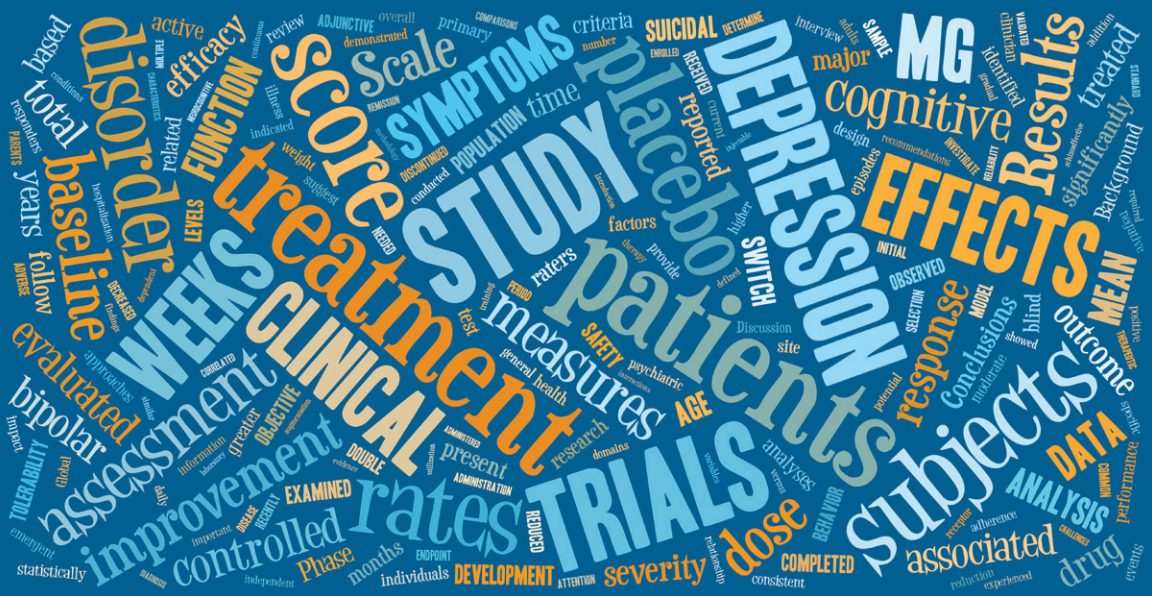
NCDEU

An Annual Meeting of the ASCP

Recognizing Unmet Needs in Psychopharmacology: From Biomarkers to Breakthrough Therapies

MAY 28 – 31, 2013



Welcome to the 53rd Meeting of NCDEU – The New NCDEU

ASCP
American Society of
Clinical Psychopharmacology

Dear Colleagues:

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 53rd year, which has played such a pivotal role in the development of modern-day psychopharmacology. When the ECDEU meeting was first held over a half century ago, psychopharmacology and indeed modern-day psychiatry was in its infancy. Yet there was enormous excitement surrounding the introduction of new medications that appeared to have a profound effect on major psychiatric illnesses. The challenges and opportunities today, 53 years later, 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.

President
American Society of Clinical Psychopharmacology

NCDEU
New Research Approaches for Mental Health Interventions

Welcome to the 53rd NCDEU Meeting

On behalf of the NCDEU Steering and Program Committees, we are delighted to welcome you to the 53rd NCDEU meeting. We introduced "the New NCDEU" in 2011 and in 2013 we continue to build on these innovations while preserving the rich history of the meeting.

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

- **2013 Program Highlights**
  - Tuesday, May 28
    - Open Forum with leaders of NIMH, NIDA, and NIAAA.
      - Submit questions online in advance or at the meeting
    - Pharma Pipeline: 12 presentations of Phase 1 and Phase 2 developments.
  - Wednesday, May 29
    - Plenary Session: Medication adherence and its relationship to successful clinical trials
  - Thursday, May 30
    - Plenary Session features FDA and EMA regulators.
  - Throughout the meeting
    - NIMH, NIDA, NCCAM, and NIAAA panels
  - Friday, May 31
    - Q&A session with FDA and EMA.
    - Submit questions on line in advance or at the meeting.
  - The New Investigator Program
    - A closed workshop for 20 New Investigators and informal breakfast sessions.
  - Workshops: 3 hour intensive interactive sessions focused on problems and solutions
    - Wednesday and Thursday Afternoons
  - *Clinical Track* – sessions focused on topics of immediate clinical relevance

- **Organization**
  - The meeting is sponsored by the American Society for Clinical Psychopharmacology (ASCP).
    - The Steering Committee organizes the meeting.
    - The Program Committee evaluates submitted proposals and develops program innovations.
  - NIH collaborations:
    - NIMH - National Institute of Mental Health
    - NIDA - National Institute of Drug Abuse
    - NIAAA National Institute on Alcohol Abuse and Alcoholism
    - NCCAM - National Center for Complementary and Alternative Medicine
  - Regulatory agency collaborations:
    - Food and Drug Administration (FDA)
    - European Medicines Authority (EMA)
  - Parthenon Management Group organizes the NCDEU Meeting.

- **And remember**
  - The NCDEU Reception 7:00 pm – 8:00 pm on Wednesday the 29th.
  - The NCDEU Fun Run/Walk 6:45am on Thursday the 30th.

NCDEU at 53 is truly a work in progress. We welcome your suggestions. Seek us out during the meeting or provide your views by completing the evaluation form.

Best Regards,

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

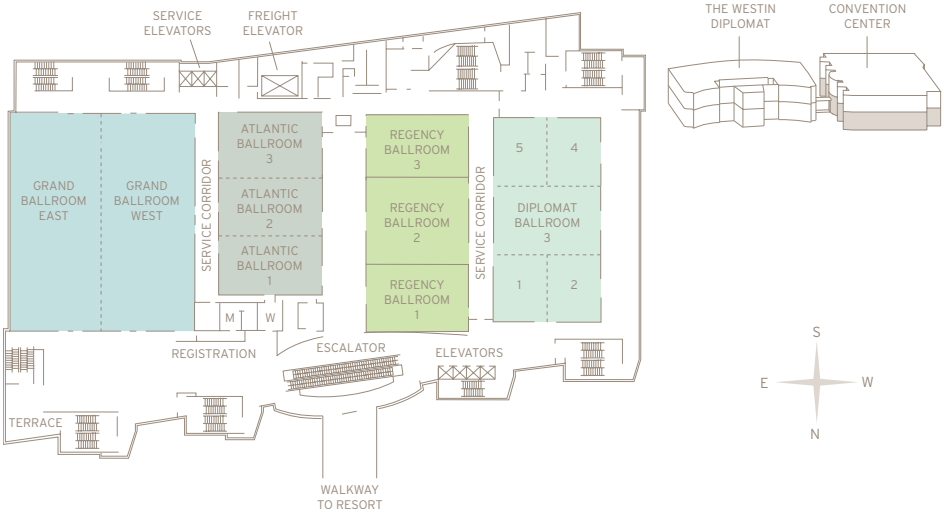
Nina Schooler, Ph.D.
Steering Committee Co-Chair

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

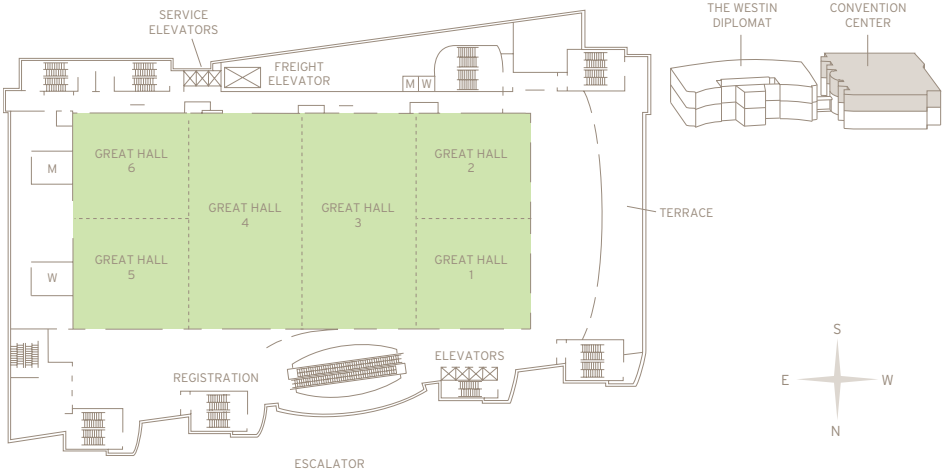
Carlos Zarate, M.D.
Program Committee Co-Chair

Hotel Maps

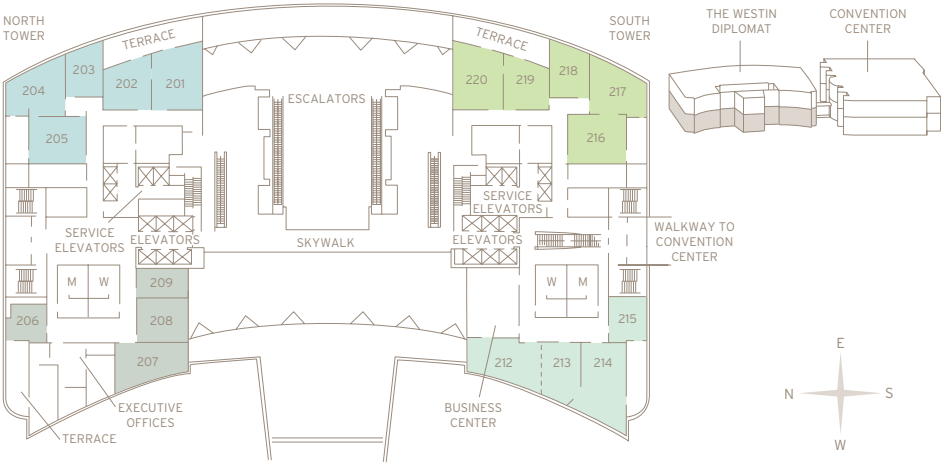
2nd Floor Convention Center



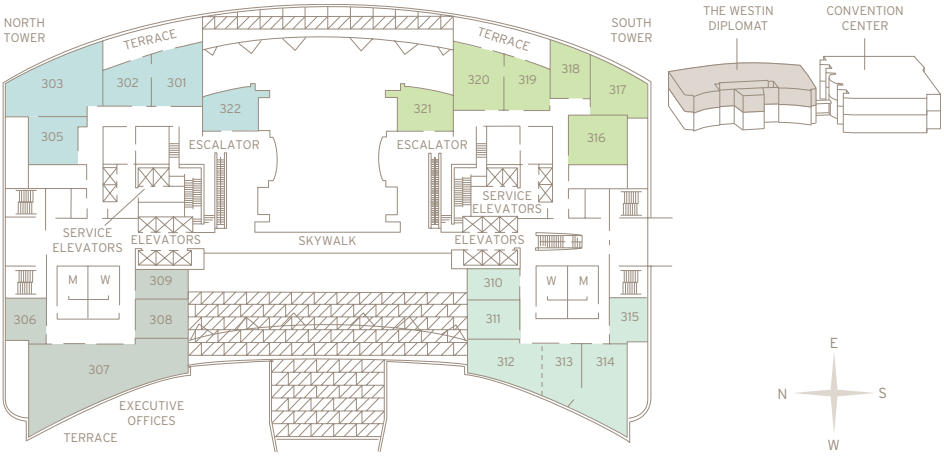
3rd Floor Convention Center



Resort, Second Floor



Resort, Third Floor



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DISCLOSURES FOR ALL NCDEU PRESENTERS CAN BE VIEWED AT WWW.NCDEUMEETING.ORG

NIH Open Forum with Leadership of NIMH, NIDA, NIAAA
Tuesday, May 28, 2013 from 2:00 pm – 3:30 pm

Dr. Antonio Noronha, Ph.D.
National Institute on Alcohol Abuse and Alcoholism

Dr. Antonio Noronha is Director of the Division of Neuroscience and Behavior (DNB) of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) at the National Institutes of Health (NIH) a position he has held since 2003. Prior to that, Dr. Noronha was Chief of the Neuroscience and Behavioral Research Branch at NIAAA from 1999 to 2003. Dr. Noronha's rational approach to organizing and planning the Institute's neuroscience and behavioral portfolio guided the research into multidisciplinary programs with the potential to make major advances. The Division developed several initiatives that have had a significant impact on NIAAA neuroscience, behavior, and genetics programs. He was also instrumental in initiating the Integrative Neuroscience Initiative on Alcoholism (INIA), a highly integrated multidisciplinary consortium of research and investigators elucidating the neurobiological mechanisms underlying neuroadaptation to alcohol. He also initiated the Neurobiology of Adolescent Drinking in Adulthood (NADIA) multidisciplinary initiative to clearly define the persistent effects of adolescent alcohol exposure in adulthood and to explore the neurobiological mechanisms underlying these effects. More recently, he initiated the National Consortium on Alcohol and Neurodevelopment in Adolescence (N-CANDA) which will determine the extent to which structural and functional deficits in neurodevelopmental maturation are caused or exacerbated by adolescent alcohol use in humans. In addition, he is responsible for NIAAA's Collaborative Studies on the Genetics of Alcoholism (COGA) which has uncovered many genes contributing to the risk for alcohol dependence. Dr. Noronha also was, and remains, involved in highly relevant trans-NIH initiatives, committees, and the NIH Blueprint for Neuroscience Research, The NIH Pain Consortium and the NIH Roadmap projects, reflecting his skill as a collaborator and has organized many symposia and workshops over the years to further alcohol research.

Dr. Noronha has a bachelor's degree in chemistry and a master's degree in biochemistry and toxicology from the University of Bombay. His doctoral degree specializing in the neurosciences is from the Stritch School of Medicine at Loyola University of Chicago, where he explored the neurochemical effects of maternal ethanol exposure on the offspring of rodents. In 1982 he was awarded a fellowship from the National Multiple Sclerosis Society and in 1985 a Visiting Fogarty International Fellowship by NINDS to conduct research on the biochemistry and immunology of the myelin-associated glycoprotein. Dr. Noronha became a Senior Staff Fellow at NINDS, where he continued his studies on the role of cell adhesion molecules and other gylcoconjugates in demyelinating disorders, in the NINDS Laboratory of Molecular and Cellular Neurobiology. He has published extensively in high-quality, peer-reviewed journals. Dr. Noronha came to NIAAA in 1990 as a Scientific Review Administrator for the Neuroscience and Behavior Subcommittee of the Alcohol Biomedical Research Review Committee. He has received numerous awards and honors during his career at the NIH including several NIH Director's Awards and the RSA Seixas Award for Distinguished Service.

