluations, comparative effectiveness research, and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist and holds a PhD in Pharmaceutical Economics, Policy, and Outcomes with a minor in Epidemiology from the University of Arizona, an MPH specializing in biostatistics, an MS in Pharmaceutical Administration, and a BS in Pharmacy, all from The Ohio State University.



Karen Davis-Bruno earned a BS in biology from Fordham University and MS and Ph.D. in Pharmacology from New York Medical College. She has experience in biotechnology product discovery and development prior to joining the USFDA as a reviewing pharmacologist in 1998 in the Division of Reproductive and Urologic Drug Products. Dr. Davis-Bruno was a Supervisory Pharmacologist in the Division of Metabolism and Endocrinology Products in the Center for Drug Evaluation Research (CDER) for 15 years before her recent promotion to Associate Director Pharmacology & Toxicology in the CDER Office of New Drugs. She serves as Chairperson of the Pharmacology Toxicology Coordinating Committee and Executive Carcinogenicity Committee. Her expertise in

juvenile animal modeling and its application to pediatric drug development has been recognized by CDER. She coordinated the development of the CDER "Guidance to Industry Nonclinical Safety Evaluation of Pediatric Drug Products". She has served on combined industry/government/academic international committees related to pediatric drug development.



Volker Fischer is a Vice President at AbbVie and is globally responsible for DMPK/Bioanalysis. The responsibilities span from early discovery to regulatory approvals for both small molecules and biologics. The responsibilities also include biomarker analytics and translational PKPD. Previously, he was an Executive Director at Novartis, originally joining the company at (Sandoz) in Basel Switzerland. Volker represents AbbVie at the IQ Drug Metabolism Leadership Group, where he currently serves as chair-elect, and at the Biosafe PKPD Expert Working Group. Volker served for several years on the Drug Metabolism Technical Group of PhRMA and as their liaison to the Preclinical Safety leadership committee. Volker was a Visiting Fellow at the National Institute of

Environmental Health Sciences in North Carolina and he has a Ph.D. in organic chemistry from the University of Tübingen, Germany.



Stephen Friend is President of Sage Bionetworks, a non-profit organization that provides the tools and environment to conduct dynamic, large-scale collaborative biomedical research. He is an authority in the field of cancer biology and a pioneer in the field of the genetics of gene expression, integrating system biology approaches to complex diseases. He believes that successful biomedical research requires the active participation from all stakeholders. He is reimagining the role of citizens in the research process and is building tools to empower them to contribute both their data and expertise as they see fit. He also believes in the importance of generating and testing novel hypotheses transparently and collaboratively. Sage Bionetworks has developed an open-source technology

platform, called Synapse, for data-intensive analysis, sharing and reuse, enabling researchers to perform cutting edge computational biology and research. He is engaging the community to crowd-source solutions to complex biomedical questions through targeted DREAM challenges. Previously, Dr. Friend was Senior Vice President and Franchise Head for Oncology Research at Merck & Co., Inc. where he led Merck's Basic Cancer Research efforts. Formerly, he and Dr. Leland Hartwell founded and co-led the Fred Hutchinson Cancer Research Center's "Seattle Project", an advanced institute for drug discovery and later they co-founded Rosetta Inpharmatics with Dr. Leroy Hood. Dr. Friend also held faculty positions at Harvard Medical School from 1987 to 1995 and at Massachusetts General Hospital from 1990 to 1995. He received his M.D/Ph.D. from Indiana University. He was named an Ashoka Fellow for his work at Sage Bionetworks.



Piet van der Graaf is the Director of the Leiden Academic Centre for Drug Research (LACDR) and Professor of Systems Pharmacology at Leiden University (The Netherlands). From 1999 – 2013 he held various leadership positions at Pfizer in Sandwich (United Kingdom) in Discovery Biology, Pharmacokinetics and Drug Metabolism (PDM) and Clinical Pharmacology/Pharmacometrics. He received his doctorate training in quantitative pharmacology with Nobel laureate Sir James Black at King's College London and worked as a postdoctoral fellow of the Royal Netherlands Academy of Sciences at Leiden University on the development of mechanism-based PKPD approaches. He is Editor-in-Chief of CPT: Pharmacometrics & Systems Pharmacology

(www.nature.com/psp) and was recently elected as Fellow of the British Pharmacological Society. He holds several patents in the field of target discovery and has co-authored more than 80 papers in the area of quantitative and translational pharmacology.



