Evaluating the Negative Symptoms of Schizophrenia in Clinical Trials Meeting

Speaker Biographies

Anthony Ahmed, Ph.D., MSP, Dr. Anthony Ahmed is an Associate Professor of Psychology in Clinical Psychiatry at Weill Cornell Medicine. He is also the Vice Chair for Psychology in the psychiatry department and serves as Attending Psychologist in the Psychotic Disorders Division at the Westchester Behavioral Health Center. Dr. Ahmed completed his doctoral training in clinical psychology at the University of Southern Mississippi, a psychology internship at the VA Maryland Health Care System/University of Maryland Baltimore. Dr. Ahmed completed a Psychotic Disorders Postdoctoral Fellowship at the Medical College of Georgia in Augusta University. Dr. Ahmed is involved in the development and dissemination of evidence-based interventions for people with schizophrenia. He also conducts clinical research including collaborations funded by Brain and Behavior Research Foundation (NARSAD), the National Institute of Health (NIH), and the Patient Centered Outcome Research Institute (PCORI). His clinical and scholarly interests include the phenomenology and treatment of cognition and negative symptoms in schizophrenia and related syndromes. His academic work has been recognized by several scholarly and clinical awards.

Rachael Blackman, MD Ph.D., is a clinical reviewer in the Division of Psychiatry. Dr. Blackman is a board-certified psychiatrist who completed an M.D./Ph.D. program at the University of Minnesota with her Ph.D. in Neuroscience. She completed her adult psychiatry residency training at Brown University, participating in the research track. Directly prior to starting at the FDA, Dr. Blackman completed a clinical research fellowship at the National Institutes of Health in the National Institute of Mental Health studying schizophrenia. Dr. Blackman has expertise in nonclinical research, clinical research, and clinical care related to schizophrenia and has authored a number of peer-reviewed journal articles.

Jack J. Blanchard, Ph.D., Dr. Blanchard's research seeks to understand the social, behavioral, and neural factors associated with negative symptoms in psychosis-spectrum disorders. This work includes the development and validation of the Clinical Assessment Interview for Negative Symptoms (CAINS).

Stephen Brannan, M.D., Dr. Brannan is the former CMO at Karuna Therapeutics and a neuroscience drug development expert who has held senior positions overseeing both clinical development and medical affairs with more than 15 years of industry experience. Previously, Dr. Brannan was the Therapeutic Head of Neuroscience at Takeda and Vice President for Clinical Research and Medical Affairs at Forum Pharmaceuticals. Dr. Brannan has been active in the development of multiple important central nervous system treatments including Cymbalta, Exelon Patch, Trintellix, and VNS for Treatment Resistant Depression while holding various senior roles at Forum, Takeda, Novartis, Cyberonics, and Eli Lilly. His experience includes drug development, registration, medical affairs, launch and lifecycle management in the areas of anxiety, depression, epilepsy, neuropathic pain, schizophrenia, migraine, cognition, and Alzheimer's and Parkinson's diseases. Dr. Brannan is a member of several scientific societies and groups, including ACNP, ISCTM (Member of both the Scientific and Executive Committees), ISCDD, AARR, IOM Neuroforum, and CNS Summit (founding member). Prior to joining the Pharmaceutical industry, Dr. Brannan worked on the faculty at the University of Texas Health Science Center at San Antonio (UTHSCSA) where he specialized in seeing Mood and Anxiety disorder patients, ran a clinical research unit, and did neuroimaging research at the Research Imaging Center. Dr. Brannan trained in psychiatry at UTHSCSA and holds a M.D. degree from the University of Texas Health Science Center at Dallas (Southwestern Medical School). He has over 50 publications and routinely gives invited talks and presentations at industry conferences.

Robert W. Buchanan, M.D. is a Professor of Psychiatry at the University of Maryland School of Medicine. Major research interests include investigation of schizophrenia phenomenology and pathophysiology; and the development of novel pharmacological approaches for negative symptoms and cognitive impairments.

