2023 ASCP ANNUAL MEETING

LOEWS MIAMI BEACH HOTEL



THE CHANGING LANDSCAPE OF CLINICAL PSYCHIATRY: NOVEL THERAPEUTICS, METHODS AND ASSESSMENTS

MIAMI BEACH FLORIDA

MAY 30 - JUNE 2, 2023



Dear Colleagues,

Welcome to Miami Beach and sunshine!

On behalf of the American Society of Clinical Psychopharmacology (ASCP), I am pleased to welcome you to our very exciting annual meeting. I want to thank the Program Committee for the Annual Meeting and the Review Sub-committee for their wonderful work putting together such an extraordinary meeting.



As we continue to navigate this post-Covid era, we all are learning new approaches in our professional and personal lives. Thus, the 2023 ASCP Annual Meeting theme of "The Changing Landscape of Clinical Psychiatry: Novel Therapeutics, Methods and Assessments" is quite timely and relevant for our attendees. The ASCP Annual Meeting has something for everyone. There are sessions that address diversity, equity, and inclusion, major mental disorders, alcohol/substance use disorders, training and career development, as well as exploring the changes in assessments, measurements, and interventions in clinical psychiatry. Our meeting also includes a very stimulating joint workshop with the American Foundation for Suicide Prevention (AFSP) and we also continue our long-standing and highly successful New Investigators' Program.

New this year, the ASCP Industry Advisory Council will be hosting an educational and interactive roundtable event led by members of industry in which attendees will have the opportunity to rotate between topic areas highlighting the various aspects of work in the development of pharmacological and other interventions. Also new this year is a joint lunch session from the Inclusivity Committee and Early Career Committee entitled, "Leveraging Data Sets: Clinics to Large Data and the Value of Diversity" which will focus on how investigators utilize existing data sets to support research aims and the importance of including diverse populations when collecting and analyzing data.

Unique to the ASCP Annual Meeting is the active participation from colleagues in government service. The Federal and Other Funding Agencies plenary will include representatives from NIMH, NIAAA, PCORI, NIDA, and the VA. We also continue to have a plenary on psychopharmacology updates, but it is under a new name, "Clinical Updates in Neurotherapeutics." Also renamed this year is the Regulatory Wrap Up. It has been reformatted and will include a panel of FDA representatives answering your questions, thus the new name is "Regulatory Challenges: Ask the Experts".

The ASCP Annual Meeting checks off all the boxes in our organization's strategic plan:

- Goal #1 Enhance the development of cutting-edge research in the field of clinical psychopharmacology and related fields by providing investigators and clinicians the opportunity to engage in the discussion, education, and dissemination of research findings and new methodologies
- Goal #2 Enhance ASCP's role as the preeminent leader in innovative education in clinical psychopharmacology and related fields to foster the development of best practices, new treatments, curricula, and training for all career levels
- Goal #3 Increase the leadership, membership, and participation of all underrepresented groups in the Society by cultivating inclusion to ensure that all feel welcomed, empowered, and valued
- Goal #4 Create opportunities for individuals from diverse backgrounds, such as early career members and NIA's, to stay engaged in the Society

ASCP continues to aspire to become an exemplary leader in creating an inclusive and welcoming environment wherein everyone can learn, develop, innovate, and flourish.

I hope you have a wonderful time learning, presenting, and seeing old and new friends at our annual meeting.

Leslie Citrome, M.D., M.P.H. President American Society of Clinical Psychopharmacology

Welcome to the ASCP Annual Meeting

On behalf of the ASCP Program Committee for the Annual Meeting and Review Sub-Committee, we are delighted to welcome you to the ASCP Annual Meeting. The ASCP is committed to continue building on the past success of NCDEU with program innovation while preserving the rich history of this meeting. Below are some of the highlights of the 2023 meeting.

The annual meeting brings together academic investigators, industry scientists, U.S. and international regulators, National Institutes of Health (NIH) and other professionals who work in drug development and clinical trials.

2023 Program Highlights

o Tuesday, May 30th:

- Conference Opening
- Inclusivity and Early Career Committee Luncheon (RSVP Only)
- Pharmaceutical Pipeline
- Individual Research Reports
- Wednesday, May 31st:
 - 24th Annual Fun Run/Walk
 - Regulatory Plenary: Pediatric Drug Development in Psychiatry
 - ASCP Lifetime Awardee Talk: The Shape of DISCOVERY: Ketamine for Treatment Resistant Depression
 - Poster Session I
 - Clinical Updates in Neurotherapeutics
 - ASCP Reception
- o Thursday, June 1st:
 - Keynote Plenary: The Changing Landscape of Clinical Psychiatry: Novel Therapeutics, Methods and Assessments
 - Update From Federal and Other Funding Agencies Plenary
 - Investigator-Industry Collaboration Session
 - Poster Session II
- Friday, June 2nd:
 - Regulatory Challenges: Ask the Experts
- The New Investigator Program
 - A closed workshop for 20 New Investigators and informal breakfast sessions
- Workshops: 2-hour intensive interactive sessions focused on problems and solutions
 - Wednesday and Thursday Afternoons

*Clinical Track – Sessions focused on topics of immediate clinical relevance +No CME Credits Offered - Per the new ACCME guidelines, these sessions cannot be accredited

- # Child/Adolescent Track Sessions focused on topics of child and adolescent relevance
- ^ Academic Track Sessions focused on topics of academic relevance
- DEI Track Sessions focused on topics of DEI relevance

Organization

- o The meeting is sponsored by the American Society of Clinical Psychopharmacology (ASCP).
 - The Program Committee for the Annual Meeting (PCAN) organizes the meeting.
 - The Review Sub-Committee evaluates submitted proposals and develops program innovations.
- Federal Agency & Other Funding Agency collaborations:
 - NIAAA National Institute on Alcohol Abuse and Alcoholism
 - NIDA National Institute of Drug Abuse
 - NIMH National Institute of Mental Health
 - PCORI Patient-Centered Outcomes Research Institute
 - VA Veterans Administration
- Regulatory agency collaborations:
- Food and Drug Administration (FDA)
- Society collaboration:
- American Foundation for Suicide Prevention (AFSP)
- o Parthenon Management Group organizes the ASCP Annual Meeting.

And Remember

- o The Fun Run/Walk is Wednesday, May 31st at 6:30 a.m. All are welcome to join!
- The ASCP Reception is Wednesday, May 31st from 6:00 p.m. 7:00 p.m.

The ASCP Annual Meeting is an opportunity for education and networking. We welcome your suggestions to make the event even better. Seek us out during the meeting or provide your views by completing the evaluation form.

Best Regards,

Sum G. Konstein MD

Susan G. Kornstein, M.D. PCAN Co-chair

Lee Cohen, M.D. Review Sub-Committee Co-chair

M HRepapat up

Mark Rapaport, M.D. PCAN Co-chair

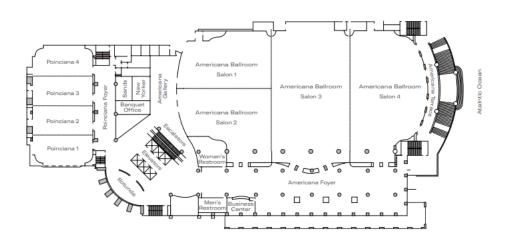
Manish Jha, M.D. Review Sub-Committee Co-chair



Hotel Maps

Hotel Loews Miami Map

Second Level



Third Level

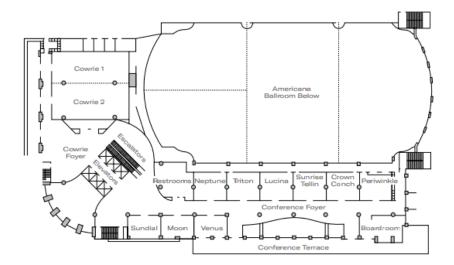


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DISCLOSURES FOR ALL ASCP PRESENTERS CAN BE VIEWED AT HTTPS://ASCPP.ORG/ASCP-MEETINGS/ASCP-ANNUAL-MEETING/



Notes



Awards Winners & Featured Speakers





Dennis S. Charney, M.D.

Icahn School of Medicine at Mount Sinai

Dennis S. Charney, M.D., is Anne and Joel Ehrenkranz Dean of the Icahn School of Medicine at Mount Sinai and President for Academic Affairs for the Mount Sinai Health System. He is a world-renowned expert in the neurobiology and treatment of mood and anxiety disorders who has made fundamental contributions to the understanding of human anxiety, fear, depression, and resilience, and has played a

key role in the discovery of new treatments for mood and anxiety disorders, including ketamine which is currently helping millions of people with treatment resistant depression. Dr. Charney was recruited to Icahn Mount Sinai in 2004 as Dean of Research. In 2007, he became the Dean of the School and Executive Vice President for Academic Affairs of what was then known as the Mount Sinai Medical Center. In 2013, he was named President for Academic Affairs for the Health System. Under Dr. Charney's leadership, Icahn Mount Sinai has become one of the nation's leading medical schools. He has recruited world-class faculty across the biomedical sciences, as well as in computational biology, information technology, and entrepreneurship to cultivate a supercharged, Silicon Valley-style atmosphere in an academic setting. Icahn Mount Sinai is among the nation's top recipients of National Institutes of Health (NIH) funding, reflecting the fact that Dr. Charney has hired faculty members who are both innovative, ambitious researchers and dedicated educators. Dr. Charney has prioritized anti-racism initiatives. He established the Mount Sinai Institute for Health Equity Research, which is working to improve health and access to care across the nation's demographic divide, and expanded Icahn Mount Sinai's efforts to promote diversity and gender equity in medicine.

Recipient of the Paul Wender Best Paper in The Journal of Clinical Psychiatry Award



ASCP

Cynthia V. Calkin, M.D., CCFP, FRCP(C) Associate Professor Dalhousie University

Nominated for: Treating Insulin Resistance With Metformin as a Strategy to Improve Clinical Outcomes in Treatment-Resistant Bipolar Depression (the TRIO-BD Study): A Randomized, Quadruple-Masked, Placebo-Controlled Clinical Trial

Dr. Cindy Calkin is a clinical researcher and Associate Professor of Psychiatry and Medical Neuroscience at Dalhousie University, Canada. She is the Medical Director of a unique multidisciplinary clinical research Mood and Metabolism Program that includes psychiatry, endocrinology and metabolism, health physics, biomedical engineering, neuroradiology, and medical neuroscience. Her group uses multimodal testing to collect detailed prospective data. Her innovation and discovery research focuses on mechanisms underlying Treatment-Resistant Bipolar Depression (TRBD) and novel mechanism-based targeted treatments. The first mechanism underlying TRBD that her group discovered is metabolic in nature. More than half of all bipolar patients have insulin resistance or type-2-diabetes (IR/T2DM) and this is associated with chronic course and poor response to mood stabilizing treatment, with psychiatric morbidity increasing 12-fold following the onset of IR. It is a novel concept to treat an underlying metabolic disorder to improve a psychiatric one. Dr. Calkin was awarded \$1.3 million from Stanley Medical Research Institute to investigate "Treating IR as a strategy to Improve Outcome in BD (TRIO-BD)", the first study to show that reversing IR improves outcome in TRBD. Dr. Calkin's work, in collaboration with Dr. Alon Friedman, has now identified a second mechanism underlying TRBD - extensive blood-brain barrier leakage.



Recipient of the Jonathan Cole Presidential Service Award



J. Craig Nelson, M.D.

University of California, San Francisco

Dr. Nelson is Professor Emeritus of Psychiatry at the University of California-San Francisco. From 1974 to 2002 he served on the faculty at Yale University School of Medicine. From 2002 to 2021 he held the Leon J Epstein M.D. Chair in Geriatric Psychiatry and was Director of Geriatric Psychiatry at UCSF. He has published over 200 articles, books

and chapters including the text, Geriatric Psychopharmacology. He continues to teach, provide clinical supervision, and participates in research at UCSF. His current area of research focuses on cognitive impairment in late life depression. Dr. Nelson was a founding member of the American Society of Clinical Psychopharmacology and served on the Board of Directors from 1992 to 2012. In the 1990s he served as chair of program committee and worked with Drs. Klein, Wender, and Jefferson to development the certification exam in psychopharmacology. He served as President of the ASCP from 1999 to 2003. He also served as Editor of the ASCP Corner in the Journal of Clinical Psychiatry from 2008 to 2018 and continues to serve on the Editorial Board of the Journal of Clinical Psychiatry.

2022-2023 ASCP Nina Schooler Early Career Research Awardee



David Liebers, M.D. New York University

Nominated for: Open Label Study of Empagliflozin in Major Depressive Disorder (MDD)

David Liebers is a PGY-3 Psychiatry Resident at NYU Grossman School of Medicine in the Research Career Development Track. Originally from Niskayuna, NY, he earned an M.D. From Harvard

Medical School, M.Phil. in History and Philosophy of Science at Trinity College, Cambridge (UK), and completed undergraduate studies at the University of Rochester. His research interest focuses on the study of novel therapeutics for mood disorders that target abnormal brain bioenergetic metabolism, and is currently recruiting for a clinical trial of SGLT2 inhibitor empagliflozin in MDD.





Muharrem Baytunca, M.D. University of Utah

Mandakh Bekhbat, Ph.D. Emory University School of Medicine

Benedetta Bigio, Ph.D. New York University School of Medicine

Brenda Cabrera Mendoza, M.D., Ph.D. Yale University

Joao De Aquino, M.D. Yale University School of Medicine

Donald Egan, M.D., M.P.H. The University of Texas Southwestern Medical Center

Gilmar Gutierrez, M.D. Queen's University Faculty of Medicine

Rahat Hossain, M.D. University of Toronto

Shixie Jiang, M.D. Stanford University School of Medicine

Boney Joseph, M.D. Mayo Clinic Bridget Kajs, Ph.D. Janssen

Steven Lamontagne, Ph.D. National Institute of Mental Health

Marzieh Majd, Ph.D., Pharm.D. Brigham and Women's Hospital, Harvard Medical School

Alessandro Miola, M.D. Mayo Clinic

Ritvij Satodiya, M.D. Emory University School of Medicine

Emily Smith, B.Sc. Centre for Addiction and Mental Health, University of Toronto

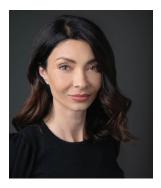
Nicolette Stogios, B.Sc. Centre for Addiction and Mental Health, University of Toronto

Brian Sweis, M.D., Ph.D. Icahn School of Medicine At Mount Sinai

Javier Vargas Medrano, Ph.D. Texas Tech University Health Sciences Center School of Medicine



Regulatory Plenary: *Pediatric Drug Development in Psychiatry* Wednesday, May 31st: 8:30 a.m. – 10:00 a.m. EDT



Valentina Mantua, M.D., Ph.D. US Food and Drug Administration

Valentina Mantua is medical doctor and psychiatrist with a PhD in neurobiology. She has over ten years of working experience in regulatory science. She served in high-level positions within the European Medicines Agency (EMA) for 7 years and also obtained relevant experience of the US regulatory environment in the last 3 years at the FDA, where is currently serving as a clinical team leader in the Division of Psychiatry.

While at EMA (January 2013-October 2019) she served as Italian delegate to several committees and working parties including the Scientific Advice Working Party, the Central Nervous System Working Party and the European (EU) Innovation Network. Her main roles and responsibilities included review of marketing authorization applications, coordination of scientific advice procedures, qualification of biomarkers, outcomes and novel methodologies for use in drug development. In her policy roles she worked towards establishing new regulatory frameworks for the regulation of innovative products and particularly digital tools for use in drug development.

She represents the FDA to external committees and working groups, including scientific societies and other government organizations such as the NIH and the FINH.

Valentina is a member of the program committee of the American Society of Clinical Psychopharmacology (ASCP); and holds a temporary professorship at the University of Modena and Reggio Emilia in Italy, where she teaches clinical research methods in neuropsychopharmacology.



ASC

Tiffany Farchione, M.D. US Food and Drug Administration

Dr. 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 in the Office of Neuroscience at FDA, Dr. Farchione is involved in the oversight of new drug review for all psychiatric drug development activities conducted under INDs, and the review of all NDAs and supplements for new psychiatric drug claims.



John J. Alexander, M.D., M.P.H. US Food and Drug Administration

Dr. Alexander is Deputy Director of the Division of Pediatrics and Maternal Health in the Center for Drug Evaluation and Research at FDA. Dr. Alexander is a pediatrician who joined the US Food and Drug Administration in 1995 as part of a joint fellowship in pediatric infectious diseases with FDA and Children's National Medical Center. After completion of his

fellowship, he became a full-time medical officer, and subsequently a team leader, in the Division of Anti-Infective Products. Dr. Alexander also obtained a Masters in Public Health degree from the George Washington University School of Public Health in 2001. He has been involved in drug regulation and pediatric drug development for more than 25 years.





Manpreet Singh, M.D. Stanford University School of Medicine

Dr. Singh is Associate Professor of Psychiatry and Behavioral Sciences and Director of the Pediatric Mood Disorders Program and the Pediatric Emotion And Resilience Lab (PEARL) at Stanford University. Her research focuses on investigating the origins and pathways for developing major mooddisorders during childhood, as well as on methods to protect and preserve function after symptom onset.

Taking a translational medicine approach, Dr. Singh's patient-oriented research focuses on meeting patient unmet needs in psychiatry through research that aims to accelerate understanding of and treatment in individuals with or at high risk for developing lifelong psychiatric disorders. She applies cutting edge research strategies to optimize existing therapeutic targets through innovations in trial design, investigations of placebo response, and pursuit of novel therapeutic targets through reverse and forward translation, fast-fail clinical trials, and direct modulation of key brain regions using transcranial magnetic stimulation and real-time neurofeedback. She is also investigating the comparative effectiveness and safety of existing pharmacotherapies and psychotherapies for youth with and at risk for major mood disorders, such as antidepressants, family focused psychotherapy, and mindfulness meditation to reduce mood symptoms and family stress.



ASC

Nina Schooler, Ph.D. State University of New York Downstate Health Sciences Center

Dr. Schooler is a Professor of Psychiatry and Behavioral Sciences in the Department of Psychiatry at State University of New York Downstate Health Sciences Center, Brooklyn, NY. Her research focuses on treatment of schizophrenia from its earliest identification to long-term course and outcomes.

