Forum on Drug Discovery, Development, and Translation

Committee

Klaus Romero

Co-Chair

Klaus Romero, M.D., M.S., FCP, is a prominent clinician scientist and scholar, who serves as both the Chief Executive Officer and Chief Science Officer at Critical Path Institute. As a recognized thought-leader, Dr. Romero established C-Path's Quantitative Medicine Program and has been an instrumental leader in the growth of the organization's portfolio of transformative consortia and public-private-partnerships across more than 16 therapeutic development areas. As both a scientist and an executive, Dr. Romero led the generation of actionable drug development tools in Alzheimer's disease, which introduced a transformation in the drug development process for this indication. In tuberculosis, Romero's leadership was instrumental in generating a drug development infrastructure that allowed the approval of the first new individual drug and the first new regimen for this disease, in more than 50 years. Dr. Romero's leadership has also resulted in the transformation of therapeutic development paradigms for many other diverse areas, like polycystic kidney, Parkinson's and Huntington's diseases, as well as type 1 diabetes prevention, kidney transplantation, Duchenne muscular dystrophy, and several other rare and orphan indications. As a trained clinical pharmacologist and epidemiologist, Dr. Romero is a fellow of the American College of Clinical Pharmacology, a founding member of the International Society of Pharmacometrics, as well as a member of the American Society for Clinical Pharmacology and Therapeutics, and the International Society of Pharmacoepidemiology. He is also an Associate Research Professor at the University of Arizona, as well as an Adjunct Professor at the University of Southern California and Arizona State University.

Ann E. Taylor

Co-Chair

Ann Taylor, M.D., is a retired Chief Medical Officer at AstraZeneca. In this role, she was responsible for AstraZeneca's global Patient Safety, Quality Assurance, and Regulatory Policy organizations, and the overall Benefit Risk assessment of our medicines. She is passionate about bringing the patient voice to everything we do. Prior to joining AstraZeneca in 2018, Dr. Taylor was Vice President and Global Head of the Program Office for the Novartis Institutes for BioMedical Research (NIBR). She also previously served as Global Head, Translational Medicine at NIBR, after having positions of increasing responsibility at Pfizer Global Research and Development. Dr. Taylor received her M.D. from Harvard Medical School, after receiving her B.A. in Biology magna cum laude from the University of California, San Diego. She completed her internship and residency in Internal Medicine, and her fellowship in Endocrinology and Metabolism at Massachusetts General Hospital, before joining the faculty there. Her research in the Reproductive Endocrine Unit at MGH focused on clinical neuroendocrinology of female reproductive disorders. At MGH, she also led a clinical research training program for students and residents. She has published over 45 journal articles. Dr. Taylor is passionate about excellence in clinical investigation, diversity in science, and leadership development.

Richardae Araojo

Member

Richardae "Chardae" Araojo, Pharm.D., M.S., is the President and Founder of Araojo Advisory Group, LLC, where she provides regulatory consulting and strategic advisory services. Dr. Araojo previously served more than 20 years at the U.S. Food and Drug Administration (FDA) and with the U.S. Public Health Service (USPHS). During that time, she held a variety of positions at the FDA including Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity in the Office of the Commissioner, and Director of the Office of Medical Policy Initiatives in the Center for Drug Evaluation and Research. While at the FDA, she led a variety of broad-based medical and clinical policy initiatives to improve the science and efficiency of clinical trials and provided leadership and direction on health disparity and health equity matters for the Agency. She also fostered collaborations and partnerships with federal agencies, academic institutions, industry, and patient and community organizations. Dr. Araojo retired from the USPHS in 2024 as a Rear Admiral (RDML) and Assistant Surgeon General. She received her Doctor of Pharmacy Degree from Virginia Commonwealth University and Master's Degree in Pharmacy Regulation and Policy from the University of Florida.

Ronald Bartek

Member

Ronald A. Bartek is co-founder and president of the Friedreich's Ataxia Research Alliance. He has served on the boards of the National Organization for Rare Disorders, the Alliance for Regenerative Medicine and the Alliance for a Stronger FDA, and is co-founder of the National Center for Advancing Translational Science (NCATS) Alliance and the Pediatric Inclusion Alliance. He has advised multiple government agencies in the capacity of the lived experience of people and families with rare and orphan diseases. Earlier in his career, he spent two decades in U.S. federal service, including roles in the U.S. Army, at the CIA, State Department and House Armed Services Committee.

Barbara E. Bierer

Member

Barbara E. Bierer, M.D., a hematologist-oncologist, is Professor of medicine at Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH). Dr. Bierer is the Faculty Director of the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center), a collaborative effort to improve standards for the planning and conduct of international clinical trials. She is also the Director and PI of SMART IRB and Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst. She serves as Faculty in the Center for Bioethics, HMS, and Affiliate Faculty in the Petrie-Flom Center for Health Law at Harvard Law School. She is a co- of the non-profit Vivli, a global clinical research data sharing platform. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research, BWH where she founded the Brigham Research Institute and the Brigham Innovation Hub. She was a member of the NASEM Committee on Science, Technology and Law. She is a past chair of SACHRP and has served or serves on the Board of Directors of AAHRPP, PRIM&R, MSH, Vivli, North Star Review Board, Clinithink, the Edward P. Evans Foundation, and Generation Patient. She has authored over 320 publications. Dr. Bierer received her BS from Yale University and MD from HMS.