Teresa Buracchio, M.D., is Director of the Office of Neuroscience in the Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA). She oversees the review of new drug programs for neurologic and psychiatric diseases, including Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, neuromuscular diseases, neurogenetic disorders, major depressive disorder, and schizophrenia. Dr. Buracchio joined FDA in 2013, where she worked as a clinical reviewer in Alzheimer's disease and dementia and a team leader in epilepsy, and neuromuscular and neurogenetic diseases, and eventually served as Director of Division of Neurology 1. Prior to joining FDA, Dr. Buracchio worked at AbbVie as an Associate Medical Director for Neuroscience Clinical Development. Dr. Buracchio received her medical degree from Rush Medical College and completed a neurology residency at Rush University Medical Center in Chicago, Illinois. Dr. Buracchio completed fellowship training in geriatric neurology at Oregon Health & Science University and Portland Veterans Affairs Medical Center in Portland, Oregon.

Michelle Campbell, Ph.D., is the Associate Director for Stakeholder Engagement and Clinical Outcomes in the Office of Neuroscience, Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research. Dr. Campbell joined the FDA in 2014 and previously was a reviewer on the Clinical Outcome Assessments (COA) Staff and Scientific Coordinator of the COA Qualification Program in OND. Dr. Campbell's focus is in patient-focused drug development and the use of patient experience data in the regulatory setting. Prior to joining FDA, Dr. Campbell spent more than 10 years conducting research in the academic-clinical setting, including five years in a neurology and developmental medicine department. Dr. Campbell earned her BA in Biology from the College of Notre Dame, her MS in Health Science from Towson University, and her PhD in Pharmaceutical Health Services Research from the University of Maryland School of Pharmacy.

Christoph U. Correll, M.D., is Professor of Psychiatry at The Zucker School of Medicine at Hofstra/Northwell, New York, USA, and Professor and Chair of the Department of Child and Adolescent Psychiatry, Charité University Medicine, Berlin, Germany. He completed his medical studies at the Free University of Berlin in Germany, and Dundee University Medical School in Scotland. Dr. Correll focuses on identification and treatment of severe mental illness, psychopharmacology, clinical trials, meta-analyses, and physical health in mental health. He has published over 900 articles that have been cited more than 78.000 times and received over 40 research awards. In June 2024, his h-index was 143 in Google Scholar. Since 2014, the beginning of this metric, he has been listed annually by Clarivate/Web of Science as one of the "most influential scientific minds" and "top 1% cited scientists in the area of psychiatry". Additionally, Dr. Correll has been holding numerous Expertscape rankings based on the number of publications and citations in the past 10 years, including being ranked consistently since 2017 as the number one cited world expert in >10 areas, including "central nervous system agents", "psychotropic drugs", "schizophrenia", "schizophrenia spectrum and other psychotic disorders", "antipsychotics", "delayed action preparations" and "weight gain".

Tiffany Farchione, M.D., 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, M.D., Dr. 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). He is involved in the regulatory oversight of all psychiatric drug development activities conducted under investigational new drug applications (INDs) and the review of all new drug applications (NDAs) for marketing a psychiatric drug in the United States. 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.

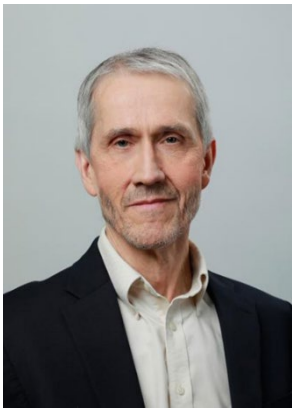
William P. Horan, Ph.D., Executive Director of Clinical Development at Bristol Myers Squibb, provides scientific and operational oversight for clinical trials in neuropsychiatry and neurology. He was previously Professor of Psychiatry & Biobehavioral Sciences at UCLA and Chief of the Psychosis Section at the VA Greater Los Angeles Healthcare System. Over the past 25 years, he has conducted treatment development and translational research on cognitive, social, and emotional disturbances that contribute to functional disability in schizophrenia and other neuropsychiatric disorders. His research has been funded by FDA, NIMH, VA, and foundation grants, and he served as a Principal Investigator in the NIMH Collaboration to Advance Negative Symptom Assessment in Schizophrenia. He has served on the editorial board of several journals and has over 150 peer-reviewed articles.