She received her Ph.D. in social psychology from Columbia University and later served in leadership positions at the National Institute of Mental Health, where she led a series of significant multicenter clinical trials of medication and psychosocial treatments for schizophrenia. She subsequently joined the Department of Psychiatry at the University of Pittsburgh, where she directed the Psychosis Research Program and was Professor of Psychiatry and Psychology. She then served as Director of Psychiatry Research at the Zucker Hillside Hospital, conducting research in treatment of first-episode psychosis and negative symptoms in schizophrenia until moving to her present position.

Dr. Schooler is a fellow of the American College of Neuropsychopharmacology, the Collegium Internationale Neuro-Psychopharmacologicum (CINP), the American Psychological Association, and the Association for Psychological Science). She has been president of the American Psychopathological Association and the Association for Clinical Psychosocial Research and has served as an elected Councillor of the CINP and the Board of the Schizophrenia International Research Society. She has published widely in the peer-reviewed psychiatric literature and has served as an editor for volumes relating to psychiatric clinical trials, clinical assessment, and research methods.

Dr. Schooler's contributions to the field have been recognized through 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 Prize from the American Psychological Foundation, the Hamilton Award from the American Psychopathological Association, the Andrew Leon Award from the International Society for CNS Clinical Trials, the Lifetime Achievement Award from the American Society for Clinical Psychopharmacology (ASCP). She has also been honored to have the ASCP Early Career Research Award named in her honor.



Clinical Updates in Neurotherapeutics

Wednesday, May 31st: 1:00 p.m. - 2:30 p.m. EDT



Gerard Sanacora, M.D., Ph.D. Yale

Dr. Sanacora is the George and Ester Gross Professor of Psychiatry, Director of the Yale Depression Research Program, and Co-Director of Yale's Interventional Psychiatry Program. Dr. Sanacora's work employs both preclinical and clinical research methodologies in attempts to expand our understanding of the underlying pathophysiology of neuropsychiatric disorders and mechanisms of effective treatment actions, with the goal of ultimately developing novel diagnostic and

treatment approaches. He has served as PI on numerous NIH, foundation, and industry sponsored studies ranging from rodent models of pathogenesis, through mechanistic neuroimaging studies introducing novel MRS methods, to large multi-center phase III clinical trials. His personal experience over the arc of this journey has provided him with unique perspectives on the challenges that impede the successful application of neuroscience advances to psychiatric practice and led him to foster a broadly diverse, open-minded but rigorous, interdisciplinary collaborative team approach to translational neuroscience. In recognition of these efforts, he recently received the 2022 Association for Clinical and Translational Sciences award for Team Science in addition to previous awards including the Anna-Monkia Stiftung international award for *investigation of the biological substrate and functional disturbances of depression*, the Joel Elkes Research Award for *Outstanding contributions to Psychopharmacology* from ACNP.



ASCP

Gary Small, M.D. David Geffen School of Medicine at UCLA

Gary Small, M.D., is Chair of Psychiatry at Hackensack University Medical Center, Behavioral Health Physician-in-Chief and the Hovnanian Family Foundation Endowed Chair in Behavioral Health for Hackensack Meridian *Health*. He is a co-inventor of the first positron emission tomography (PET) scanning method that provides images in living people of the physical evidence of Alzheimer's

disease. In addition to testing compounds that may benefit cognitive abilities and possibly delay the onset of Alzheimer's disease symptoms, Dr. Small has studied and developed lifestyle and memory training programs for improving cognition and healthy aging. Dr. Small has authored over 500 scientific works and received numerous awards and honors, including the American Psychiatric Association's Weinberg Award for Excellence in Geriatric Psychiatry. *Scientific American* magazine named him one of the world's top 50 innovators in science and technology. He is the author of 12 popular books, including *The New York Times* bestseller, *The Memory Bible*.



W. Curt LaFrance Jr., M.D., M.P.H. Rhode Island Hospital/Brown University

W. Curt LaFrance Jr., M.D., M.P.H., FAAN, FANPA, DFAPA is Director of Neuropsychiatry and Behavioral Neurology at Rhode Island Hospital, Director of the VA Mind Brain Program, Professor of Psychiatry and Neurology at Brown University, and is double boarded in neurology and psychiatry. He mentors students, residents, and faculty in neuropsychiatric diagnosis, treatment and research and he trains

clinicians around the country in neurobehavioral therapy (NBT) using distance supervision.



Keynote Plenary: The Changing Landscape of Clinical Psychiatry: Novel Therapeutics, Methods and Assessments Thursday, June 1st: 8:15 a.m. - 9:45 a.m. EDT



K. Ranga Krishnan, M.D. Rush

Chairman Psychiatry and Behavioral; science Duke University 1998 - 2009 Dean Duke-NUS Singapore 2008-2015 Dean Rush Medical College 2015- 2019 CEO Rush University Heal System 2019-2022 Executive Vice Chairman Rush University Health system 2022 to present

Chairman National Medical Research Council Singapore



Andrew Nierenberg, M.D. Massachusetts General Hospital

In addition to leading the Dauten Center, Dr. Andrew Nierenberg serves as the co-director of Mass General's Center for Clinical Research Education and as associate director of the Depression Clinical and Research Program. He also holds the Thomas P. Hackett, M.D., Endowed Chair in Psychiatry Mass

General and teaches as a professor of Psychiatry at Harvard Medical School.

Dr. Nierenberg graduated from the Albert Einstein College of Medicine of Yeshiva University, Bronx, NY. After completing his residency in psychiatry at New York University/Bellevue Hospital, he studied clinical epidemiology at Yale University as a Robert Wood Johnson Clinical Scholar. Dr. Nierenberg then joined the faculty at Harvard Medical School, first at McLean Hospital in Belmont, MA and then at Massachusetts General Hospital, where he holds his current positions. He is also Honorary Professor in the School of Medicine, Faculty of Health at Deakin University, Geelong Australia, and Honorary Skou Professor at Aarhus University in Denmark.

Dr. Nierenberg has published over 575 papers and has been listed in The Best Doctors in America for the treatment of mood and anxiety disorders in every edition since 1994. He currently serves as the Vice President of Research for the International Society for Bipolar Disorders and was honored with the Mogens Schou Award for Research in 2020 — one of many awards he has received for his pioneering work.



ASCI

John Torous, M.D. Beth Israel Deaconess Medical Center & Harvard Medical School

John Torous, M.D., MBI, is director of the digital psychiatry division, in the Department of Psychiatry at Beth Israel Deaconess Medical Center, a Harvard Medical School affiliated teaching hospital, where he also serves as a staff psychiatrist and assistant professor. He has a background in electrical engineering and computer sciences and received an

undergraduate degree in the field from UC Berkeley before attending medical school at UC San Diego. He completed his psychiatry residency, fellowship in clinical informatics, and master's degree in biomedical informatics at Harvard. Dr. Torous is active in investigating the potential of mobile mental health technologies for psychiatry and has published over 250 peer reviewed articles and 5 book chapters on the topic. He also directs a clinic that integrates digital mental health approaches like smartphone digital phenotyping to augment care for patients. He serves as editor-in-chief for JMIR Mental Health, web editor for JAMA Psychiatry, and currently leads the American Psychiatric Association's Health IT Committee.



Update from Federal and Other Funding Agencies Thursday, June 1st: 10:00 a.m. – 11:30 a.m. EDT



Josh Gordon, M.D., Ph.D. National Institute of Mental Health

Joshua A. Gordon, M.D., Ph.D. is the Director of the National Institute of Mental Health (NIMH), the lead federal agency for research on mental disorders. He oversees an extensive research portfolio of basic and clinical research that seeks to transform the understanding and treatment of mental illnesses, paving the way for prevention, recovery, and cure.

Dr. Gordon pursued a combined M.D.-Ph.D. degree at the University of California, San Francisco (UCSF). Medical school coursework in psychiatry and neuroscience convinced him that the greatest need, and greatest promise, for biomedical science was in these areas.

During his Ph.D. thesis with Dr. Michael Stryker, Dr. Gordon pioneered the methods necessary to study brain plasticity in the mouse visual system. Upon completion of the dual degree program at UCSF, Dr. Gordon went to Columbia University for his psychiatry residency and research fellowship because of the breadth and depth of the research opportunities there. Working with Dr. Rene Hen, Dr. Gordon and colleagues studied the role of the hippocampus, a brain structure known to be important for memory and emotional processes associated with anxiety and depression. He joined the Columbia faculty in 2004 as an assistant professor in the Department of Psychiatry.

Dr. Gordon's research focuses on the analysis of neural activity in mice carrying mutations of relevance to psychiatric disease. His lab studied genetic models of these diseases from an integrative neuroscience perspective, focused on understanding how a given disease mutation leads to a behavioral phenotype across multiple levels of analysis. To this end, he employs a range of systems neuroscience techniques, including in vivo imaging, anesthetized and awake behavioral recordings, and optogenetics, which is the use of light to control neural activity. His research has direct relevance to schizophrenia, anxiety disorders, and depression.

In addition to his research, Dr. Gordon was an associate director of the Columbia University/New York State Psychiatric Institute Adult Psychiatry Residency Program, where he directed the neuroscience curriculum and administered research training programs for residents. Dr. Gordon also maintained a general psychiatric practice, caring for patients who suffer from the illnesses he studied in his lab at Columbia.

Dr. Gordon's work has been recognized by several prestigious awards, including the Brain and Behavior Research Foundation – NARSAD Young Investigator Award, the Rising Star Award from the International Mental Health Research Organization, the A.E. Bennett Research Award from the Society of Biological Psychiatry, and the Daniel H. Efron Research Award from the American College of Neuropsychopharmacology.



ASCE

George Koob, Ph.D. National Institute on Alcohol Abuse and Alcoholism

George F. Koob, is Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) as of January 27, 2014. He is also a Senior Investigator at the Intramural Research Program of the National Institute on Drug Abuse where he directs the Neurobiology of Addiction Laboratory in the Integrative Neurosciences Research Branch. As

an authority on alcoholism, drug addiction and stress, he has contributed to our understanding of the neurocircuitry associated with the acute reinforcing effects of alcohol and drugs of abuse and the neuroadaptations of the reward and stress circuits associated with the transition to dependence. Dr. Koob has published over 750 peer reviewed papers and several books including the "Neurobiology of Addiction," a comprehensive treatise on emerging research in the field, and a textbook for upper division undergraduates and graduate students called "Drugs, Addiction and the Brain." He has mentored or comentored 13 Ph. D students and 84 post-doctoral fellows and 11 K99's. He received his Ph.D. in Behavioral Physiology from Johns Hopkins University in 1972. He spent much of his early career at the Scripps Research Institute as the Director of the Alcohol Research Center, and as Professor and Chair of the Scripps' Committee on the Neurobiology of Addictive Disorders. Dr. Koob is the recipient of many honors, including membership in the National Academy of Medicine (USA) and award of the Legion of Honor (France).

ASCP



Ivan Montoya, M.D., M.P.H. National Institute on Drug Abuse

Dr. Montoya is a psychiatrist and epidemiologist who specializes in the development of therapeutics for Substance Use Disorders (SUDs). He provides programmatic oversight for grants and contracts in DTMC, and manages activities and resources of the Division involved in the research of new therapeutics and the medical consequences of SUDs. He also provides

medical oversight to grants and contracts, as well as supports the development and implementation of policies and procedures for data and medical safety monitoring of clinical trials. He leads the NIH's Helping to End Addiction Long Term (HEAL) Initiative to develop new interventions to prevent and treat opioid use disorders and overdose. Previous experience includes seven years as a clinical investigator in the Intramural Research Program of NIDA, and four years in academia. He joined NIDA Extramural Research Program in December of 1999.



Elisabeth Houtsmuller, Ph.D. Patient-Centered Outcomes Research Institute

Elisabeth Houtsmuller, Ph.D., is an Associate Director in the Healthcare Delivery and Disparities Research program at the Patient-Centered Outcomes Research Institute (PCORI). Before PCORI, Houtsmuller led the Green Park Collaborative at the Center for Medical Policy Technology, where she also served as vice president of research. Prior to her work at CMTP, she was managing

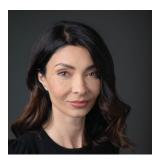
editor of health technology assessments (HTAs) at Hayes, Inc., leading a team of writers and the production of numerous HTAs on a wide range of medical and mental health topics. In addition, she led the Behavioral and Mental Health Services program at Hayes, Inc.

Earlier, Houtsmuller was an associate professor in the Department of Psychiatry at the Johns Hopkins University School of Medicine, where she served as principal investigator on several research grants, and directed a human subjects research laboratory focused on drug abuse and addiction. Her work has been published in numerous peer-reviewed papers, book chapters and health technology assessments. Houtsmuller serves as the Chair of an IRB for a small research group in Baltimore.

Houtsmuller received a Ph.D. in physiological psychology from Erasmus University in the Netherlands, and completed postdoctoral work at the Johns Hopkins University School of Medicine in Baltimore.



Regulatory Challenges: Ask the Experts Friday, June 2nd: 10:15 a.m. – 11:15 a.m. EDT



Valentina Mantua, M.D., Ph.D. US Food and Drug Administration

See Dr. Mantua's biography above.



Tiffany Farchione, M.D. US Food and Drug Administration

See Dr. Farchione's biography above.



Bernard Fischer, M.D. US Food and Drug Administration

Dr. Fischer is a psychiatrist and Deputy Director for the Division of Psychiatry in the Office of New Drugs at the U.S. Food and Drug Administration (FDA). Prior to coming 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 over 50 scientific publications.



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Meeting Announcements | ASCP

Registration Desk Hours: Botunda East - Second Level

Monday	1:00 p.m. – 5:00 p.m.
Tuesday	7:30 a.m. – 6:00 p.m.
Wednesday	7:30 a.m. – 7:00 p.m.
Thursday	7:30 a.m. – 6:00 p.m.
Friday	7:30 a.m. – 12:00 p.m.

Speaker Ready Room Hours:

New Yorker

Monday	1:00 p.m 5:00 p.m.
Tuesday	7:30 a.m 6:00 p.m.
Wednesday	7:30 a.m. – 6:00p.m.
Thursday	7:30 a.m. – 5:30 p.m.
Friday	7:30 a.m 10:30 a.m.
The meeting organizers	ask that all speakers upload their

24 hours prior to their scheduled presentation time.

ASCP Wi-Fi

SSID: ASCP2023 Access PIN: ASCP2023

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- Complimentary basic wireless internet in all guest rooms
- Fitness Center admittance

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slides no later than

ASCP Meeting Announcements

Continuing Education Credits

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American Society of Clinical Psychopharmacology 2023 ASCP Annual Meeting May 30, 2023 – June 2, 2023 Miami, FL

Joint Accreditation Statement



In support of improving patient care, this activity has been planned and implemented by Amedco LLC and American Society of Clinical Psychopharmacology (ASCP). Amedco LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation

Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Amedco Joint Accreditation #4008163

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Meeting Announcements

ASCP

Psychologists (APA) Credit Designation



This course is co-sponsored by Amedco and American Society of Clinical Psychopharmacology. Amedco is approved by the American Psychological Association to sponsor continuing education for psychologists. Amedco maintains

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The following state boards accept courses from APA providers for Counselors: AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, MD, ME, MO, NC, ND, NH, NE, NJ, NM, NV, OK*, OR, PA, RI, SC, SD, TN, TX, UT, VA, WI, WY

MI: No CE requirements.

*OK: Accepts APA credit for live, in-person activities but not for ethics and/or online courses.

The following state boards accept courses from APA providers for MFTs: AK, AR, AZ, CA, CO, CT, DE, FL, GA, IA, ID, IN, KS, MD, ME, MO, NE, NC, NH, NJ, NM, NV, OK*, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, WY

AL MFTs: Credits authorized by NBCC or any other state licensing agency will be accepted.

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Amedco is recognized by the New York State Education Department's State Board for Psychology as an approved provider of continuing education for licensed psychologists #PSY-0031. **19.25** hours.

All evaluations must be complete by Monday, July 3, 2023.

The Meeting Evaluation Survey will be available at <u>https://ascpp.org/ascp-meetings/ascp-annual-meeting/</u>. We encourage all registrants to complete the evaluation. Attendees requesting CME, MOC, or CE credits must complete the survey in order to obtain credits. There is a \$40.00 administrative fee for CME/ CE applications. Your candid input on the 2023 meeting is appreciated as we strive to improve the meeting each year.

ASCP Meeting Announcements

ASCP would like to acknowledge the generosity of the following companies whose unrestricted educational grants have contributed to the overall quality of this meeting:

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2024 ASCP Annual Meeting

Save the Date



The 2024 ASCP Annual Meeting will take place May 28-May 31, 2024. 2024 Annual Meeting will be released in September 2023.





Thank you to our sponsors for their support.

<u>GOLD</u>





SILVER









Notes

Monday, May 29, 2023 ASCP

AT-A-GLANCE

Sunday, May 28, 2023

6:00 p.m 7:00 p.m.	New Investigator Award (NIA) Meet and Greet
	(Invitation Only) Venus

Monday, May 29, 2023

8:00 a.m 4:55 p.m.	NIA Workshop (Invitation Only) Cowrie
1:00 p.m 5:00 p.m.	Registration Rotunda East - Second Level
1:00 p.m 5:00 p.m.	Speaker Ready Room New Yorker



Notes

Monday, May 29, 2023 ASCP

FULL SCHEDULE

Monday, May 29, 2023

- 8:00 a.m. 4:55 p.m. NIA Workshop (Invitation Only) Cowrie
- **Co-Chairs:** Mark Rapaport, University of Utah Huntsman Mental Health Institute Chris Sarampote, National Institute of Mental Health

The ASCP Annual Meeting offers a special program for New Investigators in an effort to promote the education and training of junior investigators in psychopharmacology. Established investigators were asked to nominate individuals who may be interested in a research career in psychopharmacology for this special program. These nominees submitted an abstract describing their current research or area of research interest, a letter of recommendation from their chair or mentor, a career statement, and a curriculum vitae. The selection of awardees was based upon the scientific merit of the abstract, the level of training of the nominee and a committee of internal and external reviewers' assessment of the relative value of the specialized program to each applicant at this time in his/her career. The awardees will participate in this special educational workshop and present their posters during the scheduled poster sessions and orals during the Individual Research Reports on Tuesday, May 30, 2023. In addition, they will receive a travel expense award and a certificate acknowledging their participation in the program at an awards ceremony on Tuesday evening, May 30, 2023. This year marks the 31st year of the New Investigator program with 20 New Investigator awardees that are indicated with a ribbon in the poster session of this program; they will also be notated with a ribbon icon in the program book.

