



NCDEU 51st Annual Meeting

A meeting sponsored by the American Society of Clinical Psychopharmacology (ASCP)

*Anticipating the Future of Drug Development:
New Targets, Integrative Biomarkers, and Beyond*



**June 13-16, 2011
Boca Raton Resort & Club
Boca Raton, Florida**

Steering Committee Chairs: William Z. Potter, M.D., Ph.D. and Nina R. Schooler, Ph.D.

Program Committee Chairs: David J. Kupfer, M.D. and Carlos A. Zarate, M.D.

www.NCDEUMeeting.org



ASCP
AMERICAN SOCIETY OF
CLINICAL PSYCHOPHARMACOLOGY

Welcome to the 51st Meeting of NCDEU – the New NCDEU



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CLINICAL PSYCHOPHARMACOLOGY

On behalf of the American Society of Clinical Psychopharmacology, we are pleased to welcome you to this year's NCDEU meeting. The ASCP is proud to sponsor the meeting, now in its 51st year, which has played such a pivotal role in the development of modern-day psychopharmacology. The challenges and opportunities confronting this field have never been greater, and we are confident that the new iteration of NCDEU with increased partnership with all relevant federal agencies and the ongoing participation of researchers from academia, the pharmaceutical and biotechnology industries, as well as many other professionals engaged in various aspects of CNS research, will continue to stimulate and facilitate further progress. We are very appreciative to the members of the NCDEU Steering and Program Committees for their role in the success of the meeting.

John M. Kane, M.D.

A handwritten signature in black ink that reads "John M. Kane".

President

American Society of Clinical Psychopharmacology



On behalf of the NCDEU Steering and Program Committees, we are delighted that you have chosen to attend this year's meeting. Last year's 50th Anniversary Meeting was a landmark event to celebrate our progress from a small gathering of investigators in a new field to a robust meeting of over 1,000 national and international researchers and staff from government, academia, industry and clinical practice. At that meeting, decisions were made that have allowed us to reinvent NCDEU – thus “the New NCDEU”.

- **Organizational Changes**

- The meeting is now formally sponsored by the American Society of Clinical Psychopharmacology (ASCP).
- A Steering Committee with responsibility for overall organization of the meeting and a Program Committee with responsibility for evaluating submitted proposals, developing program innovations, and overseeing the meeting.
- Collaborations with the National Institute of Health now include the National Institute of Mental Health (NIMH), National Institute of Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA).
- Regulatory agency collaborations now include both the Food and Drug Administration (FDA) and the European Medicines Authority (EMA).
- Parthenon Management Group is now ably organizing the NCDEU Meeting.

- **Program Innovations**

- The meeting starts on Monday, June 13th with Panel Presentations, New Research Reports and a Plenary session rather than Workshops.
- The Monday Plenary Session will be “Regulatory Perspectives on Psychiatric Drug Development from FDA and EMA.”
- The Tuesday Plenary Session will feature leadership of NIMH, NIDA and NIAAA.
- An open forum on Wednesday titled “Pharmaceutical Pipeline Presentations” focuses on compounds in Phase 1 and Phase 2, and will be complimented by posters in the Wednesday poster session.
- NIMH, NIDA and NIAA have organized panel sessions.

- **Program Continuities**

- The long-standing New Investigator Program includes a workshop for the twenty (20) new investigator awardees and informal breakfast sessions.
- NCDEU Workshops – three hour intensive and interactive sessions focused on problems and solutions will be on Tuesday & Wednesday from 3:00 pm – 6:00 pm.
- NCDEU Reception will be from 6:00 pm – 7:30 pm on Tuesday the 14th.
- The NCDEU Fun Run/Walk will begin at 6:45 am on Wednesday the 15th.

We hope that you will value the innovations to the meeting and the well-established traditions. NCDEU at 51 is truly a work in progress and we welcome your suggestions. Seek out any of us during the meeting, or provide your views by completing the evaluation form.

Best Regards,

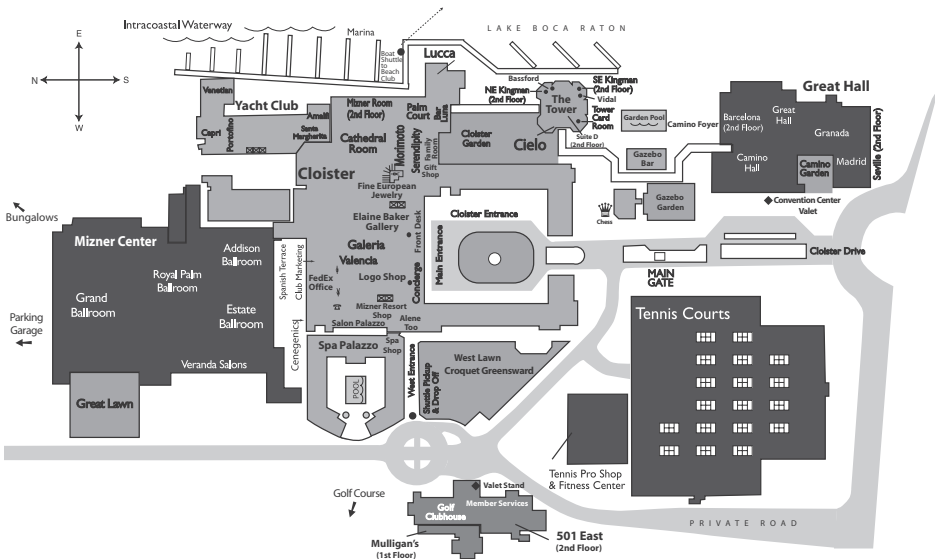
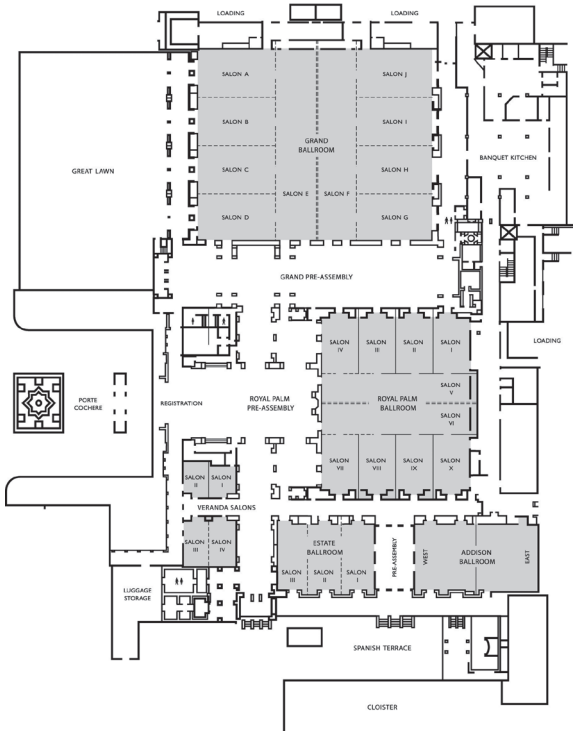
William Z. Potter, M.D., Ph.D.
Steering Committee Co-Chair

David Kupfer, M.D.
Program Committee Co-Chair

Nina Schooler, Ph.D.
Steering Committee Co-Chair

Carlos Zarate, M.D.
Program Committee Co-Chair

MIZNER CENTER



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Regulatory Plenary

Monday, June 13th from 1:30 pm – 3:00 pm

Regulatory Perspectives on Psychiatric Drug Development from Food and Drug Administration (FDA) and European Medicines Agency (EMA)



Manuel Haas, PharmD, MSc European Medical Agency

Dr. Manuel Haas is Head of the Central Nervous System and Ophthalmology section in the European Medicines Agency's Safety and Efficacy Sector (Human Medicines Development and Evaluation Unit). The "CNS" Section is responsible for the management of pre- and post-authorization activities of centralized applications for marketing authorizations, and particularly the safety and efficacy part related to medicinal products in the neurology, psychiatry and ophthalmology therapeutic areas. He is a clinical pharmacist by training. He worked for several years in hospitals in France and the UK before joining the pharmaceutical industry in regulatory affairs in 2003. Following this role, he started with the European Medicines Agency in 2004 as Scientific Administrator. He has been in his current role since September 2009.



Karl Broich, M.D. Federal Institute for Drugs and Medical Devices

Dr. Karl Broich is the Vice-President and Professor at the Federal Institute for Drugs and Medical Devices. From 1985 to 2000, Dr. Broich performed clinical and research work at hospitals of the universities of Bonn, Halle/Saale and Philadelphia (PennU) (Board certifications in Neurology, Psychiatry, Behavioural Psychotherapy). He served as Head of the Section Neurology/ Psychiatry from 2000 to 2005 and became the department head from 2005 to 2009. Since 2009, Dr. Broich has been the deputy head (Vice-President) at the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn (Germany). He also served as an alternate member of the Committee for Medicinal Products for Human Use (CHMP) from 2005 to 2009, and has served as vice-chair of CNS-Workgroup at the European Medicines Agency (EMA) since 2010. Current research activities include: clinical trials methodology CNS, biomarkers in drug development, Alzheimer's disease and other neurodegenerative disorders. He holds memberships in several learned societies of the CNS field. Dr. Broich has authored and served as a co-author for more than 90 Publications (peer reviewed articles, reviews, and book sections).



Mitchell Mathis, M.D.

Food and Drug Administration

Dr. Mitchell Mathis is the Deputy Director of Division of Psychiatry Products, Center for Drug Evaluation and Research at the FDA. He is a graduate of the Uniformed Services University of the Health Sciences School of Medicine in Bethesda, Maryland. He trained in family practice at Malcolm Grow USAF Medical Center in Maryland and in psychiatry at Walter Reed Army Medical Center in Washington, D.C. He has been practicing outpatient and emergency room psychiatry in D.C. and Maryland since 2001. He is board certified by the American Board of Psychiatry and Neurology.

Institute Directors' Plenary

Tuesday, June 14th from 8:30 am – 10:30 am



Nora Volkow, M.D.

National Institute on Drug Abuse

Dr. Nora Volkow became Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health in May, 2003. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. Her work has been instrumental in demonstrating that drug addiction is a disease of the human brain. As a research psychiatrist and scientist, Dr. Volkow pioneered the use of brain imaging to investigate the toxic effects of drugs and their addictive properties. Her studies have documented long lasting changes in the dopamine system affecting the actions of frontal brain regions involved with motivation, reward and inhibitory control in drug addicted subjects. She has also made important contributions to the neurobiology of obesity, ADHD, and the behavioral changes that occur with aging. Dr. Volkow was born in Mexico, attended the Modern American School, and earned her medical degree from the National University of Mexico in Mexico City, where she received the Premio Robins award for best medical student of her generation. Her psychiatric residency was at New York University, where she earned the Laughlin Fellowship Award as one of the 10 Outstanding Psychiatric Residents in the USA. She spent most of her professional career at the Department of Energy's Brookhaven National Laboratory (BNL) in Upton, New York, where she held several leadership positions including Director of Nuclear Medicine, Chairman of the Medical Department, and Associate Director for Life Sciences. In addition, Dr. Volkow was a professor in the Department of Psychiatry and Associate Dean of the Medical School at the State University of New York (SUNY)-Stony Brook. Dr. Volkow has published more than 475 peer-reviewed articles and more than 65 book chapters and non-peer reviewed manuscripts, and has also edited three books on the use of neuroimaging in studying mental and addictive disorders. During her professional career, she has been the recipient of multiple awards, including her selection for membership in the Institute of Medicine in the National Academy of Sciences. She was recently named one of Time Magazine's "Top 100 People Who Shape our World", and was included as one of the 20 people to watch by Newsweek magazine in its "Who's Next in 2007" feature. She was also named "Innovator of the Year" by U.S. News & World Report in 2000.



Philip Wang, M.D., Dr. P.H.

National Institute of Mental Health

Philip S. Wang, M.D., Dr.P.H. completed his undergraduate degree in biochemistry, medical school, psychiatry residency and chief residency, as well as masters and doctoral degrees in epidemiology, all at Harvard University. These training experiences impressed him with both the urgent needs as well as scientific opportunities to reduce the burdens from mental illness. In response, he has spent the majority of his professional career in research, advisory, teaching, and administrative activities, all designed to understand and improve the treatment of mental disorders. Presently, he serves as the Deputy Director of the National Institute of Mental Health (NIMH). In that role, he assists the Director in overseeing 1300 NIMH staff and \$1.4 billion spent annually on basic and clinical research to transform the understanding as well as treatment of mental illnesses, and ultimately pave the way for prevention, recovery and cure. Prior to joining NIMH, Dr. Wang served on the faculty at Harvard Medical School. He conducted studies at the Brigham and Women's Hospital on the safety, effectiveness, and cost-effectiveness of psychotropic medications with grant support from NIMH, NIDA, and AHRQ. He also conducted research in the Department of Health Care Policy at Harvard Medical School to develop and test interventions that improve the treatment and functioning of people with mental disorders with grant support from NIMH and the Robert Wood Johnson Foundation. Dr. Wang is an author of approximately 160 scientific publications in leading medical journals such as the *New England Journal of Medicine*, *Journal of the American Medical Association*, and *Lancet*. Dr. Wang has served in advisory roles at both the national and international levels. He was a member of the NIMH Services and Clinical Epidemiology study section and served on other NIH Initial Review Groups. He served as a Voting Member of the Food and Drug Administration (FDA) Psychopharmacologic Drug Advisory Committee as well as a Deputized Voting Member of the FDA Medical Devices Advisory Committee (Neurological Devices Panel) and FDA Endocrinologic and Metabolic Drugs Advisory Committee. He also served as Chair of the World Health Organization (WHO) World Mental Health Survey Initiative's Services Research Work Group. He is currently a member of the American Psychiatric Association's (APA) *Diagnostic and Statistical Manual, Fifth Revision (DSM-V)* Task Force and has consulted on several APA Workgroups that developed evidence-based treatment guidelines. Dr. Wang actively taught throughout his time at Harvard, including mentoring residents and clinical fellows on their research projects. At the Harvard School of Public Health, he taught the Introductory Psychiatric Epidemiology course, lectured in the Advanced Pharmacoepidemiology course, and advised doctoral and master's level students.



Kenneth Warren, Ph.D.

National Institute on Alcohol Abuse and Alcoholism

Dr. Kenneth Warren is a nationally-recognized expert on alcohol and pregnancy, and a long-time senior administrator at the National Institute on Alcohol Abuse and Alcoholism (NIAAA). He 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 joined NIAAA in 1976 as a staff member of the then Division of Research. He later became chief of the Biomedical Research Branch, and then deputy director of the Division of Extramural Research. From 1984 to 2005, he directed the Office of Scientific Affairs, whose responsibilities included peer review, grants management, committee management, scientific communications, and activities of the NIAAA National Advisory Council and Extramural Advisory Board. From 2002 to 2007, Dr. Warren served as Associate Director for Basic Research, and over the past year he has also served as acting director of the institute's Office of Science Policy and Communications. 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 1994, Dr. Warren received the Seixas Award from the Research Society on Alcoholism (RSA). In 2002, he received the Henry Rosett Award from the Fetal Alcohol Syndrome Study Group of RSA. 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.

Economics of Drug Development Plenary

Wednesday, June 15th from 8:30 am – 11:30 am



Ernst R. Berndt, Ph.D.

MIT Sloan School of Management

Dr. Ernst R. Berndt is the Louis E. Seley Professor in Applied Economics at the MIT Sloan School of Management, and Co-Director of the Harvard-MIT Biomedical Enterprise Program. He has served as Director of the National Bureau of Economic Research Program on Technological Progress and Productivity Measurement, and until recently was Chair of the Federal Economic Statistics Advisory Committee, an interagency committee formed by the Bureau of Labor Statistics, the Bureau of Economic Analysis, and the U.S. Census Bureau. He also served as a Panel Member of the National Science Foundation Panel on Measurement, Methodology and Statistics. Currently, he serves on the Editorial Board of Health Affairs. Berndt's health care research has been published in peer-reviewed journals such as the New England Journal of Medicine, American Journal of Psychiatry, Journal of Mental Health Policy and Economics, Journal of Health Economics, and Health Affairs. In 1985, he was named the most cited economist under age 40. Professor Berndt received his Ph.D. degree in economics from the University of Wisconsin - Madison in 1972, and was awarded an honorary doctorate from Uppsala University in Sweden in 1991. He is an elected Fellow of the Econometric Society. In the last decade, much of Professor Berndt's research has focused on economic issues in health care, with a strong emphasis on measurement of costs, outcomes and prices.