Featured Speakers

Phil Skolnick, D.Sc., Ph.D. (hon.)
National Institute on Drug Abuse, National Institutes of Health

Phil Skolnick is the Director, Division of Pharmacotherapies and Medical Consequences of Drug Abuse at the National Institute on Drug Abuse, NIH. Dr. Skolnick served as Chief Scientific Officer (2001-2009) and President (2007-2009) of DOV Pharmaceutical, Inc. He was also Research Professor of Psychiatry (2001-2009) and a member of the Center of Excellence on Drug Addiction at New York University-Langone Medical Center. Dr. Skolnick was a Lilly Research Fellow (Neuroscience) at Lilly Research Laboratories (1997-2000). Prior to this, he served as Senior Investigator and Chief, Laboratory of Neuroscience, at the National Institutes of Health from 1986-1997. Dr. Skolnick has also served as a Research Professor of Psychiatry at the Uniformed Services University of the Health Sciences, Adjunct Professor of Anesthesiology at Johns Hopkins University, and Adjunct Professor of Pharmacology and Toxicology at Indiana University School of Medicine. His awards and honors include the Experimental Therapeutics Prize from the American Society for Pharmacology and Experimental Therapeutics, an Anna Monika Prize, and the A.E. Bennett Award in Biological Psychiatry. He has twice been awarded the Doctor of Science, honoris causa. Dr. Skolnick has co authored more than 500 articles and currently serves on the editorial advisory boards of more than half a dozen journals. He is an editor of Current Protocols in Neuroscience and has edited six books, most recently, Glutamate-Based Approaches to Psychiatric Disorders (2010). The Institute of Scientific Information (ISI) has acknowledged his contributions by naming him to the elite group of “Highly Cited” authors.

Philip Sung-En Wang, M.D., Dr. P.H.
Deputy Director, National Institute of Mental Health

Philip S. Wang, M.D., Dr. P.H. completed his undergraduate degree in biochemistry and molecular biology, 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 the urgent need to uncover the neurobiological bases of mental disorders and improve their treatments. In response, he has spent the majority of his professional career in research, advisory, teaching, and administrative activities, all designed to better understand and treat mental disorders. As the Deputy Director for the National Institute of Mental Health (NIMH), he assists the Director in overseeing 1300 NIMH staff and $1.4 billion spent annually on basic and clinical research that will help pave the way for prevention, recovery and cure of mental illnesses. Prior to joining NIMH, Dr. Wang served on the faculty at Harvard Medical School, where he conducted pharmacoepidemiologic studies of off-target drug effects as well as clinical trials testing new interventions with grant support from NIMH, NIDA, AHRQ, and the Robert Wood Johnson Foundation. He is an author of approximately 180 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 several NIMH and NIH Study Sections. He has 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 was 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 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.

Medication Adherence Plenary

Wednesday, May 29, 2013 from 8:30 am – 10:00 am

Can We Afford to Conduct Clinical Trials without Monitoring Adherence?

Aidan Hampson, Ph.D.
National Institute on Drug Abuse

Dr. Aidan Hampson is a Program Officer at the National Institute on Drug Abuse (NIDA), where he oversees a portfolio of awards addressing the clinical assessment of new medications to treat Substance Use Disorders. Prior to joining NIDA, he was a Review Officer at the NIH Center for Scientific Review, and also spent eight years in pre-clinical drug development at a small pharmaceutical company in California. Dr Hampson has had a broad scientific training, starting as a marine lipid biochemist and aquatic toxicologist, until began studying cannabinoids at UC San Francisco. His training culminated with a fellowship in the lab of the late Dr. Julius Axelrod at NIMH, where he authored a US patent on "Cannabinoids as Neuroprotectants."

Thomas P. Laughren, M.D.
Laughren Psychopharm Consulting, LLC

Dr. Laughren is recently retired as Division Director for the Division of Psychiatry Products, Center for Drug Evaluation and Research at FDA. Prior to coming to FDA in September, 1983, Dr. Laughren was affiliated with the VA Medical Center in Providence, RI, and was on the faculty of the Brown University Program in Medicine. He received his medical degree from the University of Wisconsin in Madison, Wisconsin, and he also completed residency training in psychiatry at the University of Wisconsin. Dr. Laughren is board certified in general psychiatry. As Division Director for the Division of Psychiatry Products, Dr. Laughren oversaw the review of all psychiatric drug development activities conducted under INDs and the review of all NDAs and supplements for new psychiatric drug claims. He has authored and co-authored many papers on regulatory and methodological issues pertaining to the development of psychiatric drugs, and is a frequent speaker at professional meetings on these same topics. Dr. Laughren has received numerous awards for his regulatory accomplishments.

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

Dr. Litten is Associate Director, Division of Treatment and Recovery Research, National Institute on Alcohol Abuse and Alcoholism (NIAAA). He is also the Team Leader for NIAAA's Extramural Medications Development Program. He is responsible for the planning, development, and maintenance of the alcoholism treatment research portfolio. He is also responsible for the discovery, development, and clinical testing of medications to treat alcohol-use disorders and alcohol-related diseases. He is the author of over 100 publications and co-editor of 9 books and journals. Finally, Dr. Litten served as the Project Officer for the multi-site Phase 3 clinical trial COMBINE and currently serves as the Project Officer for NIAAA Clinical Investigations Group (NCIG) Phase 2 clinical trial network.

Stephanie O'Malley, Ph.D.
Yale University School of Medicine

Dr. O'Malley is a Professor and the Assistant Chair for Clinical Research in the Department of Psychiatry at the Yale University School of Medicine. Dr. O'Malley's research focuses on the development of behavioral and pharmacological treatments for alcoholism and tobacco dependence. She conducted one of the two seminal studies that led to the FDA approval of naltrexone for the treatment of alcoholism. In addition to testing specific treatments, her research seeks to incorporate new methods to evaluate treatment efficacy and enhance treatment adherence.

Phil Skolnick, D.Sc., Ph.D. (hon.)
National Institute on Drug Abuse, National Institutes of Health
See previous bio

Regulatory Plenary

Thursday, May 30, 2013 from 8:30 am – 10:00 am
New FDA and EMA Initiatives in Alzheimer's Disease, Depression, and Schizophrenia

Karl Broich, M.D.
Federal Institute for Drugs and Medical Devices (BfArM, Germany)

Dr. Karl Broich is the Vice-President and Professor at the Federal Institute for Drugs and Medical Devices. From 1985 to 2000, Dr. Broich preformed 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). 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 100 Publications (peer reviewed articles, reviews, and book sections).

Ni Khin, M.D.
Food and Drug Administration

Dr. Ni Khin is Medical Team Leader in the Division of Psychiatry Products, Center for Drug Evaluation and Research (CDER) at the FDA. In this position, she manages regulatory and clinical reviews of investigational new drugs (INDs) and New Drug Applications (NDAs) for all psychiatric indications. She joined the FDA in 2001 as Clinical Reviewer for the Psychiatry Group in the Division of Neuropharmacologic Drug Products. She also worked as Medical Officer and Branch Chief of Good Clinical Practice Branch 1 in the Division of Scientific Investigations, where she provided scientific oversight for CDER-assigned bioresearch monitoring activities. She conducted on-site data-audit inspections of clinical investigators both in the US and abroad. Prior to coming to FDA, Dr. Khin was a Senior Staff Fellow in the Geriatric Psychiatry Branch at the National Institute of Mental Health. Dr. Khin received her medical degree from the Institute of Medicine I, Rangoon, Burma (Myanmar). She completed residency training in Psychiatry at the State University of New York, Buffalo. She is board-certified in general psychiatry by the American Board of Psychiatry and Neurology. She also received a Master of Science in Microbiology from Arizona State University. In addition to her regulatory experience, she has several years of research experience in basic neuroscience and clinical psychiatry.

Islam Younis, Bs.C.,Ms.C.,Ph.D.
Food and Drug Administration

Dr. Younis is a clinical pharmacologist at the U.S. Food and Drug Administration. He has B.Sc. in Pharmacy and M.Sc. and Ph.D. in Pharmaceutical Sciences, in addition to certificates in Public Health, Drug Development and Regulatory Sciences, and Pharmacoepidemiology. Dr. Younis current research focuses on leveraging prior knowledge toward optimizing clinical trials and improving drug development efficiency. Dr. Younis has published 13 peer reviewed manuscripts and one book chapter.

Regulatory Wrap-Up
Friday, May 31, 2013 from 10:15 am – 11:45 am

Karl Broich, M.D.
Federal Institute for Drugs and Medical Devices (BfArM)
See previous bio

Featured Speakers

Bob Rappaport, M.D.
Food and Drug Administration

Dr. Rappaport graduated from the George Washington University School of Medicine and Health Sciences. He remained at the George Washington University Hospital to complete an internship in internal medicine, a residency in neurology, and a fellowship in Sleep Disorders Medicine, Polysomnography and Electroencephalography. He was an Assistant Professor of Neurology at George Washington for three years, and was Director of the EEG/Sleep Lab and of the Neurology Residency Program for two of those years. He is board certified in both Neurology and Sleep Disorders Medicine and is a Fellow of the American Academy of Sleep Medicine. Dr. Rappaport joined the Division of Neuropharmacologic Drug Products as a medical officer in 1994. After three years in that position, he was asked to join the Division of Anesthetics, Critical Care and Addiction Drug Products (DACCADP) as Team Leader for the Analgesic and Anesthetic Drug Groups. He was named Deputy Division Director in June of 1998, and continued in his role as Team Leader during that period. Dr. Rappaport became the Acting Division Director of DACCADP in November, 2002, and the Division Director in September, 2003. In 2005, due to a major reorganization, DACCADP was merged with the former Analgesics Drug Products Division. Dr. Rappaport was asked to become Division Director for the newly formed Division of Anesthesia, Analgesia and Rheumatology Products. In March of 2010, following a second reorganization, the rheumatology products were transferred to another division. Following that reorganization, the division was renamed the Division of Anesthesia, Analgesia, and Addiction Products.

Ni Khin, M.D.
Food and Drug Administration

See previous bio

Phillip Kronstein, M.D.
Food and Drug Administration

Phillip Kronstein, M.D. is a Senior Medical Officer in the Division of Psychiatry Products (DPP) at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). In this position, Dr. Kronstein manages clinical reviews of Investigational New Drugs (INDs) and New Drug Applications (NDAs). Prior to joining the FDA in January 2008, he was a Clinical Research Fellow in the Experimental Therapeutics and Pathophysiology Branch at the National Institute of Mental Health, where he conducted trials in treatment-resistant depression and bipolar disorder. He received a Bachelor's of Science in Chemistry from the University of Chicago in 1995 and a Doctor of Medicine from Tufts University School of Medicine in 2001. He completed his residency training in Psychiatry at the Johns Hopkins Hospital in June 2005. In addition to his review responsibilities at the FDA, Dr. Kronstein has been involved in regulatory research, looking at sexual dysfunction with antidepressants. He is also the Division Data Standard Lead for DPP as CDER, as part of a larger FDA initiative, continues to develop and implement standards to represent study data submitted in support of regulatory applications.

Acknowledgements

NCDEU
New Research Approaches for Mental Health Interventions

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Nina R. Schooler, Ph.D.

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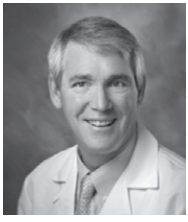
Carlos A. Zarate, M.D.

New Investigator Award Program Chairs

Lauren D. Hill, Ph.D.



Mark H. Rapaport, M.D.

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National Institute of Mental Health

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University of Pittsburgh School of Medicine

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Meeting Services

Registration Desk Hours:

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

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

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 foyer of Diplomat 1-2.
Hours:

Monday	12:00 pm – 5:00 pm
Tuesday	7:30 am – 5:00 pm
Wednesday - Thursday	7:30 am – 6:00 pm
Friday	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 Diplomat 3.

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

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

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

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

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

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 the foyer of Diplomat 1-2 or after the conference at www.ncdeumeeting.org ***Evaluations for continuing education credit must be submitted no later than July 1, 2013.*** 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

ASCP American Society of Clinical Psychopharmacology

The American Society for Clinical Psychopharmacology (ASCP) designates this live meeting for a maximum of 20.5 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Pharmacists

ACPE®

USF Health is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This application-based program has been approved for 20.5 contact hours (2.05 CEUs). The Universal program number is as follows: 0230-9999-13-008-L01-P.

To receive continuing education credit, a pharmacist must attend the accredited sessions, actively participate in questions and answers and return the program evaluation instrument. In order to receive full credit, registrants must register no late than 10 minutes after the state 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 activity is approved for (up to) 20.5 CE credits. Full attendance of the live activity is required. Partial credit will not be awarded.

Florida Licensed Social Workers

USF Health is an approved provider (BAP#433 – Exp. 3/31/15) of continuing education credits for clinical social work, marriage and family therapy and mental health counseling. This program has been reviewed and approved for up to 24.6, 50-minute contact hours.

All participants who request continuing education credits by July 1, 2013, should expect to receive their statement of credits via email in late July.

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. There is a $40.00 administrative fee for CME/CE applications. Your candid input on the 2013 meeting is appreciated as we strive to improve the meeting each year.

NCDEU Meeting Support – The 2013 NCDEU Meeting receives no corporate funding.

ASCP Exam in Advanced Clinical Psychopharmacology - Saturday, June 1, 2013, at The Westin Diplomat Resort & Spa in Hollywood, Florida, just after the meeting.

NCDEU 2014 – The 54th meeting of NCDEU will take place June 16 – 19, 2014 at the Westin Diplomat in Hollywood Beach, Florida. Details regarding abstract submission for the 2014 Meeting will be released in September, 2014.

Notes

8:30 am – 4:30 pm ***New Investigator Workshop (INVITATION ONLY)***
Diplomat 1-2

Co-Chairs: Mark H. Rapaport, M.D., Emory University 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 Tuesday evening, May 28. 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.

