Identifying Common Targets Across Brain Diseases – Implications for Treatment Development and Delivery

May 29 – June 1, 2012
Arizona Biltmore Resort & Spa
Phoenix, Arizona

Steering Committee Chairs: William Z. Potter, M.D., Ph.D. and Nina R. Schooler, Ph.D.
Program Committee Chairs: David J. Kupfer, M.D. and Carlos A. Zarate, M.D.

www.NCDEUMeeting.org
Welcome to the 52nd Meeting of NCDEU – the New NCDEU

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 52nd 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, 52 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
On behalf of the NCDEU Steering and Program Committees, we are delighted to welcome you to the 52nd NCDEU meeting.

From its beginnings 1959 as the Early Clinical Drug Evaluation Units (ECDEU) meeting and subsequently under the name New Clinical Drug Evaluation Unit (NCDEU), the meeting has expanded and added new features to become the key meeting in this domain, bringing together academic investigators, industry scientists, U.S. and international regulators from FDA and EMA, National Institutes of Health components including NIMH, NIDA, NIAAA and many other professionals working in drug development and clinical trials. It provides the opportunity to present and hear new findings many of which can impact the care of patients now and with over 1,200 attendees, it is the place for networking, planning and the training of young investigators.

2011, the first year for “the New NCDEU,” was a success and in 2012 we continue to build on those successes with program innovations while preserving the rich history of this meeting. Below is a recap of some of the features of “the New NCDEU.”

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

- Program Innovations
  - Asterisks in the program identify sessions that will be of particular interest to clinicians because they highlight treatment advances of immediate clinical relevance.
  - The meeting starts on Tuesday, May 29th with Panel Presentations, New Research Reports and the popular new feature, Pharma Pipeline Session.
  - The Wednesday Plenary Session will feature leaders of NIMH, NIDA and NIAAA to update attendees on the latest news from the NIH institutes.
  - A keynote speaker, Dr. Chris Austin, from the recently formed NIH National Center for Advancing Translational Sciences (NCATS) will provide an opportunity to learn about the activities of this new and exciting NIH Center.
  - The Thursday Plenary Session will feature the leadership of the FDA and EMA focusing on the new FDA and EMA initiatives in depression and schizophrenia.
  - NIMH, NIDA and NIAAA have organized panel sessions.
  - Friday will feature a wrap-up Q&A session with FDA and EMA representatives. Questions can be submitted prior to the meeting or during the meeting.

- Program Continuities
  - The New Investigator Program includes a workshop for the 20 New Investigators and informal breakfast sessions.
  - NCDEU Workshops – three hour intensive and interactive sessions focused on problems and solutions on Wednesday & Thursday afternoon.
  - NCDEU Reception from 6:30 pm – 8:00 pm on Wednesday the 30th.
  - The NCDEU Fun Run/Walk at 7:15 am on Wednesday the 30th.

We hope that you will value the innovations to the meeting and the well-established traditions. NCDEU at 52 is truly a work in progress and we welcome your suggestions. Seek out any of us during the meeting, or provide your views by completing the evaluation form.

Best Regards,

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

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

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

Carlos Zarate, M.D.  
Program Committee Co-Chair
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**DISCLOSURES FOR ALL NCDEU PRESENTERS**
**CAN BE VIEWED AT WWW.NCDEUMEETING.ORG**
Institute Directors’ Plenary
Wednesday, May 30th from 8:30 am – 9:30 am

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 Wang, M.D., Dr. P.H.
National Institute of Mental Health
Philip S. Wang, M.D., Dr.P.H., completed an undergraduate degree in biochemistry at Harvard University, as well as medical school, psychiatry residency and chief residency, and a masters and doctoral degrees in epidemiology. Presently, he serves as the Deputy Director of the National Institute of Mental Health (NIMH), where he assists the Director in overseeing 1300 staff and $1.4 billion spent annually on basic and clinical research to understand and treat mental illnesses, paving the way for prevention, recovery and cure. In addition to serving as Deputy Director, Dr. Wang currently serves as the Acting Scientific Director of the NIMH Division of Intramural Research Programs (DIRP).

