New Approaches to Mental Illness

IN THE ERA OF THE NATIONAL BRAIN INITIATIVE



ASCP ANNUAL MEETING
June 16 - 19, 2014
HOLLYWOOD, FL



www.ASCPMeeting.org



Dear Colleagues:

On behalf of the American Society of Clinical Psychopharmacology (ASCP), we are very pleased to welcome you to this year's "ASCP Annual Meeting." In 2010, several decisions were made that allowed ASCP to reinvent NCDEU as "the New NCDEU." Over the last three years "the New NCDEU" has been quite successful. Moving forward in 2014, the ASCP Board and the ASCP/NCDEU Steering Committee have decided to rename the meeting the "ASCP Annual Meeting."

The ASCP is proud to sponsor the meeting, now in its 54th year.

Psychopharmacology is an exciting field undergoing dramatic changes, with the identification of new molecular targets and the development of novel compounds. Our Society keeps its members abreast of such innovations. Our annual meeting serves as the vehicle for the dissemination of cutting edge psychopharmacology research. We will continue to develop ways for members to feel more connected with our Society and to include more clinically focused symposia.

Another major goal for ASCP is to increase its visibility to those interested in the practice of psychopharmacology, thereby helping our membership grow. With over 1,000 annual attendees, the meeting has also become a key opportunity for networking, planning and to develop the next generation of clinical researchers.

A very special thank you to the members of the ASCP/NCDEU Steering and ASCP Program Committees for their critical role in the success of the meeting. We are all looking forward to an exciting and highly informative ASCP Annual Meeting.

Maurizio Fava. 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. Though the name of the meeting has changed, the ASCP is committed to continue to build 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 2014 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.

· 2014 Program Highlights

- o Monday, June 16
 - Conference Opening
 - Pharma Pipeline: 10 presentations of Phase 1 and Phase 2 developments.
- o Tuesday, June 17
 - 15th Annual Fun Run/Walk
 - Regulatory Plenary: FDA Science Initiatives: A Brief Update
 - ASCP Lifetime Awardee Talk
 - Poster Session I ASCP Reception
- Wednesday, June 18
 - Keynote Plenary Session: New Approaches to Mental Illness in the Era of the National Brain Initiative
 - NIH Institute Directors Plenary
 - Poster Session II
 - Updates Session The Latest on Treatment of Mood, OCD-spectrum, and Binge Eating Disorders
 - Workshops
- o Thursday, June 19
 - Regulatory Wrap-Up Plenary with the FDA
- Throughout the meeting
 - NIMH, NIDA, NCCAM, and NIAAA panels
- o The New Investigator Program
 - A closed workshop for 20 New Investigators and informal breakfast sessions
- o Workshops: 2 hour intensive interactive sessions focused on problems and solutions
- Tuesday and Wednesday Afternoons o *Clinical Track* - sessions focused on topics of immediate clinical relevance

Organization

- 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
 - NCCAM National Center for Complementary and Alternative Medicine
 - CSR Center for Scientific Review
 - NCATS National Center for Advancing Translational Sciences
- Regulatory agency collaborations:
 - Food and Drug Administration (FDA)
- Parthenon Management Group organizes the ASCP Annual Meeting.

And remember

- o The Opening Reception is Tuesday, June 17th from 7:00 pm − 8:00 pm.
- o The Fun Run/Walk is Tuesday, June 17th at 6:45 am.

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

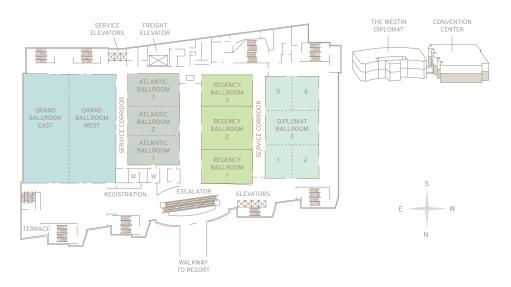
Carlos Zarate, M.D. Program Committee Co-Chair Michael E. Thase, M.D. Steering Committee Co-Chair

Michael E. Thankis

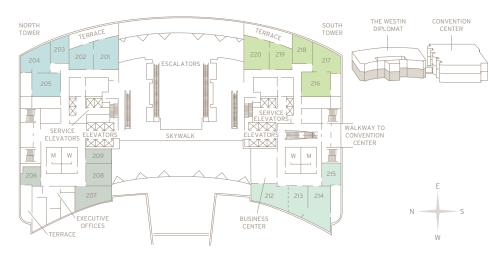
Holly A. Swartz, M.D. Program Committee Co-Chair

Hotel Maps

2nd Floor Convention Center



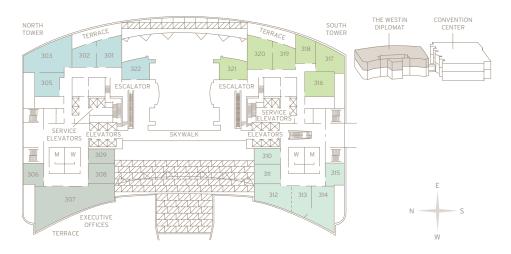
Resort, Second Floor



Hotel Maps

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Resort, Third Floor



Future ASCP Meetings | ASCP

- State of the Art Fall Psychopharmacology Update Meeting October 11-12, 2014
 New York, New York
- 2015 ASCP Annual Meeting June 22-25, 2015
 Miami Beach, Florida

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

Award Winners

ASCP

Recipient of the Donald Klein Lifetime Achievement Award



A. John Rush, M.D. Duke-National University of Singapore

Dr. Rush majored in Biochemistry at Princeton and completed his M.D. at Columbia College of Physicians and Surgeons. Following his internship in general medicine (Passavant Hospital, Northwestern University), he served in the U.S. Army before joining the Special Action Office for Drug Abuse Prevention in Washington D.C. After his psychiatric residency at the University of Pennsylvania, he became Assistant Professor at the University of Oklahoma and subsequently joined the Departments of Psychiatry

and later the Department of Clinical Sciences at the University of Texas Southwestern Medical Center at Dallas. In 2008, he became Vice Dean of Clinical Sciences and Professor at Duke-NUS (Singapore).

At Duke-NUS he founded and developed several programs designed to advance patient oriented research careers of medical, surgical and mental health, nursing and allied health practitioners including the Academic Medicine Research Institute, the Center for Quantitative Medicine, and the Medical Student III program in clinical research.

His research has focused on the development and testing of innovative treatments for mood disorders including medications, medication combinations, somatic treatments, psychotherapy, and disease management protocols (treatment algorithms). He has authored more than 600 papers and chapters and 10 books. He was Principal Investigator on the NIMH sponsored STAR*D (Sequenced Treatment Alternatives to Relieve Depression) trial and directed the NIMH Depression Trials Network (DTN). Past awards include the Mood Disorders Research Award (American College of Psychiatrists), the Paul Hoch Award (American Psychopathological Association), the Edward J. Sachar Award (Columbia College of P & S), the Nola Maddox Falcone Prize (NARSAD), the American Psychiatric Association Award for Research in Psychiatry, and the Gold Medal Award (Society of Biological Psychiatry). He has served as President of the Society of Biological Psychiatry and Society for Psychotherapy Research. He presently provides consultation to academic centers, government and industrial organizations and entities.

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Award Winners

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



Sophie Grigoriadias, M.D. Sunnybrook Health Sciences Centre

Nominated for: Antidepressant Exposure During Pregnancy and Congenital Malformations: Is There an Association? A Systematic Review and Meta-Analysis of the Best Evidence

Sophie Grigoriadis, M.D., Ph.D., FRCPC; Emily H. VonderPorten, MPH; Lana Mamisashvili, MSW; Michael Roerecke, Ph.D.; Jürgen Rehm, Ph.D.; Cindy-Lee Dennis, Ph.D.; Gideon Koren, M.D.,

FRCPC, FACMT; Meir Steiner, M.D., Ph.D., FRCPC; Patricia Mousmanis, M.D., CCFP, FCFP; Amy Cheung, M.D., MSc, FRCPC; and Lori E. Ross, Ph.D.

Dr. Grigoriadis is the Head of the Women's Mood and Anxiety Clinic: Reproductive Transitions at Sunnybrook health Sciences Centre and scientist at the Sunnybrook Research Institute. She was the Academic Leader of the Reproductive Life Stages Program at Women's College Hospital, Fellowship Director in the department of psychiatry at the University Health Network (UHN) and a Staff Psychiatrist at both sites including the Mood Disorders Psychopharmacology Unit at UHN until September 2011. She is an Associate Professor in the Mood and Anxiety Disorders and Women's Mental Health Programs, Department of Psychiatry, Faculty of Medicine, at the University of Toronto.

Dr. Grigoriadis completed her medical degree at McMaster University and her psychiatry residency at the University of Toronto. Prior to Medical school, she completed a MA and Ph.D. in Clinical Psychology at Queen's University, and internship in Clinical Psychology at the Toronto Hospital. Dr. Grigoriadis' clinical interests include women with depression especially during pregnancy, the postpartum period and during perimenopause. Her treatment strategies include both the use of pharmacotherapy as well as short-term psychotherapies. Current research focuses on the presentation of mood disorders in women across the lifespan, hormonal influences in the presentation and treatment of depression during the postpartum and perimenopause, and differences in the presentation and response to antidepressant medications among women of various ages. Dr. Grigoriadis is also actively involved in developing novel treatment strategies for depression. She is currently leading several studies including developing a tool to assist clinicians in making treatment decisions with their depressed perinatal patients and is developing treatment guidelines for the treatment of depression during the perimenopause. She is an author in the Canadian Guidelines for the Treatment of Depression. Her educational activities include teaching psychiatry residents, training family practice as well as psychiatry residents in Interpersonal Psychotherapy and teaching in continuing medical education programs.

Regulatory Plenary - *FDA Science Initiatives: A Brief Update* Tuesday, June 17, 2014 from 8:30 am – 10:00 am



Ni Khin, M.D. Food and Drug Administration

Dr. Ni Khin is Acting Division Director in Division of Good Clinical Practice Compliance, Office of Scientific Investigations, Center for Drug Evaluation and Research, FDA. She has served as Medical Team Leader in the Division of Psychiatry Products, Office of New Drugs for past 8 years. In this position, she oversaw the review of clinical protocols submitted under investigational new drug applications (INDs) for all phases of drug development. She also

managed, as cross-disciplinary team leader, regulatory and clinical reviews of New Drug Applications (NDAs) for all psychiatric indications. She joined the Agency in 2001 as a Clinical Reviewer in the Division of Neuropharmacologic Drug Products. She also worked as Medical Officer and Branch Chief of Good Clinical Practice Branch 1, Division of Scientific Investigations, where she provided scientific oversight for CDER-assigned bioresearch monitoring (BIMO) activities. She conducted on-site data-audit inspections of clinical trial sites both in the US and abroad. Prior to coming to FDA, Dr. Khin was a Senior Staff Fellow in the Geriatric Psychiatry Branch at the National Institute of Mental Health.

Dr. Khin received her medical degree from the Institute of Medicine I, Rangoon, Burma (Myanmar). She completed residency training in Psychiatry at the State University of New York, Buffalo. She is board-certified in Psychiatry by the American Board of Psychiatry and Neurology. She also received a Master of Science Degree from Arizona State University. Her regulatory research interest includes trial design and methodology to improve detection of efficacy signals as well as regulatory and scientific issues regarding use of foreign data from global trials in support of NDA's.

Celia Winchell, M.D. Food and Drug Administration

Celia Winchell is the Medical Team Leader for Addiction Products in the FDA's Division of Anesthesia, Analgesia, and Addiction Products in the Center for Drug Evaluation and Research. Since 1995, Dr. Winchell has been providing regulatory oversight for drug development in all aspects of addiction treatment, and for academic research involving drugs of abuse. Dr. Winchell holds a bachelor's degree in psychology from Harvard University, and a medical degree from the University of Virginia. She completed residency training in psychiatry at Johns Hopkins Hospital.

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Featured Speakers



Silvana Borges, M.D. Food and Drug Administration

Dr. Borges received her medical degree from the State University School of Medicine in Uruguay. She completed her medical residency and is board certified in Child & Adolescent Psychiatry. She joined the Department of Pharmacology and Therapeutics in the State University

School of Medicine as an Assistant Professor and then became an Assistant Professor and Founding Member of the "National Center for Drug Safety" in Uruguay. She was a Scholar at the Catalan Institute of Pharmacology (Barcelona, Spain) focusing her training in drug safety and pharmacoepidemiology. She received the Merck Foundation International Fellowship in Clinical Pharmacology Award and completed a fellowship in clinical pharmacology and pharmacogenetics at Indiana University, being mentored by Dr. David Flockhart. She was the recipient of the American Society for Clinical Pharmacology and Therapeutics Presidential Trainee Award for her work on the role of CYP2D6 genetic polymorphism on tamoxifen metabolism and its interaction with antidepressants. She joined the FDA in 2007 and is currently an Acting Clinical Team Leader with the Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation and Research.

<u>Plenary: New Approaches to Mental Illness in the Era of the National Brain Initiative</u>
Wednesday, June 18, 2014 from 8:15 am - 9:45 am



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

Husseini K. Manji, M.D., FRCPC, is 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.

Featured Speakers

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Thomas Insel, M.D. National Institute of Mental Health

Thomas R. Insel, M.D., is Director of the National Institute of Mental Health (NIMH), the component of the National Institutes of Health charged with generating knowledge to understand, treat and prevent mental disorders. His tenure at NIMH has been distinguished by groundbreaking findings on the genetics and neurobiology of mental disorders ads well as efforts to transform the diagnosis and treatment of serious mental illnesses. In addition

to his leadership of the NIMH, Dr. Insel has served as Chair of the Interagency Autism Coordinating Committee (Since 2002), co-chair of the NIH Blueprint for Neuroscience Research (since 2004), and Acting Director of the National Center for Advancing Translational Science (2011-2012). Currently, Dr. Insel is on the leaders for the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) effort, a Presidential initiative focused on developing new tools for understanding the brain.

Prior to his appointment as NIHM Director in the Fall 2002, Dr. Insel was Professor of Psychiatry at Emory University. There, he was founding director of the Center for Behavioral Neuroscience and director of an NIH-funded Center for Autism Research. From 1994 to 1999, he was Director of the Yerkes Regional Primate Research Center in Atlanta. While at Emory, Dr. Insel continued the line of research he had initiated at NIMH, studying the neurobiology of complex social behaviors. He has published over 280 scientific articles and four books, including the *Neurobiology of Parental Care* (with Michael Numan) in 2003.

Dr. Insel is a member of the Institute of Medicine, a fellow of the American College of Neuropsychopharmacology, and is a recipient of several awards, including the Outstanding Service Award from the U.S. Public Health Service and the 2010 La Foundation IPSEN Neuronal Plasticity Prize. Dr. Insel graduated from the combined B.A.-M.D. program at Boston University in 1974. He did his internship at Berkshire Medical Center, Pittsfield, Massachusetts, and his residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco.

