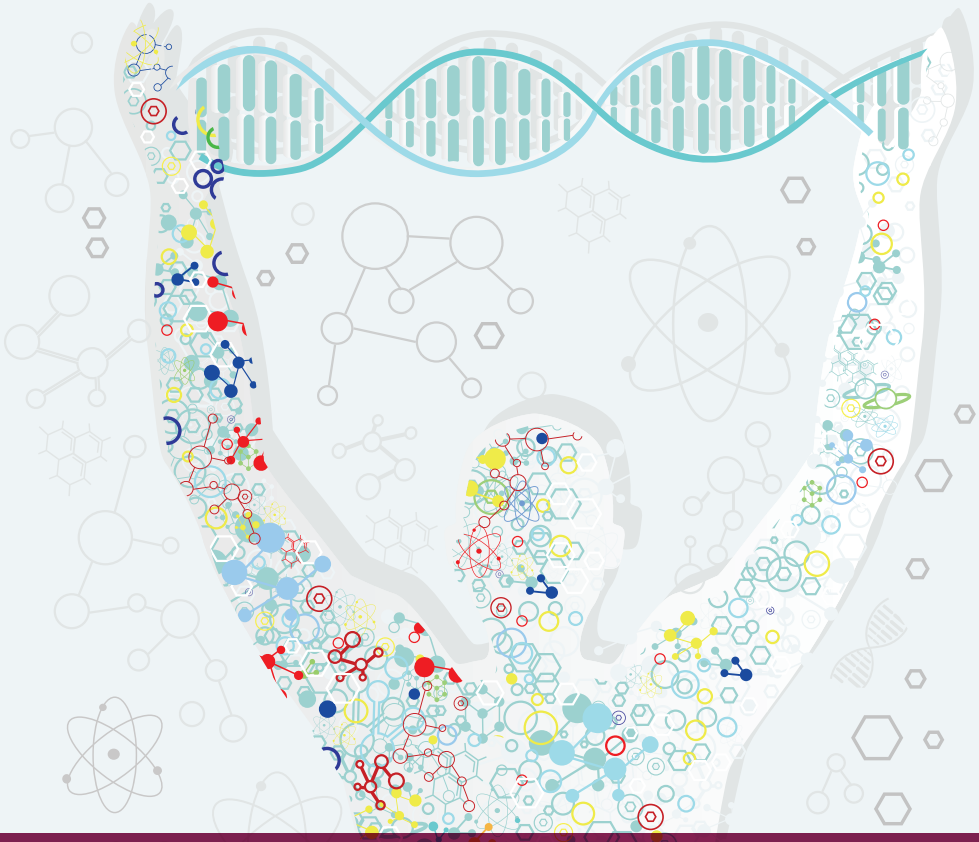
MAY 28-31, 2019 | FAIRMONT SCOTTSDALE PRINCESS



ASCP 2019 Annual Meeting

Innovations in Personalized Medicine: From Biomarkers to Patient-Centered Care

ASCP
American Society of Clinical Psychopharmacology

www.ASCPMeeting.org

ASCP
American Society of Clinical Psychopharmacology

Dear Colleagues,

Welcome to Scottsdale!

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 both the Program Committee and the Steering Committee for their wonderful work putting together an extraordinary meeting.

Our meeting includes not only a very stimulating joint workshop with the American Foundation for Suicide Prevention (AFSP) but also the 27th iteration of our very successful New Investigators' Program. Our meeting has something for everyone. There are sessions that discuss innovations in personalized medicine across not only syndrome-states and the life cycle but also in terms of public-private partnerships, teaching, as well as public health, dissemination research, and patient-centered care. And just when you think there could be nothing more to entice you out of the Arizona sun, there are talks on negotiation strategies for professionals in CNS research, clinical trial designs that move psychopharmacology toward personalized medicine, to pharmacogenomic testing in psychiatric practice to a special workshop on how to give a scientific presentation.

For the third year, we have added the Early Career Luncheon with panelists from diverse career trajectories that will discuss building scientific collaborations. In addition, we have added early career tables to each lunch sessions, where attendees of all career stages are welcome to sit and network. We have also extended the Federal Agency Updates Plenary to include Veterans Affairs, SAMHSA, and NCATS. There is, of course, the very important and unique Regulatory Session that traditionally serves as the closing session of our meeting.

The ASCP is committed to finding and testing new therapies for our patients. We want to advance not only the field of psychopharmacology but treatment research in general. Many advances first presented at our annual meeting over the years have become mainstays not only in our treatment of serious mental disorders but in the way we design and conduct our clinical trials. I am sure that we will see presentations and posters at this meeting that will become important methods for caring for our patients in the future.

Our society has taken on a new responsibility in the past year and is actively becoming one of the places that legislators, federal agencies, and other groups interested in public policy turn to for advice on therapy and research questions about brain diseases. I want to thank Alan Gelenberg who was the initial co-chair of this working group. We have now formed a standing liaison committee to address these issues as they arise. As the experts in the field we have a responsibility to our patients and society to weigh in on these important issues. Please contact our colleagues at Parthenon Management Group if you have an interest in this or any other ASCP activities or committees.

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

Michael E. Thase, M.D.
President
American Society of Clinical Psychopharmacology

Welcome to the ASCP Annual Meeting

On behalf of the ASCP Annual Meeting Steering and Program Committees, 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 2019 meeting.

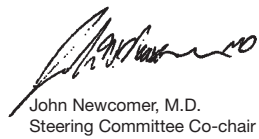
The annual meeting brings together academic investigators, industry scientists, U.S. and international regulators, National Institutes of Health (NIH) and other professionals who work in drug development and clinical trials.

- **2019 Program Highlights**
  - **Tuesday, May 28th**
    - Conference Opening
    - Early Career Luncheon (RSVP Only)
    - Pharma Pipeline: 11 presentations of Phase 1 and Phase 2 developments
    - Individual Research Reports
  - **Wednesday, May 29th**
    - 20th Annual Fun Run/Walk
    - Women's Initiative Breakfast (Welcome to all Female Attendees – RSVP Required)
    - Regulatory Plenary: *Breakthrough and Prime Regulatory Pathways*
    - ASCP Lifetime Awardee Talk: *Forty Years of Research and Practice in Psychopharmacology*
    - Poster Session I
    - ASCP Reception
  - **Thursday, May 30th**
    - Keynote Plenary Session: *Innovations in Personalized Medicine: From Biomarkers to Patient-Centered Care*
    - Federal Agency Updates Plenary
    - Poster Session II
    - Clinical Updates in Psychopharmacology
  - **Friday, May 31st**
    - Regulatory Wrap-Up Plenary with FDA & EMA regulators
  - **Throughout the meeting**
    - NIMH, NIDA, NIAAA, and FDA panels
  - **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
- **Organization**
  - The meeting is sponsored by the American Society of Clinical Psychopharmacology (ASCP).
    - The Steering Committee organizes the meeting.
    - The Program Committee evaluates submitted proposals and develops program innovations.
  - Federal agency collaborations:
    - NIAAA - National Institute on Alcohol Abuse and Alcoholism
    - NIDA - National Institute of Drug Abuse
    - NIMH - National Institute of Mental Health
    - NCATS – National Center for Advancing Translational Sciences
    - SAMHSA – Substance Abuse and Mental Health Services Administration
    - VA - U.S. Department of Veterans Affairs
  - Regulatory agency collaborations:
    - Food and Drug Administration (FDA)
    - Italian Medicines Agency (AIFA)
  - Society collaborations:
    - International Society for Bipolar Disorder (ISBD)
    - American Foundation for Suicide Prevention (AFSP)
    - International Society for CNS Clinical Trials and Methodology (ISCTM)
  - Parthenon Management Group organizes the ASCP Annual Meeting.
- **And remember**
  - The Fun Run/Walk is Wednesday, May 29th at 6:30 a.m. All are welcome to join!
  - The ASCP Reception is Wednesday, May 29th 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,

Susan G. Kornstein, M.D.
Steering Committee Co-chair

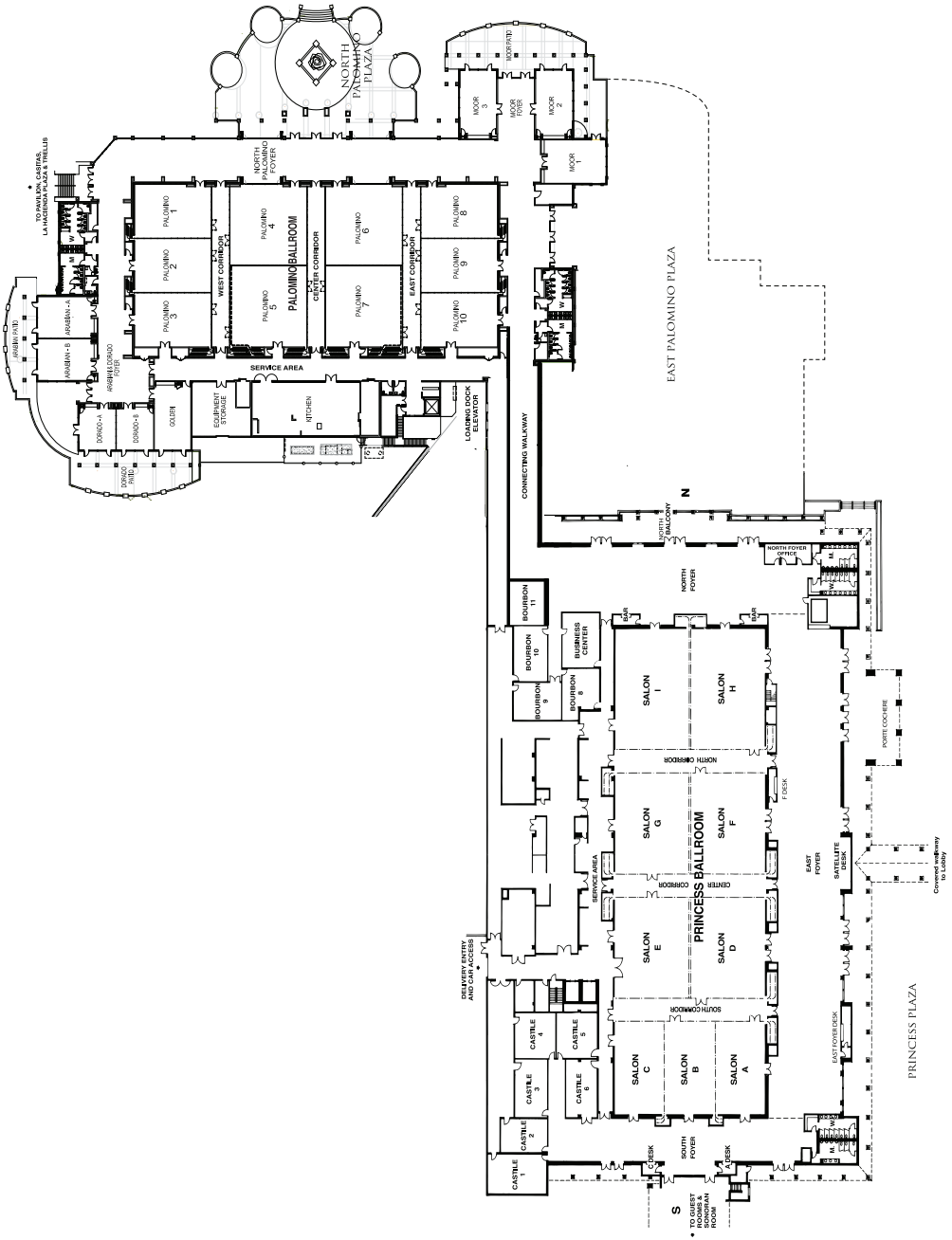


John Newcomer, M.D.
Steering Committee Co-chair

Anita Clayton, M.D.
Program Committee Co-chair

Erika Saunders, M.D.
Program Committee Co-chair

Fairmont Scottsdale Princess



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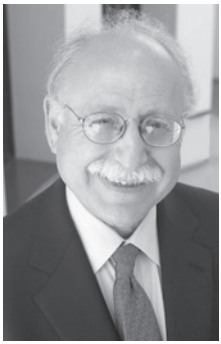
DISCLOSURES FOR ALL ASCP PRESENTERS CAN BE VIEWED AT WWW.ASCPMEETING.ORG

Recipient of the Donald Klein Lifetime Achievement Award



Alan Schatzberg, M.D.
Stanford University School of Medicine

Dr. Schatzberg received his MD from NYU in 1968. He completed his psychiatric residency at the Massachusetts Mental Health Center and a clinical fellowship in psychiatry at Harvard Medical School. After serving in the United States Air Force, he joined the staff at McLean Hospital and served in several leadership positions there. He became clinical director of the Massachusetts Mental Health Center and professor of psychiatry at Harvard Medical School, while continuing his research program at McLean Hospital on the biology and treatment of depression. In 1991, Dr. Schatzberg became the Kenneth T. Norris, Jr., Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Stanford University, where he served as chair until 2010. He now directs the Stanford Mood Disorders Center. Dr. Schatzberg has been an active investigator in the biology and psychopharmacology of depressive disorders. He has authored over 700 publications and abstracts, co-edited the Textbook of Psychopharmacology (now in its Fifth Edition), and is co-editor-in-chief of the Journal of Psychiatric Research. He has been president of the American Psychiatric Association (APA), the American College of Neuropsychopharmacology (ACNP), and the Society of Biological Psychiatry (SOBP). He has received numerous awards for excellence and leadership from the APA, ACNP, SOBP, Max Planck Psychiatric Institute, Brain and Behavior Foundation, Anna Monika Foundation, U. Pennsylvania, Weill Cornell Medical College, etc. He has three honorary doctorates and has been elected to the National Academy of Medicine.

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

Randi Schuster, Ph.D.
Harvard Medical School, Massachusetts General Hospital

Nominated for: *One Month of Cannabis Abstinence in Adolescents and Young Adults is Associated With Improved Memory*
Randi Melissa Schuster, Ph.D.; Jodi Gilman, Ph.D.; David Schoenfeld, Ph.D.; John Evenden, Ph.D.; Maya Hareli, B.A.; Christine Ulysse, M.S.; Emily Nip, B.A.; Ailish Hanly, B.A.; Haiyue Zhang, M.S.; and A. Eden Evins, M.D., M.P.H.

Dr. Randi Schuster is an assistant professor at Massachusetts General Hospital (MGH)/Harvard Medical School and the Director of Neuropsychology at the MGH Center for Addiction Medicine. She received her BA from The University of Maryland, College Park in 2007 and her PhD in Clinical Psychology from The University of Illinois at Chicago in 2014. She received specialized training in neuropsychology as a pre-doctoral intern and post-doctoral fellow at MGH/ Harvard Medical School.

Dr. Schuster's work aims to define the cognitive predecessors of adolescent cannabis use, effects of cannabis use on cognitive performance, and how these and other factors (e.g., genetics and environment) affect treatment engagement and functional (e.g., academic) outcomes. Her work explores the behavioral and biological mechanisms underlying risk for adverse outcomes secondary to early cannabis exposure, with a particular emphasis on vulnerable sub-populations including adolescents with and at risk for neuropsychiatric illness.

Dr. Schuster has been the recipient of multiple awards to fund her research from Harvard Medical School, MGH, and NIH, including a 5-year NIDA K23 grant. Her ongoing studies capitalize on her expertise in neuropsychological protocol implementation, recruitment and retention of high-risk cohorts in community-based settings, and longitudinal analytic approaches. Her K23 project examines the utility of contingency management interventions in promoting cannabis abstinence, and aims to explicate the time course of neurocognitive recovery in the early days following cannabis discontinuation among non-treatment seeking high school students. This work has been recognized for its potential clinical impact, including coverage for her most recent manuscript in over 80 global media outlets.

Recipient of the ASCP Jonathan Cole Presidential Service Award

Alan Gelenberg, M.D.
University of Arizona

Alan J. Gelenberg, M.D. is Professor Emeritus at the University of Arizona, where he headed the Department of Psychiatry for 18 years. From 2008 through 2009, he was President and CEO of Healthcare Technology Systems of Madison, Wisconsin, and from 2010 through 2014 he was Shively-Tan Professor and Chair of Psychiatry at Penn State University. He was Editor-in-Chief of the *Journal of Clinical Psychiatry* for 30 years and founding author of *Biological Therapies in Psychiatry Newsletter*, which he wrote for 40 years. He was on the faculties of Harvard, Massachusetts General Hospital, M.I.T., and the University of Wisconsin.

Dr. Gelenberg has been lead author of manuscripts in the *Lancet, New England Journal of Medicine, JAMA* and published over 300 scientific articles, editorials, and book chapters. He cochaired the ASCP's Annual Meeting Program Committee and chaired the APA's workgroup on Treatment Guidelines for Major Depressive Disorder, 3rd edition. He helped create the ASEX scale to monitor sexual side effects of antidepressants, as well as electronic versions of suicide assessment instruments. He served on an FDA panel addressing female sexual dysfunction. He is a Distinguished Life Fellow of the APA, past President of the West Coast College of Biological Psychiatry, fellow of the American College of Neuropsychopharmacology, and member of the American College of Psychiatrists. He was listed in *The Best Doctors in America* and *America's Top Doctors*, received an Exemplary Psychiatrist Award of the National Alliance for the Mentally Ill and two teaching awards at the University of Arizona. He has mentored numerous researchers, many of whom are now productive scientists, department chairs, and deans.

A native of Philadelphia, Alan Gelenberg received an A.B. from Columbia University and M.D. from the University of Pennsylvania. After a year's internship in internal medicine at Presbyterian-University of Pennsylvania Medical Center, he was a resident in psychiatry at the Massachusetts General Hospital. For six years he was a commissioned officer in the U.S. Army Reserves. Dr. Gelenberg's wife was the first woman TV news anchor in Arizona, on the air for 34 years, and a candidate for the U.S. Congress. They now live in Seattle.

New Investigator Awardees

Ali Bani-Fatemi, Ph.D.
Centre for Addiction and Mental Health

Venkat Bhat, FRCPC
University of Toronto

Tim Bigdeli, Ph.D.
State University of New York, Downstate Medical Center

Cherise Chin Fatt, Ph.D.
University of Texas Southwestern Medical Center

Andrew Czysz, M.D., Ph.D.
University of Texas Southwestern Medical Center

Jennifer Dwyer, M.D., Ph.D.
Yale Child Study Center

Jermaine Jones, Ph.D.
Columbia University Medical Center

Shamir Kalaria, Pharm.D.
University of Maryland School of Pharmacy

Reilly Kayser, M.D.
Columbia University/New York State Psychiatric Institute

Dorian Lamis, Ph.D.
Emory University School of Medicine

Matej Markota, M.D.
Mayo Clinic

Josephine McGowan, B.A.
Columbia University

Nicolas Nunez, M.D.
Mayo Clinic

Hyuntaek Oh, Ph.D.
The Menninger Clinic

Daria Piacentino, M.D.
NIH/NIAAA

Joshua Rosenblat, M.D.
University of Toronto

Jonathan Stange, Ph.D.
University of Illinois at Chicago

Victor Tang, M.D.
University of Toronto

Sanne van Rooij, Ph.D.
Emory University School of Medicine

Cory Weissman, M.D.
University of Toronto and CAMH

Regulatory Plenary: *Breakthrough and Prime Regulatory Pathways*

Wednesday, May 29th from 8:30 a.m. – 10:00 a.m.