Prior to joining NIMH, Dr. Wang served on the faculty at Harvard Medical School. An author of over 170 scientific publications in journals such as New England Journal of Medicine, Journal of the American Medical Association, and Lancet, Dr. Wang has also held international and national advisory roles. He has served on the FDA Psychopharmacologic Drugs Advisory Committee, Medical Devices Advisory Committee, and the FDA Endocrinologic and Metabolic Drugs Advisory Committee. He was also Chair of the World Health Organization World Mental Health Survey Initiative’s Services Research Work Group. Currently, he is a member of the American Psychiatric Association’s Diagnostic and Statistical Manual, Fifth Revision (DSM-V) Task Force.

Kenneth Warren, Ph.D.
National Institute on Alcohol Abuse and Alcoholism
Kenneth R. Warren, Ph.D. is the Acting Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA). An internationally recognized expert on alcohol and pregnancy, Dr. Warren has received numerous honors and awards for his work in this area including for the development of the first Surgeon General’s advisory on Alcohol and Pregnancy. Dr. Warren received his doctorate in biochemistry in 1970 and has served in several senior research positions at the NIAAA since 1976.
Keynote Session
Wednesday, May 30th, 2012 from 9:30 am – 10:30 am
A New NIH Focus on Research to Facilitate Clinical Research

Chris Austin, M.D.
National Center for Advancing Translational Sciences

Christopher Austin is Director of the Division of Preclinical Innovation (DPI) at National Center for Advancing Translational Sciences (NCATS) at the U.S. National Institutes of Health (NIH), and Scientific Director of the DPI’s NIH Center for Translational Therapeutics (NCTT). The DPI’s programs span the translational spectrum, including the Genome-wide RNAi program, the NIH Chemical Genomics Center (NCGC), the Therapeutics for Rare and Neglected Diseases (TRND) program, and the Bridging Intervventional Development Gaps (BrIDGs, formerly NIH-RAID) program. The NCGC is an ultrahigh-throughput screening, informatics, and chemistry center that profiles small molecule libraries for biological activity using its qHTS technology, and develops novel compounds as probes of biology and starting points for the development of new. The TRND program develops small molecules and biologics from lead to clinical proof-of-concept for rare and neglected diseases. The NCTT also develops new technologies and paradigms to increase the efficiency and genome-wide reach of drug development technologies, and is a partner with NTP, EPA, and FDA in the Toxicology in the 21st Century (Tox21) Program. Before joining NIH in 2002, Dr. Austin directed research programs genomics-based target discovery, pharmacogenomics, and neuropsychiatric drug development at Merck, with a particular focus on schizophrenia. Dr. Austin received his A.B. in biology *summa cum laude* from Princeton, and his M.D. from Harvard Medical School. He completed clinical training in internal medicine and neurology at the Massachusetts General Hospital, and a postdoctoral fellowship in genetics at Harvard.
Regulatory Plenary
Thursday, May 31st from 8:30 am – 10:00 am

Regulatory Plenary: New FDA and EMA Initiatives in Depression and Schizophrenia

Thomas Laughren, M.D.
Food and Drug Administration

Dr. Laughren is currently 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 oversees 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 from FDA for his regulatory accomplishments.

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).
Silvana Borges, M.D.
Food and Drug Administration
Dr. Borges received her Medical Degree from the State University School of Medicine in Uruguay. She completed her medical residency and got board certified in Child & Adolescent Psychiatry. She joined the Department of Pharmacology and Therapeutics in the State University School of Medicine as an Assistant Professor and then became an Assistant Professor and Founding Member of the “National Center for Drug Safety” in Uruguay. She was a Scholar at the Catalan Institute of Pharmacology (Barcelona, Spain) focusing her training in drug safety and pharmacoepidemiology. She received the Merck Foundation International Fellowship in Clinical Pharmacology Award and completed a fellowship in clinical pharmacology and pharmacogenetics at Indiana University, being mentored by Dr. David Flockhart. She was the recipient of the American Society for Clinical Pharmacology and Therapeutics Presidential Trainee Award for her work on the role of CYP2D6 genetic polymorphism on tamoxifen metabolism and its interaction with antidepressants. She is currently a Medical Officer with the Division of Psychiatry Products, Office of New Drugs, U.S. Food and Drug Administration.