Karl Broich, M.D.

Federal Institute for Drugs and Medical Devices

Dr. Karl Broich is the Vice-President and Professor at the Federal Institute for Drugs and Medical Devices. From 1985 to 2000, Dr. Broich performed clinical and research work at hospitals of the universities of Bonn, Halle/Saale and Philadelphia (PennU) (Board certifications in Neurology, Psychiatry, Behavioural Psychotherapy). He served as Head of the Section Neurology/Psychiatry from 2000 to 2005 and became the department head from 2005 to 2009. Since 2009, Dr. Broich has been the deputy head (Vice-President) at the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn (Germany). He also served as an alternate member of the Committee for Medicinal Products for Human Use (CHMP) from 2005 to 2009, and has served as vice-chair of CNS-Workgroup at the European Medicines Agency (EMA) since 2010. Current research activities include: clinical trials methodology CNS, biomarkers in drug development, Alzheimer's disease and other neurodegenerative disorders. He holds memberships in several learned societies of the CNS field. Dr. Broich has authored and served as a co-author for more than 90 Publications (peer reviewed articles, reviews, and book sections).



Dr. med. Thomas Kaiser

Ressortleiter Arzneimittelbewertung Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

Dr. Thomas Kaiser is a physician and system developer (IT-specialist). In 1990, he received a degree in System Development. He also received degree in Medicine in 1999. Dr. Kaiser is the Co-founder of the German Institute of Evidence-based Medicine (DleM) in Cologne. He is a member of DleM's Management Committee and Project Leader for "Drug Assessment" and "Disease Management Programmes". From 2002 to 2004, Dr.

Kaiser served as an expert in working groups for Disease Management Programmes in the Coordination Committee and Federal Joint Committee. Since 2004, Dr. Kaiser has served as Head of Drug Assessment Department at IQWiG.



Joseph Parks, M.D.

Missouri Department of Mental Health

Dr. Joseph Parks serves as the Chief Clinical Officer for the Missouri Department of Mental Health in Jefferson City. He also holds the position of Distinguished Research Professor of Science at the University of Missouri – St. Louis and Director of the Missouri Institute of Mental Health. He also serves as a Clinical Assistant Professor of Psychiatry at the University of Missouri, Department of Psychiatry in Columbia. He serves as President of the Medical Director's Council of the National Association of

State Mental Health Program Directors. He practices psychiatry on an outpatient basis at Family Health Center, a federally funded community health center established to expand services to uninsured and underinsured patients in the Columbia area. He recently served as the Division Director for the Division of Comprehensive Psychiatric Services for the Missouri Department of Mental Health. Dr. Parks has authored or coauthored a number of original articles, monographs, technical papers, and reviews on implementation of Evidence Based Medicine and Pharmacy Utilization Management and behavioral treatment programs. His work has appeared in several journals: *Journal of Organizational Behavior*, *Journal of Psychiatric Practices*, *Psychiatry Quarterly*, *Manual of Clinical Emergency Psychiatry*, *Behavioral Interviews*, *Hospital and Community Psychiatry*, and *Advanced Studies in Nursing*.



Husseini Manji, M.D., F.R.C.P.C.

Johnson and Johnson Pharmaceutical Research and Development

Husseini K. Manji, M.D. is Global Therapeutic Head, Neuroscience of Johnson and Johnson Pharmaceutical Research and Development. He was previously Chief, Laboratory of Molecular Pathophysiology & Experimental Therapeutics, NIH, and director of the NIH Mood and Anxiety Disorders Program, the largest program of its kind

in the world. He is also a visiting professor at Duke University. Dr. Manji received his B.S. (Biochemistry) and M.D. from the University of British Columbia. Following residency training, he completed fellowship training at the NIMH and obtained extensive additional training in cellular and molecular biology at the NIDDK. The major focus of his research has been the investigation of disease and treatment-induced changes in gene and protein networks that regulate synaptic and neural plasticity in neuropsychiatric disorders. His work has helped to conceptualize these illnesses as genetically-influenced disorders of synaptic and neural plasticity and has led to the investigation of novel therapeutics for refractory patients. He has also been actively involved in the development of biomarkers to help refine these multifactorial diseases into mechanism-based subcategories to develop targeted therapeutics. Dr. Manji is a previous recipient of numerous research awards, including: the NIMH Director's Career Award for Significant Scientific Achievement, the A. E. Bennett Award for Neuropsychiatric Research, the Ziskind-Somerfeld Award for Neuropsychiatric Research, the NARSAD Mood Disorders Prize, the Mogens Schou Distinguished Research Award, the American College of Neuropsychopharmacology (ACNP)'s Joel Elkes award for distinguished research, the Canadian Association of Professors Award, the Brown University School of Medicine Distinguished Researcher Award, the DBSA Klerman Senior Distinguished Researcher Award, the American Federation for Aging Research Award of Distinction, and the NIMH award for excellence in clinical care and research.

Steering Committee Chairs

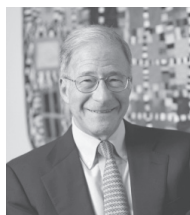


William Z. Potter, M.D., Ph.D.



Nina R. Schooler, Ph.D.

Program Chairs



David J. Kupfer, M.D.

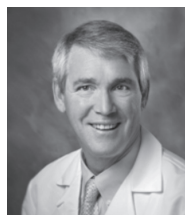


Carlos A. Zarate, M.D.

New Investigator Award Program Chairs



Lauren D. Hill, Ph.D.



Mark H. Rapaport, M.D.

Poster Chair



Maurizio Fava, M.D.

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Federal Institute of Drugs and Medical Devices

Maurizio Fava, M.D.
The Massachusetts General Hospital (ASCP Board Member)

Donald Goff, M.D.
The Massachusetts General Hospital

Robert K. Heinssen, Ph.D., A.B.P.P.
National Institute of Mental Health

John M. Kane, M.D.*
The Zucker Hillside Hospital and Albert Einstein College of Medicine
(ASCP Board Member)

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

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

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

Husseini K. Manji, M.D., F.R.C.P.C
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State University of New York, Downstate Medical Center

Philip Skolnick, Ph.D., D.Sc.
National Institute on Drug Abuse

★ Carlos A. Zarate, M.D.
National Institute of Mental Health

★New Investigator Awardee Alumnae *Representing ASCP CME Committee

New Investigator Award Program Committee

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Food and Drug Administration
- ★ Christoph U. Correll, M.D.
The Zucker Hillside Hospital and Albert Einstein College of Medicine
(ASCP Board Member)

Lauren D. Hill, Ph.D.
National Institute of Mental Health

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

Mark H. Rapaport, M.D.*
Cedars-Sinai Medical Center and University of California, Los Angeles
School of Medicine (ASCP Board Member)

Deidra Roach, M.D.
National Institute of Alcohol Abuse and Alcoholism

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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 - Alan Breier, M.D.
Indiana University Mental Health Research and Education
 - ★ Christoph U. Correll, M.D.
The Zucker Hillside Hospital (ASCP Board Member)

Michael Egan, M.D.
Merck & Company
- ★**New Investigator Awardee Alumnae** ★**Representing ASCP CME Committee**

Program Committee (continued)

Susan Essock, Ph.D.
Columbia University, New York State Psychiatric Institute

Maurizio Fava, M.D.
Massachusetts General Hospital (ASCP Board Member)

Matthew Friedman, M.D.
Dartmouth Medical School

Judy Garber, Ph.D.
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Dilip Jeste, M.D.
University of California, San Diego

Richard Keefe, Ph.D.
Duke University Medical Center

Helena Kraemer, Ph.D.
Stanford University

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

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

★ Andrew Leon, Ph.D.
Weill Cornell Medical College

★ Anil Malhotra, M.D.
The Zucker Hillside Hospital

John March, M.D., M.P.H.
Duke Clinical Research Institute

★**New Investigator Awardee Alumnae** ***Representing ASCP CME Committee**

Program Committee (continued)

Stephen Marder, M.D.
Semel Institute, UCLA

Craig Nelson, M.D.*
University of California San Francisco (ASCP Board Member)

Thomas Newton, M.D.
Baylor College of Medicine

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Massachusetts General Hospital

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

Jerrold Rosenbaum, M.D.
Massachusetts General Hospital

Bruce Saltz, M.D., P.A.
Mental Health Advocates, Inc.

Stephen Stahl, M.D.
University of California San Diego

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

Mauricio Tohen, M.D., Dr.PH, M.B.A.
UT Health Science Center San Antonio

★ Janet Williams, D.S.W.
MedAvante

★ Kimberly Yonkers, M.D.
Yale School of Medicine

★ Carlos A. Zarate, M.D.
National Institute of Mental Health

★New Investigator Awardee Alumnae *Representing ASCP CME Committee

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Meeting Services

Registration Desk Hours:

Sunday	12:00 pm – 5:00 pm
Monday	7:30 am – 5:00 pm
Tuesday	7:30 am – 6:00 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 Mizner Center.

The NCDEU Computer Center is open on the below dates and times for attendees to briefly check emails. The Computer Center is located in the Mizner Center in the Estate Salon III.

Hours:

Sunday	12:00 pm – 5:00 pm
Monday	7:30 am – 5:00 pm
Tuesday - Wednesday	7:30 am – 6:00 pm
Thursday	7:30 am – 12:00 pm

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

Sunday	12:00 pm – 5:00 pm
Monday	7:30 am – 5:00 pm
Tuesday - Wednesday	7:30 am – 6:00 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 the message board at the NCDEU registration desk.

Discounts for tennis, golf and spa services are available to all NCDEU attendees and families. Call the concierge at extension 3700 for golf or tennis. The Boca Raton Resort & Club is offering all NCDEU guests a 15% discount on golf, tennis court fees and lessons. You must identify yourself as an NCDEU guest to obtain the discount. Advance reservations are recommended. The Spa Palazzo is also offering all NCDEU registrants and their families a \$15.00 discount per person per day off all spa services of fifty (50) minutes or more. Advance reservations are recommended and can be made by calling 4772 from a house phone. Be sure to identify yourself as an NCDEU guest.

Continuing Education Credits

Disclosures are available for all NCDEU presenters online at www.ncdeumeeting.org.

Continuing Education Credits are available for physicians, pharmacists, psychologists, nurses and social workers. Applications for credit must be completed online with the meeting evaluation survey. The survey may be completed in the NCDEU Computer Center in Estate Salon III or after the conference at www.ncdeumeeting.org. ***Surveys for continuing education credit must be submitted no later than July 15, 2011.*** 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



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The American Society for Clinical Psychopharmacology (ASCP) designates this live meeting for a maximum of 22 AMA PRA Category 1 Credit(s)TM.

Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Pharmacists



The University of South Florida College of Medicine is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program has been approved for 26 contact hours. Universal program number is as follows: 0230-9999-11-008-L01-P. To receive continuing education credit, a pharmacist must attend the accredited sessions 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.

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 program has been approved for 26 contact hours.

Nurses



® The University of South Florida College of Nursing is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. A maximum of 26 contact hours may be earned by learners who successfully complete this continuing nursing education activity.

Social Workers



® USF Health is an approved provider (BAP#433 – Exp. 3/31/13) of continuing education credits for clinical social work, marriage and family therapy, and mental health counseling. This program has been reviewed and approved for up to 31, 50-minute contact hours.

All participants who request continuing education credits by July 15, 2011, will receive their statement of credits via email by August 22, 2011.

The Meeting Evaluation Survey will be available at www.ncdeumeeting.org. We encourage all registrants to complete the evaluation. Attendees requesting CME or CE credits must complete the survey in order to obtain credits. Your candid input on the 2011 meeting is appreciated as we strive to improve the meeting each year.

NCDEU Meeting Support – The 2011 NCDEU Meeting receives no corporate funding.

NCDEU 2012 – The 52nd meeting of NCDEU will take place May 28–31, 2012 at the Arizona Biltmore in Phoenix, Arizona. Details regarding abstract submission for the 2012 will be released in September, 2011.

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AT-A-GLANCE

Sunday, June 12th

8:30 am – 4:30 pm	New Investigator Workshop (Invitation Only) Grand Ballroom G-H
12:00 pm – 5:00 pm	Registration Open Mizner Center Main Entrance

[illegible]

8:30 am – 4:30 pm

Grand Ballroom G-H

New Investigator Workshop (Invitation Only)

Co-Chairs: Mark H. Rapaport, M.D., Cedars-Sinai Medical Center and University of California, Los Angeles School of Medicine
Lauren D. Hill, Ph.D., National Institute of Mental Health

The NCDEU 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 13th. This year's 20 New Investigator awardees are indicated with a ribbon in the poster section of this program.

Faculty

Mark T. Bunker, Pharm.D., B.C.P.P.
Cyberonics, Inc.

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

Lauren D. Hill, Ph.D.
National Institute of Mental Health

Andrew C. Leon, Ph.D.
Weill Medical College of
Cornell University

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

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

Mark H. Rapaport, M.D.
Cedars-Sinai Medical Center and
University of California, Los Angeles
School of Medicine

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

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

New Investigator Awardees

Chadi Abdallah, M.D.
SUNY Downstate Medical Center

Rivi Ben Dor, M.D.
NIMH

Jatinder Chawla, M.D.
SUNY Downstate Medical Center

Arman Danielyan, M.D.
Cincinnati Children's Hospital Medical Center

Marta Hauser, Ph.D.
The Zucker Hillside Hospital,
North Shore Long Island Jewish
Medical Center

Styliani Kaliora, M.D.
The Zucker Hillside Hospital

Taishiro Kishimoto, M.D., Ph.D.
The Zucker Hillside Hospital

Maju Koola, M.D., D.P.M.
Maryland Psychiatric Research Center,
University of Maryland School of
Medicine

Fernanda Laezza, M.D., Ph.D.
UTMB

Tara Lauriat, Ph.D.
St. Elizabeth's Medical Center

Nadia Iovieno, M.D.
MGH, Depression Clinic and
Research Program

Erin McGlade, Ph.D.
University of Utah Brain Institute

Jimmi Nielsen, M.D., Ph.D.
Aalborg Psychiatric Hospital

Chad Rethorst, Ph.D.
University of Texas - Southwestern
Medical Center

Amar Sahay, Ph.D.
Columbia University

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

Luke Stoeckel, Ph.D.
Harvard/MGH

Walter Swardfager, MSc
Sunnybrook Health Sciences Centre

Jeremy Veenstra-VanderWeele, M.D.
Vanderbilt University

Jennice Vilhauer, Ph.D.
Cedars-Sinai Medical Center

AT-A-GLANCE

Monday, June 13th

7:30 am – 8:30 am **New Investigator Awardee Roundtable Breakfast (Invitation Only)**
Veranda Salon IV

7:30 am – 9:00 am **Continental Breakfast**
Grand & Royal Palm Assemblies (Mizner Center)

8:30 am – 9:00 am **Conference Opening**
Grand Ballroom A-E

9:00 am – 10:30 am **Concurrent Panel Sessions**

<i>NIAAA Panel - Personalized Medicine: Genetic Polymorphisms and Medications</i>	<i>NIDA Panel - Magic Bullets and Arrows: Biologics to Treat Substance Use Disorders</i>	<i>NIMH Panel - Establishing Moderators and Biosignatures of Antidepressant Response for Clinical Care (EMBARC)</i>
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm Salon II-IV

10:30 am – 10:45 am **Coffee Break**
Grand/Royal Palm Assemblies (Mizner Center)

10:45 am – 11:45 am **Concurrent Individual Research Reports**

<i>Late Breaking Research Reports 1</i>	<i>Late Breaking Research Reports 2</i>	<i>Late Breaking Research Reports 3</i>
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm Salon II-IV