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 coming to 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 Acting Director of the Division of Psychiatry Products, 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.

Valentina Mantua, M.D., Ph.D.
Italian Medicines Agency (AIFA)

Valentina Mantua is a medical doctor and a psychiatrist with an extensive clinical experience in the field of psychosis and affective disorders both at the Maudsley NHS Trust in London and University Hospital in Pisa, Italy, where she also obtained a PhD in Neurobiology of Affective Disorders.

She joined the regulatory world in 2012 as expert CNS assessor at the Italian Medicines Agency (AIFA) and served as Italian representative in several working parties at the European Medicines Agency (EMA): the Scientific Advice Working Party (SAWP) and the Central Nervous System Working Party on (CNSWP). She is also the Italian representative at the EU-Innovation Network, supporting innovation in drug development both at a national and European level.

Keynote Plenary: *Innovations in Personalized Medicine: From Biomarkers to Patient-Centered Care*

Thursday, May 30th from 8:15 a.m. - 9:45 a.m.

Katia Howlett, Ph.D., M.B.A., M.P.P.
National Institutes of Health, National Institute of Drug Abuse

Katia Delrahim Howlett, Ph.D., M.B.A., M.P.P. is the Deputy Director of the Division of Extramural Research (DER) at the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH). Dr. Howlett received a Ph.D. in Public Health from the University of California at San Diego and San Diego State University, Master of Public Policy from Pepperdine University, and Master of Business Administration from the Johns Hopkins University. In addition to her role in DER as Deputy Director, she serves as the NIDA Clinical Trials Stewardship Policies Implementation Coordinator and Risk Manager. Prior to joining NIDA, she served as the Project Director of the NIDA Blending Initiative contract and the SAMHSA National Campaigns contract with Synergy Enterprises, Inc. Prior to that, she served as Deputy Director of the SAMHSA Underage Drinking Prevention Education Initiatives contract with University Research Company, LLC. In these roles, Dr. Howlett managed the development of evidence-based national educational trainings, materials, resources, and campaigns for researchers, healthcare professionals, children, adolescents, and families to promote the prevention of substance use disorders and the implementation of evidenced-based practices in the treatment of these illnesses in healthcare settings. Her doctoral training in Public Health focused on health behavior and the prevention of risky behaviors including primary prevention of Fetal Alcohol Spectrum Disorders and other consequences of alcohol misuse. She has expertise in the fields of mental health, public health and safety, health policy, health communication, and substance abuse and addiction. She is widely published in the fields of mental illness and substance use disorders, on topics as varied as adolescent substance abuse, technology-based health interventions, mood and anxiety disorders, and health-related quality of life.

Sumitra Muralidhar, Ph.D.
Department of Veterans Affairs

Dr. Muralidhar is the Program Director for VA's Million Veteran Program (MVP) in the Office of Research and Development (ORD). In this role, she oversees the development of policy and infrastructure for enrollment, data use and conduct of science from at least one million Veterans in a longitudinal cohort collecting genetic, clinical, lifestyle and military exposure data for future research. She served as ORD's liaison to the White House precision medicine Initiative under President Obama, and continues to represent the VA in the federal interagency group on precision medicine. She served as the designated federal officer (DFO) for VA's Genomic Medicine Program Advisory Committee- a FACA committee which advises the VA Secretary on the genomic medicine research and clinical branches within the Veterans Health Administration.

She previously served as a Senior Scientific program manager for ORD's Biomedical laboratory Research and Development Service, where she managed several scientific portfolios and programs. She obtained her Ph.D. in Molecular Biology from the University of Maryland at College Park, and her Master's in genetics from Bangalore University, India.

Holly Garriock, Ph.D.
National Institutes of Health

Holly A. Garriock, Ph.D., is the team lead for the health care provider organizations and partner awardees for the All of Us Research Program. Holly came to the program from the National Institute of Mental Health, where she managed a research portfolio of child and adolescent depression, anxiety, suicide, and trauma that supported her growth and expertise in the fields of child development and mood disorders. Holly did her undergraduate training in Canada; graduate training at the University of Arizona, where she received her Ph.D. in genetics; and postdoctoral research at the University of California, San Francisco.

Jordan Smoller, M.D., Sc.D.
Massachusetts General Hospital & Harvard Medical School

Dr. Jordan Smoller is a psychiatrist, epidemiologist, and geneticist whose research focus has been 1) understanding the genetic and environmental determinants of psychiatric disorders across the lifespan; 2) integrating genomics and neuroscience to unravel how genes affect brain structure and function; and 3) using "big data", including electronic health records and genomics, to advance precision medicine.

Dr. Smoller earned his undergraduate degree at Harvard University and his medical degree at Harvard Medical School. After completing residency training in psychiatry at McLean Hospital, he received masters and doctoral degrees in epidemiology at the Harvard School of Public Health.

Dr. Smoller is the Massachusetts General Hospital (MGH) Trustees Endowed Chair in Psychiatric Neuroscience, Professor of Psychiatry at Harvard Medical School and Professor in the Department of Epidemiology at the Harvard School of Public Health in Boston. He is Associate Chief for Research in the MGH Department of Psychiatry and Director of both the Psychiatric and Neurodevelopmental Genetics Unit and the Precision Medicine Research Unit in the MGH Center for Genomic Medicine. Dr. Smoller is a Tepper Family MGH Research Scholar and also serves as Director of the Omics Unit of the MGH Division of Clinical Research and co-Director of the Partners HealthCare Biobank at MGH. He is an Associate Member of the Broad Institute and Vice President of the International Society of Psychiatric Genetics. He is a PI in the Electronic Medical Records and Genomics (eMERGE) network and contact PI of the New England Precision Medicine Consortium as part of the NIH Precision Medicine Initiative's All of Us Research Program. He is an author of more than 300 scientific publications and is also the author of *The Other Side of Normal* (HarperCollins/William Morrow, 2012).

Federal Agency Updates Plenary
Thursday, May 30th from 10:00 a.m. – 12:30 p.m.

Terri Gleason, Ph.D.
U.S. Department of Veterans Affairs (VA)

Theresa (Terri) Gleason, Ph.D., is the Director, Clinical Science Research and Development Service, Office of Research and Development, VA Central Office, Washington, D.C.

Dr. Gleason has a distinguished research career of nearly twenty years of VA service. Prior to her appointment, Dr. Gleason held a variety of leadership assignments: (Acting) Deputy Chief Research & Development Officer, (Acting) Director, Biomedical Laboratory Research & Development Service, (Acting) Director, Clinical Science Research & Development Service, Senior Program Manager, Transformational Initiative, Program Manager, Clinical Trials, Research Lead for US DVA, Senior International Forum of Veterans Administrations, Program Manager Career Development, and Portfolio Manager Behavioral & Psychiatric Disorders Research.

George Koob, Ph.D.
National Institute on Alcohol Abuse & Alcoholism (NIAAA)

George F. Koob, is Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) as of January 27, 2014. As NIAAA Director, Dr. Koob oversees a wide range of alcohol-related research, including genetics, neuroscience, epidemiology, prevention, and treatment.

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 700 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 11 Ph. D students and over 80 post-doctoral fellows.

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. He has also served as a researcher in the Department of Neurophysiology at the Walter Reed Army Institute of Research and the Arthur Vining Davis Center for Behavioral Neurobiology at the Salk Institute for Biological Studies. Dr. Koob is the recipient of many honors, including membership in the National Academy of Medicine and award of the Legion of Honor (France).

Bruce Cuthbert, Ph.D.
National Institute of Mental Health (NIMH)

Dr. Bruce Cuthbert directs the Research Domain Criteria (RDoC) Unit at the National Institute of Mental Health, which leads NIMH's development of a research framework for psychopathology based upon dimensions of behavior and neural systems. He also served as NIMH Acting Director from 2015 to 2016. Dr. Cuthbert has led the RDoC project since its inception in 2009, also directing the Division of Adult Translational Research from 2009-2014. He returned to NIMH in 2009 following four years as a professor at the University of Minnesota. He was previously Chief of the NIMH Adult Psychopathology Branch and spent seventeen years at the University of Florida. Dr. Cuthbert received his Ph.D. in clinical psychology and psychophysiology from the University of Wisconsin-Madison, and is known for his translational research on emotions and anxiety disorders. He is a fellow of the Association for Psychological Science and a past-president of the Society for Psychophysiological Research.

Kurt Rasmussen, Ph.D.
National Institute on Drug Abuse (NIDA)

Dr. Kurt Rasmussen is the Director, Division of Therapeutics and Medical Consequences, at the National Institute on Drug Abuse (NIDA), leading their efforts to promote the development of safe and effective pharmacotherapies, behavioral therapies, and devices to treat addiction. Dr. Rasmussen is a research scientist in the field of neuropharmacology and neurotherapeutic drug development with extensive experience in senior scientific and management leadership positions in the pharmaceutical industry and government. His career spans 30-years of highly innovative scientific research in neuroscience pharmaceutical discovery, from hypothesis generation to clinical candidate evaluation. Dr. Rasmussen received his A.B., with Honors and Distinction, from Cornell University, his Ph.D., in Neuroscience and Psychology, from Princeton University and was a Postdoctoral Associate in the Department of Psychiatry at the Yale University School of Medicine. He previously worked as a Senior Research Scientist in the Neuroscience Division of Eli Lilly & Co., leading efforts to discover novel treatments for psychiatric disorders, such as depression and schizophrenia.

Thomas Clarke, Ph.D.
Substance Abuse and Mental Health Services Administration (SAMHSA)

Thomas Clarke, Ph.D., serves as the Director of the National Mental Health and Substance Use Policy Laboratory at SAMHSA. Thomas joined SAMHSA in 2012 in the Center for Behavioral Health Statistics and Quality where he worked on designing evaluations for programs in prevention, treatment, and mental health. Prior to joining SAMHSA, he worked at the Governmental Accountability Office where he developed guidance for federal agencies on designing evaluations.

Clinical Updates in Psychopharmacology
Thursday, May 30th from 2:00 p.m. – 3:30 p.m.

Jennifer Payne, M.D.
Johns Hopkins School of Medicine

Dr. Payne is an Associate Professor of Psychiatry and the Director of the Johns Hopkins Women's Mood Disorders Center. She received her medical degree from Washington University, completed her residency in psychiatry at Johns Hopkins and finished a fellowship in mood disorders through the Mood and Anxiety Disorders Program at NIH. In addition to providing outstanding clinical care for women with mood disorders, Dr. Payne conducts research into the genetic, biological, and environmental factors involved in postpartum depression and studies best practices for the management of mood disorders during and after pregnancy. She and her colleagues have recently identified two epigenetic biomarkers of postpartum depression and are working hard to replicate this work with NIH funding.

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

Gary Small, M.D., is a Professor of Psychiatry and Biobehavioral Sciences, the Parlow-Solomon Professor on Aging at the David Geffen School of Medicine at UCLA, Director of the UCLA Longevity Center, and Director of the Division of Geriatric Psychiatry at the Semel Institute for Neuroscience & Human Behavior at the University of California, Los Angeles. Dr. Small was among the team of investigators involved in the discovery of the major known genetic risk for Alzheimer's disease, APOE-4, and was the first to combine such genetic risk data with neuroimaging findings to assist in the detection of the first signs of brain aging and dementia years before patients show symptoms. He is a co-inventor of the first positron emission tomography (PET) scanning method that can provide images in living people of the abnormal brain proteins in Alzheimer's disease – amyloid plaques and tau tangles. In addition to testing novel interventions that may benefit cognition and delay the onset of Alzheimer's disease symptoms, Dr. Small has developed lifestyle and memory training programs that are available throughout the U.S. and abroad in senior centers, hospitals, and other community sites.

Gary Small, M.D. (continued)

Dr. Small has authored over 500 scientific works and has received ongoing research support from the NIH and major foundations throughout his career. He has received numerous awards and honors from the American Association for Geriatric Psychiatry, American College of Psychiatrists, International Psychogeriatric Association, and the American Psychiatric Association. He also is a past president of the American Association for Geriatric Psychiatry. *Scientific American* magazine named him one of the world's top 50 innovators in science and technology. He is the author of nine popular books on brain health and aging, including the New York Times bestseller *The Memory Bible*.

Iván 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 NIDA's implementation of NIH wide policies for the Clinical Trials Stewardship Initiative. He leads NIDA's marijuana medications development initiative and the recently published funding opportunity for the development of medications to prevent opioid use disorders and overdose, which is part of the NIH HEAL Initiative to combat the opioid use crisis. He collaborates with the IRP in research projects, with NIDA's International Office in the Latin American Initiative, and is a member of several scientific interest workgroups. Previous experience includes seven years as a clinical investigator in the Intramural Research Program of NIDA, and four years in academia. He joined NIDA in December 1999.

Regulatory Wrap-Up
Friday, May 31st from 10:15 a.m. – 11:45 a.m.

Michael Davis, M.D., Ph.D.
US Food and Drug Administration

Mike Davis currently serves as a Lead Physician (Clinical Team Leader) in the Division of Psychiatry Products at the US Food and Drug Administration (FDA). Dr. Davis completed a Medical Scientist Training Program (M.D./Ph.D.) at Case Western Reserve University, psychiatric residency training at the University of California, Los Angeles, and a research fellowship at the West Los Angeles VA Mental Illness Research, Education, and Clinical Center. His research interests focused on the development of novel therapeutics for cognitive deficits and negative symptoms associated with psychotic disorders. Prior to joining the FDA in 2016, Dr. Davis was an assistant professor at Baylor College of Medicine and staff psychiatrist at the Michael E. DeBakey VA Medical Center in Houston, Texas. In his current role at the FDA, he leads a team of clinical reviewers on the review of investigational new drug applications, new drug applications for marketing approval, and postmarketing safety information. Beyond his core work duties, Dr. Davis is actively involved with the American Society of Clinical Psychopharmacology (ASCP) and the International Society for CNS Clinical Trials and Methodology (ISCTM).

Valentina Mantua, M.D., Ph.D.
Italian Medicines Agency (AIFA)
See previous bio

Javier Muniz, M.D., FAPA
US Food and Drug Administration

Dr. Javier A. Muniz completed his psychiatry residency at Mount Sinai Medical Center in New York City in 2004. CDR Muniz joined the United States Air Force and was stationed at Andrews AFB, MD, serving in Afghanistan in the years 2004 and 2005. During his six years at Andrews, CDR Muniz was the director of the outpatient mental health clinic and for the largest substance abuse partial hospitalization program in the USAF. CDR Muniz transitioned into the USPHS in December 2008 and continued his duties for the Department of Defense at Fort Meade, MD, as the Chief of Psychiatry Services for a large Wounded Warrior Program and supporting various national security programs. Since 2014, CDR Muniz has served at the FDA. He initially worked as a medical officer in the Division of Analgesia, Anesthesia, and Addiction Products. Currently, he is the Associate Director for Therapeutic Review at the Division of Psychiatry Products, Office of New Drugs at the FDA. He is also serving as the Capitol Area Team 4 Commander, leading a team of 25 medical professionals supporting the Office of the Attending Physician for hi-visibility events at the US Capitol and DC region.

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Meeting Services

Registration Desk* Hours:

Monday	10:00 a.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.

*The registration/meeting information desk is located in the East Foyer, outside of the Princess Ballroom.

The ASCP Speaker Ready Room is open on the below dates and times for presenters to upload slides. The meeting organizers ask that all speakers upload their slides 24 hours prior to their scheduled presentation time.

The Speaker Ready Room is located in the Bourbon 11 meeting room.

Monday	12:00 p.m. – 5:00 p.m.
Tuesday - Thursday	7:30 a.m. – 6:00 p.m.
Friday	7:30 a.m. – 10:30 a.m.

ASCP Wi-Fi
SSID: Fairmont-Meeting
Access PIN: ASCP2019

Americans with Disabilities Act - It is the policy of ASCP not to discriminate against any person on the basis of disabilities. If you feel you need services or auxiliary aids mentioned in this act in order to fully participate in this continuing education activity, please call the Executive Office at 615-649-3085 or send an email to info@ascpp.org.

Discounts – All ASCP Annual Meeting attendees who booked their room at the Fairmont Scottsdale Princess through the ASCP meeting website will have the following resort amenities complimentary:

- Unlimited basic internet access in your guest rooms and resort public areas.
- Any local and 1-800 access calls from your guest room.
- Complimentary self-parking for one vehicle per room.
- Complimentary half-day admission to Trailblazers kid's adventure club access for up to three children.
- Access to 24-hour Fairmont Fitness Center.
- On-site shuttle transportation service (guest rooms, restaurants, spa, pool and meeting space).
- 50% discount off Well & Being Spa daily access fee including complimentary fitness and wellness classes, waterfall treatment pool, sauna, and rooftop pool.

ASCP Membership - If you would like to join ASCP, you can log onto our website at https://www.ascpp.org/ and register online. Membership applications are available at the ASCP membership booth, located next to the meeting registration desk in the East Princess Foyer. You may also contact the ASCP office at 615-649-3085 to request one.

ASCP Fellow Membership
If you have been a member of ASCP for 10+ consecutive years and attended 5 or more meetings, or been a member of ASCP for 20+ consecutive years, you may be eligible for fellowship membership. Contact ASCP's Executive Office, info@ascpp.org, for more information or to confirm your status.

Continuing Education Credits

Disclosures are available for all ASCP Annual Meeting presenters online at www.ASCPMeeting.org.

Continuing Education Credits are available for physicians, pharmacists, and psychologists. **Self-assessment maintenance of certification credits** are available for physicians. Applications for credit must be completed online with the meeting evaluation survey. The survey may be completed during or after the meeting at www.ASCPMeeting.org. ***Surveys for continuing education credit must be submitted no later than Monday, July 01, 2019.*** There is a $40.00 administrative fee for CME/CE applications. It is the policy of the ASCP to require disclosure of financial relationships from individuals in a position to control the content of a CME activity; to identify and resolve conflicts of interest related to those relationships; and to make disclosure information available to the audience prior to the CME activity. Presenters are required to disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentations.

The American Board of Psychiatry and Neurology has reviewed the annual meeting and has approved this program as part of a comprehensive self-assessment program, which is mandated by the ABMS as a necessary component of maintenance of certification.

Satisfactory Completion
Learners must complete an evaluation form to receive a certificate of completion. Your chosen sessions must be attended in their entirety. Partial credit of individual sessions is not available. If you are seeking continuing education credit for a specialty not listed below, it is your responsibility to contact your licensing/certification board to determine course eligibility for your licensing/certification requirement.

Physicians and Pharmacists

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INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, this activity has been planned and implemented by Amedco LLC and the 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.