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Featured Speakers



Patrick Kennedy Former US Representative and Mental Health Activist

Patrick J. Kennedy became the youngest member of the Kennedy family to hold elected office when, in 1988, he won election to the Rhode Island House of Representatives at age 21. Since then, Kennedy went on to serve 16 years in the United States House of Representatives, representing Rhode Island's first congressional district from 1994 to 2011. While in office, he distinguished himself

as a leader on issues of healthcare, sciences, veterans, technology, civil rights, and mental health.

As a founding member of the 21st Century Healthcare Caucus; the Addiction, Treatment and Recovery Caucus; and the Down Syndrome Caucus, Kennedy has been a tireless advocate for access to health and advancements in medical research.

Throughout his career, Kennedy has been a vocal advocate for healthcare reform. He was the author and chief House sponsor of the Wellstone-Domenici Mental Health Parity and Addiction Equity Act of 2008, an act that expanded access to mental health services to over 100 million Americans. He has also authored and cosponsored dozens of bills to increase the understanding and treatment of neurological and psychiatric disorders, including the National Neurotechnology Initiative Act, the Genomics and Personalized Medicine Act, the Combat PTSD Act, and the Alzheimer's Treatment and Caregiver Support Act.

Since leaving office in 2011, Patrick J. Kennedy has been devoting his efforts to promoting research in neuroscience. He co-founded One Mind for Research, a nonprofit organization, the mission of which is to be the leader in brain research in order to eliminate stigma, transform policy, and allocate resources that will help both our understanding and treatment of brain diseases. In addition to One Mind for Research, Kennedy is also an active board member of Best Buddies, Research America, and the Edward M. Kennedy Institute for the United States Senate.

The champion of mental health in Congress who believes that "the brain is the last medical frontier." Patrick J. Kennedy is a sought-after speaker on mental health, healthcare, and many other related issues. He was invited by House Minority Leader Nancy Pelosi to address the Democratic Caucus on mental health and will launch the Kennedy Forum on Community Mental Health. In 2013, he spoke at the National Institute of Mental Health Alliance for Research Progress, the US/Canada Forum on Mental Health and Productivity, and the Mental Health America Conference.

Featured Speakers

<u>Institute Directors Plenary</u> Wednesday, June 18, 2014 from 10:00 am – 12:00 pm

Thomas Insel, M.D.
National Institute of Mental Health
See previous bio



Phillip Skolnick, Ph.D., D.Sc. (hon.) National Institute on Drug Abuse

Phil Skolnick is the Director, Division of Pharmacotherapies and Medical Consequences of Drug Abuse at the National Institute on Drug Abuse, NIH. Dr. Skolnick served as Chief Scientific Officer (2001-2009) and President (2007-2009) of DOV Pharmaceutical, Inc. He was also Research Professor of Psychiatry (2001-2009) and a member of the Center of Excellence on Drug Addiction at New York University-Langone Medical Center. Dr. Skolnick was a

Lilly Research Fellow (Neuroscience) at Lilly Research Laboratories (1997-2000). Prior to this, he was a Senior Investigator and Chief, Laboratory of Neuroscience, at the NIH intramural research program (1986-1997). Dr. Skolnick has also served as a Research Professor of Psychiatry at the Uniformed Services University of the Health Sciences, Adjunct Professor of Anesthesiology at Johns Hopkins University, and Adjunct Professor of Pharmacology and Toxicology at Indiana University School of Medicine. He received a Ph.D. from the Department of Pharmacology, George Washington University School of Medicine (1972), and served as a Staff Fellow and Senior Staff Fellow at the NIH under Dr. John W. Daly (1972-1977).

His awards and honors include the Experimental Therapeutics Prize from the American Society for Pharmacology and Experimental Therapeutics, an Anna Monika Prize, and the A.E. Bennett Award in Biological Psychiatry. He has twice been awarded the Doctor of Science, honoris causa. Dr. Skolnick has co-authored more than 500 articles and currently serves on the editorial advisory board of seven journals. He is currently an editor of Current Protocols in Neuroscience, and has also edited six books. The Institute of Scientific Information (ISI) has acknowledged his contributions by naming him to the elite group of "Highly Cited" authors.

ASCP

Featured Speakers



Kenneth Warren, Ph.D., D.Sc. National Institute on Alcohol Abuse and Alcoholism

Kenneth R. Warren, Ph.D., a nationally-recognized expert on alcohol and pregnancy, and a long-time senior administrator at the National Institute on Alcohol Abuse and Alcoholism (NIAAA) became Acting Director of NIAAA on November 1, 2008, following the retirement of Ting-Kai Li, M.D. on October 31, 2008. Dr. Li had served as NIAAA Director from September 2002 through October 2008. Dr. Warren was named as the NIAAA Deputy Director in February 2008. He held numerous positions in NIAAA since joining the Institute in 1976.

A graduate of the City College of New York, Dr. Warren earned his doctorate degree in Biochemistry from Michigan State University in 1970. He subsequently undertook postdoctoral positions at the University of California, Los Angeles and at University of Michigan Mental Health Research Institute before joining the Federal government in a research position at the Walter Reed Army Institute of Research in 1974.

Dr. Warren has maintained an active interest in all areas of alcohol and health and in past years often served as the editor of the triennial Reports to Congress on Alcohol and Health. He has been particularly active in research on the effects of alcohol use during pregnancy, including fetal alcohol syndrome (FAS) and fetal alcohol spectrum disorders (FASD). Dr. Warren initiated NIAAA's research program on FAS over 30 years ago. He currently chairs the government-wide Interagency Coordinating Committee on FAS.

Dr. Warren has received numerous honors, including a superior service award from the Public Health Service in 1982 for his work in development of the first Surgeon General's Advisory on FAS. In 2007, the National Organization on Fetal Alcohol Syndrome (NOFAS) honored Dr. Warren by placing his name into their Tom and Linda Daschle FASD Hall of Fame, followed by the receipt of the NOFAS Excellence Award in 2008.



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

In September 2012, NIH Director Francis S. Collins announced the appointment of Christopher P. Austin, M.D., as director of the National Center for Advancing Translational Sciences (NCATS). Austin succeeded former acting director of NCATS and current director of the National Institute of Mental Health Thomas R. Insel, M.D.

Austin, who served as director of the NCATS Division of Pre-clinical Innovation since the creation of the Center in December 2011, is leading NCATS in its mission to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. Currently, many costly, time-consuming bottlenecks exist in the translational pipeline. Austin is applying his experiences in nearly every stage of the research pipeline to build on the Center's momentum in finding innovative ways to reduce, remove or bypass these bottlenecks and speed the delivery of new drugs, diagnostics and medical devices to patients.

Featured Speakers



After working at Merck on genome-based discovery of novel targets and drugs, Austin began his NIH career in 2002 as the Senior Advisor to the Director for translational research at the National Human Genome Research Institute, where he initiated the Knockout Mouse Project and the Molecular Libraries Roadmap Initiative. Other NIH roles have included serving as Director of the Therapeutics for Rare and Neglected Diseases program as well as the NIH Chemical Genomics Center and as Scientific Director of the NIH Center for Translational Therapeutics.

Austin earned a medical degree from Harvard Medical School and an undergraduate degree in biology from Princeton University. He completed clinical training in internal medicine and neurology at Massachusetts General Hospital as well as a fellowship in genetics at Harvard.



Richard 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.



Josephine Briggs, M.D. National Center for Complementary and Alternative Medicine

An accomplished researcher and physician, Dr. Briggs received her A.B. in biology from Harvard-Radcliffe College and her M.D. from Harvard Medical School. Previous to her appointment at NCCAM, she was director of the Division of Kidney, Urologic, and Hematologic Diseases at the NIH National Institute of Diabetes and Digestive and Kidney Diseases. In 2006, Dr. Briggs became Senior Scientific Officer

at the Howard Hughes Medical Institute. In January 2008, she returned to NIH as the NCCAM Director.

ASCP Featured Speakers

Regulatory Wrap-Up
Thursday, June 19, 2014 from 10:15 am – 11:45 am

Ni Khin, M.D. Food and Drug Administration See previous bio

Celia Winchell, M.D.
Food and Drug Administration
See previous bio

Silvana Borges, M.D.
Food and Drug Administration
See previous bio



Phillip Kronstein, M.D. Food and Drug Administration, CDER

Phillip Kronstein, M.D., is a Senior Medical Officer in the Division of Psychiatry Products (DPP) at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). In this position, Dr. Kronstein manages clinical reviews of Investigational New Drugs (INDs) and New Drug Applications (NDAs). Prior to joining the FDA in January 2008, he was a Clinical Research Fellow in the Experimental Therapeutics and

Pathophysiology Branch at the National Institute of Mental Health, where he conducted trials in treatment-resistant depression and bipolar disorder. He received a Bachelor's of Science in Chemistry from the University of Chicago in 1995 and a Doctor of Medicine from Tufts University School of Medicine in 2001. He completed his residency training in Psychiatry at the Johns Hopkins Hospital in June 2005. In addition to his review responsibilities at the FDA, Dr. Kronstein has been involved in regulatory research, looking at sexual dysfunction with antidepressants. He is also the Division Data Standards Lead for DPP as CDER, as part of a larger FDA initiative, continues to develop and implement standards to represent study data submitted in support of regulatory applications.

Acknowledgements

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Michael E. Thase, M.D.

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- ★ Kimberly Yonkers, M.D. Yale School of Medicine
- ★ Carlos A. Zarate, M.D. National Institute of Mental Health

New Investigator Award Committee

- ★ Christoph U. Correll, M.D. The Zucker Hillside Hospital
- ★ 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

Lauren D. Hill, Ph.D.

National Institute of Mental Health

Bruce Kinon, M.D.

Eli Lilly & Company

Ivan Montoya, M.D., MPH National Institute on Drug Abuse

- ★ Katharine Phillips, M.D. Rhode Island Hospital/Brown University
- Mark H. Rapaport, M.D. Emory University School of Medicine (ASCP Board Member)

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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Joseph Goldberg, M.D.
 Mount Sinai School of Medicine

John Kane, M.D. The Zucker Hillside Hospital

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Meeting Announcements | ASCP

Meeting Services

Registration Desk Hours:

 Sunday
 10:00 am - 5:00 pm

 Monday
 7:30 am - 6:30 pm

 Tuesday
 7:30 am - 6:45 pm

 Wednesday
 7:30 am - 6:00 pm

 Thursday
 7:30 am - 12:00 pm

*The registration/meeting information desk is located at the main entrance of the Grand Ballroom.

The Computer Center is open on the below dates and times for attendees to briefly check emails. The Computer Center is located in the Foyer of Diplomat 1-2. Hours:

 Sunday
 12:00 pm - 5:00 pm

 Monday
 8:00 am - 6:00 pm

 Tuesday - Wednesday
 7:30 am - 6:30 pm

 Thursday
 7:30 am - 12:00 pm

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 upload their slides 24 hours prior to their scheduled presentation time</u>.

The Speaker Ready Room is located in Diplomat 3. Hours:

 Sunday
 12:00 pm - 5:00 pm

 Monday
 8:00 am - 6:00 pm

 Tuesday - Wednesday
 7:30 am - 6:30 pm

 Thursday
 7:30 am - 12:00 pm

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

Job Announcements may be posted on a message board at the ASCP registration desk.

Discounts – All ASCP Annual Meeting attendees who booked their room at the Westin Diplomat through the ASCP meeting website will have the following resort amenities.

- · Access to Standard high-speed internet in the guest rooms for \$6 per day
- Fitness Center admittance
- Daily newspaper
- In-room coffee and tea

ASCP Meeting Announcements

Continuing Education Credits

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

Continuing Education Credits are available for physicians, pharmacists, psychologists and social workers. Applications for credit must be completed online with the meeting evaluation survey. The survey may be completed in the ASCP Computer Center in the Foyer of Diplomat 1-2 or after the conference at www.ASCPMeeting.org. Surveys for continuing education credit must be submitted no later than July 18, 2014. 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



The American Society for Clinical Psychopharmacology (ASCP) designates this live meeting for a maximum of 21.5 AMA PRA

Category 1 Credit(s)TM. 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 21.5 contact hours. Universal program number is as follows:

0230-9999-14-0130-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 AS

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 21.5 CE credits. Full attendance of the live activity is

required. Partial credit will not be awarded.

Social Workers



USF Health is an approved provider (BAP #433 – exp. 3/31/15) of continuing education credits for clinical social work, marriage and family therapy, and mental health counseling. This program has been reviewed and approved for 25.8 credit hours, 50-minute contact hours.

All participants who request continuing education credits by July 18, 2014, should expect to receive their statement of credits via email in late August.

The Meeting Evaluation Survey will be available at www.ASCPMeeting.org. 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 2014 meeting is appreciated as we strive to improve the meeting each year.

ASCP Meeting Support – The 2014 ASCP Annual Meeting received support from Otsuka Pharmaceuticals, NA for support of the New Investigator Program.

2015 ASCP Annual Meeting

The 2015 ASCP Annual Meeting will take place June 22-25, 2015 at the Loews Miami Beach Hotel in Miami, Florida. Details regarding abstract submission for the 2015 Meeting will be released in September, 2014.

ASCP |

Notes

Sunday, June 15, 2014 | ASCP

8:30am – 4:30pm New Investigator Workshop (Invitation Only)

Regency 1

Co-Chairs: Mark H. Rapaport, M.D., Emory University School of Medicine

Lauren D. Hill, 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. In addition, they will receive a travel expense award and a certificate acknowledging their participation in the program at an award ceremony on Monday evening, June 16, 2014. This year's 20 New Investigator awardees are indicated with a ribbon in the poster section of this program.

Faculty

Mark Bunker, Pharm.D.

Cyberonics, Inc.

Christoph U. Correll, M.D. The Zucker Hillside Hospital

Lori Davis, M.D.

Tuscaloosa VA Medical Center

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

and Alcoholism

Lauren Hill, Ph.D. – Chair National Institute of Mental Health Katharine Phillips, M.D.

Rhode Island Hospital/Brown University

A. John Rush, M.D.

Duke-National University of Singapore

Nina R. Schooler, Ph.D.

State University of New York, Downstate Medical Center

Holly Swartz, M.D.

University of Pittsburgh School of

Medicine

Tiffany Farchione, M.D.

Food and Drug Administration

Special thanks to the ASCP New Investigator Program supporters:

- Otsuka Pharmaceuticals, Inc.
- Pharmaceutical Product Development (PPD)

ASCP | Sunday, June 15, 2014

2014 New Investigator Awardees

Eric Achytes, M.D., M.S.

Michigan State University College of Human Medicine

Ana Andreazza, Ph.D.