Sneha Dave

Member

Sneha Dave, BA is the founder and executive director at Generation Patient, an organization representing over 25 million young adults in the U.S. and abroad with chronic conditions. Generation Patient drives meaningful change for young adults with chronic conditions, providing over 650 peer support meetings and conducting research in peer support intervention models. On a systemic level, Generation Patient leads research and policy reform, focusing on the patent system, disaggregating age data in clinical trials, and increasing oversight of pharmaceutical advertisements on social media. Sneha has spoken at venues such as Davos at the World Economic Forum, Capitol Hill, Aspen Ideas, and is a past contributor for U.S. News and World Report. She also serves on the patient editorial panel for the British Medical Journal, on a grantmaking committee with the Robert Wood Johnson Foundation, and as part of the Yale Collaboration Regulatory Rigor, Integrity, and Transparency advisory board. For her work, the We Are Family Foundation selected her as one of the most influential teenagers worldwide in 2018, and she was recognized as an American Association of People with Disabilities Emerging Leader in 2020. Sneha is proud to work with a staff team comprised entirely of young adults with chronic conditions.

Steven K. Galson

Member

Steven K. Galson, M.D, M.P.H., is on the Board of Directors of Elephas Biosciences and Biocryst Pharmaceuticals. He retired from Amgen in 2021 after almost 12 years in senior roles in Research & Development including senior vice president, Global Regulatory Affairs and Safety. Prior to this, Galson was senior vice president for Civilian Health Operations and chief health scientist at Science Applications International Corporation. Galson spent more than 20 years in government service, including two years as acting Surgeon General of the United States. Previously, he served as director of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), where he provided leadership for the center's broad national and international programs in pharmaceutical regulation. Galson began his Public Health Service (PHS) career as an epidemiological investigator at the Centers for Disease Control and Prevention (CDC) after completing a residency in internal medicine at the Hospitals of the Medical College of Pennsylvania. He was subsequently the Chief Medical Officer at the Environmental Protection Agency (EPA) and the US Department of Energy. Galson holds a B.S. from Stony Brook University, an M.D. from Mt. Sinai School of Medicine, and an M.P.H. from the Harvard School of Public Health. In 2008, Galson received an Honorary Doctor of Public Service Degree from Drexel University School of Public Health, and in 2015, he received the Jacobi Medallion Award from Icahn Mount Sinai School of Medicine. In 2018 Galson was named the Health Leader of the Year from the Commissioned Officers Association of the United States Public Health Service. Galson was previously the co-chair of the National Academies Drug Forum and is currently a member of Board on Health Sciences Policy at the National Academies.

Morgan Hanger

Member

Morgan Hanger, M.P.P., is the Executive Director of the Clinical Trials Transformational Initiative (CTTI), a public-private partnership founded between Duke University and the U.S. Food and Drug Administration to improve the quality and efficiency of clinical trials. She oversees the development of new recommendations and tools to solve complex problems related to evidence generation. Prior to CTTI, Hanger worked at health technology companies focused on patients, including as vice president of the online patient research network PatientsLikeMe, pioneering partnerships to use patient-generated health data in life sciences and regulatory settings. Hanger has also worked in health economics and outcomes research, both at Avalere Health, where she collaborated with pharma and biotech, and within the Health Outcomes Group at Memorial Sloan Kettering Cancer Center. 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.

Tesheia Harris

Member

Tesheia Harris, M.B.A., M.H.S., is the founder, a Board of Directors member and the Chief Executive Officer for the Clinical Trials Access Collaborative (CTAC), an organization focus on expanding access to clinical trial innovation. Ms. Harris has more than two decades of visionary leadership, including developing, leading, and building successful programs at multiple Universities. Most recently she served as the Director of Clinical Research at the Yale School of Medicine, where she was instrumental in the development of the Yale Center for Clinical Investigation, a center specifically formed to catalyze and grow clinical research at Yale. After leaving Yale, Ms. Harris launched the Harris and Howard Consulting Group, a specialty practice focused on clinical research across multiple sectors, including academic medicine, large clinical practices, community hospitals, and private equity. Ms. Harris began her research career in the biotech industry before moving to academia. Ms. Harris's career has focused on the development of clinical research programs and supporting infrastructure. Over her career she has overseen the clinical research operations for thousands of single and multisite trials, including hundreds of national and international trials. Ms. Harris also has a remarkable series of accomplishments as a national leader in clinical research administration and program development, including the co-founding of the Cultural Ambassadors program, helping to shepherd many innovations in the use of technology including the EHR and research management systems, along with leading many national efforts. She served as the leader for the Yale MOU and partnership with the FDA Office of Minority Health and Health Equity and, along with the other Network Partners, developed and led the Equitable Breakthroughs in Medicine Development (EQBMED). Ms. Harris is a member of The National Academy of Sciences, Engineering and Medicine's Forum on Drug Discovery, Development, and Translation and serves as a member of the external scientific advisory boards for multiple CTSA institutions and the University College of London's Biomedical Research Center's Advisory Board. She was one of the team leaders for the Clinical Trials Transformation Initiative (CTTI) on clinical trials diversity. Most recently, she has co-authored the EQBMED Site Maturity Assessment Model, which is a holistic, collaborative, site-driven, and formative assessment carried out with potential sites to catalogue their current capabilities and identify opportunities for growth in conducting industry-sponsored clinical trials and enriching access of those trials.