Credit Designation Statement – Amedco LLC designates this live activity for a maximum of 20.75 *AMA PRA Category 1 Credits*™ for physicians and 20.75 knowledge-based contact hours for pharmacists. Learners should claim only the credit commensurate with the extent of their participation in the activity.
NOTE to Pharmacists: The only official Statement of Credit is the one you pull from CPE Monitor. You must request your certificate within 30 days of the activity to meet the deadline for submission to CPE Monitor.

Psychologists
This course is co-sponsored by Amedco and ASCP. Amedco is approved by the American Psychological Association to sponsor continuing education for psychologists. Amedco maintains responsibility for this program and its content. Maximum of 20.75 hours. Partial credit will not be awarded.

All participants who request continuing education credits by Monday, July 01, 2019, should expect to receive their statement of credits via email in mid-July.

The Meeting Evaluation Survey will be available at www.ASCPMeeting.org. 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 2019 meeting is appreciated as we strive to improve the meeting each year.

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

ACADIA Pharmaceuticals Inc.
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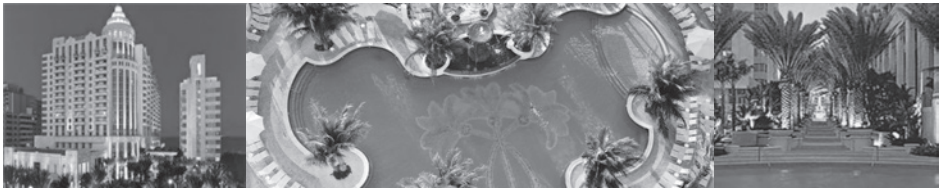
2020 ASCP Annual Meeting – Save the Date



The 2020 ASCP Annual Meeting will take place May 26 – 29, 2020 at the Loews Miami Beach Hotel in Miami, Florida. Details regarding abstract submission for the 2020 Annual Meeting will be released in September 2019.

AT-A-GLANCE

Monday, May 27, 2019

8:00 a.m. - 4:55 p.m.	**New Investigator Award (NIA) Workshop (Invitation Only)** *Salon H*
10:00 a.m. - 5:00 p.m.	**Registration** *Princess East Foyer Desk*
12:00 p.m. - 5:00 p.m.	**Speaker Ready Room** *Bourbon 11*

FULL SCHEDULE

Monday, May 27, 2019

8:00 a.m. - 4:55 p.m. **New Investigator Award (NIA) Workshop (Invitation Only)**
Salon H

Co-Chairs: Mark Rapaport, Emory University School of Medicine
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 28, 2019. 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 28, 2019. This year marks the 27th 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

Michael Davis
US Food and Drug Administration

Tiffany Farchione
US Food and Drug Administration

Bruce Kinon
Lundbeck

Iván Montoya
National Institute on Drug Abuse

Lynn Morin
National Institute on Alcohol Abuse and Alcoholism

Katharine Phillips
Weill Cornell Medical College/ NewYork-Presbyterian Hospital

Nina Schooler
SUNY Downstate Medical Center

10:00 a.m. - 5:00 p.m. **Registration**
Princess East Foyer Desk

12:00 p.m. - 5:00 p.m. **Speaker Ready Room**
Bourbon 11

AT-A-GLANCE

Tuesday, May 28, 2019

7:30 a.m. - 8:30 a.m. **NIA Breakfast Roundtable (Invitation Only)**
Castile 1

7:30 a.m. - 8:30 a.m. **ASCP Membership Committee Meeting (Invitation Only)**
Castile 3

7:30 a.m. - 9:00 a.m. **Morning Break**
Princess East Foyer

7:30 a.m. - 6:00 p.m. **Registration**
Princess East Foyer Desk

7:30 a.m. - 6:00 p.m. **Speaker Ready Room**
Bourbon 11

8:30 a.m. - 9:00 a.m. **Conference Opening+**
Salon A-E

9:00 a.m. – 10:30 a.m. **Panel Sessions**

New and Hopefully Improved! Novel Delivery Systems of Antipsychotic Medications for the Treatment of Schizophrenia*	Leveraging Prior Experience to Facilitate Pediatric Clinical Development for Psychiatry Products*	Treatment-resistant Mood Disorders Across the Lifespan: Novel Therapeutics on the Horizon*	Clinical Trial Designs That Move Psycho-pharmacology Towards Personalized Medicine
Salon F	*Salon G*	*Salon H*	*Salon I*

10:30 a.m. – 10:45 a.m. **Break**
Princess East Foyer

10:45 a.m. – 12:15 p.m. **Panel Sessions**

Biomarker Development in Autism: The Potential Impact of the Autism Biomarkers Consortium for Clinical Trials (ABC-CT)* *Salon F*	Pharmacogenomic Testing in Psychiatric Practice: Does it Deliver What it Promises?* *Salon G*	Digital Technology Advancements and Potential for Assessing Behavior in Clinical Trials* *Salon H*	ISCTM/ASCP Workshop – Developing an Advanced CNS Clinical Trial Course *Salon I*

12:15 p.m. – 1:45 p.m. **Early Career Luncheon (RSVP Only)+**
Palomino 9-10

1:50 p.m. – 4:00 p.m. **Pharmaceutical Pipelines+**
Salon A-E

4:00 p.m. – 4:15 p.m. **Break**
Princess East Foyer

4:15 p.m. – 5:30 p.m. **Individual Research Reports**

Broad Spectrum Use of Neuroleptic Agents: Benefits and Liabilities* *Salon F*	Exploring New Treatment Options in Diverse Populations* *Salon G*	Biomarkers for Depression: Subtypes and Response to Treatment* *Salon H*	Using MDMA and Transdermal Buprenorphine to Treat Trauma and Addiction, Microbiome Changes in Binge Drinking, and Understanding Why Our Phase III Trials can Fail Even When the Treatment Works* *Salon I*

6:15 p.m. – 7:45 p.m. **New Investigator Awards Ceremony (Invitation Only)**
Arabian A/B and Patio

7:45 p.m. – 9:45 p.m. **ASCP Board of Directors Meeting (Invitation Only)**
Moor 1

Of Special Interest To Clinicians** **+No CME Credits Offered

FULL SCHEDULE

Tuesday, May 29, 2019

7:30 a.m. - 8:30 a.m.	**NIA Breakfast Roundtable (Invitation Only)** *Castile 1*
7:30 a.m. - 8:30 a.m.	**ASCP Membership Committee Meeting (Invitation Only)** *Castile 3*
7:30 a.m. - 9:00 a.m.	**Morning Break** *Princess East Foyer*
7:30 a.m. - 6:00 p.m.	**Registration** *Princess East Foyer Desk*
7:30 a.m. - 6:00 p.m.	**Speaker Ready Room** *Bourbon 11*
8:30 a.m. - 9:00 a.m.	**Conference Opening+** *Salon A-E*

Panel Sessions

9:00 a.m. - 10:30 a.m.	**New and Hopefully Improved! Novel Delivery Systems of Antipsychotic Medications for the Treatment of Schizophrenia*** *Salon F*

Chair: Leslie Citrome, New York Medical College
Discussant: Stephen Marder, Semel Institute at UCLA

9:00 a.m. - 9:10 a.m.	**Introduction**
9:10 a.m. - 9:30 a.m.	**Patch Me Up: Transdermal Delivery Systems** Leslie Citrome, New York Medical College
9:30 a.m. - 9:50 a.m.	**I've Got You Under My Skin: Subcutaneous Risperidone Long-Acting Injectable** John Lauriello, University of Missouri

9:00 a.m. - 10:30 a.m. (continued)	**New and Hopefully Improved! Novel Delivery Systems of Antipsychotic Medications for the Treatment of Schizophrenia*** *Salon F*
9:50 a.m. - 10:10 a.m.	**Particle Size Matters: Developing a 1-Day Initiation Regimen for Aripiprazole Lauroxil+** Peter Weiden, Alkermes, Inc.
10:10 a.m. – 10:30 a.m.	**Discussion**
9:00 a.m. - 10:30 a.m.	**Leveraging Prior Experience to Facilitate Pediatric Clinical Development for Psychiatry Products*** *Salon G*

Chair: Hao Zhu, US Food and Drug Administration
Discussant: Adelaide Robb, Children's National Medical Center

9:10 a.m. – 9:25 a.m.	**An Overview of FDA's Effort in Improving Drug Development for Pediatric use** Lynne Yao, US Food and Drug Administration
9:25 a.m. – 9:40 a.m.	**An Update on the Division of Psychiatry Products' (DPP's) Initiatives to Facilitate Development of Drugs for Pediatric use** Tiffany Farchione, US Food and Drug Administration
9:40 a.m. – 9:55 a.m.	**Optimizing Pediatric Drug Development for Schizophrenia: FDA's Model Informed Approach to Extrapolate Efficacy** Shamir Kalaria, University of Maryland School of Pharmacy
9:55 a.m. – 10:10 a.m.	**Are We There yet? Exploring the Opportunity to Extrapolate Efficacy From Adults to Pediatrics With Bipolar I Disorder** Yaning Wang, Center for Drug Evaluation and Research, US Food and Drug Administration
10:10 a.m. – 10:30 a.m.	**Discussion**

9:00 a.m. - 10:30 a.m. **Treatment-resistant Mood Disorders Across the Lifespan: Novel Therapeutics on the Horizon***
Salon H

Chair: Bashkim Kadriu, National Institute of Mental Health
Co-Chair: Zhi-De Deng, National Institute of Mental Health
Discussant: Carlos Zarate, National Institute of Mental Health

9:00 a.m. – 9:10 a.m.	**Introduction**
9:10 a.m. - 9:25 a.m.	**Prediction of Antidepressant Treatment Outcomes With Ultra-High Field Magnetic Resonance Imaging** Christoph Kraus, Medical University of Vienna
9:25 a.m. - 9:40 a.m.	**Ketamine Treatment Modulates the Kynurenine and Arginine Pathways in Depressed Unipolar and Bipolar Patients** Bashkim Kadriu, National Institute of Mental Health
9:40 a.m. - 9:55 a.m.	**Combatting Adolescent Depression and Suicide: Pharmacotherapy With Brain Development in Mind** Jennifer Dwyer, Yale Child Study Center
9:55 a.m. - 10:10 a.m.	**Individualizing Electroconvulsive Therapy for the Treatment of Depression** Zhi-De Deng, National Institute of Mental Health
10:10 a.m. – 10:30 a.m.	**Discussion**

9:00 a.m. - 10:30 a.m. **Clinical Trial Designs That Move Psychopharmacology Towards Personalized Medicine**
Salon I

Chair: Lori Davis, Veterans Affairs Medical Center
Discussant: Michael E. Thase, Perelman School of Medicine at the University of Pennsylvania

9:00 a.m. – 9:10 a.m. **Introduction**

9:10 a.m. - 9:30 a.m. **Design and Early Results of an Aggregated N-of-1 Trial of Prazosin for PTSD: An Example of a Novel Clinical Trial Design Optimized for Both Biomarker Validation and Participant Benefit**
Rebecca Hendrickson, VA Puget Sound Health Care System

9:30 a.m. - 9:50 a.m. **Clinical Trial Design and Neurobiological Driven Endpoints in PTSD**
Steven Szabo, Duke University Medical Centers

9:50 a.m. - 10:10 a.m. **Novel Trial Design to Test Kappa Opioid Receptor Antagonism in the Treatment of Comorbid PTSD and Alcohol Use Disorder**
Lori Davis, Veterans Affairs Medical Center

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

10:30 a.m. - 10:45 a.m. **Break**
Princess East Foyer

Panel Sessions

10:45 a.m. - 12:15 p.m. **Biomarker Development in Autism: The Potential Impact of the Autism Biomarkers Consortium for Clinical Trials (ABC-CT)***
Salon F

Chair: Bernard Fischer, US Food and Drug Administration
Discussant: Tiffany Farchione, US Food and Drug Administration

10:45 a.m. – 10:55 a.m. **Introduction**

10:55 a.m. - 11:10 a.m. **The Role of Biomarkers in the Development of Novel Therapeutics for Autism Spectrum Disorder: From Early to Late Development, and from Stratification to Change Detection+**
Gahan Pandina, Janssen Research & Development, LLC

11:10 a.m. - 11:25 a.m. **The Autism Biomarkers Consortium for Clinical Trials: Study Design and Progress Through Interim Analysis**
James McPartland, Yale Child Study Center

11:25 a.m. - 11:40 a.m. **The Autism Biomarkers Consortium for Clinical Trials: EEG and ET as Discriminant Biomarkers, Test-Retest Validity, and Correlation With Clinical Status**
Sara Webb, University of Washington

11:40 a.m. – 11:55 a.m. **The FDA Approach to Biomarker Qualification for Drug Development**
Martine Solages, Center for Drug Evaluation and Research, US Food and Drug Administration

11:55 a.m. – 12:15 p.m. **Discussion**

10:45 a.m. - 12:15 p.m. **Pharmacogenomic Testing in Psychiatric Practice: Does it Deliver What it Promises?***
Salon G

Chair: Angelos Halaris, Loyola University Chicago Stritch School of Medicine
Co-Chair: John Greden, University of Michigan
Discussant: Angelos Halaris, Loyola University Chicago Stritch School of Medicine

10:45 a.m. – 10:55 a.m. **Introduction**

10:55 a.m. – 11:15 a.m. **Psychopharmacogenomics in Practice: An Overview**
Katherine Johnson, Loyola University Chicago Stritch School of Medicine

11:15 a.m. – 11:35 a.m. **Pharmacogenomic Testing in Psychiatric Practice: Does it Deliver What it Promises?**
John Greden, University of Michigan

11:35 a.m. – 11:55 a.m. **The Use of Pharmacogenomics in Medical Practice: What About Psychiatry?**
Simon Kung, Mayo Clinic

11:55 a.m. – 12:15 p.m. **Discussion**

10:45 a.m. - 12:15 p.m. **Digital Technology Advancements and Potential for Assessing Behavior in Clinical Trials***
Salon H

Chair: Jean-Pierre Lindenmayer, New York University
Co-Chair: Anzalee Khan, VeraSci and Nathan S. Kline Institute for Psychiatric Research
Discussant: Jean-Pierre Lindenmayer, New York University

10:45 a.m. – 10:55 a.m. **Introduction**

10:55 a.m. - 11:10 a.m. **Integrating Electronic Patient-Reported Outcome (PRO) Measures Into Practice for Real-Time Symptom Monitoring**
Anzalee Khan, VeraSci and Nathan S. Kline Institute for Psychiatric Research

10:45 a.m. - 12:15 p.m. (continued)	**Digital Technology Advancements and Potential for Assessing Behavior in Clinical Trials*** *Salon H*
11:10 a.m. - 11:25 a.m.	**Digital Biomarkers of Depression Relapse and Remission** Paul Dagum, Mindstrong Health
11:25 a.m. - 11:40 a.m.	**Moving From Virtual Reality Exposure to Embodied Treatment** Nanea Reeves, TRIPP
11:40 a.m. - 11:55 a.m.	**Patient Centricity in Virtual Clinical Trials** Corey Fowler, Otsuka Pharmaceuticals
11:55 a.m. – 12:15 p.m.	**Discussion**
10:45 a.m. - 12:15 p.m.	**ISCTM/ASCP Workshop – Developing an Advanced CNS Clinical Trial Course+** *Salon I*

Chair: Carla Canuso, Janssen Research & Development
Co-Chair: John Kane, The Zucker Hillside Hospital
Discussant: Stephen Marder, Semel Institute at UCLA

A Joint Steering Committee, comprised of experts with a wide range of experience in CNS drug development and clinical trial design, has been convened to select curriculum topics and identify a faculty to develop content and teach the course. As an initial step in assessing needs and interests, the Joint Steering Committee will field a survey of the ASCP and ISCTM members. The Joint Steering Committee will present the course objectives, the survey results and proposed curriculum topics during this session. This session will allow interested stakeholders to provide additional suggestions and feedback on the curriculum.

12:15 p.m. - 1:45 p.m. **Early Career Luncheon (RSVP Only)+**
Palomino 9-10

The Early Career Luncheon is an engaging opportunity to meet colleagues and learn about work life balance as well as participate in a 30 - 45 minute roundtable discussion. The following presenters will be in attendance:

- Kristina Deligiannidis, M.D., Zucker Hillside Hospital; Feinstein Institute for Medical Research; Zucker School of Medicine at Hofstra/Northwell
- Crystal Cooper, Ph.D., UT Southwestern
- Anita Clayton, M.D., University of Virginia
- Christine Ulbricht, Ph.D., MPH, University of Massachusetts Medical School

1:50 p.m. - 4:00 p.m. **Pharmaceutical Pipelines+**
Salon A-E

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

1:50 p.m. – 2:00 p.m. **Introduction**

2:00 p.m. - 2:10 p.m. **A Phase 3, Double-Blind, Placebo-Controlled Trial of SAGE-217 in Postpartum Depression: Assessment of Depressive Symptoms Across Multiple Measures**
Kristina Deligiannidis, Zucker Hillside Hospital; Feinstein Institute for Medical Research; Zucker School of Medicine at Hofstra/Northwell

2:10 p.m. - 2:21 p.m. **The Selective Orexin-1 Receptor Inhibitor JNJ-61393215 Decreases Subjective Anxiety Evoked by 35% Carbon Dioxide Inhalation in Healthy Subjects**
Giacomo Salvadore, Janssen Research & Development

2:21 p.m. - 2:32 p.m. **Translational Research With Dexmedetomidine (DM) for the Treatment of Agitation From Healthy Volunteers to Two Patient groups: Those With Schizophrenia or With Probable Senile Dementia of the Alzheimer's Type (SDAT)**
Robert Risinger, BioXcel Therapeutics

1:50 p.m. - 4:00 p.m. (continued)	**Pharmaceutical Pipelines+** *Salon A-E*
2:32 p.m. - 2:43 p.m.	**A Combination of Olanzapine and Samidorphan for Schizophrenia: Effects on Weight Gain and Metabolic Parameters in the Phase 3 ENLIGHTEN-2 Study and Subsequent Long-Term, Open-Label Safety Study** John Newcomer, South Florida Behavioral Health Network
2:43 p.m. - 2:54 p.m.	**Follow-Up on the Development of KarXT: Results of KAR-003, a Multiple Ascending Dose (MAD) Study of a Combination Product** Stephen Brannan, Karuna
2:54 p.m. - 3:05 p.m.	**AXS-05, Oral NMDA Receptor Antagonist With Multimodal Activity, in Major Depressive Disorder: Results of a Phase 2, Double-Blind, Active-Controlled Trial** Cedric O'Gorman, Axsome Therapeutics Inc.
3:05 p.m. - 3:16 p.m.	**Efficacy and Safety of SEP-363856, a Novel Psychotropic Agent With a Non-D2 Mechanism of Action, in the Treatment of Schizophrenia: A 4-Week, Randomized, Placebo-Controlled Trial** Kenneth Koblan, Sunovion Pharmaceuticals, Inc.
3:16 p.m. - 3:27 p.m.	**A Randomized, Placebo Controlled, Repeat Dose Phase 1B Study of COR388 in Older Healthy Volunteers and Patients With Alzheimer's Disease With Exploratory Efficacy Measures** Michael Detke, Cortexyme
3:27 p.m. - 3:38 p.m.	**MDMA-Assisted Psychotherapy for Treatment of Anxiety Related to Life-Threatening Illnesses** Allison Feduccia, MAPS Public Benefit Corporation
3:38 p.m. - 3:49 p.m.	**Patient Satisfaction With Injectable Weekly and Monthly Buprenorphine and Buprenorphine Treatment Experience** Natalie Budilovsky-Kelley, Braeburn

