REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Advancing Psychedelic Clinical Study Design

Wednesday, January 31 from 10am to 2pm ET
Thursday, February 1 from 10am to 1pm ET
Virtual Public Meeting

Speaker Biographies

Brian Anderson, MD,
Assistant Professor, Psychiatry
University of California, San Francisco

Dr. Brian Anderson, MD MSc, is a psychiatrist in the Psychiatric Emergency Services at Zuckerberg San Francisco General Hospital, and an Assistant Clinical Professor in the UCSF Department of Psychiatry and Behavioral Sciences. He is affiliated with the UC Berkeley Center for the Science of Psychedelics and UCSF Neuroscape. His research includes clinical trials as well as quantitative and qualitative observational methods to assess the safety, clinical implementation, and regulation of the uses of controlled substances, such as psychedelics.

Robert Barrow, MSc
Chief Executive Officer & Board Director
MindMed

Mr. Robert Barrow is an accomplished pharmaceutical executive and clinical pharmacologist with over a decade of experience leading drug development programs in a variety of disease areas. After joining MindMed as Chief Development Officer in January 2021, he was named CEO in June 2021. Mr. Barrow previously served as Director of Drug Development & Discovery at Usona Institute, where he oversaw preclinical, clinical, and regulatory development efforts for all of Usona's development programs. Prior to joining Usona, Mr. Barrow served as Chief Operating Officer of Olatec Therapeutics, LLC, a private, clinical-stage biopharmaceutical company, where he oversaw the execution of numerous early- and late-stage clinical trials in the fields of analgesics, rheumatology, immunology, and cardiovascular disease. In addition, he has been responsible for the design and execution of preclinical research programs for new molecular entity drugs in CNS conditions such as multiple sclerosis, Alzheimer's Disease and Parkinson's Disease. Mr. Barrow has also served as both a technical and business adviser to numerous pharmaceutical organizations ranging from startups to Fortune 500 companies. Mr. Barrow holds a Master's degree in pharmacology from The Ohio State University and a Bachelor of Science degree from Wake Forest University, where he graduated summa cum laude and is a CFA charterholder.

Michael P. Bogenschutz, MD
Professor, Department of Psychiatry
NYU Langone Center for Psychedelic Medicine

Dr. Michael Bogenschutz is the director of the NYU Langone Center for Psychedelic Medicine, and a Professor of Psychiatry at NYU Grossman School of Medicine. He began conducting clinical research with psychedelics in 2011, and has published expensively on topics related to psychedelics and addiction. Dr. Bogenschutz published the first contemporary pilot study of psilocybin assisted therapy for alcohol use disorder in 2016, and followed it with a large randomized controlled trial published in 2022 on the strength of those findings. Dr. Bogenschutz is now continuing that line of research as the lead investigator of a large multi-site RCT of psilocybin for AUD sponsored by B.More. Dr. Bogenschutz is also the NYU site Pi for MAPS-sponsored phase II and III trials of MDMA-assisted psychotherapy for PTSD, a NIDA sponsored trial of psilocybin assisted therapy for smoking cessation. He is also conducting NIH-funded studies of cannabidiol and topiramate for AUD and PTSD and is developing further clinical and mechanistic studies of psychedelics such as psilocybin and MDMA. Before joining as faculty to NYU in 2015, he was the Principal Investigator of the Southwest Node of the NIDA Clinical Trials Network and a Professor at the University of New Mexico Health Sciences Center, where he was Vice-Chair and Division Director of Addiction Psychiatry, and Vice-Chair for Clinical Research in the Department of Psychiatry.

Matt Butler, MD
Doctoral Clinical Research Fellow
King's College London

Dr. Matt Butler is a specialist registrar in psychiatry and a Wellcome Doctoral Clinical Research Fellow with an interest in neuropsychiatry, psychopharmacology, and non-pharmacological treatment effects. He joined King's College London in 2019 as an Academic Clinical Fellow and has since published widely in peer-reviewed journals. He is currently undertaking a neuroimaging study into the effects of the psychedelic psilocybin in functional neurological disorder. He holds MBChB (Hons) and MRes (Dist) from the University of Manchester and is a member of the Royal College of Psychiatrists. He is the editor of the upcoming edition of *Pocket Prescriber Psychiatry*.