11:45 am – 1:30 pm **Lunch on own**

1:30 pm – 3:00 pm

Plenary - Regulatory Perspectives on Psychiatric Drug Development from Food and Drug Administration (FDA) and European Medicines Agency (EMA)

Grand Ballroom A-E

3:00 pm – 3:15 pm

Coffee Break

Grand/Royal Palm Assemblies

3:15 pm – 4:45 pm

Concurrent Individual Research Reports

<i>Research Reports – Schizophrenia</i>	<i>Research Reports – Methodological Innovations</i>	<i>Research Reports – Depression</i>
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm Salon II-IV

6:00 pm – 7:30 pm

New Investigator Award Ceremony & Reception (Invitation Only)

Addison West Ballroom

7:30 am – 8:30 am ***New Investigator Awardee Roundtable Breakfast
(Invitation Only)
Veranda Salon IV***

7:30 am – 9:00 am ***Continental Breakfast
Grand/Royal Palm Assemblies (Mizner Center)***

8:30 am – 9:00 am ***Conference Opening
Grand Ballroom A-E***

Panel Sessions

9:00 am – 10:30 am ***NIAAA Panel - Personalized Medicine:
Genetic Polymorphisms and Medications
Grand Ballroom G-H***

Chairs: Antonio Noronha, Ph.D.
 National Institute on Alcohol Abuse and Alcoholism
 Raye Litten, Ph.D.
 National Institute on Alcohol Abuse and Alcoholism

9:00 am – 9:25 am ***Pharmacogenetic Approach at the Serotonin
Transporter Gene as a Method to Reduce Severe
Alcohol Consumption***
Bankole Johnson, Sc.D., M.D., Ph.D., University of
Virginia

9:25 am – 9:50 am ***Pharmacogenetics of Mu Opioid Receptor Gene
Polymorphisms for Alcohol Dependence***
David Oslin, M.D., University of Pennsylvania

9:50 am – 10:15 am ***Pharmacogenomics of Alcohol and Alcohol
Pharmacotherapies Studied in the Human
Laboratory***
Robert Swift, M.D., Ph.D., Brown University

10:15 am – 10:30 am ***General Discussion***

9:00 am – 10:30 am ***NIDA Panel - Magic Bullets and Arrows:
Biologics to treat Substance Use Disorders
Grand Ballroom I-J***

Chairs: Jane B. Acri, Ph.D., National Institute on Drug Abuse
David McCann, Ph.D., National Institute on Drug Abuse

9:00 am – 9:25 am **Vaccines for Cocaine Dependence**
Thomas Kosten, M.D., Baylor College of Medicine

9:25 am – 9:50 am **Engineered ButyrylCholinesterase for Cocaine
Addiction Treatment**
Merav Bassan, Ph.D., TEVA Pharmaceutical Industries

9:50 am – 10:15 am **Safety and Efficacy of the Nicotine Vaccine
(NicVAX) for Smoking Cessation**
Raafat Fahim, Ph.D., Nabi Biopharmaceuticals

10:15 am – 10:30 am **General Discussion**

9:00 am – 10:30 am ***NIMH Panel - Establishing Moderators and
Biosignatures of Antidepressant Response for
Clinical Care (EMBARC)
Royal Palm Salon II-IV***

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

9:00 am – 9:05 am **Introduction**
Benedetto Vitiello, M.D., National Institute of Mental Health

9:05 am – 9:30 am **Rationale and Selection of Interventions and
Outcome Variables**
Madhukar Trivedi, M.D., University of Texas Southwestern

9:30 am – 9:55 am **EMBARC Design and Methods**
Patrick McGrath, M.D., New York State Psychiatric Institute

9:00 am – 10:30 am
(continued) ***NIMH Panel - Establishing Moderators and Biosignatures of Antidepressant Response for Clinical Care (EMBARC)***
Royal Palm Salon II-IV

9:55 am – 10:20 am **Analytical Approach to EMBARC Data**
Eva Petkova, Ph.D., New York University School of Medicine

10:20 am – 10:30 am **General Discussion**

10:30 am – 10:45 am **Coffee Break**
Grand/Royal Palm Assemblies (Mizner Center)

Individual Research Reports

10:45 am – 11:45 am ***Late Breaking Research Reports 1***
Grand Ballroom G-H

Chair: Jerrold Rosenbaum, M.D., Massachusetts General Hospital

10:45 am – 11:00 am **Clinical Trials of Potential Cognitive-Enhancing Drugs in Schizophrenia: What Have We Learned So Far?**
Richard Keefe, M.D., Duke University Medical Center

11:00 am – 11:15 am **Reducing the Effect of Drug Company Promotion**
Jeffrey Mattes, M.D., Psychopharmacology Research Association of Princeton

11:15 am – 11:30 am **Double-Blind Study of Quetiapine for the Treatment of Cocaine Dependence**
Andre Tapp, M.D., VA Puget Sound Health Care System

11:30 am – 11:45 am **Clinically Unintended Medication Switches and Inability to Prescribe Preferred Medications Under Medicare Part D**
Darrel Regier, M.D., M.P.H., American Psychiatric Institute

10:45 am – 11:45 am *Late Breaking Research Reports 2*
Grand Ballroom I-J

Chair: Holly Swartz, M.D., University of Pittsburgh School of Medicine*

10:45 am – 11:00 am **Regulatory Requirements on Biomarkers for Drug Development: an EU Perspective**

Karl Broich, M.D., Federal Institute for Drugs and Medical Devices, Bonn, Germany

11:00 am – 11:15 am **Quantitative Assessment of Beta-Amyloid Aggregation with Florbetapir F18 PET as a Biomarker for MCI and AD Trials**

P. Murali Doraiswamy, M.D., Duke University*

11:15 am – 11:30 am **Characterization of the Lorazepam Dose-Response Relationship using resting-state Magnetoencephalography (MEG) and Electroencephalography (EEG)**

Todd A. Verdoorn, Ph.D., Orasi Medical

11:30 am – 11:45 am **A Novel Method to Monitor Medication Adherence and Physiologic Parameters in Psychiatric Patients Using Ingestible Markers: Early Clinical Experience**

John Kane, M.D., The Zucker Hillside Hospital

***New Investigator Awardee Alumni**

**10:45 am – 11:45 am Late Breaking Research Reports 3
Royal Palm Salon II-IV**

Chair: Katherine Beebe, Ph.D., Titan Pharmaceuticals, Inc.

10:45 am – 11:00 am **Placebo-Related Response in Clinical Trials for Bipolar Mania: What is Driving this Phenomenon and What Can be Done to Minimize it?**
Aysegul Yildiz, M.D., Dokuz Eylül University

11:00 am – 11:15 am **Affective Instability in Maintenance Treatment of Bipolar I and II Depression**
Vivek Singh, M.D., UTHSCSA

11:15 am – 11:30 am **Adjunctive Risperidone Treatment for Antidepressant-Symptoms of Chronic Military Service-Related PTSD: Findings of VA Cooperative Study #504**
John Krystal, M.D., VA National Center for PTSD,
Yale University School of Medicine & VA Connecticut Healthcare System

11:30 am – 11:45 am **The Remission from Depression Questionnaire**
Mark Zimmerman, M.D., Rhode Island Hospital

11:45 am – 1:30 pm Lunch on own

Plenary

1:30 pm – 3:00 pm ***Regulatory Perspectives on Psychiatric Drug Development from Food and Drug Administration (FDA) and European Medicines Agency (EMA)***
Grand Ballroom A-E

Chairs: Mitchell Mathis, M.D., Food and Drug Administration
Karl Broich, M.D., Federal Institute of Drugs and Medical Devices,
Bonn, Germany

Psychiatric drug development has become multinational and pharmaceutical sponsors must operate in a multinational regulatory framework. This session will provide perspectives from regulators representing FDA and EMA. Karl Broich, representing EMA, is Vice President of the German BfArM and Deputy Chair of the CNS Working Group at EMA, and Mitchell Mathis, representing FDA, is Director of the Division of Psychiatry Products. Each regulator will provide a very brief introduction to the agency each represents, and then provide a perspective on a few selected regulatory issues that are common to all regulatory agencies. Each regulator will have roughly 30 minutes to provide formal comments, and the session will then continue for the final 30 minutes with a more informal discussion with the audience on these selected issues as well as other regulatory matters of common interest to the group. The goal of the session will not be to achieve consensus on regulatory issues, but rather, to gain insight and understanding of similarities and differences in how FDA and EMA address drug development matters of common interest.

1:30 pm – 1:45 pm **The European Medicines Agency and the Centralized Procedure for Drug Approval**
Manuel Haas, PharmD, MSc, Head of the Central Nervous System and Ophthalmology Section in the European Medicines Agency

1:45 pm – 2:15 pm **FDA Perspective on Selected Regulatory Issues Pertinent to Psychiatric Drug Development**
Mitchell Mathis, M.D., Food and Drug Administration

2:15 pm – 2:45 pm **EMA Perspective on Selected Regulatory Issues Pertinent to Psychiatric Drug Development**
Karl Broich, M.D., Federal Institute of Drugs and Medical Devices, Bonn, Germany

2:45 pm – 3:00 pm **General Discussion**

Individual Research Reports

3:15 pm – 4:45 pm Research Reports – Schizophrenia Grand Ballroom G-H

Chair: Donald Goff, M.D., Massachusetts General Hospital

- | | |
|-------------------|---|
| 3:15 pm – 3:30 pm | Pioglitazone as a Treatment for Glucose and Lipid Abnormalities in Schizophrenic Patients: A Double-Blind Placebo Controlled Study
Robert Smith, M.D., Ph.D., NYU Medical School and NKI |
| 3:30 pm – 3:45 pm | Oxytocin Treatment Improves Social Cognition and Reduces Psychotic Symptoms in Schizophrenia
Cort A. Pedersen, M.D., University of North Carolina School of Medicine |
| 3:45 pm – 4:00 pm | Using EEG, PET and Other Early Pharmacodynamic Data to Inform Dose Selection in the Clinical Development of ITI-007
Kimberly E. Vanover, Ph.D., Intra-Cellular Therapies, Inc. |
| 4:00 pm – 4:15 pm | More Efficient Drug Discovery Trials in Schizophrenia: Insights from 29 Placebo-Controlled RCTs of Second-Generation Antipsychotics in the NEWMEDS Repository
Jonathan Rabinowitz, Ph.D., Bar Ilan University |
| 4:15 pm – 4:30 pm | Long-term Efficacy and Effectiveness of Antipsychotic Medication for Schizophrenia, a Data-driven Personalized, Clinical Approach
Ira D. Glick, M.D., Stanford University School of Medicine |
| 4:30 pm – 4:45 pm | Low Dose Naltrexone for Antipsychotic Induced Weight Gain in Women with Schizophrenia
Cenk Tek, M.D., Yale University School of Medicine |

3:15 pm – 4:45 pm

***Research Reports – Methodological Innovations
Grand Ballroom I-J***

Chair: Deanna Barch, Ph.D., Washington University

3:15 pm – 3:30 pm

The Usefulness of Positive Controls and Active Comparators in Proof of Concept Trials

Craig Mallinckrodt, M.D., Eli Lilly & Company

3:30 pm – 3:45 pm

Five Alternative Assessment Methods to Determine Patient Eligibility in CNS Trials

Steven D. Targum, M.D., Clintata, LLC

3:45 pm – 4:00 pm

Prospective Assessment and the Electronic Columbia-Suicide Severity Rating Scale (eC-SSRS): Using Technology to Improve Precision for Risk Estimation and Safety Monitoring, Optimize Data Collection, and Decrease Burden

Kelly L. Posner, Ph.D., Columbia University

4:00 pm – 4:15 pm

Now You See It, Now You Don't: Challenges in Measuring Hostility and Aggression

Leslie Citrome, M.D., Nathan S Kline Institute for Psychiatric Research

4:15 pm – 4:30 pm

Computer Administered Scales: View from a Third Blind Eye

Gary S. Sachs, M.D., Massachusetts General Hospital & United BioSource Corporation

4:30 pm – 4:45 pm

Issues in Training and Surveillance of Raters in CNS Clinical Trials

David G. Daniel, M.D., United Biosource Corporation

3:15 pm – 4:45 pm *Research Reports – Depression*
Royal Palm Salon II-IV

Chair: Craig Nelson, M.D., University of California, San Francisco

3:15 pm – 3:30 pm **Compound Identified by Neurogenesis Platform Shows Promising Efficacy in Treatment of Patients with Major Depressive Disorder (MDD) with Concomitant Generalized Anxiety Disorder (GAD)**

Allan H. Young, M.D., Ph.D., University of British Columbia

3:30 pm – 3:45 pm **L-methylfolate Augmentation of Selective Serotonin Reuptake Inhibitors (SSRIs) for Major Depressive Disorder: Results of Two Randomized, Double-Blind Trials**

George Papakostas, M.D., Massachusetts General Hospital and Harvard Medical School*

3:45 pm – 4:00 pm **Pilot Study of Paroxetine to Prevent Development of Depression in Primary Brain Tumor Patients**

Elana Farace, Ph.D., Penn State University College of Medicine

4:00 pm – 4:15 pm **Duloxetine vs. Placebo in the Treatment of Non-Major Chronic Depressive Disorder**

David J. Hellerstein, M.D., Columbia University

4:15 pm – 4:30 pm **Efficacy and Safety of OPC-34712, a Novel Psychotropic, as Adjunctive Treatment for Major Depressive Disorder**

Michael E. Thase, M.D., University of Pennsylvania

4:30 pm – 4:45 pm **Impact of Agreement between Clinician and Patient Ratings of Symptom Severity and Anxiety on Response to Antidepressant Treatment in Major Depressive Disorder**

Boadie W. Dunlop, M.D., Emory University School of Medicine*

6:00 pm – 7:30 pm *New Investigator Awards Ceremony & Reception – Led by Mark Rapaport and Lauren Hill (Invitation Only)*
Addison West Ballroom

***NCDEU New Investigator Awardee Alumnae**

[illegible]

AT-A-GLANCE

Tuesday, June 14th

- 7:00 am – 8:30 am **ASCP Board Meeting**
Royal Palm Salon I
- 7:30 am – 8:30 am **New Investigator Awardee Roundtable Breakfast (Invitation Only)**
Veranda Salon IV
- 7:30 am – 9:00 am **Continental Breakfast**
Grand & Royal Palm Assemblies (Mizner Center)
- 8:30 am – 10:30 am **Plenary – NIMH, NIDA & NIAAA Institute Directors**
Grand Ballroom A-E
- 10:30 am – 10:45 am **Coffee Break**
Grand/Royal Palm Assemblies (Mizner Center)
- 10:45 am – 12:15 pm **Concurrent Panel Sessions**

<i>Long Term Treatment in Schizophrenia: The NIMH PROACTIVE Study</i>	<i>Cross-Cutting Dimensional Assessment for Diagnostic Syndromes</i>	<i>Update on Child and Adolescent Psychopharmacologic Treatment Patterns and Safety in Community Practice: Evidence from Medicaid Datasets</i>
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm Salon II-IV

- 12:30 pm – 2:30 pm **Poster Session I with Box Lunches**
Royal Palm V-X

2:45 pm – 5:45 pm

Concurrent Workshops

<i>Developing Dynamic, Sequential Treatments that Optimize Mental Health Outcomes: Novel Clinical Trial Design and Data Analysis Strategies</i>	<i>Evidence-Based Evaluation and Treatment of Youth with Maladaptive Aggression</i>	<i>The Risks and Benefits of Including Suicidal Patients in Clinical Trials: Scientific, Ethical, and Regulatory Perspectives</i>	<i>The Automation of Cognitive Testing in Clinical Trials</i>
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm Salon II-IV	Location: Addison Ballroom

4:15 pm – 4:30 pm

Break During Workshops

6:00 pm – 7:30 pm

NCDEU Reception Garden Pool

7:00 am – 8:30 am **ASCP Board Meeting**
Royal Palm Salon I

7:30 am – 8:30 am **New Investigator Awardee Roundtable Breakfast**
(Invitation Only)
Veranda Salon IV

7:30 am – 9:00 am **Continental Breakfast**
Grand/Royal Palm Assemblies (Mizner Center)

Plenary Session

8:30 am – 10:30 am **Plenary – NIMH, NIDA & NIAAA Institute Directors**
Grand Ballroom A-E

Chair: David J. Kupfer, M.D., University of Pittsburgh School of Medicine
NCDEU 2011 Program Committee Chair

8:30 am – 9:00 am **Developing the Next Generation of Treatments for**
Mental Disorders
Phillip S. Wang, M.D., National Institute of Mental
Health

Monoamines have been long-standing therapeutic targets due to early, often serendipitous, clinical observations of their usefulness in the treatment of mental disorders. Although this focus has yielded our current medications and even some new therapeutic strategies, the treatment armamentarium is far from sufficient. Fortunately, discoveries in genomics and neuroscience are beginning to elucidate the neurobiological bases underlying mental illnesses. Many of these offer promising translational opportunities. This presentation will provide an overview of recent research findings illustrating potential new therapeutic targets at the genetic, epigenetic, molecular, cellular, and circuit levels. Recent efforts at the National Institute of Mental Health to foster the development of new efficacious, safe, and personalized treatments for mental disorders will also be discussed.