1:50 p.m. - 4:00 p.m. (continued)	**Pharmaceutical Pipelines+** *Salon A-E*
3:49 p.m. - 4:00 p.m.	**Snap 101: Randomized, Crossover, Active and Placebo-Controlled, Safety, Pharmacokinetic, and Pharmacodynamic Study of Three Ascending Doses of INP105 - Novel Precision Olfactory Delivery (POD) of a Nasal Formulation of Olanzapine** Jasna Hocevar-Trnka, Impel NeuroPharma
4:00 p.m. - 4:15 p.m.	**Break** *Princess East Foyer*

Individual Research Reports

4:15 p.m. - 5:30 p.m.	**Broad Spectrum Use of Neuroleptic Agents: Benefits and Liabilities*** *Salon F*

Chair: Francisco Moreno, University of Arizona

4:15 p.m. – 4:20 p.m.	**Introduction**
4:20 p.m. - 4:35 p.m.	**Enhancing Completion of Cognitive Processing Therapy for Posttraumatic Stress Disorder With Quetiapine in Veterans With Mild Traumatic Brain Injury: A Case Series*** Muhammad Baig, South Texas Veterans Healthcare System/University of Texas Health Science Center at San Antonio
4:35 p.m. - 4:50 p.m.	**Cariprazine Efficacy in Patients With Bipolar Depression and Concurrent Manic Symptoms: Post Hoc Analysis of 3 Randomized, Placebo-Controlled Studies*** Trisha Suppes, Stanford University
4:50 p.m. - 5:05 p.m.	**Morbidity and Mortality of Medications Used to Treat Insomnia: Cases Reported to U.S. Poison Control Centers 2000-2016*** J. Craig Nelson, University of California San Francisco

4:15 p.m. - 5:30 p.m. (continued)	**Broad Spectrum Use of Neuroleptic Agents: Benefits and Liabilities*** *Salon F*
5:05 p.m. - 5:20 p.m.	**C-Reactive Protein and Response to Lurasidone Treatment in Children and Adolescents With Bipolar Depression*** Andrei Pikalov, Sunovion Pharmaceuticals, Inc.
5:20 p.m. – 5:30 p.m.	**Discussion**
4:15 p.m. - 5:30 p.m.	**Exploring New Treatment Options in Diverse Populations*** *Salon G*

Chair: Larry Culpepper, Boston University

4:20 p.m. - 4:35 p.m.	**Efficacy and Safety of Lemborexant Versus Placebo in Adult and Elderly Subjects With Insomnia: 6-Month Results From SUNRISE-2*** Margaret Moline, Eisai Inc.
4:35 p.m. - 4:50 p.m.	**Serious Mental Illness Among Newly Admitted Working-Age Nursing Home Residents*** Christine Ulbricht, University of Massachusetts Medical School
4:50 p.m. - 5:05 p.m.	**Pharmacogenomic Study of Antipsychotic Medicines in Chinese Han Population*** Lili Guan, Institute of Mental Health, Peking University
5:05 p.m. - 5:20 p.m.	**Genetic Differential Diagnosis in Highly Treatment Resistant Schizophrenia*** Martilias Farrell, University of North Carolina at Chapel Hill
5:20 p.m. – 5:30 p.m.	**Discussion**

4:15 p.m. - 5:30 p.m. **Biomarkers for Depression: Subtypes and Response to Treatment***
Salon H

Chair: Brian Mickey, University of Utah School of Medicine

4:15 p.m. – 4:20 p.m. **Introduction**

4:20 p.m. - 4:35 p.m. **The Association Between Body Mass Index and Remission Rates in Patients With Treatment-Resistant Depression Who Received Intravenous Ketamine***
Balwinder Singh, Mayo Clinic

4:35 p.m. - 4:50 p.m. **The Effect of Pharmacogenomic Testing on Response and Remission Rates in the Acute Treatment of Major Depressive Disorder: A Meta-Analysis***
Joshua Rosenblat, University of Toronto

4:50 p.m. - 5:05 p.m. **Prediction of Antidepressant Treatment Outcomes With Ultra-High Field Magnetic Resonance Imaging***
Christoph Kraus, Medical University of Vienna

5:05 p.m. - 5:20 p.m. **Effect of Lifetime History of a Substance Use Disorder in Establishing Biomarkers in Major Depressive Disorder Using Reward Behavior and Brain Function***
Crystal Cooper, The University of Texas Southwestern Medical Center

5:20 p.m. – 5:30 p.m. **Discussion**

= **New Investigator Awardee**

***Of Special Interest To Clinicians** **+No CME Credits Offered**

4:15 p.m. - 5:30 p.m. **Using MDMA and Transdermal Buprenorphine to Treat Trauma and Addiction, Microbiome Changes in Binge Drinking, and Understanding Why Our Phase III Trials can Fail Even When the Treatment Works***
Salon I

Chair: Rebecca Hendrickson, VA Puget Sound Health Care System

4:20 p.m. - 4:35 p.m. **A Proposed Utility of Weekly Buprenorphine Transdermal Patch (BUP-TD) as a Viable Option for Detoxification or Maintenance Therapy for Opioid Use Disorder***
George Ide, NYCHHC

4:35 p.m. - 4:50 p.m. **Analysis of the Gut Microbiome in a Baboon Model of Alcohol Binge Drinking***
Daria Piacentino, NIAAA

4:50 p.m. - 5:05 p.m. **Give Us Your Tired, Your Poor, Your Professional Subjects: The Last Quartile of Phase 3 Enrollment**
Thomas Shiovitz, California Neuroscience Research

5:05 p.m. - 5:20 p.m. **An Open-Label, Multi-Site Phase 2 MDMA-Assisted Psychotherapy Trial for Severe Posttraumatic Stress Disorder and Supervision of New Co-Therapy Teams***
Allison Feduccia, MAPS Public Benefit Corporation

5:20 p.m. – 5:30 p.m. **Discussion**

6:15 p.m. - 7:45 p.m. **New Investigator Awards Ceremony (Invitation Only)**
Arabian A/B and Patio

7:45 p.m. - 9:45 p.m. **ASCP Board of Directors Meeting (Invitation Only)**
Moor 1

= **New Investigator Awardee**

Of Special Interest To Clinicians** **+No CME Credits Offered

AT-A-GLANCE

Wednesday, May 29, 2019

6:30 a.m. - 8:00 a.m.	**20th Annual ASCP Fun Run/Walk - All Attendees Welcome (No Prior Sign Up Necessary)** *Palomino Conference Center North Drive*
7:00 a.m. - 8:25 a.m.	**ASCP Women's Initiative Breakfast (Welcome to all Female Attendees – RSVP Required)** *Salon F*
7:30 a.m. - 8:30 a.m.	**NIA Breakfast Roundtable (Invitation Only)** *Castile 1*
7:30 a.m. - 8:30 a.m.	**ASCP Curriculum Committee Meeting (Invitation Only)** *Bourbon 9*
7:30 a.m. - 9:00 a.m.	**Morning Break** *Princess East Foyer*
7:30 a.m. - 7:00 p.m.	**Registration** *Princess East Foyer Desk*
7:30 a.m. - 6:00 p.m.	**Speaker Ready Room** *Bourbon 11*
8:30 a.m. - 10:00 a.m.	**Regulatory Plenary: Breakthrough and Prime Regulatory Pathways** *Salon A-E*
10:00 a.m. – 10:15 a.m.	**Break** *Princess East Foyer*
10:15 a.m. – 11:15 a.m.	**ASCP Awards Ceremony and ASCP Lifetime Awardee Talk – Alan Schatzberg, M.D.: Forty Years of Research and Practice in Psychopharmacology** *Salon A-E*
11:15 a.m. – 1:00 p.m.	**Early Career Networking Tables (Open to all Attendees)** *Palomino 4-10*

Of Special Interest To Clinicians** **+No CME Credits Offered

11:15 a.m. – 1:00 p.m. **Poster Session I with Lunch+**
Palomino 4-10

1:00 p.m. – 2:30 p.m. **Panel Sessions**

Bad Behavior in Clinical Trials: Strategies to Combat Research Participant Dishonesty/ Deception, Non-adherence, and "Professional Subjects" *Salon F*	Towards the Implementation of Pharmaco-genetics in Psychiatry* *Salon G*	Adapting Treatment Outcomes of Major Depressive Disorder as Research Evolves: How Biomarkers, Functional Measures, and Associated Features can Inform the Definition of Response and Remission* *Salon H*	New Mechanisms, New Opportunities: Integrating Novel Antidepressants in the Treatment of Major Depressive Disorder* *Salon I*

2:30 p.m. – 2:45 p.m. **Break**
Princess East Foyer

2:45 p.m. – 4:45 p.m. **Workshops**

ASCP Early Career Workshop: How to Give a Scientific Presentation *Salon F*	Where do We Stand With the Use of the Sequential Parallel Comparison Design in CNS Drug Trials? An Update 16 Years Later *Salon G*	Negotiation Strategies for Professionals in CNS Research: A Mid-Career Mentoring Workshop* *Salon H*	ASCP-ISBD Workshop: Update on Treatment of Bipolar Disorder* *Salon I*

5:00 p.m. – 6:00 p.m. **ASCP Business Meeting and Reception (ASCP Members Only)**
Salon H

6:00 p.m. – 7:00 p.m. **ASCP Reception**
Salon A-E

Of Special Interest To Clinicians** **+No CME Credits Offered

FULL SCHEDULE

Wednesday, May 29, 2019

6:30 a.m. - 8:00 a.m. **20th Annual ASCP Fun Run/Walk - All Attendees Welcome (No Prior Sign Up Necessary)**
Palomino Conference Center North Drive

7:00 a.m. - 8:25 a.m. **ASCP Women's Initiative Breakfast (Welcome to all Female Attendees – RSVP Required)**
Salon F

This Women's Only event will be moderated by Trisha Suppes, M.D., Ph.D., Stanford University School of Medicine. Nina Schooler, M.D., Ph.D., SUNY Downstate Medical Center, will speak on her journey in the field of psychopharmacology and experience as a woman in academia.

7:30 a.m. - 8:30 a.m. **NIA Breakfast Roundtable (Invitation Only)**
Castile 1

7:30 a.m. - 8:30 a.m. **ASCP Curriculum Committee Meeting (Invitation Only)**
Bourbon 9

7:30 a.m. - 9:00 a.m. **Morning Break**
Princess East Foyer

7:30 a.m. - 7:00 p.m. **Registration**
Princess East Foyer Desk

7:30 a.m. - 6:00 p.m. **Speaker Ready Room**
Bourbon 11

8:30 a.m. - 10:00 a.m. **Regulatory Plenary: Breakthrough and Prime Regulatory Pathways**
Salon A-E

Chair: William Potter, National Institute of Mental Health

Presenters: Tiffany Farchione, US Food and Drug Administration
Valentina Mantua, Italian Medicines Agency

This year's Regulatory Plenary will focus on FDA and EMA initiatives intended to help address unmet medical needs. FDA will discuss the Breakthrough Therapy Designation program and highlight recent approvals of Breakthrough-designated products with psychiatric indications. EMA will provide a similar update, focusing on the PRIority MEdicines (PRIME) scheme, as well as a comparison of the two programs and their benefits.

10:00 a.m. - 10:15 a.m. **Break**
Princess East Foyer

10:15 a.m. - 11:15 a.m. **ASCP Awards Ceremony and ASCP Lifetime Awardee Talk – Alan Schatzberg, M.D.: Forty Years of Research and Practice in Psychopharmacology**
Salon A-E

Chair: Michael E. Thase, Perelman School of Medicine at the University of Pennsylvania

Awards Presented to:
2019 Paul Wender Best Paper in *The Journal of Clinical Psychiatry* Award: Randi Melissa Schuster, Harvard Medical School, Massachusetts General Hospital
Nominated For: *One Month of Cannabis Abstinence in Adolescents and Young Adults is Associated With Improved Memory*

2019 Jonathan Cole Presidential Service Award: Alan Gelenberg, University of Arizona

2019 Donald Klein Lifetime Achievement Award: Alan Schatzberg, Stanford University School of Medicine

Psychopharmacology has evolved greatly in the last 4 decades. We have had the introduction of a variety of effective agents for treating patients with

depression, bipolar disorder, schizophrenia, etc. This presentation will review the experience of the Awardee in the field over these last 40 plus years. The presentation will emphasize the pluses and minuses of antidepressant drug development, including: discussion of research into side effects of the first generation agents, relative efficacy of second generation agents in more severely ill patients, need for novel treatments with unique mechanisms of action for severe and psychotic major depressions; risk of developing potential drugs of abuse for the treatment of refractory depression, and the application of biomarkers for guiding treatment decisions.

11:15 a.m. - 1:00 p.m. **Early Career Networking Tables (Open to all Attendees)**
Palomino 4-10

11:15 a.m. - 1:00 p.m. **Poster Session I with Lunch+**
Palomino 4-10
See pages 79-90 for a complete listing of posters

Panel Sessions

1:00 p.m. - 2:30 p.m. **Bad Behavior in Clinical Trials: Strategies to Combat Research Participant Dishonesty/ Deception, Non-Adherence, and "Professional Subjects"**
Salon F

Chair: Daniel Falk, NIAAA
Discussant: Daniel Falk, NIAAA

1:00 p.m. – 1:10 p.m. **Introduction**

1:10 p.m. - 1:30 p.m. **Use of a Global Research Subject Database Registry to Improve Clinical Research Subject Safety and Data Quality by Prospectively Detecting, Preventing and Assessing Preventable Violations of Inclusion and Exclusion Criteria**
Kerri Weingard, Verified Clinical Trials

1:30 p.m. - 1:50 p.m. **Defining a New Patient Behavioral Category: Prevalence of Identified Cheating and Risk to Study Outcomes in CNS Trials+**
Amanda Paley, AiCure

1:00 p.m. - 2:30 p.m. (continued)	**Bad Behavior in Clinical Trials: Strategies to Combat Research Participant Dishonesty/ Deception, Non-Adherence, and "Professional Subjects"** *Salon F*
1:50 p.m. - 2:10 p.m.	**Rates of Subject Deception in Clinical Research and Practical Strategies to Minimize the Risk of Enrolling Professional Subjects in Clinical Research** Eric Devine, Boston University School of Medicine
2:10 p.m. – 2:30 p.m.	**Discussion**
1:00 p.m. - 2:30 p.m.	**Towards the Implementation of Pharmacogenetics in Psychiatry*** *Salon G*

Chair: Daniel Mueller, University of Toronto
Co-Chair: Lisa Brown, Myriad Neuroscience
Discussant: Michael E. Thase, Perelman School of Medicine at the University of Pennsylvania

1:10 p.m. - 1:25 p.m.	**CPIC and PharmGKB Review of Relevant Gene-Drug Pairs in Psychiatric Pharmacogenetics** Michelle Whirl-Carrillo, Stanford University
1:25 p.m. - 1:40 p.m.	**Using Combinatorial Pharmacogenomic Testing to Pick Medication for Major Depressive Disorder: Results From a Large, Blinded, Randomized Control Trial** Sagar Parikh, University of Michigan, Ann Arbor
1:40 p.m. - 1:55 p.m.	**Approaches and Hurdles to Implementation of Pharmacogenetics in Psychiatry** Chad Bousman, University of Calgary
1:55 p.m. - 2:10 p.m.	**Challenges in the Delivery of Pharmacogenetic Testing** Susanne Haga, Duke University School of Medicine
2:10 p.m. – 2:30 p.m.	**Discussion**

1:00 p.m. - 2:30 p.m. **Adapting Treatment Outcomes of Major Depressive Disorder as Research Evolves: How Biomarkers, Functional Measures, and Associated Features can Inform the Definition of Response and Remission***
Salon H

Chair: Madhukar Trivedi, UT Southwestern Medical Center
Co-Chair: Manish Jha, UT Southwestern Medical Center
Discussant: Madhukar Trivedi, UT Southwestern Medical Center

1:00 p.m. – 1:10 p.m. **Introduction**

1:10 p.m. - 1:25 p.m. **Clinical Utility of Measuring Irritability in Major Depressive Disorder: Prediction of Individual-Level Acute-Phase Treatment Outcomes in Two Separate Samples of Depressed Outpatients**
Manish Jha, UT Southwestern

1:25 p.m. - 1:40 p.m. **Sex Differences in Association of Inflammation and Suicidality: Findings From Two Separate Cohorts of Patients With Major Depressive Disorder**
Cherise Chin Fatt, University of Texas Southwestern Medical Center

1:40 p.m. - 1:55 p.m. **Assessing Cognitive Performance as a Marker of Functional Outcome: Results From the Longitudinal Dallas 2K Study of Depressive Disorders**
Tracy Greer, University of Texas Southwestern Medical Center at Dallas

1:55 p.m. - 2:10 p.m. **Sleep Problems in Major Depressive Disorder: Analyzing Dysfunctional Patterns to Help Determine Biomarkers**
Brittany Mason, The University of Texas Southwestern Medical Center

2:10 p.m. – 2:30 p.m. **Discussion**

1:00 p.m. - 2:30 p.m. **New Mechanisms, New Opportunities: Integrating Novel Antidepressants in the Treatment of Major Depressive Disorder***
Salon I

Chair: Leslie Citrome, New York Medical College
Discussant: Terence Ketter, Stanford University School of Medicine

1:00 p.m. – 1:10 p.m. **Introduction**

1:10 p.m. – 1:25 p.m. **Beyond the Monoamines: The Role of Different Neurotransmitters in the Etiology of Major Depressive Disorder**
James Murrough, Icahn School of Medicine at Mount Sinai

1:25 p.m. – 1:40 p.m. **Beyond SSRIs and SNRIs: Are Drugs That Target the NMDA Receptor, Opiate System, or Modulate Serotonin 5HT-2A Receptors on the Horizon?**
Joseph Goldberg, Icahn School of Medicine at Mount Sinai

1:40 p.m. – 1:55 p.m. **Major Depressive Disorder, Suicide, and Mortality**
Bradley Gaynes, University of North Carolina

1:55 p.m. – 2:10 p.m. **Integrating the New and the Old: Best Practices to Assess and Measure Symptoms and How to Best Incorporate New Medication Interventions in Clinical Practice**
Leslie Citrome, New York Medical College

2:10 p.m. – 2:30 p.m. **Discussion**

2:30 p.m. - 2:45 p.m. **Break**
Princess East Foyer

Workshops

2:45 p.m. - 4:45 p.m. **ASCP Early Career Workshop: How to Give a Scientific Presentation**
Salon F

Chair: Mirjana Domakonda, Hartford Hospital / Institute of Living
Co-Chair: Ross Baker, Otsuka

2:45 p.m. - 3:05 p.m. **Introduction+**

3:05 p.m. - 3:35 p.m. **How to Give a Scientific Presentation**
Michael Green, University of California Los Angeles

3:35 p.m. - 4:10 p.m. **Durable Effects of Propofol Anesthesia on Depression, Glutamate, and GABA**
Brian Mickey, University of Utah School of Medicine

4:10 p.m. - 4:45 p.m. **Evidence for Altered Brain Reactivity to Norepinephrine in Veterans with a History of Traumatic Stress**
Rebecca Hendrickson, VA Puget Sound Health Care System

2:45 p.m. - 4:45 p.m. **Where do We Stand With the Use of the Sequential Parallel Comparison Design in CNS Drug Trials? An Update 16 Years Later**
Salon G

Chair: Maurizio Fava, Massachusetts General Hospital
Discussant: Tiffany Farchione, US Food and Drug Administration

2:45 p.m. - 3:00 p.m. **Introduction**

3:00 p.m. - 3:25 p.m. **Statistical Considerations in Sequential Parallel Comparison Designs**
Aparna Anderson, Statistics Collaborative, Inc.