Amita Joshi is an Executive Leader with 25 years experience in Clinical Drug Development and Clinical Pharmacology. In her role as Head of Clinical Pharmacology at Genentech, Amita is responsible for the strategic and scientific direction of Clinical Pharmacology and Pharmacometric aspects of all Genentech programs from Early Clinical Research through post-approval. The scientific staff of Clinical Pharmacology is responsible for ensuring that we identify and deliver the right dose, by the right route and by the right regimen to patients. CP accomplishes this through optimally designed Clinical assessments in our patient and healthy volunteer studies and applying quantitative modeling to assess dose-response to fully inform our understanding of the right dose for patients. In her role

Amita has overseen successful development strategies and tactics for first product approvals and/or product extensions for Kadcyra, Lucentis, Rituxan, Erivedge, Perjeta, Herceptin, Avastin, Xolair and Nutropin. Amita is also recognized by her peers in the Biotech industry for her contributions to understanding the Clinical Pharmacology of therapeutic monoclonal antibodies, has been a member of the AAPS and ASCPT scientific leadership and has chaired AAPS's National Biotechnology Conference in 2010. Amita has published more than 40 manuscripts and book chapters.



Lisa LaVange is Director of the Office of Biostatistics in the Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA). As Director, she oversees approximately 170 statistical reviewers and staff members involved in the development and application of statistical methodology for drug regulation. She is a member of the PDUFA V steering committee and serves on the CDER Antibacterial Drug Development Task Force. Prior to joining the FDA, Dr. LaVange was a professor and Director of the Collaborative Studies Coordinating Center (CSCC) in the Department of Biostatistics, Gillings School of Global Public Health at the University of North Carolina at Chapel Hill, where she served as principal investigator of the

coordinating centers for several large-scale multi-center clinical trials, epidemiology studies, and patient registries. Before joining academia, Dr. LaVange spent ten years in the pharmaceutical industry and 16 years in non-profit research. She is a fellow of the American Statistical Association, served as President of the Eastern North American Region of the International Biometric Society (IBS, 2007), and currently serves on the IBS Executive Board. She is co-editor of the Journal of Pharmaceutical Statistics and editor-in-chief of the ASA-SIAM book series.



Michael Maitland is a physician-scientist who conducts patient-oriented research to better personalize pharmacotherapy. His studies focus on the differences among patients (and not the tumors) that affect safety and efficacy of new cancer therapeutics. His team develops and tests clinical, laboratory, and genetic biomarkers to advance the development of new anticancer drugs. Dr. Maitland is an expert in the treatment of advanced solid tumors, in particular, lung cancer. He is a principal investigator on multiple National Institutes of Health grants and serves as a member of the National Cancer Institute Investigational Drug Steering Committee.



Mark B. McClellan is a senior fellow and director of the Health Care Innovation and Value Initiative at the Brookings Institution. His work at Brookings focuses on promoting quality and value in patient centered health care. A doctor and economist by training, McClellan also has a highly distinguished record in public service and in academic research. He is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-

Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House. He was also an associate professor of economics and medicine at Stanford University. McClellan holds an MD and an MPA from Harvard University and a PhD in economics from MIT.



Paul Morgan received his PhD at the University of Liverpool working with Professor Kevin Park. He later joined DMPK at Pfizer in Sandwich, UK in 1991, where he gained experience in all aspects of support in drug discovery and development across multiple therapeutic areas. Dr. Morgan had a number of site and global DMPK leadership roles within Pfizer. He contributed to the registration and launch of a number of products including Relpax, Viagra, Selzentry and Xalkori. In July 2011, he joined AstraZeneca at Alderley Park, UK, as leader of the global DMPK Centre of Excellence which brought oversight to the DMPK science strategies in support of all disease areas. In July 2012, he became leader of the global DMPK In Vivo group providing PK, Imaging and PKPD support to all iMeds and

Bioanalysis/TK support for toxicology studies. In June 2013, Dr. Morgan became head of the Translational Safety department within Drug Safety and Metabolism. In this position, he works on developing high quality, quantitative translational safety models, incorporating safety and toxicokinetic assessment, to aid preclinical safety risk assessment covering the key target organs, namely cardiovascular, CNS, hepatic and respiratory organ systems. His scientific passion is to develop and apply quantitative systems pharmacology approaches to drug discovery and development.



Richard Moscicki joined the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), as Deputy Center Director for Science Operations in April 2013. A nationally recognized expert in clinical research and development, Dr. Moscicki is bringing his extensive scientific expertise and executive leadership skills to Center operations and direction and to effective development and implementation of CDER programs. Before joining CDER, Dr. Moscicki served as senior vice president (SVP), Head of Clinical Development at Genzyme Corporation. He joined Genzyme in 1992 as Medical Director, becoming Chief Medical Officer and SVP of Biomedical and Regulatory Affairs in 1996 and holding that post until 2011. During that time, Dr. Moscicki was responsible for

worldwide global regulatory and pharmacovigilance matters and oversaw all aspects of clinical research and medical affairs for the company. Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency in Internal Medicine, followed by a four-year fellowship at Massachusetts General Hospital (MGH) in Clinical immunology and immunopathology. He remained on staff at MGH in Clinical Immunology and on the faculty of Harvard Medical School from 1979 until 2013.



