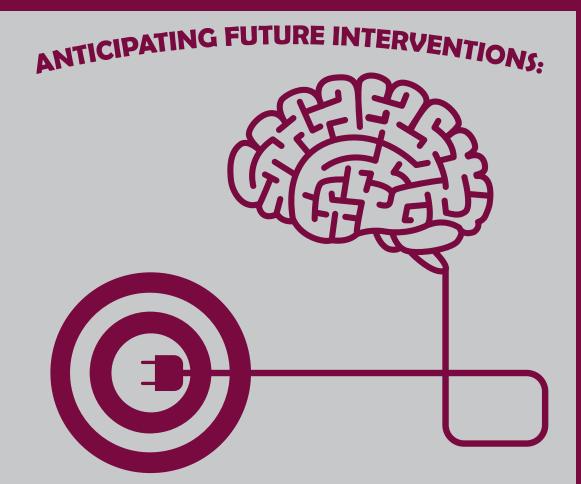
### ASCP ANNUAL MEETING FAIRMONT SCOTTSDALE PRINCESS MAY 30-JUNE 3, 2016



### DISCOVERING NEW TARGETS, INTEGRATIVE BIOMARKERS, AND BEYOND



www.ASCPMeeting.org



Dear Colleagues,

Welcome to Arizona!

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 Latin American Satellite Symposia but also the 24<sup>th</sup> iteration of our very successful New Investigators' Program. Our meeting has something for everyone. There are sessions that discuss innovation across not only syndrome-states and the life cycle but also in terms of public-private partnerships, teaching, as well as public health and dissemination research. And just when you think there could be nothing more to entice you out of the Arizona sun, there are talks on the challenges posed by medical marijuana, to the role of technology in research and clinical practice to a session that describes how you can learn "new tricks" by studying an old medication, Lithium. 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 the ASCP Executive Office 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.

MHRepapat and Mark Rapaport, M.D.

Mark Rapaport, 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 2016 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.

#### 2016 Program Highlights

#### Monday, May 30th

- Latin America Psychopharmacology Update
- Tuesday, May 31st
  - Conference Opening
  - Pharma Pipeline: 8 presentations of Phase 1 and Phase 2 developments
  - Individual Research Reports
- Wednesday, June 1st
  - 17th Annual Fun Run/Walk
  - Regulatory Plenary: Evolving Views on Pseudospecificity and Comparing Drug and Device Regulatory Pathways
  - ASCP Lifetime Awardee Talk
  - Poster Session I
  - ASCP Reception

#### Thursday, June 2nd

- Keynote Plenary Session: Beyond Single Magic Bullets: True Innovation in Neuropsychiatric Conditions
- NIH Institute Directors Plenary
- Poster Session II
- Clinical Updates in Pharmacology
- Workshops
- o Friday, June 3rd
  - Regulatory Wrap-Up Plenary with FDA regulators
- Throughout the meeting
  - NIMH, NIDA, and NCCIH panels
- The New Investigator Program
- A closed workshop for 18 New Investigators and informal breakfast sessions.
- o Workshops: 2 hour intensive interactive sessions focused on problems and solutions
- Wednesday and Thursday Afternoons
- o \*Clinical Track\* sessions focused on topics of immediate clinical relevance
- Organization
  - o The meeting is sponsored by the American Society for Clinical Psychopharmacology (ASCP).
    - The Steering Committee organizes the meeting.
    - The Program Committee evaluates submitted proposals and develops program innovations.
  - NIH collaborations:
    - NIMH National Institute of Mental Health
    - NIDA National Institute of Drug Abuse
    - NIAAA National Institute on Alcohol Abuse and Alcoholism
    - NINDS National Institute of Neurological Disorders and Strokes
    - CSR Center for Scientific Review
    - NCATS National Center for Advancing Translational Sciences
  - Regulatory agency collaborations:
    - Food and Drug Administration (FDA)
    - Center for Devices and Radiological Health (CDRH)
  - o Parthenon Management Group organizes the ASCP Annual Meeting.
- And remember
  - o The Fun Run/Walk is Wednesday, June 1st at 6:30 a.m. All are welcome to join!
  - The Opening Reception is Wednesday, June 1st from 6:15 p.m. 7:15 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,

Husseini Manji, M.D., FRCPC Steering Committee Co-Chair

M.D

Alan Gelenberg, M.D. Program Committee Co-Chair

Michael E. Than Mis

Michael E. Thase, M.D. Steering Committee Co-Chair

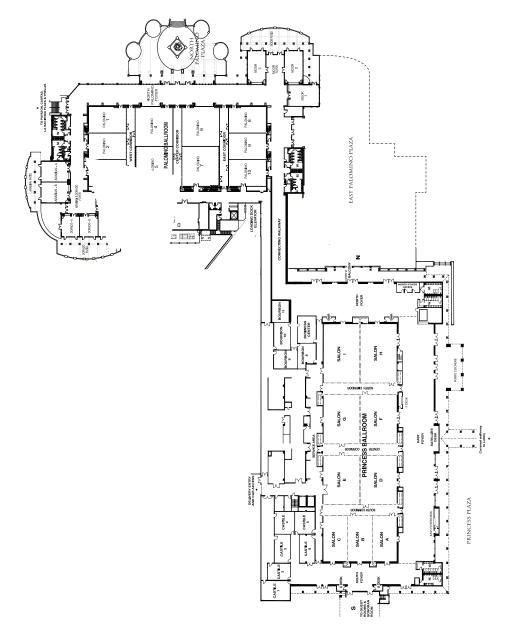
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Holly A. Swartz, M.D. Program Committee Co-Chair



# **Hotel Maps**

#### Fairmont Scottsdale Princess Conference Center Layout



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



### Notes


### Award Winners

**Recipient of the Donald Klein Lifetime Achievement Award** 



# Awards Winners & Featured Speakers



#### John Davis, M.D. UIC Psychiatric Institute / University of II at Chicago

At the time Dr. Davis entered Psychiatry, drugs to treat serious mental illness had been discovered but were not recognized by academic psychiatrists who believed that both treatment and research should be exclusively psychoanalytic, based on individual Freudian case studies. Dr. Davis was one of the

early psycho-pharmacologists who transformed psychiatry into a science through introduction of a variety of research methodologies, such as random assignment controlled studies, the development of lithium as an anti-manic agent (Bunney et al., 1968, Am J Psychiatry,1968; Colburn RW et al., 1967 Nature), the application of pharmacology to understand the mechanisms of how drugs produce improvement, the development of biologicallybased theories of mental illness, the study of the clinical pharmacology of psychotropic drugs (such as drug metabolism or drug-drug interactions) and the pooled analysis of clinical trial results.

Dr. Davis performed the first meta-analysis (a statistical technique for combining evidence from different studies) in psychiatry; the second in general medicine, showing that 'at maintenance' antipsychotic treatment prevents relapse. The resulting paper (Davis JM, 1975, Am J Psychiatry) was an ISI classic, one of the most cited papers in the year--evidence that the paper had an impact on the field. In 1976, part 2 of this meta-analysis (Davis JM, 1976, Am J Psychiatry) was published showing that maintenance-lithium reduced relapses in bipolar disease and antidepressants did so in depression. Meta-analysis has become a common form of data synthesis particularly after the Cochrane collaboration systematized it, in the 1990s. Drs. Stefan Leucht and Davis have recently updated these analyses in several papers in Lancet (Leucht et al., 2008, 2013), the American Journal of Psychiatry (2009) and other journals, which were highly cited papers and are now called "Hot New Papers" rather than "ISI Science Citation Classics."

### Award Winners

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



**ASC** 

#### Lee Baer, Ph.D. Massachusetts General Hospital

**Nominated for:** Prevalence and Impact of Obsessive-Compulsive Symptoms in Depression: A STAR\*D Report Lee Baer, Madhukar H. Trivedi, Ilana Huz, A. John Rush, Stephen R. Wisniewski, and Maurizio Fava

Lee Baer, Ph.D. is an internationally-known clinician

and researcher in obsessive-compulsive disorders and their overlap with other Axis I and Axis II disorders. He cofounded the Massachusetts General Hospital OCD Program in 1986, and the McLean OCD Institute in 1997. He co-authored the first comprehensive textbook on OCD, and has written two books on OCD for the general public. Dr. Baer led a team that developed the HANDS depression scale used by National Depression Screening Day for the past quarter century to screen hundreds of thousands of employees, students, and other individuals for major depression. Dr. Baer served for 25 years as Associate Chief of Psychology in the MGH Department of Psychiatry, and is currently senior biostatistician in the MGH Depression Research and Clinical Program, and Professor of Psychiatry, Part-Time in the Harvard Medical School Department of Psychiatry.

### Award Winners



#### New Investigator Awardees

**Greta Bushnell, B.S.** University of North Carolina at Chapel Hill

**Daniel Eskenazi, M.D., Ph.D.** New York State Psychiatric Institute, Columbia University

Britta Galling, M.D. The Zucker Hillside Hospital

Carolina Haass-Koffler, Pharm.D. Brown University

**Amy Hilty, M.D.** Otsuka Pharmaceuticals

Yusuke Iwata, M.D. CAMH Toronto

Manish Jha, M.D. UT Southwestern

Katelyn Keyloun, Pharm.D. University of Washington

Luca Lavagnino, M.D. McGovern Medical School at the University of Texas Health Science Center at Houston

Katarzyna Liwski, B.S., M.P.H. LECOM Brian Mickey, M.D., Ph.D. University of Utah School of Medicine

Dahlia Mukherjee, Ph.D. Penn State Milton S. Hershey Medical Center

Malik Nassan, M.D. Mayo Clinic

**Primavera Spagnolo, M.D., Ph.D.** National Institute on Alcohol Abuse & Alcoholism, National Institutes of Health

**Sunny Tang, M.D.** University of Pennsylvania

**Saulo Tractenberg, M.D.** Pontifical Catholic University of Rio Grande do Sul

Hanjing Emily Wu, M.D. University of Texas Health Science Center at Houston

**Xuefeng Zhang, M.D.** Baylor College of Medicine

#### <u>Regulatory Plenary</u> Wednesday, June 1st from 8:30 a.m. – 10:00 a.m.



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

Dr. Farchione received her medical degree from Wayne State University in Detroit, Michigan, and completed adult residency and child & adolescent fellowship training at the University of Pittsburgh's Western Psychiatric Institute and Clinic. Dr. Farchione is board certified in both general and child & adolescent

psychiatry. Prior to joining FDA in 2010, Dr. Farchione was affiliated with the University of Pittsburgh Medical Center, and was on the faculty of the University of Pittsburgh.

As the Deputy Director in the Division of Psychiatry Products at FDA, Dr. Farchione is involved in the oversight of new drug review for all psychiatric drug development activities conducted under INDs, and the review of all NDAs and supplements for new psychiatric drug claims.



#### William Heetderks, M.D., Ph.D. Division of Neurological and Physical Medicine Devices

Dr. Heetderks is the Deputy Director for Clinical Activities in the Division of Neurological and Physical Medicine Devices (DNPMD) at the Center for Devices and Radiological Health, FDA. This division reviews a wide variety of devices related to neurological

disease and rehabilitation including neurosurgical devices, neurostimulation devices, neurodiagnostic devices, and physical medicine and rehabilitation devices. Before coming to the FDA he was the Director of Extramural Science Programs at the National Institute of Biomedical Imaging and Bioengineering, NIH. There he directed broad research programs in medical imaging and bioengineering research and research training.

He received his Ph.D. in bioengineering from the University of Michigan, his M.D. from the University of Miami and is boarded in Internal Medicine. Earlier in his career he served for fifteen years, eventually as Director in the Neural Prosthesis Program, NINDS, a research program focused on development of enabling technologies and devices for rehabilitation of neurological disability including spinal cord injury, deafness, and blindness.



#### <u>Main Plenary: Beyond Single Magic Bullets: True Innovation</u> <u>in Neuropsychiatric Conditions</u> Thursday, June 2nd from 8:15 a.m. - 9:45 a.m.



#### Husseini Manji, M.D. Johnson & Johnson Pharmaceutical Research & Development

Husseini K. Manji, M.D., FRCPC is the Global Therapeutic Head for Neuroscience at Janssen Research & Development, LLC., a division of Johnson & Johnson. Previously, he was Chief, Laboratory of Molecular Pathophysiology & Experimental

Therapeutics, NIH, and Director of the NIH Mood and Anxiety Disorders Program. Dr. Manji received his B.S. and M.D. from the University of British Columbia. He completed fellowship training at the NIMH and completed additional training in cellular and molecular biology. His research has focused on investigation of disease-and treatment-induced changes in gene and protein networks that regulate synaptic and neural plasticity. His work has led to investigation of novel therapeutics for patients with refractory neuropsychiatric illnesses. Dr. Manji has also been involved in medical and postgraduate neuroscience education and has published extensively on the molecular and cellular neurobiology of neuropsychiatric disorders and the development of novel therapeutics. Dr. Manji has received numerous distinguished scientific and academic awards, including the NIMH Director's Career Award for Significant Scientific Achievement, and was inducted in to the U.S. Institute of Medicine of the National Academies in 2008. He has served as Chair of the American College of Neuropsychopharmacology, is a Counselor to the Society of Biological Psychiatry and serves on a variety of editorial boards of scholarly journals. He holds voluntary leadership positions in many organizations devoted to advancement of neuroscience and advocacy for people with neuropsychiatric illnesses. He has been a member of the Howard Hughes Medical Institute and NIH Research Scholars Program Advisory Committee.



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#### Vaibhav Narayan, Ph.D. Johnson & Johnson

Vaibhav is currently Head of Neuroscience Integrated Solutions, Informatics and Disease Interception at Janssen Neuroscience. The Neuroscience Therapeutic Area at Janssen is pioneering a more personalized and holistic approach to therapeutic intervention that goes 'beyond the pill', to offer data-driven and sciencebased 'integrated solutions' for preventing, diagnosing,

treating, and monitoring CNS diseases. Vaibhav's work is currently focused on utilizing state-of-the-art informatics methods for developing markers for early diagnosis, disease progression, drug response and treatment monitoring in Alzheimer's and Mood; and to develop novel 'point-of-need' tools and technologies for management of adherence and prediction of relapse in patients with Schizophrenia.

Vaibhav joined Johnson and Johnson from Eli Lilly and Co., where he headed the Discovery and Biomedical Infomatics group to enable Lilly's translational, biomarker, and tailored therapeutics strategies. Prior to Lilly, Vaibhav held multiple leadership roles in various small to mid-size biotech companies such as Celera Genomics, CuraGen Corporation and Vertex pharmaceuticals during which time he participated in multiple landmark 'Big Biology' projects, including sequencing, assembly and analysis of the human genome (Human Genome Project) and elucidation of the first complete protein-protein interaction map of a whole organism.

Vaibhav obtained his Ph.D. from Yale University jointly from the Departments of Chemistry, and Molecular Biophysics & Biochemistry in 1998, and an Executive MBA from Kellogg School of Management, Northwestern University in 2009.



#### Tanzeem Choudhury, Ph.D. Cornell University / HealthRhythms

Tanzeem Choudhury is an associate professor in Computing and Information Sciences at Cornell University and a co-founder and CTO of HealthRhythms. At Cornell, she directs the People-Aware Computing group, which works on inventing the future of technology-assisted wellbeing. Tanzeem

received her Ph.D. from the Media Laboratory at MIT. Tanzeem was awarded the MIT Technology Review TR35 award, NSF CAREER award and a TED Fellowship. For more information about her research please visit <u>http://pac.cs.cornell.edu</u>. Follow the group's work on twitter @pac\_cornell.