G. Eric Jarvis, M.D., MSc, is an Associate Professor of Psychiatry at McGill University and Director of the Cultural Consultation Service and the Culture and Psychosis Program at the Jewish General Hospital. His academic and research interests include the cultural adaptation of services for early psychosis, cultural consultation, linguistic barriers in mental health care, and religion and mental health. He is also interested in academic editing and the history of psychiatry and began as the Editor-in-Chief of Transcultural Psychiatry in 2023.

Bonnie Kaiser, Ph.D., MPH, is an Associate Professor in Anthropology and Global Health at the University of California San Diego, with training as an anthropologist (PhD) and epidemiologist (MPH).

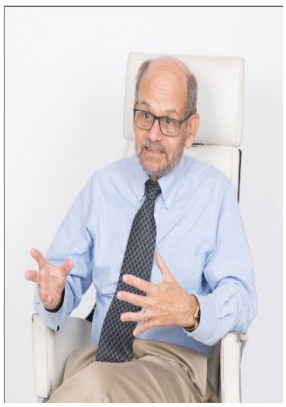
Richard Keefe, Ph.D., is Professor Emeritus of Psychiatry, Psychology, and Neurosciences at Duke University Medical Center in Durham, North Carolina, USA. He received his BA from Princeton University and his Ph.D. in clinical psychology from New York University. Dr. Keefe's research is primarily devoted to understanding cognitive dysfunction and its treatment in patients with schizophrenia and other psychiatric and neurological conditions. He has had a leadership role for cognitive methods in several large National Institute of Mental Health studies and over 100 industry trials. He has published more than 300 scientific papers and two books. Dr. Keefe is on the editorial boards of *Psychological Medicine* and *Schizophrenia Research.* He was the 2012-2014 President of the International Society for CNS Clinical Trials and Methodology. He is on the Scientific Board of the Brain and Behavioral Research Foundation. He was the co-Founder of VeraSci and CEO from 2004-2022.

Deanna L. Kelly, Pharm.D., BCPP. Dr. Kelly serves as the Acting Director of the Maryland Psychiatric Research Center and is an endowed Professor of Psychiatry at the University of Maryland Baltimore School of Medicine. She has over 27 years experience in schizophrenia research.



Brian Kirkpatrick, M.D., MSPH, graduated from the University of Texas Medical School at Houston. He completed residency, was a Robert Wood Johnson Clinical Scholar, received a Master's of Science in Public Health with a concentration in epidemiology, and completed a fellowship in neuropharmacology at the University of North Carolina Chapel Hill. Dr. Kirkpatrick joined the Maryland Psychiatric Research Center at the University of Maryland School of Medicine, and later served as Vice Chair of Psychiatry at the Medical College of Georgia. He subsequently served as Chair of the Department of Psychiatry at Scott and White Hospital/Texas A&M School of Medicine, and the Department of Psychiatry and Behavioral Sciences at the University of Nevada, Reno School of Medicine. He joined the University of Arkansas for Medical Sciences (UAMS) Department of Psychiatry in 2022. Throughout his career Dr. Kirkpatrick has focused on schizophrenia and related disorders. He co-chaired the Consensus Development Conference on Negative Symptoms sponsored by the National Institute of Mental Health (NIMH). He received competitive funding from NIMH, the National Institute of Diabetes and Digestive and Kidney Diseases, the Brain and Behavior Research Foundation, and the Scottish Rite Foundation. He served as an associate editor of Clinical Schizophrenia and Related Psychoses and is on the editorial board of Schizophrenia Bulletin.