Faculty		
Lori Davis, Veterans Affairs Medical Center	Katharine Phillips, Weill Cornell Medical College/New York- Presbyterian Hospital	
Tiffany Farchione, US Food and Drug Administration	Nina Schooler, SUNY Downstate Medical Center	
Bruce Kinon, Karuna Therapeutics		
Iván Montoya, National Institute on Drug Abuse	Holly Swartz, University of Pittsburgh School of Medicine	



Notes

Tuesday, May 30, 2023ASCP

AT-A-GLANCE

Tuesday, May 30, 2023

7:15 a.m 8:15 a.m.	PCAN Meeting (Invitation Only) Crown Conch
7:30 a.m 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Neptune
7:30 a.m 9:00 a.m.	Morning Break Americana Foyer
7:30 a.m 6:00 p.m.	Registration Rotunda East - Second Level
7:30 a.m 6:00 p.m.	Speaker Ready Room New Yorker
8:30 a.m 9:00 a.m.	Conference Opening Salon 3

9:00 a.m. - 10:30 a.m. Panel Sessions

*^ COVID-19,	* 3 Innovations	**How to Make	*Drug Discovery
Paxlovid and	in Psychophar-	Progress	and Precision
Clozapine -	macology	in Suicide	Medicine
Education and	Education:	Prevention:	Approaches to
Dissemination	Digital Psychiatry	Designing and	Reduce Clinical
of Knowledge	Courses, Patients	Conducting	Burden of
and the Need	as Teachers, and	Clinical Trials	Substance Use
for Clinical	Novel Ketamine	Among High-	Disorders
Vigilance	Journal Club	Risk Patients	
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2

10:30 a.m. - 11:00 a.m. Break

Americana Foyer

Tuesday

ASCP Tuesday, May 30, 2023

11:00 a.m. - 12:30 p.m. **Panel Sessions**

	·	5	
*#Irritability	⁺Expanding	*An Evidence-	**#Improving
Across the	Clinical Trial	Based Approach to	the Quality of
Lifespan:	Diversity:	Psychopharmacology	Psychopharma-
Causes,	LGBTQIA+	for Posttraumatic	cologic Treatment
Assessments,	Inclusion	Stress Disorder	for Children,
Treatments		(PTSD) - 2022 Update	Adolescents, and
			Adults
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2

12:30 p.m 2:00 p.m.	Inclusivity and Early Career Luncheon: Leveraging Data Sets: Clinics to Large Data and the Value of Diversity (RSVP Only) Cowrie
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- 2:00 p.m. 4:00 p.m. ⁺Pharmaceutical Pipeline Session Salon 3
- 4:00 p.m. 4:15 p.m. Break Americana Foyer
- 4:15 p.m. 5:30 p.m. Individual Research Reports

⁺ Novel Treatments and Comprehensive Evaluation for Depression and PTSD	Recent Advances in Treatment of Substance Use Disorders and Eating Disorders: Clinical Trials and Epidemiologic Studies	Recent Advances in the Treatment of Schizophrenia	⁺ Innovations in Biomarkers and Treatment Targets for Precision Medicine
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2

6:15 p.m. - 7:45 p.m. New Investigator Awards Ceremony (Invitation Only) Cowrie

7:30 p.m. - 9:30 p.m. ASCP Board Meeting (Invitation Only) Crown Conch

Tuesday, May 30, 2023ASCP

FULL SCHEDULE

Tuesday, May 30, 2023

7:15 a.m. – 8:15 a.m.	PCAN Meeting (Invitation Only) Crown Conch
7:30 a.m 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Neptune
7:30 a.m 9:00 a.m.	Morning Break Americana Foyer
7:30 a.m 6:00 p.m.	Registration Rotunda East - Second Level
7:30 a.m 6:00 p.m.	Speaker Ready Room New Yorker
8:30 a.m 9:00 a.m.	Conference Opening Salon 3

Panel Sessions

9:00 a.m 10:30 a.m.	*^ COVID-19, Paxlovid and Clozapine - Education and Dissemination of Knowledge and the Need
	for Clinical Vigilance Poinciana 1-2

Chair: Roy Chengappa, University of Pittsburgh Medical Center Discussant: Roy Chengappa, University of Pittsburgh Medical Center

9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m 9:30 a.m.	Paxlovid and Clozapine – Pharmacokinetic and Pharmacodynamic Considerations Jonathan Leung, Mayo Clinic
9:30 a.m 9:50 a.m.	Covid and the Clozapine Clinic: Educating Patients and Families about COVID-19 Induced Clozapine Toxicity and Paxlovid Jessica Gannon, University of Pittsburgh School of Medicine

ASCP Tuesday, May 30, 2023

9:00 a.m 10:30 a.m. (continued)	*^ COVID-19, Paxlovid and Clozapine - Education and Dissemination of Knowledge and the Need for Clinical Vigilance Poinciana 1-2
9:50 a.m 10:10 a.m.	Leveraging SMI Adviser's Community and Infrastructure to Rapidly Disseminate Critical Information on COVID-19, Paxlovid, and Clozapine Robert Cotes, Emory University School of Medicine
10:10 a.m. – 10:30 a.m.	Discussion
9:00 a.m 10:30 a.m.	*^ 3 Innovations in Psychopharmacology Education: Digital Psychiatry Courses, Patients as Teachers, and Novel Ketamine Journal Club Poinciana 3-4

Chair: Sagar Parikh, University of Michigan **Discussant:** Leslie Citrome, New York Medical College

9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m 9:30 a.m.	Evaluating Novel CME Approaches to Teach Clinicians How to Use Mental Health Apps and Websites Sagar Parikh, University of Michigan
9:30 a.m 9:50 a.m.	The Other Expert in the Room: Persons with Lived Experience Leslie Citrome, New York Medical College
9:50 a.m 10:10 a.m.	The Ketamine International Journal Club: A Novel Journal Club Format on the Use of Ketamine and Related Compounds For Psychiatric Disorders Sara Costi, University of Oxford
10:10 a.m. – 10:30 a.m.	Discussion

Tuesday, May 30, 2023ASCP

9:00 a.m 10:30 a.m.	**How to Make Progress in Suicide Prevention: Designing and Conducting Clinical Trials Among High Risk Patients Salon 1
Chair: Samuel Wilkinson, Discussant: Larry Alphs,	
9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m 9:25 a.m.	Testing the Real-World Effectiveness of a Synergistic, Neuroplasticity-Based Intervention for Rapid and Durable Suicide Risk Reduction Rebecca Price, University of Pittsburgh
9:25 a.m 9:40 a.m.	A Suicide Prevention Trial of Lithium at the VA: Conducting Trials in People at High Risk of Suicide Michael Ostacher, Stanford University School of Medicine
9:40 a.m 9:55 a.m.	Designing and Implementing Studies in Patients with MDD at Imminent Risk for Suicide: Insights from a Drug Development Program Carla Canuso, Janssen Research and Development
9:55 a.m 10:10 a.m.	How to Make Progress in Suicide Prevention:

Designing and Conducting Clinical Trials Among High Risk Patients Samuel Wilkinson, Yale School of Medicine

10:10 a.m. – 10:30 a.m. **Discussion**

ASCP Tuesday, May 30, 2023

9:00 a.m 10:30 a.m.	*Drug Discovery and Precision Medicine
	Approaches to Reduce Clinical Burden of
	Substance Use Disorders
	Salon 2

Chair: Madhukar Trivedi, University of Texas Southwestern Medical Center **Discussant:** Manish Jha, University of Texas Southwestern Medical Center

9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m 9:25 a.m.	Protection against Cocaine-Seeking via Enhancement of Serotonergic Aversive Response to Cocaine Thomas Jhou, Medical University of South Carolina
9:25 a.m 9:40 a.m.	Impact of Cannabis Use on COVID-19 Outcomes and New Treatment Targets for Cannabis Use Disorder Rajiv Radhakrishnan, Yale School of Medicine
9:40 a.m 9:55 a.m.	Immune Mechanisms of Response to Naltrexone-Bupropion Combination in Methamphetamine Use Disorder: Findings from the ADAPT-2 Study Madhukar Trivedi, University of Texas Southwestern Medical Center
9:55 a.m 10:10 a.m.	Setting the Stage for Personalizing Treatment of Substance Use Disorder: Neuro-Psychosocial Determinants Keren Bachi, The Addiction Institute of Mount Sinai; Icahn School of Medicine at Mount Sinai
10:10 a.m. – 10:30 a.m.	Discussion
10:30 a.m 11:00 a.m.	Morning Break Americana Foyer

Tuesday, May 30, 2023 ASCP

Panel Sessions

11:00 a.m 12:30 p.m.	**Irritability Across the Lifespan: Causes, Assessments, Treatments Poinciana 1-2		
	Chair: Maurizio Fava, Massachusetts General Hospital Discussant: Sagar Parikh, University of Michigan		
11:00 a.m. – 11:05 a.m.	Introduction		
11:05 a.m 11:30 a.m.	Irritability and Suicidal Ideation in Depressive Disorders Across Lifespan: Clinical Significance and Potential Neurocircuit Mechanisms Manish Jha, University of Texas Southwestern Medical Center		
11:30 a.m 11:55 a.m.	An Update on Irritability in Youth with Attention- Deficit/Hyperactivity Disorder Raman Baweja, Penn State College of Medicine		
11:55 a.m 12:20 p.m.	Informant Effects on Measures of Irritability in Youths and Potential Sex Differences: Findings from the TX-YDSRN Study Madhukar Trivedi, University of Texas Southwestern Medical Center		
12:20 p.m. – 12:30 p.m.	Discussion		
11:00 a.m 12:30 p.m.	*Expanding Clinical Trial Diversity: LGBTQIA+ Inclusion Poinciana 3-4		
Chair: Francisco Moreno Discussant: Francisco M	, University of Arizona Ioreno, University of Arizona		
11:00 a.m. – 11:05 a.m.	Introduction		
11.05 a m - 11.30 a m	Expanding Clinical Trial Diversity Revond Bace		

11:05 a.m. - 11:30 a.m. **Expanding Clinical Trial Diversity Beyond Race** and Ethnicity Brian Rothman, Otsuka Pharmaceutical Development and Commercialization, Inc.

ASCP Tuesday, May 30, 2023

11:00 a.m 12:30 p.m. (continued)	*Expanding Clinical Trial Diversity: LGBTQIA+ Inclusion Poinciana 3-4
11:30 a.m 11:55 a.m.	Expanding Clinical Trial Diversity Beyond Race and Ethnicity Candace Saldarini, Otsuka (OPDC)
11:55 a.m 12:20 p.m.	Expanding Clinical Trial Diversity Beyond Race and Ethnicity Mitchell Lunn, Stanford University School of Medicine
12:20 p.m. – 12:30 p.m.	Discussion
11:00 a.m 12:30 p.m.	*An Evidence-Based Approach to Psychopharmacology for Posttraumatic Stress Disorder (PTSD) - 2022 Update Salon 1

Chair: David Osser, VA Boston Healthcare System **Discussant:** Murray Raskind, Veterans Affairs Puget Sound Health Care System

- 11:00 a.m. 11:05 a.m. Introduction
- 11:05 a.m. 11:30 a.m. An Evidence-Based Approach to Psychopharmacology for Posttraumatic Stress Disorder (PTSD) - 2022 Update Laura Bajor, Veterans Affairs Medical Center
- 11:30 a.m. 11:55 a.m. Update of the Latest Treatments for Posttraumatic Stress Disorder (PTSD) Charmi Balsara, HCA FL Aventura Hospital
- 11:55 a.m. 12:20 p.m. Introduction, Methods of Algorithm Development, Considerations with Comorbidities that Could Affect the Algorithm, and Initial Steps David Osser, VA Boston Healthcare System

12:20 p.m. – 12:30 p.m. Discussion

Tuesday, May 30, 2023

11:00 a.m 12:30 p.m.	***Improving the Quality of Psychopharmacologic
	Treatment for Children, Adolescents, and Adults
	Salon 2

Chair: Ira Glick, Stanford University School of Medicine **Discussant:** John Lauriello, Thomas Jefferson University/Sidney Kimmel Medical College

11:00 a.m. – 11:05 a.m.	Introduction
11:05 a.m 11:30 a.m.	Truths and Fallacies of Psychopharmacology Nassir Ghaemi, Tufts University/Harvard Medical School
11:30 a.m 11:55 a.m.	Thinking about Prescribing: The Psychology of Psychopharmacology with Diverse Youth and Families Shashank Joshi, Stanford University School of Medicine
11:55 a.m 12:20 p.m.	Raising the Quality of Psychopharmacology Clinical Psychiatric Practice Ira Glick, Stanford University School of Medicine
12:20 p.m. – 12:30 p.m.	Discussion
12:30 p.m 2:00 p.m.	Inclusivity and Early Career Luncheon: Leveraging Data Sets: Clinics to Large Data and the Value of Diversity (RSVP Only) Cowrie

Leveraging Data Sets: Clinics to Large Data and the Value of Diversity will be chaired by Ming-Fen Ho, Ph.D., and Crystal Clark, M.D. and will focus on how early career investigators utilize existing data sets to support research aims.

Presenters: Crystal Clark, M.D., Women's College Hospital, University of Toronto John Kane, M.D., The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Mahavir Agarwal, M.D., Ph.D., Centre for Addiction and Mental Health in Canada

ASCP Tuesday, May 30, 2023

2:00 p.m. - 4:00 p.m. *Pharmaceutical Pipeline Session Salon 3

Chair: Carlos Zarate, National Institute on Mental Health **Co-Chair:** Leslie Citrome, New York Medical College

2:00 p.m. – 2:10 p.m. A Phase 2 Randomized Controlled Adjunctive Treatment Trial with CLE-100 Esketamine Tablet for Patients with Major Depressive Disorder and Inadequate Response to Antidepressants During the COVID-19 Pandemic Maurizio Fava, Massachusetts General Hospital

2:10 p.m. – 2:20 p.m. Safety and Efficacy of Karxt in Patients with Schizophrenia in the Randomized, Double-Blind, Placebo-Controlled, Phase 3 EMERGENT-2 and EMERGENT-3 Trials Stephen Brannan, Karuna Therapeutics

- 2:20 p.m. 2:30 p.m. Pharmaceutical Pipeline of BI 1358894: Clinical Evidence for an Emerging Drug for the Treatment of Mental Health Conditions Brittney Starling, Boehringer Ingelheim Pharmaceuticals Inc
- 2:30 p.m. 2:40 p.m. A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Pharmacokinetic Study of Escalating Single and Multiple Doses of CVN766, an OX1R Highly Selective Antagonist in Healthy Subjects Ottavio Vitolo, Cerevance
- 2:40 p.m. 2:50 p.m. The Therapeutic Potential of EVX-101 to Amplify Serotonin Synthesis for the Adjunctive Treatment of MDD and Other Mental illness: Emerging Profile and Post-Phase 1 Update Jacob Jacobsen, Evecxia Therapeutics

Tuesday, May 30, 2023 ASCP

2:00 p.m 4:00 p.m. (continued)	*Pharmaceutical Pipeline Session Salon 3
2:50 p.m. – 3:00 p.m.	Efficacy and Safety of Aticaprant, a Kappa Opioid Receptor Antagonist, Adjunctive to Oral SSRI/SNRI Antidepressant in Major Depressive Disorder: Results of a Phase 2a Randomized, Double-Blind, Placebo-Controlled Study Mark Schmidt, Janssen Pharmaceutica
3:00 p.m. – 3:10 p.m.	Efficacy and Safety of an Alpha 7 Nicotinic Acetylcholine Receptor Agonist, VQW-765, in Subjects with Performance Anxiety in a Randomized, Placebo-Controlled Trial Yunsheng He, Vanda Pharmaceuticals
3:10 p.m. – 3:20 p.m.	Phase 2 Study Design and New Data from the Phase 1 SAD/MAD Trial of LHP88, a Second- Generation Gingipain Inhibitor for the Treatment of P. Gingivalis-Associated Dementia Michael Detke, Detke Biopharma Consulting
3:20 p.m. – 3:30 p.m.	An Open-Label Trial Assessing Short- and Long-Term Tolerability and Efficacy of ZYN002 (Cannabidiol) Administered as a Transdermal Gel to Children and Adolescents with 22q11.2 Deletion Syndrome (INSPIRE) and Long-Term Safety and Sustained Efficacy of ZYN002 Cannabidiol Transdermal Gel in the Treatment of Behavioral Symptoms in Children and Adolescents with Fragile X Syndrome (ZYN2- CL-017) Stephen O'Quinn, Zynerba Pharmaceuticals
3:30 p.m. – 3:40 p.m.	The Emerging Safety Profile of Ulotaront: Preclinical and Clinical Evidence Seth C. Hopkins, Sunovion Pharmaceuticals, Inc.
3:40 p.m. – 4:00 p.m.	Discussion
4:00 p.m 4:15 p.m.	Afternoon Break Americana Foyer

ASCP Tuesday, May 30, 2023

Individual Research Reports

4:15 p.m 5:30 p.m.	*Novel Treatments and Comprehensive
	Evaluation for Depression and PTSD
	Poinciana 1-2

Chair: Mercedes Szpunar, Massachusetts General Hospital

4:15 p.m 4:30 p.m.	AXS-05 (Dextromethorphan-Bupropion) Significantly Improved Functioning in Major Depressive Disorder: Analysis of the Domains of the Sheehan Disability Scale Andrew Cutler, SUNY Upstate Medical University
4:30 p.m 4:45 p.m.	Reliability and Validity of the Difficult to Treat Depression Questionnaire Mark Zimmerman, Brown University
4:45 p.m 5:00 p.m.	Cariprazine as an Adjunctive Treatment for Major Depressive Disorder: Assessment of Benefit and Risk Using Number Needed to Treat and Number Needed to Harm Leslie Citrome, New York Medical College
5:00 p.m 5:15 p.m.	Efficacy and Safety Results from the Confirmatory Phase 3 Randomized, Placebo- Controlled Trial of MDMA-Assisted Therapy for Treatment of Chronic PTSD with at Least Moderate Severity Jennifer Mitchell, University of California San Francisco
5:15 p.m. – 5:30 p.m.	Discussion

Tuesday, May 30, 2023ASCP



4:15 p.m. – 5:30 p.m.	Recent Advances in Treatment of Substance Use Disorders and Eating Disorders: Clinical
	Trials and Epidemiologic Studies Poinciana 3-4