University of Toronto, Departments of Pharmacology and Psychiatry

Shinichiro Nakajima, M.D., Ph.D.

Centre for Addiction and Mental Health

Chaya Bhuvaneswaran, M.D., MPH

Department of Psychiatry, University of Massachusetts-Worcester

Kyle Burghardt, Pharm.D.

University of Michigan College of Pharmacv

Joan Camprodon, M.D., Ph.D., MPH

Massachusetts General Hospital, Harvard Medical School

Michael Davis, M.D., Ph.D.

VA Greater Los Angeles; University of California Los Angeles

Stephanie Duhoux, Ph.D.

Icahn School of Medicine at Mount Sinai

Jennifer Felger, Ph.D.

Emory University School of Medicine

Philip Gerretsen, M.D., MSW

Centre for Addiction and Mental Health

Aaron Koenig, M.D.

Western Psychiatric Institute & Clinic

Kamilla Miskowiak, Ph.D.

Psychiatric Center Copenhagen, Copenhagen University Hospital

Mark Niciu, M.D., Ph.D.

National Institutes of Health (NIH)/ National Institute of Mental Health (NIMH)

Hidehiro Oshibuchi, M.D., Ph.D.

Department of Psychiatry, University of California, San Francisco

M. Mercedes Perez-Rodriguez, M.D., Ph.D.

Icahn School of Medicine at Mount Sinai and MIRECC at James J Peters VAMC

Donna Roybal, M.D.

University of Texas Health Sciences Center at San Antonio

Diana Simeonova, Dipl. Psych., Ph.D.

Emory University School of Medicine

Nhi-Ha Trinh, M.D., MPH

Depression Clinical and Research Program, Massachusetts General Hospital

Gwyneth Zai, M.D., FRCPC, MSc

Neurogenetics Section and Department of Psychiatry, Centre for Addiction and Mental Health, University of Toronto

Clement Zai, Ph.D.

Centre for Addiction and Mental Health

Monday, June 16, 2014 | ASCP

AT-A-GLANGE

Monday, June 16, 2014

7:30am – 8:30am NIA Breakfast Roundtable (Invitation only)

Room 216

8:30am – 9:00am Conference Opening

Grand Ballroom

9:00am – 10:30am Panel Sessions

*Recognizing and Treating Catatonia across the Diagnostic Spectrum: The Impact of New DSM-5 Classification	Risks Posed by Duplicate or Inappropriate Subjects in Clinical Trials and Methods for Mitigating the Risk	Research Forum: Meditative Practices, Underlying Neurobiological Mechanisms, and Application to Mental Health	*Biological Approaches To Treat Substances Use Disorders
Location:	Location:	Location:	Location:
Diplomat 1-2	Atlantic 1	Atlantic 2	Atlantic 3

10:30am – 10:45am **Break**

Ballroom Foyers

10:45am – 12:15pm **Panel Sessions**

NIAAA Sponsored ACTIVE Update: Missing Data in Alcohol Use Disorder Clinical Trials - Issues and Analytic Methods	*Novel Treatments in Bipolar Disorder: Primary and Secondary Targets	Dimensional Symptom and Disability Measures in DSM-5	*Weighing In on Relative Risks of Fetal Exposure to Psychotropics and Psychiatric Disorders
Location:	Location:	Location:	Location:
Diplomat 1-2	Atlantic 1	Atlantic 2	Atlantic 3

ASCP | Monday, June 16, 2014

12:15pm – 2:00pm **Lunch On Own**

1:00pm – 2:00pm First Time Attendee Meet & Greet

Atlantic 1

2:00pm – 4:00pm Pharmaceutical Pipeline Presentations

Grand Ballroom

4:00pm – 4:15pm **Break**

Ballroom Foyers

4:15pm – 5:45pm Panel Sessions

Placebo Response, Response Variance and Antidepressant- placebo Differences in Recent Antidepressant Clinical Trials based on Three Patient Interview Models	*Bipolar CHOICE (Clinical Health Outcomes Initiative in Comparative Effectiveness): A Pragmatic Trial of Lithium vs. a Second Generation Antipsychotic for Bipolar Disorder	*NIAAA Panel Session: Advances in Treatments for PTSD and Alcohol Comorbidity	Novel and Underutilized Strategies to Improve Adherence and Reduce Relapse Risk in Schizophrenia
Location:	Location:	Location:	Location:
Diplomat 1-2	Atlantic 1	Atlantic 2	Atlantic 3

6:15pm – 7:45pm New Investigators' Award Ceremony & Reception (Invitation only)

Diplomat 4-5

Monday, June 16, 2014 | ASCP

FULL SCHEDULE

Monday, June 16, 2014

7:30am – 8:30am NIA Breakfast Roundtable (Invitation only)

Room 216

8:30am – 9:00am Conference Opening

Grand Ballroom

Panel Sessions

9:00am – 10:30am *Recognizing and Treating Catatonia across the

Diagnostic Spectrum: The Impact of New DSM-5

Classification

Diplomat 1-2

Chair & Discussant: Georgios Petrides, The Zucker Hillside Hospital

9:00am – 9:10am Introduction

9:10am – 9:30am Catatonia: Video Workshop on Recognition and

Management

Andrew Francis, SUNY Stony Brook

9:30am – 9:50am Pediatric Catatonia: Review and New Vagal Theory

Dirk M. Dhossche, University of Mississippi Medical

Center

9:50am – 10:10am Longitudinal Assessment of the Psychomotor

Dimension in Psychosis: Implications for

Treatment

Stanley N. Caroff, Philadelphia VA Medical Center/

University of Pennsylvania

10:10am – 10:30am **Discussion**

ASCP | Monday, June 16, 2014

9:00am – 10:30am

Risks Posed by Duplicate or Inappropriate
Subjects in Clinical Trials and Methods for
Mitigating the Risk

Atlantic 1

Chair: Jonathan Rabinowitz, Bar Ilan University **Discussant:** Janet Williams, MedAvante, Inc.

9:00am – 9:10am	Introduction
9:10am – 9:30am	Evidence and Risks of Duplicate Subjects in Clinical Trials and How You Can Minimize the Risk Jonathan Rabinowitz, Bar Ilan University
9:30am – 9:50am	The Professional Patient 'Spectrum' or Simply Inappropriate Patients: 50 Shades of Grey in Protocol Non-adherence Michael Detke, Indiana University
9:50am – 10:10am	Proven Strategies to Mitigate the Risk of Enrolling Professional Subjects in Large Depression Studies Brooke Geibel, Shire
10:10am – 10:30am	Discussion
9:00am – 10:30am	Research Forum: Meditative Practices, Underlying Neurobiological Mechanisms, and Application to Mental Health Atlantic 2

Chair: Emmeline Edwards, NIH/NCCAM Co-chair: Kristen Huntley, NIH/NCCAM Discussant: David Shurtleff, NIH/NCCAM

9:00am – 9:10am	Introduction
9:10am – 9:30am	Neuroimaging as a Tool for the Study of Meditation Kelvin O. Lim, University of Minnesota
9:30am – 9:50am	What is Known about the Effectiveness of Meditative Approaches for Resilience and Cognitive Enhancement? Amishi Jha, University of Miami

Monday, June 16, 2014 ASCP

9:00am - 10:30am (continued)	Research Forum: Meditative Practices, Underlying Neurobiological Mechanisms, and Application to Mental Health Atlantic 2
9:50am – 10:10am	Innovation and Opportunities in Neuroscientific Research on Meditation Richard J. Davidson, University of Wisconsin
10:10am – 10:30am	Discussion
9:00am – 10:30am	*Biological Approaches to Treat Substances Use Disorders Atlantic 3

Chair: Phil Skolnick, NIDA/NIH Discussant: Raye Litten, NIAAA

9:00am – 9:10am	Introduction
9:10am – 9:25am	Genetically Engineered Butyrylcholinesterase (TV-1380): An Innovative Approach to Treat Cocaine Dependence Phil Skolnick, NIDA/NIH
9:25am – 9:40am	Use of Functional Assays to Develop a Novel Anti- nicotine Vaccine Heather L. Davis, Pfizer Vaccine Immunotherapeutics
9:40am – 9:55am	Development of a Heroin Vaccine Gary R. Matyas, Walter Reed Army Institute of Research
9:55am – 10:10am	Continuing Towards Gene Transfer of Modified Human Butyrylcholinesterase to Treat Cocaine Addiction Stephen Brimijoin, Mayo Clinic
10:10am – 10:30am	Discussion
10:30am – 10:45am	Break Ballroom Foyers

ASCP | Monday, June 16, 2014

Panel Sessions

10:45am – 12:15pm NIAAA Sponsored ACTIVE Update: Missing Data in Alcohol Use Disorder Clinical Trials - Issues and Analytic Methods

Diplomat 1-2

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

Discussant: Hayo Z. Enton, Nizva		
10:45am – 10:55am	Introduction	
10:55am – 11:10am	Overview of the ACTIVE Workgroup and Mission and Importance of Missing Drinking Data in Alcohol Use Disorder Trials Raymond F. Anton, Medical University of South Carolina	
11:10am – 11:25am	How Does Drinking Change When People Stop Taking Medicines During a Clinical Trial? Implications for Missing Drinking Data Reduction and Imputation Robert L. Stout, Pacific Institute for Research and Evaluation	
11:25am – 11:40am	The Use of Pattern Mixture Models for Imputation and Analysis of Missing Drinking Data in Nalmfene Trials for Alcohol Dependence During Regulatory Approval in Europe Per Sorensen, H. Lundbeck A/S	
11:40am – 11:55am	Validity of Various Missing Drinking Data Imputation Methods – Results from Re-analysis of the US COMBINE Study Katie Witkiewitz, University of New Mexico	
11:55am – 12:15pm	Discussion	

Monday, June 16, 2014

10:45am - 12:15pm *Novel Treatments in Bipolar Disorder: Primary and **Secondary Targets** Atlantic 1

Chair: Katherine Burdick, Mount Sinai School of Medicine Discussant: Terence Ketter, Stanford University School of Medicine

10:45am – 10:55am	Introduction
10:55am – 11:10am	Methodological Considerations in the Design and Conduct of Acute Adjunctive Bipolar Depression Treatment Trials Joseph R. Calabrese, Case Western Reserve School of Medicine
11:10am – 11:25am	Effect of Lurasidone on Cognitive Impairment: From the Lab to the Clinic Andrei Pikalov, Sunovion Pharmaceuticals, Inc.
11:25am – 11:40am	Methodological Challenges to Cognitive Trials in Bipolar Disorder Katherine Burdick, Mount Sinai School of Medicine
11:40am – 11:55am	Interaction Effects between Affective Symptoms and Cognitive Function in Bipolar Disorder Clinical Trials Joseph F. Goldberg, Icahn School of Medicine at Mount Sinai
11:55am – 12:15pm	Discussion
10:45am – 12:15pm	Dimensional Symptom and Disability Measures in DSM-5 Atlantic 2

Chair: William Narrow, American Psychiatric Association

Discussant: Lori Davis, Tuscaloosa VA Medical Center and University of

Alabama School of Medicine

10:45am - 10:55am Introduction **DSM-5 Cross-cutting Dimensional Measures:** 10:55am - 11:15am Reliability, Sensitivity to Change, and Association with Disability Diana E. Clarke, American Psychiatric Association *of special interest to clinicians

ASCP Monday, June 16, 2014

10:45am - 12:15pm (continued)	Dimensional Symptom and Disability Measures in DSM-5 Atlantic 2
11:15am – 11:35am	DSM-5 Dimensional Symptom and Disability Measures in Routine Clinical Practice Settings Eve K. Mościcki, American Psychiatric Association
11:35am – 11:55am	The World Health Organization Disability Assessment Schedule in the DSM-5 Field Trials: Associations with Psychiatric Diagnosis William Narrow, American Psychiatric Association
11:55am – 12:15pm	Discussion
10:45am – 12:15pm	*Weighing In on Relative Risks of Fetal Exposure to Psychotropics and Psychiatric Disorders Atlantic 3

Chair: Lee S. Cohen, Massachusetts General Hospital
Co-chair & Discussant: Marlene Freeman, Massachusetts General Hospital

10:45am - 10:55am	Introduction
10:55am – 11:15am	The National Pregnancy Registry for Atypical Antipsychotics: Effects of Fetal Exposure on Risk for Congenital Malformations and Maternal and Newborn Outcomes Lee S. Cohen, Massachusetts General Hospital
11:15am – 11:35am	Prenatal Exposure to SSRIs: Sorting the Ever- growing Data Sonia Hernandez-Diaz, Harvard School of Public Health
11:35am – 11:55am	Impact of Maternal Psychiatric Illness on Fetal, Obstetrical and Neonatal Wellbeing Margaret Altemus, Weill Medical College, Cornell University
11:55am - 12:15pm	Discussion
12:15pm – 2:00pm	Lunch On Own
1:00pm – 2:00pm	First Time Attendee Meet & Greet Atlantic 1

*of special interest to clinicians

Monday, June 16, 2014 ASCP

2:00pm – 4:00pm	Pharmaceutical Pipeline Presentations <i>Grand Ballroom</i>		
Chair: Carlos Zarate, National Institute of Mental Health			
2:00pm – 2:10pm	A Pilot Study of a Novel Monoamine Triple Reuptake Inhibitor EB-1020 SR in the Treatment of ADHD in Adults Timothy Wilens, Massachusetts General Hospital		
2:10pm – 2:20pm	Metadoxine Extended Release (MDX): A Novel Drug Candidate for the Treatment of ADHD & Other Cognitive Disorders Jonathan Rubin, Alcobra Pharma		
2:20pm – 2:30pm	A Rapidly Acting Intranasal Treatment for the Symptoms of GAD Michael R. Liebowitz, Pherin Pharmaceuticals		
2:30pm – 2:40pm	Lupron in Combination with an Acetylcholinesterase Inhibitor Halts Cognitive Decline in Women with Alzheimer's Disease over a 48 Week Period Richard Bowen, OTB Research		
2:40pm – 2:50pm	Efficacy and Safety of a Novel mGlu2 Receptor Positive Allosteric Modulator as an Adjunctive Treatment to an SSRI/SNRI in the Treatment of Anxious Depression Justine Kent, Janssen		
2:50pm – 3:00pm	A Double-blind, Randomized, Placebo-controlled, Parallel Group, Dose Frequency Study of Intravenous Ketamine in Patients with Treatment- resistant Depression Jaskaran Singh, Janssen Research and Development, LLC		
3:00pm – 3:10pm	Randomized, Double-blind, Active-controlled, Phase 2/3 Study to Determine the Short-term (6-Week) and Long-term (6 Month) Cognitive and Anti-psychotic Efficacy, Safety and Tolerability of CYP-1020 Compared to Risperidone Jonathan Rabinowitz, Bar Ilan University		