Phillip Kronstein, M.D.
Food & 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 is currently 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.
Featured Speakers

Regulatory Wrap-Up
Friday, June 1st from 10:15 am – 11:45 am

Regulatory Wrap-Up

Thomas Laughren, M.D., Food and Drug Administration
See previous bio

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

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

Manuel Haas, PharmD, MSc
European Medical Agency
Manuel Haas is Head of the Central Nervous System and Ophthalmology section in the European Medicines Agency’s Safety and Efficacy Sector (Human Medicines Development and Evaluation Unit). The “CNS” Section is responsible for the management of pre- and post-authorisation activities of centralised applications/marketing authorisations, and particularly the Safety and Efficacy part, related to medicinal products in the neurology, psychiatry and ophthalmology therapeutic areas. He is a pharmacist by training, and holds a post-graduate diploma in hospital pharmacy as well as a Masters in Drug Development and Registration. He worked for several years in hospitals in France and the UK before joining the pharmaceutical industry in regulatory affairs in 2003. Following this role he started with the European Medicines Agency in 2004 as Scientific Administrator. He has been in his current role since September 2009.
Acknowledgements

Steering Committee Chairs

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Nina R. Schooler, Ph.D.

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David J. Kupfer, M.D.
Carlos A. Zarate, M.D.

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MedAvante

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

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

★ New Investigator Alumnae  *Representing ASCP CME Committee
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 Frank Lloyd Wright 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 South Foyer of the Frank Lloyd Wright Ballroom.

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 the McDowell Room.

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

Americans with Disabilities Act - It is the policy of ASCP not to discriminate against any person on the basis of disabilities. If 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 for Biltmore restaurants, spa, golf and tennis are available to all NCDEU attendees and families. The Biltmore is offering all NCDEU guests a 15% discount on golf, tennis court fees and lessons. You must identify yourself as an NCDEU guest to obtain the discount. Advance reservations are recommended.

Spa: NCDEU registrants and their families will receive a $15.00 discount per person per day off all spa services of fifty (50) minutes or more. Advance reservations are recommended. Be sure to identify yourself as an NCDEU guest.

Restaurant: NCDEU registered attendees will receive a 20% discount at all Biltmore restaurants during the conference.
Continuing Education Credits

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

Continuing Education Credits are available for physicians, psychologists 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 Frank Lloyd Wright Ballroom South Foyer or after the conference at www.ncdeumeeting.org. Surveys for continuing education credit must be submitted no later than July 2, 2012. There is a $40.00 administrative fee for CME/CE applications. It is the policy of the ASCP to require disclosure of financial relationships from individuals in a position to control the content of a CME activity; to identify and resolve conflicts of interest related to those relationships; and to make disclosure information available to the audience prior to the CME activity. Presenters are required to disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentations.

Physicians

The American Society for Clinical Psychopharmacology (ASCP) designates this live meeting for a maximum of 23.5 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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 21.5 CE Credits. Full attendance to each session or workshop is required. Partial credit will not be awarded.

Social Workers

USF Health is an approved provider (BAP#433 – Exp. 3/31/13) of continuing education credits for clinical social work, marriage and family therapy, and mental health counseling. This program has been reviewed and approved for up to 25.75, 50-minute contact hours.

All participants who request continuing education credits by July 2, 2012, should expect to receive their statement of credits via email late in August.
The Meeting Evaluation Survey will be available at www.ncdeumeeting.org. We encourage all registrants to complete the evaluation. Attendees requesting CME or CE credits must complete the survey in order to obtain credits. Your candid input on the 2012 meeting is appreciated as we strive to improve the meeting each year.