**8:30 am – 10:30 am
(continued)**

**Plenary – NIMH, NIDA & NIAAA Institute Directors
Grand Ballroom A-E**

9:00 am – 9:30 am

Frontiers of Medications for Addiction

Nora D. Volkow, M.D., National Institute of Drug Abuse

Neuroscientific discoveries over the past decade have enriched our understanding of the neurobiological mechanisms underlying addiction. This research has identified new molecular mechanisms and processes as potential targets for pharmacotherapies for addiction. For example, findings from genetics that have shown that the nicotine alpha 5 and beta 3 receptors may be involved in nicotine addiction suggest that compounds that interact with these receptors may be beneficial for smoking cessation. Our understanding of the neuroplastic changes that occur with addiction including modification to dopamine signaling (D1, D2 and D3 receptors) and glutamate neurotransmission (NMDA and AMPA, receptors, glutamate transporters) and of the neuronal pathways affected such as prefrontal networks involved with executive function have also identified promising new approaches to aim at reverting drug induced changes. In parallel, advances in vaccine technology have now made it feasible to develop vaccines that target specific drugs of abuse as is the case for the nicotine and cocaine vaccine which are currently being tested in humans subjects. Finally, clinical studies are also starting to reveal the potential of slow release formulations (ie naltrexone, biuprenorphine) or of medication combinations (veranicline + bupropion) as more effective strategies for the treatment of substance use disorders. However, translation of these potential medications into the clinic will require a stronger partnership between public and private efforts.

**8:30 am – 10:30 am
(continued)**

**Plenary – NIMH, NIDA & NIAAA Institute Directors
Grand Ballroom A-E**

9:30 am – 10:00 am

***Advances in Medications Development to Treat
Alcohol Dependence***

Kenneth Warren, Ph.D., National Institute of Alcohol
Abuse and Aging

Efforts to develop medications for Alcohol Use Disorders (AUD) have expanded rapidly in recent years. So far, four medications have been approved by the FDA for alcoholism treatment. However, because of the heterogeneous nature of AUD, many patients have limited or no response to these medications. Therefore, developing new medications is an important step in providing treatment to a greater number of patients. Identification of more effective targets for drug development of alcohol dependence requires a better understanding of the elements that encompass multiple aspects of dependence. Currently, there are many promising targets being investigated. Studies are also underway to improve the tools for drug development. These include validating screening models using animal and human lab paradigms to predict clinical performance, optimizing the methodology of alcohol clinical trials, and discovering and developing alcohol biomarkers. A network of clinical sites, called the NIAAA Clinical Investigations Group (NCIG), has been established to conduct proof of concept trials on promising medications. NCIG has a quick turnaround time using a pharmaceutical model of operation. In addition, over 30 Phase 2 pharmacotherapy trials are supported studying a variety of agents in various AUD populations, including the understudied populations of psychiatric and substance abuse comorbidity, comorbid medical disorder, and adolescent/young adults. Finally, progress has been made in advancing personalized medicine. For example, in recent studies, polymorphisms of several genetic sites have been shown to influence responses to several medications, including naltrexone and ondansetron. Our goal, over the next decade, is to make the translational process of drug development, from drug discovery and preclinical testing to human studies to implementation in real-world treatment settings, more efficient and effective. In carrying out this goal, it is essential to establish collaborative networks and partnerships among government, academia, pharmaceutical industry, healthcare organizations, and advocacy groups.

10:00 am – 10:30 am

General Discussion

10:30 am – 10:45 am **Coffee Break**
Grand/Royal Palm Assemblies (Mizner Center)

Panel Sessions

10:45 am – 12:15 pm **Long Term Treatment in Schizophrenia: The NIMH PROACTIVE Study**
Grand Ballroom G-H

Chair: Nina R. Schooler, Ph.D., The Zucker Hillside Hospital

10:45 am – 10:50 am **Introduction**
Nina R. Schooler, Ph.D., The Zucker Hillside Hospital

10:50 am – 11:10 am **The PROACTIVE Study: Innovations in Design and Assessment**
Nina R. Schooler, Ph.D., The Zucker Hillside Hospital

11:10 am – 11:30 am **The PROACTIVE Study Cohort: Characterization and Baseline Symptoms**
John Lauriello, M.D., University of Missouri School of Medicine

11:30 am – 11:50 am **Initial Results: Time to Relapse Comparison Between LAI and Oral Second-Generation Anti-Psychotics**
Peter F. Buckley, M.D., Georgia Health Sciences University

11:50 am – 12:00 pm **Discussant**
Joseph P. McEvoy, M.D., Duke University School of Medicine

12:00 pm – 12:15 pm **General Discussion**

10:45 am – 12:15 pm **Cross-Cutting Dimensional Assessment for Diagnostic Syndromes**
Grand Ballroom I-J

Chair: Darrel A. Regier, M.D., MPH, American Psychiatric Association

10:45 am – 10:55 am **Introduction**
Darrel A. Regier, M.D., MPH, American Psychiatric Association

10:55 am – 11:15 am **Adoption and Use of Adult Dimensional Measures for Diagnosis in DSM-5**
Jack D. Burke, M.D., The Cambridge Health Alliance

10:45 am – 12:15 pm (continued)	<i>Cross-Cutting Dimensional Assessment for Diagnostic Syndromes</i> <i>Grand Ballroom I-J</i>
11:15 am – 11:35 am	Adoption and Use of Child and Adolescent Dimensional Measures for Diagnosis in DSM-5 David Shaffer, M.D., NYSPI and Columbia University
11:35 am – 11:55 am	Considerations for Dimensional Assessment of Disability Among Psychiatric Diagnoses William E. Narrow, M.D., MPH, American Psychiatric Association
11:55 am – 12:15 pm	General Discussion

10:45 am – 12:15 pm	<i>Update on Child and Adolescent Psychopharmacologic Treatment Patterns and Safety in Community Practice: Evidence from Medicaid Datasets</i> <i>Royal Palm Salon II-IV</i>
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Chair: Julie M. Zito, Ph.D., University of Maryland

10:45 am – 11:00 am	Trends in Antipsychotic Use (1997-2006) Among Medicaid-Insured Youth Julie M. Zito, Ph.D., University of Maryland
11:00 am – 11:15 am	Simulating RCT Results Using Longitudinal, Observational Data Sets to Estimate the Safety of Second Generation Antipsychotics in Pediatric Patients Jeanette Jerrell, Ph.D., University of South Carolina School of Medicine
11:15 am – 11:30 am	Concomitant Antipsychotic Use among Youth Continuously Enrolled in Medicaid Susan dosReis, Ph.D., University of Maryland*
11:30 am – 11:45 am	Assessing Drug Safety in Concomitant Therapy for ADHD: Medicaid Data and Design Issues Almut Winterstein, Ph.D., University of Florida
11:45 am – 11:55 am	Discussion Benedetto Vitiello, M.D., National Institute of Mental Health
11:55 am – 12:15 pm	Audience Participation

***NCDEU New Investigator Awardee Alumnae**

12:30 pm – 2:30 pm

**Poster Session I with Box Lunches
Royal Palm V-X**

****See Pages 71-80 for a complete listing of poster titles and presenters.***

Workshops

2:45 pm – 5:45 pm

Developing Dynamic, Sequential Treatments that Optimize Mental Health Outcomes: Experiences with Novel Clinical Trial Design
Grand Ballroom G-H

Chair: Susan A. Murphy, Ph.D., University of Michigan

Co-Chair: Daniel Almirall, Ph.D., University of Michigan

2:45 pm – 3:10 pm

Developing Dynamic, Sequential Treatments that Optimize Mental Health Outcomes: Introduction to Adaptive Interventions and SMART Study Design Principles

Susan A. Murphy, Ph.D., University of Michigan and
Daniel Almirall, Ph.D., University of Michigan

3:10 pm – 3:15 pm

Discussion

3:15 pm – 3:40 pm

SMART Studies for Alcohol and Cocaine Dependence
James McKay, Ph.D., University of Pennsylvania
Medicine

3:40 pm – 3:45 pm

Discussion

3:45 pm – 4:10 pm

Adaptive Treatments for Children with ADHD
William E. Pelham, Ph.D., University of Buffalo

4:10 pm – 4:15 pm

Discussion

4:15 pm – 4:30 pm

Break

4:30 pm – 4:55 pm

Testing Variants of Treatments for Substance Use Disorders During Pregnancy
Hendree Jones, Ph.D., RTI International

4:55 pm – 5:00 pm

Discussion

5:00 pm – 5:25 pm

Innovative Communication Intervention for Older Nonverbal Children with Autism
Connie Kasari, Ph.D., University of California, Los Angeles

5:25 pm – 5:45 pm

Discussion

2:45 pm – 5:45 pm ***Evidence-Based Evaluation and Treatment of Youth with Maladaptive Aggression***
Grand Ballroom I-J

Chair: Christoph U. Correll, M.D., Zucker Hillside Hospital/Albert Einstein College of Medicine*

Co-Chair: Peter S. Jensen, M.D., The Mayo Clinic

2:45 pm – 2:50 pm **Introduction and Overview**

2:50 pm – 3:05 pm **Characteristics and Evaluation of Maladaptive Aggression in Youth**

Penelope Knapp, M.D., University of California Davis

3:05 pm – 3:20 pm **Discussion**

3:20 pm – 3:35 pm **Use of Antipsychotic Medications among Privately and Publicly Insured Youth: Implications for Management of Maladaptive Aggression**

Steven Crystal, Ph.D., Rutgers University

3:35 pm – 3:50 pm **Discussion**

3:50 pm – 4:05 pm **Randomized Controlled Trial-Based Treatment Guidelines for Psychosocial Interventions in Youth with Maladaptive Aggression**

Elizabeth Papadopoulos, Ph.D., Pfizer, Inc.

4:05 pm – 4:15 pm **Discussion**

4:15 pm – 4:30 pm **Break**

4:30 pm – 4:45 pm **Systematic Review of Randomized Controlled Trials of Pharmacologic Treatments for Youth with Maladaptive Aggression**

Christoph U. Correll, M.D., Zucker Hillside Hospital/
Albert Einstein College of Medicine*

4:45 pm – 5:00 pm **Discussion**

5:00 pm – 5:30 pm **Treatment of Aggression: The FDA Perspective**

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

5:30 pm – 5:45 pm **Discussion**

***NCDEU New Investigator Awardee Alumnae**

2:45 pm – 5:45 pm

The Risks and Benefits of Including Suicidal Patients in Clinical Trials: Scientific, Ethical, and Regulatory Perspectives
Royal Palm Salon II-IV

Chair: Kelly L. Posner, Ph.D., Columbia University, New York State Psychiatric Institute

2:45 pm – 2:55 pm

Introduction

Kelly L. Posner, Ph.D., Columbia University, New York State Psychiatric Institute

2:55 pm – 3:40 pm

The Case for Inclusion of Suicidal Patients In Trials: Rationale and Strategies

Barbara Stanley, Ph.D., Columbia University, New York State Psychiatric Institute

3:40 pm – 4:25 pm

A FDA Perspective on Suicidality as a Target for Psychiatric Drug Development

Mitchell Mathis, M.D., Food and Drug Administration

4:25 pm – 4:35 pm

Break

4:35 pm – 5:20 pm

Risk Aversion has a Cost: Innovative Solutions for Safety Monitoring and Management
Increased Precision and Safety with Decreased Burden

Kelly Posner, Ph.D., Columbia University, New York State Psychiatric Institute

5:20 pm – 5:45 pm

General Discussion

2:45 pm – 5:45 pm ***The Automation of Cognitive Testing in Clinical Trials***
Addison Ballroom

Chairs: Keith A. Wesnes, Ph.D., United BioSource Corporation
Amy Veroff, Ph.D., i3

2:45 pm – 2:55 pm **Welcome & Introduction**

2:55 pm – 3:20 pm **Strategies and Methods to Produce a Stable Neurocognitive Baseline at Randomization: Perspectives from CNS Vital Signs**
Martin Rohling, Ph.D., Department of Psychology,
University of South Alabama

3:20 pm – 3:45 pm **The CANTAB System**
Andrew Blackwell, Ph.D., Cambridge Cognition

3:45 pm – 4:10 pm **The CogState System**
Paul Maruff, Ph.D., CogState, Melbourne, Australia

4:10 pm – 4:30 pm **Break**

4:30 pm – 4:55 pm **Automated Tests Capture Aspects of Function Which cannot be Assessed by Traditional Techniques: Examples from The CDR System**
Keith Wesnes, Ph.D. United BioSource Corporation

4:55 pm – 5:20 pm **A Comparison of the ADAS-Cog and the Computerized Neuropsychological Test Battery: Cognitive Domains, Rater Errors, Sample Size Estimates and Power**
Amy Veroff, Ph.D., i3/ Medical and Scientific Affairs

5:20 pm – 5:45 pm **General Discussion**

6:00 pm – 7:30 pm ***NCDEU Reception***
Garden Pool

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AT-A-GLANCE

Wednesday, June 15th

- 6:45 am – 8:00 am **13th Annual NCDEU Fun Run/Walk**
Meet Outside Golf Pro Shop
- 7:00 am – 8:30 am **NCDEU Steering Committee Meeting**
Estate Salon I
- 7:30 am – 8:30 am **ASCP Maintenance of Certification Meeting**
Royal Palm Salon I
- 7:30 am – 8:30 am **New Investigator Awardee Roundtable Breakfast (Invitation Only)**
Veranda Salon IV
- 7:30 am – 9:00 am **Continental Breakfast**
Grand & Royal Palm Assemblies (Mizner Center)
- 8:30 am – 11:00 am **Plenary – *Economics of Drug Development***
Grand Ballroom A-E
- 11:00 am – 11:15 am **Coffee Break**
Grand/Royal Palm Assemblies (Mizner Center)
- 11:15 am – 12:45 pm **Concurrent Panel Sessions / Pharma Pipeline Presentations**

Pre-Clinical and Clinical Glutamate Research in Bipolar Disorder: Bipolar Disorder Career Development Institute (CDI) New Investigator Panel	Molecular Targets for Antidepressant Augmentation in Resistant Depression	Pharmaceutical Pipeline Presentations
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm II-IV

- 12:45 pm – 2:45 pm **Poster Session II with Box Lunches**
Royal Palm Salons V-X

3:00 pm – 6:00 pm

Concurrent Workshops

ISCTM Supported Workshop on Developing Medications for Personalized Medicine: Facing the Challenges of Biomarkers	Underutilization of Evidence-Based Treatment and Monitoring Strategies in Schizophrenia	Novel Approaches to the Manipulation of the Placebo Response	Do Psychotropics Increase Suicide: Methodological Innovations for Making Sense of Conflicting Evidence
Location: Grand Ballroom G-H	Location: Grand Ballroom I-J	Location: Royal Palm Salon II-IV	Location: Addison Ballroom

4:30 pm – 4:45 pm

Break During Workshops

- 6:45 am – 8:00 am** **13th Annual NCDEU Fun Run/Walk**
Meet Outside Golf Pro Shop
- 7:00 am – 8:30 am** **NCDEU Steering Committee Meeting**
Estate Salon I
- 7:30 am – 8:30 am** **ASCP Maintenance of Certification Meeting**
Royal Palm Salon I
- 7:30 am – 8:30 am** **New Investigator Awardee Roundtable Breakfast**
(Invitation Only)
Veranda Salon IV
- 7:30 am – 9:00 am** **Continental Breakfast**
Grand/Royal Palm Assemblies (Mizner Center)

Plenary Session

- 8:30 am – 11:00 am** **Plenary – Economics of Drug Development**
Grand Ballroom A-E

Chair: John Kane, M.D., The Zucker Hillside Hospital
 ASCP President, 2011

This session will begin with Dr. Ernst R. Berndt of MIT who will discuss the economic model of drug development from the perspective of a business school professor who follows the industry. Drs. Karl Broich of BfArM and Thomas Kaiser of IQWiG will discuss the benefit risk, efficacy and added value of the new legislation in Germany. Drs. Broich and Kaiser will outline their initial experience, type of interaction, and coordinated scientific advice to applicants. Examples such as ASS/Dipyrimadol or antidepressants will be presented, importance of comparators etc. Dr. Joseph Parks, the Medical Director of the Missouri Office of Mental Health, will discuss the decisions that payers (particularly public sector) have to make in establishing formulary/reimbursement policy. Finally, Dr. Hussein Manji of J&J will present an industry perspective on the risk and reward of CNS drug development.