Sally L. Hodder

Member

Sally Hodder, M.D., is currently Professor of Medicine, Associate Vice President for Clinical and Translational Research at West Virginia University and Director of the West Virginia Clinical and Translational Science Institute. She received her M.D. degree from Case Western Reserve University School of Medicine and postgraduate training at the University of California at San Francisco and University Hospitals of Cleveland. She currently directs an NIH-funded Center for Translational Research that seeks to build research infrastructure in Appalachia for purposes of improving health outcomes.

Dr. Hodder is a vocal advocate for HIV research to improve outcomes among HIV-infected women as well as for HIV prevention initiatives among US women. Her current focus of research is assessing attitudes and behaviors among rural women who inject drugs for purposes of informing the implementation of HIV prevention programs among rural women. Dr. Hodder has served and continues to serve on numerous national committees including the Advisory Council for the National Institute of Allergy and Infectious Diseases. She has authored many scientific papers and book chapters in the areas of infectious diseases and women’s health.

Patrik Johansson

Member

Patrik Johansson, M.D., M.P.H., is a professor at Washington State University’s (WSU) Elson S. Floyd College of Medicine in the Department of Medical Education and Clinical Sciences. An internal medicine primary care physician by training, his work focuses on promoting the health of rural communities through research, teaching, and service. A past clinician in health professions shortage areas, he employs community-based participatory research methods to address chronic disease disparities in partnership with rural health clinics, critical access hospitals, American Indian-serving health care systems, rural public health departments, and other healthcare organizations. He also develops and implements public health curricula for practitioners and health-professions students while actively engaging them in research, not only to facilitate their learning about research methods but also to promote them to practice in health-professions shortage areas. Dr. Johansson received his M.D. from the University of Nebraska Medical Center College of Medicine and his MPH from the Harvard TH Chan School of Public Health. He has received a number of awards for his service, research, and teaching, including the Harvard Medical School Dean’s Community Service Award, the University of Nebraska Campus Compact “Outstanding Community and Campus Collaboration Award for excellence in community-based teaching and scholarship," and the Excellence in leadership award from the Nebraska Rural Health Association for his service as the association’s secretary from 2013 to 2017.

Julie A. Johnson

Member

Julie A. Johnson, Pharm.D., is the Dr. Samuel T and Lois Felts Mercer Professor of Medicine and Pharmacology at The Ohio State University's Colleges of Medicine and Pharmacy. She is the Director of OSU's Clinical and Translational Science Institute, Associate Dean for Research (Medicine) and Associate Vice President for Research at OSU. She previously served as Distinguished Professor and Dean at the University of Florida College of Pharmacy and during her tenure the college saw tremendous growth in its faculty size and research productivity – rising to 3rd in the nation among pharmacy colleges. Dr. Johnson is an internationally recognized leader in clinical pharmacology, pharmacogenomics and genomic medicine research for which she was recognized four times as a Clarivate Analytics Highly Cited Researcher. She has received numerous awards and honors, including election to the National Academy of Medicine and elected fellow of the American Association for the Advancement of Science, and three other societies. She has received the top research awards from numerous organizations and was a member of an FDA Advisory Committee, among many other service roles with federal agencies and scientific organizations. She earned her PharmD degree from the University of Texas and completed postdoctoral training at Ohio State.

Peter Lee

Member

Peter Lee, J.D. holds the position of Martin Luther King Jr. Professor of Law at UC Davis School of Law, where he also serves as Director of the Center for Innovation, Law, and Society. He teaches and writes in the field of innovation law and policy. Among other topics, his scholarship has explored patenting in biomedical science, university-industry technology transfer, and the structure of innovative industries. He is an elected member of the American Law Institute, and he has received numerous awards for his scholarly work, including the UC Davis Chancellor’s Fellowship, the Samsung-Stanford Patent Prize, and inclusion in West/Thomson’s annual Intellectual Property Law Review. Professor Lee received his undergraduate degree in History and Science from Harvard University, and he received his J.D. from Yale Law School. He joined the UC Davis faculty after clerking for Judge Barry G. Silverman of the Ninth Circuit Court of Appeals.

Anna S. Lok

Member

Anna Suk-Fong Lok, M.D., is the Professor of Internal Medicine and Assistant Dean for Clinical Research at the University of Michigan. Dr. Lok is a clinical and translational researcher in viral hepatitis with continuous federal funding since 1993 in addition to industry funding. She was Chair of 2 NIH (NIDDK & NCI) funded clinical research network steering committees (2008-2023). She initiated 2 Clinical Trials Academy at the University of Michigan to provide didactic and experiential training to early career faculty on Trial Design (2018-) and Trial Execution (2024-) and is PI of a CTSA funded randomized trial comparing 2 protocol support strategies aimed to improve quality of investigator-initiated clinical trial protocols. Dr. Lok received an honorary DSc from her alma mater and a Distinguished University Professorship from University of Michigan, and Distinguished Achievement/Service/Mentor Awards from professional societies in the US, Canada, and Europe for her research accomplishments, leadership and service to the hepatology community. She served as the President of the American Association for the Study of Liver Diseases in 2017. Dr. Lok graduated from the University of Hong Kong medical school and completed her hepatology training at the Royal Free Hospital in London.