Chair: Keren Bachi, Icahn School of Medicine at Mount Sinai

4:15 p.m 4:30 p.m.	The Influence of Sex on Cannabinoid-Opioid Interactions: Sex-Dependent Effects of THC Among Persons Receiving Methadone Therapy for Opioid Use Disorder Joao De Aquino, Yale University School of Medicine
4:30 p.m 4:45 p.m.	Investigation of Self-Treatment with Lysergic Acid Diethylamide (LSD) and Psilocybin Mushrooms: Findings from the Global Drug Survey 2020 Emma Kopra, King's College London
4:45 p.m 5:00 p.m.	Naltrexone plus Bupropion Combination Medication Maintenance Treatment for Binge- Eating Disorder Following Successful Acute Treatments: Randomized Double-Blind Placebo- Controlled Trial Carlos Grilo, Yale University School of Medicine
5:00 p.m 5:15 p.m.	Hopelessness, Suicidality, and Co-Occurring Substance Use among Adolescent Hallucinogen Users—A National Survey Study Saral Desai, Tower Health - Phoenixville Hospital
5:15 p.m. – 5:30 p.m.	Discussion

😭 = New Investigator Awardee

ASCP Tuesday, May 30, 2023

4:15 p.m 5:30 p.m.	Recent Advances in the Treatment of
	Schizophrenia
	Salon 1

Chair: Rajiv Radhakrishnan, Yale University

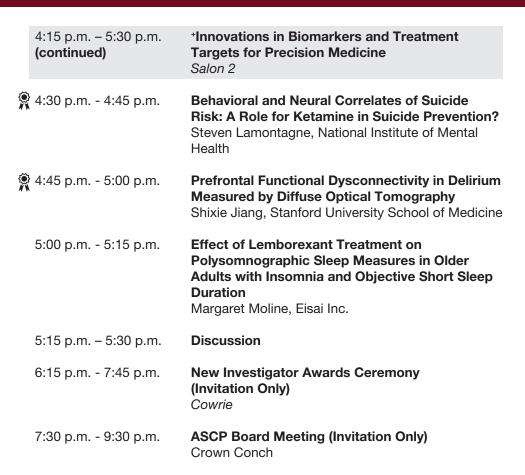
	4:15 p.m 4:30 p.m.	Investigating the Relationship Between the Kynurenine Pathway and Treatment Resistance in Schizophrenia Stefano Comai, University of Padua
	4:30 p.m 4:45 p.m.	Identifying Predictors of Clozapine- Induced Weight Gain Through a Naturalistic Retrospective Chart Review Nicolette Stogios, Centre for Addiction and Mental Health, University of Toronto
Ñ	4:45 p.m 5:00 p.m.	The Dynamic Change in Cerebral Bioenergectics in Schizophrenia Patients Muharrem Baytunca, University of Utah
	5:00 p.m 5:15 p.m.	The Efficacy of Roluperidone on Negative Symptoms and Social Functioning: Are There Qualitatively Distinct Patterns of Treatment Response? Anthony Ahmed, Weill Cornell Medical College/ NewYork-Presbyterian Hospital
	5:15 p.m. – 5:30 p.m.	Discussion
	4:15 p.m. – 5:30 p.m.	*Innovations in Biomarkers and Treatment Targets for Precision Medicine Salon 2
	Chair: Elizabeth Ballard, I	National Institute of Mental Health

4:15 p.m. - 4:30 p.m. From Relaxed Beliefs Under Psychedelics (REBUS) to Revised Beliefs After Psychedelics (REBAS) Richard Zeifman, NYU Grossman School of Medicine

🛞 = New Investigator Awardee

Tuesday, May 30, 2023

ASCP





Notes

Wednesday, May 31, 2023 ASCP

AT-A-GLANCE

Wednesday, May 31, 2023

6:30 a.m 8:00 a.m.	Annual ASCP Fun Run/Walk – All Attendees Welcome (No Prior Sign Up Necessary) Meet at the St. Moritz Lawn	
7:30 a.m 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Neptune	
7:30 a.m 9:00 a.m.	Morning Break Americana Foyer	
7:30 a.m 6:00 p.m.	Speaker Ready Room New Yorker	
7:30 a.m 7:00 p.m.	Registration Rotunda East - Second Level	
8:30 a.m 10:00 a.m.	Regulatory Plenary: Pediatric Drug Development <i>in Psychiatry</i> Salon 3	
10:00 a.m 10:15 a.m.	Break Americana Foyer	
10:15 a.m 11:15 a.m.	ASCP Awards Ceremony and ASCP Lifetime Awardee Talk – Dennis S. Charney, M.D.: The Shape of DISCOVERY: Ketamine for Treatment Resistant Depression Salon 3	
11:15 a.m 1:00 p.m.	*Poster Session I with Lunch Salon 4	
11:15 a.m 1:00 p.m.	Early Career Networking Tables (Open to all Attendees) Americana Foyer	
1:00 p.m 2:30 p.m.	*Clinical Updates in Neurotherapeutics Salon 3	
*Clinical Track. #Child/Adolescent Track. ^Academic Track		

ASCP Wednesday, May 31, 2023

2:30 p.m. - 2:45 p.m. Break

Americana Foyer

2:45 p.m. - 4:45 p.m. Workshops

Early Career Workshop: How Can I Write More? Tips and Tricks	**Facilitating Rapid Development of Medications for Substance Use Disorders and PTSD: The DoD- Pharmacotherapies for Alcohol and Substance Use Disorders Alliance (PASA)	In Press: How to Be a More Evidence- Based Author and Reviewer of the Peer- Reviewed Literature	Mid-Career Workshop: Looking at an Opportunity for Re- Focusing, Pivoting or Re-Inventing
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2

5:00 p.m. - 6:00 p.m. ASCP Business Meeting and Reception (ASCP Members Only) Poinciana 3-4

6:00 p.m. - 7:00 p.m. ASCP Reception Americana Lawn

Wednesday, May 31, 2023 ASCP

FULL SCHEDULE

Wednesday, May 31, 2023

6:30 a.m. – 8:00) a.m.	Annual ASCP Fun Run/Walk – All Attendees Welcome (No Prior Sign Up Necessary) Meet at the St. Moritz Lawn
7:30 a.m 8:30) a.m.	NIA Breakfast Roundtable (Invitation Only) Neptune
7:30 a.m 9:00) a.m.	Morning Break Americana Foyer
7:30 a.m 6:30) p.m.	Speaker Ready Room New Yorker
7:30 a.m 7:00) p.m.	Registration Rotunda East - Second Level Desk
8:30 a.m 10:0)0 a.m.	Regulatory Plenary: <i>Pediatric Drug Development</i> <i>in Psychiatry</i> <i>Salon 3</i>
Presenters:	Valentina	rchione, US Food and Drug Administration Mantua, US Food and Drug Administration cander, US Food and Drug Administration

Discussants: Manpreet Singh, Stanford University School of Medicine Nina Schooler, SUNY Downstate Health Sciences Center

This year's Regulatory Plenary will focus on pediatric drug development in psychiatry.

There is increasing evidence of time trends in the epidemiologic burden of US pediatric mental health conditions. Despite the overall number of pediatric clinical trials has increased worldwide, there are still a number of unmet needs in terms of the pharmacological treatment of pediatric psychiatric disorders and conditions for which no approved therapy is available.

The lack of well-established safety and efficacy data for this population often results in off-label prescription practices, leaving children vulnerable to potential adverse effects and poor treatment outcomes. Additionally, many psychiatric

ASCP Wednesday, May 31, 2023

8:30 a.m 10:00 a.m.	Regulatory Plenary: Pediatric Drug Development
(continued)	in Psychiatry
	Salon 3

medications are not developed with pediatric-specific formulations, making accurate dosing and administration difficult.

The FDA has released guidance documents on pediatric study plans, including content and process requirements, to streamline the development and approval of pediatric medications. Dr. Tiffany Farchione, will provide a landscape of unmet needs and the actions taken to address these unmet needs. Dr. John Alexander will talk about his experience with psychiatric study plans for various indications in psychiatry, such as ADHD, Autism Spectrum Disorder, depression and schizophrenia.

10:00 a.m 10:15 a.m.	Break Americana Foyer
10:15 a.m 11:15 a.m.	ASCP Awards Ceremony and ASCP Lifetime Awardee Talk – Dennis S. Charney, M.D.: The Shape of DISCOVERY: Ketamine for Treatment Resistant Depression Salon 3

Chair: Leslie Citrome, New York Medical College

Awards Presented to:

2023 Paul Wender Best Paper in The Journal of Clinical Psychiatry Award: Cynthia Calkin, Dalhousie University

Nominated For: Treating Insulin Resistance with Metformin as a Strategy to Improve Clinical Outcomes in Treatment-Resistant Bipolar Depression (the TRIO-BD Study): A Randomized, Quadruple-Masked, Placebo-Controlled Clinical Trial

2023 Donald Klein Lifetime Achievement Award: Dennis S. Charney, Icahn School of Medicine at Mount Sinai

The discovery of ketamine raises questions about the process of discovery. What types of environments facilitate discovery? What is the optimal size of research groups? How did the science come together that led to the initial trials? What opposition existed? What was the initial reaction? This presentation will address some of these questions.

2023 Jonathan Cole Presidential Service Award: J. Craig Nelson, University of California San Francisco

Wednesday, May 31, 2023 ASCP

11:15 a.m 1:00 p.m.	* Poster Session I with Lunch Salon 4
11:15 a.m 1:00 p.m.	Early Career Networking Tables (Open to all Attendees) Americana Foyer
1:00 p.m. – 2:30 p.m.	*Clinical Updates in Neurotherapeutics Salon 3

Chair: Lee Cohen, Massachusetts General Hospital **Co-Chair:** Rebecca Hendrickson, VA Puget Sound Health Care System

1:00 p.m. – 1:10 p.m.	Introduction
1:10 p.m. – 1:30 p.m.	Saltational Evolution in the Treatment of Depression: The Development of Rapidly Acting Antidepressant Approaches Gerard Sanacora, Yale University
1:30 p.m. – 1:50 p.m.	Detection and Treatment of Alzheimer's Disease Gary Small, David Geffen School of Medicine at UCLA
1:50 p.m. – 2:10 p.m.	Advances in Functional Neurological Disorders/ Conversion Disorders Curt LaFrance, Rhode Island Hospital/Brown University
2:10 p.m. – 2:30 p.m.	Discussion
2:30 p.m 2:45 p.m.	Afternoon Break Americana Foyer

ASCP Wednesday, May 31, 2023

<u>Workshops</u>

2:45 p.m. - 4:45 p.m. How Can I Write More? Tips and Tricks Poinciana 1-2

Chair: Rishab Gupta, Brigham and Women's Faulkner Hospital **Co-Chair:** Elizabeth Ballard, National Institute of Mental Health **Discussant:** Carlos Zarate, National Institute of Mental Health

This practical workshop will focus on productive academic writing for career advancement, teach skills to write scientific manuscripts and research proposals while engaging participants in an interactive activity of developing a specific aims page and biosketch. The first hour of the workshop will focus on the individual experiences of early career researchers in scientific writing that will be followed by brief presentations from two senior researchers on mechanics of writing manuscripts (Dr. A. John Rush) and scientific proposals (Dr. Nina Schooler). The second hour will be dedicated to hands-on interactive exercise focusing specifically on how to write a specific aims page and develop a biosketch for early career researchers who are balancing clinical duties and research demands.

Presenters: Rishab Gupta, Brigham and Women's Faulkner Hospital Elizabeth Ballard, National Institute of Mental Health Augustus Rush, Duke University School of Medicine Nina Schooler, SUNY Downstate Health Sciences Center Wednesday, May 31, 2023 ASCP

2:45 p.m 4:45 p.m.	**Facilitating Rapid Development of Medications
	for Substance Use Disorders and PTSD: The
	DoD-Pharmacotherapies for Alcohol and
	Substance Use Disorders Alliance (PASA)
	Poinciana 3-4

Chair: Thomas Kosten, Baylor College of Medicine Co-Chair: Tracy Nolen, RTI International

2:45 p.m. – 2:57 p.m.	Introduction
2:57 p.m. – 3:15 p.m.	DoD Grant Mechanisms Related to Substance Use Disorders and Overview of PASA Tracy Nolen, RTI International
3:15 p.m. – 3:33 p.m.	A Multi-Site, Placebo-Controlled Phase 2 Study of Buprenorphine and Naltrexone Extended- Release for the Treatment of Comorbid Alcohol Use and Post-Traumatic Stress Disorders Conducted During COVID-19 Lori Davis, Veterans Affairs Medical Center
3:33 p.m. – 3:51 p.m.	Successes in Translation: Rapid Medication Development for PTSD, Alcohol and Opioid Use Disorders Colin Haile, University of Houston
3:51 p.m. – 4:09 p.m.	Industry Support for Clinical Trials Sarah Akerman, Alkermes, Inc.
4:09 p.m. – 4:27 p.m.	Modulation of Noradrenergic Signaling for the Treatment of Alcohol Use Disorder in Patients with PTSD Michael De Vivo, BioXcel Therapeutics
4:27 p.m. – 4:45 p.m.	In Silico Identification of Candidate Compounds for Substance Use Disorder Repurposing Studies by Leveraging Multi-Omic Data and Resource Integration Bradley Webb, RTI International

ASCP Wednesday, May 31, 2023

2:45 p.m 4:45 p.m.	In Press: How to Be a More Evidence-Based Author and Reviewer of the Peer-Reviewed
	Literature Salon 1

Chair: Marlene Freeman, Massachusetts General Hospital, Ammon-Pinizzotto Center for Women's Mental Health

This workshop, developed by members of the ASCP-Journal of Clinical Psychiatry Liaison Task Force, is aimed at both early career and junior/mid-career clinical-investigators who wish to become more interactive members of the academic publishing community.

Presenters:Joseph Goldberg, Icahn School of Medicine at Mount Sinai
Leslie Citrome, New York Medical College
Susan Kornstein, Virginia Commonwealth University
Holly Swartz, University of Pittsburgh School of Medicine

2:45 p.m 4:45 p.m.	Mid-Career Workshop: Looking at an Opportunity for Re-Focusing, Pivoting or
	Re-Inventing Salon 2

Chair: Scott Aaronson, Sheppard Pratt

The session will be divided into two parts. The first hour will be each of our panelists sharing their personal journey and lessons learned. The second hour we will break into smaller groups for an opportunity to engage in discussions with each of our panelists.

Presenters:	Scott Aaronson, Sheppard Pratt
	Bradley Gaynes, University of North Carolina
	Gerard Sanacora, Yale
	Miles Lynn Crismon, The University of Texas at Austin
	Tiffany Farchione, US Food and Drug Administration
	Andrew Nierenberg, Massachusetts General Hospital

5:00 p.m 6:00 p.m.	ASCP Business Meeting & Reception
	(ASCP Members Only)
	Poinciana 3-4

6:00 p.m. - 7:00 p.m. ASCP Reception Americana Lawn



AT-A-GLANCE

Thursday, June 1, 2023

7:15 a.m 8:15 a.m.	NIA Breakfast Roundtable (Invitation Only) Neptune
7:30 a.m 9:00 a.m.	Morning Break Americana Foyer
7:30 a.m 5:30 p.m.	Speaker Ready Room New Yorker
7:30 a.m 6:00 p.m.	Registration Rotunda East - Second Level
8:15 a.m 9:45 a.m.	Keynote Plenary: The Changing Landscape of Clinical Psychiatry: Novel Therapeutics, Methods and Assessments Salon 3
9:45 a.m 10:00 a.m.	Break Americana Foyer
10:00 a.m 11:30 a.m.	Update From Federal and Other Funding Agencies Salon 3
11:30 a.m 12:30 p.m.	*Investigator-Industry Collaboration Session Cowrie
12:30 p.m 2:15 p.m.	*Poster Session II with Lunch Salon 4
12:30 p.m 2:00 p.m.	Early Career Networking Tables (Open to all Attendees) Americana Foyer

2:15 p.m. - 3:45 p.m. Pane

ASCP

Panel Sessions

*Repeated Psilocybin Administration in Patients with Treatment Resistant Obsessive Compulsive Disorder	Recent Updates on Assessment and Outcomes in Research on Suicidal Behaviors in Youth	Anhedonia: Translational Targets and Clinical Implications	•Enhancing Relevance for Public Health: A Focus on Diversity and Inclusion
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2

3:45 p.m. - 4:15 p.m.

Break Americana Foyer

4:15 p.m. - 6:15 p.m.

Workshop Sessions

*Best Practices to Reduce Subject and Investigator Bias in Clinical Trials	*Forging a Path to Better Clinical Trials: A Discussion on Enabling the Implementation of RWE, AIML, and Collaboration to Better Capture Patient Experience and Improve Success in Drug Development	*Psilocybin: Opportunities Across the Diagnostic Spectrum	⁺ The Academic Clinical Trialist: Saving an Endangered Species
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2



FULL SCHEDULE

Thursday, June 1, 2023

7:15 a.m 8:15 a.m.	NIA Breakfast Roundtable (Invitation Only) Neptune
7:30 a.m 9:00 a.m.	Morning Break Americana Foyer
7:30 a.m 6:00 p.m.	Registration Rotunda East - Second Level
7:30 a.m 5:30 p.m.	Speaker Ready Room New Yorker
8:15 a.m 9:45 a.m.	Keynote Plenary: The Changing Landscape of Clinical Psychiatry: Novel Therapeutics, Methods and Assessments Salon 3

Chair: Susan Kornstein, Virginia Commonwealth University

This Keynote Plenary Session will focus on the 2023 annual meeting theme about the changing landscape of clinical psychiatry: novel therapeutics, methods and assessments. First, Dr. Ranga Krishnan will provide an overview of the transformation in health care delivery from hospital-based to outpatient and telehealth with a focus on value-based care, and implications for the adoption of new treatments. Dr. Andrew Nierenberg will describe plans to develop a Bipolar Learning Health Network and its potential to transform the care of people with bipolar disorder. Finally, Dr. John Torous will discuss the evolving use of smartphone apps in psychiatry for both research and patient care.