ASCP | Monday, June 16, 2014

2:00pm - 4:00pm (continued)	Pharmaceutical Pipeline Presentations Grand Ballroom	
3:10pm – 3:20pm	Results of a Phase 2B Clinical Trial of TC-5619, a Selective Alpha 7 Neuronal Nicotinic Receptor (NNR) Agonist in the Adjunctive Treatment of Negative Symptoms and Cognitive Dysfunction in Schizophrenia David Hosford, Targacept, Inc.	
3:20pm – 3:30pm	AZD8529, a Positive Allosteric Modulator of the mGluR2 Receptor for the Treatment of Schizophrenia Alan Cross, AstraZeneca Neuroscience Innovative Medicines Unit	
3:30pm – 3:40pm	Advancing ITI-007: A Novel Product Candidate for the Treatment of Schizophrenia, Bipolar Disorder and Other Neuropsychiatric Indications Kimberly E. Vanover, Intra-Cellular Therapies, Inc.	
4:00pm – 4:15pm	Break Ballroom Foyers	
Panel Sessions		
4:15pm – 5:45pm	Placebo Response, Response Variance and Antidepressant-placebo Differences in Recent Antidepressant Clinical Trials Based on Three Patient Interview Models Diplomat 1-2	
Chair: Arif Khan, Northwest Clinical Research Center Discussant: Walter Brown, Brown University		
4:15pm – 4:25pm	Introduction	
4:25pm – 4:45pm	Examining the Utility and Futility of Surveillance Strategies for CNS Trials Steven D. Targum, Clintara, LLC	

Monday, June 16, 2014 ASCP

4:15pm – 5:45pm (continued)	Placebo Response, Response Variance and Antidepressant-placebo Differences in Recent Antidepressant Clinical Trials Based on Three Patient Interview Models Diplomat 1-2
4:45pm – 5:05pm	The Use of Blinded, Independent, Remote Ratings in Psychiatric Clinical Trials: The Good, the Bad, and the Appropriate Situation Michael Detke, Indiana University
5:05pm – 5:25pm	Magnitude of Placebo Response and Response Variance in Antidepressant Clinical Trials using Enhanced Interviews Techniques Compared to Traditional Rating Interviews Arif Khan, Northwest Clinical Research Center
5:25pm – 5:45pm	Discussion
4:15pm – 5:45pm	*Bipolar CHOICE (Clinical Health Outcomes Initiative in Comparative Effectiveness): A Pragmatic Trial of Lithium vs. a Second Generation Antipsychotic for Bipolar Disorder Atlantic 1

Chair: Terence Ketter, Stanford University School of Medicine **Co-chair:** Andrew Nierenberg, Massachusetts General Hospital **Discussant:** Mauricio Tohen, University of New Mexico

Introduction

1.1 Epps 1.0 Epps

4:15pm – 4:25pm	Introduction
4:25pm – 4:45pm	Bipolar CHOICE (Clinical Health Outcomes Initiative in Comparative Effectiveness): Rationale, Design, and Demographics Edward S. Friedman, University of Pittsburgh School of Medicine
4:45pm – 5:05pm	Bipolar CHOICE (Clinical Health Outcomes Initiative in Comparative Effectiveness) Andrew Nierenberg, Massachusetts General Hospital

ASCP Monday, June 16, 2014

4:15pm – 5:45pm (continued)	*Bipolar CHOICE (Clinical Health Outcomes Initiative in Comparative Effectiveness): A Pragmatic Trial of Lithium vs. a Second Generation Antipsychotic for Bipolar Disorder Atlantic 1
5:05pm – 5:25pm	Bipolar CHOICE Safety and Tolerability Outcomes: Focus on Obesity and Cardiometabolic Health David Kemp, Case Western Reserve University
5:25pm – 5:45pm	Discussion
4:15pm – 5:45pm	*NIAAA Panel Session: Advances in Treatments for PTSD and Alcohol Comorbidity Atlantic 2

Chair: Raye Z. Litten, NIAAA

Co-chair: Ismene L. Petrakis, Yale University School of Medicine

Discussant: Raye Z. Litten, NIAAA

4:15pm – 4:25pm	Introduction
4:25pm – 4:45pm	Pharmacotherapy of Patients with Post Traumatic Stress Disorder (PTSD) and Comorbid Alcohol Use Disorders among Veterans Ismene L. Petrakis, Yale University School of Medicine
4:45pm – 5:05pm	Prazosin for Comorbid PTSD and Alcohol Dependence: A Pilot Randomized Clinical Trial Tracy Simpson, VA Puget Sound Health Care System
5:05pm – 5:25pm	Effective Treatment Strategies for Patients with Concurrent PTSD and Addiction David Oslin, University of Pennsylvania
5:25pm – 5:45pm	Discussion

Monday, June 16, 2014 | ASCP

4:15pm – 5:45pm

Novel and Underutilized Strategies to Improve
Adherence and Reduce Relapse Risk in
Schizophrenia
Atlantic 3

Chair: Christoph Correll, The Zucker Hillside Hospital **Discussant:** Nina R. Schooler, SUNY Downstate Medical Center

4:15pm – 4:25pm	Introduction
4:25pm – 4:40pm	Response, Remission and Recovery in Schizophrenia John M. Kane, The Zucker Hillside Hospital
4:40pm – 4:55pm	Effect of Trial Design, Population and Illness Phase on the Role of Long-acting Injectable Antipsychotics for Signaling and Preventing Non-adherence in Schizophrenia Christoph Correll, The Zucker Hillside Hospital
4:55pm – 5:10pm	Leveraging Novel Technologies to Enhance Adherence Adam Hanina, Ai Cure Technologies
5:10pm – 5:25pm	Technology-based Approaches for the Detection and Prevention of Relapse in Schizophrenia Dror Ben-Zeev, Dartmouth College
5:25pm – 5:45pm	Discussion
6:15pm – 7:45pm	New Investigators' Award Ceremony & Reception (Invitation only) Diplomat 4-5

ASCP |

Notes

Tuesday, June 17, 2014 | ASCF

AT-A-GLANCE

Tuesday, June 17, 2014

6:45am – 8:00am	15th Annual Fun Run/Walk Meet in Main Lobby
7:00am – 8:30am	ASCP Board Meeting (Invitation only) Room 217
7:30am – 8:30am	NIA Breakfast Roundtable (Invitation only) Room 216
7:30am – 9:00am	Morning Break Ballroom Foyers
8:30am – 10:00am	Regulatory Plenary: FDA Science Initiatives: A Brief Update Grand Ballroom
10:00am – 10:15am	Break Ballroom Foyers
10:15am – 11:15am	ASCP Lifetime Awardee Presentation – A. John Rush: Bridging the Chasm between Research and Practice Grand Ballroom
11:15am – 1:00pm	Poster Session I with Lunch Regency Ballroom
1:15pm – 2:45pm	Panel Sessions

*Overcoming the Shortcomings of Treatment Practice Guidelines for Mood and Psychotic Disorders	NIMH/NCCAM Panel: Conducting Pragmatic Trials in Mental Health: Lessons Learned from the NIH Health Care Systems Research Collaboratory	Inflammation and Insulin Resistance: Implications for Pathophysiology and Treatment	*Long Acting Injectable Antipsychotics: Perspectives on their Role in Schizophrenia Treatment
Location:	Location:	Location:	Location:
Diplomat 1-2	Atlantic 1	Atlantic 2	Atlantic 3

ASCP | Tuesday, June 17, 2014

2:45pm – 3:15pm ASCP Business Meeting (ASCP Members Only)

Grand Ballroom

3:15pm – 3:30pm **Break**

Ballroom Foyers

3:30pm – 4:30pm Individual Research Reports

Anxiety Disorder Presentations	Depression Presentations	Schizophrenia and Bipolar Disorder Presentations	Statistical Methods, Personality Disorders, Substance Abuse, and Comorbidity Presentations
Location:	Location:	Location:	Location:
Diplomat 1-2	Atlantic 1	Atlantic 2	Atlantic 3

4:30pm – 4:45pm **Break**

Ballroom Foyers

4:45pm – 6:45pm **Workshops**

Cognitive Deficits in Depression: What are They? Are They Independent Dimensions? Are They Targets for Treatment?	*Psychopharmacology of Residual Symptoms in Mood Disorders and Schizophrenia	New Approaches to Funding Clinical Trials at NIMH
Location: Atlantic 1	Location: Atlantic 2	Location: Atlantic 3

7:00pm – 8:00pm ASCP Reception

South Palm Court

9:00pm – 12:00am Black & White Affair, hosted by Zane Courbay

Room 3641

Tuesday, June 17, 2014 | ASCP

FULL SCHEDULE

Tuesday, June 17, 2014

6:45am – 8:00am 15th Annual Fun Run/Walk

Meet in Main Lobby

7:00am – 8:30am ASCP Board Meeting (Invitation only)

Room 217

7:30am – 8:30am NIA Breakfast Roundtable (Invitation only)

Room 216

7:30am – 9:00am Morning Break

Ballroom Foyers

8:30am – 10:00am Regulatory Plenary: FDA Science Initiatives:

A Brief Update

Grand Ballroom

Chair: Ni A. Khin, M.D., U.S. Food and Drug Administration

This session will provide updates on regulatory initiatives from the US Food and Drug Administration (FDA). Dr. Ni Khin will give a brief overview of the joint FDA initiative with European Medicines Agency (EMA) to ensure data quality in clinical trials and good clinical practice compliance. Dr. Celia Winchell from FDA's Division of Anesthesia and Analgesia Products (DAAP) will discuss the challenges of determining efficacy endpoints in clinical trials for addiction treatment drugs. Specifically, she will discuss how DAAP identified a pattern of alcohol use as an alternative endpoint to complete abstinence based on recent analyses of data. Dr. Silvana Borges from FDA's Division of Psychiatry Products will present preliminary findings regarding use of active controls in depression trials. There will be an informal discussion with the audience on these selected topics as well as other regulatory issues of common interest within this context.

8:30am – 8:45am Ni A. Khin, M.D., Food and Drug Administration

8:45am – 9:05am Celia Winchell, M.D., Food and Drug Administration

9:05am – 9:25am Silvana Borges, M.D., Food and Drug Administration

9:25am – 10:00am Panel Discussion and Q&A

Tuesday, June 17, 2014

10:00am - 10:15am Break

Ballroom Fovers

10:15am - 11:15am

ASCP Lifetime Awardee Presentation – A. John Rush: Bridging the Chasm between Research and Practice Grand Ballroom

Patient centered research and comparative effectiveness research address practical issues that aim at addressing patients' concerns or choices among treatments, respectively. In addition to these important objectives, clinicians need to better understand how to deliver each treatment: to whom to deliver (or not) particular treatments; when to discontinue, switch, or augment a specific treatment; and for whom which specific treatment sequences are indicated. This presentation discusses practical, simple, efficient research design, measurement and analytic options, that could address these important clinical knowledge gaps with the aim of improving patient outcomes and treatment cost efficiencies.

11:15am - 1:00pm

Poster Session I with Lunch Regency Ballroom

*See Pages 69 through 80 for poster listing.

Panel Sessions

1:15pm - 2:45pm

*Overcoming the Shortcomings of Treatment **Practice Guidelines for Mood and Psychotic Disorders** Diplomat 1-2

Chair: Joseph F. Goldberg, Icahn School of Medicine at Mount Sinai Discussant: Michael E. Thase, Perelman School of Medicine of the University of Pennsylvania

1:15pm – 1:25pm Introduction

1:25pm – 1:45pm **Practice Guidelines for Bipolar Disorder: What's**

Useful, What's Not, and What's Missing

Joseph F. Goldberg, Icahn School of Medicine at Mount Sinai

*of special interest to clinicians

Tuesday, June 17, 2014 ASCF

1:15pm – 2:45pm (continued)	*Overcoming the Shortcomings of Treatment Practice Guidelines for Mood and Psychotic Disorders Diplomat 1-2
1:45pm – 2:05pm	Treatment Guidelines for MDD: Evidence-based, Eminence-based, or Faith-based? Alan J. Gelenberg, Penn State College of Medicine
2:05pm – 2:25pm	Practice Guidelines for Treatment of Schizophrenia: Consensus or Confusion? Peter J. Weiden, UIC Medical Center
2:25pm – 2:45pm	Discussion
1:15pm – 2:45pm	NIMH/NCCAM Panel: Conducting Pragmatic Trials in Mental Health: Lessons Learned from the NIH Health Care Systems Research Collaboratory Atlantic 1

Chair & Discussant: Emmeline Edwards, NIH, NCCAM

Co-chair: Wendy Weber, NIH, NCCAM

1:15pm – 1:25pm	Introduction
1:25pm – 1:45pm	Conducting Pragmatic Trials in Mental Health: Lessons Learned from the NIH Health Care Systems Research Collaboratory Wendy Weber, NIH, NCCAM
1:45pm – 2:05pm	Pragmatic Trial of Population-based Program to Prevent Suicide Attempts Greg Simon, Group Health Research Institute
2:05pm – 2:25pm	NIMH/NCCAM Panel: Conducting Pragmatic Trials in Mental Health: Lessons Learned from the NIH Health Care Systems Research Collaboratory Liz Delong, Duke University Medical Center
2:25pm – 2:45pm	Discussion

ASCP | Tuesday, June 17, 2014

1:15pm – 2:45pm Inflammation and Insulin Resistance: Implications for Pathophysiology and Treatment

Atlantic 2

Chair: David Kemp, Case Western Reserve University Discussant: Madhukar Trivedi, UT Southwestern

1:15pm – 1:20pm	Introduction
1:20pm – 1:35pm	PPAR-γ Agonism as a Modulator of Mood: Proof- of-concept for Pioglitazone in Bipolar Depression David Kemp, Case Western Reserve University
1:35pm – 1:50pm	Association between Kynurenine-pathway Metabolites and Gray Matter Volumes of the Hippocampus and Amygdala in Patients with Mood Disorders Jonathan Savitz, Laureate Institute for Brain Research
1:50pm – 2:05pm	Trait and State Patterns of Inflammatory Biomarkers in Bipolar Disorder Jess G. Fiedorowicz, University of Iowa
2:05pm – 2:20pm	Biomarkers of Illness Activity in Bipolar Disorder Flavio Kapczinski, Federal University of Rio Grande do Sul
2:20pm – 2:45pm	Discussion
1:15pm – 2:45pm	*Long Acting Injectable Antipsychotics: Perspectives on their Role in Schizophrenia Treatment Atlantic 3

Chair: Nina R. Schooler, SUNY Downstate Medical Center **Discussant:** John M. Kane, The Zucker Hillside Hospital

1:15pm – 1:25pm

Long Acting Injectable vs. Oral Antipsychotics for Schizophrenia: Meta-analytic Consideration of the True Effect Size by the Study Designs
Taishiro Kishimoto, Keio University School of Medicine, Department of Psychiatry