Carla Canuso, MD
Vice President, Neuropsychiatry Clinical Development
Johnson & Johnson Innovative Medicine

Dr. Carla Canuso is Vice President, Head of Neuropsychiatry Clinical Development at Johnson & Johnson Innovative Medicine. In this role she is accountable for the strategic leadership and oversight of all Neuropsychiatry-related clinical programs and clinical development activities from Phase 2 through the end of Phase 3. Since joining Johnson & Johnson in 2002, Dr. Canuso has worked on Phase 2-4 compounds for the treatment of depression, suicidality, schizophrenia, schizoaffective disorder, bipolar disorder, anxiety and epilepsy. She led the first registration programs for the treatment of patients with major depression with active suicidal ideation and intent, and schizoaffective disorder, resulting in the only FDA and EMA approvals for these conditions. She has held positions of increasing responsibility within R&D, Medical

Affairs and Neuroscience External Innovation. Dr. Canuso received a B.S. from the University of Pennsylvania and is a cum laude graduate of the Medical College of Pennsylvania (now Drexel University College of Medicine). She completed her psychiatry training at the University of Chicago and a fellowship in schizophrenia research at the Massachusetts Mental Health Center. She then joined the faculty at Harvard Medical School where she held several positions, including Medical Director of the Commonwealth Research and Evaluation Unit. Since joining the pharmaceutical industry, Dr. Canuso has remained active within the psychiatry research community and served as the President of the International Society for CNS Trials and Methodology from 2018-2020. She is a member of the American Psychiatric Association, the American Society of Clinical Psychopharmacology, and the Society of Biological Psychiatry. She has published approximately 60 manuscripts and book chapters and has served as a peer reviewer for the *American Journal of Psychiatry*, the *Journal of Clinical Psychiatry*, *Neuropsychopharmacology*, and several other journals. Additionally, Dr. Canuso generously volunteers her time for numerous non-profit organizations to strengthen education and prevent suicide.

Patrizia Cavozzoni, MD
Director of the Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Dr. Patriza Cavazzoni, MD is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center's mission is to ensure that safe, effective, and high-quality drugs are available to the public. 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 to February of 2019. Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University 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 as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications. Dr. Cavozzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and is a fellow of the Canadian Royal College of Physician and Surgeons. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship. 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 area, until she joined the FDA.

Richard C. Dart, MD, PhD
Director of the Rocky Mountain Poison & Drug Safety
Denver Health and Hospital Authority

Dr. Richard Dart is Executive Director of Rocky Mountain Poison and Drug Safety and the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System. He is Professor of Emergency Medicine and Medical Toxicology at the University of Colorado Health Sciences Center. He has published more than 350 papers and chapters, as well as served as editor for the book *The 5-Minute Toxicology Consult* and the 3rd edition of *Medical Toxicology*. He is the recipient of several awards, including a Special Citation from the Commissioner of the U.S. Food and Drug Administration, the Matthew J. Ellenhorn Award for Excellence in Medical Toxicology (American College of Medical Toxicology) and the Career Achievement Award (American Academy of Clinical Toxicology). He also serves as a Deputy Editor of the medical journal *Annals of Emergency Medicine* and is past-president of the American Association of Poison Control Centers.