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

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

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

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

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

Mark H. Rapaport, M.D.
Emory University 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

Leonardo F. Andrade, Ph.D.
University of Connecticut School of Medicine

Kristin L. Bigos, Ph.D.
Lieber Institute for Brain Development

Hsun-Hua Chou, M.D., Ph.D.
University of California, San Diego

Rasim S. Diler, M.D.
University of Pittsburgh

Raul Andero Gali, Ph.D.
Yerkes National Primate Research Center

Ebrahim Haroon, M.D.
Emory University School of Medicine

Andrei Irimia, M.S., Ph.D.
University of California, Los Angeles

Nathan Kolla, M.D., MSc., F.R.C.P.C.
University of Toronto

Niall Lally, B.A., H.Dip, M.Sc.
National Institute of Mental Health

Robert F. Leeman, Ph.D.
Yale University School of Medicine

Vincenzo De Luca, M.D., Ph.D.
Centre for Addiction and Mental Health

Luciano Minuzzi, M.D., Ph.D.
McMaster University

Olaoluwa Okusaga, M.D.
University of Texas Medical School in Houston

Jeffrey J. Rakofsky, M.D.
Emory University Department of Psychiatry and Behavioral Sciences

William B. Ruzicka, M.D., Ph.D.
McLean Hospital/Harvard Medical School

Sudhakar Selvaraj, M.B.B.S., MRCPsych., DPhil
Imperial College London

Julia M. Stephen, Ph.D.
The Mind Research Network

Susannah J. Tye, BSc. (Hon I), Ph.D.
Mayo Clinic

Elizabeth E. Van Voorhees, Ph.D.
Duke University Medical Center

Aleksandra Zgierska, M.D., Ph.D.
University of Wisconsin, School of Medicine & Public Health

3:00 pm – 6:00 pm ***ASCP Board Meeting***
Room 216

AT-A-GLANGE

Tuesday, May 28, 2013

7:30 am – 8:30 am **NIA Breakfast Roundtable**
Room 216 (invitation only)

7:30 am - 9:00 am **Continental Breakfast**
Grand Ballroom Foyer

8:30 am – 9:00 am **NCDEU Opening Session**
Grand Ballroom

9:00 am – 10:30 am **Panel Sessions**

Tackling the Brave New World of Medicines Development for Autism Spectrum Disorders Location: Atlantic 1	***Identifying and Managing Emerging Medical Comorbidities in Early Mental Illness*** Location: Atlantic 3	****From the Detection and Diagnosis to the Prevention and Treatment of Posttraumatic Stress*** Location: Atlantic 2

10:30 am – 10:45 am **Break**
Grand Foyer East & West

10:45 am – 12:15 pm **Panel Sessions**

****NCCAM Panel on Mind Altering Microorganisms: Insights on Novel Therapeutic CNS Targets*** Location: Atlantic 2	***Neuroscience vs. Serendipity in Psychiatric Drug Development: A Debate*** Location: Atlantic 3	***Placebo Analgesia: Psychological, Neurophysiological and Neurobiochemical Aspects*** Location: Atlantic 1	***Towards a Better Understanding of Medication Adherence in Patients with Serious Mental Illness (SMI)*** Location: Diplomat 1-2

12:15 pm – 2:00 pm **Lunch On Own**

****of special interest to clinicians***

2:00 pm – 3:30 pm	**Plenary Session - NIH Open Forum with Leadership of NIMH, NIDA, and NIAAA** Grand Ballroom
3:30 pm – 3:45 pm	**Break** Grand Foyer East & West
3:45 pm – 6:00 pm	**Pharma Pipeline Session** Grand Ballroom
6:15 pm – 7:45 pm	***New Investigators' Award Ceremony & Reception (invitation only***) Diplomat 4-5

FULL SCHEDULE

Tuesday, May 28, 2013

7:30 am - 8:30 am **NIA Breakfast Roundtable**
Room 216 (invitation only)

7:30 am - 9:00 am **Continental Breakfast**
Grand Ballroom Foyer

8:30 am - 9:00 am **NCDEU Opening Session**
Grand Ballroom

Panel Sessions

9:00 am – 10:30 am **Tackling the Brave New World of Medicines Development for Autism Spectrum Disorders**
Atlantic Ballroom 1

Chair: Robert H. Ring, Ph.D., Autism Speaks

9:05 am – 9:30 am **A Review of High Quality Outcome Measures for Use in Autism Spectrum Disorder (ASD) Clinical Trials**
Joseph P. Horrigan, M.D., Neuren Pharmaceuticals Limited, Auckland, New Zealand

9:30 am – 9:55 am **The Challenges Facing an Academic Interested in the Development of Novel Treatments for Autism: My Experiences with Oxytocin**
Linmarie Sikich, M.D., UNC-Chapel Hill

9:55 am – 10:20 am **STX209 (Arbaclofen) for Fragile X Syndrome and for ASD: From Gene to Animal Models to Patients**
Paul Wang, M.D., Seaside Therapeutics, Inc.

10:20 am – 10:30 am **General Discussion**
James McCracken, M.D., UCLA Neuropsychiatric Institute and Hospital

9:00 am – 10:30 am **Identifying and Managing Emerging Medical Comorbidities in Early Mental Illness**
Atlantic Ballroom 3

Chair: Benedetto Vitiello, M.D., Treatment and Prevention Intervention Branch, NIMH

9:05 am – 9:20 am **Risk Factors for Medical Co-morbidities Observed at the Onset of Psychosis**
Christoph U. Correll, M.D., Hofstra North Shore LIJ School of Medicine

9:20 am – 9:40 am **Phase-specific Pharmacotherapy for First Episode Psychosis**
Delbert Robinson, M.D., Hofstra North Shore-LIJ School of Medicine at Hofstra University

9:40 am – 10:00 am **Metabolic Effects of Antipsychotics in Previously Antipsychotic-naïve Children**
John W. Newcomer, M.D., Miller School of Medicine, University of Miami

10:00 am – 10:30 am **General Discussion**
Charles Hennekens, M.D., Florida Atlantic University

9:00 am – 10:30 am ***From the Detection and Diagnosis to the Prevention and Treatment of Posttraumatic Stress Disorder**
Atlantic Ballroom 2

Chair: Lori L. Davis, M.D., University of Alabama School of Medicine

9:05 am – 9:30 am **Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder: What does the Evidence Show?**
Bradley Gaynes, M.D., MPH, University of North Carolina

9:30 am – 10:00 am **Biomarkers and their Use in the Detection and Treatment or Prevention of PTSD**
Barbara Rothbaum, Ph.D., Emory University School of Medicine

of special interest to clinicians

9:00 am – 10:30 am (continued)	***From the Detection and Diagnosis to the Prevention and Treatment of Posttraumatic Stress Disorder** ***Atlantic Ballroom 2***
10:00 am – 10:25 am	**Diagnostic Criteria and Outcome Targets for PTSD in Clinical Trials Design** Lori L. Davis, M.D., University of Alabama School of Medicine
10:25 am – 10:30 am	**General Discussion** Lori L. Davis, M.D., University of Alabama School of Medicine
10:30 am – 10:45 am	**Coffee Break**

Panel Sessions

10:45 am – 12:15 pm	***NCCAM Panel on Mind Altering Microorganisms: Insights on Novel Therapeutic CNS Targets** ***Atlantic Ballroom 2***

Chair: Emmeline Edwards, Ph.D., Division of Extramural Research NCCAM
Co-Chair: Patricia Hibberd, M.D., Ph.D.

10:50 am – 11:10 am	**Small Molecule-mediated Modulation of Immunity and Neurobiology by the Microbiome** James Versalovic, M.D., Ph.D., Baylor College of Medicine and Texas Children's Hospital
11:10 am – 11:30 am	**Microbiota-gut-brain Communication: Does it Really Play a Role in Humans?** Emeran Mayer, M.D., Ph.D., Gail and Gerald Oppenheimer Family Center for Neurobiology of Stress, David Geffen School of Medicine at UCLA
11:30 am – 11:50 am	**Microbiome Manipulation as a Therapy in a Mouse Model of an Environmental Risk Factor for Autism** Paul H. Patterson, California Institute of Technology

of special interest to clinicians

10:45 am – 12:15 pm (continued)	***NCCAM Panel on Mind Altering Microorganisms: Insights on Novel Therapeutic CNS Targets** ***Atlantic Ballroom 2***
11:50 am – 12:10 pm	**Bacterial Microbiota-host Interactions Promote Metabolic Inflammation and Obesity: Implications for the Central Nervous System and the Brain-gut Axis** Jens Walter, Ph.D., University of Nebraska, Lincoln
12:10 pm – 12:15 pm	**General Discussion** Patricia Hibberd, M.D., Ph.D., Harvard Medical School and Massachusetts General Hospital

10:45 am – 12:15 pm	**Neuroscience vs. Serendipity in Psychiatric Drug Development: A Debate** ***Atlantic Ballroom 3***

Chair: William Z. Potter, M.D., Ph.D., NIMH

10:45 am – 10:55 am	**Debate on New Drug Development: A Perspective from within Industry** David Michelson, M.D., Merck Research Laboratories
10:55 am – 11:05 am	**The Role of CROs and Clinical Trials Networks in Designing and Implementing Clinical Development Programs: Beyond Traditional 'Arms and legs' Expectations** Larry Ereshefsky, Pharm.D., B.C.P.P., PAREXEL International
11:05 am – 11:15 am	**Discovery of All New Major Classes of Psychiatric Drugs Occurred Thru Serendipity: This Ceased in 1969, what can we Infer and do about it?** Donald F. Klein, M.D., D.Sc, NYU Langone Medical Center
11:15 am – 11:25 am	**Hybrid Academic Trial Networks: Leveraging Academic Focus to Assess Unproven Mechanisms or Drugs in Psychiatric Disorders** Ira Glick, M.D., Department of Psychiatry & Behavioral Sciences Stanford University School of Medicine

of special interest to clinicians

10:45 am – 12:15 pm (continued) **Neuroscience vs. Serendipity in Psychiatric Drug Development: A Debate**
Atlantic Ballroom 3

11:25 am – 11:35 am **Effects of Specific Mechanisms on Brain Circuits and Related Behavioral Domains**
William Z. Potter, M.D., Ph.D., NIMH

11:35 am – 12:15 pm **General Discussion**
William Z. Potter, M.D., Ph.D., NIMH

10:45 am – 12:15 pm **Placebo Analgesia: Psychological, Neurophysiological and Neurobiochemical Aspects**
Atlantic Ballroom 1

Chair: Luana Colloca, M.D., Ph.D, National Institutes of Health, National Institute of Mental Health and National Center of Complementary and Alternative Medicine

10:45 am – 11:05 am **Placebo Analgesia as a Model to Understand the Placebo Effect**
Luana Colloca, M.D., Ph.D, National Institutes of Health, National Institute of Mental Health and National Center of Complementary and Alternative Medicine

11:05 am – 11:25 am **Expectancy Effects During Opioid Analgesia: Influences of Expectations about Stimuli and Expectations about Treatments on Pain and Neural Responses**
Lauren Y. Atlas, New York University

11:25 am – 11:45 am **Molecular Mechanisms of Placebo Effects**
Jon-Kar Zubieta, M.D., Ph.D., University of Michigan, Psychiatry, Radiology

11:45 am – 12:15 pm **General Discussion**
Jon-Kar Zubieta, M.D., Ph.D., University of Michigan, Psychiatry, Radiology

10:45 am – 12:15 pm **Towards a Better Understanding of Medication Adherence in Patients With Serious Mental Illness (SMI)**
Diplomat 1 & 2

Chair: Craig N. Karson, M.D., CNK Consultants

10:45 am – 11:00 am **Understanding the Role of Long-acting Antipsychotic Medication in Recently Diagnosed, "First-episode" Schizophrenia: Information Trumps Adherence**
Peter J. Weiden, M.D., UIC Medical Center

11:00 am – 11:15 am **Understanding Adherence in Clinical Subpopulations of Patients with Serious Mental Illness (SMI)**
Martha Sajatovic, M.D., Case Western Reserve University School of Medicine

11:15 am – 11:30 am **Medical Resource Utilization in Patients Treated with Long-acting Injectable (LAI) Antipsychotics**
Craig N. Karson, M.D., CNK Consultants

11:30 am – 11:45 am **Developing Methodologies for Tracking and Improving Adherence**
Dawn Velligan, Ph.D., Department of Psychiatry, Univ. Texas Health Science Center

11:45 am – 12:15 pm **General Discussion**
Stephen Marder, M.D., Semel Institute at UCLA and VA Greater Los Angeles

12:15 pm – 2:00 pm **Lunch on own**

Plenary Session

2:00 pm – 3:30 pm **NIH Open Forum with Leadership of NIMH, NIDA, and NIAAA**
Grand Ballroom

Chair: William Z. Potter, M.D., Ph.D., NIMH

2:00 pm – 2:10 pm **Harnessing Preclinical Studies to Identify Novel Drug Targets for Alcohol Dependence**
Antonio Noronha, Ph.D., NIAAA, NIH

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is a strong supporter of basic and clinical research aimed at identifying effective medications for the treatment of alcoholism. Currently, there are four FDA approved medications for the treatment of alcoholism, each showing moderate efficacy. The modest efficacy of these medications is due to the heterogeneous nature of alcohol dependence where some individuals respond better to a particular medication compared to another. For this reason, basic, preclinical research that NIAAA supports continues to be actively engaged in finding novel drug targets that could be used for future medications development. To this end, the search for new drug targets is harnessing the power of genomics. For example, genome-wide gene expression studies are identifying networks of genes that are regulated by alcohol in the brain. This systems approach has the advantage identifying key brain signaling pathways that could be targeted for medications development. These studies are being conducted in various animal models of alcohol dependence as well as in human alcoholic brain obtained at autopsy. Important gene networks have been identified including: GABA signaling and neuroimmune signaling. Further, the tools for examining epigenetic changes after alcohol are also being applied to identify new drug targets. In this regard, histone deacetylases have been implicated in alcohol withdrawal and histone deacetylase inhibitors are effective in ameliorating some of the symptomlogy of alcohol withdrawal including anxiety. These novel drug targets should prove to be useful leads in clinical studies as we move from the bench to the bedside in ongoing translational efforts.

2:00 pm – 3:30 pm (continued) **NIH Open Forum with Leadership of NIMH, NIDA, and NIAAA**
Grand Ballroom

2:10 pm – 2:20 pm **Medications Development at NIDA**
Phillip Skolnick, Ph.D., D.Sc. (hon.), NIDA

In this brief overview, I will highlight recent developments in preclinical and clinical research with the potential to significantly impact the treatment of substance use disorders (SUDs). A novel target identified during the past year holds promise as a source of novel, non-addictive analgesics. This target is a truncated, six-TM splice variant of the μ opiate receptor; novel drug-like molecules that interact with this site are potent analgesics but do not appear to either depress respiration or produce physical dependence, and have only a limited effect on GI transit (Majumdar, et al., J. Med. Chem. 55: 6352, 2012). Converging lines of evidence suggest that both dopamine D3 and D4 receptor antagonists would be effective pharmacotherapies to treat multiple SUDs. The lack of safe and well tolerated tools has precluded testing this hypothesis in the clinic. The recent demonstration that buspirone is a high affinity antagonist at D3 and D4 receptors is consistent with its ability to block cocaine self-administration in non-human primates and reinstatement (a model of relapse) to both cocaine and methamphetamine in rodents (Bergman, et al., Int. J. Neuropsychopharmacol. 16: 445, 2013; Newman, et al., Biochem. Pharmacol. 84:882, 2012). Based on these findings, the CTN (NCT01641159) initiated a relapse prevention trial of buspirone in cocaine use disorder. Several NIDA-sponsored studies failed this year, including trials of vigabatrin to treat cocaine dependence and bupropion to treat methamphetamine dependence. Based in part on a NIDA funded study, Titan Pharmaceutical filed an NDA for an implantable form of buprenorphine, and an advisory committee meeting is scheduled for Q1 2013. Among the more promising biological approaches to treat SUDs is the development of a genetically modified butyrlcholinesterase, capable of hydrolyzing cocaine ~1000-fold more rapidly than the wild type enzyme. Consistent with findings in rodents and non-human primates, Phase I studies have demonstrated that parenteral administration of this enzyme rapidly degrades intravenously administered cocaine for at least a week. NIDA and Teva Pharmaceutical Industries, Ltd. have agreed to conduct (under a CRADA) a Phase II safety and efficacy study of TV-1380 (containing this engineered esterase) in the treatment of cocaine dependence.