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### Barbara Sahakian, Ph.D. University of Cambridge

Barbara J. Sahakian is Professor of Clinical Neuropsychology at the University of Cambridge Department of Psychiatry and Behavioural and Clinical Neuroscience Institute. She is also an Honorary Clinical Psychologist at Addenbrooke's Hospital, Cambridge. She holds a Ph.D. and a D.Sc. from the University of

Cambridge. She is a Fellow of the Academy of Medical Sciences and a Past-President of the International Neuroethics Society and the British Association for Psychopharmacology. In 2016, she was recipient of the Robert Sommer Award. Sahakian is also a Member of the International Expert Jury for the 2017 Else Kröner-Fresenius-Stiftung Prize. She is a member of ACNP, CINP Council and ECNP Review Board. She is co-author of '*Bad Moves: How Decision Making Goes Wrong and the Ethics of Smart Drugs*' (Oxford University Press, 2013) and co-editor of *The Oxford Handbook of Neuroethics* (OUP, 2011).

Sahakian has an international reputation in the fields of psychopharmacology, neuropsychology, neuropsychiatry, neuroimaging and neuroethics. She is perhaps best known for her work on 'hot' and 'cold' cognitive deficits in depression and early detection and early treatment with cholinesterase inhibitors in Alzheimer's disease. She has over 400 publications in high impact scientific journals. The ISI Web of Science database credits her with a Hirsch (h) index of 102, with some publications having over 300 citations. Sahakian co-invented the neuropsychological CANTAB tests. She serves as a Senior Consultant to Cambridge Cognition, a University of Cambridge spin-out that provides CANTAB (www.cantab.com). She is also a Consultant for Peak (Brainbow) (https://itunes.apple.com/gb/app/peak-brain-training/ id806223188?mt=8). There is now the Cambridge University & Peak Advanced Training Plan. Sahakian has contributed to Neuroscience and Mental Health Government Policy and has spoken on resilience, brain health, neuroscience and mental health at the World Economic Forum, Davos, 2014. She was also a finalist for a World Technology Award 2014 under the category of 'Health and Medicine'. She is a member of the World Economic Forum Global Agenda Council on Brain Research.

#### Institute Directors Plenary Thursday, June 2nd from 10:00 a.m. – 11:00 a.m.



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Michael E. Thase, M.D. Perelman School of Medicine at the University of Pennsylvania

Michael E. Thase, M.D., joined the faculty of the University of Pennsylvania School of Medicine in January 2007, as Professor of Psychiatry after more than 27 years at the University of Pittsburgh Medical Center and the Western Psychiatric Institute and Clinic.

Dr. Thase's research focuses on the assessment and treatment of mood disorders, including studies of the differential therapeutics of both depression and bipolar affective disorder. A 1979 graduate of the Ohio State University College of Medicine, Dr. Thase is a Distinguished Fellow of the American Psychiatric Association, a Founding Fellow of the Academy of Cognitive Therapy, a member of the Board of Directors for the American Society of Clinical Psychopharmacology, and Vice Chairman of the Scientific Advisory Board of the National Depression and Bipolar Support Alliance. Dr. Thase has been elected to the membership of the American College of Psychiatrists and the American College of Neuropsychopharmacology. Dr. Thase has authored or co-authored more than 500 scientific articles and book chapters, as well as 15 books.





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

George F. Koob, is Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) as of January 27, 2014. 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 650 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.



#### Amir Tamiz, Ph.D. National Institute of Neurological Disorders and Stroke

Dr. Tamiz is a Program Director at the National Institute of Neurological Disorders and Stroke (NINDS), Office of Translational Research (OTR) who oversees NIH Blueprint Neurotherapeutics network (BPN) and Innovation Grants to Nurture Initial Translational Efforts (IGNITE).

Prior to joining NIH in 2012, Dr. Tamiz had held scientific and management positions in research and development of therapeutic programs at Corvas International (acquired by Dendreon), CovX (now part of Pfizer), and Alba Therapeutics. Dr. Tamiz received his Ph.D. at University of Oregon and conducted postdoctoral research at the Department of Neuroscience at Georgetown University Medical Center.





#### Christopher P. Austin, M.D. National Center for Advancing Translational Sciences

Christopher P. Austin, M.D., is Director of the National Center for Advancing Translational Sciences (NCATS) at the U.S. National Institutes of Health (NIH). Austin leads the Center's work to improve the translation of observations in the laboratory, clinic and community

into interventions that reach and benefit patients—from diagnostics and therapeutics to medical procedures and behavioral changes. Under his direction, NCATS researchers and collaborators are developing new technologies, resources and collaborative research models; demonstrating their usefulness; and disseminating the data, analysis and methodologies for use by the worldwide research community.

Austin's career has spanned the spectrum of translational research, in the public and private sectors. Austin joined NIH in 2002 as the senior advisor to the director for translational research at the National Human Genome Research Institute, where he was responsible for conceptualizing and implementing research programs to derive scientific insights and therapeutic benefit from the newly completed Human Genome Project. While at NHGRI, he founded and directed the NIH Chemical Genomics Center, Therapeutics for Rare and Neglected Diseases program, Toxicology in the 21st Century initiative, and NIH Center for Translational Therapeutics. Upon creation of NCATS in 2011, he became the Inaugural Director of the NCATS Division of Pre-Clinical Innovation, and was appointed NCATS director in 2012. Prior to joining NIH, Austin worked at the pharmaceutical company Merck, where he directed programs on genome-based discovery of novel targets and drugs, with a particular focus on schizophrenia and Alzheimer's disease.

Austin is trained as a clinician and geneticist. He trained in internal medicine and neurology at the Massachusetts General Hospital in Boston, and practiced medicine in academic and community hospital settings as well as in urban primary care and in rural Alaska and Africa. He completed a research fellowship in developmental neurogenetics at Harvard, studying genetic and environmental influences on stem cell fate determination. Austin earned an M.D. from Harvard Medical School and A.B. summa cum laude in biology from Princeton University.





#### Ivan Montoya, M.D., MPH National Institutes for Neurological Disorders and Stroke / National Institutes of Health

Dr. Montoya is the Deputy Director of the Division of Therapeutics and Medical Consequences (DTMC) of the National Institute on Drug Abuse (NIDA). He received an M.D. from the University of Antioquia (Colombia), a Master's in Public Health from The Johns Hopkins

School of Public Health, and completed residency training in Psychiatry at the University of Antioquia and the University of Maryland Hospital (Baltimore). He has been a Fulbright Fellow at The Johns Hopkins School of Public Health, Visiting Foreign Fellow at the Intramural Research Program of NIDA, Director of the Practice Research Network of the American Psychiatric Association. He has published extensively in the areas of etiology, prevention, treatment (pharmacological and non-pharmacological), and medical consequences of drug abuse.



### Richard K. Nakaruma, M.D. Center for Scientific Review

Dr. Richard K. Nakamura is the Director of the Center for Scientific Review. In that capacity, he leads the review of grant applications of the National Institutes of Health. Dr. Nakamura received his Bachelor of Arts in Psychology from Earlham College and his Ph.D. in Psychology from State University of New York (Stony

Brook, NY). He was with the National Institute of Mental Health from 1976 to 2011. In 2001, he received the NIH-Asian/Pacific American Organization (APAO) Outstanding Achievement Award for Administrative Work. In 2002, Dr. Nakamura was elected by the American Association for the Advancement of Science (AAAS) to the status of AAAS Fellow. Also in 2002, Dr. Nakamura was awarded the Presidential Rank Award for outstanding leadership. In 2004 and 2005 respectively, he received leadership awards from the Federation of Behavioral Psychological and Cognitive Sciences, and from the International Society for Behavioral Neuroscience. In 2009, he was awarded the NIH Director's Award for Outstanding Administration.





#### Sarah Lisanby, M.D. Division of Translational Research National Institute of Mental Health

Sarah Hollingsworth Lisanby, M.D. is the director of Division of Translational Research at the National Institute of Mental Health (NIMH). As director for the Division of Translational Research, Dr. Lisanby oversees a research funding portfolio of approximately \$400

million and help set a national agenda for research on mental illness. She also works with Dr. Carlos Zarate and colleagues in the Division of Intramural Research Programs, creating an important bridge between the Institute's extramural and intramural research efforts.

Dr. Lisanby is one of the leading researchers in the area of neuromodulatory interventions for treating major depression, serving as a principal investigator on studies that range from basic research through clinical trials. Additionally, she is a prolific author with approximately 200 scientific articles and book chapters, and she has also received national and international recognition.

Dr. Lisanby's prodigious research life has been matched by extensive service to NIMH and beyond. She has been a member of the NIMH Board of Scientific Counselors since 2013, and has chaired or been a member of a variety of NIH Study Sections since 2004. Dr. Lisanby also serves on the FDA Neurological Devices Advisory Panel, is on five editorial boards, and has held key leadership positions with numerous professional associations, including Chair of the American Psychiatric Association Task Force to Revise the Practice on Electroconvulsive Therapy (ECT).

#### <u>Regulatory Wrap-Up</u> Friday, June 3rd from 10:15 a.m. – 11:45 a.m.

Tiffany Farchione, M.D. Food and Drug Administration See previous bio

William Heetderks, M.D., Ph.D. Division of Neurological and Physical Medicine Devices See previous bio



#### **Steering Committee Chairs**

**Program Committee Chairs** 

**New Investigator Award Program Chairs** 



Husseini Manji, M.D., FRCPC



Michael E. Thase, M.D.

Alan Gelenberg, M.D.



Holly A. Swartz, M.D.



Mark H. Rapaport, M.D.



Christopher Sarampote, Ph.D.

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Elliot Ehrich, M.D. Alkermes Pharmaceuticals

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 US Food and Drug Administration

Alan Gelenberg, M.D. Journal of Clinical Psychiatry

David J. Kupfer, M.D. University of Pittsburgh School of Medicine

Thomas P. Laughren, M.D. Food and Drug Administration

Raye Litten, Ph.D. National Institute of Alcohol Abuse and Alcoholism

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Lee Cohen, M.D. Massachusetts General Hospital

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Richard Shelton, M.D. University of Alabama at Birmingham

★ Jair Soares, M.D. University of Texas School of Medicine at Houston

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Benedetto Vitiello, M.D. National Institute of Mental Health

- Carlos A. Zarate, M.D.
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- ★ Jianping Zhang, M.D., Ph.D. The Zucker Hillside Hospital

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- ★ Lori Davis, M.D. Tuscaloosa VA Medical Center
- ★ Tiffany Farchione, M.D. Food and Drug Administration

Lindsey Grandison, Ph.D. National Institute on Alcohol Abuse and Alcoholism

Bruce Kinon, M.D. Lundbeck

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

Katharine Phillips, M.D.
 Rhode Island Hospital / Brown University

Nina R. Schooler, Ph.D. State University of New York, Downstate Medical Center

 Holly A. Swartz, M.D. University of Pittsburgh School of Medicine

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Maurizio Fava, M.D. – ASCP Past-President Massachusetts General Hospital

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 Madhukar Trivedi, M.D. UT Southwestern Medical Center

Sidney Zisook, M.D. University of California, San Diego

Meeting Announcements | ASCP

#### 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. – 6:45 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. <u>The meeting organizers ask that all speakers</u> 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	8:00 a.m. – 6:00 p.m.
Wednesday - Thursday	7:30 a.m. – 6:30 p.m.
Friday	7:30 a.m. – 12:00 p.m.

**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 <u>info@ascpp.org</u>.

**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:

- Complimentary internet in the guest rooms
- Fitness Center admittance

**ASCP Membership** - If you would like to join ASCP, you can log onto our website at 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 for more information.

# ASCP | Meeting Announcements

#### **Continuing Education Credits**

### Disclosures are available for all ASCP Annual Meeting presenters online at <u>www.ASCPMeeting.org</u>.

**Continuing Education Credits** are available for physicians, pharmacists and psychologists. Applications for credit must be completed online with the meeting evaluation survey. The survey may be completed during or after the conference at <u>www.ASCPMeeting.org</u>. *Surveys for continuing education credit must be submitted no later than June 29, 2016.* 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.

#### Physicians/Nurse Practioners

ASCP AMERICAN SOCIETY OF CLINICAL PSYCHOPHARMACOLOGY The American Society of Clinical Psychopharmacology is accredited by the Accreditation Council for Continuing Medical

Education (ACCME) to provide continuing medical education for physicians. The American Society of Clinical Psychopharmacology (ASCP) designates this live meeting for a maximum of 24.25 *AMA PRA Category 1 Credit*(s)<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

#### Pharmacists



USF Health is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This knowledge-based program has been approved for 24.25 contact hours. Universal program number is as follows:

0230-999-16-008-L01-P.

To receive continuing education credit, a pharmacist must attend the accredited sessions, actively participate in questions and answers and must return the program evaluation instrument. In order to receive full credit, registrants must arrive no later than 10 minutes after the start of the meeting and must attend the entire meeting.

# Meeting Announcements | ASCP

#### Psychologists



USF Health is approved by the American Psychological Association to sponsor continuing education for psychologists. USF Health maintains responsibility for this program and its content. This activity has been approved for 24.25 CE credits. Full attendance of the live activity is

required. Partial credit will not be awarded.

### All participants who request continuing education credits by June 29, 2016, should expect to receive their statement of credits via email in July.

**The Meeting Evaluation Survey** will be available at <u>www.ASCPMeeting.org</u>. We encourage all registrants to complete the evaluation. Attendees requesting CME 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 2016 meeting is appreciated as we strive to improve the meeting each year.

# ASCP Meeting Announcements

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

Alkermes, Inc. Otsuka America Pharmaceutical, Inc. Sunovion Pharmaceuticals

#### 2017 ASCP Annual Meeting - Save the Date



The 2017 ASCP Annual Meeting will take place May 29 – June 2, 2017 at the Loews Miami Beach Hotel in Miami, Florida. Details regarding abstract submission for the 2017 Meeting will be released in September, 2016.

Monday, May 30, 2016 ASCP

#### **AT-A-GLANCE**

#### Monday, May 30, 2016

8:30 a.m. – 4:15 p.m.	NIA Workshop (Invitation Only) Palomino 8 & 9
10:00 a.m. – 5:00 p.m.	<b>Registration</b> Princess East Foyer
12:00 p.m. – 5:00 p.m.	<b>Speaker Ready Room</b> Bourbon 11
12:00 p.m. – 2:00 p.m.	Latin America Satellite Symposia: An Update on Biomarkers and Clinical Outcomes in Psychiatry Salon I
2:00 p.m. – 4:00 p.m.	Latin America Satellite Symposia: New Therapeutic Approaches for Psychiatric Disorders* Salon I
4:00 p.m. – 5:00 p.m.	ASCP Curriculum Committee Meeting (Invitation Only) Bourbon 9



### Notes


Monday, May 30, 2016

ASCP

#### **FULL SCHEDULE**

#### Monday, May 30, 2016

#### 8:30 a.m. – 4:15 p.m. NIA Workshop (Invitation Only) Palomino 8 & 9

**Co-Chairs:** Mark H. Rapaport, M.D., Emory University School of Medicine Christopher Sarampote, Ph.D., 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. In addition, they will receive a travel expense award and a certificate acknowledging their participation in the program at an award ceremony on Tuesday evening, May 31, 2016. This year's 18 New Investigator awardees are indicated with a ribbon in the poster section of this program; they will also be notated with a ribbon icon in the program book.

