Enhancing Adoption of Innovative Clinical Trial Approaches

Hybrid Public Meeting • Kellogg Conference Hotel • Washington, D.C.

March 19, 2024 | 10:00 am – 5:00 pm ET

March 20, 2024 | 12:30 pm – 5:00 pm ET

Speaker Biographies

Amy P. Abernethy, is currently the President of Product Development and Chief Medical Officer at Verily. Dr. Abernethy recently announced that she'll be leaving Verily to start a nonprofit institute focused on advancing evidence generation. There, she will lead initiatives to inform health policy, demonstrate new capabilities in healthcare settings, and fund programs that drive innovation in clinical research. Dr. Abernethy was previously the Principal Deputy Commissioner and Acting Chief Information Officer of the US Food & Drug Administration. Prior roles include serving as CMO/CSO of Flatiron Health and multiple roles at Duke University, where she was Professor of Medicine. Dr. Abernethy went to the University of Pennsylvania and then Duke University Medical School, and received her PhD from Flinders University in Australia.

Stacey Adam is an Associate Vice President at the FNIH, leading many public-private partnerships, such as Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV); the Biomarkers Consortium (Cancer and Metabolic Disorders Steering Committees) and their projects; Accelerating Medicines Partnerships (AMPs)-Common Metabolic Diseases, Heart Failure, and Parkinson's Disease, Partnership for Accelerating Cancer Therapies (PACT); and the Lung Master protocol (Lung-MAP) clinical trial. Prior to FNIH, Dr. Adam was a Manager at Deloitte Consulting in the Federal Life Sciences and Healthcare Strategy practice. Dr. Adam conducted her postdoctoral fellowship at Stanford University School of Medicine, and she earned her Ph.D. in Pharmacology from Duke University

Jeff Allen, serves as the President and CEO of Friends of Cancer Research *(Friends).* For over 25 years, Friends has created unique scientific partnerships, accelerated policy change, and supported groundbreaking research to deliver new therapies to patients quickly and safely. As a key thought leader on issues related to the U.S. Food and Drug Administration, healthcare, and regulatory policy, he is regularly published in prestigious medical journals and policy publications and has contributed his expertise to the legislative process on multiple occasions. Recent *Friends* initiatives include the establishment of the Breakthrough Therapies designation, innovative research consortia to enhance biomarker development, and the launch of a unique cross-sector partnership to accelerate clinical trial conduct and rapidly assess if a patient's treatment is working. Jeff has been a driving force in the growth, strategy, and success of *Friends* for over 15 years

and serves on a variety of influential committees, boards, and advisory councils. He received his Ph.D. is cell and molecular biology from Georgetown University and a Bachelor of Science in Biology from Bowling Green State University.

Dr. Yuki Ando is a Principal Senior Scientist for Biostatistics of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. She has over 20 years' experience as Biostatistics Reviewer, and currently she is responsible for the biostatistics review and consultation in the new drug and device review offices in PMDA. She works also for the Office of Regulatory Science Coordination, the office which is responsible for the electronic study data submission for new drugs in the PMDA. She is a member of Real World Data Working Group and Global Clinical Study Working Group that are projects across multi-offices in the PMDA. She has experience in the development of ICH guidelines such as E14, E9(R1), E8(R1), and E20 as a EWG member, and has also advised from the statistical viewpoint in discussions on other ICH guidelines. She received a master's degree in Engineering from Tokyo Science University, and PhD in Health Science from Osaka University.

Monica M. Bertagnolli, is the 17th director of the National Institutes of Health (NIH She is the first surgeon and second woman to hold the position. As the NIH Director, Dr. Bertagnolli oversees the work of the largest funder of biomedical and behavioral research in the world. She previously served as the 16th director of the National Cancer Institute (NCI), the Richard E. Wilson Professor of Surgery in surgical oncology at Harvard Medical School, a surgeon at Brigham and Women's Hospital and a member of the Gastrointestinal Cancer Treatment and Sarcoma Centers at Dana-Farber Cancer Institute. As a physician–scientist, she led translational science initiatives from 1994 to 2011 within the NCI-funded Cooperative Groups Program (now known as NCI's National Clinical Trials Network), and from 2011–2022 served as group chair of the Alliance for Clinical Trials in Oncology, a National Clinical Trials Network member organization. In addition, from 2007–2018, she served as the chief of the division of Surgical Oncology for the Dana-Farber Brigham Cancer Center. Dr. Bertagnolli has championed collaborative initiatives to transform the data infrastructure for clinical research and is the founding chair of the minimal Common Oncology Data Elements (mCODE) executive committee. She also is a past president and chair of the board of directors of the American Society of Clinical Oncology and has served on the board of directors of the American Cancer Society and the Prevent Cancer Foundation. In 2021, she was elected to the National Academy of Medicine, having previously served on the National Academies National Cancer Policy Forum. She graduated from Princeton University with a Bachelor of Science in Engineering degree and attended medical school at the University of Utah. She trained in surgery at Brigham and Women's Hospital and was a research fellow in tumor immunology at the Dana-Farber Cancer Institute.

Amy Bertha is currently Executive Director, Regulatory Policy and Innovation at Bayer. Her prior experience includes, regulatory program and project management at U.S. FDA Center for Drug Evaluation and Research, regulatory affairs at Pfizer, and research scientist at Hoffman-La Roche. She is an organic chemist by training.