*of special interest to clinicians

Tuesday, June 17, 2014 ASCP

1:15pm – 2:45pm (continued)	*Long Acting Injectable Antipsychotics: Perspectives on their Role in Schizophrenia Treatment Atlantic 3
1:45pm – 2:05pm	PROACTIVE: Exploring Longitudinal Course to Understand Treatment Outcomes in LAI - oral Comparisons Nina R. Schooler, SUNY Downstate Medical Center
2:05pm – 2:25pm	A Comparison of Long-acting Antipsychotic Medications for Schizophrenia (ACLAIMS) Joseph P. McEvoy, Georgia Regents University
2:25pm – 2:45pm	Discussion
2:45pm – 3:15pm	ASCP Business Meeting (ASCP Members Only) Grand Ballroom
3:15pm – 3:30pm	Break Ballroom Foyers

Individual Research Reports

3:30pm - 4:30pm

	Diplomat 1-2	
Chair: Crystal Clark, Northwestern University Feinberg School of Medicine Asher Center for the Study and Treatment of Depressive Disorders		
3:30pm – 3:45pm	A Rapidly Acting Intranasal Treatment for the Symptoms of GAD Michael R. Liebowitz, Pherin Pharmaceuticals	
3:45pm – 4:00pm	Comparative Effectiveness of Prolonged Exposure (PE) and Sertraline(SER) in PTSD: Final Analyses of The Impact of Choice and Treatment Preference on Acute Outcome Matig Mavissakalian, Case Western Reserve University School of Medicine	

Anxiety Disorder Presentations

ASCP Tuesday, June 17, 2014

	3:30pm - 4:30pm (continued)	Anxiety Disorder Presentations Diplomat 1-2
	4:00pm – 4:15pm	Pharmacogenetic Study of Genetic Variations across Remote Regulatory Regions of 14 Obsessive-Compulsive Disorder Candidate Genes in Antidepressant Response Gwyneth Zai, University of Toronto
	4:15pm – 4:30pm	Emotion Recognition Deficits in Treated and Untreated Adults with ADHD Anneka Tomlinson, University of Manchester
	3:30pm – 4:30pm	Depression Presentations Atlantic 1
	Chair: Bradley Gaynes,	University of North Carolina School of Medicine
	3:30pm – 3:45pm	The Efficacy of Vortioxetine in Patients with Major Depressive Disorder and High Levels of Anxiety Symptoms: A Meta-analysis David Baldwin, University of Southampton
	3:45pm – 4:00pm	Erythropoietin Induces Growth in Left Hippocampus and Improves Verbal Memory in Patients with Severe Affective Disorders Kamilla Woznica Miskowiakm, Copenhagen University Hospital
	4:00pm – 4:15pm	Epidural Cortical Stimulation of the Left DLPFC Leads to Dose-dependent Enhancement of Working Memory in Patients with MDD Joan A. Camprodon, Massachusetts General Hospital, Harvard Medical School
	4:15pm – 4:30pm	A Phase 1B, Randomized, Double-blind, Placebo- controlled, Multiple-dose Escalation Study Evaluating the Effects of NSI-189 Phosphate, a Neurogenic Compound, in Patients with Major Depressive Disorder (MDD) Marlene Freeman, Massachusetts General Hospital



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3:30pm – 4:30pm	Schizophrenia and Bipolar Disorder Presentations Atlantic 2	
Chair: Kristina Deligiannidis, University of Massachusetts Medical School/ UMass Memorial Medical Center		
3:30pm – 3:45pm	Can Oxytocin Enhance Learning during Social Cognitive Skills Training in Schizophrenia? Michael C. Davis, VA Greater Los Angeles, University of California Los Angeles	
3:45pm – 4:00pm	Hospitalization Rates in Patients Switched from Oral Antipsychotics to Aripiprazole Once-monthly: A Mirror Study Timothy Peters-Strickland, Otsuka Pharmaceutical Development & Commercialization, Inc.	
4:00pm – 4:15pm	Lithium Enhances Mitochondrial Complex I Activity and Ameliorates DNA Methylation and Hydroxymethylation Induced by Mitochondrial Complex I Dysfunction Ana Cristina Andreazza, University of Toronto	
4:15pm – 4:30pm	Varenicline for Smoking Cessation in Bipolar Disorder: A Double-blind, Randomized, Placebo- controlled Trial Roy K.N. Chengappa, University of Pittsburgh	
3:30pm – 4:30pm	Statistical Methods, Personality Disorders, Substance Abuse, and Comorbidity Presentations Atlantic 3	
Chair: Katherine Burdick, Mount Sinai School of Medicine		

Chair: Katherine Burdick, Mount Sinai School of Medicine



3:30pm – 3:45pm Brain-derived Neurotrophic Factor Genotype and Amygdala Habituation in Borderline Personality

Disorder

M. Mercedes Perez-Rodriguez, Mount Sinai School of

Medicine

3:45pm – 4:00pm Analysis and Missing Data Handling in Psychiatry

Trials with Inevitable, High, Differential and

Informative Discontinuations

Yangchun Du, Alkermes, Inc.



ASCP | Tuesday, June 17, 2014

3:30pm – 4:30pm (continued)	Statistical Methods, Personality Disorders, Substance Abuse, and Comorbidity Presentations Atlantic 3	
4:00pm – 4:15pm	Long-term Skeletal Effects of Risperidone and SSRIs in Youths Chadi Calarge, University of Iowa	
4:15pm – 4:30pm	Impulsivity and Substance Dependence: Meta- analysis and Possible Role in Treatment Saddichha Sahoo, NIMHANS	
4:30pm – 4:45pm	Break Ballroom Foyers	
<u>Workshops</u>		
4:45pm – 6:45pm	Cognitive Deficits in Depression: What are they? Are they Independent Dimensions? Are they Targets for Treatment? Atlantic 1	
Chair: Steven D. Targum, Clintara, LLC Co-chair: Craig Nelson, UCSF Discussant: Tiffany Farchione, US Food and Drug Administration		
4:45pm – 4:50pm	Introduction	
4:50pm – 5:10pm	Cognitive Impairment in Late Life Depression: Type, Frequency, and Methods of Assessment Scott Mackin, University of California, San Francisco	
5:10pm – 5:30pm	Effects of Treatment on Cognition in Late Life Depression Craig Nelson, UCSF	
5:30pm – 5:50pm	Changes in Cognitive Symptoms before and after Buspirone-melatonin Treatment for Major	

Depressive Disorder

Disorder

5:50pm – 6:10pm

Steven D. Targum, Clintara, LLC

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Changes in Cognitive Symptoms before and after Vortioxetine Treatment in Major Depressive

Maurizio Fava, Massachusetts General Hospital

Tuesday, June 17, 2014 ASCP

4:45pm – 6:45pm (continued)	Cognitive Deficits in Depression: What are they? Are they Independent Dimensions? Are they Targets for Treatment? Atlantic 1
6:10pm – 6:30pm	Deficits in Mood Disorders: Impact on Functional Outcomes and Treatment Strategies Dan V. Iosifescu, Icahn School of Medicine at Mount Sinai
6:30pm – 6:45pm	Discussion
4:45pm – 6:45pm	*Psychopharmacology of Residual Symptoms in Mood Disorders and Schizophrenia Atlantic 2

Chair: Jonathan Alpert, Massachusetts General Hospital, Harvard Medical School

Discussant: Richard Shelton, University of Alabama at Birmingham

Introduction

4·45pm – 4·50pm

4.45pm – 4.50pm	introduction
4:50pm – 5:15pm	Methodological and Design Issues in Augmentation Trials Thomas Laughren, MGH CTNI
5:15pm – 5:40pm	New Approaches to the Treatment of Residual Symptoms of Schizophrenia Donald C. Goff, NYU Medical School
5:40pm – 6:05pm	Residual Symptoms in Bipolar Disorder: The Role of Polypharmacy Joseph F. Goldberg, Icahn School of Medicine at Mount Sinai
6:05pm – 6:30pm	Studying the Efficacy of Adjunctive Therapies for Depressive Disorders Michael E. Thase, Perelman School of Medicine of the University of Pennsylvania
6:30pm – 6:45pm	Discussion

^{*}of special interest to clinicians

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4:45pm – 6:45pm New Approaches to Funding Clinical Trials at NIMH *Atlantic* 3

Chair: William Potter, National Institute of Mental Health

Discussant: David Kupfer, University of Pittsburgh School of Medicine

4:45pm – 5:00pm	Introduction
5:00pm – 5:20pm	First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders Meg Grabb, National Institute of Mental Health
5:20pm – 5:40pm	Exploratory Clinical Trials of Novel Interventions for Mental Disorders Jill Heemskerk, National Institute of Mental Health
5:40pm – 6:00pm	Pilot Effectiveness Studies and Services Research Grants Chris Sarampote, National Institute of Mental Health
6:00pm – 6:45pm	Discussion
7:00pm – 8:00pm	ASCP Reception South Palm Court

Wednesday, June 18, 2014 | ASCP

AT-A-GLANCE

Wednesday, June 18, 2014

Location: Atlantic 1

7:00am – 8:30am	ASCP Steering Committee Meeting (Invitation only) Room 308		
7:30am – 8:30am	NIA Breakfast Roundtable (Invitation only) Room 216		
7:30am – 9:00am	Morning Break Ballroom Foyers		
8:15am – 9:45am	Keynote Session: New Approaches to Mental Illness in the Era of the National Brain Initiative Grand Ballroom		
9:45am – 10:00am	Break Ballroom Foyers		
10:00am – 12:00pm	Plenary Session - NIH Institute Directors Grand Ballroom		
12:00pm – 2:00pm	Poster Session II with Lunch Regency Ballroom		
2:00pm – 3:30pm	Updates Session – The Latest on Treatment of Mood, OCD-spectrum, and Binge Eating Disorders Grand Ballroom		
3:30pm – 3:45pm	Break Ballroom Foyers		
3:45pm – 5:45pm	5pm – 5:45pm Workshops		
New Approaches to Drug Studies for Treating Social Deficits in Autism Spectrum Disorder	Action for the Treatment of Depression and Anxiety: Scientific	*Psychiatry and Technology: A Partnership in Promoting Mental Health	

Location: Atlantic 3

Location: Atlantic 2

^{*}of special interest to clinicians

ASCP |

Notes

Wednesday, June 18, 2014 | ASCP

FULL SCHEDULE

Wednesday, June 18, 2014

7:00am – 8:30am ASCP Steering Committee Meeting (Invitation only)

Room 308

7:30am – 8:30am NIA Breakfast Roundtable (Invitation only)

Room 216

7:30am – 9:00am Morning Break

Ballroom Foyers

8:15am – 9:45am Keynote Session: New Approaches to Mental

Illness in the Era of the National Brain Initiative

Grand Ballroom

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

Brain disorders are among mankind's most devastating illnesses. Worldwide, they place an enormous societal burden on those affected. Indeed, in the United States alone this burden of illness is rapidly approaching \$1 trillion annually, a number that is only likely to escalate in coming years with the aging population. In this plenary session, Drs. Manji and Insel and Mr. Kennedy will discuss interrelated facets in our search to better understand the mechanisms underlying a wide range of mental illnesses and to develop effective new treatments for them.

Rapid advances in science and technology over the past decade have provided us with an unprecedented opportunity and the tools needed to unlock the secrets of the brain. Dr. Insel will discuss the many significant advances that have recently been made towards understanding serious mental illnesses. Although public and private resources devoted to research in this area are diminishing, a host of cutting-edge approaches—from genomics to data mining, proteomics to biomarkers, pathway modeling to protein engineering, neuroimaging to optogenetics—is nevertheless revolutionizing the way we think about, study, and approach the development of urgently needed novel treatments for mental disorders, with extremely promising results.

ASCP | Wednesday, June 18, 2014

8:15am - 9:45am (continued)

Keynote Session: New Approaches to Mental Illness in the Era of the National Brain Initiative *Grand Ballroom*

Dr. Manji will discuss the paradigm shift that must accompany future research in this area. This includes not only moving from a 'diagnose and treat' approach to a 'predict and pre-empt' model, but the need to develop novel solutions that encompass meaningful and measurable patient outcomes (for instance, the ability to rapidly resume social and work responsibilities).

Mr. Kennedy will discuss the many social issues that can and must be addressed in any "whole-world" view of mental illness, including parity for mental health, ending the discrimination against patients, and the travesty of homeless and imprisoned individuals suffering from mental disorders.

The session will emphasize the speakers' commitment to a strong, united, cross-disciplinary approach towards a key common goal: to work together across industry, academia, government, and the private sector in a concerted effort to improve the lives of the millions of individuals affected by brain disorders. With such a cooperative effort, real, tangible progress can be made.

8:15am – 8:25am

Introduction

Husseini K. Manji, M.D., FRCPC, Johnson & Johnson

8:25am - 8:55am

Thomas Insel, M.D., NIMH

8:55am - 9:25am

Patrick Kennedy, Former US Representative & Mental

Health Activist

9:25am - 9:45am

Discussion

9:45am - 10:00am

Break

Ballroom Foyers

Wednesday, June 18, 2014 | ASCP

10:00am - 12:00pm

Plenary Session – NIH Institute Directors Grand Ballroom

Chair: David Kupfer, M.D., University of Pittsburgh School of Medicine

This year's Institute Director's session will bring together directors from various NIH institutes who all have a similar goal of searching for new approaches in the research of mental disorders. Each director will have ten minutes to discuss what activities are going on within their institute regarding this goal. Thomas Insel, NIMH Director, will begin the session discussing transformation of clinical trials. Phil Skolnick will discuss one of the more challenging issues that NIDA faces is the epidemic of (both prescription and non-prescription) opiate abuse. To put the problem in perspective, it has been estimated that there are 3 million Americans currently abusing opioids: more deaths result from opiate overdose than from firearms. He will overview NIDA's efforts to combat both opiate abuse and overdose deaths. Kenneth Warren of NIAAA will discuss the current framework for medications development of alcohol use disorders. Josephine Briggs will discuss NCCAM's interest in encouraging work on the neuroscience of the mind-body interface and the mechanisms by which meditative practices such as mindfulness, hypnosis, and meditative exercise forms may impact on pain processing. Christopher Austin will address NCATS' unique role in the biomedical ecosystem and the translational science problems being prioritized by NCATS. He will also give an overview of the Center's programs and collaborative opportunities. Finally, Richard Nakamura will discuss the Center for Scientific Review's steps to measure and improve the performance of peer review. The session will continue with an open dialogue Q&A session with audience interaction.

Thomas Insel, M.D., NIMH
Phil Skolnick, Ph.D., NIDA
Kenneth Warren, Ph.D., NIAAA
Josephine Briggs, M.D., NCCAM
Christopher Austin, M.D., NCATS
Richard Nakamura, Ph.D., CSR

ASCP | Wednesday, June 18, 2014

12:00pm – 2:00pm Poster Session II with Lunch

Regency Ballroom

*See Pages 81 through 92 for poster listing.