8:15 a.m. – 8:20 a.m.	Introduction
8:20 a.m. – 8:40 a.m.	Mind Over Matter: Changing Landscape of Healthcare Delivery Implications for Mental Health Therapeutics Ranga Krishnan, Rush University

ASCP Thursday, June 1, 2023

8:15 a.m 9:45 a.m. (continued)	Keynote Plenary: The Changing Landscape of Clinical Psychiatry: Novel Therapeutics, Methods and Assessments Salon 3
8:40 a.m. – 9:00 a.m.	A Bipolar Learning Health Network: A Model for Improving Outcomes in Psychiatry Andrew Nierenberg, Massachusetts General Hospital
9:00 a.m. – 9:20 a.m.	Digital Measurements and Therapeutics John Torous, Beth Israel Deaconess Medical Center & Harvard Medical School
9:20 a.m. – 9:45 a.m.	Discussion
9:45 a.m 10:00 a.m.	Break Americana Foyer
10:00 a.m 11:30 a.m.	Update From Federal and Other Funding Agencies Salon 3
Chair: Joseph Goldberg,	Icahn School of Medicine at Mount Sinai
10:00 a.m. – 10:10 a.m.	Introduction
10:10 a.m. – 10:22 a.m.	An Update from the NIMH Josh Gordon, National Institute of Mental Health
10:22 a.m. – 10:34 a.m.	An Update from the NIAAA George Koob, National Institute on Alcohol Abuse and Alcoholism
10:34 a.m. – 10:46 a.m.	An Update from NIDA Ivan Montoya, National Institute on Drug Abuse
10:46 a.m. – 10:58 a.m.	An Update from PCORI Elisabeth Houtsmuller, Patient-Centered Outcomes Research Institute
10:58 a.m. – 11:10 p.m.	An Update from the VA TBD
11:10 p.m. – 11:30 p.m.	Discussion



11:30 a.m. - 12:30 p.m.

*Investigator-Industry Collaboration Session Cowrie

New in 2023, the ASCP Industry Advisory Council would like to invite you to an interactive and educational roundtable event led by members of industry in which attendees will have the opportunity to rotate between topic areas highlighting the various aspects of industry. Attendees will have the opportunity to rotate among the tables featuring the below topics:

- Pursuing Career Opportunities in Industry
- Industry Internships & Externships
- How to Pursue Industry Funding for Investigator-Initiated Trials
- Clinical Trial Collaboration: Pharma/CRO/Investigators
- Consulting/Advisory/Speaking Opportunities at Pharma

12:30 p.m 2:15 p.m.	*Poster Session II with Lunch Salon 4
12:30 p.m 2:00 p.m.	Early Career Networking Tables (Open to all Attendees) Americana Foyer

Panel Sessions

2:15 p.m. - 3:45 p.m. *Repeated Psilocybin Administration in Patients with Treatment Resistant Obsessive Compulsive Disorder Poinciana 1-2

Chair: Francisco Moreno, University of Arizona **Discussant:** Robin Carhart Harris, University of California San Francisco

2:15 p.m – 2:20 p.m	Introduction	
2:20 p.m 2:45 p.m.	Efficacy and Safety of Psilocybin in the Treatment of OCD Katja Allen, University of Arizona	
2:45 p.m 3:10 p.m.	Error-Related Brain Electrical Activity in OCD Before and After Treatment with Psilocybin John Allen, The University of Arizona	
*Clinical Track. #Child/Adolescent Track. ^Academic Track		

ASCP Thursday, June 1, 2023

2:15 p.m 3:45 p.m. (continued)	*Repeated Psilocybin Administration in Patients with Treatment Resistant Obsessive Compulsive Disorder Poinciana 1-2
3:10 p.m 3:35 p.m.	Psilocybin-Induced Decreases in Default-Mode Network Connectivity Predict Greater Symptom Reduction in Obsessive Compulsive Disorder Diheng Zhang, The University of Arizona
3:35 p.m 3:45 p.m.	Discussion
2:15 p.m 3:45 p.m.	Recent Updates on Assessment and Outcomes in Research on Suicidal Behaviors in Youth <i>Poinciana</i> 3-4

Chair: Madhukar Trivedi, University of Texas Southwestern **Co-Chair:** Jill Harkavy-Friedman, AFSP

2:15 p.m – 2:20 p.m	Introduction
2:20 p.m 2:45 p.m.	Update on NIMH-Funded Research into Youth Suicide Elizabeth Ballard, National Institute of Mental Health
2:45 p.m 3:10 p.m.	Ketamine as a Novel Antidepressant for Treatment-Resistant Depression in Adolescents Michael Bloch, Yale Child Study Center
3:10 p.m 3:35 p.m.	Novel Treatments and Biomarkers to Improve Outcomes for Youth with Suicidal Behaviors Madhukar Trivedi, University of Texas Southwestern Medical Center
3:35 p.m 3:45 p.m.	Discussion

2:15 p.m. - 3:45 p.m.



· ·	Implications Salon 1
Chair: Susannah Tye, The University of Queensland Discussant: Mark Frye, Mayo Clinic	
2:15 p.m – 2:22 p.m	Introduction
2:22 p.m 2:39 p.m.	Ketamine Associated Change in Anhedonia and mTOR Expression in Treatment-Resistant Depression Balwinder Singh, Mayo Clinic
2:39 p.m 2:56 p.m.	Inflammation, Thyroid Hormone Metabolism, and Reward Deficits, Among Patients with Treatment Resistant Depression Jennifer Kruse, University of California, Los Angeles
2:56 p.m 3:13 p.m.	Cellular Immunometabolic Signatures are Associated with Anhedonia in Depression with High Inflammation Mandakh Bekhbat, Emory University School of Medicine
3:13 p.m. – 3:30 p.m.	Immunometabolic Moderators of Anhedonia and Treatment Resistant Depression: Therapeutic Targets and Precision Medicine Pathways Susannah Tye, The University of Queensland
3:30 p.m. – 3:45 p.m.	Discussion

Anhedonia: Translational Targets and Clinical

ASCP Thursday, June 1, 2023

2:15 p.m. – 3:45 p.m.	Enhancing Relevance for Public Health:
	A Focus on Diversity and Inclusion
	Salon 2

Chair: Bernard Fischer, US Food and Drug Administration **Discussant:** Christina Borba, National Institute of Mental Health

2:15 p.m – 2:22 p.m	Introduction
2:22 p.m 2:39 p.m.	Diversity in Clinical Trials: Introduction Cathy Southammakosane, FDA/CDER/DPP
2:39 p.m 2:56 p.m.	Racially and Ethnically Inclusive Clinical Trials Martine Solages, Center for Drug Evaluation and Research, Food and Drug Administration
2:56 p.m 3:13 p.m.	Sex, Gender, and Sexuality in Clinical Trials Anna Weissman, FDA
3:13 p.m. – 3:30 p.m.	Inclusion of Older Adults in Clinical Trials Roberta Rasetti, FDA/CDER/DP
3:30 p.m 3:45 p.m.	Discussion
3:45 p.m 4:15 p.m.	Break Americana Foyer

Workshop Sessions

4:15 p.m. - 6:15 p.m. ***Best Practices to Reduce Subject and** Investigator Bias in Clinical Trials Poinciana 1-2

Chair: Timothy Rogier, Lotus Clinical Research

4:15 p.m. - 4:23 p.m. Introduction
4:23 p.m. - 4:51 p.m. Placebo Response Mitigation in Pain Studies Neil Singla, Lotus Clinical Research



4:15 p.m 6:15 p.m. (continued)	*Best Practices to Reduce Subject and Investigator Bias in Clinical Trials Poinciana 1-2
4:51 p.m 5:19 p.m.	Leveraging Machine Learning to Predict Individual Patients' Placebo Response Dominique Demolle, Cognivia
5:19 p.m 5:47 p.m.	Exploring the Roots of Placebo Response in CNS Trials Steven Targum, Bracket Global
5:47 p.m 6:15 p.m.	Accountability at Research SITES: STRATEGIES for Minimizing Placebo and Nocebo Responses Elan Cohen, Hassman Research Institute
4:15 p.m 6:15 p.m.	⁺ Forging a Path to Better Clinical Trials: A Discussion on Enabling the Implementation of RWE, AIML, and Collaboration to Better Capture Patient Experience and Improve Success in Drug Development Poinciana 3-4

Chair: Anthony Cannon, AbbVie, Inc. **Co-Chair:** Ed Ikeguchi, AiCure

4:15 p.m 4:27 p.m.	Introduction
4:27 p.m 4:45 p.m.	Pre-Competitive Consortia Accelerating Therapeutic Innovation Ramona Walls, Critical Path Institute
4:45 p.m 5:03 p.m.	Pre-Competitive Consortia Enabling Accelerated Therapeutic Innovation Seth C. Hopkins, Sunovion Pharmaceuticals, Inc.
5:03 p.m 5:21 p.m.	Clinical Trial Innovation Enables a Richer Understanding of the Patient Experience Erin Gallagher, This Is My Brave, Inc.
5:21 p.m 5:39 p.m.	AI/ML as a Mechanism to Streamline Trials Li Wang, AbbVie
*Clinical Tree	k #Child/Adalaaant Trook AAaadamia Trook

ASCP Thursday, June 1, 2023

4:15 p.m 6:15 p.m. (continued)	⁺ Forging a Path to Better Clinical Trials: A Discussion on Enabling the Implementation of RWE, AIML, and Collaboration to Better Capture Patient Experience and Improve Success in Drug Development Poinciana 3-4
5:39 p.m 5:57 p.m.	Innovation in Clinical Trial Conduct and Operations Erica Lawson, Otsuka (OPDC)
5:57 p.m 6:15 p.m.	Forging a Path to Better Clinical Trials: A Discussion on Enabling the Implementation of RWE, AIML, and Collaboration to Better Capture Patient Experience and Improve Success in Drug Development Yanjun Bao, AbbVie Inc.
4:15 p.m 6:15 p.m.	*Psilocybin: Opportunities Across the Diagnostic Spectrum

Salon 1

Chair: Scott Aaronson, Sheppard Pratt Discussant: Trisha Suppes, Stanford University

4:15 p.m. – 4:25 p.m.	Introduction
4:25 p.m 4:50 p.m.	Considering the Range of Psilocybin's Mechanisms of Action; Possible Explanations for Putative Transdiagnostic Efficacy Gerard Sanacora, Yale
4:50 p.m 5:15 p.m.	Psilocybin in the Treatment of OCD: Early Experience Christopher Pittenger, Yale Medical School
5:15 p.m 5:40 p.m.	Gathering Momentum: Psilocybin Therapy for Treatment Resistant Depression James Rucker, King's College London
5:40 p.m 6:05 p.m.	Synthetic Psilocybin in Bipolar Type II Depression: An Open Label Trial Scott Aaronson, Sheppard Pratt
6:05 p.m. – 6:15 p.m.	Discussion

Thursday, June 1, 2023

*The Academic Clinical Trialist: Saving an

4:15 p.m. - 6:15 p.m.



4.15 p.m 6.15 p.m.	Endangered Species Salon 2	
Chair: Joseph Goldberg, Icahn School of Medicine at Mount Sinai Co-Chair: Holly Swartz, University of Pittsburgh School of Medicine		
4:15 p.m 4:27 p.m.	Introduction	
4:27 p.m 4:45 p.m.	What Are Clinical Trialists and Why Do We Need Them? Joseph Goldberg, Icahn School of Medicine at Mount Sinai	
4:45 p.m 5:03 p.m.	How We Got Here: Evolution of Clinical Trialists in Academia Holly Swartz, University of Pittsburgh School of Medicine	
5:03 p.m 5:21 p.m.	Outcomes in Psychiatric Clinical Trials: Symptoms or Targets? James Murrough, Icahn School of Medicine at Mount Sinai	
5:21 p.m 5:39 p.m.	Developing Clinical Trial Specialists in Psychiatry: The Role of the Department of Veterans Affairs Michael Ostacher, Stanford University School of Medicine	
5:39 p.m 5:57 p.m.	A Funny Thing Happened on the Way to Becoming an Academic Researcher: I Started a Private Clinical Trials Site Andrew Cutler, SUNY Upstate Medical University	
5:57 p.m 6:15 p.m.	How Can Academic Programs Mentor and Foster the Careers of Clinical Trialists? Anita H. Clayton, University of Virginia	



Notes



AT-A-GLANCE

Friday, June 2, 2023

7:30 a.m 9:00 a.m.	Morning Break Americana Foyer
7:30 a.m 10:30 a.m.	Speaker Ready Room New Yorker
7:30 a.m 12:00 p.m.	Registration Rotunda East - Second Level

8:30 a.m. - 10:00 a.m. Panels

*Antipsychotics, Metabolic Dysfunction, and Cognition in Psychosis: Novel Insights into Biological Correlates, Genetic Predictors, and Mitigation Strategies	Digital Phenotyping and Therapeutics: Assessing the Hype vs Evidence	**Identifying Meaningful Targets of Pharmacotherapy in Mood Disorders	*New Data and New Strategies to Improve Treatment for Schizophrenia
Poinciana 1-2	Poinciana 3-4	Salon 1	Salon 2

10:00 a.m 10:15 a.m.	Break
	Americana Foyer

10:15 a.m. - 11:15 a.m. Regulatory Challenges: Ask the Experts Salon 2



Notes

ASCP

FULL SCHEDULE

Friday, June 2, 2023

7:30 a.m 9:00 a.m.	Morning Break Americana Foyer
7:30 a.m 10:30 a.m.	Speaker Ready Room New Yorker
7:30 a.m 12:00 p.m.	Registration Rotunda East - Second Level

Panel Sessions

8:30 a.m 10:00 a.m.	*Antipsychotics, Metabolic Dysfunction, and Cognition in Psychosis: Novel Insights into Biological Correlates, Genetic Predictors, and Mitigation Strategies
	· · ·
	Poinciana 1-2

Chair: Mahavir Agarwal, Centre for Addiction and Mental Health (CAMH) **Discussant:** Kristen Ward, University of Michigan

8:30 a.m. – 8:35 a.m.	Introduction
8:35 a.m 9:00 a.m.	The Effect of Olanzapine on the Skeletal Muscle Epigenome and Proteome Kyle Burghardt, Wayne State University
9:00 a.m 9:25 a.m.	The Impact of Cardiometabolic Factors on Cognitive Performance in Psychosis Spectrum Disorders: Genetic Risks, Medication Exposure and Chronic Inflammation Lusi Zhang, University of Minnesota
9:25 a.m 9:50 a.m.	An Algorithmic Pharmacological Approach to Prevention and Treatment of Antipsychotic- Induced Weight Gain Mahavir Agarwal, Centre for Addiction and Mental Health (CAMH)
9:50 a.m. – 10:00 a.m.	Discussion

8:30 a.m. – 10:00 a.m.	Digital Phenotyping and Therapeutics: Assessing the Hype vs Evidence
	Poinciana 3-4

Chair: John Torous, Beth Israel Deaconess Medical Center and Harvard Medical School

8:30 a.m. – 8:35 a.m. Introduction

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- 8:35 a.m. 9:00 a.m. Digital Tools as Measurement Devices to Assess Effects of Treatments and Drugs John Torous, Beth Israel Deaconess Medical Center and Harvard Medical School
- 9:00 a.m. 9:25 a.m. Digital Tools as Measurement Devices to Assess Effects of Treatments Michelle Ferrante, FDA
- 9:25 a.m. 9:50 a.m. Using Technology and Digital Phenotyping to Assess Functioning and Detect Treatment Responses Philip Harvey, University of Miami Miller School of Medicine
- 9:50 a.m. 10:00 a.m. **Discussion**
- 8:30 a.m. 10:00 a.m. **Identifying Meaningful Targets of Pharmacotherapy in Mood Disorders Salon 1

Chair: Joseph Goldberg, Icahn School of Medicine at Mount Sinai **Co-Chair:** Nassir Ghaemi, Tufts University/Harvard Medical School **Discussant:** Roger McIntyre, University of Toronto

8:30 a.m. – 8:35 a.m. Introduction
8:35 a.m. - 9:00 a.m. Improving Psychiatric Drug Development: Beyond the Conventional Wisdom Nassir Ghaemi, Tufts University/Harvard Medical School



8:30 a.m. – 10:00 a.m. (continued)	**Identifying Meaningful Targets of Pharmacotherapy in Mood Disorders Salon 1
9:00 a.m 9:25 a.m.	Matching Target Symptoms of Pharmacotherapy with Their Neurobiological Substrates: On Babies and Bathwaters Manpreet Singh, Stanford University School of Medicine
9:25 a.m 9:50 a.m.	On Redefining the Goals of Treatment for Difficult-to-Treat Mood Disorders: Borrowing from the Palliative Care Model Joseph Goldberg, Icahn School of Medicine at Mount Sinai
9:50 a.m. – 10:00 a.m.	Discussion
8:30 a.m. – 10:00 a.m.	*New Data and New Strategies to Improve Treatment for Schizophrenia Salon 2

Chair: Ira Glick, Stanford University School of Medicine **Discussant:** John Lauriello, Thomas Jefferson University/Sidney Kimmel Medical College

8:30 a.m. – 8:35 a.m.	Introduction
8:35 a.m 9:00 a.m.	New Data and New Strategies for the Treatment Continuum of Schizophrenia Patients Jean-Pierre Lindenmayer, New York University Grossman School of Medicine
9:00 a.m 9:25 a.m.	Should Antipsychotic Medications for Schizophrenia be Given for a Lifetime? Summary of Four Naturalistic, 6-53 Year Long-Term, Follow-Up Studies of Antipsychotic Treatment for Schizophrenia Ira Glick, Stanford University School of Medicine
9:25 a.m 9:50 a.m.	New Strategies for Managing Adverse Effects of Antipsychotics Stephen Marder, Semel Institute at UCLA
9:50 a.m. – 10:00 a.m.	Discussion

10:00 a.m 10:15 a.m	n. Break
	Americana Foyer

10:15 a.m. - 11:15 a.m. Regulatory Challenges: Ask the Experts Salon 2

This session is intended to facilitate dialogue between expert regulators from the US Food and Drug Administration and conference participants with an interest in drug development and clinical research in psychopharmacology. There will be no pre-submitted questions, but rather regulators will take questions directly from the audience.

Presenters: Tiffany Farchione, US Food and Drug Administration Bernard Fischer, US Food and Drug Administration Valentina Mantua, US Food and Drug Administration

Meeting Adjourns

11:15 a.m.

ASCP



Wednesday, May 31, 2023

11:15 a.m. - 1:00 p.m. **Poster Session I with Lunch** Salon 4

W1. A Single Arm Pivotal Trial to Assess the Efficacy of AKL-T01, a Novel Digital Intervention Designed to Improve Attention, in Adolescents Diagnosed with Attention Deficit Hyperactive Disorder (ADHD)

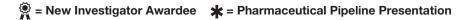
Catherine Mercaldi, Minny Suh, Ann Childress, Napolean Higgins, Scott Kollins*

Scott Kollins, Akili, Inc.