Ned Braunstein, joined Regeneron in 2009 as Executive Director and Head of Regulatory Affairs. With the company's growth with respect to number of approved products, development candidates, and as the company began conducting studies worldwide, he was named Vice President in 2013, Senior Vice President in 2015 with direct oversight of Global Regulatory Affairs, Product Safety, and Development Quality, and Executive Vice President in 2022. Today he oversees an organization of over 550 professionals across the US, Europe/UK and Japan. Previously, he had worked 13 years at Columbia College of P&S as Assistant and then Associate Professor of Medicine where he was an independently funded Principal Investigator, taught Medicine, Rheumatology, and Immunology and served on NIH and various foundation grant review boards. He then worked nine years at Merck & Co., Inc., in Clinical Research, Regulatory Affairs and Global Human Health while maintaining his teaching affiliation with Columbia. Dr. Braunstein received his B.S. and M.D. degrees from Northwestern University, trained in Internal Medicine and Clinical Rheumatology at Columbia Presbyterian Medical Center in NY, and completed a 4-year post-doctoral Medical Staff fellowship in molecular and cellular immunology in the Laboratory of Immunology, NIAID, NIH before embarking on his academic and industry career.

Kevin Bugin is an experienced pharmaceutical professional who has made significant contributions to drug development and regulatory science. He currently serves as the Deputy Director of Operations in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER). In this role, Dr. Bugin plays a key leadership role in the execution of CDER's evaluation of new drugs to ensure their safety and effectiveness. Prior to his current role, Dr. Bugin served as the Chief of Staff for the Therapeutics Response Efforts as part of the US Government's HHS and DOD operation originally known as Operation Warp Speed. His leadership during this time played an important role in the successful development and distribution of COVID-19 therapeutics. Dr. Bugin is also an adjunct faculty member at the George Washington University in the Clinical Leadership Program, where he focuses on areas of clinical research and medicines development, regulatory affairs, and the science of team science.

David Burrow is the Director of the Office of Scientific Investigations (OSI) within the Office Compliance in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). He leads CDER's Bioresearch Monitoring (BIMO) program, covering the conduct of clinical and non-clinical research, human subject protections, clinicaltrials.gov, post-market adverse drug experience reporting requirements, risk evaluation and mitigation strategies, and post marketing requirements. In this role, Dr. Burrow manages the strategic development and implementation of risk-based policy, inspection, and compliance activities to evaluate the integrity of data submitted to CDER in support of marketing applications; helps protect the rights, safety, and welfare of research participants; and helps ensure compliance with FDA laws and regulations pertaining to the BIMO programs. Dr. Burrow holds a Doctor of Pharmacy from Duquesne University, and a Juris Doctorate from Widener University School of Law.

Patrizia Cavazzoni, is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019. Dr. Cavazzoni received her medical degree at McGill University and completed a residence in psychiatry and fellowship in mood disorders at the University of Ottawa. During her training she was an investigator in clinical trials of novel antipsychotic and antidepressant medications and became a research collaborator within the International Group for The Study of Lithium Treated Patients. She subsequently received a full-time appointment to the Faculty of Medicine at the University of Ottawa, and joined the Mood Disorders Program at the Royal Ottawa Hospital, where she treated patients suffering from severe mood disorders, taught students and conducted research on genetic predictors of bipolar disorder as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications. After her tenure in academic medicine, Dr.Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA. Dr. Cavazzoni certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and is a fellow of the Canadian Royal College of Physicians and Surgeons. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.

Micky Cohen-Wolkowiez, is the Kiser-Arena Distinguished Professor of Pediatrics at Duke University and the Duke Clinical Research Institute. Micky has more than fifteen years of experience designing, planning, and conducting novel clinical trials in a variety of populations including healthy volunteers, children, adults, older adults, and pregnant women. Throughout this time, his research has been funded by the federal government, industry sponsors, and nonprofit organizations, which resulted in >180 published papers in peer-reviewed journals. Previously, he was a Scientific Advisor for the Office of Pediatric Therapeutics at the Food and Drug Administration, and has worked as a consultant for multiple pharmaceutical companies and startups. He is also serving as the Chief Medical Advisor for Lightship, a company providing clinical research services at sites, homes, remotely, and through mobile research units. He earned his medical degree at the Central University of Venezuela, completed his pediatric residency at

Nicklaus Children's Hospital, and a pediatric infectious disease fellowship at Duke University. He also has a PhD in Pharmaceutical Sciences from the University of North Carolina-Chapel Hill.

John Concato, is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), U.S. FDA. His responsibilities focus on FDA's Real-World Evidence (RWE) Program for drugs and biological products, including internal Agency processes, external stakeholder engagement, demonstration projects, guidance development, and serving as Chair of CDER's RWE Subcommittee. Dr. Concato joined FDA in 2019 after 27 years at Yale School of Medicine and the U.S. Department of Veterans Affairs (VA), where he was Professor of Medicine, Director of the VA Clinical Epidemiology Research Center, and one of two founding principal investigators of the VA Million Veteran Program mega-biobank.

Jacqueline Corrigan-Curay is the Principal Deputy Center Director in FDA's Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations. Previously, Dr. Corrigan-Curay was director of CDER's Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and as a practicing attorney in Washington, D.C.