#### Faculty

Christoph U. Correll, M.D. The Zucker Hillside Hospital	Holly A. Swartz, M.D. University of Pittsburgh School of Medicine
Lori Davis, M.D. Tuscaloosa VA Medical Center	Tiffany Farchione, M.D. Food and Drug Administration
Lindsey Grandison, Ph.D. National Institute on Alcohol Abuse and Alcoholism	Ivan Montoya, M.D., M.P.H. National Institute on Drug Abuse
Bruce Kinon, M.D. Lundbeck	Katharine Phillips, M.D. Rhode Island Hospital/Brown University
Nina R. Schooler, Ph.D. State University of New York	,

# ASCP | Monday, May 30, 2016

10:00 a.m. – 5:00 p.m.	Registration Open Princess East Foyer	
12:00 p.m. – 5:00 p.m.	Speaker Ready Room <i>Bourbon 11</i>	
12:00 p.m. – 2:00 p.m.	Latin America Satellite Symposia: An Update on Biomarkers and Clinical Outcomes in Psychiatry Salon I	
Chair: Mauricio Tohen, University of New Mexico		
12:00 p.m. – 12:20 p.m.	Small Non-coding RNA as Predictors and Mediators of Antidepressant Response Gustavo Turecki, McGill University	
12:20 p.m. – 12:40 p.m.	Outcome in First Episode Non-affective Psychosis Mauricio Tohen, University of New Mexico	
12:40 p.m. – 1:00 p.m.	Temporal Lobe Epilepsy: Where Neurology Meets Immunopsychiatry Antonio Teixeira, University of Texas Health Science Center at Houston	
1:00 p.m. – 1:10 p.m.	Discussion	
1:10 p.m. – 1:30 p.m.	<b>Neurobiology of Alcohol Use Disorders</b> Nancy DiazGranados, National Institute on Alcohol Abuse and Alcoholism	
1:30 p.m. – 1:50 p.m.	Paediatric Bipolar Disorder – Brain Mechanisms, Early Detection and Prospects for New Interventions Jair Soares, University of Texas School of Medicine at Houston	
1:50 p.m. – 2:00 p.m.	Discussion/Break	

Monday, May 30, 2016 ASCP

2:00 p.m. – 4:00 p.m.	Latin America Satellite Symposia: New
	Therapeutic Approaches for Psychiatric
	Disorders*
	Salon I

Chair: Rodrigo Machado-Vieira, NIMH, NIH

2:00 p.m. – 2:20 p.m.	Early Life Stress in Mood Disorders: HPA Axis Response to GR and MR Agonists and Antagonists Mario Juruena, King's College London/University of Sao Paulo
	Sao Paulo
2:20 p.m. – 2:40 p.m.	Translating Neurotrophic and Plasticity Pathways into New Treatments for Mood Disorders Rodrigo Machado-Vieira, NIMH, NIH
2:40 p.m. – 3:00 p.m.	<i>New Treatments for Alcoholism: a Focus on the Gut-Liver-Brain Axis</i> Lorenzo Leggio, NIAAA, NIDA, NIH
3:00 p.m. – 3:10 p.m.	Discussion
3:10 p.m. – 3:30 p.m.	<b>Promising Medications to Treat Substance Use Disorders</b> Ivan Montoya, NIDA, NIH
3:30 p.m. – 3:50 p.m.	<b>New Glutamate Modulators for Mood Disorders</b> Carlos A. Zarate, NIMH, NIH
3:50 p.m. – 4:00 p.m.	Final Remarks
4:00 p.m. – 5:00 p.m.	ASCP Curriculum Committee Meeting (Invitation Only) <i>Bourbon 9</i>



### Notes


Tuesday, May 31, 2016 ASCP

#### AT-A-GLANCE

#### Tuesday, May 31, 2016

6:30 a.m. – 8:30 a.m.	ASCP Board Meeting (Invitation Only) Moor 1
7:30 a.m. – 6:00 p.m.	<b>Registration</b> Princess East Foyer
7:30 a.m. – 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Castile 1
7:30 a.m. – 6:00 p.m.	<b>Speaker Ready Room</b> Bourbon 11
8:30 a.m. – 9:00 a.m.	Conference Opening Princess Ballroom A-E

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

ADHD in Adults with a Focus on Assessment, Comorbidity and Associated Features*	Public-private Partnerships to Develop Medications for Alcohol Use Disorder: Recent Successes and New Opportunities for Collaboration with NIAAA	Mobile Health: Real-time Monitoring in Bipolar Disorder and Addictions*	Pathway to Treatment of Cognitive Impairment in Depression
Salon F	Salon G	Salon H	Salon I

10:30 a.m. – 10:45 a.m. Break

**Princess East Foyer** 

# ASCP Tuesday, May 31, 2016

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

State Versus Trait Anhedonia: A Neurobiological Link Between Depression, ADHD and Substance Abuse	Unraveling the Complexities of Psychotropic Prescribing during Pregnancy*	Frontiers of Pharmacotherapy for Autism Spectrum Disorders*	Biomarker Based Clinical Trials in Drug Development
Salon F	Salon G	Salon H	Salon I

12:15 p.m. – 2:00 p.m. L	unch On Own.
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2:00 p.m. – 4:00 p.m.	Pharmaceutical Pipelines	
	Princess Ballroom 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

Substance Use Disorders, Treatments for Alzheimer's Disease, and Speeding Drug Discovery	Improving Assessment and Clinical Trial Methodology	Mood Disorders: Targets, Approaches, and Outcomes	Advances in Schizophrenia*
Salon F	Salon G	Salon H	Salon I

6:15 p.m. – 7:45 p.m.

New Investigator Awards Ceremony (Invitation Only) Arabian A/B

\*of special interest to clinicians

Tuesday, May 31, 2016 ASCP

### **FULL SCHEDULE**

### Tuesday, May 31, 2016

6:30 a.m. – 8:30 a.m.	ASCP Board Meeting (Invitation Only) Moor 1
7:30 a.m. – 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Castile 1
7:30 a.m. – 6:00 p.m.	Registration Princess East Foyer
7:30 a.m. – 9:00 a.m.	Morning Break Princess East Foyer
7:30 a.m. – 6:00 p.m.	Speaker Ready Room <i>Bourbon 11</i>
8:30 a.m. – 9:00 a.m.	Conference Opening Princess Ballroom A-E
Panel Sessions	

9:00 a.m. – 10:30 a.m. ADHD in Adults with a Focus on Assessment, **Comorbidity and Associated Features\*** Salon F

Chair: Frederick Reimherr, University of Utah School of Medicine Discussant: Mark Stein, University of Washington

9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m. – 9:30 a.m.	ADHD in Adults with a Focus on Comorbidity and Associated Features Calvin Sumner, NCS Pearson - Clinical Assessment
9:30 a.m. – 9:50 a.m.	<b>Personality Disorder in Adult ADHD</b> Thomas Gift, University of Rochester, Rochester, NY

## ASCP Tuesday, May 31, 2016

9:00 a.m. – 10:30 a.m. (continued)	ADHD in Adults with a Focus on Assessment, Comorbidity and Associated Features* Salon F
9:50 a.m. – 10:10 a.m.	Violence in Adult ADHD - The Role of ADHD on Type of Aggression Florence Philipp-Wiegmann, Institute for Forensic Psychology and Psychiatry, Saarland Universität, Homburg/Saar, Germany
10:10 a.m. – 10:30 a.m.	Discussion
9:00 a.m. – 10:30 a.m.	Public-private Partnerships to Develop Medications for Alcohol Use Disorder: Recent Successes and New Opportunities for Collaboration with NIAAA Salon G
Chair: Raye Litten, NIAAA	A
9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m. – 9:30 a.m.	Infrastructure to Facilitate Drug Development: Public-Private Partnerships Raye Litten, NIAAA
9:30 a.m. – 9:50 a.m.	Moderators of Varenicline Treatment Effects in a Double-blind, Placebo-controlled Trial for Alcohol Dependence: An Exploratory Analysis Daniel Falk, NIAAA/NIH
9:50 a.m. – 10:10 a.m.	A Double-blind, Placebo-controlled Trial Assessing the Efficacy of ABT-436 (V1b antagonist) for Alcohol Dependence Megan Ryan, NIAAA
10:10 a.m. – 10:30 a.m.	Discussion

Tuesday, May 31, 2016 ASCP

9:00 a.m. – 10:30 a.m.	Mobile Health: Real-time Monitoring in Bipolar Disorder and Addictions* Salon H
Hershey Medical Center	enn State College of Medicine, Penn State Milton S. er, Stanford University School of Medicine
9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m. – 9:30 a.m.	Detection of Mood States from Acoustic Features Acquired Using Smartphones Melvin McInnis, University of Michigan Medical School
9:30 a.m. – 9:50 a.m.	Daily Mood Monitoring of Symptoms Using Smartphones in Bipolar Disorder: Feasibility of Ecological Momentary Assessment Erika Saunders, Penn State College of Medicine, Penn State Milton S. Hershey Medical Center
9:50 a.m. – 10:10 a.m.	Understanding the Relationships Between Affect and Craving in Early Abstinence: Ecological Momentary Assessment of Patients in Treatment for Prescription Opioid Dependence Scott Bunce, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine
10:10 a.m. – 10:30 a.m.	Discussion
9:00 a.m. – 10:30 a.m.	Pathway to Treatment of Cognitive Impairment in Depression Salon I

Chair: Richard Keefe, Duke University Medical Center Discussant: Tiffany Farchione, US Food and Drug Administration

9:00 a.m. – 9:10 a.m.	Introduction
9:10 a.m. – 9:30 a.m.	<b>Cognitive Impairment and Disability in Major</b> <b>Depression: What is the Nature of the Problem?</b> Philip Harvey, Miller School of Medicine, University of Miami

#### \*of special interest to clinicians

## ASCP Tuesday, May 31, 2016

9:00 a.m. – 10:30 a.m. (continued)	Pathway to Treatment of Cognitive Impairment in Depression Salon I
9:30 a.m. – 9:50 a.m.	<b>Review of Treatment Studies to Date – What Do We Need?</b> Maurizio Fava, Massachusetts General Hospital
9:50 a.m. – 10:10 a.m.	Methods and Design of Trials for Treatment of Cognitive Impairment of MDD Richard Keefe, Duke University 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.	State Versus Trait Anhedonia: A Neurobiological
	Link Between Depression, ADHD and Substance
	Abuse
	Salon F

**Chair:** Martin Katzman, START Clinic for Mood and Anxiety Disorders **Discussant:** Larry Klassen, Eden Mental Health Centre

10:45 a.m. – 10:55 a.m.	Introduction
10:55 a.m. – 11:15 a.m.	Understanding the Biological Basis of Co- occurring Depression and Attention-Deficit/ Hyperactivity Disorder Irvin Epstein, University of Toronto
11:15 a.m. – 11:35 a.m.	Anhedonia: A Predictor of Cognitive Dysfunction, Attention-Deficit/Hyperactivity Disorder and Treatment Outcome in a Subset of Depressed Patients Tia Sternat, START Clinic for Mood & Anxiety Disorders

## Tuesday, May 31, 2016 ASCP

ate Versus Trait Anhedonia: A Neurobiological nk Between Depression, ADHD and Substance puse <i>Jon F</i>
e Neurobiology of Cognitive Dysfunction and hedonia: A Common Link Between Psychiatric sorders and the Effects on Treatment Selection artin Katzman, START Clinic for Mood and Anxiety sorders
scussion
nraveling the Complexities of Psychotropic escribing During Pregnancy* <i>Ion G</i>

Chair: Lee Cohen, Massachusetts General Hospital Co-Chair: Marlene Freeman, Massachusetts General Hospital Discussant: Alan Gelenberg, *Journal of Clinical Psychiatry* 

10:45 a.m. – 10:55 a.m.	Introduction
10:55 a.m. – 11:15 a.m.	Second Generation Antipsychotics in Reproductive Age Women: Current Results from the National Pregnancy Registry for Atypical Antipsychotics Lee Cohen, Massachusetts General Hospital
11:15 a.m. – 11:35 a.m.	Baseline BMI and Gestational Weight Gain in Women with Psychiatric Illness: Impact of Psychotropic Use and Clinical Implications Marlene Freeman, Massachusetts General Hospital
11:35 a.m. – 11:55 a.m.	<b>Obstetrical, Pregnancy, and Socioeconomic</b> <b>Predictors for Postpartum Psychiatric Disorders</b> Samantha Meltzer-Brody, University of North Carolina at Chapel Hill
11:55 a.m. – 12:15 p.m.	Discussion

## ASCP | Tuesday, May 31, 2016

#### 10:45 a.m. – 12:15 p.m. Frontiers of Pharmacotherapy for Autism Spectrum Disorders\* Salon H

**Chair:** Stephen Zukin, Johns Hopkins University School of Medicine **Discussant:** Jeremy Veenstra-Vanderweele, Columbia University & New York State Psychiatric Institute

- 10:45 a.m. 10:55 a.m. Introduction
- 10:55 a.m. 11:15 a.m. Endpoint Selection and Stratification Variables for Clinical Trials in Autism: Lessons from the Arbaclofen Program Paul Wang, Autism Speaks
- 11:15 a.m. 11:35 a.m. Designing Clinical Trials to Enhance Functioning in Developmental Disorders: Moving from Single Dose Studies of Oxytocin to Sustained Treatment Trial in Autism Linmarie Sikich, Duke University Medical Center
- 11:35 a.m. 11:55 a.m. **Opportunities and Challenges in Autism Drug Development: The Industry Perspective** Federico Bolognani, Roche Innovation Center Basel / F. Hoffmann-La Roche, Ltd.
- 11:55 a.m. 12:15 p.m. Discussion

#### 10:45 a.m. – 12:15 p.m. Biomarker Based Clinical Trials in Drug Development Salon I

Chair: Madhukar Trivedi, UT Southwestern Medical Center Discussant: William Potter, National Institute of Mental Health

- 10:45 a.m. 10:55 a.m. Introduction
- 10:55 a.m. 11:15 a.m. Towards Imaging Biomarkers for Treatment Selection in Major Depressive Disorder Helen Mayberg, Emory University School of Medicine

## Tuesday, May 31, 2016

10:45 a.m. – 12:15 p.m. **Biomarker Based Clinical Trials in Drug** (continued) **Development** Salon I 11:15 a.m. – 11:35 a.m. Rationale for the Design of the NIMH FAST-MAS **Biomarker-based Clinical Trial** Andrew Krystal, Duke Clinical Research Institute and Department of Psychiatry and Behavioral Sciences Duke University School of Medicine 11:35 a.m. - 11:55 a.m. Interleukin-6 Inhibition as a Potential Treatment Strategy for Depression: A Proof of Concept Study with Sirukumab in Depressed Patients with Suboptimal Response to Antidepressants and Elevated Peripheral Inflammatory Markers Giacomo Salvadore, Janssen Pharmaceuticals 11:55 a.m. – 12:15 p.m. Discussion 12:15 p.m. – 2:00 p.m. Lunch - On Own 2:00 p.m. – 4:00 p.m. **Pharmaceutical Pipeline Presentations** Princess Ballroom A-E

SCP

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

2:00 p.m. – 2:15 p.m.	Centanafadine Sr (CTN-SR) Demonstrates Brain Occupancy at Norepinephrine Transporter (NET), Serotonin Transporter (SERT) and Dopamine Transporter (DAT) Using Single Photon Emission Tomography (SPECT) in Healthy Volunteers (HVs) Anthony McKinney, Bio-Pharma
2:15 p.m. – 2:30 p.m.	Dasotraline: A Novel Drug Candidate Being Evaluated for the Treatment of Attention-Deficit/ Hyperactivity Disorder and Binge Eating Disorder Robert Goldman, Sunovion