W2. Rethinking the Role of Serotonin in Attention Deficit Hyperactivity Disorder

Matia Solomon^{*}, Brittney Yegla, Jeffrey Newcorn, Jonathan Rubin, Trevor Robbins, Vladimir Maletic Matia Solomon, Supernus Pharmaceuticals Inc

- W3. Treatment of Opioid Use Disorder in Correctional Facilities- A Review of Current Practices Thersilla Oberbarnscheidt* Thersilla Oberbarnscheidt, University of Pittsburgh Medical Center, Western Psychiatric Hospital
- W4. BMB-101 a Selective 5-HT2C Receptor (5-HT2CR) Agonist that May Have Utility in Substance Abuse Disorders Mark Smith*, Kathryn Cunningham, Christina Merritt, Alan Kozikowski, Andrew Cao, Hailey Bock, Joseph Hennessey, John McCorvy, Alex Vasilkevich, Jesse Damsker, Jianmin Duan, Alessandro Lovera, Ian McDonald, Jan Torleif Pedersen Mark Smith, VistaGen Therapeutics
- W5. Sex and Diet-Dependent Gene Alterations in Human and Rat Brains with a History of Nicotine Exposure Javier Vargas Medrano*, Luis M. Carcoba, Guadalupe Vidal-Martinez, Zuber D. Mulla, Victoria Diaz, Alejandra Ruiz-Velasco, Fabian Alvarez-Primo, Gabriela Colina, Sergio D. Iñiguez, Peter M. Thompson, Laura E. O'Dell, Bharathi S. Gadad Javier Vargas Medrano, Texas Tech University Health Sciences Center School of Medicine



Posters

- W6. Using Big Data to Understand the Safety Profile of Gabapentin in People with Opioid Use Disorder: An Analysis of Multistate Administrative Claims Data Matthew Ellis, Kevin Xu*, Thiago Fidalgo, Vitor Tardelli, Mance Buttram, Richard Grucza Kevin Xu, Washington University in St. Louis
- W7. Efficacy and Safety of an Alpha 7 Nicotinic Acetylcholine Receptor Agonist, VQW-765, in Subjects with Performance Anxiety in a Randomized, Placebo-Controlled Trial Yunsheng He*, Christos M. Polymeropoulos, Michael A. Mohrman, Sunny Q. Truslow, Gunther Birznieks, Changfu Xiao, Mihael H. Polymeropoulos Yunsheng He, Vanda Pharmaceuticals
 - W8. A Phase 2, Double-Blind, Placebo-Controlled Study for BNC210, an Alpha7 Nicotinic Receptor Negative Allosteric Modulator (NAM) for the Acute Treatment of Social Anxiety Disorder (PREVAIL): Top-Line Efficacy and Safety Results

Spyros Papapetropoulos*, Elisabeth Doolin, Michael Odontiadis, Dharam Paul, Errol De Souza, Charles Taylor, Murray Stein Spyros Papapetropoulos, Bionomics Ltd

W9. A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Pharmacokinetic Study of Escalating Single and Multiple Doses of CVN766, an OX1R Highly Selective Antagonist in Healthy Subjects

> Nicola Brice, Kim Matthews, Lee Dawson, April Purcell, Ricardo Soto, Martin Bexon, Philip Ryan, Mark Carlton, Ottavio Vitolo* Ottavio Vitolo, Cerevance

W10. MM-402, R(–)-3,4-Methylenedioxymethamphetamine, Demonstrates Prosocial and Therapeutic-Like Effects in Fmr1 Knockout Mice, a Preclinical Model of Autism Spectrum Disorder (due to Fragile X syndrome).

Gennady Smagin*, Julie Tripp, Robert Silva, Robert Barrow Gennady Smagin, Mind Medicine Inc

😤 = New Investigator Awardee 🛛 🜟 = Pharmaceutical Pipeline Presentation



W11. Sex Differences in Mitochondrial Metabolism of Acetyl-L-Carnitine in Subjects with Cognitive Impairments

Benedetta Bigio*, Ricardo Lima-Filho, Olivia Barnhill, Felipe Kudos, Claudia Drummond, Naima Assunção, Bart Vanderborght, Fernanda Tovar-Moll, Paulo Mattos, Sergio Ferreira, Fernanda De Felice, Mychael Lourenco, Carla Nasca

Benedetta Bigio, New York University School of Medicine

W12. Electrophysiological Correlates of a Ketamine Infusion Captured via the Portable Cumulus Neurocognitive Platform Using Repeated Sampling from the Clinic and the Home

Brian Murphy, Florentine Barbey, Derek Buhl, Massimiliano Bianchi, Alison Buick, Lena Danyeli, John Dyer, Florian Gotting, Igor Izyurov, Nooshin Javaheripour, Marina Krylova, Hugh Nolan, Patricio O'Donnell, Shani Waninger^{*}, Walter Martin Shani Waninger, Cumulus Neuroscience

- W13. Using a Translational EEG Measure of Synaptic Function for Patient Stratification in Major Depressive Disorder Clinical Trials Jeffrey Burgdorf*, Ronald Burch, John Donello, Anantha Shekhar, Joseph R. Moskal Jeffrey Burgdorf, Northwestern University
- W14. Anhedonia is a Consequence of Memory Constraints and is Ameliorated by κ-Opioid Antagonism Bilal Bari*, Andrew Krystal, Diego Pizzagalli, Samuel Gershman

Bilal Bari, Massachusetts General Hospital

- W15. Evaluation of Mania and Hypomania in Late-Phase Clinical Trials of Lumateperone in the Treatment of Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder Mauricio Tohen, Susan G. Kozauer, Tobie Escher*, Yifan Mo, Willie R. Earley, Suresh Durgam Tobie Escher, Intra-Cellular Therapies, Inc.
- W16. Changes in Metabolic Parameters Associated with Lumateperone in Late-Phase Clinical Trials for the Treatment of Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder Bradford Loo*, Suresh Durgam, Susan G. Kozauer, Jason Huo, Robert E. Davis, Sharon Mates, Christoph U. Correll Bradford Loo, Intra-Cellular Therapies, Inc.

W17. Modifiable Behavioral Targets Associated with Subsyndromal Symptoms of Depression in Bipolar Disorder

Jennifer Nicoloro-SantaBarbara*, Megan Shanahan, Katherine E. Burdick

Jennifer Nicoloro-SantaBarbara, Brigham and Women's Hospital, Harvard Medical School

W18. Long-Term Lithium-Therapy and Thyroid Disorders in Bipolar Disorder: A Historical Cohort Study

Nicolas Nunez*, Boney Joseph, Vanessa Pazdernik, Rakesh Kumar, Mehak Pahwa, Mete Ercis, Aysegul Ozerdem, Alfredo Cuellar-Barboza, Francisco Romo-Nava, Susan McElroy, Brandon J. Coombes, Joanna Biernacka, Marius Stan, Mark Frye, Balwinder Singh Nicolas Nunez, Mayo Clinic

- W19. Olanzapine/Samidorphan Effects on Weight Gain: A Pooled Analysis of Phase 2 and 3 Randomized, Double-Blind Studies Christoph Correll, Michael Doane*, David McDonnell, Meihua Wang, Sarah Akerman, Stephen R. Saklad Michael Doane, Alkermes, Inc.
- W20. Assessing Temporal Performance of Machine Learning Pipelines Predicting Data Quality Issues in a Schizophrenia Clinical Trial Alan Kott*, Andrei Iacob, Emanuel Pintillii, Dorin Ariton, David Daniel Alan Kott, Signant Health
- W21. Risk of Psychiatric Disorders Post Antibiotic Use in Inpatient Adults: A Multicenter Retrospective Cohort Study Yezhe Lin*, Matthew Glover, Rakesh Kumar, JL West, Alexandra Hanlon, Ilan Kerman, Sarah Clinton, Anita Kablinger Yezhe Lin, Virginia Tech Carilion School of Medicine
- W22. The Impact of Metabolic Dysregulation on Cognition in Mood Disorders: A Systematic Review and Meta-Analysis Kateryna Maksyutynska^{*}, Nicolette Stogios, Femin Prasad, Jashan Gill, Zaineb Hamza, Riddhita De, Emily Smith, Angelina Horta, Margaret Hahn, Sri Mahavir Agarwal Kateryna Maksyutynska, Centre for Addiction and Mental Health, University of Toronto
- W23. Steroid Efficacy in Adolescents with COVID-19- Associated Neuropsychiatric Sequelae Baris Olten*, Laura Markley, Sumru-Bilge Johnson Baris Olten, Akron Children's Hospital
 - 😤 = New Investigator Awardee 🛛 🜟 = Pharmaceutical Pipeline Presentation



W24. Agitation in Alzheimer's Dementia: Defining a Meaningful Within-Patient Change for the Cohen-Mansfield Agitation Inventory (CMAI) Dorothee Oberdhan, Juliette Meunier, Angély Loubert, Kristin Creel, Klaus Groes Larsen, Jyoti Aggarwal* Jyoti Aggarwal, Otsuka Pharmaceutical Development and Commercialization, Inc. (OPDC)

W25. Phase 2 Study Design and New Data from the Phase 1 SAD/MAD Trial of LHP88, a Second-Generation Gingipain Inhibitor for the Treatment of P. Gingivalis-Associated Dementia Michael Detke*, Marwan Sabbagh, Leslie Holsinger, Joanna Bolger, Jianhong Wang, Mark Ryder, Suzanne B. Hendrix, Samuel P. Dickson, Craig Mallinckrodt, Casey Lynch, Stephen Dominy Michael Detke, Detke Biopharma Consulting

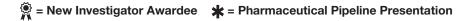
W26. Rapid Improvements in MADRS with Zuranolone in Major Depressive Disorder and Postpartum Depression: Results from the LANDSCAPE and NEST Clinical Development Programs Anita H. Clayton*, Kristina M. Deligiannidis, J. Antoni Ramos-Quiroga, Robert Lasser, Abdul J. Sankoh, Bridgette Leclair, Mona Kotecha, James Doherty Anita H. Clayton, University of Virginia

W27. Safety and Efficacy of Zuranolone Repeat Treatment Using PHQ-9 Depression Severity in Patients with Major Depressive Disorder from the SHORELINE Study

Gregory W. Mattingly, Andrew Czysz, Theresa Vera, Maxwell Adams, James Doherty, Gregory Mattingly* Gregory Mattingly, Washington University

- W28. Comparative Treatment Patterns Among Medicaid-Insured Patients with Major Depressive Disorder with Insomnia Maryia Zhdanava, Tiina Drissen*, Hrishikesh Kale, Dominic Pilon, John Sheehan, Zia Choudhry, Porpong Boonmak, Aditi Shah, Manish Jha Tiina Drissen, Janssen Scientific Affairs, LLC
- W29. Intranasal Esketamine Versus Intravenous Ketamine: An Observational Study Comparing the Efficacy and Tolerability of Two Novel 'Standard of Care' Treatments for Treatment Resistant Depression

Gilmar Gutierrez*, Gustavo Vazquez Gilmar Gutierrez, Queen's University



Posters

W30. Assessing Individuals' Experiences with Zuranolone for Major Depressive Disorder: Qualitative Interviews with Participants from the Open-Label Shoreline Study

Dana DiBenedetti, Ming-Yi Huang*, Katherine Kosa, Ellison Suthoff, Vijayveer Bonthapally, Robert Lasser, Mark Pollack, Jim Doherty, Catherine Mak, Andrew J. Cutler, Greg W. Mattingly Ming-Yi Huang, Sage Therapeutics

😤 W31. Concordance Between Patient-Reported Outcomes (PROs) and Clinician-Reported Outcomes (ClinROs) for Suicidality from the Suicide Ideation and Behavior Assessment Tool (SIBAT) in Two Phase 3 Studies

> Bridget Kajs*, Xin Qiu, Qing Men, Dong Jing Fu, Rosanne Lane, Carla Canuso Bridget Kajs, Janssen

- W32. Esketamine Nasal Spray Versus Psychoactive Comparator for Rapid Reduction of Depressive Symptoms in Adolescent Patients with Major Depressive Disorder at Imminent Suicide Risk Colette Kosik-Gonzalez*, Dong-Jing Fu, Nancy Chen, Rosanne Lane, Wayne C. Drevets, Carla M. Canuso Colette Kosik-Gonzalez, Janssen Pharmaceuticals, Inc.
- W33. Development of Machine Learning Model for Estimating PHQ-9 **Scores from Clinical Notes**

Jonathan Gerber, Carl Marci*, Michelle Leavy, Pedro Alves, Costas Boussios

Carl Marci, OM1, Inc.

W34. Sleep Disturbances are Highly Predictive of Major Depressive **Disorder Recurrence**

Maurice Ohayon, Maggie McCue, Michael Martin*, Andrew Krystal, Marie-Lise Cote Michael Martin, Takeda Pharmaceuticals North America, Inc.

W35. A Randomized, Placebo-Controlled, Exploratory, Double-Blind Study to Assess the Safety and Efficacy of Intravenous PCN-101 in **Treatment-Resistant Depression**

Maju Mathews*, Kevin Craig, Cedric Burg, Mouhannad Jumma, Vicki Klutzaritz, Terence Kelly Maju Mathews, Perception Neuroscience



Sector Sector



W36. Brexpiprazole: A Systematic Review on Current Studies in Major Depressive Disorder

Ritvij Satodiya*, Adam Bied, Maxwell Miller, Tapan Parikh Ritvij Satodiya, Emory University School of Medicine

- W37. An Open Label Study of the Safety and Efficacy of Psilocybin in Veterans with Severe Treatment-Resistant Depression
 Sara Ellis, Trisha Suppes*, Eileen Fischer, Wendy Feng, Katie Eisen, Melanie Lean, Betsy Conlan, Jihun Lyu, Michael Ostacher, Scott Aaronson
 Trisha Suppes, Stanford University
- W38. Impact of AXS-05 (Dextromethorphan-Bupropion) on Patient-Reported Insomnia Symptoms: Results from the GEMINI Trial Zachariah Thomas*, Manish Jha, Caroline Streicher, Herriot Tabuteau, Andrew Cutler Zachariah Thomas, Axsome Therapeutics
- W39. The Safety and Efficacy of COMP360 Psilocybin Therapy in Treatment-Resistant Depression: Results from a Long-Term Observational Follow-Up Study

Guy M. Goodwin, Lindsey Marwood, Sunil Mistry, Ania Nowakowska, Zainib Shabir, Hollie Simmons, Emma Teoh, Joyce Tsai^{*}, Ekaterina Malievskaia

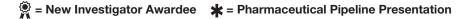
Joyce Tsai, COMPASS Pathways Ltd.

- W40. Efficacy of Spravato to Auvelity Cross-Titration in MDD Bennett Wechsler*, Anthony Rothschild Bennett Wechsler, University of Massachusetts Medical School
- W41. 50% Improvement: Should Treatment Response go Beyond Symptom Improvement when Evaluating the Treatment of Depression?

Mark Zimmerman*, Sin-Ying Lin Mark Zimmerman, Brown University

W42. Efficacy and Safety of Aticaprant, a Kappa Opioid Receptor Antagonist, Adjunctive to Oral SSRI/SNRI Antidepressant in Major Depressive Disorder: Results of a Phase 2a Randomized, Double-Blind, Placebo-Controlled Study

Mark Schmidt*, Iva Kezik, Vanina Popova, Peter Van Der Ark, Darrel J. Pemberton, Guy Mareels, Wayne C. Drevets Mark Schmidt, Janssen Pharmaceuticals



Posters

- W43. Efficacy and Safety of Esmethadone (REL-1017) in Patients with Major Depressive Disorder and Inadequate Response to Standard Antidepressants: A Phase 3 Randomized Controlled Trial Maurizio Fava, Stephen M. Stahl, Luca Pani, David Bushnell, Cedric O'Gorman, Sara De Martin, Clotilde Guidetti, Andrea Mattarei, Stefano Comai, Franco Folli, Sergio Traversa, Charles E. Inturrisi, Paolo L. Manfredi, Marco Pappagallo* Marco Pappagallo, Relmada Therapeutics, Inc.
- W44. The Impact of Subanesthetic Dose of Intravenous Ketamine on Working Memory in Individuals with Treatment-Resistant Depression

Adam Fijtman*, Mani Yavi, Abigail Vogeley, Dede Greenstein, Jessica Gilbert, Carlos Zarate Adam Fijtman, NIH/NIMH

W45. Effects of NLS-12 (oxafuramine) on Memory in the Novel Object **Recognition Test in Mice**

Eric Konofal*, Jean-Charles Bizot, Fabienne Massé, Sabrina David, David Trovero, Bruno Figadere, George Apostol Eric Konofal, APHP Hôpitaux de Paris, Hôpital Robert Debré

W46. Effects of NLS-11 (benedin) on Memory in the Novel Object **Recognition Test in Mice**

Eric Konofal*, Jean-Charles Bizot, Sabrina David, Fabienne Massé, David Trovero, Bruno Figadere, George Apostol Eric Konofal, APHP Hôpitaux de Paris, Hôpital Robert Debré

W47. Effects of Solriamfetol on Cognitive Function in Participants with Cognitive Impairment Associated with Excessive Daytime Sleepiness in Obstructive Sleep Apnea: Results of the Sharp Study Hans Van Dongen, Eileen Leary*, Christopher Drake, Richard Bogan, Judith Jaeger, Russell Rosenberg, Caroline Streicher, Hannah Kwak, Jay Bates, Herriot Tabuteau Eileen Leary, Axsome Therapeutics

W48. Two Randomized, Double-Blind, Placebo-Controlled Trials of Adjunctive Troriluzole, a Novel Glutamate Modulating Agent, in **Obsessive Compulsive Disorder**

Mary Sarah Olson, Melissa Beiner, Alissa Rybicki, Deborah Smith, Timothy McCormack, Lia Donahue, Vladimir Coric, Azim Munivar* Azim Munivar, Biohaven Pharmaceuticals



😤 = New Investigator Awardee 🛛 🜟 = Pharmaceutical Pipeline Presentation



W49. An Open-Label Trial Assessing Short- and Long-Term Tolerability and Efficacy of ZYN002 (Cannabidiol) Administered as a Transdermal Gel to Children and Adolescents with 22q11.2 Deletion Syndrome (INSPIRE)

Helen Heussler, Jonathan Cohen, Caroline Buchanan, Carol O'Neill, Stephen O'Quinn*, Terri Sebree Stephen O'Quinn, Zynerba Pharmaceuticals

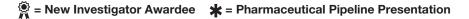
W50. Long-Term Safety and Sustained Efficacy of ZYN002 Cannabidiol Transdermal Gel in the Treatment of Behavioral Symptoms in Children and Adolescents with Fragile X Syndrome (ZYN2-CL-017) Nancy Tich, Anthony Thibodeau, Terri Sebree, Thomas Dobbins, Stephen O'Quinn* Stephen O'Quinn, Zynerba Pharmaceuticals