Donna R. Cryer, is Founder and Chief Executive Officer of Global Liver Institute (GLI), the premier patient-driven liver health nonprofit operating with offices and partnerships across five continents. Moved by her own experience as a 29-year liver transplant recipient, Mrs. Cryer serves as a fierce advocate for the transformative potential of patient engagement in health policy, research, data, and system design. Through GLI, Mrs. Cryer has raised more than $10 million for liver health initiatives and convenes more than 200 organizations within the liver cancers, nonalcoholic steatohepatitis (NASH), pediatric and rare liver diseases, and general liver health communities across GLI's Councils and its Liver Action Network, facilitating collaborative multi-stakeholder agenda setting and bringing accountability to innovation, regulation, and adoption of best practices to optimize outcomes. Her expertise and effectiveness in advancing the voice of patients in defining and designing equitable healthcare has been recognized by the United States Congress and the White House. Mrs. Cryer serves on the Boards of Directors for the Council of Medical Specialty Societies (CMSS), Sibley Memorial Hospital/Johns Hopkins Medicine, and the Color of Gastrointestinal Illness (COGI). She also serves on the Executive Committee for the Clinical Trials Transformation Initiative and the Board of Advisors for ChronWell, Inc, a digital

health and therapeutics company. She was the first patient to serve on the American Board of Internal Medicine Gastroenterology Specialty Board, was one of the founding members of the AASLD Patient Advisory Committee, and is the Community Representative on the AASLD NASH Task Force. Mrs. Cryer received an undergraduate degree from Harvard and a Juris Doctorate from the Georgetown University Law Center.

Lucia D'Apote Lucia holds the position of Executive Director ELMAC (Europe, Latin America, Middle East & Africa & Canada) and JAPAC within the Global Regulatory and R&D Policy at Amgen. Her knowledge and expertise in regulatory policy, regulatory science foresight and regulatory affairs span 25 years in Industry and regulatory bodies. Lucia joined Amgen in 2018 and she represents Amgen in trade associations working groups including EFPIA Regulatory Science Committee, Clinical Research Expert Group and HTA subgroups. Prior to joining Amgen, she spent 12-year at the European Medicines Agency. In her most recent position at EMA, she drafted within a small team the EMA Regulatory Science Strategy to 2025. Lucia covered several regulatory affairs management roles in pharma industry in the previous 9 years. A biotechnologist by training, she holds a PhD in Molecular Biology and a Master in Regulatory Affairs Science.

Rob DiCicco is the Vice President of Portfolio Management at TransCelerate Biopharma Inc. There Rob is accountable for the delivery of initiatives related to digital transformation, clinical content and reuse, Pragmatic Trials and Real Word Data. In addition, he also represents TransCelerate on the Vulcan Advisory Committee. Prior to taking on this his current responsibilities he was the Deputy Chief Health Officer for Life Sciences at IBM Watson Health now Merative Health. He has had a long career in Pharmaceutical R&D spanning nearly 30 years; 25 with GlaxoSmithKline where he served in a variety of leadership positions. There Rob was the Global Project Leader for oncology clinical development programs leading to successful regulatory approvals as well as a line head for multiple clinical organizations over the years. Rob was TransCelerate's first Common Protocol Template workstream leader and helped to launch their Digital Data Flow as an Oversight Committee Member. He was also one of the team leads for the Clinical Trials Transformation Initiative (CTTI) sponsored Mobile Clinical Trials Novel Endpoints project. Rob received his Doctor of Pharmacy Degree from the University of the Sciences in Philadelphia. His areas of expertise and interest include clinical trial design, clinical operations, protocol quality and ethics in research.

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. In 2020, she 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.

M. Khair ElZarrad is the Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER). He has served as the Deputy Director of OMP since 2017. As Director of OMP, Dr. ElZarrad leads the development, coordination, and implementation of medical policy programs and strategic initiatives. He works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Before joining FDA, he served as senior science policy analyst and Director of the Clinical and Healthcare Research Policy Division at the Office of the Director of the National Institutes of Health (NIH). He also served as a fellow on both the FDA's Interagency Oncology Taskforce, as well as the National Cancer Institute's Cancer Prevention Fellowship Program within the Division of Cancer Control and Population Sciences. Dr. ElZarrad earned his doctoral degree in medical sciences with a focus on understanding cancer metastases from the University of South Alabama College of Medicine, his Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health, and his bachelor's degree in biochemistry from Samford University.

David Feldman received a PhD in biology from the State University of New York at Binghamton and was a post-doctoral fellow at the Cleveland Clinic. He then spent over 30 years in Pharma, where he led a pre-clinical research laboratory supporting drug discovery projects in kidney disease, thrombosis, atherosclerosis, hyperlipidemia, and hypertension. In 2015, David joined the National Kidney Foundation to follow his passion for learning about kidney diseases and helping and educating patients who live with these conditions. As a Senior Medical Project Director, one of his responsibilities is to organize Externally Led Patient-focused Drug Development (EL-PFDD) meetings on kidney diseases. These meetings convene patients and the FDA, along with Pharma and other stakeholders, to bring the patient voice to regulatory decision makers: patients' experiences, perspectives, aspirations regarding their diseases, and treatments they have taken. These meetings focus on rare conditions for which treatments are inadequate or non-existent, usually rare diseases. David's other main function is to organize NKF Scientific Workshops and Working Groups, which illuminate important emerging topics in clinical nephrology. David is especially fulfilled by applying his scientific background to support patients who live with kidney disease.

Ryan Ferguson is the Director of the VA Cooperative Studies Program Coordinating Center in Boston, MA, where he is involved in the design and conduct of large multi-center randomized clinical trials. Dr. Ferguson joined the Cooperative Studies Program in 2001 and has since focused on clinical trial methodologies for conducting pragmatic comparative effectiveness trials. He currently serves as a Principal Investigator for the VA's Point of Care Research Program which is focused primarily on pragmatic clinical trials and innovation in translational science. In addition to his interests in clinical trials methodology and pragmatic trials, Dr. Ferguson's research interests are focused on the epidemiology of acute kidney injury and chronic kidney disease. Dr.