- 8:30 am – 8:50 am** **Economic Considerations in**
Psychopharmaceutical Drug Development
Ernst R. Berndt, Ph.D., MIT Sloan
- 8:50 am – 9:00 am** **Q&A**

8:30 am – 11:00 am (continued)	<i>Plenary – Economics of Drug Development Grand Ballroom A-E</i>
9:00 am – 9:20 am	Benefit Risk, Efficacy and Added Value: The New Legislation in Germany: What is Needed for Drug Approval? Karl Broich, M.D., Federal Institute of Drugs and Medical Devices (BfArM), Bonn, Germany
9:20 am – 9:30 am	Q&A
9:30 am – 9:50 am	Benefit Risk, Efficacy and Added Value: The New Legislation in Germany: What is Needed for Added Value? Dr. med. Thomas Kaiser, Ressortleiter Arzneimittelbewertung, Institut für Qualität und Wirtschaftlichkeit in Gesundheitswesen (IQWiG)
9:50 am – 10:00 am	Q&A
10:00 am – 10:20 am	Payers Decisions in Establishing Formulary/ Reimbursement Policy Joseph Parks, M.D., Medical Director of the Missouri Office of Mental Health
10:20 am – 10:30 am	Q&A
10:30 am – 10:50 am	The Risks and Rewards of CNS Drug Development for the Pharmaceutical Industry Hussein Manji, M.D., Johnson & Johnson Pharmaceuticals
10:50 am – 11:00 am	Q&A
11:00 am – 11:15 am	<i>Coffee Break Grand/Royal Palm Assemblies (Mizner Center)</i>

Panel Sessions / Pharma Pipeline Presentations

11:15 am – 12:45 pm ***Pre-Clinical and Clinical Glutamate Research in Bipolar Disorder: ‘Bipolar Disorder Career Development Institute (CDI) New Investigator Panel Grand Ballroom G-H***

Chair: Joseph R. Calabrese, M.D., Case Western Reserve University, University Hospitals Case Medical Center

Co-Chair: Bryan K. Tolliver, M.D., Ph.D., Medical University of South Carolina

11:15 am – 11:35 am **Glutamate Neurotransmission as a Potential Therapeutic Target in Bipolar Disorder: Overview of Evidence and Implications for Treatment of Co-Occurring Disorders**
Bryan K. Tolliver, M.D., Ph.D., Medical University of South Carolina

11:35 am – 11:55 am **Brain Glutamatergic Characteristics of Pediatric Offspring of Parents with Bipolar Disorder**
Manpreet Singh, M.D., Stanford University School of Medicine*

11:55 am – 12:15 pm **Abnormal Glutamatergic Neurotransmission and Neuronal- Glial Interactions in Acute Mania**
Dost Ongur, M.D., Ph.D., McLean Hospital/Harvard Medical School

12:15 pm – 12:45 pm **Discussion**
Mary Phillips, M.D., University of Pittsburgh School of Medicine

11:15 am – 12:45 pm ***Molecular Targets for Antidepressant Augmentation in Resistant Depression Grand Ballroom I-J***

Chair: Madhukar H. Trivedi, M.D., University of Texas Southwestern Medical Center

11:15 am – 11:17 am **Welcome and Introduction**
Madhukar H. Trivedi, M.D., University of Texas Southwestern Medical Center

***NCDEU New Investigator Awardee Alumnae**

11:15 am – 12:45 pm
(continued)

Molecular Targets for Antidepressant Augmentation in Resistant Depression
Grand Ballroom I-J

11:17 am – 11:37 am

The Dopamine Transporter as a Target in Resistant Depression

Madhukar H. Trivedi, M.D., University of Texas Southwestern Medical Center

11:37 am – 11:55 am

Agonists and Antagonists of Serotonin and Norepinephrine Receptors. Using Deductive Logic to Identify Molecular Targets for Augmentation Strategies in MDD

George Papakostas, M.D., Massachusetts General Hospital (MGH)*

11:55 am – 12:13 pm

The Role of Nicotinic Receptors in the Development of Augmentation Strategies

Leslie Jacobson, M.D., Pfizer

12:13 pm – 12:30 pm

Therapeutic Effects of Methylation and One-Carbon Cycle Compounds in MDD and their Augmentation Properties

Maurizio Fava, M.D., Massachusetts General Hospital (MGH)

12:30 pm – 12:45 pm

Panel Discussion

11:15 am – 12:45 pm

Pharmaceutical Pipeline Presentations
Royal Palm II-IV

Chair: Carlos Zarate, M.D., National Institute of Mental Health
NCDEU 2011 Program Chair*

11:15 am – 11:25 am

The Alpha7 Neuronal Nicotinic Receptor (NNR) Agonist TC-5619 had Beneficial Effects and was generally Well Tolerated in a Phase 2 Trial in Cognitive Dysfunction in Schizophrenia (CDS)

Geoffrey Dunbar, M.D., Targacept, Inc.

11:25 pm – 11:35 pm

SRX246: A Novel Vasopressin 1a Antagonist for Stress-related Disorders

Neal Simon, Ph.D., Azevan Pharmaceuticals, Inc.

***NCDEU New Investigator Awardee Alumnae**

11:15 am – 12:45 pm (continued)	Pharmaceutical Pipeline Presentations Royal Palm II-IV
11:35 am – 11:45 am	The PNB01 Clinical Development Program: A Novel Boosting Antidepressant Therapy Erik Buntinx, M.D., PharmaNeuroBoost NV
11:45 am – 11:55 am	Augmentation with OPC-34712, a Novel Psychotropic, Improves Self-Reported Depressive Symptoms in Patients Treated for Major Depressive Disorder Aleksandar Skuban, M.D., Otsuka America Pharmaceutical, Inc.
11:55 am – 12:05 pm	Reduction in HPA Axis Activation after Acute Psychosocial Stress by CXB722 in Healthy Volunteers Daniel Burch, M.D., CeNeRx BioPharma
12:05 pm – 12:15 pm	Early Clinical Development of the Amyloid Anti-Aggregation Agent (ELND005) as a Potential Treatment of Alzheimer's Disease (AD) Susan Abushakra, M.D., Elan Pharmaceuticals, Inc.
12:15 pm – 12:25 pm	Biomarkers of Neuronal and Glial Homeostasis Andreas Jeromin, Ph.D., Banyan Biomarkers, Inc.
12:25 pm – 12:35 pm	Use of CSF Biomarkers to Guide Clinical Drug Development of a Gamma Secretase Inhibitor ELND006 in Alzheimer's Disease Eliseo Salinas, M.D., Elan Pharmaceuticals, Inc.
12:35 pm – 12:45 pm	Evaluation of a Unique Nanogram-Dose Intranasal Aerosol for the Acute Management of Social Anxiety Disorder Symptoms Michael Liebowitz, M.D., Columbia University
12:45 pm – 12:55 pm	Update On Recent Neuropsychiatric Therapeutics Research David Michelson, M.D., Merck
12:45 pm – 2:45 pm	Poster Session II with Box Lunches Royal Palm Salons V-X *See Pages 81-89 for a complete listing of poster titles and presenters.

Workshops

3:00 pm – 6:00 pm ***ISCTM Supported Workshop on Developing Medications for Personalized Medicine: Facing the Challenges of Biomarkers***
Grand Ballroom G-H

Chair: Larry Alphas, M.D., Ph.D., Ortho-McNeil Janssen

3:00 pm – 3:15 pm	Overview and Objectives Larry Alphas, M.D., Ph.D., Ortho-McNeil Janssen
3:15 pm – 3:35 pm	Biomarkers as Tools for Early Drug Development: NIMH Perspective Robert Heinssen, Ph.D., National Institute of Mental Health
3:35 pm – 3:45 pm	Statistical, Regulatory, Industry Response Panel Discussion
3:45 pm – 3:55 pm	Open Discussion
3:55 pm – 4:15 pm	Development of Predictive Biomarkers in CNS: Methodological Challenges George Garibaldi, M.D., Roche
4:15 pm – 4:25 pm	Academic, Regulatory, Statistical Response Panel Discussion
4:25 pm – 4:30 pm	Open Discussion
4:30 pm – 4:45 pm	Break
4:45 pm – 5:00 pm	Biomarkers as Tools for Drug Development: Statistical Challenges Andrew Leon, Ph.D., Cornell Medical Center*
5:00 pm – 5:10 pm	Academic, Regulatory, Industry Response Panel Discussion
5:10 pm – 5:15 pm	Open Discussion

***NCDEU New Investigator Awardee Alumni**

**3:00 pm – 6:00 pm
(continued)**

ISCTM Supported Workshop on Developing Medications for Personalized Medicine: Facing the Challenges of Biomarkers
Grand Ballroom G-H

5:15 pm – 5:30 pm

Biomarkers as Tools for Drug Approval: Regulatory Perspective on Efficacy And Safety Issues
Ni Khin, M.D., Food & Drug Administration

5:30 pm – 5:45 pm

Biomarkers as Tools for Drug Approval: Regulatory Perspective on Efficacy and Safety Issues
Karl Broich, M.D., Federal Institute of Drugs and Medical Devices, Bonn, Germany

5:45 pm – 5:55 pm

Academic, Statistical, Industry Response
Panel Discussion

5:55 pm – 6:00 pm

Open Discussion

3:00 pm – 6:00 pm

Underutilization of Evidence-Based Treatment and Monitoring Strategies in Schizophrenia
Grand Ballroom I-J

Chair: John Kane, M.D., The Zucker Hillside Hospital

Co-Chair: Christoph Correll, M.D., The Zucker Hillside Hospital*

3:00 pm – 3:10 pm

Welcome and Introduction
John Kane, M.D., The Zucker Hillside Hospital

3:10 pm – 3:40 pm

The Role of Clinician, Patient and Shared Decision-Making in the Application of Evidence-Based Treatment and Monitoring
Stephan Heres, M.D., Technischen Universitaet Muenchen

3:40 pm – 3:50 pm

Discussion

3:50 pm – 4:20 pm

Long-Acting Injectable Antipsychotic Medications in the Community Treatment of Schizophrenia
Mark Olfson, M.D., Columbia University College of Physicians and Surgeons

4:20 pm – 4:30 pm

Discussion

***NCDEU New Investigator Awardee Alumni**

**3:00 pm – 6:00 pm
(continued)**

***Underutilization of Evidence-Based Treatment
and Monitoring Strategies in Schizophrenia
Grand Ballroom I-J***

4:30 pm – 4:45 pm

Break

4:45 pm – 5:10 pm

Underutilization of Clozapine

John M. Kane, M.D., The Zucker Hillside Hospital

5:10 pm – 5:20 pm

Discussion

5:20 pm – 5:45 pm

**Inadequate Adherence to Monitoring Guidelines
for Cardiometabolic Monitoring of Antipsychotics**

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

5:45 pm – 6:00 pm

Discussion

Philip S. Wang, M.D., Dr. PH, National Institute of
Mental Health

3:00 pm – 6:00 pm

***Novel Approaches to the Manipulation of the
Placebo Response
Royal Palm II-IV***

Chair: Maurizio Fava, M.D., Massachusetts General Hospital

3:00 pm – 3:05 pm

Welcome and Introduction

Maurizio Fava, M.D., Massachusetts General Hospital

3:05 pm – 3:35 pm

**The Use of Biomarkers to Refine Subject
Enrollment in CNS Clinical Trials**

Ian Cook, M.D., University of California, Los Angeles*

3:35 pm – 3:45 pm

Q&A

3:45 pm – 4:15 pm

**Relevance of Recruitment Centers' Placebo
Response for the Outcome of Multicentric
Randomized Clinical Trials in Early Clinical
Discovery**

Emilio Merlo-Pich, M.D., GlaxoSmithKline

4:15 pm – 4:25 pm

Q&A

4:25 pm – 4:45 pm

Break

***NCDEU New Investigator Awardee Alumnae**

**3:00 pm – 6:00 pm
(continued)**

***Novel Approaches to the Manipulation of the
Placebo Response
Royal Palm Salon II-IV***

4:45 pm – 5:10 pm

**Reducing the Placebo Response with the
Sequential Parallel Comparison Design**
Roy Tamura, Ph.D. – Eli Lilly & Company

5:10 pm – 5:15 pm

Q&A

5:15 pm – 5:40 pm

**Administering Placebo Effects in a Manner
Analogous to Dose Escalation**
Ted Kaptchuk, OMD – Harvard Medical School

5:40 pm – 5:45 pm

Q&A

5:45 pm – 6:00 pm

Discussion
Maurizio Fava, M.D. – Massachusetts General
Hospital

3:00 pm – 6:00 pm

***Do Psychotropics Increase Suicide:
Methodological Innovations for Making Sense of
Conflicting Evidence
Addison Ballroom***

Chair: Sue M. Marcus, Ph.D., Columbia University New York State
Psychiatric Institute; University of Chicago Center for Health
Statistics

3:00 pm – 3:25 pm

**Adverse Effects of Antidepressants in Pediatric
Anxiety Disorders**
Jeffrey A. Bridge, Ph.D., The Research Institute at
Nationwide Children's Hospital and The Ohio State
University

3:25 pm – 3:35 pm

Discussion - Presentation 1
Caleb Alexander, M.D., University of Chicago Medical
Center

3:35 pm – 3:45 pm

General Discussion

**3:00 pm – 6:00 pm
(continued)**

***Do Psychotropics Increase Suicide:
Methodological Innovations for Making Sense of
Conflicting Evidence***
Addison Ballroom

3:45 pm – 4:10 pm

**Methods for Detecting Suicidality Outcomes in
Observational Comparative Effectiveness and
Safety**

Heather Orton Anderson, Ph.D., and Robert J. Valuck,
Ph.D., R.Ph., University of Colorado, Denver

4:10 pm – 4:20 pm

Discussion - Presentation 2

Caleb Alexander, M.D., University of Chicago Medical
Center

4:20 pm – 4:30 pm

General Discussion

4:30 pm – 4:45 pm

Break

4:45 pm – 5:10 pm

**The Controversy about Antiepileptic Drugs and
Suicide: Addressing Confounding by Indication
and Other Biases**

Sue M. Marcus, Ph.D., Columbia University New
York State Psychiatric Institute; University of Chicago
Center for Health Statistics