2:00 pm – 3:30 pm (continued)	**NIH Open Forum with Leadership of NIMH, NIDA, and NIAAA** ***Grand Ballroom***
2:20 pm – 2:30 pm	**NIMH Update** Philip Wang, M.D., Dr.P.H., NIMH This presentation will provide an overview of recent national issues involving mental health as well as research activities by NIMH to respond to these. Recent research findings that suggest opportunities to develop better diagnostic, treatment, and preventive interventions will also be covered.
2:30 pm – 3:30 pm	Q & A / Discussion
3:30 pm – 3:45 pm	**Break**
3:45 pm- 6:00 pm	***Pharma Pipeline Session**

Chair: Carlos Zarate, M.D., NIMH

3:45 pm – 3:56 pm	**Safety, Pharmacokinetic and Positron Emission Tomography Evaluation of Serotonin and Dopamine Transporter Occupancy Following Multiple-dose Administration of the Triple Monoamine Reuptake Inhibitor BMS-820836** Zubin Bhagwagar, M.D., DPhil, MRCPsych, Bristol-Myers Squibb and Yale University
3:56 pm – 4:07 pm	**Early Development of ALKS 3831: A Novel Drug Candidate for the Treatment of Schizophrenia** Bernard L. Silverman, M.D., Alkermes, Inc.
4:07 pm – 4:18 pm	**PH 10 May be a New Rapidly Acting Intranasally Administered Antidepressant** Michael R. Liebowitz, M.D., Pherin Pharmaceuticals
4:18 pm – 4:29 pm	**Dose Response Analysis of Lisdexamfetamine Dimesylate for Treatment of Binge Eating Disorder** Susan McElroy, M.D., Lindner Center of HOPE, The University of Cincinnati College of Medicine

of special interest to clinicians

3:45 pm- 6:00 pm	*Pharma Pipeline Session (continued)
4:29 pm – 4:40 pm	**Suvorexant: Orexin Receptor Antagonism and Insomnia** David Michelson, M.D., Merck Research Laboratories
4:40 pm – 4:51 pm	**Pharmacology, Safety and Efficacy in Major Depressive Disorder of CX-157, a Reversible Inhibitor of Monoamine Oxidase A** Daniel J. Burch, M.D., PPDi
4:51 pm – 5:02 pm	**A Randomized, Double-blind, Study of Vortioxetine versus Agomelatine in Adults with Major Depressive Disorder (MDD) Switched after Inadequate Response to SSRI or SNRI Treatment** Marianne Dragheim, M.D., H. Lundbeck A/S
5:02 pm – 5:13 pm	**Treatment of Depression with OnabotulinumtoxinA: A Randomized, Double-blind, Placebo Controlled Trial** Eric Finzi, M.D.,Ph.D., Chevy Chase Cosmetic Center
5:13 pm – 5:24 pm	**Gepirone-ER: Effective Treatment of Major Depression and Accompanying Sexual Dysfunction** Louis F. Fabre, Jr., M.D. Ph.D., Fabre Kramer Pharmaceuticals, Inc.
5:24 pm – 5:35 pm	**REFRESH: A Phase2 RP 5063 Efficacy and Safety in Schizophrenia and Schizoaffective Disorder** Marc Cantillon, M.D., Reviva Pharmaceuticals
5:35 pm – 5:46 pm	**Broad Therapeutic Potential for ITI-007 and IC200131** Kimberly Vanover, Ph.D., Intra-Cellular Therapies, Inc.
5:46 pm – 5:57 pm	**EVP-6124, an Alpha-7 Nicotinic Partial Agonist, Produces Positive Effects on Cognition, and Clinical Function in Patients with Chronic Schizophrenia on Stable Antipsychotic Therapy** Ilise Lombardo, M.D., EnVivo Pharmaceuticals
6:15pm – 7:45pm	**New Investigators' Award Ceremony & Reception (Invitation Only)**

of special interest to clinicians

AT-A-GLANCE

Wednesday, May 29, 2013

7:00 am – 8:30 am **NCDEU Steering Committee Meeting**
Room 303

7:30 am – 8:30 am **NIA Breakfast Roundtable**
Room 216 (invitation only)

7:30 am - 9:00 am **Continental Breakfast**
Grand Ballroom Foyer

8:30 am – 10:00 am **Plenary Session - Medication Adherence: Can we Afford to Conduct Clinical Trials without Monitoring Adherence?**
Grand Ballroom

10:00 am – 10:15 am **Break**
Grand Foyer East & West

10:15 am – 11:15 am **Individual Research Reports**

Individual Research Reports: Bipolar Disorder and Clinical Assessment	***Individual Research Reports: Childhood and Adolescent & Sleep Disorders***	***Individual Research Reports: Depression***	***Individual Research Reports: Schizophrenia and Clinical Trial Methodology***
Location: Atlantic 1	Diplomat 1-2	Atlantic 3	Atlantic 2

11:15 am – 1:15 pm **Poster Session I with Lunch**
Regency Ballroom

1:15 pm – 2:45 pm **Panel Sessions**

New Insights on Placebo Response in Antidepressant Trials	***Pharmacogenetics (and Pharmocogenetics) of Psychotropic Drug Response***	***Reviving Drug Development Paradigms for CNS Disorders***	****Schizophrenia and Co-occurring Substance Use Disorders: Exploring Common Neurocircuits and Effective Treatments: NIAAA Panel Session***
Atlantic 1	Diplomat 1-2	Atlantic 3	Atlantic 2

2:45 pm – 3:00 pm **Break**
Grand Foyer East & West

3:00 pm – 6:00 pm **Workshops**

Clinically Relevant or Not? Treatments for Bipolar Depression	***Critical Elements of Adjunctive Trial Design in MDD***	****New Advances in Child Psychopharmacology***	***The Under Utilization of Clozapine: Reasons and Solutions***
Atlantic 1	Atlantic 2	Atlantic 3	Diplomat 1-2

7:00 pm – 8:00 pm **NCDEU Reception**
South Palm Court

****of special interest to clinicians***

FULL SCHEDULE

Wednesday, May 29, 2013

7:00 am – 8:30 am **NCDEU Steering Committee Meeting**
Room 303

7:30 am – 8:30 am **NIA Breakfast Roundtable (invitation only)**
Room 216

7:30 am – 9:00am **Continental Breakfast**
Grand Ballroom Foyer

Plenary Session

8:30 am – 10:00 am **Can We Afford To Conduct Clinical Trials Without Monitoring Adherence?**
Grand Ballroom

Chairs: Phil Skolnick, Ph.D., D.Sc. (hon.), NIDA
Raye Litten, Ph.D., NIAAA

8:30 am – 8:55 am **Is Understanding Medication Adherence the Cornerstone of a Successful Clinical Trial?**
Phillip Skolnick, Ph.D., D.Sc. (hon.), NIAAA

The "gold standard" for measuring medication adherence in clinical trials is pill count. When monitored by pill count, adherence is generally reported as >90%. However, in studies where adherence is monitored by measuring drug (and/or metabolite) levels at periodic intervals, these rates are consistently and dramatically lower. In this presentation, I will describe studies that illustrate how low rates of medication adherence preclude rigorous hypothesis testing and may contribute to the high failure rate of neuropsychiatric drugs at the proof-of-concept stage and beyond.

8:30 am – 10:00 am (continued) **Can We Afford To Conduct Clinical Trials Without Monitoring Adherence?**
Grand Ballroom

8:55 am – 9:20 am

Can we Afford to Conduct Clinical Trials without Monitoring Adherence?
Aidan Hampson, Ph.D., NIDA

In all pharmacotherapeutic clinical trials, whether aimed at cardiovascular or psychiatric indications, there is a ghost in the machine; "Adherence"- did the subjects take the medication as prescribed? This question is important to the trial sponsor, but critical to patients who would have had access to a new efficacious medication if a trial failure had not stopped further development. Even worse, if a medication is approved despite poor adherence in the trials, the minimum toxic dose might appear higher than in reality. Post marketing, this can result in patients experiencing toxic side effects when adhering to recommended dosages. Unfortunately, assessing true compliance in a trial is difficult, monitored medication ingestion is very labor intensive for subjects and clinical staff and so is usually only suitable for small trials. This talk will briefly discuss the current "standard" procedures in use to monitor medication compliance, as well ways in which NIDA is trying to sponsor the development of new improved tools designed to aid trial clinicians to wrestle the adherence "ghost."

9:20 am – 9:45 am

Behavioral and Technological Strategies to Enhance Medication Adherence
Stephanie O'Malley, Ph.D., Yale University School of Medicine

Given the critical role of medication adherence to the success of a clinical trial, researchers have investigated means to enhance adherence, including educational, behavioral and technological strategies. The efficacy of these approaches will be presented and the potential value of personalizing adherence strategies based on the person's past history of medication adherence and on their adherence within the trial will be discussed. The use of new technologies, such as text messaging, to increase adherence and tailor interventions will also be illustrated.

9:45 am – 10:00 am

General Discussion
Thomas Laughren, M.D.

10:00 am – 10:15 am **Coffee Break**

Concurrent Individual Research Reports

10:15 am – 11:15 am **Bipolar Disorder and Clinical Assessment**
Atlantic Ballroom 1

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

10:15 am – 10:30 am **Valacyclovir Improves Cognition in Individuals with Bipolar Disorder who are HSV-1 Positive**
Jennifer L. Payne, M.D., Johns Hopkins School of Medicine

10:30 am – 10:45 am **An Innovative Method for Tracking Changes in Prescribed Medication, Clinical Decision Making, and Outcome in Comparative Effectiveness Research**
Noreen A. Reilly-Harrington, Ph.D., Massachusetts General Hospital, Harvard Medical School

10:45 am – 11:00 am **Dimensional Assessment of Mood-spectrum Psychopathology in Individuals with Bipolar I, II and Unipolar Disorder: Continuities and Distinctions**
Holly A. Swartz, M.D., University of Pittsburgh School of Medicine

11:00 am – 11:15 am **Use of "Dual" Ratings Criteria to Improve Subject Selection and Trial Outcomes**
Steven D. Targum, M.D., Massachusetts General Hospital, Department of Psychiatry

10:15 am – 11:15 am **Childhood and Adolescent & Sleep Disorders**
Diplomat 1& 2

Chair: Leslie Citrome, M.D., M.P.H., New York Medical College

10:15 am – 10:30 am **The Sleep Effects of Lurasidone: A Placebo-controlled Cross-over Study using a 4-hour Phase-advance Model of Transient Insomnia**
Andrew Krystal, M.D., M.S., Duke University School of Medicine

10:30 am – 10:45 am **Extended Oxytocin Treatment of Children with Autistic Disorder**
Terrence C. Bethea, M.D., University of North Carolina at Chapel Hill

10:45 am – 11:00 am **Randomized, Controlled, Phase 2 Trial of STX209 for Social Function in Autism Spectrum Disorder (ASD)**
Paul Wang, M.D., Seaside Therapeutics, Inc.

11:00 am – 11:15 am **Effect of D-cycloserine (DCS) on the Core Social Deficit in High-functioning Adolescents and Young Adults with ASD**
Maria Urbano, M.D., Eastern Virginia Medical School

10:15 am – 11:15 am **Depression**
Atlantic Ballroom 3

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

10:15 am – 10:30 am **The Future of Psychiatric Measurement**
Robert D. Gibbons, Ph.D., University of Chicago

10:30 am – 10:45 am **Differences In Cognitive Function between 5HT1A Genotypes in a Large Sample of Patients with Major Depressive Disorder**
Keith Wesnes, Ph.D., Bracket

10:45 am – 11:00 am **The Remission from Depression Questionnaire as an Outcome Measure in the Treatment of Depression**
Mark Zimmerman, M.D., Brown University

10:15 am – 11:15 am (continued) **Depression**
Atlantic Ballroom 3

11:00 am – 11:15 am **Methylphenidate Augmentation of Citalopram is Effective in Reducing Depression Severity and Improving Cognition in Geriatric Depression: a Double-blind, Placebo-controlled Trial**
Helen Lavretsky, M.D., UCLA Semel Institute for Neuroscience and Human Behavior

10:15 am – 11:15 am **Schizophrenia and Clinical Trial Methodology**
Atlantic Ballroom 2

Chair: Bruce Kinon, M.D., Eli Lilly and Company

10:15am – 10:30 am **Circadian Rhythms in Cognitive Functioning among Patients with Schizophrenia: Impact on Signal Detection in Clinical Trials of Pro-cognitive Therapies**
Richard Keefe, Ph.D., Duke University Medical Center

10:30 am – 10:45 am **Perspectives on Long-acting Injectable Antipsychotics for Schizophrenia: Consideration of Ethnic and Cultural/Racial Differences in Planning Individual Treatment**
Rimal B. Bera, M.D., University of California

10:45am – 11:00 am **Using Pharmacokinetic Sampling to Identify Patient Characteristics that Predict Medication Compliance in Schizophrenia Clinical Trials**
George M. Haig, PharmD, MBA, AbbVie

11:00 am – 11:15 am **Can an Electronic Patient-reported Outcome Device be Successfully used in a Multicenter Trial in Patients Diagnosed with Schizophrenia?**
Virginia L. Stauffer, PharmD, Eli Lilly and Company

11:15 am – 1:15 pm **Poster Session I with Lunch**
Regency Ballroom

Concurrent Panel Sessions

1:15 pm – 2:45pm **New Insights on Placebo Response in Antidepressant Trials**
Atlantic Ballroom 1

Chair: Jonathan Rabinowitz, Ph.D., Bar Ilan University

1:15 pm – 1:40 pm **Improving Efficiency of RCT's of Antidepressant Trials: Lessons Learned from the NewMeds Repository of RCT Data from AstraZeneca, Eli Lilly, Lundbeck, and Pfizer**
Jonathan Rabinowitz, Ph.D., Bar Ilan University

1:40 pm – 2:00 pm **The Role of Expectations in the Placebo Response**
Maurizio Fava, M.D., Massachusetts General Hospital

2:00 pm – 2:20 pm **Placebo Response in Major Depressive Disorder Trials: The Particular Problems of Therapeutic Alliance and Expectation Bias**
Michael J. Detke, M.D., Ph.D., MedAvante / Indiana University School of Medicine

2:20 pm – 2:45 pm **General Discussion**
Bruce Kinon, M.D., Eli Lilly and Company

1:15 pm – 2:45 pm **Pharmacogenetics (and Pharmacogenomics) of Psychotropic Drug Response**
Diplomat 1 & 2