Ferguson's published work includes first authored publications, abstracts, presentations, and book chapters on pragmatic trials and trial design. Dr. Ferguson is on faculty at Boston University Chobanian and Avedisian School of Medicine as an Assistant Professor of Medicine in the department of General Internal Medicine, and at Boston University School of Public Health where he is an adjunct Clinical Assistant Professor of Epidemiology. He is also a member of the Society for Clinical Trials, the Society for Epidemiologic Research, and the American Statistical Association.

Angie Goldsberry has over 20 years of drug development experience, primarily working in rare disease. She is currently a Development Asset Lead for Biogen. In her role, she provides strategic and multi-disciplinary drug development expertise and ensures efficient execution of the integrated development plan aligned with asset goals. She recently joined Biogen in 2023 as part of the Reata acquisition and continues to lead the Reata clinical assets as part of her current role. During her career she has held various roles with increasing levels of responsibility. At Reata, Angie was the Vice President, Product Development, and led a cross-functional team of statisticians, statistical programmers, medical writers, and clinical data scientists. She worked across the entire clinical pipeline during her 12-year tenure with Reata, including involvement in indication selection, development of clinical trial protocols and statistical analysis plans, participation in regulatory interactions, supporting NDA and MAA submissions, publications, and development strategy. Prior to joining Reata, she worked on post-marketing trials in dermatology with Galderma. She started her industry career working on Phase 1 trials at a contract research organization. Angie received a B.S. in education and an M.S. in statistics from the University of Nebraska Lincoln.

John D. Halamka, is president of the Mayo Clinic Platform, a digital initiative that brings together solution developers, data partners and healthcare service providers to transform healthcare. Mayo Clinic Platform tools and solutions reached 45 million people in 2023. Trained in emergency medicine and medical informatics, Dr. Halamka has been developing and implementing healthcare information strategy and policy for more than 40 years. Prior to his appointment at Mayo Clinic, he was chief information officer at Beth Israel Deaconess Medical Center, where he served governments, academia and industry throughout the world. As the International Healthcare Innovation Professor at Harvard Medical School, Dr. Halamka helped the George W. Bush administration, the Obama administration and governments worldwide plan their healthcare information strategies. Dr. Halamka completed his undergraduate studies at Stanford University, earned his medical degree at the University of California, San Francisco, and pursued graduate work in bioengineering at the University of California, Berkeley. He completed his residency at Harbor — UCLA Medical Center in the Department of Emergency Medicine. He continues to practice emergency medicine and is Professor of Emergency Medicine and the Michael D. Brennan, M.D., President's Strategic Initiative Professor at Mayo Clinic College of Medicine and Science. He was elected to the National Academy of Medicine in 2020.

Nicole Mayer Hamblett, is a Professor of Pediatrics and Adjunct Professor of Biostatistics at the University of Washington. She is the Co-Executive Director of the Cystic Fibrosis Therapeutics Development Network (CF TDN) Coordinating Center at Seattle Children's Research Institute. She has led the design and analysis of numerous large multicenter clinical studies which have advanced clinical care and outcomes in CF. Dr. Hamblett collaborates on regulatory strategy for complex drug development issues relevant to rare diseases. She is currently a principal investigator on therapeutic trials optimizing treatment regimens in CF, studies to advance biomarkers supporting therapeutic development for novel CFTR modulator therapies, and methodologic work to innovate clinical trials for rare diseases, in particular to support a pipeline of nucleic acid-based therapies for people with CF ineligible for CFTR modulators. She serves on a number of national scientific advisory committees for the Cystic Fibrosis Foundation and is an advisory committee member for the Food and Drug Administration.

Gerrit Hamre, is a new Research Director in Medical Product Development and Regulatory Policy at the Duke-Margolis Institute for Health Policy. Gerrit has worked for nearly 20 years in the pharmaceutical industry with a focus on clinical research, regulatory, and commercial roles. Central to much of his career work is extensive internal and external stakeholder engagement to advance innovative, evidence-based healthcare solutions. He has often worked in the drug development and approval environment. Highlights of Gerrit's career so far have included his work in the Food and Drug Administration's Office of Legislation and as a Peace Corps Volunteer in South Africa.

Morgan Hanger is the Executive Director of the Clinical Trials Transformation Initiative (CTTI), a public-private partnership between Duke University and the U.S. Food and Drug Administration. She has deep experience convening organizations to solve complex problems related to evidence generation, and is passionate about data ethics and transparency. Prior to CTTI, Hanger worked at health technology companies focused on patients: streamlining receipt of specialty products, simplifying Medicare plan selection, and fostering robust learning through data sharing. Notably, Hanger served as vice president of the online patient research network PatientsLikeMe (PLM), where she led partnerships to utilize patient-generated health data in life sciences and regulatory settings. There she created products to streamline patient input into clinical trial design and to leverage the PLM platform for decentralized trials. Prior to PLM, Hanger worked in advisory services for Avalere Health, where she helped pharma, biotech, and professional societies create more effective research strategies. She has also held positions within the Health Outcomes Group at Memorial Sloan Kettering Cancer Center, supporting research on equity and cost in oncology, and at the Congressional Budget Office, investigating options for federally supported comparative effectiveness research. Ms. Hanger graduated summa cum laude from New York University with a BA in politics and holds a master's degree in public policy from the University of California, Berkeley.