Michael Pacanowski is the Associate Director for Genomics and Targeted Therapy in the Office of Clinical Pharmacology at the FDA. He is charged with helping to maximize the impact and value of individualized therapy principles in drug development and regulatory evaluation. He oversees policy, process, and scientific matters related to pharmacogenomics/targeted therapy aspects of IND, NDA, and BLA review. Dr. Pacanowski also serves as the Office's lead on enhancement of clinical development through use of innovative tools (e.g., biomarkers, alternative trial designs). Dr. Pacanowski received his Pharm.D. from the Philadelphia College of Pharmacy and his M.P.H. from the University of Florida. He completed a residency in Clinical Pharmacology

at Bassett Healthcare in Cooperstown, NY, and a clinical research fellowship in Cardiovascular Pharmacogenomics at the University of Florida.



Carl Peck obtained a B.A. in mathematics and chemistry from the University of Kansas in 1963 and the M.D. in 1968. Following training in internal medicine, he undertook a research fellowship in clinical pharmacology at the University of California San Francisco (1972-74). From 1974 to 1980, Dr. Peck was employed at the Letterman Army Institute of Research, San Francisco, CA, as Chief of the Army Blood Preservation Research Program. In 1980, Dr. Peck became Director of the Division of Clinical Pharmacology and, Professor, Departments of Medicine and Pharmacology, Uniformed Services University, Bethesda, Maryland. Dr. Peck joined the FDA as Director, Center for Drug Evaluation and Research, in October 1987. He was promoted to Assistant Surgeon General in the Public Health

Service in October 1990. Retiring from FDA in late 1993, Dr. Peck was appointed “Boerhaave” Professor of Clinical Drug Research at Leiden University in The Netherlands. In 1994 Professor Peck joined the faculty of the Georgetown University Medical Center, as the founding Director of the Center for Drug Development Science. In 1999, Dr. Peck received the FDA Distinguished Alumnus Award. Sweden’s University of Uppsala conferred an honorary doctorate degree (Doctor Honoris Causa) to Dr. Peck in January 2002 in recognition of "outstanding contributions to the science of drug development". Dr. Peck founded NDA Partners LLC in 2003 and in 2004, CDDS moved to UCSF, located in the UC-Washington Center. Throughout his career, he has mentored more than 40 postdoctoral fellows and graduate students and co-founded the American (2007) and Chinese (2009) Courses in Drug Development and Regulatory Science (ACDRS, CCDRS). In March 2012, Dr. Peck received the ASCPT Gary Neal Prize for Innovation in Drug Development. 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 150 original research papers, chapters and books.



Mark Rogge serves as Biogen’s head of clinical pharmacology and pharmacometric activities where he supports all pipeline and business development initiatives. He also has responsibilities on numerous early development activities related to corporate collaborations and activities focused on best development practices. He has over 25 years of experience in developing small and large molecules in the therapeutic areas of neurology, inflammation, oncology and hematology. During his career, he has served in senior leadership positions within emerging and large companies. In those roles, he has built successful scientific organizations and led efforts to improve the culture and value of early drug development within the R&D organization. In the scientific community, he has

served as the Pharmacokinetics, Pharmacodynamics and Drug Metabolism Chair for AAPS, the Chair of BioSafe, BIO’s preclinical safety and pharmacokinetics expert committee, is a Fellow of the American College of Clinical Pharmacology and is currently serving as Chair of the Clinical Pharmacology Leadership Group within the International Consortium for Innovation and Quality in Pharmaceutical Development. He also serves on the editorial advisory board for the Journal of Pharmaceutical Sciences and has been active with the NC3Rs consortium on reduction of animal use in the development of biosimilar therapeutics. He has published 46 peer-reviewed manuscripts, is co-editor of Preclinical Drug Development, and has given over 60 presentations related to optimization of early clinical development. Mark received his undergraduate degree in Pharmacy from the University of Wisconsin and his Ph.D. in Pharmaceutical Chemistry from the University of Michigan.



Steve Ryder is SVP and Chief Development Officer at Alexion Pharmaceuticals, a biotechnology company dedicated to transforming the lives of patients with rare and ultra-rare devastating illness. Prior to joining Alexion, Steve was founding President of Astellas Pharma Global Development, the development organization of Astellas Pharma, Inc, a Japanese-based global R&D-based pharmaceutical company. Prior to joining Astellas, Steve worked for Pfizer R&D and Ayerst Laboratories in various positions in pharmaceutical development. His experience covers a broad array of therapeutic areas, with special focus on endocrine/metabolic, CNS and cardiovascular therapeutics including both small molecule and biological new medicinal development. He has held leadership

positions in both the BIO and PhRMA associations, is past-President of the American Society of Clinical Pharmacology and Therapeutics, served as the Industry Representative on the FDA Endocrine and Metabolic Drugs Advisory Committee, and is an active member of the editorial boards for several scientific journals. He has been a member and Chair of the Board of Directors of Gaylord Hospital (a specialty care hospital in Wallingford CT). Steve graduated from Mt. Sinai School of Medicine, completed training in Internal Medicine and Endocrinology/Metabolism at SUNY Stonybrook, followed by a Research Associate position at the Berson Laboratory of the Bronx VAMC.