Chair: Anil K. Malhotra, M.D., The Zucker Hillside Hospital

1:15 pm – 1:40 pm **Pharmacogenomic Approaches to Drug-induced Adverse Events**
Anil K. Malhotra, M.D., The Zucker Hillside Hospital

1:40 pm – 2:05 pm **Genetic Predictors of Antipsychotic Pharmacokinetics and Pharmacodynamics**
Kristin L. Bigos, Ph.D., Lieber Institute for Brain Development

1:15 pm – 2:45 pm (continued)	**Pharmacogenetics (and Pharmacogenomics) of Psychotropic Drug Response** ***Diplomat 1 & 2***
2:05 pm – 2:30 pm	**Regulatory Considerations in the Role of Pharmacogenetic Markers in Psychiatric Drug Development** Thomas Laughren, M.D.
2:30 pm – 2:45 pm	**General Discussion** Roy Perlis, M.D., M.Sc., Massachusetts General Hospital/HMS

1:15 pm – 2:45 pm	**Reviving Drug Development Paradigms for CNS Disorders** ***Atlantic Ballroom 3***

Chair: Charles Bowden, M.D., University of Texas Health Science Center, San Antonio

1:15 pm – 1:30 pm	**Introduction** Charles Bowden, M.D., University of Texas Health Science Center, San Antonio
1:30 pm – 1:45 pm	**Therapeutic Potential of Mood Stabilizers in Multiple Brain Disorders: Insights from Preclinical Studies** De-Maw Chuang, Ph.D., National Institute of Mental Health, National Institutes of Health
1:45 pm – 2:00 pm	**Refining the Intracellular Targets for Mood Stabilizers: A Journey from the Synapse to the Mitochondria and Back Again** Trevor Young, M.D., Ph.D., FRCP(C), University of Toronto
2:00 pm – 2:15 pm	**Bridging Translational and Clinical Research Strategies** Steven Romano, M.D., Pfizer, Inc.
2:15 pm – 2:45 pm	**General Discussion** Eduard Vieta, M.D., Ph.D., Hospital Clinic, University of Barcelona, IDIBAPS, CIBERSAM

1:15 pm – 2:45 pm	***Schizophrenia and Co-Occurring Substance Use Disorders: Exploring Common Neurocircuits and Effective Treatments: NIAAA Panel Session** ***Atlantic Ballroom 2***

Chair: Raye Z. Litten, III, Ph.D., NIAAA

1:20 pm – 1:45 pm	**Neurocircuitry of Addiction Vulnerability in Mental Illness** Andrew Chambers, M.D., Addiction Psychiatry, Indiana University School of Medicine
1:45 pm – 2:10 pm	**Developing Treatments for Schizophrenia and Co-occurring Substance Use Disorder: Targeting Brain Reward Circuitry** Alan Ivan Green, M.D., Geisel School of Medicine at Dartmouth
2:10 pm – 2:35 pm	**Schizophrenia and Co-occurring Substance Use Disorders: Exploring Common Neurocircuits and Effective Treatments: NIAAA Panel Session** Ismene Petrakis, M.D., Yale University School of Medicine
2:35 pm – 2:45 pm	**General Discussion** Raye Z. Litten, III, Ph.D., NIAAA
2:45 pm- 3:00 pm	**Break**

Concurrent Workshops

3:00pm – 6:00pm	**Clinically Relevant or Not? Treatments for Bipolar Depression** ***Atlantic Ballroom 1***

Chair: Leslie Citrome, M.D., M.P.H., New York Medical College

3:00 pm – 3:30 pm	**What is Clinical Relevance and can it be Measured?** Leslie Citrome, M.D., M.P.H., New York Medical College
3:30pm – 4:00 pm	**Current Landscape for the Treatment of Bipolar Depression** Terence A. Ketter, M.D., Stanford University School of Medicine
4:00 pm – 4:30 pm	**Incremental Advances in Tolerability: the Case for Lurasidone** Joseph R. Calabrese, M.D., University Hospitals Case Medical Center
4:30 pm – 4:45 pm	**Break**
4:45 pm – 5:30 pm	**Incremental Advances in Efficacy: the Case for Adjunctive Armodafinil** Mark A. Frye, M.D., Mayo Clinic
5:30 pm – 6:00 pm	**General Discussion** Terence A. Ketter, M.D., Stanford University School of Medicine

3:00 pm – 6:00 pm	**Critical Elements of Adjunctive Trial Design in MDD** ***Atlantic Ballroom 2***

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

3:00 pm – 3:30 pm	**Adjunctive Therapies Trials Designs: Basics and Unanswered Questions** Michael E. Thase, M.D., Perelman School of Medicine of the University of Pennsylvania; Philadelphia VA Medical Center

3:00 pm – 6:00 pm (continued)	**Critical Elements of Adjunctive Trial Design in MDD** ***Atlantic Ballroom 2***
3:30 pm – 4:00 pm	**Effects of Response to the Initial Antidepressant on Acute Phase Outcome in Adjunctive Treatment Trials** Craig Nelson, M.D., University of California San Francisco
4:00 pm – 4:30 pm	**Methodological Challenges in CNS Drug Trials Targeting Residual Symptoms in Depression** Maurizio Fava, M.D., Massachusetts General Hospital
4:30 pm – 4:45 pm	**Break**
4:45 pm – 5:30 pm	**Industry Perspective: Developing Treatments that Go Beyond First-line Therapy in Major Depressive Disorder** Robert Berman, M.D., Bristol-Myers Squibb
5:30 pm – 6:00 pm	**General Discussion** Tiffany Farchione, M.D., FDA

3:00pm – 6:00pm	***New Advances in Child Psychopharmacology** ***Atlantic Ballroom 3***

Chair: Benedetto Vitiello, M.D., NIMH

3:00 pm – 3:30 pm	**What is the Current Evidence of the Efficacy and Safety of Treatments for Children with Bipolar Disorder?** Adelaide S. Robb, M.D., Children's National Medical Center
3:30pm – 4:30 pm	**A Randomized Trial of Augmenting and Switching Medications in Child Bipolar Disorder** John T. Walkup, M.D., Weill Cornell Medical College and New York-Presbyterian Hospital
4:30 pm- 4:45 pm	**Break**

of special interest to clinicians

3:00pm – 6:00pm (continued)	***New Advances in Child Psychopharmacology** ***Atlantic Ballroom 3***
4:45 pm – 5:30 pm	**Challenges and Rewards in Trials to Evaluate Treatment Strategies for Partial Responders to First-line Therapy** Joseph Blader, Ph.D., Stony Brook State University of New York
5:30 pm – 6:00 pm	**General Discussion** Benedetto Vitiello, M.D., NIMH

3:00pm – 6:00pm	**The Under Utilization of Clozapine: Reasons and Solutions** ***Diplomat 1 & 2***

Chair: J.P. Lindenmayer, M.D., New York University School of Medicine

3:00 pm – 3:30 pm	**Lack of Knowledge of the Benefits of Clozapine for Persistent Psychosis and Suicide Risk along with Overestimation of the Dangers of Agranulocytosis Limit its Utilization** Herbert Y. Meltzer, M.D., Northwestern University, Feinberg School of Medicine
3:30 pm – 4:00 pm	**Efficacy of Clozapine and Reasons Under Utilization** Ira Glick, M.D., Department of Psychiatry & Behavioral Sciences, Stanford University School of Medicine
4:00 pm – 4:30 pm	**A Multi-dimensional Clozapine Utilization Campaign in a Public Psychiatric Setting** J.P. Lindenmayer, M.D., New York University School of Medicine
4:30 pm – 4:45 pm	**Break**
4:45 pm – 5:30 pm	**The Under Utilization of Clozapine: Reasons and Solutions** Peter Buckley, M.D., Georgia Health Sciences University

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3:00pm – 6:00pm (continued)	**The Under Utilization of Clozapine: Reasons and Solutions** ***Diplomat 1 & 2***
5:30 pm – 6:00 pm	**General Discussion** J.P. Lindenmayer, M.D., New York University School of Medicine
7:00 pm- 8:00 pm	**NCDEU Reception** ***South Palm Court***

AT-A-GLANCE

Thursday, May 30, 2013

6:45 am – 8:00 am **13th Annual NCDEU Fun Run/Walk**
Meet in main lobby

7:30 am - 9:00 am **Continental Breakfast**
Grand Ballroom Foyer

7:30 am – 8:30 am **NIA Breakfast Roundtable (invitation only)**
Room 216

8:30 am – 10:00 am **Regulatory Plenary - New FDA & EMA Initiatives in Alzheimer's Disease, Depression and Schizophrenia**
Grand Ballroom

10:00 am – 10:15 am **Break**
Grand Foyer East & West

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

Clozapine: How Far Have We Come?	****Formal Assessment of Suicidal Ideation, Behavior and Risk in Clinical Trials and Emergency Settings: Implications of Recent Research***	***NIAAA Sponsored Panel: When One Drink is not Enough: Recent Considerations of Drinking Outcome Measures for Alcohol Clinical Trials from the ACTIVE Workgroup***	***Studying Sexual Dysfunction: How do we Manage Confounding Factors of Disease State Symptoms, Primary Disorder, and Medication Adverse Effects?***
Location: Atlantic 3	Location: Atlantic 1	Location: Atlantic 2	Location: Diplomat 1-2

11:45 am – 1:45 pm **Poster Session II with Lunch**
Regency Ballroom

****of special interest to clinicians***

1:45 pm – 2:00 pm **Break**
Grand Foyer East & West

2:00 pm – 5:00 pm **Workshops**

***Advancing Treatment Discovery in Major Depression: Ketamine and other Novel Antidepressant Approaches** Location: Atlantic 1	***Impediments/ Barriers to Effective Teaching-Learning in Psycho-pharmacology** Location: Atlantic 2	***Placebo Response in Antidepressant Clinical Trials: Patient Characteristics, Study Design Features, and Data Analytic Techniques** Location: Atlantic 3	***The Right Answer to the Right Question: Meeting the Global Challenges of Measurement for Effectiveness Studies in Psychiatry** Location: Diplomat 1-2

of special interest to clinicians

FULL SCHEDULE

Thursday, May 30, 2013

6:45 am – 8:00 am	**13th Annual NCDEU Fun Run/Walk** ***Meet in Hotel Main Lobby***
7:30 am - 9:00 am	**Continental Breakfast** ***Grand Ballroom Foyer***
7:30 am - 8:30 am	**New Investigator Awardee Roundtable Breakfast** ***Room 216 (invitation only)***
7:30 am - 9:30 am	**Continental Breakfast** ***Grand Ballroom Foyer***

Plenary Session

8:30 am – 10:00 am	**New FDA & EMA Initiatives in Alzheimer's Disease, Depression and Schizophrenia** ***Grand Ballroom***
8:30 am – 8:35 am	**Introduction** **Chair:** Karl Broich, M.D., Federal Institute for Drugs and Medical Devices (BfArM)
8:35 am – 8:55 am	**Biomarkers in Drug Development Between Hype and Hope: the Qualification Process at EMA** Karl Broich, M.D., Federal Institute for Drugs and Medical Devices (BfArM) Biomarkers have become a popular topic in many fields of medicine and all stages of drug development. Recent progress in basic research coupled with advances in various types of –omics and neuroimaging in large data bases has fostered hope that drug development, diagnostic procedures and clinical management of CNS disorders will be challenged. From a regulatory point of view biomarkers can already be used to better define homogeneous study populations and to select the most promising drug candidates in their effective

8:35 am – 8:55 am **(continued)**

Biomarkers in Drug Development between Hype and Hope: The Qualification Process at EMA

dosages for phase III clinical trials, however, further qualification and validation of specific biomarkers in large-scale international controlled multicenter studies is necessary before they can be accepted as primary outcome measures in pivotal phase III clinical trials - until now no biomarker has been sufficiently validated to be acceptable as a surrogate endpoint in pivotal CNS clinical trials. Establishing biomarkers as surrogate endpoints is an important goal particularly in conditions like Alzheimer's disease, especially in their early (preclinical, presymptomatic) stages, as traditional clinical outcome measures might be too insensitive to change or need unfeasible treatment durations for clinical trial conditions. Improvements can only be accomplished by active synergistic collaboration between academic, industrial and regulatory partners. Therefore EMA updated the guidance document to applicants on "Qualification of novel methodologies for drug development." The EMA approach and experience from qualification procedures for biomarkers in Alzheimer's disease will be provided.

8:55 am – 9:15 am

Update on FDA Exploratory Analyses of Aggregated Efficacy Data from Depression Trials
Ni Khin, M.D., Food and Drug Administration

Reports of rising placebo response, declining treatment effects, and substantial failure rates in depression trials are of great concern. There have been exploratory analyses of trial-level data to investigate these trends, however, these approaches have significant limitations with regard to identifying possible contributing factors. To address this problem, we recently established a pilot patient-level database, comprised of approximately 7800 patients with major depressive disorder who were enrolled in short-term randomized controlled trials. Exploratory analyses of this dataset have been initiated to evaluate the effect of trial duration and different endpoints, including various definitions of sustained treatment response and various rating scale item subsets, on trial efficiency. Preliminary findings from these analyses will be presented.

9:15 am – 9:25 am **FDA Initiative to Optimize Design Elements of Schizophrenia Drug Trials**
Islam Younis, Bs.C.,Ms.C.,Ph.D., Food and Drug Administration

Reports of rising placebo response, declining treatment effects, and substantial failure rates in schizophrenia trials are of great concern. There have been exploratory analyses of trial-level data to investigate these trends, however, these approaches have significant limitations with regard to identifying possible contributing factors. To address this problem, we recently established a pilot patient-level database from short-term randomized controlled trials in patients with schizophrenia. Exploratory analyses of this dataset have been initiated to evaluate the effect of trial duration and different endpoints, including various rating scale item subsets, on trial efficiency. The goal is to optimize trial design and increase the efficiency of schizophrenia drug development programs. Details of the initiative and preliminary findings will be discussed.

9:25 am – 10:00 am **General Discussion**
Karl Broich, M.D., Federal Institute for Drugs and Medical Devices (BfArM)

10:00 am – 10:15 am **Coffee Break**

Concurrent Panel Sessions

10:15 am – 11:45 am **Clozapine: How Far Have We Come?**
Atlantic Ballroom 3

Chair: John M. Kane, M.D., The Zucker Hillside Hospital
Co-Chair: Christoph U. Correll, M.D., Hofstra North Shore-LIJ School of Medicine

10:15 am – 10:35 am **An Update on the Quest to Identify Clozapine's Mechanisms of Action**
Donald Goff, M.D., New York University Medical Center

10:35 am – 11:05 am **Clozapine: Evidence, Guidelines and Obstacles to Utilization**
John M. Kane, M.D., The Zucker Hillside Hospital

11:05 am – 11:35 am **Increasing Utilization of Clozapine through Knowledge about Risk Factors for and Management of Serious and Non-serious Adverse Effects**
Christoph U. Correll, M.D., Hofstra North Shore-LIJ School of Medicine

11:35 am – 11:45 am **General Discussion**
Thomas Laughren, M.D.