Michael Davis, MD, PhD
Chief Medical Officer
Usona Institute

Dr. Michael (Mike) C. Davis, M.D., Ph.D., is a psychiatrist and pharmacologist serving as a Chief Medical Officer at Usona Institute. Prior to his current position at Usona, Dr. Davis served as a Clinical Team Leader in the Division of Psychiatry in the Office of New Drugs at the FDA, where he led a team of psychiatrists in the clinical review of Investigational New Drug (IND) and New Drug Applications (NDAs) for psychiatric indications and provided advice to commercial and academic sponsors. Dr. Davis completed a Medical Scientist Training Program (MD/PhD) at Case Western Reserve University, psychiatric residency training at the Semel Institute for Neuroscience at Behavior at UCLA, and a clinical research fellowship at the West Los Angeles VA Mental Illness Research, Education, and Clinical Center (MIRECC). After completing his fellowship, Dr. Davis worked as a Staff Psychiatrist at the Michael E. DeBakey VA Medical Center in Houston, TX, and an Assistant Professor at Baylor College of Medicine. Professionally, Dr. Davis is an active member of the American College of Neuropsychopharmacology (ACNP), the International Society for CNS Clinical Trials and Methodology (ISCTM), and the American Society of Clinical Psychopharmacology (ASCP), and he has presented nationally and internationally on topics including regulatory issues in psychedelic drug development, estimands, and digital health technologies.

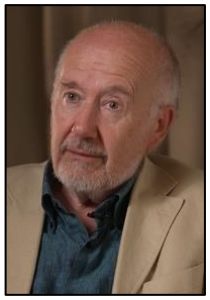
Tiffany Farchione, MD
Director, Division of Psychiatry, Office of Neuroscience, Office of New Drug, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Tiffany Farchione received her medical degree from Wayne State University in Detroit, Michigan, and completed adult residency and child & adolescent fellowship training at the University of Pittsburgh's Western Psychiatric Institute and Clinic. Dr. Farchione is board certified in both general and child & adolescent psychiatry. Prior to joining FDA in 2010, Dr. Farchione was affiliated with the University of Pittsburgh Medical Center and was on the faculty of the University of Pittsburgh. As the Director of the Division of Psychiatry at FDA, Dr. Farchione is involved in the oversight of new drug review for all psychiatric drug development activities conducted under investigational new drug applications, and the review of all new drug applications and supplements for new psychiatric drug claims.

Bernard Fischer, MD
Deputy Director, Division of Psychiatry, Office of Neuroscience, Office of New Drug, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Bernard Fischer is a psychiatrist and the Deputy Director of the Division of Psychiatry in the Office of New Drugs at the U.S. Food and Drug Administration (FDA). Prior to the FDA, he spent more than 10 years in academic medicine researching schizophrenia at the Maryland Psychiatric Research Center (MPRC) and the Department of Veterans Affairs. Dr. Fischer earned his medical degree from the Medical College of Virginia. He completed a 5-year research/clinical residency in psychiatry at the University of Maryland/Sheppard Pratt followed by a post-doctoral fellowship in schizophrenia research at the MPRC. He holds a master's degree in biomedical ethics and has been board certified in both psychiatry and addiction medicine. He has authored or co-authored more than 50 scientific publications.

Guy Goodwin, DPhil
Chief Medical Officer
Compass Pathways



Guy Goodwin, FMedSci is Chief Medical Officer, Compass pathways. He is Emeritus Professor of Psychiatry at the University of Oxford, Oxford, UK. He completed his medical degree and DPhil in neurophysiology at the University of Oxford and, following training in psychiatry, became a Clinical Scientist and Consultant Psychiatrist at the MRC Brain Metabolism Unit at the Royal Edinburgh Hospital, Edinburgh, UK. His research interests have been in the treatment of bipolar disorder and the application of neuroscience in understanding the neurobiology of mood disorders, with a focus on developing new treatments. His current interest is the potential to transform treatment using new technology and new drugs, notably the psychedelics. He is a Fellow of the American College of Neuropsychopharmacology and has previously held the position of President of the British Association for Psychopharmacology and president of the European College of Neuropsychopharmacology (ECNP). He is Emeritus Senior Investigator on the faculty of UK National Institute for Health Research (NIHR).