W51. Psychopharmacology and Transcranial Magnetic Stimulation in Veterans Receiving TMS for MDD

Zachary Zuschlag*, Michael Norred, Nupur Godbole, Lauren Daneman Zachary Zuschlag, James A. Haley Veterans Hospital

- W52. Efficacy and Engagement with a Digital Therapeutic in Patients with Experiential Negative Symptoms of Schizophrenia Brendan D. Hare*, Uma Vaidyanathan, Cassandra Snipes, Eehwa Ung, Timothy R. Campellone, Alankar Gupta, Shaheen E. Lakhan, Cornelia Dorner-Ciossek Brendan D. Hare, Click Therapeutics Inc.
- W53. MDMA-Assisted Psychotherapy for Borderline Personality Disorder Daniel Roberts*, Jenna Traynor, Stephen Ross, Richard Zeifman, Lois Choi-Kain Daniel Roberts, NYU School of Medicine
- W54. Psilocybin for the Treatment of Obsessive Compulsive Disorder Katja Allen^{*}, John Allen, Francisco Moreno Katja Allen, University of Arizona
- W55. Does Pharmacogenomic Testing Affect Clinical Management for Poor and Ultrarapid Metabolizers of Cytochrome P-450 2D6 and 2C19 in Minority populations? – A Retrospective Review Yuliang Hu*, Simon Kung

Yuliang Hu, Mayo Clinic



Posters

W56. Clozapine Therapeutic Drug Monitoring: Investigating Tolerability and Redefining Thresholds for Safety

Araba Chintoh*, Selai Akseer, Marcos Sanches, Gary Remington Araba Chintoh, University of Toronto

- W57. Incremental Burden of Dementia Among Patients with Parkinson's Disease Psychosis: Analysis of Medicare Beneficiaries Nazia Rashid*, Krithika Rajagopalan, Daksha Gopal, Dilesh Doshi Nazia Rashid, ACADIA Pharmaceuticals Inc
- W58. A Post-Hoc Exploratory Analysis of the Prevalence of Anxiety Symptoms in Acutely Exacerbated Schizophrenic Patients at Baseline in Clinical Trials David Daniel*, Xingmei Wang, Alan Kott David Daniel, Signant Health
- W59. Development of a Population Pharmacokinetic Model to Describe the Pharmacokinetics of Aripiprazole 2-Month Ready-to-Use, a Novel Long-Acting Injectable Formulation of Aripiprazole for Administration Once Every 2 Months

Yanlin Wang, Matthew Harlin*, Frank Larsen, Xiaofeng Wang, Wansu Park, Benjamin Rich, Jogarao V. Gobburu, Arash Raoufinia Matthew Harlin, Otsuka Pharmaceutical Development and Commercialization, Inc. (OPDC)

- W60. The Pharmacodynamic Effects of TAAR1 Agonist Ulotaront on Metabolic Biomarkers of Glucose, C-Peptide and Insulin Following a Meal in Patients with Schizophrenia Snezana Milanovic, Yu-Luan Chen, Kuangnan Xiong, Seth C. Hopkins*, Kenneth S. Koblan Seth C. Hopkins, Sunovion Pharmaceuticals, Inc.
- W61. Long-Term Safety and Symptom Trajectory with Aripiprazole Lauroxil in Female Patients with Schizophrenia: A Post Hoc Subgroup Analysis

Deanna L. Kelly, Sergey Yagoda, James McGrory* James McGrory, Alkermes, Inc.

W62. Site-Independent Replication of Clinical Metrics in a Study of Karxt in Subjects with an Acute Exacerbation of Psychosis in Schizophrenia

Steven Targum*, Inder Kaul, Sharon Sawchak, Stephen Brannan, Steven Paul

Steven Targum, Bracket Global

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W63. Review of the TAAR1 Agonist Ulotaront: Part II - Summary of Initial Clinical Efficacy/Safety Results

Seth C. Hopkins, Heather Dworak, Courtney Zeni*, Kenneth S. Koblan Courtney Zeni, Sunovion Pharmaceuticals

- W64. Effects of Menstrual Cycle on Symptoms in Individuals with Schizophrenia On and Off Medication Rachael Blackman*, Katherine Cole, Nicole Smith, Shau-Ming Wei, Peter Schmidt, Daniel Eisenberg, Karen Berman Rachael Blackman, National Institute of Mental Health
- W65. Looking into "Long COVID": The Potential for a Common Biologic Mechanism Relating Persistent Central and Autonomic Symptoms After COVID-19 Infection, and Prior Exposure to Traumatic Stress Rebecca Hendrickson*, Christine Cheah, Marlene Tai, Kathleen Pagulayan, Catherine McCall, Abigail Schindler, John Oakley Rebecca Hendrickson, VA Puget Sound Health Care System
- W66. The National Pregnancy Registry for Psychiatric Medications: Risk of Major Malformations Following Fetal Exposure to Atypical Antipsychotics

Adele Viguera, Marlene Freeman, Ella Rossa, Parker Killenberg, Ellen Sojka, David Chitayat, Sonia Hernández-Díaz, Lee Cohen* Lee Cohen, Massachusetts General Hospital, Ammon-Pinizzotto Center for Women's Mental Health

W67. Differential Trajectories of Depressive Symptom Response to IV Ketamine - Examining Sleep, Core Emotional and Atypical Symptoms Changes in a Large, Real World Sample of Depressed Adults

Brittany Obrien*, Jaehoon Lee, Seungman Kim, Allison Wells, Nicholas Murphy, Amanda Tamman, Lynette Averill, Alan C. Swann, Sanjay J. Mathew

Brittany Obrien, Baylor College of Medicine

W68. Reducing Cannabis Overuse with Prazosin: Interim Results from ReCOUP, a Pilot Feasibility Study

Garth Terry*, Rebecca Hendrickson, Anita Ranta, Shofer Jane, Jon Reid, Carol Xiang, Andrew Saxon, Elaine Peskind, Murray Raskind Garth Terry, VA Puget Sound Health Care System

W69. ANC-501: A Novel V1b Receptor Antagonist for the Treatment of MDD

Stephen Kanes*, Phil Perera Stephen Kanes, EmbarkNeuro

W70. Effect of a Subcutaneous Weekly and Monthly Buprenorphine (CAM2038) Extended-Release Dose on Opioid Use Disorder (OUD) Treatment Outcomes

Natalie Budilovsky-Kelley*, Michael Frost, Genie Bailey, Fredrik Tiberg, Peter Hielmstrom Natalie Budilovsky-Kelley, Braeburn

W71. Treatment Patterns, Acute Care Healthcare Resource Use and Costs of Patients with Treatment Resistant Depression Completing Induction Phase of Esketamine in Commercial and Medicare Advantage Plans

Kruti Joshi, Maryia Zhdanava, Aditi Shah, Arthur Voegel, Cindy Chen, Dominic Pilon, Lisa Harding, Brianne Brown* Brianne Brown, Janssen Scientific Affairs, LLC

W72. Real-World Outcomes, Characteristics and Ability to Work of Patients with Treatment-Resistant Depression in the United States Natasha Jones, Kruti Joshi, Manish Jha, Jason Shepherd, Alexander Gillespie, Ashlev Mortimer, Sophie Kirkman, Kruti Joshi, Meredith Castro*

Meredith Castro, Janssen Scientific Affairs

W73. A Case Series Providing Clinical Evidence that Methylone Produces **Rapid Improvements in Depression** Lynnette Averill, Terence Ching, Magi Farre, Blake Mandell, Martin Stogniew, Mark Seelig, Amanda Jones*, Benjamin Kelmendi

Amanda Jones, Transcend Therapeutics

W74. A Phase 3 Open-label Safety Trial of Fasedienol (PH94B) Nasal Spray in the Treatment of Anxiety in Adults with Social Anxiety Disorder (SAD)

Jaakko Lappalainen, Ester Salman, Rita Hanover, Brittney Reed, Ross Baker*, Mark Smith, Michael Liebowitz, Elizabeta Dushaj, Jaakko Lappalainen

Ross Baker, VistaGen Therapeutics



Sector Sector



W75. BRII-296 Demonstrates a Favorable Safety Profile for Sedation Results from a Phase 1 Study of Safety, and Pharmacokinetics of BRII-296, an Extended-Release Injectable Formulation of Brexanolone in Healthy Adult Subjects

Ji Ma, Leela Vrishabhendra, David Margolis, Chetana Trivedi, Kamlesh Patel, Heather Snyder, Oyeniyi Oyesina, Aiyang Tao, Clauida Prilliman, Aleksandar Skuban, Lianhong Xu, Aleksandar Skuban* Aleksandar Skuban, Brii Biosciences

W76. Clinical Correlates of Lithium Use in Patients with Bipolar Disorder Francisco Barrera, Thomas Blom, Alfredo Cuellar-Barboza, Alessandro Miola*, Jorge Sanchez-Ruiz, Miguel Prieto, Marin Veldic, Balwinder Singh, Manuel Gardea Resendez, Nicolas Nunez, Aysegul Ozerdem, Joanna Biernacka, Mark Frye, Susan McElroy, Francisco Romo-Nava Alessandro Miola, Mayo Clinic

W77. The Potential Role of the M1/M4 Muscarinic Receptor Agonist KarXT in the Treatment of Cognitive Impairment in Patients with Schizophrenia

Philip Harvey*, Colin Sauder, Samantha E. Yohn, Elizabeth Wragg, Francesca Cormack, Andrew Miller, Stephen Brannan, Steven Paul Philip Harvey, University of Miami Miller School of Medicine

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Thursday, June 1, 2023

12:30 p.m. - 2:15 p.m. Poster Session II with Lunch Salon 4

- T1. Centanafadine (CTN) Sustained Release (SR) in the Treatment of Adult Attention-Deficit/Hyperactivity Disorder: Secondary Outcomes from a Phase 2A Study Eva Kohegyi, Zhen Zhang, Jessica McDonough* Jessica McDonough, Otsuka Pharmaceutical Development and Commercialization, Inc. (OPDC)
- T2. Understanding Patient Profiles in Treatment Modalities for **Treatment Resistant Depression in Commercial and Medicare** Advantage Plans

Kruti Joshi, Maryia Zhdanava, Aditi Shah, Arthur Voegel, Cindy Chen, Dominic Pilon, Lisa Harding, Brianne Brown* Brianne Brown, Janssen Scientific Affairs, LLC

T3. **Qelbree® (Viloxazine Extended-Release Capsules): Final Results of** the Long-Term, Phase 3, Open-Label Extension Trial in Adults with ADHD

Andrew Cutler*, Ann Childress, Lenard A. Adler, Joseph Hull, Nicholas Fry, Kobby Asubonteng, Jonathan Rubin Andrew Cutler, SUNY Upstate Medical University

- 👷 T4. Polygenic Risk-Based Drug-Repositioning for Alcohol Use Disorder in in the National Health and Resilience in Veterans Study Cohort Brenda Cabrera Mendoza*, Antonella De Lillo, Joel Gelernter, Robert H. Pietrzak, Renato Polimanti Brenda Cabrera Mendoza, Yale University
- 👷 T5. The Possibility of Affecting Risky Sexual Behaviors Through Pharmacological Methods: A Secondary Analysis of the ADAPT-2 Trial

Donald Egan*, Manish Jha Donald Egan, University of Texas Southwestern Medical Center

Sector Sector



T6. Benzodiazepine Prescriptions and Risk of Psychiatric Disorders in Patients with Anxiety Disorders: A Real-World Multicenter Retrospective Cohort Study

Yezhe Lin*, Ching-Fang Sun, Akhil Pola, Anita Kablinger, Robert Trestman

Yezhe Lin, Virginia Tech Carilion School of Medicine

- **T7.** Facing Changes in Cannabis Use During the Covid-19 Pandemic Thersilla Oberbarnscheidt* Thersilla Oberbarnscheidt, University of Pittsburgh Medical Center, Western Psychiatric Hospital
- T8. Cannabis Use in Pregnant Females: Importance for a Need of Biomarker for Perinatal Cannabis Use Ritvij Satodiya*, Akhgar Ghassabian, Francisco X. Castellanos Ritvij Satodiya, Emory University School of Medicine
 - T9. Explore-Exploit Dynamics and Stress Among Healthcare Workers During the COVID-19 Pandemic

Erika Kaske, Cathy Chen, Collin Meyer, Amita Kapoor, Becket Ebitz, Nicola Grissom, David Darrow, Alexander Herman* Alexander Herman, University of Minnesota

T10. ERG as a Potential Biomarker of SSRI-Responsive PTSD: A Pilot Study

Katharine Liang*, Rebecca Hendrickson, Murray Raskind Katharine Liang, VA Puget Sound Health Care System

T11. Clinical/Demographic and Biological Correlates of Cognitive Impairment in Patients with Bipolar Disorder Marzieh Majd*, Jennifer Nicoloro-SantaBarbara, Julia Lebovitz, Emma Galante, Megan Shanahan, Katherine E. Burdick

Marzieh Majd, Brigham and Women's Hospital, Harvard Medical School

T12. CSF and Peripheral Inflammatory Biomarkers After COVID-19 Infection in a Pregnant Population

Emma Smith, Frederieke Gigase, Brett Collins, Mara Graziani, Juliana Camacho Castro, Rebecca Jessel, Andres Ramirez-Zamudio, Anna Rommel, Margaret McClure, Julie Spicer, Daniel Katz, Robert Pietrzak, Veerle Bergink, Lotje DeWitte, M. Mercedes Perez-Rodriguez* M. Mercedes Perez-Rodriguez, Icahn School of Medicine at Mount Sinai

Posters

T13. Propensity Weighting Method to Assess the Treatment Effect in Clinical Trials for Major Depressive Disorders Accounting for Heterogeneous Placebo Effect Using an Artificial Intelligence Approach

Roberto Gomeni* Roberto Gomeni, PharmacoMetrica

T14. Preferences for Characteristics of Oral Antipsychotic Treatments: Survey Results of Patients Living with Schizophrenia or Bipolar I Disorder

Michael Doane*, Marco Boeri, Caroline Vass, Cooper Bussberg, Hemangi R. Panchmatia, Sabina Gasper, Leslie Citrome, Martha Sajatovic Michael Doane, Alkermes, Inc.

T15. Efficacy of Lumateperone in Pooled Short-Term Late-Phase Clinical Trials for the Treatment of Major Depressive Episodes Associated with Bipolar II Disorder

Suresh Durgam, Hassan Lakkis, Susan G. Kozauer, Changzheng Chen, Ian D'Souza^{*}, Roger S. McIntyre Ian D'Souza, Intra-Cellular Therapies, Inc.

- T16. Lumateperone in the Treatment of Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder: Evaluation of Extrapyramidal and Motor Symptoms in Late-Phase Clinical Trials Margaret Martin*, Suresh Durgam, Susan G. Kozauer, Changzheng Chen, John M. Kane Margaret Martin, Intra-Cellular Therapies, Inc.
- T17. Older Age of First Psychiatric Hospitalization and Lower Rates of Depression Spectrum, Attention Deficit and Hyperactivity Comorbid Disorders and Nicotine Use are Associated with Abrupt Onset Mania: a Community-Based Cohort Study Alessandro Miola*, Nicolas Nunez, Javier Ortiz-Orendain, Manuel Gardea Resendez, Mete Ercis, Brandon J. Coombes, Manuel Fuentes Salgado, Peggy M Gruhlke, Ian Michael, Michael J. Bostwick, Alastair J. McKean, Aysegul Ozerdem, Mark A. Frye

Alessandro Miola, Mayo Clinic

T18. Telepsychiatry for Bipolar Disorder: A Systematic Review of the Literature

Abigail Farrell*, Nevita George, Selen Amado, Hannah O'Connor, Janet Wozniak

Abigail Farrell, University of Houston

- T19. Safety and Efficacy of Synthetic Psilocybin in Bipolar Type II Depression: An Open Label Trial Scott Aaronson*, Audrey Shoultz, Tammy Miller, Andrew Van der Vaart, MacKenzie Forbes, Trisha Suppes Scott Aaronson, Sheppard Pratt
- T20. A Validated Rating Scale to Accurately Determine the Treatment Effects in Childhood Onset Fluency Disorder (Stuttering)--the MLGSS

Gerald Maguire*, George Garibaldi, Gonçalo Leal, Smiljana Ristic, Simon Roitt, Rebecca Scherrer Gerald Maguire, CenExel CIT

T21. Replicating and Extending the Reliability, Criterion Validity, and Treatment Sensitivity of the PANSS10 and PANSS20 for Pediatric Trials

Joan Busner*, Eric Youngstrom, Joshua Langfus, David Daniel, Robert Findling

Joan Busner, Signant Health and Virginia Commonwealth University School of Medicine

- **T22.** Administrating and Training on the Placebo-Control Reminder Script: A Deeper Dive into the Tool's Psychometric Properties Elan Cohen*, Howard Hassman, David Walling, Vera Grindell, Katarzyna Wyka, Brett English, Cassie Blanchard, Jaclyn Lobb, Djouher Hough, Stephanie Iglesias, Larry Ereshefsky Elan Cohen, Hassman Research Institute
- T23. Risk of Drug Overdose Following Simultaneous Benzodiazepine and SSRI Treatment in Young Adults Greta Bushnell*, Moira Rynn, Tobias Gerhard, Deborah Hasin, Katherine Keyes, Magdalena Cerda, Mark Olfson Greta Bushnell, Rutgers University
- T24. Using the Ketogenic Diet as an Intervention to Treat Chronic Mental Disorders

Janine DeSimone*, Kim Backman Janine DeSimone, Stony Brook University

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T25. Excessive Daytime Sleepiness in a Real-World Study of Participants with Obstructive Sleep Apnea with or without Comorbid Depression Sairam Parthasarathy, Jerry Zhang, Danielle Hyman, James Doherty, Ragy Saad, Benjamin Fox, Nell Marshall, Samantha Floam*, Gregory Parks

Samantha Floam, Axsome Therapeutics

T26. Efficacy, Safety and Tolerability of Brexpiprazole for the Treatment of Agitation in Alzheimer's Dementia: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Trial, and a 12-Week Extension Trial

George T. Grossberg, Daniel Lee, Mary Slomkowski, Nanco Hefting*, Dalei Chen, Klaus Groes Larsen, Eva Kohegyi, Mary Hobart, Jeffrey L Cummings

Nanco Hefting, H. Lundbeck A/S

T27. Effects of Brexpiprazole Across Agitation Behaviors in Alzheimer's Dementia: Cohen–Mansfield Agitation Inventory Factor Scores from Two Phase III Fixed-Dose Trials

Daniel Lee, Mary Slomkowski, Nanco Hefting, Dalei Chen, Klaus Groes Larsen, Eva Kohegyi, Mary Hobart, Maia Miguelez*, Pedro Such Maia Miguelez, Otsuka Pharmaceutical Development and Commercialization. Inc.