NCDEU Meeting Support – The ASCP appreciates the generous support of the Eli Lilly and Company to the New Investigator Program.

### AT-A-GLANCE

**Monday, May 28th**

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>8:30 am – 4:30 pm</td>
<td>New Investigator Workshop (Invitation Only)</td>
<td>Aztec</td>
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<tr>
<td>12:00 pm – 5:00 pm</td>
<td>Registration Open</td>
<td>Frank Lloyd Wright Ballroom Foyer</td>
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<tr>
<td>4:00 pm</td>
<td>ASCP Board Meeting</td>
<td>Kaibab</td>
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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 29. This year’s 20 New Investigator awardees are indicated with a ribbon in the poster section of this program.

**Faculty**

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The Zucker Hillside Hospital

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

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

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

Wilson Compton, M.D.  
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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
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Daniel Blumberger, M.D., M.S.  
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Crystal Clark, M.D.  
VA Pittsburgh Healthcare System

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Michelle Hilgeman, B.S., Ph.D.  
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Felipe Jain, M.D.  
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Masoud Kamali, M.D.  
University of Michigan Health Systems

Kari Nations, Ph.D.  
University of Texas

Rakesh Karmacharya, M.D., Ph.D.  
Massachusetts General Hospital

Anzalee Khan, Ph.D.  
Nathan S. Kline Institute for Psychiatric Research

Douglas Kondo, M.D.  
University of Utah Brain Institute

Lorenzo Leggio, M.D., Ph.D., M.S.  
Brown University

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Colin Sauder, M.S.  
Stony Brook University

Erika Saunders, M.D.  
Penn State College of Medicine

Simone Vigod, M.D., M.S.  
Women’s College Hospital and University of Toronto

*Andrew Leon Memorial Travel Awardee
Tuesday, May 29th

7:30 am – 8:30 am  New Investigator Awardee Roundtable
(Invitation Only)
Aztec

7:30 am – 9:30 am  Continental Breakfast
Frank Lloyd Wright Ballroom Foyer

8:30 am – 9:00 am  Conference Opening & Andrew Leon Memorial
Frank Lloyd Wright Salon E-F

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

<table>
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<tr>
<th>NIDA Panel - Common Targets for the Treatment of Substance Use Disorders and Co-occurring Psychiatric Disorders</th>
<th>NIMH Panel - Research Domain Criteria (RDoC): Implications for Randomized Clinical Trials</th>
<th>*The Clinical Implications of Chronic Hyponatremia in Mental Health and Aging: New Findings</th>
<th>New Opportunities and Strategies for NIMH Funding</th>
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<tr>
<td>Location: Frank Lloyd Wright Salon A-B</td>
<td>Location: Frank Lloyd Wright Salon C-D</td>
<td>Location: Frank Lloyd Wright Salon G-H</td>
<td>Location: Frank Lloyd Wright Salon I-J</td>
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10:30 am – 10:45 am  Coffee Break
Frank Lloyd Wright Ballroom Foyer

*of special interest to clinicians
10:45 am – 11:45 am  **Concurrent Individual Research Reports**

<table>
<thead>
<tr>
<th>Trial Design and Methodology</th>
<th>*New Treatments in Depression &amp; Anxiety</th>
<th>Special Issues in Patient Grouping: Biomarkers, Medical Comorbidity and Attitudes</th>
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<td>Location: Frank Lloyd Wright Salon C-D</td>
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</table>

11:45 am – 1:00 pm  **Lunch on own**

1:00 pm – 3:00 pm  **Pharmaceutical Pipeline Session**  
Frank Lloyd Wright Salon E-F

3:00 pm – 3:15 pm  **Coffee Break**  
Frank Lloyd Wright Ballroom Foyer

3:15 pm – 4:45 pm  **Concurrent Panel Sessions**

<table>
<thead>
<tr>
<th><strong>NIDA &amp; NIAAA Panel - Neuroimmune Targets for Treatment of Substance and Alcohol Use Disorders</strong></th>
<th><em>Rapidly-Acting Antidepressant Therapies: The NIMH-Sponsored RAPID Network</em></th>
<th><em>Emerging Clinical Evidence on Oxytocin in Schizophrenia</em></th>
<th>Identifying Common Targets in Treating Impulse Control Disorders</th>
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<td>Location: Frank Lloyd Wright Salon G-H</td>
<td>Location: Frank Lloyd Wright Salon I-J</td>
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</table>