Martin Mendoza

Member

Martin Mendoza, Ph.D., serves as the Chief Population Health Officer at the Centers for Medicare and Medicaid Services (CMS) and Director of the CMS Office of Minority Health (OMH). In this role, Dr. Mendoza leads OMH in its mission towards the advancement and integration of health equity in the development, evaluation, and implementation of CMS’s policies, programs, and partnerships. Prior to CMS, Dr. Mendoza served as the first Director of Health Equity for the National Institutes of Health's (NIH) All of Us Research Program where he provided leadership and high-level expertise to improve inclusion and equity in precision medicine. Before joining All of Us, Dr. Mendoza 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 submit a diversity action plan to FDA. Dr. Mendoza’s original idea and recommendation became federal public law in December 2022. Dr. Mendoza has also served as director of the Division of Policy and Data in the Office of Minority Health in the U.S. Department of Health and Human Services Office of the Secretary, as well as in multiple NIH Institutes including the National Institute of Neurological Disorders and Stroke, the National Cancer Institute, and the National Human Genome Research Institute where he assisted in the genetic mapping of the Human Genome Project. Dr. Mendoza is a graduate of the University of Maryland, Baltimore County, and received his Ph.D. in cancer biology from Johns Hopkins University.

Mark N. Namchuk

Member

Mark Namchuk is the Puja and Samir Kaul Professor of the Practice of Biomedical Innovation and Translation at Harvard Medical School. He Joined HMS is 2020 as the Executive Director of the school’s Therapeutics initiative and was appointed a Professor of the Practice in the Department of Biological Chemistry and Molecular Pharmacology in 2021. The therapeutics initiative accelerates the progression of breakthrough biological insight towards a medicine and includes a scientific core to support drug discovery and an on-campus biotech incubator. The initiative houses several educational programs including the therapeutics graduate program for PhD students and a Masters in therapeutic sciences. Namchuk joined HMS after a 24-year career in biotech. From 2015-2020 he was the SVP of research and nonclinical and pharmaceutical development at Alkermes. Previously, he spent 17 years Vertex, the last 4 years as an SVP of Research. During his time in biotech he played a key scientific or leadership role in R&D efforts across numerous areas including oncology, infectious disease, immunology, CNS disorders and orphan diseases. Namchuk obtained a B.Sc. in chemistry from the University of Alberta, a PhD in bio-organic chemistry from the University of British Columbia and was an HFSP post-doctoral fellow at UCSF.

Anaeze C. Offodile, II

Member

Anaeze C. Offodile II, M.D., M.P.H, is a double board-certified physician with clinical expertise in oncologic reconstruction, a health services researcher with a focus on alternative payment models and care redesign, and a healthcare administrator with management experience in academia. He leads strategy efforts and care transformation initiatives at MSK by continuing to develop the core infrastructure, management systems, and processes for enterprise strategy and business development. He pilots new initiatives, facilitates alignment on strategic institutional priorities, leverages data sources to cultivate innovative digital analytics and products, develops collaborations with outside groups, and partners with key internal leaders to competitively position MSK for the future.

Howard B. Rosen

Member

Howard B. Rosen, is Adjunct Professor, Chemical Engineering at Stanford and Lecturer in Management at Stanford Graduate School of Business (GSB) where he designs and teaches courses on entrepreneurship in engineering and science-based industries and in developing economies. He has broad experience including serving on boards of directors, senior-level general management positions, functional roles in strategy, marketing, finance, business development, and R&D. Mr. Rosen has experience in anti-infectives, oncology, pain, cardiovascular, respiratory, CNS diseases, urology, ophthalmology and metabolic diseases. Technically, he is an expert in the design, development and commercialization of drug delivery systems. Between 1996 and 2008, Mr. Rosen served as Vice President, Commercial Strategy at Gilead Sciences, Inc., and prior to Gilead as Vice President, Strategy, Vice President, Product Development, and President at ALZA Corporation, (starting in 2001 a part of Johnson & Johnson). Mr. Rosen is a member of the NAE and AIMBE. He was the Henry Ford II Scholar (first-in-class) and Arjay Miller Scholar at Stanford GSB and was elected to Sigma Xi and Tau Beta Pi Honor Societies. At ALZA, he received the Gerstel Award for Excellence and the TOPS Award. He received a B.S. in chemical engineering with distinction from Stanford in 1980, an S.M. in chemical engineering from the Massachusetts Institute of Technology in 1982, and an MBA from Stanford in 1987. Mr. Rosen was a moderator for the NASEM Chronic Disease Workshop held in February 2021 and has reviewed multiple NASEM reports related to biotechnology. He is currently NAE Home Secretary.