2:00pm – 3:30pm Updates Session – The Latest on Treatment of

Mood, OCD-spectrum, and Binge Eating Disorders

Grand Ballroom

Chair: Maurizio Fava, Massachusetts General Hospital

Recent advances in clinical neuroscience have led to the development of novel treatments of mood, OCDspectrum, and binge eating disorders. The purpose of this symposium is to provide an overview of the latest developments in the pharmacological treatments for these conditions. Dr. Papakostas will review new approaches to the treatment of depression, as well as to the identification of subpopulations of depressed patients more likely to benefit from a given treatment. Dr. Ketter will present an update on new therapeutic developments in the treatment of bipolar disorder, such as the approval by the FDA of asenapine, risperidone long-acting injectable (LAI), ziprasidone, aripiprazole, and lurasidone therapy for bipolar disorder. In addition, Dr. Ketter will discuss the International Society for Bipolar Disorders (ISBD) Antidepressant Use in Bipolar Disorders Task Force controversial report from 2013. Finally, Dr. Ketter will present data concerning some novel pharmacological treatments for bipolar disorder. Dr. McElroy will also provide an overview of the treatments for hoarding disorder and binge eating disorder, new discrete diagnostic entities in DSM-5. Psychological treatments are effective for both conditions, but not all patients respond and pharmacotherapy is emerging as an important treatment option. Serotonin reuptake inhibitors have been the most widely studied agents, but both conditions respond modestly at best to these compounds. Newer agents showing promise include antiepileptics and psychostimulants. Available research on the pharmacotherapy of HD and BED will be reviewed, and future directions will be discussed.

2:00pm - 2:20pm

Hoarding Disorder and Binge Eating Disorder Susan McElroy, University of Cincinnati College of Medicine

Wednesday, June 18, 2014 ASCP

2:00pm - 3:30pm (continued)	Updates Session – The Latest on Treatment of Mood, OCD-spectrum, and Binge Eating Disorders Grand Ballroom
2:20pm – 2:40pm	Update on Bipolar Disorder Pharmacotherapy Terence Ketter, Stanford University School of Medicine
2:40pm – 3:00pm	Update on Treatment of Major Depressive Disorder George I. Papakostas, Massachusetts General Hospital, Harvard Medical School
3:00pm – 3:30pm	Discussion
3:30pm – 3:45pm	Break Ballroom Foyers
Workshops	

Workshops

3:45pm – 5:45pm	New Approaches to Drug Studies for Treating
	Social Deficits in Autism Spectrum Disorder
	Atlantic 1

Chair: Meg Grabb, National Institute of Mental Health

Co-chair: Ann Wagner, NIMH/NIH

Discussant: Alessandro Bertolino, F. Hoffmann-La Roche Ltd.

3:45pm – 3:50pm	Introduction
3:50pm – 4:10pm	Measuring Social Disability in Autism Spectrum Disorder Lawrence Scahill, Emory University
4:10pm – 4:30pm	Honing in on Targets for Compound Selection in ASD Trials: The NIMH FAST-ASD Network James T. McCracken, UCLA Semel Institute
4:30pm – 4:50pm	Incorporating Potential Functional Biomarkers in Clinical Trials in ASD Bryan H. King, Seattle Children's Hospital and University of Washington
4:50pm – 5:10pm	Eye-tracking Measures of Social Disability as Outcome Measures in School-age Children with ASD Warren Jones, Marcus Autism Center
5:10pm – 5:45pm	Discussion

ASCP Wednesday, June 18, 2014

3:45pm – 5:45pm *Novel Mechanisms of Action for the Treatment of Depression and Anxiety: Scientific Updates

Atlantic 2

Chair: Timothy Petersen, Clintara, LLC

Co-chair: Jaskaran Singh, Janssen Research and Development, LLC

Discussant: Randall D. Marshall, Alkermes

3:45pm – 3:50pm	Introduction
3:50pm – 4:10pm	A Review of Pre-clinical Data Gerard Sanacora, Yale University
4:10pm – 4:30pm	Ketamine: Rationale, Empirical Evidence and New Routes of Delivery James W. Murrough, Icahn School of Medicine at Mount Sinai
4:30pm – 4:50p	Treatment of Suicidality with Novel Mechanisms Sanjay Mathew, Baylor College of Medicine
4:50pm – 5:10pm	The Role of Pherines for Rapid Relief of Depressive and Anxiety Symptoms Michael R. Liebowitz, Pherin Pharmaceuticals
5:10pm – 5:30pm	Novel Developments in Non-invasive Neurostimulation for the Treatment of Mood Disorders Dan V. Iosifescu, Icahn School of Medicine at Mount Sinai
5:30pm – 5:45pm	Discussion

Wednesday, June 18, 2014 | ASCP

3:45pm – 5:45pm *Psychiatry and Technology: A Partnership in Promoting Mental Health

Atlantic 3

Chair: Holly A. Swartz, University of Pittsburgh School of Medicine **Discussant:** Ellen Frank, University of Pittsburgh School of Medicine

3:45pm – 3:50pm	Introduction
3:50pm – 4:10pm	MoodSwings 2.0 for Bipolar Disorder: www.moodswings.net.au Victoria E. Cosgrove, Stanford University School of Medicine
4:10pm – 4:30pm	MoodRhythm: Pilot Testing a Smartphone App for Monitoring Mood and Daily Routines Mark Matthews, Cornell University
4:30pm – 4:50pm	Using Smartphones to Enhance Skill Acquisition and Utilization in CBT for Child Anxiety Jennifer Silk, University of Pittsburgh
4:50pm – 5:10pm	Computerized Adaptive Testing (CAT) and the Future of Psychiatric Measurement Robert Gibbons, University of Chicago
5:10pm – 5:45pm	Discussion

ASCP |

Notes

Thursday

Thursday, June 19, 2014 | ASCP

AT-A-GLANCE

Thursday, June 19, 2014

7:30am – 9:00am Morning Break

Ballroom Foyers

8:30am – 10:00am Panel Sessions

Clinical Trials in Early Stage Alzheimer's Disease: Current Methodological and Regulatory Considerations	The NIMH- Funded RAPID Network Studies	Leveraging the Internet and Social Media to Improve Pathways to Care and Shorten DUP in Schizophrenia	Practical Trials in Psychiatry: The Need, The Opportunities
Location:	Location:	Location:	Location:
Diplomat 1-2	Atlantic 1	Atlantic 2	Atlantic 3

10:00am – 10:15am **Break**

Ballroom Foyers

10:15am – 11:45am Plenary: Regulatory Wrap-up Session

Grand Ballroom

12:00pm Meeting Adjourns

ASCP |

Notes

Thursday, June 19, 2014 | ASCP

FULL SCHEDULE

Thursday, June 19, 2014

7:30am – 9:00am Morning Break

Ballroom Foyers

Panel Sessions

8:30am – 10:00am Clinical Trials in Early Stage Alzheimer's

Disease: Current Methodological and Regulatory

Considerations

Diplomat 1-2

Chair & Discussant: Kathleen Welsh-Bohmer, Joseph and Kathleen Bryan Alzheimer's Disease Research Center

8:30am – 8:40am	Introduction
8:40am – 9:00am	What Are We Trying to Measure in Preclinical and Prodromal Alzheimer's Disease? Lon S. Schneider, Keck School of Medicine of USC
9:00am – 9:20am	What are the Optimal Cognitive Outcome Measures for Trials in Preclinical Alzheimer's Disease? Keith Wesnes, Bracket Global
9:20am – 9:40am	Drug Development Cognition Challenges Marc Cantillon, Kyowa Hakko Kirin Pharma, Inc.
9:40am – 10:00am	Discussion

ASCP | Thursday, June 19, 2014

8:30am – 10:00am The NIMH-Funded RAPID Network Studies Atlantic 1

Chair: Maurizio Fava, Massachusetts General Hospital

Co-chair: Mi Hillefors, NIMH

Discussant: Carlos A. Zarate, NIMH

8:30am – 8:40am Introduction

8:40am – 9:00am A POC of Low-field Magnetic Stimulation:

Methodological Issues and Innovations in the Implementation of a Novel Device Study in MDD Maurizio Fava, Massachusetts General Hospital

9:00am – 9:20am Potential Rapid Antidepressant Augmentation with

a Selective Kappa Antagonist

Sitra Tauscher-Wisniewski, Lilly Research Labs

9:20am – 9:40am A Dose-finding Study of I.V. Ketamine in

Treatment-resistant Depression

Gerard Sanacora, Yale University School of Medicine

9:40am – 10:00am **Discussion**

8:30am – 10:00am Leveraging the Internet and Social Media to

Improve Pathways to Care and Shorten DUP in

Schizophrenia *Atlantic 2*

Chair: John M. Kane, The Zucker Hillside Hospital Discussant: Donald C. Goff, NYU Medical School

8:30am – 8:40am Introduction

8:40am – 8:55am **Duration of Untreated Psychosis and it's**

Correlates in Patients with Schizophrenia-

spectrum Disorders: Results from a Large Meta-

analysis of First Episode Studies

Christoph Correll, The Zucker Hillside Hospital

8:55am – 9:10am Understanding Pathways to Care in Early-course

Psychotic Disorders

Michael T. Compton, Hofstra North Shore-LIJ School

of Medicine at Hofstra University

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8:30am – 10:00am (continued)	Leveraging the Internet and Social Media to Improve Pathways to Care and Shorten DUP in Schizophrenia Atlantic 2
9:10am – 9:25am	Early Detection of Psychosis through Self-report Screening Rachel Loewy, University of California
9:25am – 9:40am	Reducing DUP in the Age of Social Media and the Internet John M. Kane, The Zucker Hillside Hospital
9:40am – 10:00am	Discussion
8:30am – 10:00am	Practical Trials in Psychiatry: The Need, The Opportunities Atlantic 3

Chair & Discussant: Benedetto Vitiello, NIMH

Co-chair: Nina R. Schooler, SUNY Downstate Medical Center

8:30am – 8:40am	Introduction
8:40am – 8:55am	Practical, Pragmatic, and Possible Psychopharmacology Clinical Trials: Lessons Learned from the AHRQ Bipolar CHOICE study Andrew Nierenberg, Massachusetts General Hospital
8:55am – 9:10am	Expanding the Place of Practice-based Clinical Trials on the Explanatory-pragmatic Spectrum Greg Simon, Group Health Research Institute
9:10am – 9:25am	A Regulatory Perspective on Practical Clinical Trials Thomas Laughren, MGH CTNI
9:25am – 9:40am	PCORI and Practical Trials in Mental Health Grayson Norquist, The University of Mississippi Medical Center
9:40am – 10:00am	Discussion

ASCP | Thursday, June 19, 2014

10:00am - 10:15am Break

Ballroom Foyers

10:15am – 11:45am Plenary: Regulatory Wrap-up Session

Grand Ballroom

Chair: Ni A. Khin, M.D., U.S. Food and Drug Administration

Phillip Kronstein, M.D., Food and Drug Administration Celia Winchell, M.D., Food and Drug Administration Silvana Borges, M.D., Food and Drug Administration

12:00pm Meeting Adjourns

Tuesday, June 17, 2014

Poster Session 1

- P-1 A Double-blind, Randomized, Placebo-controlled, Parallel Group,
 Dose Frequency Study of Intravenous Ketamine in Patients with
 Treatment-Resistant Depression
 Jaskaran Singh, Janssen Research and Development, LLC
- P-2 A Pilot Study of a Novel Monoamine Triple Reuptake Inhibitor EB-1020 SR in the Treatment of ADHD in Adults
 Timothy Wilens, Massachusetts General Hospital Andrew J. Cutler, Ann Childress, Randall D. Marshall, Mark Bradshaw, Frank Bymaster, Anthony McKinney, Stephen W. Hurt, Catherine O'Brien, Timothy Hsu
- P-3 AZD8529, a Positive Allosteric Modulator of the mGiuR2
 Receptor for the Treatment of Schizophrenia
 Alan Cross, AstraZeneca Neuroscience Innovative Medicines Unit
- P-4 Efficacy and Safety of a Novel mGlu2 Receptor Positive Allosteric Modulator as an Adjunctive Treatment to an SSRI/SNRI in the Treatment of Anxious Depression
 Justine Kent, Janssen
 Ella Daly, Ceusters Marc, Iva Kezic, Rosanne Lane, Lim Pilar, De Smedt Heidi, Mazzucco Christine, Peter DeBoer, Luc Van Nueten, Wayne Drevets
- P-5 Lupron in Combination with an Acetylcholinesterase Inhibitor
 Halts Cognitive Decline in Women with Alzheimer 's Disease over
 a 48 Week Period
 Richard Bowen, OTB Research
 Craig Atwood
- P-6
 Results of a Phase 28 Clinical Trial of TC-5619, a Selective Alpha 7 Neuronal Nicotinic Receptor (NNR) Agonist in the Adjunctive Treatment of Negative Symptoms and Cognitive Dysfunction in Schizophrenia
 David Hosford, Targacept, Inc.
 Chris Dvergsten, Jessica Beaver, Anthony Segreti, Steven Toler, Gaston Farr, Melissa Joseph, John Jett, Patrick Lippiello, Merouane Bencherif
- P-7 A Rapidly Acting Intranasal Treatment for the Symptoms of GAD Michael Liebowitz, Pherin Pharmaceuticals Louis Monti, Rita Hanover, Bernard Grosser
- P-8 Metadoxine Extended Release (MDX): A Novel Drug Candidate for the Treatment of ADHD & Other Cognitive Disorders Jonathan Rubin, Alcobra Pharma Yaron Daniely, Lenard Adler

^{*}P-# References a Pharmaceutical Pipeline Presentation.