# ASCP Tuesday, May 31, 2016

2:00 p.m. – 4:00 p.m. (continued)	Pharmaceutical Pipeline Presentations Princess Ballroom A-E
2:30 p.m. – 2:45 p.m.	A Phase 1 Single- and Multiple-rising Dose Study of the Safety & Pk of EMB-001, a Potential Treatment for Substance Use Disorders, with Exploratory Efficacy Measures in Tobacco Use Disorder Michael Detke, Indiana University School of Medicine
2:45 p.m. – 3:00 p.m.	A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL*) for the Treatment of Military-related PTSD Gregory Sullivan, Tonix Pharmaceuticals, Inc.
3:00 p.m. – 3:15 p.m.	PeRSEVERe: A Study of Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, including Suicidal Ideation, in Subjects Assessed to be at Imminent Risk for Suicide Carla Canuso, Janssen Research & Development
3:15 p.m. – 3:30 p.m.	SRX246: A First-in-class Vasopressin 1a Receptor Antagonist in Phase Ii Trials for Mood and Behavioral Disorders Michael Brownstein, Azevan Pharmaceuticals, Inc.
3:30 p.m. – 3:45 p.m.	Drug Development Strategies for Schizophrenia Using a Novel PDE10A Inhibitor: TAK-063 Tom Macek, Takeda Development Center - Americas
3:45 p.m. – 4:00 p.m.	Phase 2 Study of Bremelanotide in Premenopausal Women with Female Sexual Dysfunctions: Responder Analyses based on Minimum Clinically Important Differences Derived from Receiver Operating Characteristic Curves Stanley Althof, Case Western Reserve University School of Medicine

## Tuesday, May 31, 2016 ASCP

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

### **Individual Research Reports**

4:15 p.m. – 5:30 p.m.	Substance Use Disorders, Treatments for Alzheimer's Disease, and Speeding Drug
	Discovery
	Salon F

Chair: Timothy Mariano, Brigham and Women's Faulkner Hospital

R	4:15 p.m. – 4:30 p.m.	Pharmacogenetics of Dopamine Beta Hydroxylase in Cocaine Dependence Therapy with Doxazosin Xuefeng Zhang, Baylor College of Medicine
2	4:30 p.m. – 4:45 p.m.	Ghrelin as a Novel Possible Target to Treat Alcohol Craving and Role of Endogenous Hormones Serum Levels as a Biomarker Carolina Haass-Koffler, Brown University
	4:45 p.m. – 5:00 p.m.	Impact of Concomitant Antidepressant Use on Drinking and Mood Outcomes in Bipolar Alcoholics: Results from a Randomized Controlled Trial of Lamotrigine Bryan Tolliver, Medical University of South Carolina
	5:00 p.m. – 5:15 p.m.	The Coding and Noncoding Transcriptional Landscape of Neurons and Glia in Vivo Adarsh Reddy, Trinitas Regional Medical Center
	5:15 p.m. – 5:30 p.m.	Effect of Renal and Hepatic Impairment on the Pharmacokinetics of Encenicline Gordon Loewen, FORUM Pharmaceuticals

Second Se

## ASCP Tuesday, May 31, 2016

4:15 p.m. – 5:30 p.m.	Improving Assessment and Clinical Trial
	Methodology
	Salon G

Chair: Ahmad Hameed, Penn State College of Medicine

4:15 p.m. – 4:30 p.m.	How Do Key Co-primary Measures of Functional Capacity Predict Real World Function in Schizophrenia? Richard Keefe, Duke University Medical Center
4:30 p.m. – 4:45 p.m.	<b>Do Suicidality Phenomena Follow a Linear or a</b> <b>Non-linear Progression over Time?</b> David V. Sheehan, University of South Florida College of Medicine
4:45 p.m. – 5:00 p.m.	Is it Possible to Reduce Biases and Inaccuracies in Large Scale Clinical Trials? Mark Opler, ProPhase, LLC
5:00 p.m. – 5:15 p.m.	Nine Problems in the Descriptions of the Psychiatric Inclusion and Exclusion Criteria in Publications of Antidepressant Efficacy Trials Mark Zimmerman, Brown University
5:15 p.m. – 5:30 p.m.	Validation of the Tablet-based Brief Assessment of Cognition (BAC App) for Schizophrenia Brian Saxby, NeuroCog Trials
4:15 p.m. – 5:30 p.m.	Mood Disorders: Targets, Approaches, and Outcomes Salon H

Chair: Crystal Clark, Northwestern University

4:15 p.m. – 4:30 p.m. MoodNetwork: An Innovative Approach to Patient-centered Care Andrew Nierenberg, Massachusetts General Hospital

## Tuesday, May 31, 2016

4:15 p.m. – 5:30 p.m. Mood Disorders: Targets, Approaches, and (continued) Outcomes Salon H 😤 4:30 p.m. – 4:45 p.m. A Genome Wide Association Study Implicates Gabaergic Neurotransmission in Early Onset **Bipolar Disorder** Malik Nassan, Mayo Clinic 🛱 4:45 p.m. – 5:00 p.m. Early and Sustained Work Productivity Improvement Predicts Subsequent Clinical Course in Major Depressive Disorder Manish Jha, UT Southwestern 😤 5:00 p.m. – 5:15 p.m. Adherence and Persistence across Antidepressant Therapeutic Classes: A **Retrospective Claims Analysis among Insured** US Patients with Major Depressive Disorder Katelyn Keyloun, University of Washington Vilazodone Inhibiting Pro-inflammatory Gene 5:15 p.m. – 5:30 p.m. Expression and Immunologic Activation Compared to Paroxetine in Geriatric Depression Helen Lavretsky, David Geffen School of Medicine at UCLA 4:15 p.m. – 5:30 p.m. Advances in Schizophrenia\* Salon I

**Chair:** Mohammed Ahmed, University of California, San Diego and Veterans Medical Center, San Diego

4:15 p.m. – 4:30 p.m. Prevalence, Risk Factors and Outcome of Metabolic Syndrome in Veterans with Serious Mental Illness Stanley Caroff, Perelman School of Medicine University of Pennsylvania

## ASCP Tuesday, May 31, 2016

4:15 p.m. – 5:30 p.m. (continued)	Advances in Schizophrenia* Salon I
4:30 p.m. – 4:45 p.m.	Relative Efficacy and Safety of Individual Second-generation Antipsychotics in Treating First Episode Psychosis: A Systematic Review and Meta-analysis Jianping Zhang, The Zucker Hillside Hospital
4:45 p.m. – 5:00 p.m.	Worldwide Clozapine Therapeutic Drug Monitoring (TDM) from Capillary Blood, using the Dried Blood Spot (DBS) Technique: A Major Step Forward in Adequate Dosing and Treatment of Therapy-resistant Schizophrenia Dan Cohen, Mental Health Organization North- Holland North
5:00 p.m. – 5:15 p.m.	Successfully Overcoming Clozapine Under prescription: The Dutch Approach as an Evidence-based Model for Scaling-up Innovation and Good Practice Abroad Dan Cohen, Mental Health Organization North- Holland North
5:15 p.m. – 5:30 p.m.	Threshold of Dopamine D2/3 Receptor Occupancy for Hyperprolactinemia in Older Patients with Schizophrenia Yusuke Iwata, CAMH Toronto
6:15 p.m. – 7:45 p.m.	New Investigator Awards Ceremony

Arabian A/B

Wednesday, June 1, 2016 ASCP

### AT-A-GLANCE

### Wednesday, June 1, 2016

6:30 a.m. – 8:00 a.m.	17th Annual ASCP Fun Run/Walk Open to ALL Attendees! Palomino Conference Center North Drive
7:30 a.m. – 6:45 p.m.	<b>Registration</b> Princess East Foyer
7:30 a.m. – 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Castile 1
7:30 a.m. – 6:30 p.m.	<b>Speaker Ready Room</b> Bourbon 11
8:30 a.m. – 10:00 a.m.	<b>Regulatory Plenary with FDA: Evolving Views on Pseudospecificity and Comparing Drug and Device Regulatory Pathways</b> Princess Ballroom A-E
10:00 a.m. – 10:15 a.m.	<b>Break</b> Princess East Foyer
10:15 a.m. – 11:15 a.m.	ASCP Best Paper in Journal of Clinical Psychopharmacology Award Presentation and ASCP Lifetime Awardee Talk - Evidence in Clinical Psychiatry: 60 Years in Psychiatric Practice and Research Princess Ballroom A-E
11:15 a.m. – 1:00 p.m.	<b>Poster Session I with Lunch</b> Palomino 1 - 7

## ASCP | Wednesday, June 1, 2016

1:00 p.m. – 2:30 p.m. Pa

Panel Sessions

Drinking Change, Consequences, and Biomarkers in Alcohol Clinical Trials: Results from the Alcohol Clinical Trials Initiative (ACTIVE)	Novel Approaches to Treatment- Resistant Depression (TRD)*	Revisiting Experimental and Clinical Therapeutics of Cannabidiol	Lithium: The Old New Wonder Drug*
Salon F	Salon G	Salon H	Salon I

2:45 p.m. – 3:15 p.m.

ASCP Business Meeting (Members Only) Salon I

3:15 p.m. – 3:30 p.m.

Break Princess East Foyer

3:30 p.m. – 5:30 p.m. Workshops

An Integrated Technology Approach for Preventing Relapse in Recently Hospitalized Schizophrenia Patients	Managing the Unique Challenges Associated with Rapid Acting Antidepressant Trials	The Hidden Truth in Psychiatric Trials - Medication Adherence is Highly Variable - Problems, Implications, and Solutions	Is Suicidal Ideation a Symptom or a Syndrome?
Salon F	Salon G	Salon H	Salon I

5:45 p.m. – 6:15 p.m. First Timer Reception Moor 2

6:15 p.m. – 7:15 p.m. ASCP Reception Princess Ballroom A-E

\*of special interest to clinicians

Wednesday, June 1, 2016 ASCP

### FULL SCHEDULE

Wednesday, June 1, 2016

6:30 a.m. – 8:00 a.m.	17th Annual ASCP Fun Run/Walk - Open to ALL Attendees! All participants receive a FREE ASCP T-shirt!
7:30 a.m. – 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Castile 1
7:30 a.m. – 9:00 a.m.	Morning Break Princess East Foyer
8:30 a.m. – 10:00 a.m.	Regulatory Plenary with FDA: Evolving Views on Pseudospecificity and Comparing Drug and Device Regulatory Pathways

Chair & Discussant: Mark H. Rapaport, Emory University School of Medicine

This year's plenary session will focus on two topics:

- The Division of Psychiatry Products' evolving stance on pseudospecificity. Historically, the Division has viewed a number of potential labeling claims (e.g., cognitive dysfunction associated with major depressive disorder) to be artificially narrow and, thus, pseudospecific. DPP is now more willing to consider indications that were previously deemed pseudospecific. Dr. Farchione will discuss the Division's current views, as well as trial design considerations for any development programs designed to evaluate an indication that was once considered pseudospecific.
- 2) A comparison of the regulatory review process for drugs and devices. Representatives from both the Division of Psychiatry Products in the Center for Drug Evaluation and Research (Dr. Farchione) and the Division of Neurological and Physical Medicine Devices in the Center for Devices and Radiological Health (Dr. Heetderks) will compare and contrast the regulatory requirements and review processes in the two Centers as they related to the treatment of psychiatric illnesses.

8:30 a.m. – 8:40 a.m.	Introduction
8:40 a.m. – 9:05 a.m.	The Division of Psychiatry Products' Evolving Stance on Pseudospecificity Tiffany Farchione, US Food and Drug Administration
9:05 a.m. – 9:30 a.m.	A Comparison of the Regulatory Review Process for Drugs and Devices William Heetderks, CDRH, FDA
9:30 a.m. – 10:00 a.m.	Discussion and Q&A

## ASCP | Wednesday, June 1, 2016

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

10:15 a.m. – 11:15 a.m. ASCP Best Paper in Journal of Clinical Psychopharmacology Award Presentation and ASCP Lifetime Awardee Talk - Evidence in Clinical Psychiatry: 60 Years in Psychiatric Practice and Research Princess Ballroom A-E

**Best Paper Award Presentation to:** Lee Baer, Massachusetts General Hospital

Nominated for: Prevalence and Impact of Obsessive-Compulsive Symptoms in Depression: A STAR\*D Report

**Lifetime Awardee:** John Davis, UIC Psychiatric Institute, University of II at Chicago, Chicago, IL

When I wrote my first scientific papers 60 years ago, academic psychiatry was entirely psychoanalytic. Don Klein and I participated in the development of modern psychopharmacology, writing Diagnosis and the Drug treatment of Mental Disorders, which was both research and clinically based. Over the last 40 years, the clinical side has atrophied, and research is less clinically relevant. I will place modern research in historical prospective, with a focus interpretation of research to make it more clinically relevant. I will start with the application of pharmacology to understand mechanisms of how drugs produce improvement, the biologically-based theories of mental illness, and the clinical pharmacology of psychotropic drugs (such as drug metabolism or drug-drug interactions), updating this with current work in molecular biology. I performed, in 1975 the first meta-analysis in psychiatry; the second in general medicine, showing maintenance treatment prevents relapse, update this with recants network meta-analyses. I will summarize clinical evidence, provide prospective, but the focus is on how to apply clinical studies to individual patients, to tell sense from nonsense, and to the balance of benefit to risk. I will present the efficacy of psychotropic drugs in the perspective of drug used in internal medicine.

11:15 a.m. – 1:00 p.m. Poster Session I with Lunch Palomino 1 - 7 See pages 73 - 82 for a complete listing of posters

## Wednesday, June 1, 2016 | ASCP

### Panel Sessions

1:00 p.m. – 2:30 p.m.	Drinking Change, Consequences, and
	<b>Biomarkers in Alcohol Clinical Trials: Results</b>
	from the Alcohol Clinical Trials Initiative (ACTIVE)
	Salon F

**Chair:** Raymond Anton, Medical University of South Carolina **Discussant:** Raye Litten, NIAAA

1:00 p.m. – 1:10 p.m.	Introduction
1:10 p.m. – 1:25 p.m.	<b>FDA Guidance on Developing Drugs for the</b> <b>Treatment of Alcoholism</b> Rachel Skeete, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, US Food and Drug Administration
1:25 p.m. – 1:40 p.m.	The Relationship of who Drinking Risk Categories to Alcohol Consequences: Consistency in Population Studies and Clinical Trials Katie Witkeiwitz, University of New Mexico
1:40 p.m. – 1:55 p.m.	Novel Efficacy Endpoints Based on Shifts in the World Health Organization (WHO) Risk Levels of Drinking: Treatment Effects in Alcohol Pharmacotherapy Trials Daniel Falk, NIAAA/NIH
1:55 p.m. – 2:10 p.m.	<b>Use of Alcohol Consumption Biomarkers in</b> <b>Clinical Trials</b> Raymond Anton, Medical University of South Carolina
2:10 p.m. – 2:30 p.m.	Discussion

## ASCP | Wednesday, June 1, 2016

### 1:00 p.m. – 2:30 p.m. Novel Approaches to Treatment-Resistant Depression (TRD)\* Salon G

**Chair:** Maurizio Fava, Massachusetts General Hospital **Co-Chair:** George Papakostas, Massachusetts General Hospital **Discussant:** Carlos Zarate, National Institute of Mental Health

1:00 p.m. – 1:10 p.m.	Introduction
1:10 p.m. – 1:25 p.m.	NIMH Approach to Fostering New Rapidly Acting Therapies for TRD Mi Hillefors, National Institute of Mental Health
1:25 p.m. – 1:40 p.m.	<b>Low-field Magnetic Stimulation in TRD: The Rapid Study in TRD</b> Maurizio Fava, Massachusetts General Hospital
1:40 p.m. – 1:55 p.m.	The Use of Alternative and Complementary Therapies in TRD Mark H. Rapaport, Emory University School of Medicine
1:55 p.m. – 2:10 p.m.	Novel Non-monoamine-based Drug Therapies for TRD George Papakostas, Massachusetts General Hospital
2:10 p.m. – 2:30 p.m.	Discussion
1:00 p.m. – 2:30 p.m.	Revisiting Experimental and Clinical Therapeutics of Cannabidiol Salon H

**Chair:** Antonio Teixeira, University of Texas Health Science Center at Houston **Discussant:** Antonio de Oliveira, Federal University of Minas Gerais

1:00 p.m. – 1:10 p.m.	Introduction
1:10 p.m. – 1:30 p.m.	Potential Role of Cannabidiol in Neurodegenerative Diseases Antonio Teixeira, University of Texas Health Science Center at Houston