Joseph C. Wu

Member

Joseph Wu, Ph.D., M.D., is Director of Stanford Cardiovascular Institute and Simon H. Stertzer, MD, Professor of Medicine and Radiology at Stanford University. Dr. Wu received his MD from Yale University and PhD (Molecular & Medical Pharmacology) at University of California, Los Angeles. He is board certified in cardiovascular medicine. His lab works on cardiovascular genomics and induced pluripotent stem cells (iPSCs). The main goals are to (i) understand basic disease mechanisms, (ii) implement precision medicine for patients, and (iii) accelerate drug discovery via “clinical trial in a dish” concept. Dr. Wu has published >600 manuscripts with H-index of 140 on Google scholar. He is listed as top 0.1% of highly cited researchers by Web of Science for past 6 years (2018-2023). Dr. Wu has received several awards, including the NIH Director’s New Innovator Award, NIH Roadmap Transformative Award, Presidential Early Career Award for Scientists and Engineers (PECASE) given out by President Obama at the White House, American Heart Association (AHA) Distinguished Scientist Award, AHA Merit Award, and Burroughs Wellcome Foundation Innovation in Regulatory Science Award. Dr. Wu serves on the FDA Cellular, Tissue, and Gene Therapies Advisory Committee. He is on the Board of the Keystone Symposia and American Heart Association. He is the immediate past President of the American Heart Association (2023-2024). Dr. Wu is an elected member of American Society for Clinical Investigation (ASCI), Association of University Cardiologists (AUC), American Institute for Medical and Biological Engineering (AIMBE), American Association of Physicians (AAP), Academia Sinica (Taiwan), American Association for the Advancement of Science (AAAS), Asian American Academy of Science and Engineering (AAASE), National Academy of Inventors (NAI), and National Academy of Medicine (NAM).

Stacey J. Adam

Ex Officio Member

Linda S. Brady

Ex Officio Member

Linda Brady, Ph.D., serves as the Director of the Division of Neuroscience and Basic Behavioral Science at the National Institute of Mental Health (NIMH). In this role, she provides scientific, programmatic, and administrative leadership for an extramural research program portfolio in basic neuroscience to support NIMH's mission of transforming the understanding and treatment of mental illnesses. Dr. Brady has directed programs in neuropharmacology, drug discovery, and clinical therapeutics and organized Consortia focused on ways to accelerate the development and clinical application of radiotracers in clinical research. She has provided leadership for the National Cooperative Drug/Device Discovery/Development Groups for the Treatment of Mental Disorders and First in Human and Early-Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders initiatives. Dr. Brady serves as co-chair of the Neuroscience Steering Committee of the Biomarkers Consortium, a public-private research partnership of the Foundation for the National Institutes of Health (FNIH) that focuses on discovery, development, and qualification of biological markers to support drug development, preventive medicine, and medical diagnostics. She serves as co-chair of the Steering Committee for the Accelerating Medicines Partnership® Schizophrenia (AMP® SCZ), a public-private partnership to generate tools to improve success in developing early-stage interventions for patients who are at risk of developing schizophrenia. She is a member of the National Academies Forum on Neuroscience and Nervous System Disorders. Dr. Brady was trained in pharmacology and neuroscience. She completed her Ph.D. at Emory University School of Medicine, followed by post-doctoral work and research positions at the Uniformed Services University of the Health Sciences and the NIMH Intramural Research Program. She is the author of more than 70 peer reviewed scientific publications and is a member of the Society for Neuroscience and a Fellow and Past President of the American College of Neuropsychopharmacology. Dr. Brady has received NIH Director's Awards in recognition of her activities in biomarker development, public-private partnerships, drug development for mental disorders, collaboration and leadership of AMP® SCZ, and a National Alliance on Mental Illness Distinguished Service Award.

Cherié Butts

Ex Officio Member

Lynda Chin

Ex Officio Member

Lynda Chin, M.D. is a physician, scientist, and entrepreneur, currently serving as CEO of Apricity Health, a company she founded to harness dynamic patient data to enhance care and accelerate precision drug discovery. Previously, she was the Chief Innovation Officer for Health at the UT System and the founding Chair of Department of Genomic Medicine at MD Anderson Cancer Center, following a distinguished research career at Dana-Farber/Harvard and the Broad Institute.

Dr. Chin has a proven track record of building innovative models that bridge research and patient care, integrating science, technology, and data to accelerate therapeutic development. She pioneered the Applied Cancer Science model, bringing industry-seasoned drug developers into academia, first at Dana-Farber and later at MD Anderson, to create innovative partnerships with biopharma in drug discovery. This work laid the foundation for Apricity Health's platform that connects care delivery and drug discovery verticals to unlock the value of dynamic data from every patient in precision drug discovery.

An elected member of the National Academy of Medicine, Dr. Chin has received numerous honors for her contributions to precision medicine. She earned her M.D. from Albert Einstein College of Medicine, with clinical training at Columbia Presbyterian and Montefiore Medical Centers.