Mark Opler, Ph.D., MPH holds the titles of Chief Research Officer at WCG Inc. and Executive Director of the PANSS Institute. Dr. Opler has served as a faculty member in the Departments of Psychiatry and Environmental Medicine at New York University School of Medicine and in the Department of Neuroscience at Columbia University, College of Physicians and Surgeons. His academic research focuses on the etiology, phenomenology, and treatment of serious and persistent mental disorders. He is a co-author and developer of several clinical assessment tools, including the SNAPSI, CGI-DS, and NY-AACENT. He is a contributor to the latest edition of the PANSS Manual©. Dr. Opler has received research support from the US NIMH, the Brain & Behavior Foundation (formerly NARSAD), the Stanley Medical Research Institute, and the Qatar National Research Fund. He has co-authored more than 50 peer-reviewed publications and has contributed to multiple book chapters and review articles on clinical assessment, research methodology, and mental health. He received his PhD and MPH from Columbia University and his BSc from SUNY at Stony Brook. He is a graduate of the Psychiatric Epidemiology Training Program at Columbia University and completed his postdoctoral fellowship at the New York State Psychiatric Institute.



Stephen R. Marder, M.D., is a Professor of Psychiatry, and the Director of the Section on Psychosis at the UCLA Semel Institute for Neuroscience and Human Behavior. He is also the Director of the VISN 22 Mental Illness Research, Education Clinical Center (MIRECC) for the Department of Veterans Affairs. Dr. Marder's research has focused on improving the lives of individuals with psychotic disorders, particularly schizophrenia. His research -- supported by the VA, the Brain and Behavior Research Foundation, and the National Institute of Mental Health -- has focused on the development of pharmacological, psychosocial, and rehabilitation approaches for improving functioning and quality of life. Dr. Marder has received the Exemplary Psychiatrist Award from the National Alliance for the Mentally Ill, the Stanley Dean Research Award of the American College of Psychiatry, the Alexander Gralnick Award from the American Psychiatric Association, the Kempf Award from the American Psychiatric Association, the American Psychiatric Association Award for Research, the Wayne Fenton Award for Outstanding Clinical Care from the Schizophrenia Bulletin, and the Lieber Prize for Schizophrenia Research.

Matthew M. Racher, CRPS, MSW is a social worker with experience working in the fields of mental health care and harm reduction. Following a diagnosis of schizophrenia in his early twenties, he engaged in mental health advocacy as a peer and pursued his Master of Social Work degree at Barry University in South Florida. He is a proponent of the effectiveness of peer and family support, early intervention, and community-based treatment. Matthew enjoys his musical endeavors alongside his advocacy efforts. He is in a band known as FogDog, in which he has played live music across various local and national events in support of mental health. Matthew is currently engaged in his pursuits towards licensure as a clinical social worker and aspires to further advance his counseling skills and techniques to help individuals living with a mental health condition.

Roberta Rasetti, M.D., Ph.D., joined the FDA in late 2020 as a physician in the Division of Psychiatry. She received her MD and PhD from the University of Turin, Italy, and completed an adult residency at the University of Pennsylvania, Department of Psychiatry. Dr. Rasetti is board certified in general psychiatry in both the United States and Europe. Prior to joining the FDA in 2020, Dr. Rasetti was affiliated with the Georgetown University School of Medicine and was on the faculty of Georgetown University and a Clinical Fellow at the National Institute of Mental Health, where she focused on schizophrenia research. As a medical reviewer in the Division of Psychiatry at the FDA, Dr. Rasetti is involved in the review of new drug applications and supplements for new psychiatric drugs.

David S. Reasner, Ph.D., is the Division Director, Division of Clinical Outcome Assessment, at FDA within the U.S. Department of Health and Human Services. The Division of Clinical Outcome Assessment (DCOA) comprises multidisciplinary measurement experts and is located in the Office of Drug Evaluation Sciences (ODES) - Office of New Drugs (OND), in FDA's Center for Drug Evaluation and Research (CDER). DCOA integrates the patient voice into drug development through COA endpoints that are meaningful to patients, valid, reliable, and responsive to treatment. David is a member of ASA and ISPOR. He earned his undergraduate Psychology degree from Duke University and went on to complete a Ph.D. in Biopsychology at Cornell University as well as post-doctoral training in Neuroscience at the Worcester Foundation for Experimental Biology.