\*of special interest to clinicians

Wednesday, June 1, 2016 ASCP

1:00 p.m. – 2:30 p.m. (continued)	Revisiting Experimental and Clinical Therapeutics of Cannabidiol Salon H
1:30 p.m. – 1:50 p.m.	Potential Role of Cannabidiol (CBD) on the Mood Disorders Therapeutics João Luciano de Quevedo, The University of Texas Health Science Center at Houston
1:50 p.m. – 2:10 p.m.	Cannabidiol and Endocannabinoids as Potential Approaches against Cocaine Neurotoxicity Fabricio Moreira, Federal University of Minas Gerais
2:10 p.m. – 2:30 p.m.	Discussion
1:00 p.m. – 2:30 p.m.	Lithium: The Old New Wonder Drug* Salon I

**Chair:** James Kocsis, New York Presbyterian Hospital **Discussant:** Andrew Nierenberg, Massachusetts General Hospital

1:00 p.m. – 1:10 p.m.	Introduction
1:10 p.m. – 1:25 p.m.	Why, When and How Do I Prescribe Lithium Today? James Kocsis, New York Presbyterian Hospital
1:25 p.m. – 1:40 p.m.	Can Lithium Extend the Antidepressant Effects of Ketamine? A Randomized Controlled Trial James Murrough, Icahn School of Medicine at Mount Sinai
1:40 p.m. – 1:55 p.m.	Results of Recent Pragmatic Studies of Lithium in Bipolar Disorder Michael E. Thase, Perelman School of Medicine at the University of Pennsylvania
1:55 p.m. – 2:10 p.m.	Neuronal Hyperexcitability in a Stem Cell Model of Bipolar Disorder is Reversed by Lithium John Kelsoe, University of California - San Diego
2:10 p.m. – 2:30 p.m.	Discussion

#### \*of special interest to clinicians

## ASCP | Wednesday, June 1, 2016

2:45 p.m. – 3:15 p.m.	ASCP Business Meeting (Members Only) Salon I	
3:15 p.m. – 3:30 p.m.	Break Princess East Foyer	
<u>Workshops</u>		
3:30 p.m. – 5:30 p.m.	An Integrated Technology Approach for Preventing Relapse in Recently Hospitalized Schizophrenia Patients Salon F	
Chair: John Kane, The Zucker Hillside Hospital Co-Chair: Nina R. Schooler, SUNY Downstate Medical Center Discussant: Donald Goff, NYU Langone Medical Center/Nathan Kline Institute		
3:30 p.m. – 3:40 p.m.	Introduction	
3:40 p.m. – 4:00 p.m.	Improving Care and Reducing Costs: Background and Rational John Kane, The Zucker Hillside Hospital	
4:00 p.m. – 4:20 p.m.	<b>Components of the Health Technology Program</b> Delbert Robinson, Hofstra NS-LIJ School of Medicine	
4:20 p.m. – 4:40 p.m.	Baseline Characteristics and Initial Usage Data for Recently Hospitalized Schizophrenia Patients using an Integrated Technology Approach to Prevent Relapse vs Controls Receiving Usual Care	

Eric Achtyes, Michigan State University College of Human Medicine

4:40 p.m. – 5:00 p.m. Patient Experience of Technology Enhanced Treatment: What they liked; Barriers to Use and skills they Acquired Nina R. Schooler, SUNY Downstate Medical Center

5:00 p.m. – 5:30 p.m. **Discussion** 

Wednesday, June 1, 2016 ASCP

3:30 p.m. – 5:30 p.m.	Managing the Unique Challenges Associated with Rapid Acting Antidepressant Trials Salon G
Chair: Gerard Sanacora, Co-Chair: Sanjay Mathew Discussant: Sarah Lisant	v, Baylor College of Medicine
3:30 p.m. – 3:45 p.m.	Introduction
3:45 p.m. – 4:00 p.m.	Challenges of Measuring Rapid Changes in Suicidality: Implications for Clinical Trials James Murrough, Icahn School of Medicine at Mount Sinai
4:00 p.m. – 4:15 p.m.	Integrating Human Biomarkers in Trials Involving Interventions with Rapid Antidepressant and Antisuicidal Effects Carlos A. Zarate, National Institute of Mental Health
4:15 p.m. – 4:30 p.m.	Assessment of Rapid Improvement of Depression: Challenges Across the Age Spectrum Jaskaran Singh, Neuroscience TA, Janssen R & D, LLC., Janssen Pharmaceutical Companies of JNJ
4:30 p.m. – 4:45 p.m.	<b>Study Design Challenges in Developing Rapid</b> <b>Onset Antidepressants</b> Suresh Durgam, Forest Research Institute, A Subsidiary of Actavis, plc
4:45 p.m. – 5:00 p.m.	Managing Placebo Response and Patient Expectations in Clinical Trials Ronald Marcus, Cerecor
5:00 p.m. – 5:30 p.m.	Discussion

## ASCP | Wednesday, June 1, 2016

3:30 p.m. – 5:30 p.m.	The Hidden Truth in Psychiatric Trials -
	Medication Adherence is Highly Variable -
	Problems, Implications, and Solutions
	Salon H

Chair: Daniel Burch, PPD Co-Chair: Atul Mahableshwarkar, Takeda Global Research & Development

3:30 p.m. – 3:40 p.m. Introduction 3:40 p.m. – 3:55 p.m. Evidence and Impact of Non-adherence Daniel Burch, PPD 3:55 p.m. – 4:15 p.m. Methodological Approaches to Enhancing Medication Adherence in CNS Clinical Trials Maurizio Fava, Massachusetts General Hospital 4:15 p.m. – 4:30 p.m. Brief Overview of Technical Solutions Atul Mahableshwarkar, Takeda Global Research & Development 4:30 p.m. – 4:40 p.m. **Regulatory View** Tiffany Farchione, FDA Discussion 4:40 p.m. – 5:30 p.m. 3:30 p.m. – 5:30 p.m. Is Suicidal Ideation a Symptom or a Syndrome? Salon I

Chair: Steven Targum, Bracket Global

- 3:30 p.m. 3:40 p.m. Introduction
- 3:40 p.m. 4:10 p.m. Suicidal Ideation: One Piece of a Larger Puzzle Jill Harkavy-Friedman, American Foundation for Suicide Prevention
- 4:10 p.m. 4:40 p.m. **There are Several Suicidality Disorders** David V. Sheehan, University of South Florida College of Medicine

## Wednesday, June 1, 2016 | ASCP

3:30 p.m. – 5:30 p.m. (continued)	Is Suicidal Ideation a Symptom or a Syndrome? Salon I
4:40 p.m. – 5:10 p.m.	Characterization of Suicide Ideation in Depressed Patients Identified to be at Risk for Suicide and Ketamine Treatment Response Larry Alphs, Janssen
5:10 p.m. – 5:30 p.m.	Discussion
5:45 p.m. – 6:15 p.m.	First Timer Reception <i>Moor 2</i>
6:15 p.m. – 7:15 p.m.	ASCP Reception Princess Ballroom A-E



### Notes



### AT-A-GLANCE

#### Thursday, June 2, 2016

Salon F

7:00 a.m. – 8:30 a.m.	ASCP Steering Committee Meeting (Invitation Only) Moor 1	
7:30 a.m. – 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Castile 1	
7:30 a.m. – 6:00 p.m.	Registration Princess East Foyer	
7:30 a.m. – 6:30 p.m.	<b>Speaker Ready Room</b> Bourbon 11	
8:15 a.m. – 9:45 a.m.	Keynote: Beyond Single Magic Bullets: True Innovation in Neuropsychiatric Conditions Princess Ballroom A-E	
9:45 a.m. – 10:00 a.m.	<b>Break</b> Princess East Foyer	
10:00 a.m. – 12:00 p.m.	NIH Institute Directors Plenary Princess Ballroom A-E	
12:00 p.m. – 2:00 p.m.	Poster Session II with Lunch Palomino 1-7	
2:00 p.m. – 3:30 p.m.	Psychopharmacology State-of-the-Art Updates Princess Ballroom A-E	
3:30 p.m. – 3:45 p.m.	<b>Break</b> Princess East Foyer	
3:45 p.m. – 5:45 p.m.	Workshops	
Implementation of Universal Depression Screening and Measurement Based Care in Busy Clinical Practices: Lessons Learned from Project VitalSign6		Medical Marijuana: Promise and Peril*

3:45 p.m. – 5:45 p.m. Special Session: How to Use the Model Psychopharmacology Curriculum in Various Teachings Salon G

Salon H



### Notes


ASCP

### FULL SCHEDULE

Thursday, June 2, 2016

7:00 a.m. – 8:30 a.m.	ASCP Steering Committee Meeting (Invitation Only) <i>Moor 1</i>
7:30 a.m. – 8:30 a.m.	NIA Breakfast Roundtable (Invitation Only) Castile 1
7:30 a.m. – 9:00 a.m.	Morning Break Princess East Foyer
8:15 a.m. – 9:45 a.m.	Keynote Session: Beyond Single Magic Bullets: True Innovation in Neuropsychiatric Conditions Princess Ballroom A-E

Chair: Husseini Manji, M.D., Johnson & Johnson

Worldwide, neuropsychiatric diseases are some of the most debilitating and disabling medical conditions. In addition, because of demographic trends and the lack of effective treatments to modify disease course, the economic and societal burden of these disorders are projected to increase in the coming years. These diseases are caused by dysregulations that span genetic, epigenetic, proteomic, and brain circuitry (connectomics) networks, and they affect complex phenotypes, including memory, cognition, emotion, function, and behavior. Effectively addressing such complex, multi-scale, multi-level disorders will necessarily require multi-pronged interventions that go 'beyond the pill' and use newly-developed advances in mobile computing, devices, and computer-based therapies to intercept these diseases in their earliest stages, when they still modifiable, and before irreversible damage has occurred.

Psychiatric diseases are chronic diseases of the young, in that they often take hold in late adolescence/early adulthood and have a subsequent dynamic course characterized by relapses and recurrences of increasing frequency. Each episode of illness inflicts considerable trauma to patients and caregivers, as well as considerable cost to the healthcare system. For example, patients with schizophrenia and a recent history of relapse generate direct medical costs that are three- to five-fold higher than other medical disorders; relapses are also disproportionately associated with negative outcomes such as higher prevalence of substance use disorders and worsening functional status. Furthermore, recent neuroimaging studies have revealed that relapses and

### 8:15 a.m. – 9:45 a.m. (continued)

ASCP

Keynote Session: Beyond Single Magic Bullets: True Innovation in Neuropsychiatric Conditions Princess Ballroom A-E

recurrences are not just symptomatic exacerbations of the illness, but actually may cause irreversible atrophic changes in the brain that represent progression of underlying neuropathology. As a result, there is a strong imperative to move from reactive treatment of relapses and recurrences to a more proactive regimen of prediction and preemption. Significant technological advances have been made, particularly with regard to methods capable of remotely capturing rich phenotypic information from streamed data drawn from wearable devices over prolonged observation periods. Such advances provide new ways to monitor long-term outcomes and, via real-time analysis of data streams, to remotely detect changes in clinical status. The reliable identification of such changes and biosignatures will fundamentally re-engineer health care systems to provide more precise care and interventions early in the course of relapse/ deterioration, or even before clinical changes are apparent. It should be noted that, while predicting and preempting relapse has immense value, intercepting these diseases in their prodromal stages-prior to conversion to clinical diagnosis – should remain the ultimate goal. This is particularly true of diseases like Alzheimer's disease wherein overt clinical symptoms typically appear almost a decade before the onset of pathology. Interestingly, computer-based cognitive tests have the potential to convert cognition from a subjective and noisy endpoint to a sensitive and quantitative biomarker that will facilitate early detection of Alzheimer's disease and aid the development of sensitive efficacy endpoints for early AD clinical trials. In the future, more sensitive measures of functional decline based on wearable technology and data from smart homes and devices ('internet of things') will help us track disease course and develop customized interventions (cognitive prosthetics) that increase independence and improve quality of life for Alzheimer's patients.

Finally, increasing our understanding of the role that dysfunction in circuit dynamics and synaptic plasticity play as causal drivers of cognitive impairment and psychiatric disorders will lead to increased use of device- and computerbased interventions. Indeed, the most effective therapeutic combinations may well be those that meld pharmacological and non-pharmacological approaches to simultaneously target molecular pathology and brain circuitry.

In this session, the speaker will explore—via specific examples—how novel technologies can be harnessed to develop integrated solutions that will help us move from a 'diagnose and treat' to a 'predict and preempt' paradigm, with the ultimate goal of modifying disease course and improving patient outcomes.



8:15 a.m. – 9:45 a.m. (continued)	Keynote Session: Beyond Single Magic Bullets: True Innovation in Neuropsychiatric Conditions Princess Ballroom A-E
8:15 a.m. – 8:25 a.m.	Introduction
8:25 a.m. – 8:45 a.m.	Data and Informatics Challenges in Moving from a 'Diagnose and Treat' to a 'Predict and Preempt' Paradigm Vaibhav Narayan, Ph.D., Johnson & Johnson
8:45 a.m. – 9:05 a.m.	Improving Brain Health and Trajectories and Outcomes for Neuropsychiatric Disorders using Technologies Barbara Sahakian, Ph.D., D.Sc., FMEDSci, University of Cambridge
9:05 a.m. – 9:25 a.m.	Sensing Behavioral Symptoms of Mental Health and Delivering Personalized Interventions Using Mobile and Wearable Technologies Tanzeem Choudhury, Ph.D., Cornell University / HealthRhythms
9:25 a.m. – 9:45 a.m.	Discussion
9:45 a.m. – 10:00 a.m.	Break Princess East Foyer
10:00 a.m. – 12:00 p.m.	NIH Institute Directors Plenary Princess Ballroom A-E

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

The NIH Institute Directors session will provide updates on NIAAA, NINDS, NCATS, NIDA, CSR, and NIMH.

George Koob, Ph.D., NIAAA Amir Tamiz, Ph.D., NINDS Christopher P. Austin, M.D., NCATS Ivan Montoya, M.D., MPH, NIDA Richard K. Nakamura, Ph.D., CSR Sarah Lisanby, M.D., NIMH

12:00 p.m. – 2:00 p.m.	Poster Session II with Lunch Palomino 1 - 7
	See pages 83 - 91 for a complete listing of posters

2:00 p.m. – 3:30 p.m. Psychopharmacology State-of-the-Art Updates Princess Ballroom A-E

Chair: Holly A. Swartz, University of Pittsburgh School of Medicine

ASC

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. This session will focus on the following topics:

- Terence Ketter will discuss advances in treatments for Bipolar Disorder.
- Barbara Mason will discuss the evidence base for FDA-approved medications to treat alcohol use disorder, including potential differential treatment effects for males and females.
- Mark Rapaport will provide updates on complementary and alternative approaches to treating mood and anxiety disorders.