3:25 p.m. - 3:50 p.m. **Clinical and Regulatory Perspective on Utilization of SPCD in Registrational Trials**
Thomas Laughren, Massachusetts General Hospital Clinical Trials Network and Institute

2:45 p.m. - 4:45 p.m. (continued)	**Where do We Stand With the Use of the Sequential Parallel Comparison Design in CNS Drug Trials? An Update 16 Years Later** *Salon G*
3:50 p.m. - 4:15 p.m.	**How Do Adjunctive Study Designs for MDD Translate Into Clinical practice?** George Papakostas, Massachusetts General Hospital
2:45 p.m. - 4:45 p.m.	**Negotiation Strategies for Professionals in CNS Research: A Mid-Career Mentoring Workshop*** *Salon H*

Chair: Lori Davis, Veterans Affairs Medical Center
Discussant: Mark Rapaport, Emory University School of Medicine

3:00 p.m. - 4:15 p.m.	**Negotiation Strategies for Professionals in CNS Research: A Mid-Career Mentoring Workshop*** David Kupfer, University of Pittsburgh School of Medicine/Western Psychiatric Institute and Clinic
4:15 p.m. – 4:45 p.m.	**Discussion**
2:45 p.m. - 4:45 p.m.	**ASCP-ISBD Workshop: Update on Treatment of Bipolar Disorder*** *Salon I*

Chair: Trisha Suppes, Stanford University
Co-Chair: Michael Berk, Deakin University

2:45 p.m. – 3:05 p.m.	**Introduction**
3:05 p.m. - 3:30 p.m.	**Neurostimulation in the Management of Bipolar Depression** Scott Aaronson, Sheppard Pratt Health System
3:30 p.m. - 3:55 p.m.	**Treatment of Bipolar Depression: Use of Antidepressants and Recent Guideline Recommendations** Trisha Suppes, Stanford University

2:45 p.m. - 4:45 p.m. (continued)	**ASCP-ISBD Workshop: Update on Treatment of Bipolar Disorder*** *Salon I*
3:55 p.m. - 4:20 p.m.	**Novel Therapies for Bipolar Disorder** Michael Berk, Deakin University
4:20 p.m. - 4:45 p.m.	**Inflammation/Metabolic Mediators of Psychopathology in Mood Disorders** Lakshmi Yatham, University of British Columbia
5:00 p.m. - 6:00 p.m.	**ASCP Business Meeting and Reception (ASCP Members Only)** *Salon H*
6:00 p.m. - 7:00 p.m.	**ASCP Reception** *Salon A-E*

AT-A-GLANCE

Thursday, May 30, 2019

7:00 a.m. - 8:00 a.m.	**ASCP Steering Committee (Invitation Only)** *Moor 1*
7:15 a.m. - 8:15 a.m.	**NIA Breakfast Roundtable (Invitation Only)** *Castile 1*
7:30 a.m. - 9:00 a.m.	**Morning Break** *Princess East Foyer*
7:30 a.m. - 6:00 p.m.	**Registration** *Princess East Foyer Desk*
7:30 a.m. - 6:00 p.m.	**Speaker Ready Room** *Bourbon 11*
8:15 a.m. - 9:45 a.m.	**Keynote Plenary: Innovations in Personalized Medicine: From Biomarkers to Patient-Centered Care** *Salon A-E*
9:45 a.m. - 10:00 a.m.	**Break** *Princess East Foyer*
10:00 a.m. - 12:30 p.m.	**Federal Agency Updates Plenary** *Salon A-E*
12:30 p.m. – 2:00 p.m.	**Early Career Networking Tables (Open to all Attendees)** *Palomino 4-10*
12:30 p.m. – 2:00 p.m.	**Poster Session II with Lunch+** *Palomino 4-10*
2:00 p.m. – 3:30 p.m.	**Clinical Updates in Psychopharmacology*** *Salon A-E*
3:30 p.m. – 3:45 p.m.	**Break** *Princess East Foyer*

3:45 p.m. – 5:45 p.m. **Workshops**

ASCP/AFSP Workshop: Inclusion of Suicidal Individuals in Treatment Trials	Methodological Challenges in Implementing Clinical Trials to Address the Questions Posed in Developing Personalized Medicine Treatments	Psychedelic Drug Development: Perspectives from the Division of Psychiatry Products, US Food and Drug Administration*	TMS, Ketamine or ECT: 3 Case Presentations
Salon F	*Salon G*	*Salon H*	*Salon I*

FULL SCHEDULE

Thursday, May 30, 2019

7:00 a.m. – 8:00 a.m.	**ASCP Steering Committee (Invitation Only)** *Moor 1*
7:15 a.m. – 8:15 a.m.	**NIA Breakfast Roundtable (Invitation Only)** *Castile 1*
7:30 a.m. – 9:00 a.m.	**Morning Break** *Princess East Foyer*
7:30 a.m. – 6:00 p.m.	**Registration** *Princess East Foyer Desk*
7:30 a.m. – 6:00 p.m.	**Speaker Ready Room** *Bourbon 11*
8:15 a.m. – 9:45 a.m.	**Keynote Plenary: Innovations in Personalized Medicine: From Biomarkers to Patient-Centered Care** *Salon A-E*

Chair: Madhukar Trivedi, UT Southwestern Medical Center

In contrast to the rest of medicine, psychiatric conditions are still considered behavioral or emotional conditions, implying that both our diagnostic and treatment strategies rely solely on clinical symptom presentation. As such, treatment recommendations are traditionally given without factoring individual variability in biological factors, such as genes, brain structure and function, or other factors beyond symptom clusters. As a result, treatments for psychiatric conditions remain largely trial and error, and most of our disorders have very low remission rates across treatment strategies. It is time for us to take move Psychiatry into the modern age of precision medicine, where we take a comprehensive look at the complex interplay between clinical and biological phenotypes. Identification of clinical and biological markers that can predict treatment outcomes will be crucial, and with recent technological advances in machine learning and computational systems, we are perfectly situated to make great strides in our treatments. Some of these steps have already begun through large trials in depression, bipolar disorder, and schizophrenia, among others. This presentation will focus on major depressive disorder as an example of strides we are making in towards precision medicine.

8:15 a.m. – 9:45 a.m. (continued)	**Keynote Plenary: Innovations in Personalized Medicine: From Biomarkers to Patient-Centered Care** *Salon A-E*
8:15 a.m. – 8:20 a.m.	**Introduction**
8:20 a.m. – 8:35 a.m.	**The Adolescent Brain Cognitive Development (ABCD) Study: An Open Science Data Resource** Katia Howlett, National Institute on Drug Abuse
8:35 a.m. – 8:50 a.m.	**The Million Veteran Program: A Longitudinal Cohort of U.S. Veterans for Genetic and Epidemiological Research** Sumitra Muralidhar, Department of Veteran Affairs
8:50 a.m. – 9:05 a.m.	**Current Status of *All of Us* Research Program** Holly Garriock, Health Care Provider Team Lead for *All of Us* Research Program
9:05 a.m. – 9:20 a.m.	**The *All of Us* Research Program: Opportunities for Mental Health Research** Jordan Smoller, Massachusetts General Hospital & Harvard Medical School
9:20 a.m. – 9:45 a.m.	**Discussion**
9:45 a.m. – 10:00 a.m.	**Break** *Princess East Foyer*
10:00 a.m. - 12:30 p.m.	**Federal Agency Updates Plenary** *Salon A-E*

Chair: Michael E. Thase, Perelman School of Medicine at the University of Pennsylvania

10:00 a.m. – 10:05 a.m.	**Introduction**
10:05 a.m. – 10:25 a.m.	**Psychopharmacology Research in the Department of Veterans Affairs** Terri Gleason, U.S. Department of Veterans Affairs

10:00 a.m. - 12:30 p.m. (continued)	**Federal Agency Updates Plenary** *Salon A-E*
10:25 a.m. – 10:45 a.m.	**What Science Can Tell About the Treatment of Alcohol Use Disorders: View from the Dark Side** George Koob, National Institute on Alcohol Abuse & Alcoholism
10:45 a.m. – 11:05 a.m.	**Personalized Medicine: NIMH Update** Bruce Cuthbert, National Institute of Mental Health
11:05 a.m. – 11:25 a.m.	**Opportunities and Challenges in Addiction Research** Kurt Rasmussen, National Institute on Drug Abuse
11:25 a.m. – 11:45 a.m.	**21st Century Cures Act: SAMHSA Update** Thomas Clarke, Substance Abuse and Mental Health Services Administration
11:45 a.m. – 12:30 p.m.	**Discussion**
12:30 p.m. - 2:00 p.m.	**Early Career Networking Tables (Open to all Attendees)** *Palomino 4-10*
12:30 p.m. - 2:00 p.m.	**Poster Session II with Lunch+** *Palomino 4-10* *See pages 91-102 for a complete listing of posters*

2:00 p.m. - 3:30 p.m. **Clinical Updates in Psychopharmacology***
Salon A-E

Chair: Erika Saunders, Penn State College of Medicine, Penn State Milton S. Hershey Medical Center

The purpose of this symposium is to provide an overview of the recent advances in clinical psychopharmacology leading to the development of novel treatments for mood disorders. The session will focus on the psychopharmacology of perinatal depression, diagnosing dementia vs. delirium vs. depression in the elderly, and medications to prevent and treat opioid use disorders and overdose.

2:00 p.m. - 2:30 p.m. **Psychopharmacology of Perinatal Depression**
Jennifer Payne, Johns Hopkins School of Medicine

2:30 p.m. - 3:00 p.m. **Diagnosing Dementia Vs. Delirium Vs. Depression in the Elderly**
Gary Small, David Geffen School of Medicine at UCLA

3:00 p.m. - 3:30 p.m. **Medications to Prevent and Treat Opioid Use Disorders and Overdose**
Iván Montoya, National Institute on Drug Abuse

3:30 p.m. - 3:45 p.m. **Break**
Princess East Foyer

Workshops

3:45 p.m. - 5:45 p.m. **ASCP/AFSP Workshop: Inclusion of Suicidal Individuals in Treatment Trials**
Salon F

Co-Chair: Madhukar Trivedi, UT Southwestern Medical Center
Co-Chair: Jill Harkavy-Friedman, American Foundation for Suicide Prevention

3:45 p.m. – 3:55 p.m. **Introduction**

3:55 p.m. – 4:15 p.m. **The Importance of Including Patients at Risk of Suicide in Clinical Research**
Gerard Sanacora, Yale Department of Psychiatry

3:45 p.m. - 5:45 p.m. (continued)	**ASCP/AFSP Workshop: Inclusion of Suicidal Individuals in Treatment Trials** *Salon F*
4:15 p.m. – 4:35 p.m.	**Enrolling High-Risk Patients in Clinical Trials: A Lived Experience** Sidney Zisook, University of California, San Diego
4:35 p.m. – 4:55 p.m.	**Considerations for Investigators Including Participants at Elevated Risk of Suicide in Research and Asking Questions about Suicide in Mental Health Research** Galia Siegel, National Institute of Mental Health
4:55 p.m. – 5:45 p.m.	**Discussion**
3:45 p.m. - 5:45 p.m.	**ISCTM - ASCP Workshop: Methodological Challenges in Implementing Clinical Trials That Address the Questions Posed By Developing Personalized Medicine Treatments** *Salon G*

Chair: Nina Schooler, SUNY Downstate Medical Center
Co-Chair: Stephen Marder, Semel Institute at UCLA

3:45 p.m. – 4:00 p.m.	**Introduction**
4:00 p.m. – 4:15 p.m.	**Opportunities From Genomics for Advancing Precision Psychiatry** Jordan Smoller, Massachusetts General Hospital & Harvard Medical School
4:15 p.m. – 4:20 p.m.	**Discussion**
4:20 p.m. – 4:35 p.m.	**Role of Adaptive Design Methodologies in Precision Medicine: Adaptive Enrichment Designs by Modifying Pre-Specified Enrollment Criteria** Ronald Marcus, Supernus
4:35 p.m. – 4:40 p.m.	**Discussion**

3:45 p.m. - 5:45 p.m. (continued)	**ISCTM - ASCP Workshop: Methodological Challenges in Implementing Clinical Trials That Address the Questions Posed By Developing Personalized Medicine Treatments** *Salon G*
4:40 p.m. – 4:55 p.m.	**Novel Ways in Which Machine Learning Can Speed the Integration of Biomarkers into Clinical Trials+** Isaac Galatzer-Levy, AiCure
4:55 p.m. – 5:00 p.m.	**Discussion**
5:00 p.m. – 5:15 p.m.	**Measurement in Personalized Medicine** Eric Achtyes, Michigan State University College of Human Medicine
5:15 p.m. – 5:20 p.m.	**Discussion**
5:20 p.m. – 5:35 p.m.	**The Contribution of Regulatory Science to Personalized Medicine in Psychiatry** Valentina Mantua, Italian Medicines Agency
5:35 p.m. – 5:45 p.m.	**Discussion**
3:45 p.m. - 5:45 p.m.	**Psychedelic Drug Development: Perspectives From the Division of Psychiatry Products, US Food and Drug Administration*** *Salon H*

Chair: Javier Muniz, Food and Drug Administration
Co-Chair: Juliette Toure, Center for Drug Evaluation and Research, US Food and Drug Administration
Discussant: Charles Grob, Harbor-UCLA Medical Center

3:45 p.m. – 3:50 p.m.	**Introduction**
3:50 p.m. - 4:05 p.m.	**Bridging the Past, Present, and Future of Psychedelic Drug Research and Development** Sean Belouin, United States Public Health Service

3:45 p.m. - 5:45 p.m. (continued)	**Psychedelic Drug Development: Perspectives From the Division of Psychiatry Products, US Food and Drug Administration*** *Salon H*
4:05 p.m. - 4:20 p.m.	**Challenges in Conducting Clinical Research with Schedule I Hallucinogens** Katherine Bonson, US Food and Drug Administration
4:20 p.m. - 4:35 p.m.	**The Path to Psychedelic Drug Product Development** Nancy Dickinson, US Food and Drug Administration
4:35 p.m. - 4:50 p.m.	**Clinical Trial Design: Establishing Safety and Effectiveness in Psychedelic Drug Development** Bernard Fischer, US Food and Drug Administration
4:50 p.m. - 5:05 p.m.	**Regulatory Perspectives on Psychotherapy in Psychedelic Drug Development** Michael Davis, US Food and Drug Administration
5:05 p.m. - 5:20 p.m.	**Placebo Response: Challenges in Maintaining the Blind in Psychedelic Clinical Trials** Javier Muniz, US Food and Drug Administration
5:20 p.m. – 5:45 pm	**Discussion**
3:45 p.m. - 5:45 p.m.	**TMS, Ketamine or ECT: 3 Case Presentations** *Salon I*

Chair: Michael Henry, Massachusetts General Hospital

3:45 p.m. – 3:55 p.m.	**Introduction**
3:55 p.m. - 4:25 p.m.	**Treatment Selection in Transcranial Magnetic Stimulation (TMS): A Case-Based Discussion** Joan Camprodon, Massachusetts General Hospital, Harvard Medical School
4:25 p.m. - 4:55 p.m.	**Definition and Prevalence of Treatment Resistance in Depression** Maurizio Fava, Massachusetts General Hospital

3:45 p.m. - 5:45 p.m. (continued)	**TMS, Ketamine or ECT: 3 Case Presentations** *Salon I*
4:55 p.m. - 5:25 p.m.	**Ketamine for Treatment-Resistant Depression: Symptom Improvement Vs. Functional Recovery in Clinical Setting** Cristina Cusin, Massachusetts General Hospital
5:25 p.m. - 5:45 p.m.	**Prolonged Severe Depression in a 70 Yo With Bipolar Disorder: ECT?** Michael Henry, Massachusetts General Hospital

AT-A-GLANCE

Friday, May 31, 2019

7:30 a.m. - 9:00 a.m. **Morning Break**
Princess East Foyer

7:30 a.m. - 12:00 p.m. **Registration**
Princess East Foyer Desk

7:30 a.m. - 10:30 a.m. **Speaker Ready Room**
Bourbon 11

8:30 a.m. - 10:00 a.m. **Panel Sessions**

CNS Clinical Trials in China: Achievements, Challenges, and Opportunities*	Repurposing Drugs for Schizophrenia: Insights From Immune and Renin-Angiotensin Systems*	Second-Generation Glutamatergic Agents for Major Depressive Disorder*	Nonstimulants for ADHD: Rationale, Emerging Treatments, and the Role of Biomarkers*
Salon F	*Salon G*	*Salon H*	*Salon I*

10:00 a.m. – 10:15 a.m. **Break**
Princess East Foyer

10:15 a.m. - 11:45 a.m. **Regulatory Wrap-Up Plenary**
Salon A-E

12:00 p.m. **Meeting Adjourns**

FULL SCHEDULE

Friday, May 31, 2019

7:30 a.m. - 9:00 a.m. **Morning Break**
Princess East Foyer

7:30 a.m. - 12:00 p.m. **Registration**
Princess East Foyer Desk

7:30 a.m. - 10:30 a.m. **Speaker Ready Room**
Bourbon 11

Panel Sessions

8:30 a.m. - 10:00 a.m. **CNS Clinical Trials in China: Achievements, Challenges, and Opportunities***
Salon F

Chair: Jianping Zhang, The Zucker Hillside Hospital
Co-Chair: Hua Jin, University of California at San Diego and VA San Diego Healthcare System
Discussant: Donald Goff, NYU Langone Medical Center

8:30 a.m. – 8:40 a.m. **Introduction**

8:40 a.m. - 8:55 a.m. **An Improvement Plan to Promote China's Clinical Research in Psychiatry**
Yifeng Shen, Shanghai Mental Health Center