Nancy Kass, is Vice Provost for Graduate and Professional Education, Johns Hopkins University and Phoebe R. Berman Professor of Bioethics and Public Health in the Johns Hopkins Berman Institute of Bioethics and the Johns Hopkins Bloomberg School of Public Health, where she also Professor of Health Policy and Management. In 2009-2010, Dr. Kass was based in Geneva, Switzerland, working with the World Health Organization (WHO). Dr. Kass received her B.A. from Stanford University, completed doctoral training in health policy from the Johns Hopkins School of Public Health and post-doctoral training at the Kennedy Institute of Ethics, Georgetown University. As Vice-Provost, Dr. Kass focuses on issues related to the quality of PhD education, promoting transparency about PhD programs, diversity of the student body, career preparedness, research and professional experiences for students, and mentoring. In her faculty role, Dr. Kass conducts empirical work in bioethics, public health, and human research. Her publications are in the field of U.S. and international research ethics, public health ethics, and ethics and the learning healthcare system. Dr. Kass served as consultant to the President's Advisory Committee on Human Radiation Experiments, the National Bioethics Advisory Commission, and the National Academy of Sciences. Dr. Kass is Chair of the NIH Precision Medicine Initiative Central IRB, previously co-chaired the National Cancer Institute (NCI) Committee to develop Recommendations for Informed Consent Documents and served on the NCI's central IRB. Dr. Kass is an elected member of the National Academy of Medicine and an elected Fellow of the Hastings Center.

Luke Kosinski, is a Scientific Director in the Quantitative Medicine program at the Critical Path Institute (C-Path). Dr. Kosinski uses statistical modeling and R programming to better understand disease progression and to accelerate the medical product development process. He received a bachelor's of English with minors in philosophy and math from Arizona State University, a Master of Philosophy from Louisiana State University, a Master of Biomedical Sciences from Midwestern University, and a Ph.D. in Molecular and Cellular Biology with a minor focus in statistics from the University of Arizona. At C-Path, Dr. Kosinski has applied his skills for innovative trial design and statistical modeling-related efforts. He has led the development of tools for innovative trial design methodologies as part of a broad agency agreement at the FDA for model-informed drug development. He has led analyses to support various consortium, including the regulatory endorsement at the EMA of the Integrated Box Scoring System as a secondary endpoint in trials for kidney transplant patients, developing and refining models of Huntington's disease progression and patient dropout, and supervising modeling efforts for polycystic kidney disease. He has most recently become involved in disease staging in Parkinson's disease and continues to employ his modeling and trial design skills for ongoing C-Path and Quantitative Medicine program efforts.

Esther Krofah is the executive vice president of Health for the Milken Institute, leading FasterCures, the Center for Public Health, Feeding Change and the Center for the Future of Aging. She has extensive experience managing efforts to unite diverse stakeholders to solve critical issues and achieve shared goals that improve patients' lives. Most recently, Krofah was the director of public policy at GlaxoSmithKline (GSK), where she led engagement with the US Department of Health and Human Services (HHS) and relevant Executive Branch agencies on broad healthcare policy issues. Before GSK, Krofah was a deputy director of HHS' Office of Health Reform. She also served as program director at the National Governors Association (NGA) healthcare division and worked in consulting at Deloitte Consulting LLP. Krofah received a B.A. from Duke University and a Masters of Public Policy from the Harvard University John F. Kennedy School of Government.

Martin Landray is Chief Executive of Protas (www.protas.co.uk), a non-profit company focused on transforming the ability of clinical trials to address major public health conditions, through the use of smart design, effective use of data and technology, and improved policy and regulation. As Professor of Medicine & Epidemiology at University of Oxford, he has over 20 years' experience of leading large trials of treatments for cardiovascular and kidney disease. He co-leads the RECOVERY trial, the world's largest trial of treatments for COVID-19, which has identified 4 effective treatments for severe COVID-19, including the cheap steroid drug, dexamethasone, which has now saved an estimated 1 million lives worldwide. He is now applying that experience and approach to substantially reduce the costs, improve the quality, and increase the accessibility of clinical trials to meet the needs of those affected by other common, high priority conditions. He was a lead contributor to the G7 100 Days Mission for Pandemic Preparedness. In June 2021, he was knighted for services to public health and science.

Bea Lavery is the Vice President, Portfolio Strategy Lead in Product Development Regulatory at Genentech, a member of the Roche Group. In her current role, Bea oversees Roche's global regulatory development strategies and execution for the pharmaceutical portfolio, across all disease areas and platforms. Bea joined Genentech in 2001 in the immunology research department, and transitioned to oncology regulatory affairs in 2005. Bea has held a number of leadership positions over the years in regulatory affairs, including Global Head of Oncology Regulatory Affairs. Originally from Canada, Bea received her Bachelors and Masters Degrees from the University of Calgary, specializing in Microbiology and Infectious Disease research. Bea is currently based in Basel, Switzerland.

Anastasia Lesogor, works as Executive Director, Senior Global Program Clinical Head in Global Drug Development at Novartis Pharma in Basel, Switzerland. She is responsible for leading the global clinical development team targeting the registration, approval and life cycle management of RNA-based therapeutics in the Cardiovascular and Metabolism therapeutic area. Anastasia has been working at Novartis for more than 15 years and has been involved in development and registration of various assets. ®.Prior to Novartis Anastasia worked at Vifor Pharma in Switzerland where she was responsible for the development of intravenous iron drugs in various indications, including heart failure, chronic kidney disease and iron deficiency anemia. Anastasia has 20+ years of experience in drug development with a proven track record of successfully leading large multinational teams across all functions and stages of global drug development, which has resulted in multiple global regulatory drug approvals, including new molecular entities and label extensions. She is an author of numerous manuscripts and abstracts published in peer-reviewed journals and has presented at major scientific conferences. Prior to move to the industry Anastasia worked as a cardiologist in different medical scientific centers. In addition, she received her post-graduate certificate in Medical Genetics at Harvard Medical School and recipient of several research grants, academic and corporate awards.