Michael Sand, Ph.D., M.P.H. has 35 years' experience as a clinical scientist in the pharmaceutical industry, focused on developing novel compounds for serious mental illness. He has authored or co-authored over 160 peer-reviewed abstracts, papers and book chapters in human sexuality and psychopharmacology and served as a Work Group Advisor to the DSM-V Committee on Sexual and Gender Identity Disorders. He currently serves as a consultant to a number of pharmaceutical companies and the NIMH. In his spare time, he is an avid hiker, mountaineer, skier and sailor. He lives in Monroe, Connecticut with his wife and a border collie who he fears is smarter than he is.

Nina Schooler, Ph.D., Dr Schooler is Professor of Psychiatry and Behavioral Sciences at State University of New York Downstate Health Sciences Center, New York, NY. One focus of her research has been treatment of psychosis and schizophrenia early in the course of illness. Recent examples include 1) a study of treatment for first episode psychosis (FRP) conducted at 34 clinical sites in the US that compared an integrated psychosocial and pharmacologic treatment to usual community care, 2) a clinical trial that compared a long-acting injectable antipsychotic to oral medication in schizophrenia patients early in their treatment exposure and 3) participation in the ESPRITO hub that is part of the EPINET program of the NIMH that focuses on Coordinated Specialty Care programs for first episode psychosis. She is a fellow of the American College of Neuropsychopharmacology, the Collegium Internationale Neuropsychopharmacologicum (CINP), the American Psychological Association, and the Association for Psychological Science. Dr. Schooler has been President of the American Psychopathological Association and the Association for Clinical Psychosocial Research, a CINP Councilor and a member of the Schizophrenia International Research Society (SIRS) Board of Directors. Her contributions to the field have been recognized by the Gralnick Foundation-High Point Hospital Award from the Education and Research Foundation of the National Association of Psychiatric Health Systems, the Alexander Gralnick Research Investigator Award from the American Psychological Foundation, the Samuel Hamilton Award from the American Psychopathological Association, the Andrew Leon Career Research Award from the International Society for Clinical Trials Methodology and the Donald F Klein Lifetime Achievement Award from the American Society for Clinical Psychopharmacology (ASCP). She has been honored that the ASCP Nina Schooler Early Career Research Award is given in her name. Most recently she was awarded the SIRS Lifetime Achievement Award. She received her PhD in Social Psychology from Columbia University in New York, and her career path has included leadership positions at the National Institute of Mental Health. Her academic career has taken her to the Department of Psychiatry at the University of Pittsburgh and the Zucker Hillside Hospital, prior to her present position at SUNY Downstate.

Brandon Staglin, M.S., as Co-founder and Chief Advocacy & Engagement Officer of One Mind, Brandon Staglin channels his deep experience in leadership, advocacy, and personal schizophrenia recovery to drive brain health research, services, and media to heal lives. His best-known advocacy work has been for the growth of science-driven, large-scale. continuously improving prevention and early intervention services for youth facing serious psychiatric illness. He has published numerous articles in well-known journals and earned numerous advocacy awards. Brandon is a member of the CEO Alliance for Mental Health, and has served on guiding councils of global, national and regional influence including for the World Economic Forum, the National Institute of Mental Health, the Foundation for the National Institutes of Health, the State of California, Stop Stigma Together, and Stanford University School of Medicine. He earned a Master of Science in Healthcare Administration and Interprofessional Leadership from UCSF in September 2018, and Bachelor of Arts degrees in Engineering Sciences and Anthropology from Dartmouth College in 1993. Brandon's lived experience with schizophrenia makes him grateful to be enjoying life in health and happy every day he can contribute to the health of others.