Ido Hartogsohn, PhD
Assistant Professor at Graduate Program for Science, Technology and Society Studies
Bar-Ilan University

Dr. Ido Hartogsohn, Ph.D. is an assistant professor at the program for Science, Technology and Society at Bar Ilan University. Hartogsohn's research engages the historical, sociological and cultural dimensions of the psychedelic experience with an emphasis on the role of context, or set and setting, in shaping psychedelic experiences for individuals and cultures at large. His book *American Trip: How Set and Setting Shaped the American Psychedelic Experience* explores the role of society and culture in shaping the results of mid-twentieth century American psychedelic research and the reception of psychedelics into American and global culture.

Peter Hendricks, PhD
Professor, Department of Health Behavior
University of Alabama at Birmingham

Dr. Peter S. Hendricks is a Professor in the Department of Health Behavior at the University of Alabama. Hendricks is a psychologist whose expertise lies in substance abuse treatment and prevention. He is currently researching the use of psilocybin to see if it will help individuals addicted to cocaine to stop using as well as the role of psilocybin in the treatment of chronic pain. Hendricks is also a scientific advisor to Eleusis.

Valentina Mantua, MD, PhD
Senior Staff Fellow, Division of Psychiatry, Office of Neuroscience, Office of New Drug, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Valentina Mantua is medical doctor and psychiatrist with a PhD in neurobiology. She has over ten years of working experience in regulatory science. Between 2012 and 2019 she served as Italian delegate to several committees and working parties of the European Medicines Agency (EMA) including the Scientific Advice Working Party, the Central Nervous System Working Party and the European (EU) Innovation Network. Dr. Mantua moved to the US Food and Drug Administration (FDA) in 2019, where she is currently serving as a clinical team leader in the Division of Psychiatry. She holds a temporary professorship at the University of Modena and Reggio Emilia in Italy.

Mason Marks, MD, JD
Visiting Professor of Law
Harvard Law School

Dr. Mason Marks, MD, JD is a Visiting Professor of Law at Harvard Law School and the Florida Bar Health Law Section Professor at Florida State University College of Law. At Harvard Law School's Petrie-Flom Center, Professor Marks is the Senior Fellow and Project Lead of the Project on Psychedelics Law and Regulation (POPLAR). He is also a Visiting Fellow at Yale Law School's Information Society Project. Professor Marks's legal research focuses on health law, drug policy, and the integration of emerging technologies such as artificial intelligence into healthcare. An expert on the fast-emerging psychedelics industry, he frequently provides technical advice to state and federal agencies and lawmakers on the controlled substances landscape. His law and policy research has been published by leading academic journals such as the New England Journal of Medicine, JAMA, Nature Medicine, and the Harvard Law Review Forum. He has published op-eds with the Washington Post, Los Angeles Times, the Guardian, Wired, Slate, and other news outlets. His legal commentary has been featured by the New York Times, Wall Street Journal, Washington Post, the Economist, ABC News, Fox News, Politico, NPR, and others. His book on psychedelic law and politics is under contract with Yale University Press.

Jennifer Mitchell, PhD
Associate Chief of Staff for Research and Development
University of California, San Francisco

Dr. Jennifer Mitchell is a Professor in the UCSF Department of Neurology and Associate Chief of Staff for Research and Development at the San Francisco VA. She holds an affiliate appointment at UC Berkeley, is a member of the Berkeley Center for the Science of Psychedelics (BCSP) and serves the State of California DOJ as a member of the Research Advisory Panel (RAP-C). Her research is focused on identifying and developing novel therapeutics for drug and alcohol abuse, PTSD, stress, anxiety, and depression and on understanding the neural mechanisms responsible for these disorders. Dr. Mitchell has extensive and diverse experience with human and animal pharmacology, hypothesis-driven neuroscience, human proof-of-concept studies, and clinical trials. For the past few years, her work has centered around the development of psychedelic medicines for a broad range of mental health conditions, including PTSD.