2:00 p.m. – 2:20 p.m.	Terrence Ketter, M.D., Stanford University School of Medicine
2:20 p.m. – 2:40 p.m.	Barbara Mason, Ph.D., The Scripps Research Institute
2:40 p.m. – 3:00 p.m.	Mark H. Rapaport, M.D., Emory University School of Medicine
3:00 p.m. – 3:30 p.m.	Discussion
0.00	Dual

3:30 p.m. – 3:45 p.m. Break Princess East Foyer

ASCP

### Workshops

	3:45 p.m. – 5:45 p.m.	Implementation of Universal Depression Screening and Measurement Based Care in Busy Clinical Practices: Lessons Learned from Project VitalSign6 Salon F
<ul> <li>Chair: Manish Jha, UT Southwestern Medical Center</li> <li>Co-Chair: Madhukar Trivedi, UT Southwestern Medical Center</li> <li>Discussant: Tracy Greer, University of Texas Southwestern Medical Center a Dallas</li> </ul>		
	3:45 p.m. – 3:55 p.m.	Introduction
	3:55 p.m. – 4:15 p.m.	Making Evidence-based Treatment of Depression Easily Accessible: Forging Collaborations with Primary Care Clinics Madhukar Trivedi, UT Southwestern Medical Center
	4:15 p.m. – 4:35 p.m.	Enhancing Measurement Based Care: Why Does Functional Recovery Matter? Tracy Greer, University of Texas Southwestern Medical Center at Dallas
	4:35 p.m. – 4:55 p.m.	Harnessing Health Information Technology to Implement Measurement Based Care: Demonstration of VitalSign6 Software Manish Jha, UT Southwestern Medical Center
	4:55 p.m. – 5:45 p.m.	Discussion

🖗 = New Investigator Awardee

3:45 p.m. – 5:45 p.m.	Medical Marijuana: Promise and Peril* Salon H	
<b>Chair:</b> Susan Weiss, National Institute of Health/NIDA <b>Co-Chair:</b> Steven Gust, NIH		
3:45 p.m. – 3:55 p.m.	Introduction	
3:55 p.m. – 4:15 p.m.	<b>Medical Marijuana in 2016: What a Clinician Needs to Know</b> Kevin Hill, McLean Hospital	
4:15 p.m. – 4:35 p.m.	<b>The Endocannabinoid System as a Target for</b> <b>Therapeutic Drugs</b> Daniele Piomelli, University of California, Irvine	
4:35 p.m. – 4:55 p.m.	Medical Marijuana for Psychiatric Indications: Is the Cart Before the Horse? Deepak D'Souza, Yale University School of Medicine & VACHS	
4:55 p.m. – 5:15 p.m.	<b>Medical Marijuana in Canada</b> Didier Jutras-Aswad, Centre hospitalier de l'Université de Montréal	
5:15 p.m. – 5:45 p.m.	Discussion	
Special Session		
3:45 p.m. – 5:45 p.m.	How to Use the Model Psychopharmacology Curriculum in Various Teachings Salon G	

Chair: Ira Glick, Stanford University School of Medicine

ASCP

This workshop will focus on how to teach cutting edge clinical psychopharmacology for a) psychiatric residents, b) primary care physicians, and c) medical students in the US and globally. The target audience is program directors, chairs, and teachers of psychopharmacology and psychiatry.

### Friday, June 3, 2016



### AT-A-GLANCE

#### Friday, June 3, 2016

7:30 a.m. – 12:00 p.m.	Registration Princess East Foyer
7:30 a.m. – 12:00 p.m.	Speaker Ready Room Bourbon 11

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

Shared Pharmacological Targets for Substance Use and Other Psychiatric Disorders	Psychotherapy, Pharmacotherapy and Devices to Treat Bipolar II Depression: New Evidence*	Applicability of Industry/ Regulatory Antidepressant Clinical Trials to Clinical Practice	The Intersection of Pharmacology and Neuromodulation in Treatment Refractory Mood Disorders*
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.	<b>Regulatory Wrap-Up Plenary</b> Princess Ballroom A-E

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



### Notes


### Friday, June 3, 2016

ASCP

### **FULL SCHEDULE**

#### Friday, June 3, 2016

7:30 a.m. – 9:00 a.m.	Morning Break East Princess Foyer
7:30 a.m. – 12:00 p.m.	Registration Princess East Foyer
7:30 a.m. – 12:00 p.m.	Speaker Ready Room Bourbon 11

**Panel Sessions** 

8:30 a.m. – 10:00 a.m. Shared Pharmacological Targets for Substance Use and Other Psychiatric Disorders Salon F

Chair & Discussant: Ivan Montoya, DHHS/National Institute on Drug Abuse

8:30 a.m. – 8:40 a.m.	Introduction
8:40 a.m. – 9:00 a.m.	Pimavanserin: A New Treatment for Parkinson's Psychosis that may have Efficacy as a Treatment for Cocaine Use Disorders Jane Acri, NIDA/NIH/DTMC
9:00 a.m. – 9:20 a.m.	<b>Testing the Efficacy and Safety of a FAAH- Inhibitor in the Treatment of Cannabis Dependence</b> Deepak D'Souza, Yale University School of Medicine & VACHS
9:20 a.m. – 9:40 a.m.	Characterization of Agonist-Antagonist Opioid Modulation with ALKS 5461 in Major Depression Elliot Ehrich, Alkermes, plc
9:40 a.m. – 10:00 a.m.	Discussion

## Friday, June 3, 2016

## 8:30 a.m. – 10:00 a.m. Psychotherapy, Pharmacotherapy and Devices to Treat Bipolar II Depression: New Evidence\* Salon G

**Chair:** Holly A. Swartz, University of Pittsburgh School of Medicine **Discussant:** Michael E. Thase, Perelman School of Medicine at the University of Pennsylvania

- 8:30 a.m. 8:40 a.m. Introduction
- 8:40 a.m. 9:00 a.m. A Recent Treatment Study Addressing if Bipolar II Response to Treatment Really is the Same as Bipolar I Disorder Trisha Suppes, Stanford University
- 9:00 a.m. 9:20 a.m. Interpersonal and Social Rhythm Therapy and Quetiapine as Treatments for Bipolar II Depression Holly A. Swartz, University of Pittsburgh School of Medicine
- 9:20 a.m. 9:40 a.m. Safety and Efficacy of Cranial Electrotherapy Stimulation in Treatment of Bipolar II Depression Igor Galynker, Icahn School of Medicine at Mount Sinai
- 9:40 a.m. 10:00 a.m. Discussion

8:30 a.m. – 10:00 a.m. Applicability of Industry/Regulatory Antidepressant Clinical Trials to Clinical Practice Salon H

**Chair:** Arifulla Khan, Northwest Clinical Research Center **Discussant:** Walter Brown, Alpert Medical School, Brown University

8:30 a.m. – 8:40 a.m.	Introduction
8:40 a.m. – 9:00 a.m.	Do Depressed Patients in Registration Clinical Trials Reflect the "Real World" Practice?
	Maurizio Fava, Massachusetts General Hospital

## Friday, June 3, 2016

ASCP

8:30 a.m. – 10:00 a.m. (continued)	Applicability of Industry/Regulatory Antidepressant Clinical Trials to Clinical Practice Salon H
9:00 a.m. – 9:20 a.m.	Should the Lack of Generalizability of Antidepressant Efficacy Trials Have Implications for Product Labelling? Mark Zimmerman, Brown University
9:20 a.m. – 9:40 a.m.	Incidence of Suicidal Behavior among Antidepressant Clinical Trial participants: 1991-2013 Arifulla Khan, Northwest Clinical Research Center
9:40 a.m. – 10:00 a.m.	Discussion
8:30 a.m. – 10:00 a.m.	The Intersection of Pharmacology and Neuromodulation in Treatment Refractory Mood Disorders* Salon I

**Chair:** Michael Henry, Massachusetts General Hospital **Discussant:** William Potter, National Institute of Mental Health

8:30 a.m. – 8:40 a.m.	Introduction
8:40 a.m. – 9:00 a.m.	The Use of Ketamine in Treatment-Resistant Depression: From Research to Clinical Cristina Cusin, Massachusetts General Hospital
9:00 a.m. – 9:20 a.m.	The Effects of ECT on the Depressed Brain: A Meta Analysis of Imaging and EEG Studies Michael Henry, Massachusetts General Hospital
9:20 a.m. – 9:40 a.m.	<b>Circuit-level Mechanism of Action of</b> <b>Neuromodulation Therapies</b> Joan Camprodon, Harvard Medical School/ Massachusetts General Hospital
9:40 a.m. – 10:00 a.m.	Discussion

\*of special interest to clinicians

## Friday, June 3, 2016

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

10:15 a.m. – 11:45 a.m. Regulatory Wrap-Up Plenary Princess Ballroom A-E

Chair: Mark H. Rapaport, Emory University School of Medicine

Tiffany Farchione, US Food and Drug Administration

William Heetderks, CDRH, FDA

12:00 p.m.

ASC

Meeting Adjourns



#### Wednesday, June 1, 2016

Poster Session I with Lunch Palomino 1-7 11:15 a.m. - 1:00 p.m.

 HLD200, A Novel Delivery System of Methylphenidate, in Children with Attention-Deficit/Hyperactivity Disorder Flovd Sallee\*, University of Cincinnati

Sharon Wigal, Ann Childress, Mary Ann McDonnell, Scott Kollins, Norberto DeSousa

2. Centanafadine Sr (CTN-SR) Demonstrates Brain Occupancy at Norepinephrine Transporter (NET), Serotonin Transporter (SERT) and Dopamine Transporter (DAT) Using Single Photon Emission Tomography (SPECT) in Healthy Volunteers (HVs) Anthony McKinney\*, Bio-Pharma Danna, Jonnings, Olivier Parret, Gany Wispiewski, Konnoth Marek

Danna Jennings, Olivier Barret, Gary Wisniewski, Kenneth Marek, Catherine O'Brien, Gary Maier, Connie Reininger, Gilles Tamagnan, David Alagille, John Seibyl

★ 3. Dasotraline: A Novel Drug Candidate being Evaluated for the Treatment of Attention-Deficit/Hyperactivity Disorder and Binge Eating Disorder

Robert Goldman\*, Sunovion Nga Tong, Tracy Wetter, Kenneth S. Koblan, Seth C. Hopkins, Antony Loebel

4. A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL\*) for the Treatment of Military-related PTSD

Gregory Sullivan\*, Tonix Pharmaceuticals, Inc. Judith Gendreau, R. Michael Gendreau, Amy Schaberg, Bruce Daugherty, Heather Jividen, Ashild Peters, Perry Peters, Seth Lederman

5. An Open Label Pilot Study of Adjunctive Asenapine for the Treatment of Posttraumatic Stress Disorder

Lori Davis\*, Veterans Affairs Medical Center Patricia Pilkinton, Badari Birur, Seth Norrholm, Felicia Moody

## ASC

#### Posters

6. Lurasidone in the Treatment of Bipolar Depression: Effect of Baseline **Depression Severity on Clinical Outcome** Andrei Pikalov\*, Sunovion Pharmaceuticals, Inc.

Joyce Tsai, Josephine Cucchiaro, Antony Loebel

7. A Retrospective Study of Transcranial Magnetic Stimulation (TMS) in the Treatment of Bipolar Depression

Scott Aaronson\*, Sheppard Pratt Health System Kathy Daddario

8. Discrepancy Between Subjective and Objective Sleep Parameters in Symptomatic and Euthymic Bipolar Disorder Compared to Healthy Controls

Venkatesh Krishnamurthy\*, Penn State Milton S. Hershey Medical Center Dahlia Mukherjee, Aubrey Reider, Julio Fernandez-Mendoza, Gagan Singh, Scott Seamen, Erika Saunders

9. Treating Pediatric Anxiety: The use of SSRIs and other Prescription Medications

Greta Bushnell\*, University of North Carolina at Chapel Hill Stacie Dusetzina, Scott Compton, Bradley Gaynes, Alan Brookhart, Til Stürmer

10. Virgil Investigative Study Platform: Improving Signal Detection in **Psychiatry Clinical Trials** 

Janet Williams\*, MedAvante Selam Negash, Briana Webber-Lind, Lisa Stein, Christopher Randolph

11. Access to Information on Schizophrenia Patients' Medication Adherence Can Change Prescriber's Treatment Practices Felicia Forma\*, Otsuka Pharmaceutical Development & Commercialization, Inc.

Jason Shafrin, Suepattra May, Anshu Shrestha, Charles Ruetsch, Nicole Gerlanc, Ainslie Hatch, Darius Lakdawalla, Jean-Pierre Lindenmayer

12. The eCOA and Paper Revised Negative Symptom Assessment-16 (NSA-16) Instruction Manual and Semi-structured Interview– Version 3.0

David Daniel\*, Bracket Global, LLC Larry Alphs, Dawn Velligan



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13. A Retrospective Analysis of the Effects of Subject Characteristics on Completion Rates in Phase 1 Studies in Subjects with Stable Schizophrenia

David Krefetz\*, PRA Health Sciences Juliet Brown

14. Reduced Inhibitory Control Mediates the Relationship Between Cortical Thickness in the Right Superior Frontal Gyrus and Body Mass Index

Luca Lavagnino\*, McGovern Medical School at the University of Texas Health Science Center at Houston

Benson Mwangi, Isabelle Bauer, Bo Cao, Sudhakar Selvaraj, Alan Prossin, Jair C. Soares

15. Attention-Deficit/Hyperactivity Disorder and Depression: Sequential and Concurrent Disorders

Tia Sternat\*, START Clinic for Mood & Anxiety Disorders Munira Mohamed, Melissa Furtado, Alex Canzonieri, Sara Armata, Catherine Cameron, Irvin Epstein, Martin Katzman

16. Improving Alzheimer's Disease Data Quality Through Video Monitoring

Theresa Shackleford\*, ePharmasolutions

#### **17. OPEN BOARD**

18. Categorical Improvements in Disease Severity in MDD Patients Treated with Vilazodone: Post Hoc Analysis of 4 Randomized, Placebo-controlled Trials

Suresh Durgam\*, Forest Research Institute, A Subsidiary of Actavis, plc Changzheng Chen, John Edwards, Carl Gommoll, Leslie Citrome

19. Adjunctive Brexpiprazole (OPC-34712) in Patients with MDD and Anxiety Symptoms: Results from Post-hoc Analyses of Two Pivotal Studies

Ruth A. Duffy\*, Otsuka Pharmaceutical Development and Commercialization, Inc. Dusan Kostic, Emmanuelle Weiller, Peter Zhang, Anna Eramo, Ross Baker, Catherine Weiss

#### 20. OPEN BOARD

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### Posters

21. A Post Hoc Subgroup Analysis of the Impact of Vortioxetine on Functional Capacity, as Measured by UPSA, in MDD Patients with **Subjective Cognitive Dysfunction** 

Richard Keefe\*, Duke University Medical Center William Jacobson, George Nomikos, Elizabeth Merikle, Wei Zhong, Christina Kurre Olsen, Michael Cronguist Christensen

- **\*** 22. PeRSEVERe: A Study of Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, including Suicidal Ideation, in Subjects Assessed to be at Imminent Risk for Suicide Carla Canuso\*, Janssen Research & Development Jaskaran Singh, Maggie Fedgchin, Larry Alphs, Rosanne Lane, Christine Pinter, Husseini Manji, Wayne C. Drevets
  - 23. Moderating Factors Affect Signal Detection with MSI-195 vs. Placebo in a Major Depressive Disorder Augmentation Trial Beth Cameron\*, MSI Methylation Sciences, Inc. Steven Targum, Maurizio Fava, David MacDonald, Ludvina Ferreira
  - 24. Lurasidone for Major Depressive Disorder with Mixed Features: Effect of Concurrent Anxiety Severity Marlene Freeman\*, Massachusetts General Hospital Joyce Tsai, Yongcai Mao, Daisy Ng-Mak, Andrei Pikalov, Antony Loebel
  - 25. Effect of Adjunctive Brexpiprazole and Adjunctive Aripiprazole on Weight: An Analysis of Long-term Trials in Major Depressive Disorder Emmanuelle Weiller\*, H. Lundbeck A/S Ruth A. Duffy, Keva K. Gwin, Ross Baker, Catherine Weiss
  - 26. Validation and Determination of Minimal Clinically Important Differences and Treatment Response for the UCSD Performancebased Skills Assessment (UPSA) in Major Depressive Disorder Philip Harvey\*, Miller School of Medicine, University of Miami William Jacobson, Wei Zhong, George Nomikos, Christina Kurre Olsen, Michael Cronquist Christensen, Elizabeth Merikle
  - 27. Symptomatic and Functional Remission as a Therapeutic Objective in Major Depressive Disorder: Vortioxetine Comparative Data in Working Population