Vikram Sinha is the Director, Division of Pharmacometric at the USFDA. In his current role, Vikram leads the Pharmacometrics Division. The Division plays a critical role in understanding the impact of variability in response to drugs and relates it to assessing benefit and risk. He leads a multidisciplinary team of quantitative clinical pharmacologists, statisticians, engineers, and data management experts. This dedicated pharmacometrics division not only plays a critical role in reviewing submissions, but also conducts its own analyses. Within CDER, pharmacometric work is conducted with the intent to aid the decision to approve and label the drug product. There is particular attention on providing a consulting function on drug dosing for patients and advice on trial design decisions by

sponsors. Previously, Vikram was at Eli Lilly, where he was scientific lead for global pharmacokinetics/pharmacodynamics and pharmacometrics. At Lilly, he was accountable for developing quantitative translational strategies, clinical plans, and regulatory strategies in the area of clinical pharmacology. He served as drug development lead in a variety of areas including cardiovascular and endocrine disorders, inflammation, and oncology. His expertise includes developing and applying drug-disease models in translating preclinical data, designing early clinical development programs including clinical pharmacology studies, optimizing dose and trial design, and developing global bridging strategies through regulatory interactions. He has 16 years of experience in the pharmaceutical industry. He has made notable contributions to the general scientific community through teaching, publications, and engagement with industry/government consortia dedicated to advancing innovation in the area of drug discovery and development. Vikram earned a bachelor's degree in pharmacy and a doctorate degree in pharmaceutical sciences from the University of Arizona. He completed post-doctoral training at the University of Nebraska Medical Center.



James Sullivan began his career in industry as a nuclear chemist at Bristol-Myers Squibb. After completing his PhD at Boston University in 2008, where he worked on genome annotation and functional genomics, Dr. Sullivan joined Vertex Pharmaceuticals Inc. While at Vertex, Dr. Sullivan worked in drug development for Hepatitis C, for which he developed computational pipelines using both nucleotide and inferred amino acid sequence data to identify drug-resistant variation in viral populations and to inform treatment modalities to minimize the emergence of resistant variants. Additional computational work in Hepatitis C focused on improving the understanding of population-

level dynamics between the viral quasispecies within individual patients. Dr. Sullivan currently serves as a Director in the Clinical Biomarkers group and leads his functional area in the Cystic Fibrosis franchise. His professional experiences include basic research as both a chemist and a molecular biologist, as well as late-stage clinical drug development scientist. His clinical research interests include improving knowledge of disease pathophysiology to inform precision medicine and end-to-end drug development. Dr. Sullivan has published extensively in areas spanning basic research through clinical development.



Robert Temple has been Deputy Center Director for Clinical Science at FDA's Center for Drug Evaluation and Research since 2009, participating in the direction of the Center's operations. He is also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple served as Director, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of promotion through the Office of Prescription Drug Products (formerly, Division of Drug Marketing, Advertising, and Communication) and for assessing quality of clinical trials. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has

written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using "enrichment" designs.



Vissia Viglietta received her MD and PhD from the University of Rome "La Sapienza". She is an instructor in Neurology at Brigham and Women's Hospital/Harvard Medical School focusing on activation and regulation of T cells in autoimmune diseases. Vissia previously worked at EMD Serono as medical director responsible for Phase 3 program of oral cladribine in MS. Vissia joined Biogen in 2011 as medical director in a global cross-functional team resulting in the successful submission and approval of Tecfidera marketing authorization for the treatment of patients with relapsing multiple sclerosis.



Janet Woodcock is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). As of January 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.



Issam Zineh is Director of the Office of Clinical Pharmacology (OCP) at the U.S Food and Drug Administration (FDA). From 2008-2012, Dr. Zineh was the Associate Director for Genomics in OCP. He also served as Co-Director of the CDER Biomarker Qualification Program until 2015. He is an experienced applied clinical pharmacologist who was formerly on the faculty of the University of Florida (UF) Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. Dr. Zineh received his PharmD from Northeastern University and completed his residency at Duke University Medical Center. He completed a fellowship in cardiovascular pharmacogenomics at UF where he also obtained his MPH in Health Policy and

Management. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of 240 regulatory, research, project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.