Craig H Lipset is Co-Founder and Co-Chair of the Decentralized Trials & Research Alliance, a global non-profit organization dedicated to the adoption of more accessible clinical research participation. He is Adjunct Assistant Professor in Health Informatics at Rutgers University, and an Adjunct Instructor at the University of Rochester Center for Health + Technology. Craig serves on the Board of Directors as Vice President for the Foundation for Sarcoidosis Research, as well as on the Editorial Board for *Therapeutic Innovation & Regulatory Science.* He is an external advisor to EveryCure, IMI Trials at Home, HL7 Project Vulcan and the Duke i-Cubed Innovation Center. As Managing Partner of Clinical Innovation Partners, Craig is an advisor to technology and biopharmaceutical companies, leading universities, and the venture community seeking to develop and implement innovative solutions for clinical research. He serves on the Board of Directors for Circuit Clinical, EmPath Labs, and MedVector. For nearly a decade Craig was the Head of Clinical Innovation at Pfizer, leading digital initiatives, patient engagement and collaborations across all therapeutic areas around the globe.

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Institute for Health Policy at Duke University. Dr. McClellan is a doctor and an economist who has addressed a wide range of strategies and policy reforms to improve health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical innovation. At the center of the nation's efforts to combat the pandemic, Dr. McClellan is the co-author of a roadmap that details the steps needed for a comprehensive COVID-19 response and safe reopening of our country. His current work on responding to the COVID-19 public health emergency spans virus containment and testing strategies; reforming health care toward more resilient models of delivering better, more equitable care; accelerating the development of therapeutics and vaccines, and building a more robust global response to the pandemic. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership.

Amy McKee is the Chief Medical Officer at Parexel International and has over 20 years' experience in drug development, including 11 years at the U.S. Food and Drug Administration. Her expertise in drug development includes clinical trial design for new molecular entities as monotherapy and in combination regimens, line extensions and asset prioritization. She has led and managed complex submissions to FDA, as well as experience in scientific advice and regulatory submissions to the European Medicines Agency and rest-of-world agencies. During her time at the FDA, she held several positions, including Deputy Center Director of the Oncology Center of Excellence, Supervisory Associate Director of the Office of Hematology and Oncology Products and Deputy Office Director of OHOP among others. Dr. McKee developed and implemented the multi-disciplinary reviews for marketing applications (NDAs & BLAs) within oncology and co-authored inter-center and intra-center draft Guidances to Industry on drug development. She received her M.D. from Tulane University School of Medicine and completed pediatrics residency training at Tufts University and the pediatric hematology-oncology fellowship training at Johns Hopkins and the national Cancer Institute.

Martin Mendoza, serves as the director of health equity for the *All of Us* Research Program. In this role, he provides leadership and high-level expertise to improve inclusion and equity in precision medicine and leads the program's efforts to promote health equity. Before joining *All of Us*, Martin led extramural research for minority health in the Office of the Commissioner at the U.S. Food and Drug Administration (FDA). He is a recognized expert in clinical trial diversity and has testified on it before Congress. He is also the primary author of the pivotal FDA guidance recommending that clinical trial sponsors be required to submit a diversity and inclusion plan to FDA. Martin's original idea and recommendation became federal law in December 2022. Martin has also served as director of the Division of Policy and Data in the Office of Minority Health in the Office of the Secretary at the U.S. Department of Health and Human Services, as well as in the Division of Clinical Research at the National Institute of Neurological Disorders and Stroke. He conducted his primary research training in the National Cancer Institute's Pediatric Oncology Branch and helped to map chromosome 7 as part of the Human Genome Project during his tenure at the National Human Genome Research Institute. Martin is a graduate of the University of Maryland, Baltimore County, and received his Ph.D. in cancer biology from Johns Hopkins University.

Neal J. Meropol, is a medical oncologist, clinical investigator, outcomes researcher and health tech executive, currently serving as Vice President of Research Oncology at Flatiron Health. In this role, he oversees the clinical teams supporting retrospective and prospective evidence generation, providing scientific and clinical leadership in leveraging Flatiron's EHR-based technology platforms to streamline drug development and inform patient care. Dr. Meropol is currently the co-chair of the NCI Streamlining Clinical Trials Working Group. He previously served as chair of the NCI Clinical Trials and Translational Research

Advisory Committee (CTAC), chair of the National Cancer Institute Gastrointestinal Cancer Steering Committee, and completed a four-year term as an elected member of the American Society of Clinical Oncology (ASCO) Board of Directors. A committed educator, Dr. Meropol was chair of the AACR/ASCO Methods in Cancer Clinical Research Vail Workshop, and ASCO Leadership Development Program. He has authored more than 300 manuscripts, book chapters, and editorials related to cancer prevention, treatment, decision making and health economics.

Robert Metcalf, is currently the Group Vice President of the CDDA, China & Japan Medical, a component of Lilly Research Laboratories and Medical Affairs. In this role, Robert has responsibility for worldwide delivery of clinical research across all therapeutic areas and phases of clinical development as well as Medical Affairs in both China and Japan. After completing his Ph.D. in Pharmacology and Toxicology at Queen's University in Canada, Robert joined Eli Lilly Canada in the Regulatory Affairs organization where he led successful approval efforts, for neuroscience and anti-infective new chemical entities. Robert has held a number of leadership roles in Regulatory Affairs, Project Management, Quality, and Health Outcomes in Canada, the US, and Japan. In 2005, Robert was named Executive Director, Global Patient Safety, and in 2009 was named Vice President, Global Ethics and Compliance where he had responsibility for providing Ethics and Compliance leadership to functional and geographic areas across Eli Lilly. Robert returned to Lilly Research Laboratories as Vice President Global Regulatory Affairs-North America, with responsibility for leading Lilly's interactions with the FDA, including submissions, review, and approvals, as well as representing industry in engagement with the FDA on key policy topics, including negotiation of user fee agreements (specifically PDUFA VI). In 2017, Robert assumed responsibility for Global Clinical Development. In 2020, Robert was promoted to his current position as Group Vice President, CDDA, China & Japan Medical.