George I. Papakostas\*, Massachusetts General Hospital Rebecca Nielsen, Melanie Brignone, Brigitte Tonnoir



😤 = New Investigator Awardee 🛛 🗱 = Pharmaceutical Pipeline Presentation



28. A Population Dose-response Analysis of Lurasidone in the Treatment of Major Depressive Disorder with Mixed Features

Yu-Yuan Chiu\*, Sunovion Pharmaceuticals, Inc. Jongtae Lee, Sunny Chapel, Felix Agbo, Antony Loebel

- 29. Vilazodone Efficacy in Subgroups of Patients with MDD: Post Hoc Analysis of 4 Randomized, Double-blind, Placebo-controlled Trials Rocsanna Namdar\*, Allergan Susan Kornstein, Suresh Durgam, Changzheng Chen, Carl Gommoll, John Edwards
- **30. Efficacy of Vortioxetine on Cognitive Functioning in Working Subjects** with Major Depressive Disorder

Michael Cronquist Christensen\*, H. Lundbeck A/S Roger S. McIntyre, Ioana Florea, Brigitte Tonnoir, Henrik Loft, Raymond Lam

31. Measurement of Adherence to Antidepressants and Outcomes Among Patients with Both Major Depressive Disorder and Type 2 Diabetes

Charles Vega\*, University of California, Irvine, College of Medicine Russell Becker, Lisa Mucha, Betty Lorenz, Michael Eaddy, Augustina Ogbonnaya

32. The DSM-5 Anxious Distress Specifier Interview: Reliability and Validity

Mark Zimmerman\*, Brown University Emily Walsh, Lia Rosenstein, Douglas Gazarian, Heather Clark

33. Ethics of Medical Marijuana: Medicalization of Treatment with Paucity of Proof

Kimberly Kjome\*, Ascension, UT-Dell Medical School, Texas A&M Medical School, UT-Southwestern Medical School, UTMB-Galveston Medical School Leigh Brown

#### 34. A Classification of Suicidality Disorder Phenotypes

David V. Sheehan\*, University of South Florida College of Medicine Jennifer M. Giddens

### **Posters**

- 35. Chime (Childhood Impulsive Aggression and Molindone ER): Doubleblind, Placebo-controlled Study of SPN-810 Added to Standard ADHD Therapy in Children with Impulsive Aggression and ADHD Scott Brittain\*, Supernus Pharmaceuticals, Inc. Gianpiera Ceresoli-Borroni, Tesfaye Liranso, Welton O'Neal, Stefan Schwabe, Robert Findling
- 36. Lost in Translation: Translatability of Psychiatric Terms The Example of the Mini-international Neuropsychiatric Interview (M.I.N.I.) Marie-Pierre Emery\*, Mapi Research Trust Anne Boudrot, David V. Sheehan, Catherine Acquadro
- 37. Human Factors Evaluation of a Novel Digital Health Feedback System in Psychiatry

Timothy Peters-Strickland\*, Otsuka Pharmaceutical Jane L. Smith, Benjamin Bartfeld, Linda Pestreich, Shashank Rohatagi, Ainslie Hatch, Felicia Forma, Praveen Raja, John Docherty

38. Involving the Caregivers in Digital Health-enhanced Care of Patients with Serious Mental Illness: Recommendations from an Expert Consensus Survey

Ainslie Hatch\*, Otsuka America Pharmaceutical, Inc. John Docherty, Julia E. Hoffman, Ruth Ross

39. Factors Affecting the Use of Digital Health Tools by Healthcare Professionals for Patients with Serious Mental Illness: An Expert Consensus Survey

Ainslie Hatch\*, Otsuka America Pharmaceutical, Inc. Julia E. Hoffman, Ruth Ross, John Docherty

- 40. Web-based Curriculums for Teaching Psychopharmacology: Revision of the Resident, Medical Student, and Primary Care Curriculums Ira Glick\*, Stanford University School of Medicine
- **41. Predictors of Medication Adherence Evaluated by Urine Drug Monitoring in Patients Prescribed Antipsychotic Agents** Mancia Ko\*, Ingenuity Health, A Service of Ameritox, Ltd. Patricia Woster, Stephen Marder, Thomas Smith
- **42. Prevention of Drug Interactions Involving Psychotropic Drugs** Marina Tsoy-Podosenin\*, St. John's Episcopal Hospital Subramoniam Madhusoodanan
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- **43.** Psychiatric Comorbidity in Patients with Pseudobulbar Affect Andrea Formella\*, Avanir Pharmaceuticals, Inc. Joao Siffert
- 44. Intranasal Oxytocin Modulates Neural Responses to Incentive Stimuli in Humans

Brian Mickey\*, University of Utah School of Medicine Joseph Heffernan, Curtis Heisel, Marta Pecina, David Hsu, Jon-Kar Zubieta, Tiffany Love

45. Efficacy of Lurasidone in Patients with Schizophrenia with Prominent Positive Symptoms: A Pooled Analysis of Short-term Placebocontrolled Studies

Steven Potkin\*, University of California, Irvine, School of Medicine Michael Tocco, Yongcai Mao, Josephine Cucchiaro, Antony Loebel

- **46.** Effects of Aripiprazole Once-monthly and Paliperidone Palmitate on Work Readiness in Patients from the Qualify Study Stratified by Age Steven Potkin\*, University of California, Irvine, School of Medicine Jean-Yves Loze, Carlos Forray, Ross Baker, Christophe Sapin, Timothy Peters-Strickland, Maud Beillat, Anna-Greta Nylander, Peter Hertel, Simon Nitschky Schmidt, Anna Eramo, Karina Hansen, Dieter Naber
- 47. Preclinical and Initial Clinical Characterization of APN1125, an α7 Nicotinic Acetylcholine Receptor Agonist for the Treatment of Cognitive Disorders

Michael Detke\*, Indiana University School of Medicine Gerald Koelsch, John Ng, Raymond Ng, Geoffrey Bilcer, Terence Kelly

- 48. A Phase 1 Single- and Multiple-rising Dose Study of the Safety & Pk of EMB-001, a Potential Treatment for Substance Use Disorders, with Exploratory Efficacy Measures in Tobacco Use Disorder Michael Detke\*, Indiana University School of Medicine Carol Gloff, Gary Connor, Sherry McKee, Frank Greenway, Mark Leibowitz, Julie Straub, Ann Robbins, Doug Feltner, Nicholas Goeders
  - **49. Symptom Stability in a 52-week Schizophrenia Extension Study of Treatment with Long-acting Injectable Aripiprazole Lauroxil** Robert Risinger\*, Alkermes Arielle Stanford, Yangchung Du, Jacqueline Zummo, Hassan Jamal, Chih-Chin Liu, Amy Claxton

### **Posters**

50. Addressing Adherence Challenges among Recently Diagnosed Schizophrenia Patients: Results from an RCT Comparing a Psychoeducation-based vs. a CBT-based Brief Psychosocial Intervention

Katarzyna Liwski\*, LECOM Douglas Turkington, Sara Tai, Peter Weiden

#### 51. The Efficacy of Lurasidone in Improving Cognition

Rachel Vedder\*, Affiliated Research Institute, Inc. Mohammed Ahmed, Walter Litwin, Hunter Hansen, Christina Ellis, Prakash Bhatia

52. Olfactory Deficits in 22q11.2 Deletion Syndrome Are Significant Compared to Non-deleted Individuals with Clinical Risk and Schizophrenia

Sunny Tang<sup>\*</sup>, University of Pennsylvania James Yi, Erich Dress, Andrew Wiemken, Tyler Moore, Monica Calkins, Paul Moberg, Raquel Gur, Bruce Turetsky

53. Maintenance Electroconvulsive Therapy (ECT) for Clozapine-resistant Schizophrenia

Georgios Petrides<sup>\*</sup>, The Zucker Hillside Hospital Raphael Braga, Chitra Malur, Samuel Bailine, Nina R. Schooler, Anil Malhotra, Majnu John, Alan Mendelowitz

- 54. Metabolic Syndrome in Patients with Schizophrenia Receiving Longterm Treatment with Lurasidone, Quetiapine XR, or Risperidone Michael Tocco\*, Sunovion John Newcomer, Andrei Pikalov, Hanzhe Zheng, Josephine Cucchiaro, Antony Loebel
- 55. Effects of Paliperidone Palmitate 3-month and 1-month Formulations on Personal and Social Performance Scale Domain Scores in Patients with Schizophrenia

Dong Jing Fu\*, Ortho-McNeil Janssen Scientific Affairs, LLC Adam Savitz, Ibrahim Turkoz

56. Efficacy of Cariprazine in Negative, Cognitive, and Social Function Symptoms in Schizophrenia: A Post Hoc Analysis of a Randomized, Controlled Trial

Andrew Cutler\*, Florida Clinical Research Center Suresh Durgam, Kaifeng Lu, István Laszlovszky, Erzsébet Szalai, Willie Earley

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- 57. Randomized, Double-blind, Placebo-controlled, Phase 3 Study of Encenicline as Pro-cognitive Treatment in Patients with Schizophrenia on Chronic Stable Atypical Antipsychotic Therapy Stephen Brannan\*, FORUM Pharmaceuticals Nancy Dgetluck, Dana Hilt
- 58. Long-term Cariprazine Treatment for the Prevention of Relapse in Patients with Schizophrenia: Analysis of Additional Efficacy Outcomes

Raffaele Migliore\*, Allergan Suresh Durgam, Willie Earley, Kaifeng Lu, István Laszlovszky, György Németh, Henry Nasrallah

- 59. The Effect of Tropisetron on the Improvement of P50 Deficits and Aspects of Cognitive Performance in Patients with Schizophrenia Hanjing Emily Wu\*, University of Texas Health Science Center at Houston Xiang Y. Zhang
  - 60. Psychopharmacological Treatment of Severely Aggressive Inpatients in a State Psychiatric Hospital Elizabeth Sumner\*, Duke University Medical Center Stephen Oxley
  - 61. Paliperidone Palmitate 3-monthly vs. 1-monthly Injectable in Schizophrenia Patients with or without prior Exposure to Oral Risperidone or Paliperidone

Maju Mathews\*, Janssen Research & Development, LLC Huiling Pei, Adam Savitz, Isaac Nuamah, Erica Elefant, David Hough, Larry Alphs, Srihari Gopal

★ 62. Phase 2 Study of Bremelanotide in Premenopausal Women with Female Sexual Dysfunctions: Responder Analyses based on Minimum Clinically Important Differences Derived from Receiver Operating Characteristic Curves

Stanley Althof\*, Case Western Reserve University School of Medicine Johna Lucas, Raymond Rosen, Robert Jordan, Sally Greenberg, Leonard R. DeRogatis

63. Hemodynamic and Pharmacokinetic Interactions of Intranasal Bremelanotide and Ethanol in a Phase 1, Randomized, Placebocontrolled, Double-blind, Three-period, Three-way Crossover Study Johna Lucas\*, Palatin Technologies, Inc. Anita Clayton, Robert Jordan, Leonard R. DeRogatis

😤 = New Investigator Awardee 🛛 🗱 = Pharmaceutical Pipeline Presentation

#### Posters

64. Effect of Asenapine on Measures of Hostility in Adults with Bipolar I Disorder or Schizophrenia

Leslie Citrome\*, New York Medical College Ronald Landbloom, Xiao Wu, Suresh Durgam

- 65. Vortioxetine for Major Depressive Disorder: Number Needed to Treat, Number Needed to Harm, and Likelihood to be Helped or Harmed Leslie Citrome\*, New York Medical College
- 66. Symptomatic Remission Status in Patients with Schizophrenia Treated with Paliperidone Palmitate (1-month and 3-month Formulations)

Arun Singh\*, Janssen Pharmaceuticals R&D Adam Savitz, Srihari Gopal, Haiyan Xu, Isaac Nuamah, David Hough, Maju Mathews

67. Lurasidone in the Treatment of Sleep Disturbance Associated with Bipolar Depression: Post-hoc Analysis of a Placebo-controlled Trial Followed by a Long-term Extension Study Michael E. Thase\*. Perelman School of Medicine at the University of

Michael E. Thase\*, Perelman School of Medicine at the University of Pennsylvania

Joyce Tsai, Cynthia Siu, Andrei Pikalov, Antony Loebel

68. Direct and Indirect Effects of Levomilnacipran ER on Functional Impairment in Adults with MDD: Post Hoc Path Analyses

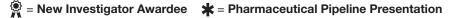
Michael E. Thase\*, Perelman School of Medicine at the University of Pennsylvania

Pierre Blier, Carl Gommoll, Changzheng Chen, Angelo Sambunaris, Kenneth Kramer

69. Comparative Evaluation of Vortioxetine as a Switch Therapy in Patients with Major Depressive Disorder

Michael E. Thase\*, Perelman School of Medicine at the University of Pennsylvania

Natalya Danchenko, Melanie Brignone, Ioana Florea, Francoise Diamand, Paula Jacobsen, Eduard Vieta





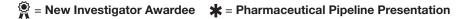
#### Thursday, June 2, 2016

Poster Session II with Lunch Palomino 1-7 12:00 p.m. - 2:00 p.m.

1. Correlation of HLD200 Drug Exposure with Permanent Product Measure of Performance (PERMP)-Correct Scores in Children with ADHD

Floyd Sallee\*, University of Cincinnati Ann Childress, Norberto DeSousa, Bev Incledon, Angus McLean

- 2. Algorithm for Adult Attention-Deficit/Hyperactivity Disorder Management from the Psychopharmacology Algorithm Project at the Harvard South Shore Program Bushra Awidi<sup>\*</sup>, Harvard South Shore Psychiatry Program David Osser
- 3. Circuit Modulation by Striatal Cholinergic Interneurons Daniel Eskenazi\*, New York State Psychiatric Institute, Columbia University Stephen Rayport
  - 4. Factors Influencing Generalized Anxiety Disorder (GAD) Diagnosis and Management: Perspectives from Practicing Clinicians Purvi Smith\*, Health and Wellness Partners Andrew Goddard, Larry Culpepper, Joseph Lieberman, Katia Zalkind, Anthony Greco, Jani Hegarty, Randi Roberts
  - 5. The Role of Clinical Outcome Assessment (COA) Data in the Drug Approval Process of Products for the Treatment of Autism Spectrum Disorder in the USA and Europe: A Review of Guidance Documents and Authorizations of Medicinal Products Marie-Pierre Emery\*, Mapi Research Trust Caroline Anfray, Catherine Acquadro, Cécile Perret, Patricia Anderson
  - 6. Efficacy of Lurasidone in Bipolar Depression: Pooled Results of Two Adjunctive Studies with Lithium or Valproate Joyce Tsai\*, Sunovion Pharmaceuticals Maurcio Tohen, Andrei Pikalov, Antony Loebel





- 7. Safety and Efficacy of Cariprazine in FDA-approved Dose Ranges for Schizophrenia and Bipolar I Disorder: A Pooled Post Hoc Analysis Willie Earley\*, Allergan Suresh Durgam, Kaifeng Lu, György Németh, István Laszlovszky
- 8. Actigraphy Biomarker Data Correlate with Bipolar Disorder Mood Symptoms

Terence Ketter\*, Stanford University School of Medicine Shefali Miller, Nathaniel Stockham, Saloni Shah, Dennis Do, Anshul Sitaram

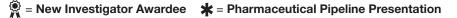
9. Potential Biomarkers of Depression and Mania: The Association of Sleep, Kynurenine and Tryptophan in Acute Bipolar Disorder Dahlia Mukherjee\*, Penn State Milton S. Hershey Medical Center Venkatesh Krishnamurthy, Aubrey Reider, Adem Can, Maureen Groer, Dietmar Fuchs, Teodor Postolache, Erika Saunders