Javier Muniz, MD
Associate Director, Division of Psychiatry, Office of Neuroscience, Office of New Drug, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Javier A. Muniz completed his psychiatry residency at Mount Sinai Medical Center in New York City in 2004. During residency, CDR Muniz joined the United States Air Force Reserves, transitioning to Active Duty upon graduation, and was stationed at Andrews AFB, MD. He served in Afghanistan in the years 2004 and 2005. During his six years at Andrews, CDR Muniz was the director of the outpatient mental health clinic and for the largest substance abuse partial hospitalization program in the USAF. CDR Muniz transitioned into the USPHS in December 2008 and continued his duties for the Department of Defense at Fort Meade, MD, as the Chief of Psychiatry Services

for a large Wounded Warrior Program and supporting various national security programs. Since 2014, CDR Muniz has served at the FDA. He initially worked as a medical officer in the Division of Analgesia, Anesthesia, and Addiction Products. Currently, he is the Associate Director at the Division of Psychiatry Products, Office of New Drugs at the FDA.

Suresh Muthukumaraswamy, PhD Associate
Professor Pharmacy
University of Auckland

Dr. Suresh Muthukumaraswamy is an Associate Professor in psychopharmacology in the School of Pharmacy at The University of Auckland. Dr. Muthukumaraswamy's main research interests are in understanding how therapies alter brain function and behaviour and in testing methodologies to measure these changes in both healthy individuals and patient groups. Dr. Muthukumaraswamy began studying the psychedelics as postdoctoral fellow in 2011 with studies of psilocybin then later ketamine and LSD. He has received several Health Research Council of New Zealand research grants to support this work including grants to investigate the effects of microdoses of LSD. Dr. Muthukumaraswamy has published over 130 papers, with his work receiving more than 10,000 citations.

Mark H. Rapaport, MD
Chief Executive Officer
University of Utah Health

Dr. Mark Hyman Rapaport, MD, Professor, joined the department January 1, 2021 as new Chairman of the Department of Psychiatry and CEO of the Huntsman Mental Health Institute (HMHI). Dr. Rapaport serves as the second William H. and Edna D. Stimson Presidential Endowed Chair, University of Utah School of Medicine. From 2011-2020, Dr. Rapaport was Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine and Chief of Psychiatric Services at Emory Healthcare in Atlanta, GA. Prior to that appointment, he was the Chairman of Psychiatry and Behavioral Neurosciences at Cedars-Sinai Medical Center and a Professor of Psychiatry at both Cedar-Sinai and the David Geffen School of Medicine at UCLA. He was the first holder of the Polier Chair while at Cedars-Sinai, and also previously served as Director of the Mental Health Outpatient Clinical Research Center in the Department of Psychiatry at University of California, San Diego. He served as the first Chair of the National Institute on Drug Abuse (NIDA) Clinical Trials Network's Data Safety Monitoring Board and Chair of its Special Review Committee, and also serves on NIH and NIMH Review Committees. Dr. Rapaport has received peer-reviewed grant funding from the National Institute of Mental Health (NIMH), the National Center for Complimentary and Alternative Medicine, The Stanley Medical Research Institute, the Veterans Affairs Research Board, and the National Alliance for Research on Schizophrenia and Depression (NARSAD) Foundation. His research interests focus on human psychoneuroimmunology, psychopharmacology research, clinical trial methodology, quality of life, and complementary and alternative medicine.

Charles L. Raison, MD
Mary Sue and Mike Shannon Chair for Healthy Minds, Children & Families
University of Wisconsin-Madison

Dr. Charles Raison, MD, is a Professor of Human Ecology and Psychiatry in the Department of Psychiatry, School of Medicine and Public Health, University of Wisconsin-Madison. Dr. Raison also serves as Director of Clinical and Translational Research for Usona Institute, as Director of the Vail Health Behavioral Health Innovation Center, Director of Research on Spiritual Health for Emory Healthcare and as Visiting Professor in the Center for the Study of Human Health at Emory University in Atlanta, GA. Dr. Raison's research focuses on the examination novel mechanisms involved in the development and treatment of major depression and other stress-related emotional and physical conditions, as well as for his work examining the physical and behavioral effects of compassion training. More recently, Dr. Raison has taken a leadership role in the development of psychedelic medicines as potential treatments for major depression. He was named one of the world's most influential researchers by Web of Science for the decade of 2010-2019. With Vladimir Maletic he is author of "The New Mind-Body Science of Depression" published by W.W. Norton in 2017.