8:55 a.m. - 9:10 a.m. **Pharmacogenomic Study of Antipsychotic Medicines in Chinese Han Population**
Lili Guan, Peking University

9:10 a.m. - 9:25 a.m. **Association of Hippocampal Atrophy With Duration of Untreated Psychosis and Molecular Biomarkers During Initial Antipsychotic Treatment of First-Episode Psychosis**
Hao Hu, Shanghai Mental Health Center

8:30 a.m. - 10:00 a.m. (continued)	**CNS Clinical Trials in China: Achievements, Challenges, and Opportunities*** *Salon F*
9:25 a.m. - 9:40 a.m.	**Minocycline Adjunctive Treatment to Risperidone for Negative Symptoms in Schizophrenia: Association With Pro-Inflammatory Cytokine Levels** Jingping Zhao, Second Xiangya Hospital, Central South University
9:40 a.m. – 10:00 a.m.	**Discussion**
8:30 a.m. - 10:00 a.m.	**Repurposing Drugs for Schizophrenia: Insights From Immune and Renin-Angiotensin Systems*** *Salon G*

Chair: Antonio Teixeira, University of Texas Health Science Center at Houston
Discussant: João Salgado, Federal University of Minas Gerais

8:30 a.m. – 8:40 a.m.	**Introduction**
8:40 a.m. - 9:00 a.m.	**Immune Dysfunction as a Target for Therapeutic Intervention in Schizophrenia** Antonio Teixeira, University of Texas Health Science Center at Houston
9:00 a.m. - 9:20 a.m.	**Renin–Angiotensin–Aldosterone System in Schizophrenia. New Treatment Opportunities?** David De Lucena, Federal University of Ceará
9:20 a.m. - 9:40 a.m.	**Repurposing Immunomodulatory Drugs to Treat Schizophrenia** Danielle Macedo, Federal University of Ceará
9:40 a.m. – 10:00 a.m.	**Discussion**

8:30 a.m. - 10:00 a.m. **Second-Generation Glutamatergic Agents for Major Depressive Disorder***
Salon H

Chair: George Papakostas, Massachusetts General Hospital
Co-Chair: Maurizio Fava, Massachusetts General Hospital
Discussant: Sanjay Mathew, Baylor College of Medicine

8:30 a.m. – 8:40 a.m. **Introduction**

8:40 a.m. - 8:55 a.m. **Clinical Development of Intranasal Esketamine for Treatment Resistant Depression+**
Jaskaran Singh, Neuroscience TA, Janssen R & D, LLC, Janssen Pharmaceutical Companies of JNJ

8:55 a.m. - 9:10 a.m. **Clinical Development of AV-101 for Major Depressive Disorder**
Mark Smith, VistaGen Therapeutics

9:10 a.m. - 9:25 a.m. **Overview of Rapastinel for the Treatment of Major Depressive Disorder+**
Armin Szegedi, Allergan

9:25 a.m. - 9:40 a.m. **Characterization of the AMPA Receptor Potentiators With Little Agonistic Effects TAK-137/TAK-653 as Potential Antidepressants**
Haruhide Kimura, Takeda Pharmaceutical Company Limited

9:40 a.m. – 10:00 a.m. **Discussion**

8:30 a.m. - 10:00 a.m. **Nonstimulants for ADHD: Rationale, Emerging Treatments, and the Role of Biomarkers***
Salon I

Chair: Jeffrey Newcorn, Icahn School of Medicine at Mount Sinai
Discussant: James McGough, UCLA Semel Institute for Neuroscience & Human Behavior

8:30 a.m. – 8:40 a.m. **Introduction**

8:40 a.m. - 9:00 a.m. **Nonstimulant Alternatives for ADHD: Rationale, Promises/Limitations, and the Need for Biomarker Predictors of Differential Response**
Jeffrey Newcorn, Icahn School of Medicine at Mount Sinai

9:00 a.m. - 9:20 a.m. **Alternatives to Typical Stimulants as Emerging Treatments for ADHD: What's in the Pipeline?**
Timothy Wigal, NeuroLife Sciences-1

9:20 a.m. - 9:40 a.m. **Glutamatergic Modulation in ADHD Youths Harboring Genetic Variants Disrupting Glutamatergic Network Pathways**
Josephine Elia, Nemours/A.I. duPont Hospital for Children

9:40 a.m. – 10:00 a.m. **Discussion**

10:00 a.m. - 10:15 a.m. **Break**
Princess East Foyer

10:15 a.m. - 11:45 a.m. **Regulatory Wrap-Up Plenary**
Salon A-E

Chair: William Potter, National Institute of Mental Health
Speakers: Javier Muniz, US Food and Drug Administration
Michael Davis, US Food and Drug Administration
Valentina Mantua, Italian Medicines Agency (AIFA)

12:00 p.m. **Meeting Adjourns**

Wednesday, May 29, 2019

Poster Session I with Lunch
11:15 a.m. - 1:00 p.m.
Palomino 4-10

W1. The National Pregnancy Registry for Psychiatric Medications: Effects of Fetal Exposure to Aripiprazole on Risk for Major Malformations
Marlene Freeman, Massachusetts General Hospital, Ammon-Pinizzotto Center for Women's Mental Health
Marlene Freeman*, Adele Viguera, Lina Goez-Mogollon, Taylor Church, Sara McElheny, Amanda Young, David Chitayat, Sonia Hernández-Díaz, Lee Cohen

W2. The National Pregnancy Registry for Psychiatric Medications: Effects of Fetal Exposure to Atypical Antipsychotics on Risk for Major Malformations
Lee Cohen, Massachusetts General Hospital
Adele Viguera, Marlene Freeman, Lina Goez-Mogollon, Sara McElheny, Taylor Church, Amanda Young, David Chitayat, Sonia Hernández-Díaz, Lee Cohen*

W3. Is Dimensional Scale Data More Sensitive Than Categorical Data in Detecting an Anti-Suicidality Efficacy Signal?
David Sheehan, University of South Florida College of Medicine
David Sheehan*, Jennifer M. Giddens

W4. The Alpine Study: A Randomized, Double-Blind, Active-Controlled Study of Starting Aripiprazole Lauroxil With a 1-Day Initiation Regimen in Acutely Ill Patients With Schizophrenia
Peter Weiden, Alkermes, Inc.
Peter Weiden*, Amy Claxton, Yangchung Du, Sergey Yagoda, David Walling, Jelena Kunovac

W5. Open-Label Study of Magnetic Seizure Therapy (MST) for Suicidal Ideation in Treatment-Resistant Depression
Cory Weissman, University of Toronto and CAMH
Cory Weissman*, Daniel Blumberger, Julia Dimitrova, Zafiris Daskalakis

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W6. Using Resting State Intrinsic Network Connectivity to Identify Suicide Risk in Mood Disorders
Jonathan Stange, University of Illinois at Chicago
Jonathan Stange*, Lisanne Jenkins, Stephanie Pocius, Kayla Kreutzer, Katie Bessette, Sophie DelDonno, Leah Kling, Runa Bhaumik, John Keilp, K. Luan Phan, Scott Langenecker

W7. Bremelanotide for Hypoactive Sexual Desire Disorder in the Reconnect Studies: Analysis of Baseline Free Testosterone Level Quartile Subgroups
Anita Clayton, University of Virginia
Anita Clayton*, James Simon, Sheryl Kingsberg, Robert Jordan, Johna Lucas, Laura Williams, Julie Krop

W8. Efficacy and Safety of Lurasidone in Children and Adolescents With Bipolar Depression: Results From a 2-Year Open-Label Extension Study
Michael Tocco, Sunovion Pharmaceuticals, Inc.
Melissa DelBello, Robert Goldman, Michael Tocco*, Andrei Pikalov, Ling Deng, Antony Loebel

W9. Long-Term Efficacy of Lurasidone in Antipsychotic-Naïve Vs. Antipsychotic-Exposed Adolescents With Schizophrenia: Post-Hoc Analysis of a Two Year, Open-Label Study
Michael Tocco, Sunovion Pharmaceuticals, Inc.
Christoph Correll, Robert Goldman, Michael Tocco*, Andrei Pikalov, Jay Hsu, Antony Loebel

W10. Functional Recovery Among Patients With Schizophrenia Receiving Aripiprazole Once-Monthly in a 52-Week, Open-Label, Maintenance Study
Heather Fitzgerald, Lundbeck
Jessica Madera, Sharon Liu, Timothy Peters-Strickland, Pedro Such, Heather Fitzgerald*, Ross A. Baker

W11. Efficacy and Safety of SEP-363856, a Novel Psychotropic Agent With a Non-D2 Mechanism of Action, in the Treatment of Schizophrenia: A 4-Week, Randomized, Placebo-Controlled Trial
Kenneth Koblan, Sunovion Pharmaceuticals, Inc.
Kenneth Koblan*, Seth C. Hopkins, Justine Kent, Hailong Cheng, Robert Goldman, Antony Loebel

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✱ **W12. A Combination of Olanzapine and Samidorphan for Schizophrenia: Effects on Weight Gain and Metabolic Parameters in the Phase 3 ENLIGHTEN-2 Study and Subsequent Long-Term, Open-Label Safety Study**
John Newcomer, South Florida Behavioral Health Network
John Newcomer*, Christoph Correll, Rene Kahn, Bernard Silverman, Lauren DiPetrillo, Christine Graham, Ying Jiang, Yangchung Du, Adam Simmons, Craig Hopkinson, David McDonnell

W13. Body and Brain Imaging Correlates of Antipsychotic (AP)-Induced Glucose Dysregulation in AP-Naïve Schizophrenia Patients
Sri Mahavir Agarwal, Centre for Addiction and Mental Health
Sri Mahavir Agarwal*, Araba Chintoh, Nicole MacKenzie, Eric Plitman, Fernando Caravaggio, Eyesha Hashim, General Leung, Anish Kirpalani, Gary Remington, Ariel Graff-Guerrero, Margaret Hahn

W14. A Real-World Analysis of Outcomes Related to Veterans With Schizophrenia Who Transitioned to Once-Every-3-Months Paliperidone Palmitate Vs. Those Who Remained on Once-Monthly Paliperidone Palmitate
Qian Cai, Janssen Scientific Affairs, LLC
Panagiotis Mavros, Charmi Patel, Antoine El Khoury, Ahong Huang, Li Wang, Richa Bashyal, Qian Cai*

W15. Effect of Aripiprazole Once Monthly on Personal and Social Functioning of Patients With Schizophrenia: Post-Hoc Analyses of Acute and Long-Term Maintenance Studies
Maxine Chen, Otsuka Pharmaceutical Development & Commercialization, Inc.
Ross Baker, Pedro Such, Cathy Zhao, Maxine Chen*, Jessica Madera

W16. A Phase 3, Multicenter Study to Assess the Long-Term Safety, Tolerability and Efficacy of ALKS 3831 in Subjects With Schizophrenia
David McDonnell, Alkermes, Inc.
Sergey Yagoda, Christine Graham, Adam Simmons, Christina Arevalo, Yansong Cheng, David McDonnell*

W17. Polygenic Prediction and Prospective Studies of Treatment Outcomes in Schizophrenia
Tim Bigdeli, SUNY Downstate Medical Center
Tim Bigdeli*, Nina Schooler, Mihaela Aslan, John Concato, Philip Harvey, Ayman Fanous

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W18. The Impact of Second-Generation Antipsychotic Side-Effects on Functioning From a Schizophrenia Patient Perspective: A Global Patient Centered Survey
Catherine Weiss, Otsuka Pharmaceutical Development & Commercialization, Inc.
Catherine Weiss*, Stine Meehan, William R. Lenderking, Huda Shalhoub, Carla Dias-Barbosa, Jun Chen, Andrea Schulz, Mallik Greene, Laëtitia Bouérat Duvold

W19. Symptomatic Stability in Schizophrenia With Aripiprazole Once Monthly: Post-Hoc Efficacy Analyses From Long-Term Maintenance Studies
Pedro Such, H. Lundbeck A/S
Jessica Madera, Pedro Such*, Cathy Zhao, Ross A. Baker

W20. Should Antipsychotic Medications for Schizophrenia be Given for a Lifetime?: Replication of a Naturalistic, Long-Term, Follow-Up Study of Antipsychotic Treatment
Ira Glick*, Stanford University School of Medicine

W21. Teaching and Practice of Clinical Psychopharmacology
Ira Glick*, Stanford University School of Medicine

W22. New Edition: A Model Psychopharmacology Curriculum for Teachers of Psychiatric Residents
Ira Glick*, Stanford University School of Medicine

W23. Taking Our Cue From Patients: Collaborative Design of a Mobile Intervention for Depression and Anxiety
Ellen Frank, University of Pittsburgh School of Medicine
Ellen Frank*, Mark Matthews, Tara Moore

W24. Discussion of Innovative Psychopharmacology in Treatment-Refractory Patient Population in Psychiatry
Mujeeb Shad*, Oregon Health & Science University

W25. The Million Veteran Program: Implications for Precision Medicine
Sumitra Muralidhar, Department of Veterans Affairs
Sumitra Muralidhar*, Rachel Ramoni

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W26. The Effects of Valbenazine on Abnormal Involuntary Movement Scale (AIMS) Items 8, 9, and 10: Results From the Kinect 4 Study
Stephen Marder, Semel Institute at UCLA
Jean-Pierre Lindenmayer, Carlos Singer, Joshua Burke, Leslie Lundt, Khodayar Farahmand, Scott Siegert, Stephen Marder*

W27. Unexpected Findings: Low Correlation Between Clinician-Administered Madrs Ratings and Patient-Reported Ham-D Scores in a Clinical Trial for Major Depressive Disorder
William Yavorsky, Cronos CCS
William Yavorsky*, Cynthia McNamara, Brian Saxby, Kristy Wolanski, Francisco Burger, Guillermo DiClemente

W28. Dasotraline for Treatment of Adults With Binge-Eating Disorder: Effect on Binge-Related Obsessions and Compulsions
Ling Deng, Sunovion Pharmaceuticals, Inc.
Leslie Citrome, Robert Goldman, Matthew Mandel, Joyce Tsai, Ling Deng*, Andrei Pikalov, Antony Loebel

W29. Steady-State Pharmacokinetic Properties of a Sublingual Formulation of Cyclobenzaprine (CBP) HCL (TNX-102 SL): Comparison to Simulations of Oral Immediate Release CBP
Gregory Sullivan, Tonix Pharmaceuticals, Inc.
Gregory Sullivan*, Regina Kiu, Bernd Meibohm, Seth Lederman

W30. A Phase 1 Study of the Safety, Tolerability and Pharmacokinetics of Single and Multiple Doses of DNS-7801, a Highly Selective Phosphodiesterase-1 Inhibitor
Brett English, United States Navy
Brett English*, Becky Crean, Christina Charriez, David Carpenter, Phil Perera, Jef Vivian, Marco Peters

W31. An Indirect Treatment Comparison of Valbenazine and Deutetrabenazine in Adults With Tardive Dyskinesia: Comparison of Randomized, Placebo-Controlled Trials
Michael Serbin, Neurocrine Biosciences, Inc.
Saurabh Aggarwal, Michael Serbin*, Chuck Yonan

W32. Effects of Pharmacological Treatment on White Matter in Treatment Naive Vs. Treated OCD Patients: A Systematic Review of DTI studies
Raza Sagarwala, Saint Louis University School of Medicine
Raza Sagarwala*, Henry Nasrallah

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W33. Patterns of Resting State Functional Connectivity Differentially Predict Treatment Outcomes to Sertraline Versus Placebo in Patients With Major Depressive Disorder: Results From the Embarc Study
Cherise Chin Fatt, University of Texas Southwestern Medical Center
Cherise Chin Fatt*, Crystal Cooper, Manish Jha, Gregory Fonzo, Bruce Grannemann, Thomas Carmody, Tracy Greer, Benji Kurian, Maurizio Fava, Patrick McGrath, Phillip Adams, Melvin McInnis, Ramin Parsey, Myrna Weissman, Mary Phillips, Amit Etkin, Madhukar Trivedi

W34. Clinical and Cognitive Impact of Insulin Resistance in a Population-Based Cohort of Patients With Major Depressive Disorder
Andrew Czysz, The University of Texas Southwestern Medical Center
Andrew Czysz*, Tracy Greer, Bruce Grannemann, Brittany Mason, Philipp Scherer, Madhukar Trivedi

W35. Response Prediction in Anti-Psychotic Placebo-Controlled Clinical Trials in Patients With Major Depressive Disorder
Srikanth Gottipati, Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)
Srikanth Gottipati*, Bharath Ramaswamy, Merzu Belete, Timothy Peters-Strickland, Matthew Leoni, Dhruv Singh, Abhinav Dulur, Ananya Jain, Nikita Nangia, Ujwal Kadu

W36. Efficacy and Tolerability of a Switch to Levomilnacipran Extended Release Versus Adjunctive Quetiapine Extended Release in Major Depressive Disorder
Steven Szabo, Duke University Medical Centers
Steven Szabo*, Narei Hong, Prakash Masand, Angelo Sambunaris, Nitin Jindal, Anusha Agrawal, Ashwin Patkar

W37. Early Tolerability Predicts Later Tolerability After Dosing of Esketamine Nasal Spray for Treatment-Resistant Depression
David Williamson, Janssen Scientific Affairs, LLC
David Williamson*, Jagadish Gogate, H. Lynn Starr, Jennifer Kern Sliwa, Lew Manera, Sheldon Preskorn, Andrew Winokur, Ella Daly

W38. Personalized Goal Attainment After a Switch to Vortioxetine in a Phase 4 Open-Label Trial in Adults With Major Depressive Disorder (MDD): Health Outcomes and Progress Toward Functional Recovery
Maggie McCue, Takeda Pharmaceuticals U.S.A., Inc.
Maggie McCue*, Sagar Parikh, Debra Lawrence, Sara Sarkey, Anna Eramo, Maelys Touya

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W39. Personalized Goal Attainment After a Switch to Vortioxetine in Adults With Major Depressive Disorder (MDD): Results of a Phase 4 Open-label Clinical Trial
Maggie McCue, Takeda Pharmaceuticals U.S.A., Inc.
Maggie McCue*, Sagar Parikh, Lisa Mucha, Sara Sarkey, Anna Eramo, Clement Francois

W40. How Should Samples be Selected When Evaluating the Effectiveness of Treatments for Depression in Routine Clinical Practice?
Mark Zimmerman, Brown University
Mark Zimmerman*, Reina Kiefer, Caroline Balling, Sophie Kerr, Theresa Morgan

W41. Propofol as an Antidepressant: Evidence for Modulation of Excitation-Inhibition Balance
Brian Mickey, University of Utah School of Medicine
Brian Mickey*, Scott Tadler

W42. Efficacy of Esketamine Augmentation in Major Depressive Disorder
George Papakostas, Massachusetts General Hospital
George Papakostas*, Maurizio Fava, Naji Salloum, Rebecca Hock, Manish Jha, James Murrough, Sanjay Mathew, Dan Iosifescu