10:15 am – 11:45 am ***Formal Assessment of Suicidal Ideation, Behavior and Risk in Clinical Trials and Emergency Settings: Implications of Recent Research**
Atlantic Ballroom 1

Chair: Alan J. Gelenberg, M.D., Penn State University

10:15 am – 10:35 am **Clinical and Operational Aspects of the Columbia Suicide Severity Rating Scale (C-SSRS) and Sheehan Suicide Tracking Scale (STS and S-STS) in a Psychometric Evaluation Study**
Ahmad Hameed, M.D., Penn State Milton S. Hershey Medical Center and College of Medicine.

of special interest to clinicians

10:15 am – 11:45 am ***Formal Assessment of Suicidal Ideation, Behavior and Risk in Clinical Trials and Emergency Settings: Implications of Recent Research**
Atlantic Ballroom 1

10:35 am – 10:50 am **Prospective Assessment of Suicidal Ideation and Behavior in Clinical Trials: A Pharma Perspective**
Phillip Chappell, M.D., Pfizer Inc.

10:50 am – 11:05 am **IV Ketamine for Treatment of Acute Suicidal Ideation for Patients with Depression in the Emergency Department**
Cheryl McCullumsmith, M.D., Ph.D., University of Alabama at Birmingham, Department of Psychiatry and Behavioral Neurobiology

11:05 am – 11:20 am **Assessing Efficacy when the Outcome Measures are Suicidal Ideation or Behavior: Focus on High Risk Populations**
Maria Oquendo, M.D., Columbia University and New York State Psychiatric Institute

11:20 am – 11:45 am **General Discussion**
Michael Thase, M.D., Perelman School of Medicine of the University of Pennsylvania; Philadelphia VA Medical Center

10:15 am – 11:45 am **NIAAA Sponsored Panel: When One Drink is not Enough: Recent Considerations of Drinking Outcome Measures for Alcohol Clinical Trials from the ACTIVE Workgroup**
Atlantic Ballroom 2

Chair: Raymond F. Anton, M.D., Distinguished University Professor, Dept. of Psychiatry, Medical University of South Carolina

10:15 am – 10:40 am **FDA Approach to Clinical Trials for Alcoholism Treatment Drugs**
Celia Winchell, M.D., Center for Drug Evaluation and Research, Food and Drug Administration

of special interest to clinicians

10:15 am – 11:45 am (continued) **NIAAA Sponsored Panel: When One Drink is not Enough: Recent Considerations of Drinking Outcome Measures for Alcohol Clinical Trials from the ACTIVE Workgroup**
Atlantic Ballroom 2

10:40 am – 11:00 am **Current European Regulatory Perspective on the Development of Medications for Alcohol Use Disorders**
Michael Büehlen, M.D., Federal Institute for Drugs and Medical Devices (BfArM), Germany

11:00 am – 11:20 am **Exploration of Endpoints for Alcohol Clinical Trials**
Raye Z. Litten, III, Ph.D., NIAAA

11:20 am – 11:45 am **General Discussion**
Raymond F. Anton, M.D., Distinguished University Professor, Dept. of Psychiatry, Medical University of South Carolina

10:15 am – 11:45 am **Studying Sexual Dysfunction: How do we Manage Confounding Factors of Disease State Symptoms, Primary Disorder, and Medication Adverse Effects?**
Diplomat 1 & 2

Chair: Anita H. Clayton, M.D., Department of Psychiatry & Neurobehavioral Sciences, University of Virginia

10:20 am – 10:35 am **Interaction of Factors Affecting Sexual Functioning**
Anita H. Clayton, M.D., Department of Psychiatry & Neurobehavioral Sciences, University of Virginia

10:35 am – 11:00 am **Summary of Findings from FDA Regulatory Science Forum on Measuring Sexual Dysfunction in Depression Trials**
Phillip Kronstein, M.D., Division of Psychiatry Products/CDER/FDA

11:00 am – 11:15 am **Optimizing the Efficiency of Early Drug Development for Sexual Dysfunction and the Lorexys Phase I-b/II-a Experience**
Robert E. Pyke, M.D., Ph.D., S1 Biopharma, Inc.

11:15 am – 11:45 am **General Discussion**
Ni Khin, M.D., Food and Drug Administration

11:45 am- 1:45 pm	**Poster Session II with Lunch** ***Regency Ballroom***
1:45 pm- 2:00 pm	**Break**

Concurrent Workshops

2:00pm – 5:00pm	***Advancing Treatment Discovery in Major Depression: Ketamine and Other Novel Antidepressant Approaches** ***Atlantic Ballroom 1***

Chair: James W. Murrough, M.D., Mount Sinai School of Medicine
Co-Chair: Sanjay Matthew, M.D., Michael E. Debakey VA Medical Center, Houston, TX; Baylor College of Medicine

2:00 pm – 2:25 pm	**Antidepressant Efficacy of Ketamine in Treatment-resistant Major Depression: A Two-site, Randomized, Parallel-arm, Midazolam-controlled, Clinical Trial** James W. Murrough, M.D., Mount Sinai School of Medicine
2:25 pm – 2:55 pm	**Ketamine Biomarkers in Depression: Promising Science and Answered Questions** Giacomo Salvadore, M.D., Janssen Pharmaceuticals
2:55 pm – 3:30 pm	**Rapid Antidepressant Effects and Biomarkers of Clinical Response to Scopolamine** Maura Furey, Ph.D., Experimental Therapeutics and Pathophysiology Branch/NIMH
3:30 pm – 3:45 pm	**Break**
3:45 pm – 4:10 pm	**The Efficacy of Minocycline for Bipolar Depression and its Impact on Glutamatergic and Antioxidant Metabolites** Dan V. Iosifescu, M.D., M.Sc., Mount Sinai School of Medicine

of special interest to clinicians

2:00pm – 5:00pm (continued)	***Advancing Treatment Discovery in Major Depression: Ketamine and Other Novel Antidepressant Approaches** ***Atlantic Ballroom 1***
4:10 pm – 4:40 pm	**Speed of Response to ECT: Rediscovering the "Gold Standard"** Charles H. Kellner, M.D., Mount Sinai School of Medicine
4:40 pm – 5:00 pm	**General Discussion** Sanjay Matthew, M.D., Michael E. Debakey VA Medical Center, Houston, TX; Baylor College of Medicine
2:00 pm – 5:00 pm	**Impediments/Barriers to Effective Teaching-learning of Psychopharmacology** ***Atlantic Ballroom 2***

Chair: Ira Glick, M.D., Stanford University School of Medicine

2:00 pm – 2:45 pm	**The Seven Sins of Psychopharmacology Teaching** Ira Glick, M.D., Stanford University School of Medicine
2:45 pm – 3:30 pm	**Barriers to Teaching Psychopharmacology to Residents and Medical Students** Marlene P. Freeman, M.D., Director of Clinical Services, Perinatal and Reproductive Psychiatry; Medical Director, CTNI, Harvard Medical School, Massachusetts General Hospital
3:30 pm –3:45 pm	**Break**
3:45 pm – 4:15 pm	**Inpatient Psychopharmacology in Teaching Hospitals: The Good News and the Bad News** J.P. Lindenmayer, M.D., New York University School of Medicine
4:15 pm – 5:00 pm	**You have Searched, You have Found, Now what? Going Digital and Building an Electronic Library** Leslie Citrome, M.D., MPH, New York Medical College

of special interest to clinicians

2:00pm – 5:00pm **Placebo Response in Antidepressant Clinical Trials: Patient Characteristics, Study Design Features, and Data Analytic Techniques**
Atlantic Ballroom 3

Chair: Bret R. Rutherford, M.D., Columbia University College of Physicians and Surgeons

2:00 pm – 2:45 pm **A Model of Placebo Response in Antidepressant Clinical Trials**
Bret R. Rutherford, M.D., Columbia University College of Physicians and Surgeons

2:45 pm – 3:30 pm **Predictors of Placebo Response in Depression**
Craig Nelson, M.D., University of California San Francisco

3:30 pm – 3:45 pm **Break**

3:45 pm – 4:20 pm **Evidence that Study Design Impacts Response Rates in Antidepressant Clinical Trials**
Steven Roose, M.D., Columbia University

4:20 pm – 5:00 pm **Are Relatively Small Effect Sizes in RCTs Synonymous with Trivial Benefits for Depressed Patients?**
Michael E. Thase, M.D., Perelman School of Medicine of the University of Pennsylvania; Philadelphia VA Medical Center

2:00 pm – 5:00 pm **The Right Answer to the Right Question: Meeting the Global Challenges of Measurement for Effectiveness Studies in Psychiatry**
Diplomat 1 & 2

Chair: Mark G. Opler, Ph.D., M.P.H., Department of Psychiatry, NYU School of Medicine

2:05 pm – 2:45 pm **Are Regional Differences Important in Effectiveness Research?**
Istvan Bitter, M.D., Ph.D., D.Sc., Semmelweis University, Budapest, Hungary

2:00 pm – 5:00 pm (continued)	**The Right Answer to the Right Question: Meeting the Global Challenges of Measurement for Effectiveness Studies in Psychiatry** ***Diplomat 1 & 2***
2:45 pm – 3:30 pm	**Clinical Evaluation of Extrapyramidal Symptoms in Psychiatric Patients Receiving Antipsychotics Using the Drug-induced Extrapyramidal Symptoms Scale (DIEPSS)** Toshiya Inada, M.D., Ph.D., Institute of Neuropsychiatry, Seiwa Hospital
3:30 pm – 3:45 pm	**Break**
3:45 pm – 4:25 pm	**Statistical Approaches in Effectiveness Trials** Anzalee Khan, Ph.D., Psychometrics, ProPhase LLC; Nathan S. Kline Institute for Psychiatric Research
4:25 pm – 5:00 pm	**Measurement of Outcomes for Depression: A US Investigator's Perspective** Madhukar Trivedi, M.D., UT Southwestern Medical Center

AT-A-GLANCE

Friday, May 31, 2013

7:30 am - 9:00 am **Continental Breakfast**
Grand Ballroom Foyer

8:30 am – 10:00 am **Panel Sessions**

****New Therapeutic Opportunities for the Treatment of Depression***	***Pursuing Unmet Needs in the Treatment of Cocaine and marijuana Addiction: New Clinical Trials of Potentially Breakthrough Therapies in NIDA's Clinical Trials Network***	***Rediscovering Catatonia: The Impact of New DSM-5 Classification***	***The Spectrum of Mixed states: A Bipolar CHOICE Study***
Location: Atlantic 3	Location: Atlantic 2	Location: Diplomat 1-2	Location: Atlantic 1

10:00 am – 10:15 am **Break**
Grand Foyer East & West

10:15 am – 11:45 am **Regulatory Wrap Up**
Grand Ballroom

12:00 pm **Meeting Adjourns**

****of special interest to clinicians***

Notes

FULL SCHEDULE

Friday, May 31, 2013

7:30 am – 9:00 am **Continental Breakfast**
Grand Ballroom Foyer

Concurrent Panel Sessions

8:30 am – 10:00 am ***New Therapeutic Opportunities for the Treatment of Depression**
Atlantic Ballroom 3

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

8:30 am – 8:55 am **Efficacy and Safety of Vortioxetine, an Novel Multimodal Antidepressant**
Marianne Dragheim, M.D., H. Lundbeck A/S

8:55 am – 9:10 am **NK-1 Antagonists: A Potential Novel Class of Antidepressant Agents**
Emiliangelo Ratti, M.D., NeRRe Therapeutics Ltd

9:10 am – 9:25 am **Opioid Modulation: A Novel Mechanism for the Treatment of Depression: Results of the ALKS 5461 Phase 2 Study**
Maurizio Fava, M.D., Massachusetts General Hospital

9:25 am – 9:40 am **Rapid Antidepressant Effect of GLYX-13, a Novel and Selective NMDAR Partial Agonist**
Ronald M. Burch, M.D., Ph.D., Naurex, Inc.

9:40 am – 10:00 am **General Discussion**
Jonathan Alpert, M.D., Ph.D., Massachusetts General Hospital, Harvard Medical School

of special interest to clinicians

8:30 am – 10:00 am **Pursuing Unmet Needs in the Treatment of Cocaine and Marijuana Addiction: New Clinical Trials of Potentially Breakthrough Therapies in NIDA's Clinical Trials Network**
Atlantic Ballroom 2

Chair: Steven Sparenborg, Ph.D., Center for the Clinical Trials Network, NIDA, NIH

8:30 am – 9:00 am **N-Acetylcysteine for Marijuana Addiction: Rationale and Design for a Placebo-controlled Randomized Trial in NIDA's Clinical Trials Network**
Kevin M. Gray, M.D., Medical University of South Carolina

9:00 am – 9:20 am **NIDA CTN Pharmacological Trials for Stimulant-dependence: Recent Findings and Current Targets**
Theresa Winhusen, Ph.D., University of Cincinnati College of Medicine

9:20 am – 9:40 am **Cocaine Use Reduction with Buprenorphine (CURB) Study**
Christie Thomas, M.P.H., Integrated Substance Abuse Programs, UCLA

9:40 am – 10:00 am **General Discussion**
Madhukar Trivedi, M.D., UT Southwestern Medical Center

8:30 am – 10:00 am **Rediscovering Catatonia: The Impact of New DSM-5 classification**
Diplomat 1 & 2

Chair: Georgios Petrides, M.D., Associate Professor of Psychiatry, Hofstra Nothshore-LIJ School of Medicine, The Zucker Hillside Hospital

8:30 am – 8:50 am **Rediscovering Catatonia: the Impact of New DSM-5 Classification**
Max Fink, M.D., Stony Brook University School of Medicine

8:50 am – 9:10 am **Update on Pediatric Catatonia**
Dirk Dhossche, Ph.D., University of Mississippi Medical Center

9:10 am – 9:30 am **Pharmacological Treatment of Catatonia**
Gregory Fricchione, M.D., Professor of Psychiatry, Harvard Med, Massachusetts General Hospital

9:30 am – 9:50 am **Drug-induced Catatonia; Implications of New Drug Development**
Stanley N. Caroff, M.D., Philadelphia VA Medical Center and the Perelman School of Medicine, University of Pennsylvania

9:50 am – 10:00 am **General Discussion**
Georgios Petrides, M.D., Associate Professor of Psychiatry, Hofstra Nothshore-LIJ School of Medicine, The Zucker Hillside Hospital

8:30 am – 10:00 am **The Spectrum of Mixed States: A Bipolar CHOICE Study**
Atlantic Ballroom 1

Chair: Andrew A. Nierenberg, M.D., Massachusetts General Hospital

8:30 am – 8:55 am **Clustering of Depressive and Manic Symptoms in Bipolar Disorder**
Michael E. Thase, M.D., Perelman School of Medicine of the University of Pennsylvania; Philadelphia VA Medical Center