Lisa Robin
Chief Advisory Officer
Federation of State Medical Boards

Lisa Robin is Chief Advocacy Officer at the Federation of State Medical Boards (FSMB). She currently leads the FSMB Washington, DC office. Ms. Robin earned her bachelors and masters degrees from Texas Christian University. During her tenure with the FSMB, Ms. Robin has been active in policy development and promulgation on issues pertinent to medical regulation, with a special focus on telemedicine and license portability and regulatory structure and function. In addition to policy development, Ms. Robin, as an executive member of the C-Suite, is involved with the overall administration of the FSMB and is directly responsible for FSMB's state and federal government affairs and policy, communications/public affairs and the FSMB Research and Education Foundation.

Martine Solages, MD
Clinical Team Lead, Division of Psychiatry, Office of Neuroscience, Office of New Drug, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Martine Solages is a board-certified pediatrician, general psychiatrist, and child and adolescent psychiatrist. She received her medical degree from the Yale School of Medicine. She completed pediatrics residency at Johns Hopkins Hospital, general psychiatry residency at Yale University, and child and adolescent psychiatry fellowship at the Yale Child Study Center. Dr. Solages joined FDA in 2018 and is currently a Clinical Team Lead in the Division of Psychiatry. Before entering government service, Dr. Solages was on faculty at Children's National Hospital in Washington D.C., where she was the Associate Director of the Psychiatric Consultation Liaison Service and the Associate Director of the Child and Adolescent Psychiatry Fellowship Program.

Marta Sokolowska, PhD
Deputy Center Director of Substance Use and Behavioral Health, Center for Drug Evaluation Research
U.S. Food and Drug Administration

Dr. Marta Sokolowska is the Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER). She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs. Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use. Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Franz Vollenweider, MD, FMH
Chief Psychiatrist and Co-Director of the Center for Psychiatric Research
University of Zürich

Dr. Franz X. Vollenweider is Professor of Psychiatry at the University of Zürich, Chief Psychiatrist and directs the Neurophenomenology and Consciousness Unit at the Center for Psychiatry Research, Psychiatric University Hospital Zurich. Since 1997, he also directs the Heffter Research Center Zurich for advancing the field of psychedelic science and medicine. Since his receiving his doctorate in 1989, Dr. Vollenweider has focused on basic and clinical research addressing affective and psychotic disorders as well as the foundation of psychedelics-induced altered mental states. He is respected internationally for his pioneering research into the mechanism of psychedelics using concepts from cognitive neuroscience and system biology including EEG-ERP, fMRI, MRS, and TMS techniques, and in particular for demonstrating that the psychedelic effects in humans are primarily mediated through serotonin-2A receptor activation in the brain. His current research focuses on the effects of psychedelics on self-referential processing, emotion regulation, and social interaction to identify potentially drug targets for the treatment of depression. In 2019, he co-initiated the first transnational EU ERA-NET Research Program including Germany, Switzerland, France, and Italy for exploring the clinical potential of psilocybin in the treatment of alcohol dependence. For three decades, his group has had continuous funding from the Swiss National Science Foundation, the Swiss Federal Health Office, the Swiss Neuromatrix Foundation, the ERA-NET Neuron Program, the Heffter Research Institute (USA), the Usona Institute (USA), and the NARSAD Foundation (USA). Dr. Vollenweider has published over 200 peer-reviewed papers, including many addressing the

psychophysiology of psychedelics, entactogens, and psychostimulants. He has received the Achievement Award of the Swiss Society of Psychiatry (1990), the Heffter Research Institute Award (1997), the Götz Prize of the University of Zürich (2000), the British Association of Psychopharmacology Prize (2002), and multiple Awards from the European College of Neuropsychopharmacology (1999, 2003, 2010, 2016), among others.