5:10 pm – 5:20 pm

Discussion - Presentation 3

Caleb Alexander, M.D., University of Chicago Medical
Center

5:20 pm – 5:30 pm

General Discussion

5:30 pm – 5:40 pm

Overall Discussion

Caleb Alexander, M.D., University of Chicago Medical
Center

5:40 pm – 6:00 pm

General Discussion

Thursday, June 16, 2011

8:30 am – 10:00 am **Concurrent Panel Sessions**

<p>The Treatment of Early-Age Mania Study (TEAM)</p>	<p>An Integrated Approach to Biomarker Discovery in Mood Disorders</p>	<p>NIMH Panel - Accelerating Discovery of Preemptive and Personalized Interventions for Mental Disorders: A Report from the National Advisory Mental Health Council</p>	<p>NIDA Panel - Non-Substitution Therapies to Treat Substance Use Disorders</p>
<p>Location: Royal Palm Salon I-II</p>	<p>Location: Royal Palm Salon III-IV</p>	<p>Location: Royal Palm Salon VII-VIII</p>	<p>Location: Royal Palm Salon IX-X</p>

10:15 am – 11:45 am **Panel Sessions**

<p>NIAAA Panel - The Alcohol Clinical Trials Initiative (ACTIVE) Group</p> <p>Location: Royal Palm Salon III-IV</p>	<p>The Evolving Concept of Mixed Depression</p> <p>Location: Royal Palm Salon VII-VIII</p>	<p>Genomics of Treatment Response and Side Effects in Severe Mental Illness</p> <p>Location: Royal Palm Salon IX-X</p>
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7:30 am – 9:00 am **Continental Breakfast**
Grand/Royal Palm Assemblies (Mizner Center)

Panel Sessions

8:30 am – 10:00 am ***The Treatment of Early-Age Mania Study (TEAM)***
Royal Palm Salon I-II

Chair: Mark A. Riddle, M.D., Johns Hopkins

8:30 am – 8:35 am **Introduction**
Mark A. Riddle, M.D., Johns Hopkins

8:35 am – 8:55 am **TEAM: Design, Methods, and Sample Characteristics**
John T. Walkup, M.D., Weill Cornell Medical College & New York-Presbyterian Hospital

8:55 am – 9:15 am **TEAM: Primary Outcomes**
Karen D. Wagner, M.D., University of Texas Galveston

9:15 am – 9:35 am **TEAM: Searching for Predictors & Moderators of Treatment Effects**
Benedetto Vitiello, M.D., National Institute of Mental Health

9:35 am – 10:00 am **Discussion**
Graham J. Emslie, M.D., University of Texas Southwestern

8:30 am – 10:00 am ***An Integrated Approach to Biomarker Discovery in Mood Disorders***
Royal Palm Salon III-IV

Chair: Sidney H. Kennedy, M.D., FRCP, University Health Network, Canada

8:30 am – 8:35 am **Introduction**
Sidney H. Kennedy, M.D., FRCP, University Health Network, Canada

8:35 am – 8:52 am **Neuroimaging Biomarkers**
Sidney H. Kennedy, M.D., FRCP, University Health Network, Canada

8:30 am – 10:00 am
(continued)

An Integrated Approach to Biomarker Discovery in Mood Disorders
Royal Palm Salon III-IV

8:52 am – 9:09 am **Genetic Biomarkers**
Allan Young, M.D., Ph.D., FRCPC, University of British Columbia

9:09 am – 9:26 am **Metabolomic Biomarkers**
Roger McIntyre, M.D., FRCPC, University Health Network, Canada

9:26 am – 9:43 am **Proteomics and Bioinformatics**
Kenneth Evans, Ph.D., Ontario Cancer Biomarker Network

9:43 am – 10:00 am **General Discussion**
Robert M. Post, M.D., Bipolar Collaborative Network

8:30 am – 10:00 am

NIMH Panel - Accelerating Discovery of Preemptive and Personalized Interventions for Mental Disorders: A Report from the National Advisory Mental Health Council
Royal Palm Salon VII-VIII

Chair: David Sommers, Ph.D., National Institute of Mental Health

8:30 am – 9:00 am **Workgroup Background, Process, and Recommendations**
TBA

9:00 am – 9:30 am **A Neurodevelopmental Perspective on Intervention Development**
LinMarie Sikich, M.D., University of North Carolina at Chapel Hill

9:30 am – 10:00 am **Optimizing NIMH-Supported Clinical Trials Research**
Robert Heinssen, Ph.D., National Institute of Mental Health

8:30 am – 10:00 am ***NIDA Panel - Non-Substitution Therapies to Treat Substance Use Disorders***
Royal Palm Salon IX-X

Chair: Phil Skolnick, Ph.D., D.Sc., National Institute of Drug Abuse

Co-Chair: David McCann, Ph.D., National Institute of Drug Abuse

8:30 am – 8:55 am **Glutamate-Based Approaches to Substance Use Disorders**
Lori A. Knackstedt, Ph.D., Medical University of South Carolina

8:55 am – 9:00 am **Discussion**

9:00 am – 9:25 am **The Promise of Selective 5-HT₂CR Agonists as Abstinence Enhancers**
Kathryn A. Cunningham, Ph.D., University of Texas Medical Branch

9:25 am – 9:30 am **Discussion**

9:30 am – 9:55 am **Kappa Opioid Antagonists show Therapeutic Potential in Animal Models of Stress-induced Mood Disorders and Drug Addiction Risk**
Charles Chavkin, Ph.D., University of Washington

9:55 am – 10:00 am **Discussion**

10:00 am – 10:15 am **Coffee Break**
Grand/Royal Palm Assemblies (Mizner Center)

Panel Sessions

10:15 am – 11:45 am ***NIAAA Panel - The Alcohol Clinical Trials Initiative (ACTIVE) Group***
Royal Palm Salon III-IV

Chair: Raymond Anton, M.D., Medical University of South Carolina

10:15 am – 10:25 am **Introduction**
Raymond Anton, M.D., Medical University of South Carolina

10:25 am – 10:40 am **Alcohol Use Disorders as a Target for Clinical Drug Development: Perspective from Industry**
Joseph Palumbo, M.D., Johnson & Johnson
Pharmaceutical Research and Development

10:40 am – 10:55 am **Evolution of FDA Approach to Clinical Trials for Alcoholism Treatment Drugs**
Celia Winchell, M.D., Center for Drug Evaluation and Research

10:55 am – 11:10 am **ACTIVE Collaboration: Outcomes Measurement in Alcohol Use Disorders**
Rebecca Robinson, M.S., Global Health Outcomes
Lilly Research Labs

11:10 am – 11:25 am **Alcohol Trials: Treatment Endpoints, Grace Periods, Trial Duration, and Placebo Effect**
Raye Z. Litten, Ph.D., National Institute on Alcohol Abuse and Alcoholism

11:25 am – 11:45 am **General Discussion**

10:15 am – 11:45 am *The Evolving Concept of Mixed Depression*
Royal Palm Salon VII-VIII

Chair: Terence A. Ketter, M.D., Stanford University

10:15 am – 10:20 am Introduction

Terence A. Ketter, M.D., Stanford University

10:20 am – 10:35 am Is Irritable Depression a Form of Mixed Depression? - Lessons from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D)

Roy Perlis, M.D., M.Sc., Massachusetts General Hospital*

10:35 am – 10:50 am Mixed Depression in the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) and the Stanley Foundation Bipolar Network (SFBN)

Terence A. Ketter, M.D., Stanford University

10:50 am – 11:05 am Proposals for Mixed Depression in the Diagnostic and Statistical Manual of Mental Disorders-5th Edition (DSM-5)

Ellen Frank, Ph.D., Western Psychiatric Institute

11:05 am – 11:20 am Potential Therapeutic Implications of Mixed Depression

Charles L. Bowden, M.D., University of Texas Health Science Center

11:20 am – 11:35 am Regulatory Implications of Mixed Depression

Mitchell Mathis, M.D., Food and Drug Administration

11:35 am – 11:45 am General Discussion

***NCDEU New Investigator Awardee Alumni**

10:15 am – 11:45 am ***Genomics of Treatment Response and Side Effects in Severe Mental Illness***
Royal Palm Salon IX-X

Chair: Philip Harvey, Ph.D., University of Miami Miller School of Medicine
Co-Chair: Amanda Myers, Ph.D., University of Miami Miller School of Medicine

10:15 am – 10:20 am **Introduction**
Philip Harvey, Ph.D., University of Miami Miller School of Medicine
Amanda Myers, Ph.D., University of Miami Miller School of Medicine

10:20 am – 10:35 am **Genomic Influences on the Quality of Depression as a Response to Early Trauma**
Amanda Myers, Ph.D., University of Miami Miller School of Medicine

10:35 am – 10:50 am **Genomics Influences on Psychotic Symptoms and Treatment Nonresponse in Depression**
Alan Schatzberg, M.D., Stanford University School of Medicine

10:50 am – 11:05 am **Metabolic Syndromes in Schizophrenia: General vs. Specific Genomic Influences**
John Newcomer, M.D., University of Washington School of Medicine

11:05 am – 11:20 am **Disability as a Heritable Phenotype in Severe Mental Illness**
Philip Harvey, Ph.D., University of Miami Miller School of Medicine

11:20 am – 11:30 am **Discussion**
Claes Wahlsted, M.D., Ph.D., The Scripps Research Institute

11:30 am – 11:45 am **General Discussion**



12:00 pm ***Meeting Adjourns***

Tuesday, June 14

12:30 pm – 2:30 pm

Poster Session I


Royal Palm Salon V-X

- 1 **A Combined EEG-Behavioral Test of Maintenance of Attention can Differentiate ADHD from Normal Adults**
Bijan Bastani, NorthCoast Clinical Trials
MO Modarress
- 2 **Extensive Comorbid Personality Disorder Symptoms are Associated with Limited Response to ADHD Treatment**
Fred Reimherr, University of Utah
Erika Williams, Barrie Marchant, John Olsen, Corinne Halls, Reid Robison
- 3 **Pharmacokinetic Profile of Clonidine Hydrochloride Extended-Release Tablets in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder**
Raul Silva, Academic Behavioral Center, New York
- 4 **Escitalopram in the Treatment of Non-Depressed Elderly Patients with Generalized Anxiety Disorder**
Olga Brawman-Mintzer, Medical University of South Carolina
Paul Nietert, Kathryn Vankirk, Erin Jones, Marilyn Stuckey, Crystal Flynn Longmire, Jacobo Mintzer
- 5 **Transient Spikes in Depressive Symptoms over the Course of Psychotherapy and Pharmacotherapy Treatment for Chronic PTSD**
Stephanie Keller, Case Western Reserve University
Norah Feeny, Lori Zoellner
-  6 **The FGF14:Nav Channel Complex as a New Target of GSK3**
Fernanda Laezza, UTMB
Alexander Shavkunov, Tetyana Buzhdygan
-  7 **Impact of Increasing Adult Hippocampal Neurogenesis on Cognition and Mood**
Amar Sahay, Columbia University
- 8 **Understanding of Influence on Placebo Response by Investigators and Site Staff in CNS Clinical Trials**
David Daniel, United BioSource Corporation
Antony Loebel, Josephine Cucchiario, Jean Dries



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- 9 **Executive Functioning of Adolescents with Depression Associated with Bipolar Disorder**
Arman Danielyan, Cincinnati Children's Hospital Medical Center
Jeffrey Welge, Paula Shear, Caleb Adler, Kiki Chang, Melissa DelBello
- 10 **DSM-5 Mixed Features Specifier may Increase Complexity without Enhancing Milder Mixed Symptom Detection in Bipolar Disorder Patients: A 36 Case Series**
Terence Ketter, Stanford University
Shefali Srivastava, Po Wang
- 11 **Zonisamide for Bipolar Depression: A Randomized, Double-Blind, Placebo-Controlled, Adjunctive Trial**
Michael Knable, Bethesda Behavioral Sciences
Deborah Daupinais, Norman Rosenthal
- 12 **Does Shorter vs. Longer Time to Stabilization in Patients with Bipolar I Disorder Predict Relapse Prevention? A Post-Hoc Analysis of an Adjunctive Aripiprazole Clinical Trial (CN138-189)**
Prakash Masand, Duke University Medical Center
Mauricio Tohen, Amy Everitt, Ross Baker, Robert Forbes, Berit Carlson
- 13 **Relationship of Baseline Metabolic Status to Efficacy Outcomes in Bipolar Disorder Patients: Analysis of Pooled Data from Ziprasidone Monotherapy Clinical Trials**
Elizabeth Pappadopulos, Pfizer Inc.
Roger McIntyre, Francine Mandel
- 14 **Tolerability Profile of Ziprasidone versus Placebo during Acute Treatment of Schizophrenia, Mania or Bipolar Depression**
Elizabeth Pappadapulos, Pfizer Inc.
Keming Gao, Onur Karayal, Sheela Kolluri, Joseph Calabrese
-  15 **Resting State Functional Connectivity in Adolescents with Bipolar I Disorder**
Manpreet Singh, Stanford University School of Medicine
Ryan Kelley, Erica Sanders, Tenah Acquaye, Sherrie Li, Meghan Howe, Allan Reiss, Kiki Chang
- 16 **Lithium for the Reduction of Aggression in Conduct Disordered Outpatients**
Richard Malone, Drexel University College of Medicine
Beeta Verma, Manely Ghaffari, Susan West, Jacqueline Cater



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- 17 **Assessing Feasibility, Reliability, and Validity of Computer-Automated Interactive SMS Text Messages to Self-Report Depression Symptoms in Children and Adolescents Using the Quick Inventory of Depressive Symptomatology–Adolescent**
James Mundt, Center for Psychological Consultation
Graham Emslie, Tracy Reyes, Taryn Mayes, Krystle Joyner, Jessica King

- 18 **Primary Endpoint Results from the Metabolic Effects of Antipsychotics in Children (MEAC) Study**
John Newcomer, Washington University School of Medicine
Ginger Nicol, Michael Yingling, Karen Flavin, Julie Schweiger, Martha Hessler, Kenneth Schechtman

- 19 **Assessing the Reliability of Tanner Staging in CNS Trials: A Cross-Cultural Comparison of European, US, and Indian Raters**
Brian Rothman, ProPhase LLC
Mark Opler, Christoph Correll, Gil Zalsman, Ananda Pandurangi, Eva Kohegyi, Nicole Menlow

- 20 **The Impact of Back Pain in the CO-MED Trial**
Benji Kurian, University of Texas Southwestern Medical Center
A. John Rush, Stephen Wisniewski, David Morris, James Luther, Robert Howland, Madhukar Trivedi

- 21 **Baseline Metabolic Comorbidities among Patients Newly Initiating Antipsychotic Therapy: A US Health Claims Database Analysis**
John Newcomer, Washington University School of Medicine
Glenn Phillips, Phillip Sarocco, Andrei Pikalov, Masaaki Ogasa, Cynthia Siu, Antony Loebel

-  22 **Serum BDNF Concentrations are Associated with Cognitive Performance and Cardiopulmonary Fitness in Subjects with Coronary Artery Disease**
Walter Swardfager, Sunnybrook Health Sciences Centre
Nathan Herrmann, Mahwesh Saleem, Paul Oh, Krista Lancôt

- 23 **Reconsidering the Criterion for Excluding Comorbid Substance Use Disorders from Clinical Trials for the Treatment of Depression**
Lori Davis, VA Medical Center

- 24 **Clinical Practice Informing Drug Development Targets in ASD**
Jessica Hellings, University of Kansas Medical Center
Andrew Thome, Patricia Smith, Muhammad Bhatti