6:00 pm – 7:30 pm  **New Investigator Award Ceremony & Reception (Invitation Only)**  
Aztec

*of special interest to clinicians*
7:30 am – 8:30 am  New Investigator Awardee Roundtable  
*(Invitation Only)*
Aztec

7:30 am – 9:30 am  Continental Breakfast  
*Frank Lloyd Wright Ballroom Foyer*

8:30 am – 9:00 am  Conference Opening & Andrew Leon Memorial  
*Frank Lloyd Wright Salon E-F*

**Panel Sessions**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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</table>
| 9:00 am – 10:30 am | NIDA Panel - Common Targets for the Treatment of Substance Use Disorders and Co-occurring Psychiatric Disorders  
*Frank Lloyd Wright Salon A-B* |

**Chairs:**  David McCann, Ph.D., National Institute on Drug Abuse  
Wilson M. Compton, M.D., M.P.E., National Institute on Drug Abuse

9:00 am – 9:20 am  Substance Use Disorders and Co-occurring Psychiatric Disorders: Prevalence and Current Treatment Approaches  
Wilson M. Compton, M.D., M.P.E., National Institute on Drug Abuse

9:20 am – 9:40 am  Bupropion: Beyond Smoking Cessation and Depression  
David McCann, Ph.D., National Institute on Drug Abuse

9:40 am – 10:00 am  NOP Receptors as Targets for the Treatment of Drug Addiction and Co-occurring Psychiatric Disorders  
Lawrence Toll, Ph.D., Torrey Pines Institute for Molecular Studies

10:00 am – 10:20 am  Preclinical Pharmacological Characterization of Structurally Unique, Potent, Kappa Opioid Receptor Antagonists in Animal Models of Alcohol Dependence and Mood Disorders  
Linda Rorick-Kehn, Ph.D., Lilly Research Laboratories