Luther T. Clark

Ex Officio Member

Luther Clark, M.D., is Deputy Chief Patient Officer and Global Director, Scientific Medical and Patient Perspective in the Office of the Chief Patient Officer at Merck. In this role, he is responsible for (1) gathering internal and external scientific and medical information to assist with decision-making at the highest levels; (2) collaborating across Merck to increase the voice of patients, directly and indirectly in decision-making; (3) collaborating with key internal and external stakeholders in development of a systematized approach for collecting and incorporating patient insights across the patient journey and product lifecycle; and (4) representing Merck externally, expanding bi-directional exchange with key patient and professional leaders and organizations. Dr. Clark leads Merck's Patient Insights Team, is co-leader of the team that champions Health Care Equities (including promotion of health literacy and research diversity) and chairs the Patient Engagement, Health Literacy & Clinical Trials Diversity Investigator Initiated Studies Research Committee. Prior to joining Merck, Dr. Clark was Chief of the Division of Cardiovascular Medicine at the State University of New York Downstate Medical Center (SUNY Downstate) and founding Director of the NIH-funded Brooklyn Health Disparities Research Center. Dr. Clark earned his Bachelor of Arts degree from Harvard College and his Medical degree from Harvard Medical School. He is a Fellow of the American College of Cardiology and the American College of Physicians, and a past member of the Board of Directors of the Founders Affiliate of the American Heart Association. He is a nationally and internationally recognized leader in cardiovascular education, clinical investigation, cardiovascular disease prevention, and health equity. He has authored more than 100 publications and edited and was principal contributor to the textbook Cardiovascular Disease and Diabetes (McGraw-Hill). Dr. Clark has received numerous awards and honors, including the Harvard University Alumni Lifetime Achievement Award for Excellence in Medicine. He is the current President of the Health Science Center at Brooklyn Foundation, SUNY Downstate Medical Center.

Tammy R.L. Collins

Ex Officio Member

Tammy Collins, PH.D., joined the Burroughs Wellcome Fund (BWF) in 2022, where she serves as a Program Officer directing the Career Awards at the Scientific Interface (CASI) program and the Innovations in Regulatory Science Awards (IRSA). Prior to joining BWF, Dr. Collins served as Training Director at the National Institutes of Health | National Institute of Environmental Health Sciences (NIH | NIEHS) and was Chair-elect of the NIH-wide Training Directors' Committee. She published research on NIEHS postdoctoral scholar outcomes in Nature Biotechnology and led a national effort for the Graduate Career Consortium to review career outcome classification and visualization methodologies in North America, where she received an NIH Director's Award for these collective efforts. She helped develop the NIEHS Scientific Director's Traineeship for Inclusion, Diversity, and Equity (STrIDE) and was a member of the Trainee Subcommittee of the NIH Anti-Racism Steering Committee, part of the overarching NIH UNITE initiative. A first-generation student, Dr. Collins obtained her bachelor's in chemistry from Appalachian State University (ASU), where she became ASU's first Goldwater Scholar, and her Ph.D. in biochemistry from Duke University. After a brief postdoc at Duke, she joined NIEHS as a postdoc in 2009 where she developed her passion for helping foster scientific leaders.

Jeffrey M. Drazen

Ex Officio Member

Jeffrey M. Drazen, M.D., was born in Missouri. He attended Tufts University, with a major in physics, and Harvard Medical School, and served his medical internship at Peter Bent Brigham Hospital in Boston. Thereafter, he joined the Pulmonary Divisions of the Harvard hospitals. He served as Chief of Pulmonary Medicine at the Beth Israel Hospital, Chief of the combined Pulmonary Divisions of the Beth Israel and Brigham and Women's Hospitals, and finally as the Chief of Pulmonary Medicine at Brigham and Women's Hospital. Through his research, he defined the role of novel endogenous chemical agents in asthma. This led to four new licensed pharmaceuticals for asthma with over 5 million people on treatment worldwide. In 2000, he assumed the post of Editor-in-Chief of the New England Journal of Medicine. During his tenure, the Journal has published major papers advancing the science of medicine, including the first descriptions of SARS and papers modifying the treatment of cancer, heart disease and lung disease. The Journal, which has over a million readers every week, has the highest impact factor of any journal publishing original research.

Kenneth Getz

Ex Officio Member

Kenneth Getz, MBA is the Executive Director and a professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine, where he conducts grant-funded research on pharmaceutical R&D management and execution; protocol design optimization; contract service provider and investigative site management; e-clinical technology and data usage; and patient and community engagement. He is also the chairman of CISCRP – a nonprofit internationally-recognized organization that he founded to educate and raise public and patient awareness of the clinical research enterprise – and president of the Otsuka Patient Assistance Foundation. A well-known speaker at conferences, symposia, universities, investor meetings and corporations, Ken has published extensively in peer-review journals, books and in the trade press and writes a bi-monthly column nominated for a Neal Award in Applied Clinical Trials. He holds a number of board appointments in the private and public sectors and serves on the editorial boards of Pharmaceutical Medicine, Life Science Leader and Therapeutic Innovation and Regulatory Science. Ken received an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University. He is the founder of CenterWatch, a leading publisher in the clinical trials industry, and one of several businesses that he has created and sold.

David J. Glass

Ex Officio Member

David J. Glass, MD is a Vice President of Research at Regeneron Pharmaceuticals. He earned his Bachelor of Science in Biochemistry from Columbia University, and his MD from New York Medical College. He then went on to do postdoctoral work in Stephen Goff's lab at Columbia, before joining Regeneron shortly after it was founded. He is a fellow of the AAAS and a member of the American Society for Clinical Investigation, in addition to being a member of the NAS. His group helped to define the key signaling pathways that mediate skeletal muscle hypertrophy – especially the IGF1/Akt/mTORC1 pathway as being one key mechanism, and Akt inhibition of the Foxo transcription factor family as another key mechanism. More recently his group has focused on Aging to understand sarcopenia – the age-related loss of skeletal muscle mass and function. He's also interested in more general mechanisms of Aging which contribute to age-related disorders. Dr. Glass has worked to improve the reproducibility of the published literature. Towards that end, he authored a book titled, "Experimental Design for Biologists," published by Cold Spring Harbor Press. He's also taught a course by the same name for many years at Harvard Medical School, and will be teaching the same course at Columbia University's Vagelos School of Medicine. Dr. Glass is a co-founder of the Elsevier journal Skeletal Muscle.