Posters

Memantine in the Treatment of Executive Function Deficits in Adults with ADHD: A Pilot Randomized Double Blind Controlled Clinical Trial

> Joseph Biederman, Massachusetts General Hospital Ronna Fried, Laura M. Tarko, Craig Surman, Stephen V. Faraone, Thomas Spencer



Effects of Lisdexamfetamine Dimesylate on Brain Reward Circuitry in Adults with ADHD

Stephanie Duhoux, Icahn School of Medicine at Mount Sinai Kurt Schulz, Beth Krone, Anne-Claude V. Bédard, Juan D. Pedraza, Lenard Adler, Stuart F. White, James Blair, Jeffrey Newcorn

- The Methylphenidate-atomoxetine Crossover Study in ADHD Youth: Measuring and Comparing Response Mark Stein, The University of Washington Tom Hildebrandt, Jeffrey Newcorn
- The Role of Aldosterone and Cortisol in Alcohol Use Disorders in a Baclofen Treatment Study
 Elie G. Aoun, Brown University, Butler Hospital
 Carolina Haass-Koffler, Robert Swift, Giovanni Addolorato, George Kenna, Lorenzo Leggio
- Addiction Severity Index Family Composite Scale More Reliable
 Than Combined Family/Social Composite
 Wayne H. Denton, Florida State University
 Jacob B. Priest, Sarah B. Woods
- 6 Periodic Placebo Effect in an Addiction Therapy Trial Bernard L. Silverman, Alkermes, Inc. Jacqueline Zummo, Asli Memisoglu, David Gastfriend, Walter Ling, Evgeny Krupitsky



Adrenergic Receptor Modulation for the Treatment and Prevention of Post-traumatic Stress Disorder and Co-morbid Disorders
Chaya G. Bhuvaneswaran, University of Massachusetts-Worcester



An Epigenome-wide Assessment of Atypical Antipsychotic Side Effects in Bipolar Disorder

Kyle J. Burghardt, University of Michigan College of Pharmacy Vicki L. Ellingrod





9 Biomarkers of Cardiometabolic Risk in Antipsychotic Treated Youth

Ginger E. Nicol, Washington University School of Medicine Michael D. Yingling, Julia A. Schweiger, John Newcomer

10 Plasma Polyunsaturated Fatty Acid Markers Differ in Symptomatic Bipolar Disorder

Erika Saunders, Penn State College of Medicine, Penn State University

Kaizong Ma, Eric Schaefer, Alan Gelenberg, Stanley Rapoport

11 Reliable Change Index and Clinical Significance in Clinical Trials Using the Positive and Negative Syndrome Scale (PANSS)

Mark Opler, ProPhase LLC, New York University School of Medicine Anzalee Khan, Linda Gao, Brian Rothman, Luka Lucic

12 Prenatal Stress Evokes Long-term Changes in Brain Glucose Metabolism

Boguslawa Budziszewska, Institute of Pharmacology, Polish Academy of Sciences

Anna Kurek, Jan Detka, Agnieszka Basta-Kaim, Monika Leśkiewicz, Marta Kubera

13 Efficacy and Safety of Treatment with Lurasidone Adjunctive with Lithium or Valproate in Bipolar I Depression: Results of Two 6-week Studies

Joseph R. Calabrese, Case Western Reserve School of Medicine Trisha Suppes, Kaushik Sarma, Robert Silva, Hans Kroger, Josephine Cucchiaro, Andrei Pikalov, Antony Loebel

14 MoodSwings 2.0 (www.moodswings.net.au): An Online Intervention for Bipolar Disorder

Victoria E. Cosgrove, Stanford University School of Medicine Trisha Suppes, Sue Lauder, Emma Gliddon, Karishma Raju, Seetal Dodd, E. Grace Fischer, Michael Berk

15 Clinically Relevant Change Using CGI-BP in Patients with Acute Depressive Episodes of Bipolar I or II Disorder in Quetiapine XR Study

Catherine Datto, AstraZeneca

Jason Wright, Scott LaPorte, Michelle Shay

Posters

Number Needed to Treat for Discontinuation Due to Adverse Events, Somnolence, ≥ 7% Weight Gain, Extrapyramidal Side Effects, Response, and Remission of Atypical Antipsychotics in Acute Bipolar Depression

Keming Gao, Case Western Reserve University

17 Lurasidone in Bipolar I Depression: A 24 Week, Open-label Extension Study

Terence Ketter, Stanford University School of Medicine Kaushik Sarma, Robert Silva, Hans Kroger, Josephine Cucchiaro, Antony Loebel

18 Sleep Patterns across the Bipolar Spectrum: Similarities and Differences between Mood States and Across Diagnostic Subtypes

Jessica C. Levenson, University of Pittsburgh Holly A. Swartz, Ellen Frank, David J. Kupfer

19 Global Improvement in Bipolar Mania Patients Treated with Cariprazine

Robert E. Litman, CBH Health, LLC Kaifeng Lu, Krisztián Nagy, István Laszlovszky, Suresh Durgam

- 20 Psychopharmacology Algorithm for Acute Mania David Osser, Harvard Medical School Othman Mohammad
- 21 The Psychopharmacology Algorithm Project at the Harvard South Shore Program: 2014 Update on Bipolar Depression Dana Wang, Harvard Medical School, VA Boston Healthcare System Arash Ansari, David Osser
- 22 Correlation between Different Levels of Placebo Response Rate and Clinical Trial Outcome in Bipolar Depression George I. Papakostas, Massachusetts General Hospital, Harvard Medical School Nadia Iovieno, Rosemary Walker



Resilience in High-risk Infants and Toddlers of Mothers with Bipolar Disorder: A Longitudinal Investigation

Diana I. Simeonova, Emory University School of Medicine Theresa Nguyen, Kerry Ressler, W. Edward Craighead





24 A Dimensional Assessment of Anxiety and Tic Severity in Tourette's Disorder

Barbara Coffey, Icahn School of Medicine at Mount Sinai, Nathan S. Kline Institute for Psychiatric Research Vilma Gabbay



Computerized Adaptive Diagnosis and Testing in Psychiatric Outpatients Seeking Care at a Large, Free-standing Psychiatric Hospital

Eric D. Achtyes, Michigan State University College of Human Medicine Scott Halstead, LeAnn D. Smart, Robert D. Gibbons

26 A Dimensional Rating System for Psychiatric Disorders in Psychiatric Outpatients

Mark Zimmerman, Rhode Island Hospital

A Clinically Useful Self-report Measure of the DSM-5 Anxious Specifier of Major Depressive Disorder

Mark Zimmerman, Rhode Island Hospital

28 Reduction of Placebo Response in Depression Trials via Independent Remote (SAFER) Patient Interviews

Martina J. Flynn, Massachusetts General Hospital Clinical Trials Network and Institute

Marlene Freeman, Maurizio Fava, David Mischoulon, James Pooley, Daniel Burch, Heather Bryson

29 A Comparison of Cross-cultural Regional Norms for the MATRICS Consensus Cognitive Battery (MCCB)

Richard S. E. Keefe, NeuroCog Trials, Duke University Ioan Stroescu, Vicki G. Davis, Alexandra S. Atkins

30 Magnitude of Change with Antidepressants and Placebo in Antidepressant Clinical Trials Using Structured, Taped and Appraised Rater Interviews Compared to Traditional Semistructured Interviews

Arif Khan, Northwest Clinical Research Center James Faucett, Walter Brown

The Impact of Implementing a National Research Subject Database to Prevent Dual Enrollment in Early and Late Phase Central Nervous System Trials

Kerri Weingard, Accumed Research Associates & Verified Clinical Trials Mitchell Efros



Posters

32	Early Life Stress as a Risk Factor for Substance Use Disorders Clinical and Neurobiological Substrates		
	Sajoy Purathumuriyil Varghese, Rosalind Franklin University of Medicine and Science		

33 Panic Disorder: Theoretical Overlap with Narcolepsy
Thomas W. Uhde, MUSC
Bernadette M. Cortese, Priyattam Shiromani, Orlena Merritt-Davis,
Yury Yaroslavsky, Ravi Singareddy, Kimberly R. Leslie, Martha
Strachan, Jennifer Runion, David Bachman, Richard K. Bogan

A Five Year Observational Study of Patients with Treatment
Resistant Depression Treated with VNS Therapy® or Treatment
as Usual: Comparative Response/Remission Rates, Duration of
Response, and Quality of Life

Scott T. Aaronson, Sheppard Pratt Health System Mark T. Bunker, Peter Sears, Francis Ruvuna

Prenatal Stress Influences the Proper Functioning of the Primary Microglial Cells and Leads to Behavioral Changes in Adult Offspring - A Link to Depression

Agnieszka Basta-Kaim, Institute of Pharmacology, Polish Academy of Sciences

Joanna Slusarczyk, Bogusława Budziszewska, Monika Le kiewicz, Marta Kubera

The Efficacy of Vilazodone in Achieving Remission in Patients with Major Depressive Disorder: Post Hoc Analyses of a Phase IV Trial

Leslie Citrome, New York Medical College Carl Gommoll, Xiongwen Tang, Rene Nunez, Maju Mathews

37 Clinical Relevance of Levomilnacipran ER Treatment in Patients with Major Depressive Disorder: Improvements in Functional Impairment Categories

Andrew J. Cutler, Florida Clinical Research Center, LLC Carl Gommoll, Changzheng Chen, William M. Greenberg, Adam Ruth

38 Levomilnacipran Inhibits both Norepinephrine and Serotonin Reuptake across the Clinical Dose Range

Tobie Escher, Forest Research Institute
Joann O'Connor, Laishun Chen, Carl Gommoll, Stephen Zukin



39 Increased ACC and Striatal Total Choline Levels in Adolescent Depression

Vilma Gabbay, Icahn School of Medicine at Mount Sinai; Nathan S. Kline Institute for Psychiatric Research Ana I. Vallejo, Amy R. Johnson

40 Cognitive Domains Impacted by Vortioxetine Treatment of Patients with Major Depressive Disorder (MDD)

John E. Harrison, Metis Cognition Ltd. Søren N. Lophaven, Christina Kurre Olsen

41 A Head-to-head, Randomized, Comparison Study of Vortioxetine vs. Escitalopram in Patients Well Treated for MDD and Experiencing Treatment-emergent Sexual Dysfunction Paula L. Jacobsen, Takeda Development Center Americas

Paula L. Jacobsen, Takeda Development Center Americas Atul R. Mahableshwarkar, Yinzhong Chen, Lambros Chrones, Anita Clayton

The Role of Pro-inlammatory Cytokines in Modulation of Activity of Serotoninergic System in Women with Postpartum Depressive Symptoms and in Animal Models of Depression

Marta Kubera, Institute of Pharmacology, Polish Academy of Sciences Katarzyna Curzytek, Weronika Duda, Joanna Slusarczyk, Monika Leskiewicz, Krystyna Golembiowska, Magdalena Regulska, Agnieszka Basta-Kaim, Bogusława Budziszewska, Wladyslaw Lason, Michael Maes

43 Anti-anhedonic Effect of Ketamine and its Neural Correlates in Major Depressive Disorder

Níall Lally, National Institutes of Health Allison C. Nugent, David Luckenbaugh, Carlos Zarate

44 ALKS 5461, a Novel Opioid Modulator as Adjunctive Treatment for Depression: Addressing Abuse Potential, Safety and Efficacy Randall D. Marshall, Alkermes, Inc.

Ryan Turncliff, J. Alexander Bodkin, Lauren E. DiPetrillo, Richard Leigh-Pemberton, Michael E. Thase, Madhukar Trivedi, Asli Memisoglu, Maurizio Fava

45 Effects of Vilazodone on Sexual Dysfunction in Major Depressive Disorder: A Randomized, Double-blind Trial with Placebo and Active Controls

Maju Mathews, Forest Research Institute Carl Gommoll, Dalei Chen, Rene Nunez

Posters

46 A 8-week Randomized, Double-blind Trial Comparing Efficacy, Safety and Tolerability of Three Vilazodone Dose Initiation Strategies Following Switch from SSRIs or SNRIs in Major Depressive Disorder

Robert Millet, Duke University Shilpa Rele, Sungman Kim, Jong-Woo Paik, Seonghwan Kim, Varun Kasula, Prakash Masand, Ashwin Patkar

Adjunctive Lanicemine (AZD6765) in Patients with Major Depressive Disorder and a History of Inadequate Response to Antidepressants: Post-hoc Analyses of a Randomized, Placebo Controlled Study (PURSUIT)

Sanjeev Pathak, AstraZeneca

Hong-Lin Su, Joel Posener, Khanh Bui, Michael Quirk, Tim Piser, Sanjay Mathew, Gerard Sanacora

The Rosenberg Hassman Mood Scale - An Update on the Development of This Depression Rating Scale with Feedback from 50 Patients

Leon I. Rosenberg, Center for Emotional Fitness Keith Wesnes, Sanju George, Howard Hassman, Mary Gelovich

49 Efficacy of Vortioxetine vs. Placebo in Adults with Major Depressive Disorder (MDD): Meta-analyses of MADRS Single Items from 9 Short-term Studies

Michael E. Thase, Perelman School of Medicine of the University of Pennyslvania

Atul R. Mahableshwarkar, Henrik Loft, Marianne Dragheim

50 mTOR Signaling Correlates with Treatment Response to Ketamine in a Preclinical Model of Treatment Resistant Depression Susannah J. Tye, Mayo Clinic Adam Walker, Blair Price, Chunling Hu, Shari Sutor, Mark A. Frye

A Novel Trial Design to Assess Rapid and Sustained
Antidepressant Effects of an Oral NR2B Specific NMDA Receptor
Antagonist, CERC-301

James Vornov, Cerecor, Inc.

Maurizio Fava, Michael Detke, Chao Wang, Larry Ereshefsky, Richard C. Shelton, Michael E. Thase, Madhukar Trivedi



52	An International Study of the GRID-HAMD: Has It Fulfilled Its
	Promise?

Janet Williams, MedAvante, Inc. Matej Ondrus, Melanie Rishton, Jennie K. Persson, Marlene Popescu, Risto Valjakka

Validation of the Yale-Brown Obsessive Compulsive Scale
Modified for Binge Eating to Support Use in Clinical Trials as a
Measure of Treatment Benefit

Linda Deal, Shire Development LLC Robert Wirth, Barry Herman, Maria Gasior, Susan McElroy

Acquired Binge-eating Behaviour Produces Alterations in Dopaminergic Neurochemistry in the Brains of Rats

Peter Hutson, Shire Jane Gosden, Mike Prow, David J. Heal, Sharon Cheetham

55 **Definitive Verification and Monitoring of Oral Medication Adherence Using Breath Analysis**

Donn M. Dennis, Xhale SMART, Inc. Eileen Loskie

56 Predictors of Pharmacological Treatment Response in Grooming Disorders

Brian L. Odlaug, University of Copenhagen Jon E. Grant, Eric Leppink, Katherine L. Derbyshire

- 57 Web-based Curriculums for Teaching Psychopharmacology:
 Revision of the Resident and the Medical Student Curriculums
 Ira Glick, Stanford University School of Medicine
- The Effects of Social Support on Suicidality in an Adult Inpatient Psychiatric Population as Assessed by the C-SSRS and S-STS Ahmad Hameed, Penn State College of Medicine Amanda M. White, Michael Mitchell, Eric A. Youngstrom, Roger E. Meyer, Alan J. Gelenberg
- 59 Deconstructing Drug Company Promotion: Pursuing Truth: Slides for a 1 Hour Lecture in a Psychopharmacology Course

 Jeffrey Mattes, Psychopharmacology Research Association of Princeton

Posters

60 Metabotropic Glutamate Receptor 7 (GRM7) Pharmacogenetics in First Episode Psychosis

James M. Stevenson, University of Illinois College of Pharmacy James L. Reilly, Margret S. H. Harris, Konasale M. Prasad, Judith A. Badner, Vishwajit Nimgaonkar, Matcheri S. Keshavan, John A. Sweeney, Jeffrey R. Bishop

61 Medical Informatics in Psychiatric Practice: Current Status and Unmet Needs

Farifteh Duffy, American Psychiatric Association/American Psychiatric Foundation

Laura Fochtmann, Robert M. Plovnick, Diana E. Clarke, Eve K. Mościcki, William Narrow

62 All-cause Discontinuation and Safety of Aripiprazole Oncemonthly for the Treatment of Schizophrenia: A Pooled Analysis of Two Double-blind, Randomized, Controlled Trials

Ross A. Baker, Otsuka Pharmaceutical Development & Commercialization, Inc.