#### 10. OPEN BOARD

11. The Suicide Ideation and Behavior Assessment Tool: Validation of a Novel Measure of Suicidal Ideation and Behavior and Perceived Risk of Suicide Larry Alphs\*, Janssen

Carla Canuso, David Williamson, SIBAT Consortium

- 12. Addressing Data Quality Challenges in Rare Disease Clinical Trials Magda Perez\*, inVentiv Health Chris Brady, Julie Marsh, Kristi Bertzos, Lori Vivian
- 13. Marijuana Effect on Differentiating an Opioid from Placebo During the Discrimination Phase of a Human Abuse Potential Study Clark Johnson\*, PRA Health Sciences Michael Smith, Shawn Searle, Vicky Newton, Lynn Webster
- 14. ITI-007 Dose Selection Across Psychiatric and Neurological Therapeutic Indications Jelena Saillard\*, Intra-Cellular Therapies, Inc. Kimberly E. Vanover, Robert E. Davis, Cedric O' Gorman, Michal Weingart, Sharon Mates





15. Methodological Considerations in the Assessment of Abuse Potential in Phase 1-3 Clinical Trials of CNS Drugs

Michael Hufford\*, Pinney Associates Jack Henningfield, Reginald Fant, Sidney Schnoll

- 16. An Evaluation of Urine Drug Monitoring in the Treatment of Patients with Serious Mental Illness Patricia Woster\*, Ingenuity Health Mancia Ko, Thomas Smith
- 17. Brain-derived Neurotrophic Factor (BDNF) Val66Met Polymorphism Induces Memory Deficits in Elderly Saulo Tractenberg\*, Pontifical Catholic University of Rio Grande do Sul

Saulo Tractenberg<sup>\*</sup>, Pontifical Gatholic University of Rio Grande do Sul Lucas Azeredo, Mateus Levandowski, Tatiana de Nardi, Julia Kommers-Molina, Wieck Andrea, Rodrigo Grassi-Oliveira

18. MIN-117 – A Promising New Antidepressant with a Novel Mechanism of Action Profile

Michael Detke\*, Indiana University School of Medicine Corinne Staner, Nadine Noel, Jay Saoud, Joseph Reilly, Remy Luthringer

19. OPEN BOARD

#### 20. OPEN BOARD

21. Lurasidone for Major Depressive Disorder with Mixed Features: Effect of Irritability

Andrei Pikalov\*, Sunovion Pharmaceuticals, Inc. Alan C. Swann, Joyce Tsai, Yongcai Mao, Antony Loebel

#### 22. OPEN BOARD

23. A Five Year Study of Vagus Nerve Stimulation Compared to Treatment as Usual in Historical ECT Responders and Non-responders Scott Aaronson\*, Sheppard Pratt Health System Peter Sears, Pradheep Raman, Jennifer Sklar, Mark Bunker

### Posters

24. Impact of Vortioxetine on Functional Capacity in MDD Patients with Cognitive Dysfunction: A UCSD Performance-based Skills Assessment (UPSA) Post Hoc Analysis

William Jacobson\*, Takeda Pharmaceuticals Philip D. Harvey, Wei Zhong, George Nomikos, Christina Kurre Olsen, Michael Cronquist Christensen, Elizabeth Merikle

25. SAGE-547 (Allopregnanolone) and SAGE-217: Investigational Neuroactive Steroids Targeting the GABAA Receptors for Treatment of CNS Disorders

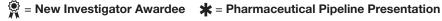
Stephen Kanes\*, Sage Therapeutics Helen Colquhoun, Handan Gunduz-Bruce, James Doherty, Shane Raines, Ethan Hoffman, David R. Rubinow, Samantha Meltzer-Brody

- 26. Evaluation of the Efficacy and Safety of Alks 5461 as Adjunctive Therapy in MDD: Results of FORWARD-3 and FORWARD-4 Studies Elliot Ehrich\*, Alkermes, plc William Martin, Asli Memisoglu, Sanjeev Pathak, Arielle Stanford, Irena Webster, Ying Jiang, Michael E. Thase, Maurizio Fava
- 27. Psychiatrist Attitudes about Novel and Emerging Treatments for Depression: Off-label Ketamine Dawn Roberts\*, Bradley University

Aman Singh, Jane Larouche, Laura Jorgenson, Peter Alahi

- 28. Validation of Patients for a CNS Trial of Major Depressive Disorder Martina Flynn\*, Massachusetts General Hospital David Mischoulon, Janet Witte, Vincent Pisano, Max Martinson, Marlene Freeman, Mi Hillefors, George Papakostas, Maurizio Fava
- 29. Susceptibility of Male and Female C57BL/6 Mice to Oxidative Stress in the Hippocampus in an LPS Model of Depression Caitlin Millett\*, Penn State Milton S. Hershey Medical Center Erika Saunders, Shannon Kelleher
- 30. Direct and Indirect Effects of Levomilnacipran ER on Functional Impairments in MDD Patients with Cognitive Difficulties: Post Hoc Path Analyses

Ken Kramer\*, Allergan Roger S. McIntyre, Philip Harvey, Carl Gommoll, Changzheng Chen, Keith Wesnes





- 31. Effects of Adjunctive Brexpiprazole on Chronobiologic Parameters in Patients with Major Depressive Disorder and Sleep Disturbances Amy Hilty\*, Otsuka Pharmaceuticals Aurelia Mittoux, Peter Meisels, Ross Baker, Andrew Krystal
  - 32. Treatment Patterns, Healthcare Resource Utilization, and Costs Following First-line Antidepressant Treatment in MDD: A Retrospective US Claims Database Analysis Vanessa Perez\*, Takeda Pharmaceuticals International, Inc. Genevieve Gauthier, Annie Guerin, Maryia Zhdanava, Clément François, William Jacobson, George Nomikos, Elizabeth Merikle
  - **33. The Digit Symbol Substitution Test (DSST): Psychometric Properties and Clinical Utility in Major Depressive Disorder** Judith Jaeger\*, Albert Einstein College of Medicine
- 34. Into the Island of Addiction: Insights into the Mechanisms of Action of Repetitive Transcranial Magnetic Stimulation Primavera Spagnolo\*, National Institute on Alcohol Abuse & Alcoholism, National Institutes of Health
  - 35. Case Study of Magnesium in the Treatment of Impulse Attack Suicidality Disorder

David V. Sheehan\*, University of South Florida College of Medicine Jennifer M. Giddens

- 36. Extended-release Molindone for Impulsive Aggression: Phase 2 Double-blind, Placebo-controlled Trial in Children with ADHD Receiving Optimized Stimulant Monotherapy and Behavioral Therapy Scott Brittain\*, Supernus Pharmaceuticals, Inc. Jennifer D. Stocks, Janet K. Johnson, Tesfaye Liranso, Robert L. Findling
- 37. Teaching the Teachers of Clinical Psychopharmacology Ira Glick\*, Stanford University School of Medicine Carl Salzman
- 38. Assessment of Amphetamine Withdrawal Symptoms of Lisdexamfetamine Dimesylate Treatment for Adults with Binge Eating Disorder

Judith Kando\*, Sunovion Maria Gasior, Barry Herman, Jana Radewonuk, Reginald Fant, Sidney Schnoll, Susan McElroy

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39. Caregiver Burden in Schizophrenia: Pooled Analysis of the Involvement Evaluation Questionnaire Data for Paliperidone Palmitate **3-month Formulation** 

Arun Singh\*, Janssen Pharmaceuticals R&D Srihari Gopal, Haiyan Xu, Kelly McQuarrie, Adam Savitz, Isaac Nuamah, Kimberly Woodruff, Maju Mathews

40. A Case Series on the Effectiveness of Lurasidone in Patients with Stuttering

Janet Charoensook\*, UC Riverside Carlos Fernandez, Shalin Patel, Julia Hoang, Gerald Maguire

- 41. Psychiatric Stability Maintained in Tardive Dyskinesia Subjects Treated with Valbenazine (NBI-98854) Jean-Pierre Lindenmayer\*, New York University Richard Josiassen, Joshua Burke, Scott Siegert, Bill Aurora
- 42. Kinect 3: A Randomized, Double-blind, Placebo-controlled Phase 3 Trial of Valbenazine (NBI-98854) for Tardive Dyskinesia Mary Ann Knesevich\*, University Hills Clinical Research Stephen Marder, Robert A. Hauser, Grace S. Liang, Christopher O'Brien

#### 43. MoodNetwork.org: A Seminal Online Study

Andrew Nierenberg\*, Massachusetts General Hospital Louisa Sylvia, Casey Hearing, Alexandra K. Gold, Rebecca Montana, Roberta Tovey, Anthony Debenedictis, Allen Doederlein, Susan Edgman-Levitan, Muffy Walker, Donna Holland Barnes, Jonathan Alpert, Jordan Smoller, Marlene Freeman, Thilo Deckersbach

- 44. Results from an Expert Consensus Survey: Patient-related Factors in the Use of Digital Health Tools in Patients with Serious Mental Illness Ainslie Hatch\*, Otsuka America Pharmaceutical, Inc. Julia Hoffman, Ruth Ross, John Docherty
- 45. A Treatment Refinement Study to Optimize the Habit Formation Program for Improving Adherence to Oral Medications in Schizophrenia and Schizoaffective Disorder

Ainslie Hatch\*, Otsuka America Pharmaceutical, Inc. John Docherty, Deborah Profit, Erica Lawson, Anke Adenwala, Dawn Velligan



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- 46. Randomized, Double-blind, Placebo-controlled, Phase 3 Study of Encenicline as Pro-cognitive Treatment in Patients with Schizophrenia Steven Potkin\*, University of California, Irvine, School of Medicine Stephen Brannan, Nancy Dgetluck, Dana Hilt
- 47. Cariprazine for Negative Symptoms of Schizophrenia: A Pooled Post Hoc Analysis of 2 Randomized, Double-blind, Placebo- and Activecontrolled Trials

Suresh Durgam\*, Forest Research Institute, A Subsidiary of Actavis, plc Willie Earley, Kaifeng Lu, György Németh, István Laszlovszky, Balázs Szatmári, Henry Nasrallah

48. Understanding Factors Impacting on Cgi-S Vs. Cgi-I Discrepancies: An Exploratory Analysis

David Daniel\*, Bracket Global, LLC Alan Kott

49. Switching Patients with Acute Schizophrenia to Brexpiprazole: Posthoc Analysis of a Double-blind Randomized Maintenance Treatment Study

Ruth A. Duffy\*, Otsuka Pharmaceutical Development and Commercialization, Inc. Catherine Weiss, John Ouyang, Anna Eramo, Emmanuelle Weiller, Ross Baker

50. Relationship Between Response to Aripiprazole Once-monthly and Paliperidone Palmitate on Work Readiness and Functioning: A Posthoc Analysis of QUALIFY, A Head-to-head Study in Schizophrenia Ross Baker\*, Otsuka

Steven Potkin, Jean-Yves Loze, Carlos Forray, Christophe Sapin, Timothy Peters-Strickland, Maud Beillat, Anna-Greta Nylander, Peter Hertel, Simon Nitschky Schmidt, Anna Eramo, Karina Hansen, Dieter Naber

51. Long-term Safety and Durability of Effect of Aripiprazole Lauroxil in a One-year Schizophrenia Extension Study Robert Risinger\*, Alkermes Arielle Stanford, Yangchung Du, Jacqueline Zummo, Hassan Jamal, Chih-Chin Liu, Amy Claxton

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52. A Multicenter, 8-week Study to Assess Usability of a Digital Health Feedback System in Adults with Schizophrenia Treated with Oral **Aripiprazole** 

Timothy Peters-Strickland\*, Otsuka Pharmaceutical Linda Pestreich, Ainslie Hatch, Shashank Rohatagi, Ross Baker, John Docherty, Lada Markovtsova, Praveen Raja, Peter Weiden, David Walling

- 53. Efficacy and Safety of Intramuscular Ziprasidone in Chinese Schizophrenia Patients with Agitation: A Randomized, Blind, Active Parallel-controlled, Multicenter Clinical Trial Yifeng Shen\*, Shanghai Mental Health Center Jianfeng Lou, Huafang Li
- 54. Effect of Brexpiprazole and Aripiprazole on Weight: An Analysis of Long-term Trials in Schizophrenia

Catherine Weiss\*, Otsuka Pharmaceutical Development & Commercialization, Inc. Keva K. Gwin, Ruth A. Duffy, Ross Baker, Emmanuelle Weiller

55. Aripiprazole Lauroxil Pharmacokinetics: Application of Modeling and Simulation for Dosing Considerations of a Long-acting Injectable Antipsychotic in Persons with Schizophrenia Marjie Hard\*, Alkermes, Inc. Brian Sadler, Richard Mills, Karen Rowland Yeo, Ryan Turncliff, Leslie

Citrome

- 56. Handwriting Kinematics in the Assessment of Pharmacotherapeutic **Outcomes in Psychiatric Populations** Michael Caligiuri\*, University of California, San Diego Hans-Leo Teulings
- 57. Effects of Aripiprazole Once-monthly and Paliperidone Palmitate in Patients with Schizophrenia and Concomitant Substance use: A Posthoc Analysis of QUALIFY, A Head-to-head Study

Phyllis Salzman\*, Otsuka Pharmaceutical Development & Commercialization, Inc.

Dieter Naber, Ross Baker, Anna Eramo, Carlos Forray, Karina Hansen, Christophe Sapin, Maud Beillat, Timothy Peters-Strickland, Anna-Greta Nylander, Peter Hertel, Jean-Yves Loze, Henrik Steen Andersen, Steven Potkin



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#### 58. Long-term Effectiveness of Aripiprazole Once-monthly is Maintained in the Qualify Extension Study

Anna Eramo\*, Lundbeck Dieter Naber, Ross Baker, Carlos Forray, Karina Hansen, Christophe Sapin, Timothy Peters-Strickland, Anna-Greta Nylander, Peter Hertel, Simon Nitschky Schmidt, Jean-Yves Loze, Steven Potkin

- 59. Antipsychotic Augmentation Vs Monotherapy in Schizophrenia: Systematic Review, Meta-analysis and Metaregression Analysis Britta Galling\*, The Zucker Hillside Hospital Alexandra Roldán, Frozan Walyzada, Liz Rietschel, Katsuhiko Hagi, Wei Zheng, Xiao-Lan Cao, Yu-Tao Xiang, Mathias Zink, John M. Kane, Jimmi Nielsen, Stephan Leucht, Christoph Correll
  - 60. A Phase 2, EFFICACY, SAFETY, and Tolerability Study of ALKS 3831 in Schizophrenia with Alcohol Use Disorder

Bernard Silverman\*, Alkermes, Inc. Sanjeev Pathak, David McDonnell, Lauren DiPetrillo, Adam Simmons, Ying Jiang, Jacqueline Zummo, Hassan Jamal

- 61. Evaluation of Paliperidone Palmitate Long-acting Injectable Therapy by Duration of Illness in Patients with Schizophrenia Maju Mathews\*, Janssen Research & Development, LLC Brianne Browne, Ibrahim Turkoz, Branislav Mancevski
- 62. The National Pregnancy Registry for Atypical Antipsychotics: Effects of Fetal Exposure on Risk for Major Malformations Lee Cohen\*, Massachusetts General Hospital Adele Viguera, Marlene Freeman, Tao Hou, Alexandra Sosinsky, Gina Savella, Danna Moustafa, Sonia Hernández-Díaz
- 63. Relationship Between Depression and Pregnancy in Rural Guatemala: A Pilot Study

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### Notes

## **FUTURE ASCP MEETINGS**



## 2016 ASCP Fall Meeting October 29-30, 2016

Grand Hyatt New York, New York



### 2017 ASCP Annual Meeting May 29 – June 2, 2017 Loews Miami Beach, Miami Beach, Florida



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