Penny M. Heaton

Ex Officio Member

Penny Heaton, M.D., is the Chief Medical Officer of Johnson & Johnson, where she leads efforts to address global health challenges, focusing on Medical Safety, Epidemiology, and Bioethics in alignment with the company's Credo. She also heads the Communicable Diseases unit within J&J's Innovative Medicine R&D, advancing the late-stage ExPEC vaccine program, supporting HIV products, and tackling infectious diseases that affect low-income countries. With over 20 years of experience in infectious diseases and vaccine development, Penny previously served as CEO of the Bill & Melinda Gates Medical Research Institute (Gates MRI), leading the development of investigational products for TB, malaria, and other diseases. She also worked as Director of Vaccine Development at the Gates Foundation, addressing diseases like HIV and polio. She began her career at the CDC, working on diarrheal disease surveillance and outbreak investigations, which sparked her passion for infectious diseases. Penny is a graduate of the University of Louisville School of Medicine, board-certified in Pediatrics, and a fellow of the American Academy of Pediatrics.

Lyric A. Jorgenson

Ex Officio Member

Lyric Jorgenson, PhD, is the Associate Director for Science Policy at NIH and the Director of the Office of Science Policy. As an internationally recognized expert in science policy, she is a key member of the NIH senior leadership team and the principal policy advisor to the NIH Director. Dr. Jorgenson specializes in conceptualizing and developing policies and initiatives that drive vital biomedical research forward in a responsible manner. As the NIH's top policy advisor, Dr. Jorgenson scans the research landscape to proactively identify areas where national research policies and programs are needed for NIH to achieve its health mission. Dr. Jorgenson's leadership has been instrumental in creating policies that protect and promote the U.S. bioeconomy, maximizing public access to federally funded research projects, safeguarding research participant protections, and enabling technological innovation to flourish responsibly. Dr. Jorgenson is especially dedicated to ensuring that all voices have an opportunity to meaningfully engage in policy development and implementation. Her philosophy is that evidence-based policy must be responsive to the needs of both the scientific community and the public which funds NIH through its tax dollars. Prior to her appointment as the NIH Associate Director for Science Policy, Dr. Jorgenson held numerous senior leadership roles across the U.S. Government. In 2016, she was selected by then Vice President Joe Biden to serve as the Deputy Executive Director of the Cancer Moonshot. In this role she directed and coordinated cancer-related activities and leveraged investments across sectors to dramatically accelerate progress in defeating cancer. Before joining the Vice President's office, she spearheaded the creation of several world-class research initiatives, including President Obama's BRAIN Initiative and the National Center for Advancing Translational Sciences (NCATS). Dr. Jorgenson has authored numerous articles about NIH policy initiatives in leading peer-reviewed publications including JAMA, Nature Biotechnology, and Neuron. She was also selected to serve as guest editor for the Cancer Journal on a special Cancer Moonshot edition. She is frequently interviewed by media outlets and contacted by Congressional offices to discuss NIH policy positions and has received more than a dozen awards for her service. A Midwest native, Dr. Jorgenson earned a bachelor's degree in psychology from Denison University in Ohio and a PhD from the Graduate Program for Neuroscience at the University of Minnesota-Twin Cities.

Esther Krofah

Ex Officio Member

Esther Krofah, MPP, is the executive vice president of Health at the Milken Institute, leading FasterCures, Public Health, the Future of Aging, and Feeding Change. 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. Prior to 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 BA from Duke University and a master's in public policy from the Harvard University John F. Kennedy School of Government.

Heather Pierce

Ex Officio Member

Heather Pierce, JD, MPH, is Senior Director for Science Policy and Regulatory Counsel at the Association of American Medical Colleges (AAMC) and was the inaugural Director of Policy for the AAMC's Center for Health Justice and served as the AAMC's acting Chief Scientific Officer. Prior to joining AAMC, Ms. Pierce was an attorney in the Health Care Group of the law firm of Ropes & Gray LLP in New York. Pierce is AAMC's leader for science policy issues including human subject protections, clinical research, research data sharing, and interactions between industry, government, and academia in biomedical research. She is the subject matter expert for the AAMC's Forum on Conflict of Interest and for Convey, the AAMC's global financial interest disclosure system. Pierce is Vice Chair of the Board of Directors for the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and was previously the Chair of the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R). She regularly speaks at national forums on issues related to the protection of human subjects, regulatory burden, research security, research ethics, biospecimens, scientific misconduct, and legislation and policymaking related to research, and has published articles and commentaries on these topics in Nature, Science, The New England Journal of Medicine, JAMA, Milbank Quarterly, the Journal of Public Health Management and Practice, and The American Journal of Bioethics. Pierce received her law degree from NYU School of Law and her MPH in Health Law from Boston University School of Public Health.