W43. Efficacy and Safety of AXS-05, an Oral NMDA Receptor Antagonist With Multimodal Activity, in Major Depressive Disorder: Results of a Phase 2, Double-Blind, Active-Controlled Trial
Ashley Anderson, Axsome Therapeutics Inc.
Ashley Anderson*, Mark Jacobson, Kellie Kennon, Cedric O'Gorman, Herriot Tabuteau

W44. Integrated Analysis of Efficacy and Safety of Brexanolone Injection in Women With Postpartum Depression From Three Pivotal Trials
Kristina Deligiannidis, Zucker Hillside Hospital; Feinstein Institute for Medical Research; Zucker School of Medicine at Hofstra/Northwell
Samantha Meltzer-Brody, Helen Colquhoun, Robert Riesenberg, C. Neill Epperson, Kristina Deligiannidis*, David Rubinow, Haihong Li, Danielle Dray, Stephen Kanes

W45. Adverse Side Effects Associated With Subanesthetic Intravenous Dose of Ketamine
Elia Acevedo, National Institute of Mental Health
Elia Acevedo*, Grace Cavanaugh, Lawrence Park, Carlos Zarate

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W46. Combinatorial Pharmacogenomic Testing Predicts Improved Outcomes for Depression Patients Who Switched From Test-Incongruent to Test-Congruent Medications: Sub-Analysis of the Guided Randomized Controlled Trial
Sagar Parikh, University of Michigan
Sagar Parikh*, Anthony Rothschild, Michael E. Thase, Boadie Dunlop, Charles Debattista, Charles Conway, Brent Forester, Francis Mondimore, Richard Shelton, Matthew Macaluso, James Li, Alexa Gilbert, Lindsey Burns, Michael Jablonski, John Greden

W47. A Pivotal Study of the Oral GABA-A Receptor Positive Allosteric Modulator SAGE-217 in Major Depressive Disorder: Analysis of HAM-D Total Score, Subscales, and Individual Items
Handan Gunduz-Bruce, Sage Therapeutics, Inc.
Handan Gunduz-Bruce*, Robert Lasser, Christopher Silber, Abdul Sankoh, Haihong Li, Jeffrey Jonas, James Doherty, Stephen Kanes

W48. Ketamine's Prophylactic Effects on Attenuating Learned Fear Are Partially Mediated by Long-Term Changes in Ventral Hippocampal Excitatory Neural Activity Patterns
Josephine McGowan, Columbia University
Josephine McGowan*, Christine Denny

W49. A Randomized, Placebo Controlled, Repeat Dose Phase 1B Study of COR388 in Older Healthy Volunteers and Patients With Alzheimer's Disease With Exploratory Efficacy Measures
Michael Detke, Cortexyme
Michael Detke*, Casey Lynch, Leslie Holsinger, Shirin Kapur, Debashish Raha, Dave Hennings, Mark Ryder, Ira Goodman, Steve Thein, Steve Dominy, Florian Ermini, Ursula Haditsch

W50. Use of Psychotropic Medications and Frailty in Long-Stay Nursing Home Residents
Yiyang Yuan, University of Massachusetts Medical School
Yiyang Yuan*, Kate Lapane, Christine Ulbricht

W51. Is There a Value in Screening for Depression and Anxiety in Individuals Who Smoke?
Ahmad Hameed, Penn State College of Medicine
Ahmad Hameed*, Dallas Hamlin, Courtney Lester, Myra Qureshi, Susan Veldheer, Jonathan Foulds

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✱ **W52. The Selective Orexin-1 Receptor Inhibitor JNJ-61393215 Decreases Subjective Anxiety Evoked by 35% Carbon Dioxide Inhalation in Healthy Subjects**
Giacomo Salvadore, Janssen Research & Development
Giacomo Salvadore*, Sander Brooks, Cathy Bleys, Kanaka Tatikola, Bart Remmerie, Gabriel Jacobs, John Moyer, Abigail Nash, Luc Van Nueten, Wayne Drevets

W53. Translational Research With Dexmedetomidine (DM) for the Treatment of Agitation From Healthy Volunteers to Two Patient Groups: Those With Schizophrenia or With Probable Senile Dementia of the Alzheimer's Type (SDAT)
Sheldon Preskorn, Kansas University School of Medicine
Sheldon Preskorn*, Rishi Kakar, Hrishikesk Khan, Sammeer Sharma, Vincent O'Neill, Robert Risinger, Frank Yocca

W54. Understanding Subject Behaviors and Travel Habits in Preventable Inclusion and Exclusion Protocol Violations in CNS Clinical Trials by Using Verified Clinical Trials' Research Subject Database Registry
AnnMarie McDougall, Verified Clinical Trials
AnnMarie McDougall*, Mitchell Efros, Bingnan Li, Maria Demonte

✱ **W55. Snap 101: Randomized, Crossover, Active and Placebo-Controlled, Safety, Pharmacokinetic, and Pharmacodynamic Study of Three Ascending Doses of INP105 - Novel Precision Olfactory Delivery (POD) of a Nasal Formulation of Olanzapine**
Jasna Hocevar-Trnka, Impel NeuroPharma
Jasna Hocevar-Trnka*, Stephen Shrewsbury, Kelsey Satterly, Meghan Swardstrom

W56. Treatment of Depression and Suicidal Ideation in Bipolar Disorder With Magnetic Seizure Therapy
Victor Tang, University of Toronto
Victor Tang*, Daniel Blumberger, Julia Dimitrova, Alanah Throop, Shawn McClintock, Daphne Voineskos, Jonathan Downar, Benoit H. Mulsant, Paul Fitzgerald, Zafiris Daskalakis

W57. Peripheral Blood Levels of Brain-Derived Neurotrophic Factor in First Episode Psychosis as a Measurable Diagnostic and Prognostic Tool: A Meta-Analysis
Sukhbir Singh, The Zucker Hillside Hospital
Sukhbir Singh*, Roy Dipta, Taylor Marzouk, Jianping Zhang

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W58. Endogenous Cannabinoids and the Tryptophan/Kynurenine Pathway in Mood Disorders
Stefano Comai, San Raffaele Vita-Salute University
Stefano Comai*, Megan Singh, Nicolas Nunez, Michael Gabrash, Argel Aguilar Valles, Tobias Atkin, Linda Booij, Nahum Sonenberg, Danilo De Gregorio, Garrett Sauber, Cecilia Hillard, Gabriella Gobbi

W59. Effect of Amygdala Ablation on PTSD Symptoms and Biomarkers
Sanne van Rooij, Emory University School of Medicine
Sanne van Rooij*, Kelly Bijanki, Timothy Ely, Jennifer Stevens, Cory Inman, Sierra Carter, Tanja Jovanovic, Jon Willie

W60. Innovations in Personalized Medicine: A Pilot Study Looking at the Potential Vs. the Promise in Major Depressive Disorder
Charles Wilcox, Pharmacology Research Institute
Charles Wilcox*, Nader Oskooilar, Mellissa Henry, Judy Morrissey, My-Linh Tong, David Rosenberg

W61. Genome-Wide Association Study of Aggression and Violence in Schizophrenia
Ali Bani-Fatemi, Centre for Addiction and Mental Health
Ali Bani-Fatemi*, Kevin Wang, Anvesh Roy, Lavaniya Kiruparajah, Nathan Kolla, Vincenzo De Luca

W62. Inflammation and the Dimensions of Depression: A Review
Marzieh Majd, Pennsylvania State University
Marzieh Majd*, Erika Saunders, Christopher G. Engeland

W63. Utility of an Electronic, Audiotaped Version of the Vineland Adaptive Behavior Scale (Vineland-II) in Rater Quality Monitoring for Studies of Autism Spectrum Disorder (ASD)
Joan Busner, Bracket Global, LLC
Joan Busner*, Tom G. Willgoss, Elizabeth Jones, Janice Smith

W64. Clinical Laboratory Data Suggesting That More Naloxone is not Needed to Induce Withdrawal Among Heroin Users Who Also use Fentanyl
Jermaine Jones, Columbia University Medical Center
Jermaine Jones*, Elliana Sherwin, Suky Martinez, Sandra Comer

W65. Increased Cannabis use in Psychotic Individuals With History of Physical and Sexual Trauma
Anahita Bassir Nia, Yale University School of Medicine
Anahita Bassir Nia*, Claire Mann, Sharron Spriggs, Yasmin Hurd

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✱ **W66. Patient Satisfaction With Injectable Weekly and Monthly Buprenorphine and Buprenorphine Treatment Experience**
Natalie Budilovsky-Kelley, Braeburn
Genie Bailey, Michael Frost, Sonnie Kim, Natalie Budilovsky-Kelley*, Fredrik Tiberg

W67. Early-Onset Efficacy and Safety Pilot Study of Amphetamine Extended-Release Oral Suspension (AMPH EROS) in the Treatment of Children With Attention-Deficit/Hyperactivity Disorder
Judith Kando, Tris Pharma
Thomas King, Barry Herman, Judith Kando, Antonio Pardo, Judith Kando*

W68. Evaluation of the Effect of SPN-812 Extended-Release Viloxazine on the Pharmacokinetics of Vyvanse® in Healthy Adults
Shamia Faison, Supernus Pharmaceuticals, Inc.
Shamia Faison*, Nicholas Fry, Toyin Adewole, Oyinkansola Odebo, Jiahong Xu, Azmi Nasser

W69. Morning Postural Stability in Older Adults Treated With Lemborexant Versus Placebo and Zolpidem Tartrate Extended Release
Margaret Moline, Eisai Inc.
Gary Zammit, Russell Rosenberg, David Mayleben, Dinesh Kumar, Gleb Filippov, Jocelyn Cheng, Antonia LoPresti, Carlos Perdomo, Margaret Moline*

W70. ARTISTS: An Open-Label, Long-Term Safety Study of Deutetrabenazine for the Treatment of Tourette Syndrome in Children and Adolescents
Maria Wieman, Teva Pharmaceuticals
Joseph Jankovic, Barbara Coffey, Daniel Claassen, David Stamler, Barry Gertz, Elisabeth Garofalo, Maria Wieman*, Juha-Matti Savola

W71. Botulinum Toxin Therapy of Social Anxiety Disorder: A Case Series
Eric Finzi, George Washington University Medical Center
Eric Finzi*, Norman Rosenthal

W72. Botulinum Toxin Therapy of Bipolar Depression: A Case Series
Eric Finzi, George Washington University Medical Center
Eric Finzi*, Lori Kels, Jared Axelowitz, Bruce Shaver, Christian Eberlein, Tillman Krueger, Axel Wollmer

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W73. Efficacy of Adjunctive Armodafinil in Bipolar Depression: A Meta-Analysis of Randomized Controlled Trials
Nicolas Nunez, Mayo Clinic
Nicolas Nunez*, Balwinder Singh, Francisco Romo- Nava, Marin Veldic, Alfredo Cuellar-Barboza, Colin Colby, Alejandra Cabello Arreola, Jennifer Vande Voort, Paul Croarkin, Joanna Biernacka, Susan McElroy, Mark Frye

W74. Cardiac Safety of Esketamine Nasal Spray in Treatment-Resistant Depression: Results From the Clinical Development Program
Jaskaran Singh, Janssen R & D, LLC, Janssen Pharmaceutical Companies of JNJ
Teodora Doherty, Ewa Wajs, Rama Melkote, Christian Funck-Brentano, Michael A. Weber, Janice Miller, Jaskaran B. Singh, Jaskaran Singh*

W75. Impact of Midazolam Vs. Saline on Effect Size Estimates in Controlled Trials of Ketamine as a Rapid-Acting Antidepressant
Samuel Wilkinson, Yale School of Medicine
Samuel Wilkinson*, Cristan Farmer, Elizabeth Ballard, Sanjay Mathew, Michael Grunebaum, James Murrough, Peter Sos, Gang Wang, Ralitza Guerguieva, Carlos Zarate, Jr.

W76. Differential Influence of Serotonin Transporter-Linked Polymorphic Region 5-HTTLPR Genotype by Race on Suicidal Behaviors Among Patients Diagnosed With Bipolar Disorder
Dorian Lamis, Emory University School of Medicine
Dorian Lamis*, Shufang Sun, Shweta Kapoor

W77. A Randomized Controlled Trial of Ketamine for Adolescent Treatment-Resistant Depression
Jennifer Dwyer, Yale Child Study Center
Jennifer Dwyer*, Gerard Sanacora, Michael Bloch

W78. Insurance Coverage of Pharmacogenomic Testing Among Patients With Depression
Heather Anderson, University of Colorado School of Pharmacy
Heather Anderson*, Kristy Crooks, David Kao, Nicholas Mendola, Christina Aquilante

W79. Managing Esketamine Treatment Frequency Toward Successful Outcomes: Analysis of Phase 3 Data
Michel Nijs, Janssen Research and Development, LLC
Leah Aluisio*, Michel Nijs, Ewa Wajs, Benoit Rive, Ella Daly, Adam Janik, Stephane Borentain, Jaskaran Singh, Frank Wiegand, Allitia DiBernardo

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Thursday, May 30, 2019

Poster Session II with Lunch
12:30 p.m. - 2:00 p.m.
Palomino 4-10

T1. Establishment of the Massachusetts General Hospital Postpartum Psychosis Project (MGHP3)
Lee Cohen, Massachusetts General Hospital
Lee Cohen*, Marlene Freeman, Taylor Church, Magdalena Collum, Alexandra Sosinsky, Joshua Roffman

T2. Premenstrual Suicidal Ideation as a Dimension of Premenstrual Syndrome: A Cross-Sectional Study of a Clinical Sample
Sara Carlini, Zucker Hillside Hospital
Sara Carlini*, Kristina Deligiannidis

T3. Bremelanotide for Hypoactive Sexual Desire Disorder: Contraceptive Subgroups Efficacy Analysis
Anita Clayton, University of Virginia
Anita Clayton*, Sheryl Kingsberg, James Simon, Robert Jordan, Laura Williams, Julie Krop

T4. Treatment Utilization Among Medicaid Patients With Newly Diagnosed Schizophrenia
Qian Cai, Janssen Scientific Affairs, LLC
Qian Qia, Charmi Patel, Ali Bonakdar, Edward Kim, Nancy Connolly, Pankaj Kumar Shukla, Antoine El Khoury, Qian Cai*

T5. Insulin Sensitivity and Glucose Metabolism of Olanzapine and a Combination of Olanzapine and Samidorphan: Phase 1 Study in Healthy Volunteers
John Newcomer, South Florida Behavioral Health Network
William Martin, Christine Graham, Linda Morrow, Carine Beysen, Frederico G.S. Toledo, Daiva Bajorunas, Ying Jiang, Bernard Silverman, David McDonnell, Mark Namchuk, John Newcomer*

T6. Extrapolating Evidence of Antipsychotic Efficacy From Adults to Adolescents: A Quantitative Approach to Influence Regulatory Policy
Shamir Kalaria, University of Maryland School of Pharmacy
Shamir Kalaria*, Mathangi Gopalakrishnan, Ramana Uppoor, Mehul Mehta, Tiffany Farchione, Mitchell Mathis, Hao Zhu

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T7. The Efficacy of Lumateperone 42 mg in the Treatment of Schizophrenia: A Pooled Analysis of Phase 2 and 3 Randomized Controlled Trials
Kimberly Vanover, Intra-Cellular Therapies, Inc.
Carol Tamminga, Kimberly E. Vanover, Michal Weingart, Robert E. Davis, Andrew Satlin, Kimberly Vanover*

T8. Results From a 12-Month Open-Label Safety Study of Lumateperone (ITI-007) in Patients With Stable Symptoms of Schizophrenia
Suresh Durgam, Intra-Cellular Therapies, Inc.
Suresh Durgam*, Kimberly E. Vanover, Michal Weingart, Jelena Saillard, Shawn I. Hossain, Steven J. Glass, Susan G. Kozauer, Sharon Mates, Andrew Satlin, Robert E. Davis

T9. The Safety and Tolerability of Lumateperone 42 mg for the Treatment of Schizophrenia: A Pooled Analysis of 3 Randomized Placebo-Controlled Trials
John Kane, The Zucker Hillside Hospital
John Kane*, Kimberly E. Vanover, Michal Weingart, Robert E. Davis, Suresh Durgam, Andrew Satlin

✱ **T10. Follow-Up on the Development of KarXT: Results of KAR-003, a Multiple Ascending Dose (MAD) Study of a Combination Product**
Stephen Brannan, Karuna
Stephen Brannan*, Andrew Miller, Steven Paul, Alan Breier

T11. Analysis of Sexual Function in a Study With Aripiprazole Once-Monthly Versus Paliperidone Palmitate Once-Monthly
Pedro Such, H. Lundbeck A/S
Jessica Madera, Pedro Such*, Louise Rosenberg Christ, Heather Fitzgerald, Ross A. Baker

T12. Asenapine Transdermal Patch (Asenapine Transdermal System, HP-3070) in the Treatment of Adults With Schizophrenia: Efficacy and Safety in a Phase 3 Randomized, Double-Blind, Placebo-Controlled, 6-Week, Inpatient Study
Leslie Citrome, New York Medical College
Leslie Citrome*, David Walling, Courtney Zeni, Marina Komaroff, Alexandra Park

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T13. Phase 1 Healthy Volunteer Pharmacokinetic and Safety Profile of D-Serine Compared to CTP-692, a Novel Deuterium-Modified D-Serine for Adjunctive Treatment of Schizophrenia
Vinita Uttamsingh, Concert Pharmaceuticals, Inc.
Vinita Uttamsingh*, Emily McIntyre, Darren Wong, Christopher Brummel, Sunanda Vedananda, Virginia Braman, James Cassella

T14. Clozapine Prescribing and Patient Characteristics Among OEF/OIF Veterans Treated at the Department of Veterans Affairs: A Descriptive Report
Zachary Zuschlag, James A. Haley Veterans Hospital
Zachary Zuschlag*, Christopher Fowler, Vanessa Panaite, Susan Schultz

T15. A Phase 1 Study of the Safety, Tolerability and Pharmacokinetics of Single and Multiple Doses of DNS-6288, a Highly Selective Phosphodiesterase-2 Inhibitor
Brett English, United States Navy
Brett English*, Brittani Basobas, Silvia Myhre, Yan Wang, David Carpenter, Phil Perera, Jef Vivian

T16. External Monitoring and PANSS Data Quality: Focus on Identical Ratings Across Visits
David Daniel, Bracket Global, LLC
David Daniel*, Prateek Verma, Alan Kott

T17. Identifying Young Cannabis Users at Risk of Developing Psychosis
Matej Markota, Mayo Clinic
Matej Markota*, William Bobo, Paul Croarkin

T18. Quality of Rest and Treatment Adherence in Seriously Mentally Ill Patients Receiving Treatment With a Digital Medicine System
Zahra Heidary, Otsuka Pharmaceutical Development & Commercialization, Inc.
Zahra Heidary*, Timothy Peters-Strickland, Jonathan Knights