Gregory P. Strauss, Ph.D., is the Franklin Professor of Psychology at the University of Georgia, where he directs the Clinical Affective Neuroscience Laboratory and Georgia Psychiatric Risk Evaluation Program. His program of research focuses on negative symptoms in adults with schizophrenia and youth at clinical high-risk for psychosis. He has contributed to knowledge regarding the phenomenology of negative symptoms as a multi-factorial dimension and how it is defined in the DSM5; the development and validation of clinical rating scale (BNSS, NSI-PR) and digital phenotyping (geolocation, accelerometry, ambient speech, ambulatory videos) assessments; the identification of neurobiological and psychological mechanisms of negative symptoms; and evaluating the efficacy of novel psychosocial, pharmacological, and cognitive training interventions for negative symptoms. To date, he has published over 230 papers that have been widely cited. His research has been recognized with several awards (e.g., rising star award from SIRS, early career award from NAN, Wechsler early career award from APF) and supported by >$82M in grants from federal and private organizations such as the NIH, NSF, Brain & Behavior Research Foundation, and VA MIRECC.

Laura L. Swett, Ph.D., is a Social Science Analyst in the Division of Clinical Outcome Assessment (DCOA), Office of Drug Evaluation Science (ODES), Office of New Drugs (OND), Center for Drug Evaluation Research (CDER), within the US Food and Drug Administration (FDA). Dr. Swett has a Ph.D. in social science research from the Catholic University of America, focusing on cognitive health in aging persons. Prior to joining the FDA in 2021, Dr. Swett worked for Evidera/PPD, a clinical research consultancy organization, specializing in clinical outcome measurement. Dr. Swett supports the Divisions of Psychiatry, Antivirals, and Anti-infectives at the FDA. She enjoys mentoring early career professionals and teaching classes related to COA assessment.

Sophia Vinogradov, M.D., I serve as Professor and Department Head for the University of Minnesota Department of Psychiatry and Behavioral Sciences. I lead a translational clinical neuroscience laboratory focused on unraveling the mysteries of cognitive dysfunction in psychosis. My journey includes serving as Co-Principal Investigator of an NIMH P50 Conte Center and a regional NIMH EPINET hub, where we delve deep into the intricate mechanisms underlying dysfunctional state representations in psychosis, pioneering innovative approaches for enhanced well-being. I spearhead groundbreaking research on cognitive training and neural plasticity in psychosis spectrum illnesses. Collaborating with esteemed experts like Dr. David Redish, my investigations extend to computational modeling, shedding light on impaired representational processes crucial for neuroplasticity. My expertise spans diverse areas, including remote scalable assessments, social cognition interventions, and the development of novel treatment paradigms. Leading a network of early psychosis clinics in Minnesota, I integrate cutting-edge assessments seamlessly into clinical practice, shaping the future of psychiatric care. Driven by a passion for scientific advancement and clinical excellence, I am eager to leverage our latest project, an EPINET R01, to propel the Learning Health System in Early Psychosis to new heights. With a focus on improving clinical and functional outcomes, my multidisciplinary approach promises transformative breakthroughs for individuals navigating the complexities of psychosis spectrum illnesses.

Heidi Wehring, PharmD, BCPP, Dr. Heidi Wehring joined the FDA in 2020 as a clinical reviewer in the Division of Psychiatry. She received her Doctor of Pharmacy degree from the University of Iowa in Iowa City, Iowa, and completed a psychiatric pharmacy practice residency and a psychiatry fellowship at the University of Maryland-Baltimore. Dr. Wehring is a board-certified psychiatric pharmacist (BCPP). Prior to joining the FDA in 2020, Dr. Wehring was on the faculty of Maryland Psychiatric Research Center at the University of Maryland-Baltimore School of Medicine, where she focused on schizophrenia research. As a clinical reviewer in the Division of Psychiatry at the FDA, Dr. Wehring is involved in the review of new drug applications, including supplements and investigational new drug applications.

Peiling Yang, Ph.D., is a Supervisory Mathematical Statistician in Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA. She joined the FDA in 1999 as a statistical reviewer for oncological drug applications. In 2005, she was promoted to Statistical Team Leader supporting the Division of Psychiatry. In addition to her supervisory role, she is currently serving as the acting Team Leader, actively engaging in the review of psychiatric drug applications. Beyond her review work, Dr. Yang has been instrumental in drafting statistical advice for several guidance documents related to psychiatry. Throughout her tenure at the FDA, Dr. Yang has received numerous awards in recognition of her significant contributions to the new drugs regulatory review program.