8:55 am – 9:20 am **Depressive Symptoms in Mania/Hypomania**
Joseph R. Calabrese, M.D., University Hospitals Case Medical Center

9:20 am – 9:45 am **Manic/Hypomanic Symptoms During Depression**
Mauricio Tohen, M.D., DrPH, MBA, University of New Mexico Health Science Center

9:45 am – 10:00 am **General Discussion**
Susan McElroy, M.D., Lindner Center of HOPE, The University of Cincinnati College of Medicine

10:00 am – 10:15 am **Coffee Break**

Plenary Session

10:15 am – 11:45 am **Regulatory Wrap-up**
Grand Ballroom

Speakers: **Bob Rappaport, M.D.,** Food and Drug Administration
Karl Broich, M.D., Federal Institute for Drugs and Medical Devices (BfArM)
Ni Khin, M.D., Food and Drug Administration
Phillip Kronstein, M.D., Food and Drug Administration

12:00 pm **Meeting Adjourns**

Wednesday, May 29, 2013

Poster Session I
Regency Ballroom

1 **The Effects of Behavioral Parent Training and Acute Stimulant Medication Treatment for Parents with ADHD**
Dara Babinski, University of Florida
James G. Waxmonsky, William E. Pelham

2 **Disposition of d,l-methylphenidate in Organic Cation Transporter 3 (Oct3) Knockout Mice**
John S. Markowitz, University of Florida
Hao-Jie Zhu, Brinda Bryan

3 **Does Pharmacological Treatment of ADHD in Adults Enhance Parenting Performance?**
James G. Waxmonsky, Florida International University
Daniel Waschbusch, Dara Babinski, Hugh Humphery, Kathleen I. Crum, Janine J. Slavec, Junea N. Augustus, William E. Pelham, Melissa Bernsetein

4 **Symptoms of Personality Disorder are Reduced Following Successful ADHD Treatment**
Tammy A. Steans, Psychiatric and Behavioral Solutions, LLC
Frederick W. Reimherr, Barrie K. Marchant, Kathleen Reimherr, Phillip Gale

5 **Safety and Feasibility of Aerobic Exercise for Women Veterans with PTSD**
Geetha Shivakumar, UT Southwestern Medical Center and Dallas VA Medical Center

6 **Preferential Effects of Metadoxine ER on Inattentive Subtype Attention-Deficit/Hyperactivity Disorder**
Lenard Adler, NYU School of Medicine
Yaron Daniely, Jeffrey H. Newcorn, Stephen V. Faraone, Joseph Biederman

7 **Duloxetine versus Placebo in the Treatment of Patients with Generalized Anxiety Disorder Who were 65 Years of Age and Older**
Karla Alaka, Eli Lilly and Company
Jonna Ahl, Hector J. Duenas, Brita Dorn, Susan Ball, Marcin Bugaj, Alan Lenox-Smith, William Noble, Leszek Bidzan, Angel L. Montejo, Autar Munshi, Margot Schmitz

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8 **An Open-label Phase II Pilot Study of the Safety and Efficacy of Selegiline Transdermal System (STS) for Patients with Social Phobia**
Kimberly Portland, Mylan Specialty L.P.
Terry Painter, Dorothea Sanchez

9 **A Randomized Placebo-controlled Double-blind Trial of Mirtazapine for the Treatment of Posttraumatic Stress Disorder**
Patricia Pilkinton, Tuscaloosa VA Medical Center
Lori L. Davis, Pamela Parker, Jennifer Cribb

10 **Oprl1 Regulation of Amygdala-dependent Fear in Mice and Humans with PTSD**
Raul Andero Gali, Department of Psychiatry and Behavioral Sciences Center for Behavioral Neuroscience, Yerkes National Primate Research Center

11 **Determinants of Poor Sleep Quality in Inter-episode Bipolar Disorder**
Erika F.H. Saunders, Penn State College of Medicine
Novick M. Danielle, Julio Fernandez-Mendoza, Masoud Kamali, Scott A. Langenecker, Alan J. Gelenberg, Melvin G. McInnis

12 **Cognitive Effects of Quetiapine XR in Patients with Euthymic Bipolar Disorder**
Jeffrey J. Rakofsky, Emory University Department of Psychiatry and Behavioral Sciences
Boadie W. Dunlop, John L. Beyer, Alison M. Oliver, Erika E. Mansson, Madhur T. Sancheti, Philip D. Harvey

13 **Efficacy and Safety of Low- and High-dose Cariprazine in Patients with Acute Manic or Mixed Episodes Associated with Bipolar I Disorder**
Joseph R. Calabrese, University Hospitals Case Medical Center
Paul E. Keck, Kaifeng Lu, István Laszlovszky, Anju Starace, György Németh, Suresh Durgam

14 **Lurasidone Monotherapy for the Treatment of Bipolar I Depression: Results of the 6-week, Double-blind, Placebo-controlled Study (PREVAIL-2)**
Josephine Cucchiaro, Sunivion Pharmaceuticals, Inc.
Antony Loebel, Robert Silva, Kaushik Sarma, Hans Kroger, Jay Hsu, Joseph R. Calabrese, Gary Sachs

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15 **Treatment Service Utilization in a Comparativeness Effectiveness Study of Bipolar Disorder**
Emily E. Bernstein, Massachusetts General Hospital
Louisa Sylvia, Dan V. Iosifescu, Edward Friedman, Charles Bowden, Terence A. Ketter, Noreen A. Reilly-Harrington, Leah W. Shesler, Andrew Leon, Joseph R. Calabrese, Michael Ostacher, Dustin Rabideau, Michael E. Thase, Andrew A. Nierenberg

16 **Comparison of Characteristics of Patients who Continued Versus Discontinued Lithium After One Year of Treatment**
Rehan Malik, New York Medical College

17 **Impact of the Proposed DSM-V Diagnostic Criteria for Mixed Features in Bipolar Disorder on Treatment Using an Analysis of Aripiprazole Clinical Data**
Ross A. Baker, Otsuka Pharmaceutical Development & Commercialization, Inc.
Roger S. McIntyre, Maia Miguelez, Sabrina Vogel. Marler, Zia Rahman

18 **Long-term Safety and Tolerability of Open-label Cariprazine in Patients with Bipolar I Disorder**
Terence A. Ketter, Stanford University School of Medicine
Gary Sachs, Kaifeng Lu, István Laszlovszky, Krisztián Nagy, Anju Starace, Suresh Durgam

19 **Transcranial Magnetic Stimulation (TMS) for Treatment Resistant Bipolar Depression: A Naturalistic Case Series with Clinical Outcomes and Observations**
William S. Gilmer, Northwestern University
Kailee M. Lorenzen

20 **Translation, Linguistic Validation and Cultural Adaptation of Patient-, Caregiver- and Clinician-rated Scales in Multinational Clinical Trials**
Ana Ramirez, Inventiv Health Clinic
Rebecca M. Smith, Michelle Simon, Richa Gaur

21 **Inverse Localization and Quantification of Epileptiform Electrical Activity Recorded from Acute Traumatic Brain Injury Patients via Electroencephalography**
Andrei Irimia, University of California, Los Angeles

22 **Differential Efficacy of Adjunctive Quetiapine SR in Mixed States of Bipolar Disorder: Findings from a Randomized, Double-blind, Placebo-controlled Study**
Vivek Singh, Univ of Texas Health Science Center at San Antonio
Charles Bowden

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23 **Rater Performance on Certification Exercises for the ADI-R and ADOS in a Global Autism Spectrum Disorders Trial**
Chris A. Brady, InventivHealth
Sarah Podolin, Cristina Maneru, Jan Sedway, Kristi Bertzos, Christine Moore, Fiona K. Miller, Jennifer Endre Olson

24 **Severity Classification on the Hamilton Depression Rating Scale**
Mark Zimmerman, Brown University

25 **Clinical and Operational Aspects of the Columbia Suicide Severity Rating Scale (C-SSRS) and Sheehan Suicidality Tracking Scale (S-STS) in a Psychometric Evaluation Study**
Ahmad Hameed, Penn State Milton S. Hershey Medical Center and College of Medicine
Michael Mitchell, Eric A. Youngstrom, Roger E. Meyer, Venkatesh Basappa Krishnamurthy, Alan J. Gelenberg

26 **Use of a Community Sample to Explore External Validity in a Randomized Clinical Trial**
Carlos I. Alatorre, Eli Lilly and Company
Stephen Able, Virginia Haynes, Todd M. Durell

27 **What PANSS Items do Site Raters have the Most Trouble Rating?**
David G. Daniel, Bracket Global, LLC
Jean Dries

28 **Comparative Validation of the ISST-Plus, the S-STS, and the C-SSRS for Assessing Suicidal Thinking and Behavior**
David V. Sheehan, University of South Florida College of Medicine
Larry Alphs, Lian Mao, Qin Li, Roberta May, Emily A. Hammond, Cheryl McCullumsmith, Christopher R. Gray, Xiaohua Li, David Williamson

29 **A Prospective Trial of Customized Adherence Enhancement Plus Long-acting Injectable Antipsychotic Medication in Homeless or Recently Homeless Individuals with Schizophrenia or Schizoaffective Disorder**
Martha Sajatovic, Case Western Reserve University School of Medicine
Jennifer Levin, Luis F. Ramirez, David Hahn, Curtis Tatsuoka, Christopher Bialko, Kristin Cassidy, Edna Fuentes-Casiano, Tiffany D. Williams

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30 **Intensive Rater Training to Standardize Cognitive Assessment in a Multi-center Parkinson's Disease Trial**
Kari R. Nations, INC Research
Russell Tanenbaum, Claire Reinhold, Elizabeth Grubb, Linda Lintz, Azhar Choudhry

31 **Use of 'Dual' Ratings Criteria to Improve Subject Selection and Trial Outcomes**
Steven D. Targum, Massachusetts General Hospital, Department of Psychiatry
Pamela C. Wedel

32 **Methodological Challenges in a Two-site Randomized, Controlled Trial of Ketamine in Major Depression**
Kaylene Rojas, Baylor College of Medicine
Caitlin Ridgewell, Dan V. Iosifescu, Sanjay J. Mathew

33 **A Randomized, Placebo-controlled Trial of the Dopamine-ß-Hydroxylase (DBH) Inhibitor, Nepicastat, for the Treatment of PTSD in OIF/OEF Veterans: Preliminary Results**
Michelle M. Hilgeman, Tuscaloosa VA Medical Center
Lori L. Davis, Dewleen G. Baker, Patricia Pilkinton, Alfred A. Bartolucci, Mark Hamner, David P. Graham, Thomas Kosten

34 **Central Review of the ADAS-Cog: Identification of Rater-errors in Alzheimer's Disease Clinical Trials**
Kristi Bertzos, InVentiv Health Clinical
Magdalena Perez-Villanueva, Chris Brady, Julie L. Marsh

35 **Visual Attentional Biases for Dysphoric and Social Stimuli in AD Patients with Apathy and Depression**
Sarah A. Chau, Sunnybrook Health Sciences Centre
Moshe Eizenman, Krista Lanctot

36 **Take the Rater Challenge: Live Calibration on Psychomotor Symptoms**
Janet B.W. Williams, MedAvante
Lisa Kestler, Sharron E. Dawes, Danielle Popp, Krzysztof Smigorski, Lori M. Price, Michael J. Detke

✱ 37 **Pharmacology, Safety and Efficacy in Major Depressive Disorder of CX-157, a Reversible Inhibitor of Monoamine Oxidase A**
Daniel J. Burch, PPDi

✱ 38 **Treatment of Depression with OnabotulinumtoxinA: A Randomized, Double-blind, Placebo Controlled Trial**
Eric Finzi, Chevy Chase Cosmetic Center
Norman Rosenthal

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39 **Adjunctive L-Methylfolate 15 mg: Effect in Depressed Patients when Assessed by Levels of Biomarker and Genotype**
George I. Papakostas, Massachusetts General Hospital and Harvard Medical School
Richard C. Shelton, Teodoro Bottiglieri, Joshua Roffman, Stephen M. Stahl, Maurizio Fava, John Zajecka

40 **Delaying the Progression of Driving Impairment in Individuals with Mild Alzheimer's Disease**
Peter J. Holland, Charles E. Schmidt College of Medicine, Florida Atlantic University
Ruth M. Tappen, Lori J. Fisher, Anna Lisa Curtis

41 **A Single-dose Pharmacokinetic Study of Levomilnacipran SR in Subjects with Normal and Impaired Hepatic Function**
Laishun Chen, Forest Research Institute
Ramesh Boinpally, Antonia Periclou, Parviz Ghahramani, William M. Greenberg

✱ 42 **Gepirone-ER: Effective Treatment of Major Depression and Accompanying Sexual Dysfunction**
Louis F. Fabre, Fabre Kramer Pharmaceuticals, Inc.
Louis C. Smith

43 **Early Improvement and Sustained Response with Vilazodone in Patients with Major Depressive Disorder – Pooled Analyses from 2 Phase III Trials**
Maju Mathews, Forest Research Institute
Rakesh Jain, Dalei Chen, John Edwards

✱ 44 **A Randomized, Double-blind, Study of Vortioxetine versus Agomelatine in Adults with Major Depressive Disorder (MDD) Switched after Inadequate Response to SSRI or SNRI Treatment**
Marianne Dragheim, H. Lundbeck A/S
Rebecca Z. Nielsen

45 **Clinically Meaningful Response in Severe Major Depressive Disorder: Analysis of Correlation between CGI-I and MADRS from Phase II Study with AZD6765**
Michael C. Quirk, AstraZeneca Neuroscience, Research & Development | Innovative Medicines
Hong-Lin Su, Sanjeev Pathak, Timothy M. Piser

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46 **A Phase II Randomized, Double-blind, Placebo-controlled Trial of GLYX-13 for the Rapid Treatment of Major Depressive Disorder Using Central Ratings**
Michael J. Detke, MedAvante, Inc.; Indiana University School of Medicine
Danielle Popp, Ronald M. Burch, Janet B.W. Williams, Lori M. Price

47 **A Pragmatic Megatrial to Optimise the First- and Second-line Treatments for Patients with Major Depression: SUN(^_^)D Study Protocol and Initial Results**
Mitsuhiko Yamada, National Center of Neurology and Psychiatry
Tatsuo Akechi, Shinji Shimodera, Norio Watanabe, Masatoshi Inagaki, Naohiro Yonemoto, Toshi A. Furukawa

48 **Anti-anhedonic Effects of Ketamine and Its Neural Correlates in Bipolar Depression**
Niall Lally, Experimental Therapeutics and Pathophysiology Branch, National Institute of Mental Health, National Institutes of Health
Allison Nugent, David Luckenbaugh, Carlos Zarate

49 **Safety and Tolerability of Levomilnacipran SR in Major Depressive Disorder: Analysis of 5 Short-term, Double-blind, Placebo-controlled Trials**
Michael E. Thase, Perelman School of Medicine of the University of Pennsylvania; Philadelphia VA Medical Center
William M. Greenberg, Anjana Bose, Carl Gommoll, Changzheng Chen