Ilse Wiechers, MD, MPP, MHS
Deputy Executive Director, VHA Office of Mental Health and Suicide Prevention
U.S. Department of Veterans Affairs

Dr. Ilse Wiechers serves as the Deputy Executive Director in VHA Office of Mental Health and Suicide Prevention (OMHSP). In this role, she leads the operations of OMHSP and the timely development and implementation of policies and programs that ensure Veteran-centered, evidence-based and high-quality mental health and suicide prevention services to over 1.9 million Veterans every year. She also leads OMHSP's legislative policy and partnership work, engaging regularly with key Congressional and Veteran Service Organization stakeholders. She has been instrumental in the development of VHA's portfolio of innovative mental health treatments including ketamine, esketamine, and psychedelic-assisted therapy. Dr. Wiechers is a practicing board certified Adult and Geriatric Psychiatrist who completed her medical education at Duke University, residency at MGH/McLean Hospitals, and fellowship at Yale. She received a master's degree in Public Policy from Duke University and a master's degree in Health Science from Yale University. She is an alumna of the VA Advanced Fellowship Program in Mental Illness Research and Treatment, the Yale RWJF/VA Clinical Scholars Program, and the John A. Hartford Foundation's Center of Excellence in Geriatric Medicine and Geriatric Psychiatry Training Program. Dr. Wiechers serves as faculty at University of California San Francisco and Yale, is a Distinguished Fellow of the American Association for Geriatric Psychiatry and the American Psychiatric Association and has been elected to the membership of the American College of Psychiatrists. She has authored over 30 peer-reviewed publications, 2 invited editorials, 15 book chapters, and co-edited a book on mental health advocacy.

David Yaden, PhD
Assistant Professor
Johns Hopkins University

Dr. David B. Yaden, PhD, completed his doctorate in Psychology at the University of Pennsylvania and is currently an Assistant Professor and the Roland Griffiths Professor of Psychedelic Research at Johns Hopkins University School of Medicine in the Department of Psychiatry and Behavioral Sciences at the Center for Psychedelic and Consciousness Research. His research focus is on the psychology of psychedelic experiences—as well as other naturally occurring positively transformative experiences. Specifically, Dr. Yaden is interested in understanding how brief experiences can result in long-term changes to well-being and therapeutic effects, as well as their relevant risks and related ethical issues. He is the co-founder of The Hub for Psychedelic Ethics (HOPE) at Oxford. He is the co-author of *The Varieties of Spiritual Experiences: A Twenty-First Century Update* for Oxford University Press.

Berra Yazar-Klosinski, PhD
Chief Scientific Office
Lykos Therapeutics

Dr. Berra Yazar-Klosinski, Ph.D., the chief scientific officer of Lykos Therapeutics (formerly MAPS PBC), provides scientific leadership for global Research & Development efforts to bring psychedelic products to target markets. She utilizes scientific background to nurture ideas from proof of concept through New Drug Application filing, most recently with MDMA-assisted therapy for treatment of PTSD. Dr. Yazar-Klosinski began working on the development of MDMA-assisted therapy when she joined MAPS in 2009 and has been with Lykos since its inception in 2014. Dr. Yazar-Klosinski has developed a strong track record of success with FDA, EMA, and other regulatory agencies. Prior to Lykos, Dr. Yazar-Klosinski worked with Geron Corporation and Millennium Pharmaceuticals. She earned her B.S. in Biology with a minor in Drama from Stanford University and her Ph.D. in Molecular, Cell, and Developmental Biology from the University of California, Santa Cruz.

Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the Food and Drug Administration

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her JD *magna cum laude* from Georgetown University Law Center. She is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.