W. Wolfgang Fleischhacker, Raymond Sanchez, Lan-Feng Tsai, Timothy Peters-Strickland, Anna Eramo, John Kane

63 Subject Recruitment Strategies: A New Cross-functional Team Approach

Kim Cheshire-Kinney, Janssen Research & Development, LLC Stephen Rodriguez, James O'Neill, Lucy Mahalchick, Allen Wu

Accelerated Aging in Severe Mental Illness Using Levels of Advanced Glycated Endproducts as Indicator. Research Findings and Clinical Consequences

Dan Cohen, Mental Health Organization North-Holland North Annet Nugter, Andries Smit

65 A Double-blind, Placebo-controlled, Randomized Withdrawal Study of Lurasidone for the Maintenance of Efficacy in Patients with Schizophrenia

Josephine Cucchiaro, Sunovion Pharmaceuticals, Inc. Rajiv Tandon, Antony Loebel, Debra Phillips, David Hernandez, Yongcai Mao, Andrei Pikalov

66 Categorical Improvements in Disease Severity in Schizophrenia Patients Treated with Cariprazine

Suresh Durgam, Forest Research Institute Stephen Zukin, Kaifeng Lu, Marc Debelle, István Laszlovszky, Stephen Volk



67 Efficacy and Safety of Aripiprazole Once-monthly in Obese and Non-obese Patients with Schizophrenia: A Post Hoc Analysis Anna Eramo, H. Lundbeck A/S Marc De Hert, Wally Landsberg, Lan-Feng Tsai, Ross A. Baker



The Effects of Caloric Vestibular Stimulation on Illness Awareness in Schizophrenia: A Pilot, Proof of Concept Study

Philip Gerretsen, Centre for Addiction and Mental Health David D. Pothier

69 Comparative Outcomes after Switching from Risperidone Longacting Injectable to Paliperidone Long-acting Injectable or Oral Antipsychotics

> David Hough, Janssen Research & Development Erica Voss, Larry Alphs, Patrick Ryan, Paul Stang

- 70 Exploring Neuropathological Deficits and New Drug Targets for Major Psychiatric Disorders Using the Stanley Neuropathology Consortium Datasets and RNA-Seq Data
 Sanghyeon Kim, Stanley Medical Research Institute
- 71 Clozapine May Exert Its Superior Efficacy on Schizophrenia through Its Serotonin 5HT2C Receptor Inverse-agonism Sanghyeon Kim, Stanley Medical Research Institute
- 72 An Open-label Extension Study of Lurasidone Safety and Efficacy in Patients with Schizophrenia Previously Randomized to Lurasidone or Risperidone

Andrei Pikalov, Sunovion Pharmaceuticals, Inc. Gregory Mattingly, Michael Tocco, Debra Phillips, Jane Xu, Antony Loebel

73 Correlates or Social Cognition and Neurocognition to Functional Outcomes

Brian Rothman, ProPhase, LLC Jean-Pierre Lindenmayer, Anzalee Khan, Mark Opler, Linda Gao

74 A Randomized Blind Parallel Intramuscular Haloperidol-controlled Multicenter Clinical Trial to Evaluate the Efficacy and Safety of Intramuscular Levosulpiride in the Treatment of Chinese Patients with Agitation of Schizophrenia

Yifeng Shen, Shanghai Mental Health Center Huafang Li



ASCP Posters

75	Varenicline Effects on Smoking, Cognition, and Psychiatric Symptoms in Schizophrenia: Results of a Double-blind Placebo
	Controlled Study
	Robert C. Smith, NYU School of Medicine and Nathan Kline Institute
	for Psychiatric Research

- Paliperidone Research in Demonstrating Effectiveness (PRIDE):
 Managing Schizophrenia Patients with a History of Incarceration
 H. Lynn Starr, Janssen Scientific Affairs, LLC
 Larry Alphs, Lian Mao, Stephen Rodriguez
- 77 A Randomized, Placebo-controlled Repeat-dose Thorough QT Study of Inhaled Loxapine in Healthy Volunteers
 Paul P. Yeung, Teva Pharmaceuticals
 James V. Cassella, Daniel A. Spyker
- 78 Lamotrigine: Are We Dosing it Optimally in Pregnant Women with Bipolar Disorder?
 Crystal T. Clark, Northwestern University Feinberg School of Medicine
- 79 Sexual Symptoms Associated with Leuprolide Acetate Therapy in Infertility Patients Treated for Endometriosis
 Julia "Jill" K. Warnock, University of Oklahoma-HSC- Tulsa
 J. Clark Bundren



Wednesday, June 18, 2014

Poster Session 2

1 A Novel Computer-prompted Tandem Rating Assessment for Adult ADHD Clinical Trials

> Joan Busner, Penn State College of Medicine and Bracket Andrew J. Cutler, Gary S. Sachs, Dan DeBonis, Timothy Hsu, Catherine O'Brien, Timothy Wilens

2 Emotional Dysregulation as an Adult ADHD Subtype

Frederick W. Reimherr, Psychiatric & Behavioral Solutions, University of Utah

Tammy A. Steans, Kathleen Reimherr, Phillip D. Gale, Thomas Gift, Paul H. Wender, Barrie K. Marchant

3 Emotion Recognition Deficits in Treated and Untreated Adult ADHD Patients

Anneka Tomlinson, University of Manchester Robert Baskind, Joe Johnson, Kay Marshall, Joanna C. Neill

4 Attenuation of Ethanol Withdrawal by Ceftriaxone-induced Upregulation of Glutamate Transporter EAAT2

> Ulas M. Camsari, Mayo Clinic Osama Abulseoud

5 A Double-blind, Placebo-controlled Trial Assessing the Efficacy of Varenicline Tartrate for Alcohol Dependence

Raye Z. Litten, NIAAA

Joanne B. Fertig, Daniel E. Falk, Megan L. Ryan

6 Progesterone Treatment for Postpartum Cocaine Users

Kimberly Yonkers, Yale School of Medicine Mehmet Sofuoglu, Kathleen Carroll

7 Desvenlafaxine ER vs. Placebo in Social Anxiety Disorder

Michael R. Liebowitz, Pherin Pharmaceuticals Ester Salman, Ann E. Johnson, Rita Hanover

8 The Predictive Value of Gene Variants Used to Guide Antidepressant Selection

Kevin M. Furmaga, Pine Rest CMHS and Michigan State University College of Human Medicine (Psychiatry)

Andrew C. Rose, LeAnn D. Smart, Alan T. Davis, Eric D. Achtyes

ASCP Posters

Determining Pharmacological Selectivity of the Kappa Opioid Receptor Antagonist LY2456302 Using Translational Rat to Human Pupillometry Studies

Linda Rorick-Kehn, Lilly Research Laboratories, Eli Lilly and Co

10 A Naturalistic Study of the Clinical Utility of Pharmacogenetic Testing in Psychiatric Patients

Rachel Scott, Genomind Herbert Harris, Kathryn Gardner, Jay Lombard, Francis X. Brennan

11 How Cardinal are Cardinal Symptoms in Pediatric Bipolar Disorder? A Familial Risk Analysis

Joseph Biederman, Massachusetts General Hospital Stephen V. Faraone, Laura M. Tarko, Mariely Hernandez, Janet Wozniak

12 High EPA Omega-3 Fatty Acids and Inositol as Monotherapy and in Combination in the Treatment of Pediatric Bipolar Disorder: A Pilot Double-blind Randomized Clinical Trial

Joseph Biederman, Massachusetts General Hospital Stephen V. Faraone, Laura M. Tarko, Mariely Hernandez, Janet Wozniak

13 Identifying Patients Meeting the DSM-5 Criteria for Bipolar Disorder Episodes with Mixed Features in Bipolar Disorder Studies with Quetiapine XR

Catherine Datto, AstraZeneca

Jason Wright, Scott LaPorte, Michelle Shay

- Lurasidone Monotherapy for Bipolar Depression: Influence of Baseline Thyroid Function on Treatment Response Joseph F. Goldberg, Icahn School of Medicine at Mount Sinai Andrei Pikalov, Kei Watabe, Antony Loebel
- 15 Screening and Validation of Novel Kinase Signaling Pathways for Neuronal Excitability

Wei-Chun Hsu, University of Texas Medical Branch at Galveston Miroslav Nenov, Alexander Shavkunov, Neli Panova-Elektronova, Fernanda Laezza

Mediators of Effects of Lurasidone on Functioning and Quality of Life: Results from a Randomized, Double-blind, Placebocontrolled Trial in Patients with Bipolar I Depression
Terence Ketter, Stanford University School of Medicine
Cynthia Siu, Krithika Rajagopalan, Andrei Pikalov, Antony Loebel



17 Predictors of Improvement in Quality of Life Associated with Lurasidone Treatment of Bipolar I Depression: Results from a 6-month Continuation Study

Terence Ketter, Stanford University School of Medicine Cynthia Siu, Mariam Hassan, Krithika Rajagopalan, Andrei Pikalov, Antony Loebel

Baseline Patient Characteristics of Bipolar II Compared to Bipolar
 I Disorder in Trials of Acute Bipolar Depression

Jamie Mullen, AstraZeneca Catherine Datto, Louisa Feeley, Scott LaPorte



Neural Correlates of Social Stress in Youth with Bipolar Disorder Donna Roybal, University of Texas Health Sciences Center at San Antonio

Amy Garrett, Victoria E. Cosgrove, Spencer Boucher, Jennifer Pearlstein, Paige Staudenmaier, Jade Garneau-Fournier, Amy Parkinson, Kiki Chang

20 The Young Mania Rating Scale in Bipolar Disorder: Evaluation of Sleep and Rater Training

> Jan Sedway, inVentiv Health Clinical Cristina Maneru, Sandor Palfi

21 Factors Influencing the Diagnosis and Treatment of Bipolar Depression: A Healthcare Professional Perspective

Purvi K. Smith, Health and Wellness Partners Andrei Pikalov, Gary S. Sachs, Jani Hegarty



Sequence Analysis of Drug Target Genes with Suicide Severity in Bipolar Disorder

Clement Zai, Centre for Addiction and Mental Health, University of Toronto

Vanessa Goncalves, Vincenzo De Luca, Arun K. Tiwari, John B. Vincent, James Kennedy

23 Immunological Stress Responsivity as a Potential Risk Factor in Pediatric Mood Disorders

> Victoria E. Cosgrove, Stanford University School of Medicine Staudenmaier Paige, Jennifer Pearlstein, Sherrie Li, Kiki Chang



Posters

24 Inter-rater Reliability of the Scales for Outcomes of Parkinson's Disease – Cognition (SCOPA-COG) in MODERATO: A Randomized, Placebo-controlled Trial to Assess the Effect of Rasagiline on Mild Cognitive Impairment in PD Patients

Kari Nations, INC Research Robin C. Hilsabeck, Russell Tanenbaum, ElizaBeth Grubb, Azhar Choudhry

25 Risk-based Monitoring for Aberrant Rating Patterns and Patient Selection Anomalies in Global Schizophrenia Trials
David Daniel, Bracket Global, LLC

David Daniei, Bracket Globai, LLC Alan Kott

26 Feasibility, Integrity and Efficiency of the Sequential Parallel Comparison Clinical Trial Design

Marc de Somer, Alkermes, Inc. Yangchun Du, Asli Memisoglu, Randall D. Marshall, Richard Leigh-Pemberton, Bernard L. Silverman, Elliot Ehrich, Maurizio Fava

27 Blinded Dual Ratings Confirm Primary Site-based Ratings in an MDD Trial

Richard Leigh-Pemberton, Alkermes, Inc.

Asli Memisoglu, Steven D. Targum, J Cara Pendergrass, Philip Rauh, Randall D. Marshall, Bernard L. Silverman, Marc de Somer, Elliot Ehrich

28 Complexity in Protocol Design: Does It Lead to Better Clinical Trial Outcomes?

Robert Molpus, CNS Healthcare Patricia Brown, Rebecca Hummel, Mark Joyce, Linda Harper, Terri Wood, Angela Menosky, John D. Ehrhardt, Ruth Hummel

29 Impact of BPRS Interview Length on Ratings Precision during a Schizophrenia Trial

Steven D. Targum, Clintara, LLC J. Cara Pendergrass, Laura Zumpano, Philip Rauh, Nicholas DeMartinis

30 Attenuation of Impulsivity in Bipolar Alcoholics Who Reduce Heavy Drinking: Prospective Evidence from a Randomized Placebo-controlled Trial

Bryan Tolliver, Medical University of South Carolina James J. Prisciandaro, Delisa Brown, Helena Brenner



31 Efficacy of Quetiapine-XR Monotherapy or Adjunctive Therapy to Antidepressant in Acute Major Depressive Disorder with Generalized Anxiety Disorder: A Randomize, Placebo-controlled Pilot Study

Keming Gao, Case Western Reserve University



Does Algorithm-based Depression Care Mitigate Cognitive Decline in Older Adult Outpatients?

Aaron M. Koenig, Western Psychiatric Institute & Clinic Meryl A. Butters, Charles F. Reynolds

33 Pro-cognitive Effects of Ketamine and Underlying
Neurocircuitry in Subjects with MDD as Assessed by fMRI and
Neuropsychological Testing
Lynnette A. Averill, Yale School of Medicine, National Center for PTSD

34 Confirming MDDScore as an Aid in the Diagnosis of Major Depressive Disorder

John A. Bilello, Ridge Diagnostics, Inc. Linda M. Thurmond, Katie Smith, Robert A. Rubin, Suzin M. Wright, Floyd Taub, Michael E. Henry, Richard C. Shelton, George I. Papakostas

The Effect of Vortioxetine on Sexual Dysfunction during the Treatment of Adults with Major Depressive Disorder (MDD) or Generalized Anxiety Disorder (GAD)

Anita H. Clayton, University of Virginia Paula L. Jacobsen, Atul R. Mahableshwarkar, William Palo, Yinzhong Chen, Marianne Dragheim

The Effects of Buprenorphine and Samidorphan, Alone and in Combination, on Monoamine Release within the Nucleus Accumbens Shell and Medial Prefrontal Cortex of Male Wistar Rats

Daniel Deaver, Alkermes, Inc. Jacobi I. Cunningham, Mark S. Todtenkopf, Reginald L. Dean, David Everman



The Neurocircuitry of Increased Inflammation in Depression: Preliminary Findings

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