50 **Desvenlafaxine is Neither a Perpetrator nor a Victim of Drug-drug Interactions Mediated by Cytochrome P450 2D6 or 3A4**
Sheldon H. Preskorn, Psychiatry, Kansas University School of Medicine, Wichita
Matthew Macaluso, Alice Nichols

51 **Qualitative Development and Cognitive Evaluation of the Symptoms of Major Depressive Disorder (S-MDD) Scale: A New Patient-reported Outcome (PRO) Measure Developed Using a Consortium-based Approach**
Steven I. Blum, Forest Research Institute
Kelly P. McCarrier, Lucy Abraham, Elizabeth N. Bush, Donald M. Bushnell, Linda L. Carpenter, Stephen Joel Coons, Christy Houle, Mona L. Martin, Maju Mathews, Madhukar Trivedi, Michael E. Thase

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52 **A Pooled Analyses of Data from 5 Levomilnacipran SR Double-blind, Placebo-controlled Trials: Efficacy in Major Depressive Disorder across Patient Subgroups**
Stuart A. Montgomery, Imperial College School of Medicine, University of London
Anjana Bose, Carl Gommoll, Changzheng Chen

 53 **Effect of Serotonergic Antidepressant on Endogenous Brain Serotonin in Major Depressive Disorder and Treatment Response**
Sudhakar Selvaraj, Imperial College London

54 **Distinct White Matter Alterations are Associated with Major Depression and Anhedonia Severity in Adolescents**
Vilma Gabbay, Mount Sinai School of Medicine
Amy R. Johnson, Ana Vallejo, Guoxin Kang

✱ 55 **Dose Response Analysis of Lisdexamfetamine Dimesylate for Treatment of Binge Eating Disorder**
Susan McElroy, Lindner Center of HOPE, The University of Cincinnati College of Medicine
James Reynolds, Joseph Gao, Maria Gasior

56 **Efficacy of Lisdexamfetamine in a Rat Model of Binge-eating Disorder**
Thomas Babcock, Shire Development, LLC
Peter Hutson, Steven Vickers, David J. Heal, David Hackett

57 **Web-based Curriculums for Teaching Psychopharmacology: Revision of the Resident and the Medical Student Curriculums**
Ira Glick, Stanford University School of Medicine

 58 **Elevation of Monoamine Oxidase A in Borderline Personality Disorder with High Suicidal Ideation: An [11C] Harmine Positron Emission Tomography Study**
Nathan Kolla, University of Toronto
Paul Links, Jeffrey Meyer

59 **Patient Functioning and Medication Satisfaction with Paliperidone Palmitate Following Treatment of Acute Exacerbation of Schizoaffective Disorder**
Dong Jing Fu, Janssen Scientific Affairs, LLC
Ibrahim Turkoz, R. Bruce Simonson, David Walling, Nina Schooler, Jean-Pierre Lindenmayer, Jessica Panish, Larry Alphs

60 **Pre-Diabetic Patients in a Diet/Exercise Program: The Use of Metformin with Regards to Trends in Psychiatric Illness**
Deanna C. Fernandes, University of Florida

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61 **External Trigeminal Nerve Stimulation: Adjunctive Neuromodulation for Comorbid Post-traumatic Stress Disorder and Major Depression**
Ian A. Cook, UCLA Depression Research and Clinic Program, Semel Institute for Neuroscience & Human Behavior at UCLA
Christopher M. DeGiorgio, Andrew F. Leuchter

62 **Implementation of an Innovative Tool for Tracking Changes in Prescribed Medication in Comparative Effectiveness Research: Lessons Learned**
Leah W. Shesler, Massachusetts General Hospital
Noreen A. Reilly-Harrington, Louisa Sylvia, Stephanie Salcedo, Dustin Rabideau, Andrew Leon, Dan V. Iosifescu, Michael Ostacher, Thilo Deckersbach, Andrew A. Nierenberg

63 **The Role of the Pharmacist Researcher on an Interdisciplinary Correctional Mental Health Research Team**
Megan Ehret, University of Connecticut

64 **Failed Trials and Protocol Design: Is there a Relationship?**
Robert B. Molpus, Clinical Neuroscience Solutions, Inc.
Patricia Brown, John Mark Joyce, Linda S. Harper, Terrie Wood

65 **Characteristics of Duplicate Subjects in a Clinical Trial Subject Registry**
Thomas M. Shiovitz, California Neuroscience Research
N. Bailey Manlosa, Lilit Gevorgyan, Charles S. Wilcox, Marlene Zarrow

66 **Effects of Levomilnacipran SR on Measures of Attention in a Phase 3 Trial of Major Depressive Disorder (MDD)**
Keith Wesnes, Bracket
Anjana Bose, Carl Gommoll, Changzheng Chen

67 **The Application of Cognitive Neuroscience to Clinical Research III: Evidence from a Cognitive Task of Compromised Neurogenesis in Schizophrenics**
Keith Wesnes, Bracket

68 **Effects of Aripiprazole Once-monthly vs. Placebo on Domains of Personal and Social Performance in Younger and Older Patients with Schizophrenia**
Anna Eramo, Lundbeck Pharmaceuticals Services
Ross A. Baker, William Carson, Pamela Perry, Raymond Sanchez, Joan Zhao, Robert D. McQuade, John M. Kane, W. Wolfgang Fleischhacker

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69 **Identification of the Causal Relationships between Neurocognition, Psychopathology, and Functional Outcomes in Schizophrenia**
Jean-Pierre Lindenmayer, Department of Psychiatry NYU
Anzalee Khan, Timothy Michaels

70 **Long-acting Injectable vs. Daily Oral Antipsychotic Treatment Trials in Schizophrenia: Do Pragmatic vs. Explanatory Study Designs Matter?**
Cynthia Bossie, Janssen Medical Affairs
Larry Alphs

71 **Evaluation of Treatment Patterns of Medicaid Insured Patients with Schizophrenia Who Initiate Treatment with Extended Release Paliperidone Palmitate**
Donna Zubek, Otsuka Pharmaceutical America, Inc.
Siddhesh Kamat, Anna Eramo, Stephen Boccuzzi, Steve Offord, Jay Lin, Craig Karson, Benjamin Gutierrez

 72 **Memantine Effects on Matrics Consensus Cognitive Battery Performance in Healthy Adults and Schizophrenia Patients**
Hsun-Hua Chou, University of California, San Diego
Savita G. Bhakta, Jo. A. Talledo, Sarah Lamb, Bryan Balvaneda, Gregory Light, Elizabeth W. Twamley, Neal Swerdlow

✱ 73 **EVP-6124, an Alpha-7 Nicotinic Partial Agonist, Produces Positive Effects on Cognition, and Clinical Function in Patients with Chronic Schizophrenia on Stable Antipsychotic Therapy**
Ilise Lombardo, EnVivo Pharmaceuticals

74 **Comparison of Resting State Dynamics in Healthy, Schizophrenia and Bipolar Disease**
Jessica Turner, Mind Research Network (MRN)

75 **Hospitalization Rates in Patients Previously Treated with Oral Antipsychotics vs. Prospectively Treated with Aripiprazole Once-monthly: A Mirror Study**
John Kane, The Zucker Hillside Hospital
Joan Zhao, Ross A. Baker, Anna Eramo, Robert D. McQuade, Timothy S. Peters-Strickland

76 **Efficacy of Cariprazine on PANSS Items and Marder Factors: Post Hoc Analysis of a Phase III, Double-blind, Placebo-controlled Trial in Schizophrenia**
John Kane, The Zucker Hillside Hospital
Leslie Citrome, Robert E. Litman, Stephen Zukin, Oksana Mokliatchouk, Krisztián Nagy, István Laszlovszky, Suresh Durgam

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77 **Broad Therapeutic Potential for ITI-007 and IC200131**
Kimberly Vanover, Intra-Cellular Therapies, Inc.

✱ 78 **Onset of Efficacy in Schizophrenia Symptom Domains with Long-acting Injectable Paliperidone Palmitate vs Oral Risperidone**
Larry Alphs, Janssen Scientific Affairs, LLC
Dong Jing Fu, Jennifer K. Sliwa, Yi-Wen Ma, H. Lynn Starr, Cynthia Bossie

✱ 79 **REFRESH: A Phase2 RP 5063 Efficacy and Safety in Schizophrenia and Schizoaffective Disorder**
Marc Cantillon, Reviva Pharmaceuticals
Mike Li, Sarath Kanekal, Robert M.J. Ings, Grace Tung, Laxminarayan Bhat

80 **Randomized Trial of Antipsychotic Augmentation with Gluten-free Diet in Anti-gliadin Antibody-positive Schizophrenia Patients: Proof-of-Concept**
Olaoluwa Okusaga, University of Texas Medical School in Houston

81 **Long-term Impact of Daytime Sleepiness on Cognitive Outcome in a 6-Month, Double-blind Study of Lurasidone and Quetiapine XR in Patients with Schizophrenia**
Philip D. Harvey, University of Miami Miller School of Medicine
Antony Loebel, Josephine Cucchiaro, Andrei Pikalov, Cynthia Siu, Henry Nasrallah

82 **An Analysis of Patient and Prescriber Perspectives on Long-acting Antipsychotics for Schizophrenia Based on In-office Discussions**
Rimal B. Bera, University of California
Steven G. Potkin, Donna Zubek, Gina Lau

83 **AZD8529, A Positive Allosteric Modulator at the mGluR2 Receptor, does Not Improve Symptoms in Schizophrenia: A Proof of Principle Study**
Robert E. Litman, CBH Health, LLC
Mark A. Smith, Jim Doherty, Alan Cross, Shane Raines, Stephen Zukin

✱ 84 **Early Development of ALKS 3831: A Novel Drug Candidate for the Treatment of Schizophrenia**
Bernard L. Silverman, Alkermes, Inc.
John M. Kane, Mark S. Todtenkopf, Dan Deaver, Elliot Ehrich

85 **Genome-wide Assessment of DNA Methylation in Post-mortem Human Hippocampus in Psychotic Disorders**
William B. Ruzicka, McLean Hospital, Harvard Medical School

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✱ 86 **Suvorexant: Orexin Receptor Antagonism and Insomnia**
David Michelson, Merck Research Laboratories

87 **The National Pregnancy Registry for Atypical Antipsychotics: Effects of Fetal Exposure on Risk for Congenital Malformations and Maternal and Newborn Outcomes**
Lee S. Cohen, Massachusetts General Hospital, Harvard Medical School
Adele C. Viguera, Sarah E. Masnik, Molly Kwiatkowski, Shannon Murphy, Elizabeth Lemon, Sonia Hernandez-Diaz

88 **Double Blind Placebo Controlled Pilot Study of Adjunctive Quetiapine SR in the Treatment of Premenstrual Dysphoric Disorder (PMDD)**
Samantha Meltzer-Brody, UNC Center for Women's Mood Disorders
Brenda Pearson, Robert M. Hamer, Susan Girdler

89 **Initial 2-Week Outcomes Following 2 Methods of Switching to Iloperidone From Risperidone, Olanzapine, or Aripiprazole in Patients with Schizophrenia**
Leslie Citrome, New York Medical College
Ira Glick, Peter J. Weiden, Adam Winseck, Farid Kianifard, Xiangyi Meng

90 **Efficacy of Subcutaneous Bremelanotide Self-administered at Home by Premenopausal Women with Female Sexual Dysfunction: A Placebo-controlled Dose-ranging Study**
Anita Clayton, University of Virginia
Robert Jordan, Jeffrey D. Edelson, Sally Greenberg, Leonard R. DeRogatis, Sheryl Kingsberg, Raymond C. Rosen, Stanley E. Althof, David J. Portman, Michael Krychman

91 **Prefrontal Cortical-Striatal Hippocampal Dysfunction measured on the Radial-Arm Maze is predictive of Cocaine Sensitization in rats with Neonatal Ventral Hippocampal Lesions**
Kalyan N. Rao, Indiana University School of Medicine
Alena Sentir, Alan Breier, Andrew Chambers

92 **Hypomethylation in Female Bipolar Patients with Metabolic Syndrome Taking Olanzapine and Clozapine**
Kyle J. Burghardt, University of Michigan College of Pharmacy
Vicki L. Ellingrod

93 **The Impact of Continuous Versus Intermittent High Frequency Stimulation of the Nucleus Accumbens on Ethanol Preference and Circadian Locomotor Activity in Alcohol Preferring Rats**
Osama Abulseoud, Mayo Clinic

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Thursday, May 30, 2013

Poster Session II
Regency Ballroom

1 **Developing Treatments for Schizophrenia and Co-occurring Substance Use Disorder: Targeting Brain Reward Circuitry**
Alan Ivan Green, Geisel School of Medicine at Dartmouth
Adina S. Fischer, Robert Roth, Susan Whitfield-Gabrieli, Danielle Gulick, Mary Brunette

2 **Mindfulness Meditation for Alcohol Relapse Prevention: Findings from a Randomized Controlled Trial**
Aleksandra Zgierska, University of Wisconsin, School of Medicine & Public Health, Department of Family Medicine

3 **Restoring Glutamate Homeostasis to Prevent Relapse in a Rodent Model**
Lori A. Knackstedt, University of Florida, Psychology Dept.

4 **The Serotonin-preferring Triple Reuptake Inhibitor Amitifadine Decreases Alcohol Intake and Impulsivity in Rodents**
Randall D. Marshall, Euthymics Bioscience, Inc.
Pierre V. Tran, Mark Egli, Howard C. Becker, Kelle M. Franklin, Nicholas J. Grahame, Richard L. L. Bell, Marcelo F. Lopez, Franklin P. Bymaster

5 **A Human Alcohol Self-administration Paradigm to Model Individual Differences in Impaired Control over Alcohol Use: Initial and Secondary Findings**
Robert F. Leeman, Yale University School of Medicine
William Corbin, Christine Nogueira, Suchitra Krishan-Sarin, Marc Potenza, Stephanie O'Malley

6 **Predictors of Drinking Outcome during Follow-up in COMBINE**
Stephanie O'Malley, Yale University School of Medicine
Ralitza Gueorguieva, Ran Wu, Lisa M. Fucito

7 **Advanced Brain Imaging, Physiology, and Genetics for Clinical Trials in Neurolgical and Psychiatric Disease**
Jeffrey D. Lewine, The Mind Research Network

8 **A Proof of Concept Study of Tolcapone for Pathological Gambling: Relationships with COMT Genotype and Brain Activation**
Jon Grant, University of Chicago
Brian L. Odlaug, Samuel Chamberlain, Adam Hampshire, Liana Schreiber, Suck Won Kim

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9 **Gene Expression Profile in a Preclinical Model of Antidepressant Resistance: Towards a Biomarker Signature**
Susannah J. Tye, Mayo Clinic
Adam J. Walker, Nicky Konstantopoulos

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