Marilyn Metcalf is the Global Vaccines Lead for Patient Engagement at GSK. She and her team partner with patients, caregivers, and other collaborators to make GSK's vaccine clinical trials more participant-friendly and the portfolio of prophylactic and therapeutic vaccines more centered on the needs of vaccines. She also founded GSK's Oncology Patient Council (OPC) to ensure oncology patients' and caregivers' voices were heard by pharma leadership, medicine development stakeholders, and enterprise-wide audiences. As Head of the first dedicated Benefit Risk Evaluation team in pharma, she created GSK's benefit-risk framework to enhance senior leaders' medicine development decisions by including quantification and visualization of the balance across efficacy, effectiveness, and safety. Marilyn was the Head of GSK's International Decision Sciences team and Head of GSK's Pharmacovigilance Centre of Innovation. Previously she was Family Health International's Project Director of the NIH Master Contract for HIV Vaccine Research and led Centocor's Decision Sciences and R&D Portfolio Management team. She co-chaired US Patients as Partners in 2020 and 2021; co-chaired the National Academies of Sciences, Engineering, and Medicine Science of Patient Input Action Collaborative; and is a lead author of CIOMS Working Group XI's Guidance for patient involvement in the development and safe use of medicines. She will be a keynote at Pharmageddon USA 2024.

Al Richmond, is executive director of Community-Campus Partnerships for Health - CCPH, founded in 1998 to promote health equity and social justice through partnerships between communities and

academic institutions. He is a global thought leader advocating for the authentic and strategic engagement of communities in bio- medical research and discovery. For over two-decades he has provided leadership in health equity initiatives, all of which were designed to address the persistent health disparities that are pervasive in the US and globally. His commitment to equity allows him to provide leadership to multiple COVID19 projects, including RADxUP, and Co-PI of the North Carolina CEAL Project. Al also serves as Co-PI of the Community Engagement Alliance Consultative Resource. Al has served as a member of PCORI's Patient Engagement Advisory Panel and as Project Lead with multiple projects funded through the Eugene Washington PCORI Engagement Award Program. He enjoys supporting other professionals and non-profit leaders as a certified professional and business coach.

Sarem Sarem is Co-Chair of the pharmacometrics working group in Health Products and Food Branch and a senior pharmacometrics assessor at the pharmaceutical drugs directorate in Health Canada, where Sarem provides internal consultation and expert review for advanced modeling and simulation studies, including pharmacokinetic and exposure-response models and physically based pharmacokinetic simulations supporting drug claims and clinical trial designs. Sarem is a topic leader in the expert working group for ICH Model Informed Drug Development MIDD Guidance. Sarem has Ph.D in pharmacometrics from the University of Montreal and work expertise as a pharmacist and in the pharmaceutical industry.

Richard Schilsky is Professor emeritus at the University of Chicago having retired in 2021 from his position of Executive Vice President and Chief Medical Officer (CMO) of ASCO. Dr. Schilsky is also a Past President of ASCO, having served in the role during 2008-2009, and former Board member of Conquer Cancer, the ASCO Foundation. Before joining ASCO staff in 2013, Dr. Schilsky spent the majority of his career at the University of Chicago where he joined the faculty in 1984. Over the next nearly 30 years, Dr. Schilsky served in many leadership roles including as Director of the University of Chicago Cancer Research Center, Associate Dean for Clinical Research in the Biological Sciences Division and as the Chief the Section of Hematology/Oncology in the Department of Medicine. He is a highly respected leader in the field of clinical oncology and specializes in new drug development and treatment of gastrointestinal cancers. From 1995 to 2010, Dr. Schilsky served as chair of the Cancer and Leukemia Group B, a national cooperative clinical research group funded by the National Cancer Institute (NCI), now part of the Alliance for Clinical Trials in Oncology. He has extensive experience working with both the NCI and the Food and Drug Administration (FDA) having served as a member and chair of the NCI Board of Scientific Advisors, as a member of the NCI Clinical and Translational Research Committee, and as a member and chair of the Oncologic Drugs Advisory Committee of the FDA. Presently, he serves as chair of the Board of the Reagan-Udall Foundation for the FDA, and as a member of the Board of Directors of Friends of Cancer Research and of the European Organization for Research and Treatment of Cancer (EORTC). Dr. Schilsky has served on the editorial boards of many cancer journals, including the Journal of Clinical Oncology. He presently serves on the

editorial board of the New England Journal of Medicine. Dr. Schilsky is the author of more than 450 original research articles, reviews and commentaries.

Peter Stein, is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters. A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience. Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.