T19. From Science to Practice: Strategies for Pharmacotherapists Managing Complicated Grief
Sidney Zisook, University of California, San Diego
Sidney Zisook*, Alana Iglewicz, Naomi Simon, Charles Reynolds, Barry Lebowitz, Katherine Shear

T20. Rare Ophthalmologic Side Effects of Aripiprazole
Zohaib Abbasi, Cleveland Clinic
Zohaib Abbasi*, Christopher Sola

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T21. Efficacy and Safety of Dasotraline in Adults With Binge-Eating Disorder: A Randomized, Double-Blind, Fixed-Dose Trial
Ling Deng, Sunovion Pharmaceuticals, Inc.
Robert Goldman, James Hudson, Susan McElroy, Carlos Grilo, Joyce Tsai, Ling Deng*, Justine Kent, Antony Loebel

T22. Effect of Dasotraline on Body Weight in Patients With Binge-Eating Disorder
Ling Deng, Sunovion Pharmaceuticals, Inc.
Leslie Citrome, Robert Goldman, Matthew Mandel, Joyce Tsai, Ling Deng*, Andrei Pikalov, Antony Loebel

T23. A Modified-Release Drug Delivery Technology Containing Amphetamine-Ion Exchange Complexes
Barry Herman, Tris Pharma
Barry Herman*, Thomas King, Judith Kando, Antonio Pardo

T24. Cumulative Burden of Illness in Veterans With Tardive Dyskinesia and Serious Mental Illness
Stanley Caroff, Perelman School of Medicine University of Pennsylvania
Stanley Caroff*, Shirley Leong, Christopher Roberts, Cabrina Campbell, Rosalind Berkowitz

T25. Comprehensive Model of Information Seeking for Understanding the Probability of Requesting Pharmacogenomic Testing for Psychotropic Medications
Gurtej Gill, West Virginia University/Charleston Area Medical Center
Maggie Driscoll, Gurtej Gill*, Patrick L. Kerr, Carol Freas, Muhammad J. Shah, Fahd Mousa

T26. "Living With Tardive Dyskinesia": A Patient Education Initiative
Lorraine McStay, Physicians Postgraduate Press, Inc.
Lorraine McStay*, John Shelton, Lee Harrington

T27. Cannabinoid Augmentation of Exposure-Based Cognitive Behavioral Therapy for OCD: A Pilot Study
Reilly Kayser, Columbia University/New York State Psychiatric Institute
Reilly Kayser*, Marissa Raskin, Ivar Snorrason, Margaret Haney, H. Blair Simpson

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T28. A Study to Assess Digitally Enabled Engagement in Major Depressive Disorder
Maggie McCue, Takeda Pharmaceuticals U.S.A., Inc.
Maggie McCue*, Chris Blair, Ben Fehnert, Francesca Cormack, Sara Sarkey, Anna Eramo, Ellen Rhodes, Chris Kabir, Dave Kemp

T29. Validation of Goal Attainment Scaling for Depression: Initial Findings From an Open-Label Study in Patients Switching to Vortioxetine
Maggie McCue, Takeda Pharmaceuticals U.S.A., Inc.
Mark Opler, Andrea Norcini Pala, Sagar Parikh, David Hellerstein, Anna Eramo, Lambros Chrones, Maggie McCue*

T30. Development of a Real-World Ketamine Database Registry: Centers of Psychiatric Excellence (COPE)
Steven Szabo, Duke University Medical Centers
Steven Szabo*, Ashwin Patkar, Kurian Abraham, Michael Banov, Tammy Rader, Manish Zinzuvadia, Azfar Malik, Elena Vidrascu, Prashant Gajwani, Raman Gopalkrishnan, Nelson Handal, Prakash Masand

T31. Response Analysis of Brexanolone Injection by Hamilton Rating Scale for Depression Total Score, Individual Items, and Subscales in Three Pivotal Studies in Women With Postpartum Depression
Kristina Deligiannidis, Zucker Hillside Hospital; Feinstein Institute for Medical Research; Zucker School of Medicine at Hofstra/Northwell
Samantha Meltzer-Brody, Helen Colquhoun, Robert Riesenberg, C. Neill Epperson, Kristina Deligiannidis*, David Rubinow, Haihong Li, Mark Opal, Stephen Kanes

T32. Assessment of Withdrawal Symptoms: Long-Term, Open-Label Study of Esketamine Nasal Spray and an Oral Antidepressant in Treatment-Resistant Depression
Leah Aluisio, Janssen
Leah Aluisio*, Ewa Wajs, Allitia DiBernardo, Nancy Chen, Wayne C. Drevets, Ella Daly, Peter Zannikos, Valerie Curran, Andrew Krystal, Guang Chen, Roseanne Lane

T33. The Antidepressant AV-101 is a Substrate for LAT1 (SLC7A5) at the Blood-Brain Barrier
Waseema Patel, University of Liverpool
Waseema Patel*, Mark Smith, H. Ralph Snodgrass, Munir Pirmohamed, Ana Alfirevic, David Dickens

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T34. Using Machine Learning Algorithms and Available Data to Take the "Trial and Error" out of Prescribing
Dekel Taliaz, Taliaz Ltd.
Dekel Taliaz*, Amit Spinrad, Omri Teltsh, Dana Averbuch, Gilad Fuchs, Zohar Barnet Itzhaki

T35. An Integrative Network Analysis Identifies Novel Pathways in Treatment Response to Antidepressants
Venkat Bhat, University of Toronto
Venkat Bhat*, Chiara Pastrello, Brock Schuman, Yingchen Fan, Wendy Lou, Daniel Mueller, Gustavo Turecki, Igor Jurisica, Jane Foster, Sidney Kennedy

T36. Emotional Proprioception: Treatment of Emotional Disorders With Afferent Facial Feedback
Eric Finzi, George Washington University Medical Center
Eric Finzi*, Norman Rosenthal

T37. Efficacy of Adjunct Buprenorphine/Samidorphan in the Treatment of Major Depressive Disorder According to Baseline Disease Characteristics
Sanjeev Pathak, Alkermes, Inc.
Arielle D. Stanford, William Martin, Asli Memisoglu, Sanjeev Pathak*

T38. Effect of Esketamine Nasal Spray on Cognition in Patients With Treatment Resistant Depression: Results From Five Phase 3 Studies
Randall Morrison, Ortho-McNeil Janssen Scientific Affairs
Randall Morrison*, Jaskaran Singh, Ella Daly, Maggie Fedgchin, Ewa Wajs, Leah Alusio, Rachel Ochs-Ross, Vanina Popova, Keith Karcher, Rosanne Lane, Pilar Lim, Kimberly Cooper, Paul Maruff, David Hough, Wayne C. Drevets, Husseini Manji

T39. Is the DSM-5 Anxious Distress Specifier Sufficient for Measuring Anxiety in Depressed Patients?: Implications for Measurement-Based Care
Mark Zimmerman, Brown University
Mark Zimmerman*, Sophie Kerr, Caroline Balling, Reina Kiefer, Kristy Dalrymple

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T40. Understanding the Patient Experience Through the Self-Reported Review of the Value of Esketamine (STRIVE) Study in Patients With Treatment-Resistant Depression
Jill Abell, Janssen Scientific Affairs
Jill Abell*, H. Lynn Starr, Jagadish Gogate, Allyson Larish, Carol Jamieson, Ella Daly, Michelle Kramer

T41. A Phase-2, Double-Blind, Placebo-Controlled, Sequential Parallel Comparison Design Study to Evaluate the Efficacy and Safety of Adjunctive Pimavanserin in Major Depressive Disorder
Maurizio Fava, Massachusetts General Hospital
Maurizio Fava*, Bryan Dirks, Marlene Freeman, Richard Shelton, Michael Thase, Madhukar Trivedi, George Papakostas, Keith Liu, Srdjan Stankovic

T42. A Phase 3, Double-Blind, Placebo-Controlled Trial of SAGE-217 in Postpartum Depression: Topline Assessment of Secondary Efficacy Measures of Anxiety and Depression
Robert Lasser, Sage Therapeutics, Inc.
Robert Lasser*, Kristina M. Deligiannidis, Handan Gunduz-Bruce, Christopher Silber, Abdul Sankoh, Sigui Li, Jeffrey Jonas, James Doherty, Stephen Kanes

T43. Efficacy and Safety of Anyu Peibo in Chinese Patients With MDD: A Phase II Randomized, Double-Blind, Placebo-Paralleled, Multi-Center Clinical Trial
Yifeng Shen, Shanghai Mental Health Center
Yifeng Shen*, Huafang LI

T44. Short-Term and Long-Term Efficacy of Adjunctive Brexpiprazole in Adults With MDD: Effect on the Inventory of Depressive Symptomatology Self-Report (IDS-SR) Scale
Stine Meehan, H. Lundbeck A/S
Stine Meehan*, Catherine Weiss, Klaus Groes Larsen, Dalei Chen, Ross Baker, Mary Hobart

T45. Time to Relapse After a Single Administration of Intravenous Ketamine Augmentation in Unipolar Treatment-Resistant Depression
Naji Salloum, Harvard Medical School/Massachusetts General Hospital
Naji Salloum*, George Papakostas, Maurizio Fava, Rebecca Hock, Marlene Freeman, Martina Flynn, Bettina Hoeppner, Cristina Cusin, Dan Iosifescu, Madhukar Trivedi, Gerard Sanacora, Sanjay Mathew, Charles Debattista, Dawn Ionescu

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T46. Rapastinel for the Treatment of Major Depressive Disorder: A Patient-Centric Clinical Development Program
Ken Kramer, Allergan
Armin Szegedi, Robert Hayes, Raffaele Migliore, Marc Debelle, Anju Starace, Kavneet Kohli, Ken Kramer*, Richard Shelton

T47. Is There an Increase in the Psychiatric Adverse Events in Smokers Using Usual Nicotine Content Cigarettes Verses Smokers Using Reduced Nicotine Content Cigarettes?
Ahmad Hameed, Penn State College of Medicine
Ahmad Hameed*, Courtney Lester, Myra Qureshi, Emily Wasserman, Susan Veldheer, Jonathan Foulds

T48. A Manualized Eight-Week Videoconference-Based Virtual Cognitive Behavioral Therapy (CBT) Group for Chronic Low Back Pain (CLBP)
Timothy Mariano, Harvard Medical School
Timothy Mariano*, Limeng Wan, Tara Wilfert, Robert Edwards, Robert Jamison

T49. Feasibility of a Specialized Avatar System as a Rater Training Tool for CNS Clinical Trials
Joan Busner, Bracket Global, LLC
Joan Busner*, Samantha Silverman, Margot E. Oakley, Alan Kott, David G. Daniel

✱ **T50. Translational Research With Dexmedetomidine (DM) for the Treatment of Agitation From Healthy Volunteers to Two Patient groups: Those With Schizophrenia or With Probable Senile Dementia of the Alzheimer's Type (SDAT)**
Sheldon Preskorn, Kansas University School of Medicine
Sheldon Preskorn*, Rishi Kakar, Sammeer Sharma, Vincent O'Neill, Robert Risinger, Frank Yocca

T51. Rethinking Drug Side-Effect Verification
Josef Witt-Doerring, Baylor College of Medicine

T52. A Subject-Targeted Placebo-Control Reminder Script: An In-Depth Empirical Exploration of How Subject Characteristics Moderate Placebo Response
Elan Cohen, Hassman Research Institute
Elan Cohen*, Howard Hassman, David Walling, Katarzyna Wyka, Roberta Ball, Jaclyn Lobb, Dakota Hazzard, Ashok Joseph, Larry Ereshefsky

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T53. Using a Computer Simulated Rater to Evaluate Clinical Trial Outcomes: Carbamazepine Extended-Release for the Treatment of Bipolar Depression
Gary Sachs, Massachusetts General Hospital & Harvard Medical School
Lori Davis, Gary Sachs*, Dan DeBonis

T54. Psychopharmacological Treatment of Inattention in Children Prenatally Exposed to Teratogenic SUBSTANCES: More is MORE?
Gaby Ritfeld, Emory University School of Medicine
Gaby Ritfeld*, Julie Kable, Jennifer Holton

T55. Outcome Prediction for Patients With Bipolar Disorder Using Prodromal and Onset Data
Srikanth Gottipati, Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)
Srikanth Gottipati*, Yijun Shao, Yan Cheng, Qing Zeng-Treitler

T56. Application of Multimodal Neurocognitive Measures as a Marker of Bipolar Disorder: A Machine Learning Approach
Rashmin Achalia, Achalia Neuropsychiatry Clinic
Rashmin Achalia*, Naren Rao, Ganesan Venkatasubramanian

T57. Lurasidone and Metabolic Syndrome: Results From Short and Long-Term Clinical Studies in Patients With Bipolar Depression
Michael Tocco, Sunovion Pharmaceuticals, Inc.
Michael Tocco*, John W. Newcomer, Andrei Pikalov, Yongcai Mao, Antony Loebel

T58. Drug/Placebo Responders Vs. Drug/Placebo Partial Responders: Which Group is More Likely to Contribute to Signal Detection in Clinical Trials? Results From a Lurasidone Study in Patients With Bipolar Depression
Andrei Pikalov, Sunovion Pharmaceuticals, Inc.
Antony Loebel, Andrei Pikalov*, Cynthia Siu, Jay Hsu, Michael Tocco, Justine Kent, Robert Goldman

T59. The Broad Efficacy of Cariprazine Across Symptoms in Patients With Bipolar I Disorder: Post Hoc Analysis of Randomized, Placebo-Controlled Trials
Willie Earley, Allergan
Willie Earley*, Joseph Calabrese, Trisha Suppes, Maria Burgess, Lakshmi N. Yatham, Eduard Vieta, Roger S. McIntyre, Mehul Patel

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T60. Grey and White Matter Structure Associates With the Activation of the Tryptophan to Kynurenine Pathway in Bipolar Disorder
Stefano Comai, San Raffaele Vita-Salute University
Sara Poletti, Elisa Melloni, Cristina Colombo, Flavia Valtorta, Francesco Benedetti, Stefano Comai*

✱ **T61. MDMA-Assisted Psychotherapy for Treatment of Anxiety Related to Life-Threatening Illnesses**
Allison Feduccia, MAPS Public Benefit Corporation
Allison Feduccia*, Lisa Jerome, Philip Wolfson, Michael Mithoefer

T62. Effects of a Novel Combination Drug on Psychostimulant Cue Reactivity and Nicotine Withdrawal Symptoms in Abstinent Psychostimulant use Disorder Patients
Tong Lee, Generys Biopharmaceuticals Corp.
Tong Lee*, Ashwin Patkar, Steven Szabo, Dale Christensen, Eunho Lee, Brett Froeliger, Francis McClernon

T63. Functional Connectivity Between the Orbitofrontal Cortex and Dorsal Striatum in Addiction
Hyuntaek Oh, The Menninger Clinic
Hyuntaek Oh*, Savannah Gosnell, Michelle Patriquin, Ramiro Salas

T64. Lowest Effective Dose of Buprenorphine in Office Based Opioid Maintenance Treatment
Vishal Kwatra, St. Vincent Charity Medical Center
Theodore Parran, Vishal Kwatra*, Gaurav Mathur, Chris Adelman

T65. Further Evaluation of the Validity of the MADDERS System for Evaluating Abuse Potential of CNS-Active Medications in Clinical Trials
Harrison Elder, Analgesic Solutions
Harrison Elder*, Ryan Lanier, Nathalie Erpelding, Nathaniel Katz

T66. Efficacy and Safety of DR/ER-MPH, a Delayed-Release and Extended-Release Methylphenidate, in Children With ADHD: Results From a Pivotal Phase 3 Classroom Trial
Floyd Sallee, Ironshore Pharma
Ann Childress, Andrew Cutler, Andrea Marraffino, Norberto DeSousa, Bev Incledon, Floyd Sallee*

= **New Investigator Awardee** ✱ = **Pharmaceutical Pipeline Presentation**

T67. Evaluation of the Effect of SPN-812 Extended-Release Viloxazine on the Pharmacokinetics of Concerta® in Healthy Adults
Shamia Faison, Supernus Pharmaceuticals, Inc.
Shamia Faison*, Nicholas Fry, Toyin Adewole, Oyinkansola Odebo, Jiahong Xu, Azmi Nasser

T68. ARTISTS2: A Well-Controlled, Fixed-Dose Study of Deutetrabenazine for the Treatment of Tics Associated With Tourette Syndrome
Maria Wieman, Teva Pharmaceuticals
Joseph Jankovic, Barbara Coffey, Daniel Claassen, David Stamler, Barry Gertz, Elisabeth Garofalo, Maria Wieman*, Juha-Matti Savola

T69. ARTISTS1: A Study of Deutetrabenazine for the Treatment of Tourette Syndrome in Children and Adolescents
Maria Wieman, Teva Pharmaceuticals
Joseph Jankovic, Barbara Coffey, Daniel Claassen, David Stamler, Barry Gertz, Elisabeth Garofalo, Maria Wieman*, Juha-Matti Savola

T70. Effect of Polygenic Risk Scores on Violence in Schizophrenia
Vincenzo De Luca, Centre for Addiction and Mental Health
Vincenzo De Luca*, Samia Tasmim, Oluwagbenga Dada, Nathan Kolla

T71. The Application of PET Neuroimaging Probes Targeting Epigenetics
Changning Wang, Harvard Medical School/Massachusetts General Hospital

T72. A Preclinical Study of Rapastinel Versus Ketamine in Opioid Use Disorder
Steven Szabo, Duke University Medical Centers
Ashwin Patkar, Nidesh Lamhicchane, Christopher Armstrong, Julia Ferrante, David Walker, Ahaan Patkar, Cynthia Kuhn, Prakash Masand, Steven Szabo*

T73. The Patient's Perspective in Benefit-Risk: How a Preference Study Supported the Esketamine Application for Regulatory Approval in Treatment-Resistant Depression
Eva Katz, Janssen Research and Development
Eva Katz*, Angelyn Fairchild, Reed Johnson, Shelby Reed, Jaskaran Singh, Ella Daly, Allitia DiBernardo, Carol Jamieson, David Hough, Bennett Levitan

T74. A Phase 3, Double-Blind, Placebo-Controlled Trial of SAGE-217 in Postpartum Depression: Assessment of Depressive Symptoms Across Multiple Measures

Kristina Deligiannidis, Zucker Hillside Hospital; Feinstein Institute for Medical Research; Zucker School of Medicine at Hofstra/Northwell
Kristina Deligiannidis*, Robert Lasser, Handan Gunduz-Bruce, Christopher Silber, Abdul Sankoh, Sigui Li, Jeffrey Jonas, James Doherty, Stephen Kanes

T75. Development of the N-Methyl-D-Aspartate Receptor (NMDAR) Antagonist D-Methadone for the Treatment of Depression and Other CNS Disorders

Ottavio Vitolo, Relmada Therapeutics Inc.
Ottavio Vitolo*, Paolo Manfredi, Charles Inturrisi, Gina DiGuglielmo, Taleen Hanania, Galina Bernstein, Sara DeMartin, Manoela Fogaca, Ron Duman, Sergio Traversa

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