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- 25 **The LORS Enabled Dialogue: A Collaborative Intervention to Promote Insight and Recovery in Psychotic Disorders**
Sharon Sousa, University of Massachusetts Dartmouth
- 26 **Validation of a Global Assessment Measure for Fatigue**
Steven Targum, Clintara LLC
Howard Hassman, Maurizio Fava
-  27 **Ketamine Effect on Neuronal Remodeling in Treatment Resistant Depression as assessed by Magnetic Resonance Imaging**
Chadi Abdallah, SUNY Downstate Medical Center
- 28 **Clinical Utility of a Multianalyte Biomarker Panel for Major Depressive Disorder (MDD)**
John Bilello, Ridge Diagnostics
Michael Henry, Perry Renshaw, Richard Shelton, George Papakostas, Bo Pi
- 29 **Improvement of Clinicians' Assessments of Patients at Inclusion Visits in an MDD Clinical Trial**
Joan Busner, Penn State College of Medicine and United BioSource
Stuart Montgomery, David Daniel, Gary Sachs
- 30 **Efficacy of Adjunctive Aripiprazole in Major Depressive Disorder Patients with No or Minimal Improvement after Antidepressant Monotherapy (CN138-139, CN138-163, CN138-165)**
Daniel Casey, Oregon Health & Science University
Kimberly Laubmeier, Elizabeth Bellocchio, James Eudicone, Zia Rahman, Robert McQuade, Ross Baker
- 31 **Prescribing Patterns for Patients with Major Depressive Disorder in the Primary Care Setting: Results from the Clinical Outcomes in Measurement-Based Treatment (COMET) Trial**
Trina Chang, Massachusetts General Hospital and Harvard Medical School
Yonghua Jing, Albert Yeung, Iftekar Kalsekar, Tony Hebden, Robert McQuade, Susan Brenneman, Lee Baer, Jonathan Kurlander, Angela Watkins, Jean Siebenaler, Maurizio Fava





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- 32 **Clinical Outcomes in Measurement-based Treatment (COMET) Trial: Effectiveness of Communicating Patient-Reported Outcomes on the PHQ9 to Primary Care Physicians in Treatment of Depression**
Trina Chang, Massachusetts General Hospital and Harvard Medical School
Albert Yeung, Yonghua Jing, Lee Bauer, Iftekar Kalsekar, Tony Hebden, Robert McQuade, Susan Brennenman, Jonathan Kurlander, Angela Watkins, Jean Siebenaler, Maurizio Fava
- 33 **Regional PET Activation with Trigeminal Nerve Stimulation in Major Depression**
Ian Cook, David Geffen School of Medicine at UCLA
Lara Schrader, Cheri Geist, Daniel Silverman, Patrick Miller, Mary Susselman, Christopher DeGiorgio
- 34 **Do Early Levels of Serum BDNF Predict Treatment Outcome in Major Depression?**
Ian Cook, UCLA Depression Research & Clinic Program and Laboratory for Brain, Behavior, and Pharmacology
Fernando Gomez-Pinilla, Aimee Hunter, Andrew Leuchter
- 35 **Defining Remission in Major Depression Disorder: Does Duration Matter?**
Sanjay Dubé, Eli Lilly and Company
Susan Ball, JonDavid Sparks, Thomas Konechnik, Mary Anne Dellva, Peter Classi, Celine Goldberger
- 36 **Efficacy of Exercise Augmentation of SSRI Treatment in Improving Cognitive Function in Major Depressive Disorder**
Tracy Greer, UT Southwestern
Bruce Grannemann, Matthieu Chansard, Madhukar Trivedi
- 37 **Pilot RCT of SSRI vs Bupropion on Suicidal Behavior and Ideation in At-Risk Depressed Patients**
Michael Grunebaum, Columbia University
Steven Ellis, Naihua Duan, Ainsley Burke, Maria Oquendo, John Mann
- 38 **Efficacy of Desvenlafaxine 50 mg Compared with Placebo in Patients with Moderate or Severe Major Depressive Disorder: A Pooled Analysis of 6 Randomized, Placebo-Controlled Studies**
Jeff Musgnung, Pfizer Inc
George Papakostas, Larry Culpepper, Rana Fayyad, Christine Guico-Pabia




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- 39 **Creating a New Clinically Relevant Endpoint in the PIPICIT Trial Programme: The ESR (Early and Sustained Antidepressant Response)**
Ludo Haazen, PharmaNeuroBoost NV
Michael Thase, Remi van den Broeck, Erik Buntinx
- 40 **Augmentation by LDX of Escitalopram but not of Venlafaxine in the Porsolt Behavioral Despair Test in Mice**
David Hackett, Shire Development Inc.
Vincent Castagné
- 41 **Simultaneous Measurement with Hysteresis Analyses of the Effects of Lisdexamfetamine Dimesylate and d Amphetamine on Striatal Levels of Extracellular Dopamine, Locomotor Activity, and Plasma Drug Concentrations in Freely Moving Rats**
David Heal, RenaSci Consultancy Ltd
Helen Rowley, David Hackett
- 42 **Outcome of Behavioral Activation Therapy in Medication-Responsive Chronic Depression with Persistent Psychosocial Dysfunction: A Pilot Study**
David Hellerstein, Columbia University
Gregory Erickson, Donna O'Shea, Jonathan Stewart, Patrick McGrath, Deborah Deliyannides, Ronit Kishon, Martin McElhiney, Rengin Isik, Ying Chen
- 43 **Effects of the Insulin Sensitizer Pioglitazone on Cognitive Functioning in Patients with Major Depressive Disorder and Abdominal Obesity**
David Kemp, Case Western Reserve University
Stephen Ganocy, Karu Jayathilake, Herbert Meltzer, Elizabeth Fein, Sarah Obral, Carla Conroy, Robert Bilder, Joseph Calabrese
-  44 **Effects of Exercise on Inflammatory Cytokines in Nonremitted Major Depressive Disorder**
Chad Rethorst, University of Texas - Southwestern Medical Center
-  45 **Treating Major Depressive Disorder by Creating Positive Expectations for the Future: A Pilot Study for the Efficacy of Future Directed Therapy (FDT)**
Jennice Vilhauer, Cedars-Sinai Medical Center
Young Sabrina, Chanel Kealoha, Josefine Borrmann, Waguhi IsHak, Mark Rapaport, Narineh Hartoonian, Jim Mirocha



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- 46 **Striatal and Anterior Cingulate GABA Deficits as Possible Treatment Targets in Adolescents with Tourette's Disorder: A Proton MR Spectroscopy Study**
 Vilma Gabbay, New York University
 Barbara Coffey, Xiangling Mao, Dikoma Shungu
- 47 **New Model Curriculums for Teaching Psychopharmacology to Residents, Medical Students, and Primary Care Prescribers**
 Ira Glick, Stanford University
 Bruce Lydiard
- 48 **Serious Problems with how Uncontrolled Studies are Conducted and Followed Up**
 Rajnish Mago, Thomas Jefferson University
 Alexandra Lane, Rajeev Mahajan
- 49 **Recent Developments in Improving Signal Detection and Reducing Placebo Response**
 Craig Mallinckrodt, Eli Lilly
 Roy Tamura, Yoko Tanaka
-  50 **Citicoline Administration and Improved Attentional Performance with Healthy Adult Women**
 Erin McGlade, University of Utah Brain Institute
 Allison Locatelli, Toshikazu Kamiya, Masahiko Morita, Koji Morishita, Yoichiro Sugimura, Deborah Yurgelun-Todd
- 51 **Bayesian Analysis of Weighted-Z tests in Adaptive Trial Design**
 Cynthia Siu, Data Power (DP), Inc.
 Carla Brambilla, Fabrizio Ruggeri
- 52 **Innovative Web-Based Technologies for Enhancing Quality Implementation of Evidence-Based Interventions and Fostering Better Treatment Outcomes**
 Melissa DeRosier, 3-C Institute for Social Development
 Danielle Swick, Chris Hehman
- 53 **Short-term Treatment of Acute Schizophrenia with Lurasidone vs. Quetiapine XR: Effect on Daytime Sleepiness**
 Henry Nasrallah, University of Cincinnati College of Medicine
 Andrei Pikalov, Josephine Cucchiaro, Jane Xu, Antony Loebel



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- 54 **Using a Computerized Diagnostic Instrument as a Tool for Identifying Best Practices**
Melanie Elliott Wilson, TeleSage, Inc.
Benjamin Brodey, Milo Fryling, David Ayer, Heather Nelms, Jackie Koble, Philip Maier, Scott McConnell, Michael First
- 55 **Efficacy of Iloperidone in Schizophrenia According to Baseline Symptom Severity: Results From a Pooled Analysis of 4 Phase III Clinical Trials**
Gus Alva, ATP Clinical Research
Marla Hochfeld, Xiangyi Meng
- 56 **Open-Label Comparison of Olanzapine Long-Acting Injection and Oral Olanzapine: A 2-Year, Randomized Study in Outpatients with Schizophrenia**
Elizabeth Brunner, Lilly Research Laboratories
Holland Detke, Peter Weiden, Pierre-Michel Llorca, Moutaz Choukour, Susan Watson, Haya Ascher-Svanum
- 57 **Long-Term Safety and Tolerability Of Lurasidone in Schizophrenia or Schizoaffective Disorder: A 12-Month, Double-Blind, Active-Controlled Study**
Leslie Citrome, New York University School of Medicine
Josephine Cucchiaro, Kaushik Sarma, Debra Phillips, Robert Silva, Satoru Tsuchiya, Antony Loebel
- 58 **What can a 5-factor PANSS Analysis tell us about Iloperidone's Efficacy Profile and Optimal Dose?**
Leslie Citrome, New York University, School of Medicine
Marla Hochfeld, Xiangyi Meng
- 59 **Long-Term Safety and Tolerability of Lurasidone in Patients with Schizophrenia: Results of a 6-Month, Open-Label Extension Study**
Josephine Cucchiaro, Sunovion Pharmaceuticals Inc.
Stephen Stahl, Doreen Simonelli, Joseph Severs, Andrei Pikalov, Antony Loebel
- 60 **Metabolic and Body Mass Parameters Observed with JNJ-37822681, a Novel Fast- Dissociating D2 Receptor Antagonist, Versus Olanzapine**
Ella Daly, Johnson and Johnson PRD
Justine Kent, Luc Janssens, John Newcomer, Nancy Van Osselaer, Gitta Husken, Peter De Boer, Luc Tritsmans, Mark Schmidt




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- 61 **Early Prediction of Sustained Treatment Response with JNJ-37822681, a Novel, Fast- Dissociating D2 Receptor Antagonist, Compared to Olanzapine in Schizophrenia**
Ella Daly, Janssen Pharmaceutica
Ion-George Anghelescu, Luc Janssens, Justine Kent, Peter de Boer, Nancy van Osselaer, Luc Tritsmans, Luc van Nueten, Mark Schmidt
- 62 **Global Inter-Rater Reliability, Scale Validity, and Local Perception: PANSS Ratings and Reactions from 4 Countries**
Ashleigh DeFries, ProPhase LLC
Mark Opler, Stacy Liechti, Evgenia Ivanova, Larry Yang, Sean Lane
- 63 **Factors Associated with the Initiation of Clozapine**
Susan Essock, Columbia University Department of Psychiatry
Jennifer Manuel, Yan Wu, Maria Pangilinan, Scott Stroup
- 64 **Rates of Remission among Patients with Schizophrenia Treated with Olanzapine Long-Acting Injection**
Peter Feldman, Lilly Research Laboratories
David McDonnell, Holland Detke, Chakib Battioui, Hong Liu-Seifert, Haya Ascher-Svanum
- 65 **The Management of Antipsychotic Treatment Discontinuation and Interruptions using Model-based Simulations**
Dong-Jing Fu, Ortho-McNeil Janssen Scientific Affairs
John Sheehan, Bart Remmerie, Jennifer Kern Sliwa, Larry Alphs, Mahesh Samtani
- 66 **Early Stage Analysis of Alternative Interventions in Patients with Schizophrenia after First Psychotic Episode**
Nicolas Furiak, Medical Decision Modeling Inc.
Megha Bansal, Harry Smolen
- 67 **Risk of Cardiovascular Morbidity and Sudden Death with Risperidone and Paliperidone Treatment: Analysis of 64 Randomized, Double-Blind Trials**
Srihari Gopal, Janssen Research & Development
David Hough, Keith Karcher, Isaac Nuamah, Joseph Palumbo, Jesse Berlin, Alan Baseman, Yimei Xu, Justine Kent
- 68 **Cognitive Performance in Patients with Acute Schizophrenia Treated with Lurasidone: A Double-Blind, Placebo-Controlled Trial**
Philip Harvey, University of Miami Miller School of Medicine
Andrei Pikalov, Josephine Cucchiaro, Antony Loebel



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- 69 **The Effect of Eszopiclone on Stages of Sleep: Results from Studies in Adult and Elderly Patients with Primary Insomnia**
Gary Zammit, Clinilabs, Inc
Todd Grinnell, Jacqueline Zummo, Edward Schweizer, Randall Marshall
-  70 **Effects of Medically-Induced Menopause on Mood and Behavior in Healthy Young Women**
Rivi Ben Dor, NIMH
Veronica Harsh, Paige Fortinsky, David Rubinow, Peter Schmidt
- 71 **OPEN BOARD**
- 72 **Headaches Associated with Ovarian Suppression**
Julia “Jill” Warnock, University of Oklahoma
David Morris, J. Clark Bundren




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Wednesday, June 15

12:45 pm – 2:45 pm

Poster Session II


Royal Palm Salon V-X


- 


1 Comparison of Efficacy between Buprenorphine and Tarmadol in Detoxification of Opioid (Heroin) Dependent Subjects
 Jatinder Chawla, SUNY Downstate Medical Center
 Rakesh Lal, Hemraj Pal, Raka Jain, Nina Schooler
- 2

Specific Genetic Variants facilitating Disulfiram Pharmacotherapy for Cocaine Dependence
 Thomas Kosten, Baylor
 David Nielsen, Jan Lindsay
- 3

Prevalence of Metabolic Syndrome (MS) in Veterans with Alcohol Related Disorders Alone and Alcohol and Marijuana Related Disorders Combined
 Roopa Sethi, Carilion Clinic
 Benjamin Griffeth, Anita Kablinger, Lauren Lehman
- 4

Predictive Ability of the Treatment Motivation Questionnaire (TMQ) in Substance Abuse Treatment
 Roopa Sethi, Carilion Clinic
 Steven Lash, Stephanie Fearer
- 

5 Real-Time fMRI Neurofeedback Targeting Inhibitory Control Brain Activation Decreases Emotional Reactivity to Smoking Cues in Cigarette Smokers
 Luke Stoeckel, Harvard/MGH
 Xiaoqian Chai, Oliver Hinds, Alex Tighe, Alice Coakley, Susan Whitfield-Gabrieli, John Gabrieli, Eden Evins
- 

6 Reduction in HPA Axis Activation after Acute Psychosocial Stress by CXB722 in Healthy Volunteers
 Daniel Burch, CeNeRx BioPharma
 Manhaz Asgharnejad
- 

7 Evaluation of a Unique Nanogram-Dose Intranasal Aerosol for the Acute Management of Social Anxiety Disorder Symptoms
 Michael Liebowitz, Columbia University
 Ester Salman, Norman Rosenthal, Humberto Nicolini, Louis Monti



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* Pharma Pipeline Presentation

- 8 **Low Intensity Focused Ultrasound Pulsation: A Novel Noninvasive Intervention for Diagnosing and Treating Brain Disease**
Alexander Bystritsky, UCLA
William Melega, Seung-Schik Yoo

- 9 **Does Shorter vs. Longer Stabilization in Patients with Bipolar I Disorder Predict Relapse Prevention? Analysis of Results from an Adjunctive Aripiprazole Clinical Trial (CN138-392)**
Zia Rahman, Bristol-Myers Squibb
Charles Bowden, Mark Frye, Robert Hirschfeld, James Eudicone, Ross Baker, Robert Forbes, Berit Carlson

- 10 **Customized Adherence Enhancement for Individuals with Bipolar Disorder receiving Atypical Antipsychotic Therapy**
Martha Sajatovic, University Hospitals - Case Medical Center
Jennifer Levin, Weronika Micula-Gondek, Tiffany Williams, Christopher Bialko, Kristin Cassidy, Curtis Tatsuoka

- 11 **How Does Bipolar Depression Respond to Antidepressant Medication?**
Jessica Stewart, Harvard Longwood Psychiatry Residency Training Program
Jonathan Stewart