Joni Rutter

Ex Officio Member

Joni L. Rutter, Ph.D., is the director of the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH). Rutter oversees the planning and execution of the Center's complex, multifaceted programs that aim to overcome scientific and operational barriers impeding the development and delivery of new treatments and other health solutions. Under her direction, NCATS supports innovative tools and strategies to make each step in the translational process more effective and efficient, thus speeding research across a range of diseases, with a particular focus on rare diseases. By advancing the science of translation, NCATS helps turn promising research discoveries into real-world applications that improve people's health. In her previous role as the NCATS deputy director, Rutter collaborated with colleagues from government, academia, industry and nonprofit patient organizations to establish robust interactions with NCATS programs. Prior to joining NCATS, Rutter served as the director of scientific programs within the All of Us Research Program, where she led the scientific programmatic development and implementation efforts to build a national research cohort of at least 1 million U.S. participants to advance precision medicine. During her time at NIH, she also has led the Division of Neuroscience and Behavior at the National Institute on Drug Abuse (NIDA). In this role, she developed and coordinated research on basic and clinical neuroscience, brain and behavioral development, genetics, epigenetics, computational neuroscience, bioinformatics, and drug discovery. Rutter also coordinated the NIDA Genetics Consortium and biospecimen repository. Throughout her career, Rutter has earned a national and international reputation for her diverse and unique expertise via more than 50 publications in journals, and she has received several scientific achievement awards, including a SmithKline Beecham Student Award in Pharmacology, a Janssen Research Foundation Young Investigator Award, and a Fellowship Achievement Award from the National Cancer Institute (NCI). Rutter received her Ph.D. from the Department of Pharmacology and Toxicology, Dartmouth Medical School, Hanover, New Hampshire, and completed a fellowship at NCI within the Division of Cancer Epidemiology and Genetics.

Mark Taisey

Ex Officio Member

Mark Taisey serves as Amgen's senior vice president, Global Regulatory Affairs and Strategy, responsible for the company's interactions with health authorities around the world.

Taisey has worked in Regulatory Affairs for more than 30 years. He joined Amgen in 2014 as vice president, Global Regulatory Affairs. Prior to working at Amgen, he was president, Global Regulatory Affairs, at Eisai, where he had regulatory responsibility for Eisai's pipeline and portfolio of marketed products across all functions and regions.

Taisey worked at Pfizer from 2002-2007, ending his tenure as the executive director and worldwide therapeutic area leader for oncology. In that role, he had global regulatory responsibility for all oncology and infectious disease compounds in development. Earlier in his career, he held multiple regulatory leadership roles of increasing responsibility with Bristol-Myers Squibb, the DuPont Pharmaceutical Company, GD Searle & Company and Sterling Drug.

In addition to his corporate roles, Taisey served as an industry representative for the Biotechnology Innovation Organization (BIO) during the Prescription Drug User Fee Act (PDUFA) V negotiations, and for the Pharmaceutical Research and Manufacturers of America (PhRMA) during the PDUFA VI and VII negotiations. He also served as the chair of the Regulatory Steering Group within PhRMA from 2019-2020. He currently serves as an ad hoc representative to the ICH Management Committee for PhRMA.

Taisey holds a degree in Chemistry from the University of Rochester.

Amir Tamiz

Ex Officio Member

Amir Tamiz, Ph.D., is Associate Director at National Institute of Neurological Disorders and Stroke (NINDS) and the Director of the Division of Translational Research (DTR). The mission of DTR is to accelerate application of basic research findings to patient use for neurological disorders and stroke by providing funding, expertise, and resources to the research community. Dr. Tamiz and his team advance this mission – thru several flagship programs spanning therapeutics and device development, model development and screening, and biomarker discovery and validation. His team is also responsible for administration of Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Dr. Tamiz joined NINDS in 2012 and assumed leadership role for the NIH Blueprint Neurotherapeutics network (BPN) and Innovation Grants to Nurture Initial Translational Efforts (IGNITE) program. Prior to joining NIH, Dr. Tamiz had held scientific and management positions in research and development of therapeutic programs at Corvas International (acquired by Dendreon), CovX (now part of Pfizer), and Alba Therapeutics. Dr. Tamiz received his Ph.D. at University of Oregon and conducted postdoctoral research at the Department of Neuroscience at Georgetown University Medical Center.

Pamela Tenaerts

Ex Officio Member

Pamela Tenaerts, M.D., M.B.A., is the Chief Medical Officer at Medable, Inc. Dr. Tenaerts leads efforts to drive responsible adoption of decentralized research methodologies with evidence-based metrics and best practices. Dr. Tenaerts joined 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, a Board Member of the MedStar Research Institute and a member of the PCORI Clinical Trials Advisory Panel. Tenaerts is one of the leading advocates for innovation in clinical trials, with an emphasis on protocol design and QbD, patient engagement, responsible evidence generation and clinical trial methodology improvements. With more than 30 years' experience in the conduct of clinical trials across several 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 an MBA from the University of South Florida. She speaks multiple languages

Jennie Walgren

Ex Officio Member

Cris Woolston

Ex Officio Member

Cris Woolston, Ph.D., is Head of Science Policy at Sanofi, where he is responsible for formulating and coordinating Sanofi's position on, and response to, public policy issues of strategic and operational significance to biomedical innovation, research and development. At Sanofi, Dr. Woolston has held positions of responsibility encompassing R&D strategy, research portfolio prioritization, information management, business transformation. Dr. Woolston was born in Scotland and obtained his Ph.D. in molecular virology in the UK in 1983. He pursued research into viral gene structure and function in the UK academic sector until joining Sanofi R&D in 2001.