T28. Equitable Pricing of a Novel Anti-Alzheimer's Therapeutic: Your Viewpoint Determines Your View

Charles Wilcox* Charles Wilcox, Praxis Research Consulting

- T29. A Prediction Model to Identify Candidates for Atypical Antipsychotic Adjunctive Treatment of Major Depressive Disorder Roger McIntyre, François Laliberté, Guillaume Germain, Malena Mahendran, Nadia Nabulsi, Mousam Parikh* Mousam Parikh, AbbVie
- T30. A Phase 1 SAD and MAD Trial of EVX-101, a Novel Gastro-Retentive Prolonged-Release 5-HTP/ Low-Dose Carbidopa Tablet, in Healthy Subjects Taking Escitalopram

David Carpenter*, Litza Mckenzie, Sarah Beaudoin, Clare Totaro, Vanessa Zann, Jennifer Hart, Rebecca Klein, Joel Raskin, Jacob Jacobsen

David Carpenter, Evecxia Therapeutics



Sector Sector



T31. A Prospective, Multi-Center, Randomized, Controlled, Blinded Trial of Vagus Nerve Stimulation for Difficult to Treat Depression: The Recover Trial Baseline Data

Charles Conway, Scott Aaronson, Harold A. Sackeim, Christopher Kriedt, Mark Bunker, Bryan D. Olin, Lisa Lee, Jeffrey Way, Britt M. Gott, A. John Rush, Malia Addison, Malia Addison* Malia Addison, Washington University in St. Louis

T32. Examining Site Rater Baseline Inflation in Depression Trials: A Comparison of Independent Rater Screening Ham-D Versus Site Baseline Raters Madrs Scores Conversions

Jenicka Engler*, Cynthia McNamara, Cristian Sirbu, Nikolina Apostolova, Brian Saxby Jenicka Engler, Cropos Clinical Consulting

Jenicka Engler, Cronos Clinical Consulting

T33. Does Lamotrigine Affect the Antidepressant Effect of Ketamine/ Esketamine in Patients with Treatment-Refractory Depression? A Case-Series of 12 Patients

Boney Joseph*, Nicolas Nunez, Simon Kung, Jennifer Vande Voort, Kathryn Schak, Emily Johnson, Daniel Adewunmi, Stacey Boehm, Sarah Brown, Brooke Carpenter, Michael Govrik, Grigoriy Malyshev, Nathan Smits, Balwinder Singh Boney Joseph, Mayo Clinic

T34. Effect of Adjunctive Cariprazine on Symptoms of Anhedonia in Patients with Major Depressive Disorder Roger McIntyre, Vladimir Maletic, Prakash Masand, Andrea Wilson, Jun

Yu, Kenneth Kramer, Julie Adams, Majid Kerolous* Majid Kerolous, AbbVie

T35. Sodium-Glucose Cotransporter-2 Inhibitors in Major Depressive Disorder

David Liebers^{*}, Wataru Ebina, Carla Nasca, Dan Iosifescu David Liebers, New York University School of Medicine

T36. Treatment Disparities for Major Depressive Disorder Maurice Ohayon, Maggie McCue, Michael Martin*, Andrew Krystal, Marie-Lise Cote Michael Martin, Takeda Pharmaceuticals North America, Inc.

Posters

T37. Healthcare Resource Utilization Associated with Switching Versus Augmenting Antidepressant Monotherapy in Treatment of Major **Depressive Disorder**

Theresa Cerulli, Prakash Masand*, Nadia Nabulsi, François Laliberté, Guillaume Germain, Jacob Klimek, Malena Mahendran, Majid Kerolous, Sally Wade, Mousam Parikh Prakash Masand, Duke-NUS

T38. Barriers to Esketamine Nasal Spray Treatment Among Adults with Treatment Resistant Depression

Kruti Joshi, Pinyao Rui, Joshua Liberman, Lisa Harding, Meredith Castro*

Meredith Castro, Janssen Scientific Affairs

- T39. Phase 1 Results and Phase 2 Clinical Development of RE104: A Novel Serotonergic Psychedelic 4-OH-DiPT Prodrug Robert Alexander*, Jasna Hocevar-Trnka, Aviva Asnis-Alibozek, Nathan Bryson, Beatrix Taylor, Robert Alexander, Matthew W. Johnson Robert Alexander, Reunion Neuro
- T40. Elevated Anxiety in Patients with Unresolved Major Depressive Disorder

Augustus Rush*, Ellison Suthoff, Michael Witte, Kelly Chan, Sheryl Ker, Yida Won, Joshua Wong, Marci Potter, Madhav Namjoshi, Deborah Freedman, Andy Czysz, Steve Hass, Tito Ghosh Augustus Rush, Duke University School of Medicine

- T41. A Randomized Placebo-Controlled Multicenter Trial of Monotherapy with TNX-601 ER* (Tianeptine Hemioxalate Extended-Release Tablets) for Treatment of Major Depressive Disorder (MDD) Gregory Sullivan*, Ashild Peters, David Hsu, Darryl Rideout, Timothy Roush, Bruce Daugherty, Perry Peters, Seth Lederman Gregory Sullivan, Tonix Pharmaceuticals, Inc.
- T42. Distinct Forms of Regret Linked to Resilience Versus Susceptibility to Stress are Regulated by Different Brain Regions Romain Durand-de Cuttoli, Freddyson Martinez-Rivera, Long Li, Angelica Minier-Toribio, Leanne Holt, Flurin Cathomas, Farzana Yasmin, Salma Elhassa, Jasmine Shaikh, Sanjana Ahmed, Scott Russo, Eric Nestler. Brian Sweis* Brian Sweis, Icahn School of Medicine At Mount Sinai



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- T43. Increased Placebo Response Associated with Greater Frequency of Study Visits in Major Depressive Disorder (MDD) Clinical Trials Robin Tan*, Dar Alon, Andy Czysz, Theresa Vera, Ramon Iovin, Ellison Suthoff, Madhukar Trivedi Robin Tan, Sage Therapeutics, Inc.
- T44. Assessment of Withdrawal Symptoms After Discontinuation of AXS-05 (Dextromethorphan-Bupropion) Treatment: Results from the GEMINI Trial Rakesh Jain, Caroline Streicher, Amanda Jones, Zachariah Thomas*, Herriot Tabuteau

Zachariah Thomas, Axsome Therapeutics

- T45. Cellular Immunometabolic Signatures are Associated with Anhedonia in Depression with High Inflammation Mandakh Bekhbat* Mandakh Bekhbat, Emory University School of Medicine
 - T46. No Indication of Abuse Potential and Absence of Withdrawal Signs and Symptoms from Esmethadone (REL-1017): Results from a Phase 3 Randomized Controlled Trial in Patients with Major Depressive Disorder

Megan Shram, Jack Henningfield, Charles Gorodetzky, Sara De Martin, Frank Vocci, Frank Sapienza, Thomas Kosten, David Bushnell, Clotilde Guidetti, Cedric O'Gorman, Franco Folli, Sergio Traversa, Charles E. Inturrisi, Paolo L. Manfredi, Marco Pappagallo* Marco Pappagallo, Relmada Therapeutics, Inc.

- **T47.** Racial and Ethnic Issues in Clinical Psychopharmacology: A Thematic Review of Literature Andrew Olagunju^{*}, Jeffrey Wang Andrew Olagunju, McMaster University
- T48. Benzofuran Derivatives Increase Extracellular Monoamines and Have MDMA-Like Effects in Rats Matthew Baggott*, Candace Johnson, Rachel Burroughs, Donna Walther, Michael Baumann, Lisa Baker Matthew Baggott, Tactogen Inc

Posters

T49. Effects of NLS-8 (melafenoxate) on Memory in a Model of Alzheimer's Disease, the Scopolamine-Induced Amnesia in the Novel Object Recognition Test in Mice Eric Konofal*, Jean-Charles Bizot, Sabrina David, Fabienne Massé,

David Trovero, Bruno Figadere, George Apostol Eric Konofal, APHP Hôpitaux de Paris, Hôpital Robert Debré

T50. Effects of NLS-4 (lauflumide) and Modafinil in a Rat Model of **Chronic Severe Fatigue**

Eric Konofal*, Jean-Charles Bizot, Fabienne Massé, Julie Combeau, Norinne Lacerda-Queiroz, Sabrina David, Laurent Benel, George Apostol Eric Konofal, APHP Hôpitaux de Paris, Hôpital Robert Debré

T51. Effects of the Selective AMPA Modulator NBI-1065845 on the Pharmacokinetics of Ethinyl Estradiol Levonorgestrel or Midazolam in Healthy Adults

Swan Lin*, Adrian Ionescu, Jessica Maynard-Scott, Mike Kennedy, David Walling, Maura Furey, Jaskaran Singh Swan Lin, Neurocrine Biosciences

T52. Preclinical Pharmacology of Solriamfetol: Potential Mechanisms for Wake Promotion

Hema Gursahani, Thierry Jolas, Maryse Martin, Sandrine Cotier, Sandrine Hughes, Wayne Macfadden, Gregory Parks*, Craig Chepke Gregory Parks, Axsome Therapeutics

T53. Pharmacological Profile and Relationship Between PDE10A Enzyme Occupancy and Preclinical Efficacy for MK-8189, a Novel PDE10A Inhibitor

Sean Smith^{*}, Monika Kandebo, Eric Hostetler, Izzat Raheem, Mark Layton, Liza Gantert, Kerry Riffel, Christopher Cox, Jason Uslaner Sean Smith, Merck and Co., Inc.

- T54. Weight Loss Following PDE10A Inhibitor Schizophrenia Treatment Explained by Adipose Tissue Physiology Changes in Obese Mice Michal Tomaszewski, Xiangjun Meng, Hyking Haley, Charles Harrell, Terrence Mcdonald, Corin Miller, Sean Smith, Sean Smith* Sean Smith. Merck and Co., Inc.
- T55. Biomarker for Parkinson's Disease Using Resting State EEG and Machine Learning

Habimana Fonseca-Sabune, Arnaud Fosso-Pouangue, Cecile Low-Cam, Fatima Chhade, Mahmoud Hassan, Julia Trabulsi, Carl Saab* Carl Saab, Cleveland Clinic Foundation

- Sector Sector



T56. Computational Linguistic Analysis of Speech Tasks Indexes Symptom Severity and Change in Arabic-Speaking Individuals with Schizophrenia

Michael J. Spilka, Mengdan Xu, Jessica Robin, Faisal Al-Husry, Ruba Jabar, Amal Al-Tabba, William Simpson* William Simpson, Winterlight Labs

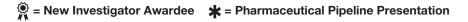
- T57. Mapping the Future of Interventional Psychiatry for the Obsessive-Compulsive Related Disorders: A Scoping Review Rahat Hossain*, Mark Sinyor, Sean Nestor, Peggy Richter, Nir Lipsman, Clement Hamani, Peter Giacobbe Rahat Hossain, University of Toronto
 - T58. Effect of Lemborexant on Sleep Onset and Sleep Maintenance in Patients with Comorbid Insomnia Disorder and Mild Obstructive Sleep Apnea

Margaret Moline, Jocelyn Cheng*, Dinesh Kumar, Barbara Ramos, Alan D. Lowe Jocelyn Cheng, Eisai Inc.

- **T59. Trazodone for Treating Insomnia: Abuse and Safety Risks** Margaret Moline*, Timothy R. Juday, Jocelyn Y. Cheng, Jack Henningfield, August R. Buchhalter, Mark Sembower, Steve Pype, Emerson M. Wickwire, Ric Procyshyn Margaret Moline, Eisai Inc.
- T60. Skilled Nursing Facility Stays and Long-Term Care Admissions Avoided with Pimavanserin or Other Atypical Antipsychotics: A Cost-Offset Analysis of Patients with Parkinson's Disease Psychosis

Aaron Grossman, Nazia Rashid*, Vinod Yakkala, Dilesh Doshi, Krithika Rajagopalan Nazia Rashid, ACADIA Pharmaceuticals Inc

T61. Dysglycemia and Clinical Improvement in Patients with Schizophrenia Treated with Antipsychotics: A Systematic Review Emily Smith*, Emily Au, Sandra Pereira, Eesha Sharma, Ganesan Venkatasubramanian, Gary Remington, Sri Mahavir Agarwal, Margaret Hahn Emily Smith, Centre for Addiction and Mental Health, University of Toronto



Posters

T62. A Comparison of Oral Aripiprazole with an Ingestible Sensor with **Oral Atypical Antipsychotic Treatment and Impact on Psychiatric** Hospitalizations in Adults with Schizophrenia in a Real-World Care Setting

Dusica Hadzi Boskovic*, Sandipan Bhattacharjee, Jeffrey M. Cochran, Min Min Chan, Rifgi Alkhatib, Christian Liman, Simran Thadani, Mayowa Oyesanya, Joydeep Sarkar

Dusica Hadzi Boskovic, Otsuka Pharmaceutical Development and Commercialization. Inc.

T63. Pharmacokinetic Simulations of Aripiprazole 2-Month Ready-to-Use Long-Acting Injectable to Inform Administration in Adult Patients with Schizophrenia or Bipolar-I Disorder

Yanlin Wang, Matthew Harlin*, Frank Larsen, Xiaofeng Wang, Wansu Park, Benjamin Rich, Jogarao V. Gobburu, Arash Raoufinia Matthew Harlin, Otsuka Pharmaceutical Development and Commercialization, Inc. (OPDC)

- T64. Predicted Panss Score After Weekly LYN-005, a Long-Acting Oral Formulation of Risperidone, Administration Isabella Kuan, Todd Dumas, Richard Scranton, Nayana Nagaraj, Xuemin Jiana* Xuemin Jiang, Lyndra Therapeutics
- T65. Aripiprazole 2-Month Ready-to-Use: A Novel Long-Acting Injectable Antipsychotic Formulation for Administration Once Every 2 Months Matthew Harlin, Daiki Kaneko, Murat Yildirim, Pedro Such*, Jessica Madera-McDonough, Frank Larsen Pedro Such, H. Lundbeck A/S
- T66. LATITUDE: Long-Acting Antipsychotic Treatments in Community Telepsychiatry: Knowledge, Attitudes, and Perceived Barriers Sergey Yagoda*, Meera Narasimhan, Suzanne Hardeman, Casey Childers, Amanda Edgar, Amy Claxton, Elizabeth Keane, Batool Haider, Brittany D. Roy, Cory Saucier Sergey Yagoda, Alkermes, Inc.
- T67. Review of the TAAR1 Agonist ulotaront: Part I From Discovery to Clinic

Seth C. Hopkins, Courtney Zeni*, Colleen Synan, Kenneth S. Koblan Courtney Zeni, Sunovion Pharmaceuticals



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- **T68.** Opioid Treatment for Pain and Cognitive Impairment: A Case Report Nelima Basar*, Sachidanand Peteru, Sophia Youn, Arsen Askandaryan Nelima Basar, NYIT College of Osteopathic Medicine
- T69. Patient Journey of Civilian Adults Treated for Post-Traumatic Stress Disorder – A Chart Review Study Lori L. Davis, Jyoti Aggarwal*, Annette Urganus, Patrick Gagnon-Sanschagrin, Jessica Maitland, Jerome Bedard, Remi Bellefleur, Martin Cloutier, Annie Guérin Jyoti Aggarwal, Otsuka Pharmaceutical Development and Commercialization, Inc. (OPDC)
- T70. Methylone: Distinct Pharmacological and Mechanistic Effects Compared with MDMA Jennifer Warner-Schmidt*, Martin Stogniew, Blake Mandell, Sarah J. Olmstead, Benjamin Kelmendi Jennifer Warner-Schmidt, Transcend Therapeutics
- **T71.** Risk of Major Malformations in Infants After First-Trimester Exposure to Stimulants: Results from the Massachusetts General Hospital National Pregnancy Registry for Psychiatric Medications Mercedes Szpunar*, Marlene Freeman, Lauren Kobylski, Ella Rossa, Peter Gaccione, David Chitayat, Adele Viguera, Lee Cohen Mercedes Szpunar, Massachusetts General Hospital, Center for Women's Mental Health
- T72. Efficacy and Safety of Iloperidone in Acute and Mixed Mania Associated with Bipolar I Disorder: A Double-Blind, Placebo-Controlled, Phase III Study

Emily Czeisler^{*}, Rosarelis Torres, Sandra Smieszek, Changfu Xiao, Christos Polymeropoulos, Gunther Birznieks, Mihael Polymeropoulos Emily Czeisler, Vanda Pharmaceuticals Inc.

T73. Prevalence of Major Depressive Disorder and Access to Psychotherapy Services Among Major Depressive Disorder Patients in the United States Xue Han, Monal Kohli, Lisa Abramovitz, Minyi Lu*, Miran Foster, Sandipan Bhattacharjee

Minyi Lu, Otsuka America Pharmaceuticals, Inc.

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- T74. Relationship Between Dose-Dependent Subject Psychedelic Effects, Therapeutic Alliance, and Response to COMP360 Psilocybin Treatment with Psychological Support Guy M Goodwin, Lindsey Marwood, Sunil Mistry, Hollie Simmons, Joyce Tsai*, Ekaterina Malievskaia Joyce Tsai, COMPASS Pathways Ltd.
- T75. Major Depressive Disorder Disease and Patient Characteristics Associated with Inadequate Treatment Experience: Results from the SUPPORT Study

Roger McIntyre, Gregory Mattingly*, Pamela Romero Cruz, Dale Kappus, Iresha Abeynayake, Herriot Tabuteau Gregory Mattingly, Washington University

T76. Efficacy of Viloxazine Er (Qelbree®) for ADHD in Adults Based onPrior Stimulant Exposure Gregory Mattingly*, Joel Young, Jami Earnest, Jennifer Koch, Peibing Qin, Jonathan Rubin

Gregory Mattingly, Washington University

T77. Dermatographic Urticaria Secondary to Duloxetine Administration Paul Clancy*, Kareem Seoudy, Keri Ann Stevenson, Jennifer Payne Paul Clancy, University of Virginia School of Medicine

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