- 12 **Impact of Ethnicity on Efficacy and Safety of Ziprasidone in Patients with Schizophrenia or Bipolar Disorder**
Douglas Vanderburg, Pfizer, Inc.
Charles Bowden, Onur Karayal, Sheela Kolluri

- * 13 **Early Clinical Development of the Amyloid Anti-Aggregation Agent (ELND005) as a Potential Treatment of Alzheimer's Disease (AD)**
Susan Abushakra, Elan Pharmaceuticals, Inc.
Pierre Tariot, Earvin Liang, Gerald Crans, Eliseo Salinas

- 14 **EVP-6124, an α -7 Agonist for the Treatment of Cognitive Deficits in Alzheimer's - Synergies with AChEIs**
Chaya Bhuvaneshwaran, EnVivo Pharmaceuticals
Gerhard Koenig, Daniel Bertrand, Dana Hilt

- 15 **Utilization of Antipsychotics in Patients with Diagnosis of Dementia in Veterans Affairs Medical Center**
Mohammad Chowdhury, Carilion Clinic
Roopa Sethi, Mamta Sapra



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* Pharma Pipeline Presentation

16 **The Assessment of Raters in an Alzheimer's Study: Experience in Asia**

Amy Veroff, i3 / Scientific Services and Technology
Joan Shen, Johnna Wu, Qi Shen, Huali Wang

17 **Attention Deficits Play a Major Role in the Profile of Cognitive Dysfunction in Parkinson's Disease**

Keith Wesnes, United BioSource Corporation
David Miller, Liesl Allcock, Martin Eccles, Louise Robinson, Andrea Stutt, David Burn



18 **Does the Presence of an Open-Label Antidepressant Lead-In Period Influence Study Outcome in Clinical Trials Examining Augmentation/Combination Strategies in Treatment Partial/Non-Responders with Major Depressive Disorder?**

Nadia Iovieno, MGH, Department of Psychiatry
George Papakostas



19 **Efficacy and Tolerability of ECT using Ketamine Anesthesia: A Double-Blind Randomized Controlled Pilot Study**

Styliani Kaliora, The Zucker Hillside Hospital
Georgios Petrides

20 **Changes in Suicide Risk Measures and Depressive Symptoms with Low Dose Lithium Combined with Citalopram Compared to Citalopram with Placebo in a Group of Severely Ill Depressed and Suicidal Patients**

Arif Khan, Northwest Clinical Research Center
Shirin Khan, Joy Hobus, James Faucett, Vishaal Mehra, Earl Giller, Richard Rudolph

21 **'Placebo control' in Antidepressant Trials: A Misnomer**

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



22 **Baseline GABA Level Correlates with Response to Antidepressant Treatment in Women with Depression, Anxiety, and Insomnia**

Tara Lauriat, St. Elizabeth's Medical Center
J. Eric Jensen, Perry Renshaw, Michael Henry



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* Pharma Pipeline Presentation

- 23 **BDNF Genotype and Response to Pharmacotherapy and Psychotherapy for Depression**
Jessica Levenson, University of Pittsburgh Medical Center
Alison Gilbert, Paola Rucci, Vishwajit Nimgaonkar, David Kupfer, Ellen Frank
- 24 **The Effects of Desvenlafaxine 50 mg on the Pharmacokinetics of Midazolam, a CYP3A4 Substrate, in Healthy Subjects**
Alice Nichols, Pfizer Inc.
Tanya Ramey, Shannon Lubaczewski, Yali Liang, Kyle Matschke, Gabriel Braley
- 25 **Safety of Selegiline Transdermal System in Clinical Practice: Analysis of Adverse Events from Post-Marketing Exposures**
Ashwin Patkar, Duke University Medical Center
Chi-Un Pae, J. Alexander Bodkin, Kimberly Blanchard Portland, Sunil Mehra, Soumya Prasad, Michael Thase
- 26 **Reductions in CSF Abeta42 in Cognitively-Intact Elderly with Major Depressive Disorder: Possible Implications for the Pathophysiology and Treatment**
Nunzio Pomara, Nathan S. Kline Institute for Psychiatric Research
Davide Bruno, Jay Nierenberg, John Sidsis, Pankaj Mehta, Henrik Zetterberg, Kaj Blennow
- 27 **Selegiline Transdermal System (STS) for Anxious Depression: A Post Hoc Analysis of 3 Randomized, Placebo-Controlled, Double-Blind Studies**
Donald Robinson, World Wide Drug Development
Kimberly Blanchard Portland, Sunil Mehra
- 28 **Fluoxetine Blood Levels and Weekly Drug Use Correlate with Treatment Response in Major Depression with Comorbid Alcoholism**
Ihsan Salloum, University of Miami Miller School of Medicine
Jack Cornelius, Antoine Douaihy, Levent Kirisci
- 29 **Vasopressin 1A Receptor Antagonists as a Novel Treatment for PTSD: Preclinical & Phase 1 Study**
Neal Simon, Azevan Pharmaceuticals, Inc.



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* Pharma Pipeline Presentation


- * 30 Augmentation with OPC-34712, a Novel Psychotropic, Improves Self-Reported Depressive Symptoms in Patients Treated for Major Depressive Disorder**
 Aleksandar Skuban, Otsuka America Pharmaceutical, Inc.
 Arif Khan, Mary Hobart, Peter Zhang, Ye Yang, Claudette Brewer, Robert McQuade, Robert Forbes
- * 31 The PNB01 Clinical Development Program: A Novel Boosting Antidepressant Therapy**
 Erik Buntinx, PharmaNeuroBoost NV
 Ludo Haazen, Remi van den Broeck, Didier de Chaffoy, Michael Thase
- 32 Efficacy and Safety of Desvenlafaxine 25 and 50 mg/d in a Randomized, Placebo-Controlled Study of Depressed Outpatients**
 Karen Tourian, Pfizer Inc.
 Eunhee Hwang, Linda Mele, Tadashi Umeda, Cecile Vialet
- 33 A Randomized, Double-blind, Placebo-Controlled Study of Desvenlafaxine 10 and 50 mg/d Efficacy and Safety in Depressed Outpatients**
 Karen Tourian, Pfizer Inc.
 Michael Liebowitz, Eunhee Hwang, Linda Mele
- 34 Depressed Patients who were Partial or Non-Responders to Citalopram Reached Remission Equally often with Add-On TC-5214, a Neuronal Nicotinic Channel Modulator**
 Geoffrey Dunbar, Targacept Inc.
 David Hosford, Madhukar Trivedi
- 35 Effects of Lisdexamfetamine Dimesylate, a Long-Acting Prodrug Stimulant, on Quality of Life and Fatigue in MDD Patients With Residual Symptoms: Results of a Placebo-controlled Augmentation Trial**
 Madhukar Trivedi, Univ. Texas Southwestern
 Andrew Cutler, Cynthia Richards, Robert Lasser, Brooke Geibel, Joseph Gao, Angelo Sambunaris, Ashwin Patkar
- 36 Sustained Remission, Number Needed to Treat, and Complete Remission in a Placebo-Controlled Levomilnacipran Study in Major Depressive Disorder**
 Peter Werner, Forest Research Institute
 Jennifer Li, Lucilla Mansuy, Anjana Bose



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* Pharma Pipeline Presentation


- 37 **A Randomized, Double-Blind, Placebo-Controlled, Pooled Data Single-Site Assessment of the Efficacy and Safety of Vilazodone in Patients with Major Depressive Disorder**
Charles Wilcox, Pharmacology Research Institute
Nader Oskooilar, Barbara Katz, Daniel Grosz, My-Linh Tong, Judy Morrissey, Mellissa Henry, Don De Francisco
- 38 **Psychometric Properties of Chinese Translations of the Quick Inventory of Depressive Symptomatology, Self Report**
Albert Yeung, MGH Depression Clinical and Research Program
Gregory Feldman, Paola Pedrelli, Katherine Hails, Maurizio Fava, Tracy Reyes, James Mundt
- 39 **An Open-Label Trial of Dronabinol, a Cannabinoid Agonist, in the Treatment of Trichotillomania**
Jon Grant, University of Minnesota
Brian Odlaug
- 40 **Gender Differences in a Placebo-Controlled Trial of Fluoxetine for Body Dysmorphic Disorder**
Katharine Phillips, Rhode Island Hospital/Alpert Medical School of Brown University
Megan Kelly
- 41 **Clinical Predictors of Weight Change during Long-Term Risperidone Treatment**
Chadi Calarge, The University of Iowa
Diqiong Xie, Miriam Zimmerman
- 42 **A Comparison Between Risperidone and Paliperidone: Are These Two Different Drugs?**
Maria Corena-McLeod, Mayo Clinic Jacksonville
Natalia Gorron, Elliott Richelson
-  43 **An Open Label Trial of Arbaclofen in Autism Spectrum Disorder Shows Improvements in Multiple Symptom Domains**
Jeremy Veenstra-VanderWeele, Vanderbilt University
Bryan King, Craig Erickson, Lawrence Ginsberg, Raun Melmed, Lawrence Scahill, Linmarie Sikich, James McCracken, Barbara Rathmell, Randall Carpenter, Mark Bear, Paul Wang



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* Pharma Pipeline Presentation

- 44 **Relationship between the Clinical Global Impression of Severity for Schizoaffective Disorder Scale and Established Mood Scales for Mania and Depression**
Dong-Jing Fu, Ortho-McNeil Janssen Scientific Affairs, LLC
Ibrahim Turkoz, Cynthia Bossie, John Sheehan, Larry Alphas
-  45 **15 Years of Research on Transition Rates to Psychosis: How Prodromal are our Putatively Prodromal Patients?**
Marta Hauser, The Zucker Hillside Hospital, North Shore Long Island Jewish Medical Center
- 46 **Retrospective Comparison of Medical Advance Directive Inquiry and Documentation for In-Patients in Psychiatry, Surgery and Internal Medicine in Salem Veterans Affairs Medical Center (SVAMC)**
Echezona Anunobi, Carilion Clinic
Mark Detweiler, Roopa Sethi, Reena Thomas
- 47 **I Was Blind, But Now I See: A Site's Perspective and Lessons Learned**
Patricia Brown, CNS Healthcare
Melissa Ball, Brian Hunter
- 48 **The Importance of Rigor in Post-Baseline Assessments in CNS Clinical Trials**
Michael Detke, MedAvante
Janet Williams, Kenneth Kobak
- 49 **Variation in MADRS Reliability Over the Course of Randomized Controlled Trials: Comparison of Computer vs Site-Based Rater Administration**
Gary Sachs, Mass General & United BioSource Corporation
Suzanne Edman, Daniel DeBonis
- 50 **Predictors of Response and Sustained Response With Iloperidone: Results from 2 Phase III Studies**
Richard Jackson, Wayne State University
Greg Mattingly, Marla Hochfeld, Xiangyi Meng
- 51 **A Meta-Analysis of Pharmacodynamic Testing with the NeuroCart used in the Early Phase Drug Development of CNS Depressant Agents**
Joop van Gerven, Centre for Human Drug Research
Justin Hay



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- * 52 The Alpha7 Neuronal Nicotinic Receptor (NNR) Agonist TC-5619 had Beneficial Effects and was Generally Well Tolerated in a Phase 2 Trial in Cognitive Dysfunction in Schizophrenia (CDS)**
Geoffrey Dunbar, Targacept Inc.
Jeffrey Lieberman, Anthony Segreti, David Hosford
- 53 The Virtual Reality Functional Capacity Assessment Tool (VRFCAT): A New Co-Primary Cognitive Measure for Schizophrenia Drug Trials**
Richard Keefe, Duke University Medical Center
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- 54 eSNP Association Analysis across Different Brain Regions for Prioritization of Schizophrenia Candidate Genes from Previous Genetic Association Studies for Therapeutic Targets**
Sanghyeon Kim, SMRI
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- 55 Response to Atypical Antipsychotic Therapy among Patients with Predominant Versus Prominent Negative Symptoms**
Bruce Kinon, Lilly Research Laboratories
Virginia Stauffer, Guochen Song, Haya Ascher-Svanum, Lei Chen, Peter Feldman, Robert Conley
- 56 Serotonin 6 Receptor Gene and Schizophrenia: Case-Control Study, Meta-Analysis and Endophenotype-Related Traits of Cognitive Function and Acoustic Startle Response**
Taro Kishi, The Zucker Hillside Hospital
Yasuhisa Fukuo, Tomo Okochi, Toshiya Inada, Norio Ozaki, Christoph Correll, Nakao Iwata
- 57 Nicotine Addiction, Endophenotype-Related Traits (Cognitive Function and Prepulse Inhibition) of Schizophrenia, and Neuronal Nicotinic Acetylcholine Receptor Genes (CHRNA4 and CHRNA2)**
Taro Kishi, The Zucker Hillside Hospital
Yasuhisa Fukuo, Tomo Okochi, Christoph Correll, Nakao Iwata
- 58 Relapse Prevention in Schizophrenia: A Systematic Review and Meta-Analysis of Second Generation Antipsychotics versus First Generation Antipsychotics**
Taishiro Kishimoto, The Zucker Hillside Hospital
Vishesh Agarwal, Allyssa Brody, Taro Kishi, Gennady Gelman, John Kane, Christoph Correll



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- 59 **Improving the Value of Care for Individuals with Serious Mental Illness through Implementation and Evaluation of CommonGround**
Jane Kogan, Community Care Behavioral Health Organization
Bradley Stein, Mark Mihalyo, Mark Sorbero, James Schuster



- 60 **Insight and its Association with Baseline Characteristics of People with Schizophrenia Randomized to Long Acting Injectable Risperidone or Oral Atypical Antipsychotics**
Maju Koola, Maryland Psychiatric Research Center, University of Maryland
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- 61 **Prior Trial Experience and Stipend Amount not associated with Improvement on Placebo in Antipsychotic Randomized Controlled Trials for Schizophrenia**
Robert Litman, CBH Health, LLC
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- 62 **Lurasidone in the Treatment of Acute Schizophrenia: Results of the Double-Blind, Placebo-Controlled, 6-Week, Pearl 3 Trial**
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Meeting Location: Boca Raton Hotel, 501 East Camino Real, Boca Raton, Florida 33433

Hotel Phone Number: +1-561-447-3622

ASCP Executive Office Number: +1-615-649-3085

Additionally, your contact should have the following:

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- Your transportation information

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- Review hotel safety information posted on the inside of the sleeping room door (including emergency exits and where fire extinguishers are located).
- Should an emergency situation arise, contact your family as soon as possible.

In case of fire:

The fire alarm sound is followed by an announcement urging you to vacate the facility. Should this occur, do not attempt to use the elevators. Emergency exits are marked with illuminated EXIT signs. In case of fire, ASCP and hotel staff will be available to assist you in exiting the facility.

In case of medical emergency:

If you are in your hotel room or anywhere on hotel property, dial extension 49, this will connect you directly into the hotel dispatcher who will disperse security and EMS personnel. If you are attending a meeting event, contact the nearest hotel or ASCP staff person. (If this is not possible, have someone else do it for you.) Please make sure someone informs the ASCP staff of the emergency.

In case of a weather-related emergency (i.e., tornado, hurricane, earthquake, etc):

The ASCP Executive Office continually monitor local weather situations and will alert you to any potential emergencies. Should these arise during a meeting event the ASCP and hotel staff will direct you to a pre-determined safe location. Should these emergencies interfere with your transportation or hotel room stay; the ASCP staff will assist you in altering your arrangements. Should these emergencies arise during non-meeting events the hotel staff will direct you to a pre-determined safe location. In case of emergency evacuation, the nearest emergency shelter would likely be located at Boca Raton Community High School, 1501 NW 15th Court, Boca Raton, FL, 33486, 561-338-1420 (location is confirmed at the time of the emergency). Please make your way from your room to this location as soon as possible.

In case of other emergency situations:

The ASCP staff works closely with the hotel staff and city officials to monitor all potential situations. The hotel has an emergency evacuation plan in place. Should a situation arise, ASCP staff will provide the appropriate information regarding emergency shelter locations, medical care, transportation, etc.



ASCP

AMERICAN SOCIETY OF
CLINICAL PSYCHOPHARMACOLOGY

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