Pamela Tenaerts is Chief Scientific Officer at Medable, Inc. Dr. Tenaerts leads efforts at Medable to drive responsible adoption of decentralized research methodologies with evidence-based metrics and best practices. Dr. Tenaerts joins Medable from Duke University, where she led the Clinical Trials Transformation Initiative's (Public Private Partnership co-founded by Duke University and the Food and Drug Administration) efforts to develop and drive adoption of practices that increase the quality and efficiency of clinical trials. She is a member of the Drug Forum at the National Academies of Science, a Dime Founding Members Council member and a Board Member of the MedStar Research Institute. Tenaerts is one of the leading advocates for innovation in clinical trials, with an emphasis on patient engagement, responsible evidence generation and clinical trial methodology improvements. With more than 30 years' experience in the conduct of clinical trials across a number of stakeholders, she practiced medicine in both the emergency department and as a family practitioner in the private practice setting before embarking on a career in research. She received her MD from Catholic University of Leuven, Belgium, and a MBA from the University of South Florida. She speaks multiple languages.

Andrew Thomson is a statistician with 17 years' experience in the regulatory system. He is currently at the EMA, in the Taskforce dedicated to Data, Analytics and Methodology. Here he provides methodological support across all therapeutic areas and stages of clinical development. He is the main scientific secretariat for EMA's Methodology Working Party, the principle body for developing methodological guidance in the European medicines regulatory network. Globally, he is the regulatory chair for the development of Annex 2 of ICH E6, which focuses on Real World Evidence, and trials with decentralised and pragmatic elements. He is also the Regulatory Chair for ICH E11A on paediatric extrapolation and also led the E11A statistics subgroup. In the area of extrapolation, he was heavily involved in the development of the EMA's draft reflection paper on extrapolation of efficacy and safety in paediatric medicine development. Prior to joining the EMA in 2014, he spent 7 years at the UK Regulator, the MHRA, initially as a Statistical Assessor in the Licensing Division, and subsequently Head of Epidemiology in the Vigilance & Risk Management of Medicines Division.

Jennifer Urwongse is a Director of Decentralized Clinical Trial (DCT) Strategy and Innovation at the PPD clinical research business of Thermo Fisher Scientific. Jennifer has been a DCT subject matter expert (SME) since 2015, advising sponsors on how to leverage decentralized solutions that minimize patient and site burden while supporting inclusive representation amongst diverse communities for global clinical trials. She provides patient-centric DCT strategies that help accelerate patient recruitment and increase patient engagement and retention. Jennifer also engages with DCT providers to assess innovative solutions / capabilities for partnership opportunities that overcome barriers to clinical trial participation and create more inclusive clinical trials. Recent speaking engagements include serving as a panelist for a global Xtalks webinar presenting on "Clinical Trial Diversity: Harnessing the Power of Technology for More Inclusive Studies" and speaking at the World Orphan Drug Congress USA 2023 presenting on "A Wholistic Approach to Patient-Centered Rare Disease Clinical Trials." Jennifer Urwongse obtained her BA in Economics from the University of Virginia and her MBA at the Massachusetts Institute of Technology Sloan School of Management

Cynthia Verst is president, Design and Delivery Innovation, Research & Development Solutions at IQVIA and has nearly 30 years of end-to-end clinical development experience across the healthcare ecosystem (e.g. provider, pharma, payer, and across three CROs). In this role Dr. Verst is responsible for driving innovation and transformation throughout the trial lifecycle. Having previously served as president of both clinical operations and real world and late phase research for IQVIA, Dr. Verst brings a holistic and comprehensive view of clinical research, and champions the advanced use of real-world data, analytics and technology to advance therapies for

patients. Recognized by *FierceBiotech* as a top woman in biotech, and as a *PharmaVoice* Top 100 leader, she currently sits on the Board of Directors for ACRO and is currently the Immediate Past Chair of the DIA Board of Directors. Prior to joining IQVIA (then Quintiles), she served as senior vice president, Global Late Phase Research for OptumInsight (a division of UnitedHealth Group), where she and her team successfully established and grew a new global Late Phase Research Business Unit. Dr. Verst began her career in biopharma at Procter & Gamble Pharmaceuticals as section head in its North American Medical and Technical Affairs group, successfully leading the Phase IIIB/IV research requirements of marketed products. Dr. Verst holds a doctorate and bachelor's degree in Pharmacy from the University of Cincinnati, a master's degree in Structural and Cellular Biology from the University of Illinois, and bachelor's degrees in Biology and Chemistry from Northern Kentucky University.

Janet Woodcock recently completed a long career at FDA. She served as Director of the Center for Drug Evaluation and Research for over twenty years in several stretches. Most recently she served as Principal Deputy Commissioner and prior to that as Acting FDA Commissioner. She held multiple other senior positions at FDA including at the Center for Biologics Evaluation and Research. She was the therapeutics lead for "Operation Warp Speed" during the COVID pandemic. Her most recent effort was spearheading a major reorganization of FDA's foods program and the Office of Regulatory Affairs. This proposal is currently under review. Dr. Woodcock completed many major regulatory initiatives during her FDA tenure.

John Zhong is the Rapporteur of ICH E20 Expert Working Group. He represents PhRMA leading the working group to develop the ICH E20 Guideline on Adaptive Clinical Trials, a global harmonized regulatory guideline on adaptive designs. He previously participated on the FDA expert panel for public meeting on "Promoting the Use of Complex Innovative Designs in Clinical Trials". He also served as a representative of industry organizations in meetings with health authority to advance the use of innovative clinical trial designs for drug development. Dr. Zhong has more than 20 years of industry experience providing leadership and strategy for clinical development across numerous therapeutic areas with different treatment modalities in all phases of drug development. He played a critical leadership role in drug development programs using innovative clinical trial approaches that resulted in new treatments for patients with unmet needs. Dr. Zhong currently is the Vice President of Biometrics at REGENXBIO and previously held leadership positions in biostatistics and innovative analytics at Biogen, Human Genome Sciences, and some industry innovation working groups. He has authored or co-authored more than 50 articles in peer-reviewed medical and statistical journals.

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