10:20 am – 10:30 am  General Discussion  
Phil Skolnick, Ph.D., D. Sc., National Institute on Drug Abuse
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker(s)</th>
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</table>
| 9:00 am – 10:30 am | **NIMH Panel - Research Domain Criteria (RDoC): Implications for Randomized Clinical Trials**  
*Frank Lloyd Wright Salon C-D* | **Chair:** Robert Heinssen, Ph.D., National Institute of Mental Health  
9:00 am – 9:25 am: **Introducing the NIMH Research Domain Criteria Project (RDoC)**  
Sarah Morris, Ph.D., National Institute of Mental Health  
9:25 am – 9:50 am: **Conceptualizing Clinical Trials within the RDoC Framework**  
Richard Keefe, Ph.D., Duke University  
9:50 am – 10:15 am: **FDA Perspective: Regulatory Considerations for RDoC-Inspired Trials**  
Robert Levin, M.D., Food and Drug Administration  
10:15 am – 10:30 am: **General Discussion**  
Robert Heinssen, Ph.D., National Institute of Mental Health |
| 9:00 am – 10:30 am | **The Clinical Implications of Chronic Hyponatremia in Mental Health and Aging: New Findings**  
*Frank Lloyd Wright Salon G-H* | **Chairs:** Richard C. Josiassen, Ph.D., Drexel University College of Medicine  
Joseph Verbalis, M.D., Georgetown University Medical Center  
9:00 am – 9:20 am: **Hyponatremia – An Old Disorder with New Findings**  
Joseph Verbalis, M.D., Georgetown University Medical Center  
9:20 am – 9:40 am: **Psychomotor Symptomatology of Hyponatremia**  
Arthur J. Siegel, M.D., McLean Hospital  
9:40 am – 10:00 am: **Fluid Balance Disorders in the Elderly**  
Myron Miller, M.D., Johns Hopkins Bayview Medical Center |
*of special interest to clinicians*
<table>
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<td>10:00 am – 10:20 am</td>
<td>Hyponatremia in Psychosis and Depression:&lt;br&gt;Treatment Guidelines and Future Directions&lt;br&gt;Richard C. Josiassen, Ph.D., Drexel University College of Medicine</td>
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<td>10:20 am – 10:30 am</td>
<td>General Discussion&lt;br&gt;Joseph Verbalis, M.D., Georgetown University Medical Center</td>
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<td>9:00 am – 10:30 am</td>
<td>New Opportunities and Strategies for NIMH Funding&lt;br&gt;&lt;em&gt;Frank Lloyd Wright Salon I-J&lt;/em&gt;</td>
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<td><strong>Chair:</strong> Christopher Sarampote, Ph.D., National Institute of Mental Health</td>
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<td>9:00 am – 9:15 am</td>
<td>Demystifying Review at NIMH&lt;br&gt;Aileen Schulte, Ph.D., National Institute of Mental Health</td>
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<tr>
<td>9:15 am – 9:30 am</td>
<td>Dimensional Approaches to Research Classification in Psychiatric Disorders (RDoC)&lt;br&gt;Michael Kozak, Ph.D., National Institute of Mental Health</td>
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<tr>
<td>9:30 am – 9:45 am</td>
<td>Innovative Pilot Studies of Novel Mechanism of Action Compounds for Treating Psychiatric Disorders&lt;br&gt;Christopher Sarampote, Ph.D., National Institute of Mental Health</td>
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<tr>
<td>9:45 am – 10:00 am</td>
<td>Late Breaking News from NIMH&lt;br&gt;Tracy Waldeck, Ph.D., National Institute of Mental Health</td>
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<td>10:00 am – 10:15 am</td>
<td>Catching and Shepherding Your Application&lt;br&gt;Jean G. Noronha, Ph.D., National Institute of Mental Health</td>
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<td>General Discussion&lt;br&gt;Tracy Waldeck, Ph.D., National Institute of Mental Health</td>
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<tr>
<td>10:30 am – 10:45 am</td>
<td>Coffee Break</td>
<td>Frank Lloyd Wright Ballroom Foyer</td>
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<td>Individual Research Reports</td>
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<td>Trial Design and Methodology</td>
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<td>Chair:</td>
<td>Alan Breier, M.D., Indiana University</td>
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<td>10:45 am – 11:00 am</td>
<td>A Research Tool to Assess Age-related Declines in Cognitive Function</td>
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<td></td>
<td>Keith A. Wesnes, B.S., Ph.D., Bracket, Swinburne University</td>
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<td>11:00 am – 11:15 am</td>
<td>Adverse Events in Regulatory Clinical Trials of Second Generation Antipsychotics: Changes Over Time during the Past Two Decades</td>
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<td>Laszlo Tombor, M.D., Semmelweis University</td>
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<td>11:15 am – 11:30 am</td>
<td>Are Large Numbers of Investigative Sites Associated with Symptom Improvement on Placebo in Antipsychotic Randomized Controlled Trials (RCTs)? A Meta-Analytic Review</td>
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<td>Robert Litman, M.D., CBH Health, LLC</td>
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<td>11:30 am – 11:45 am</td>
<td>Prediction of Suicide in Clinical Trials using the C-SSRS</td>
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<td>Kelly Posner, M.D., Columbia University</td>
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<tr>
<td>10:45 am – 11:45 am</td>
<td>*New Treatments in Depression &amp; Anxiety</td>
<td>Frank Lloyd Wright Salon C-D</td>
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<td>Chair:</td>
<td>Richard Keefe, Ph.D., Duke University</td>
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<td>10:45 am – 11:00 am</td>
<td>Personalized Therapy with Adjunctive L-methylfolate in Patients with SSRI-Resistant Depression</td>
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<td>Maurizio Fava, M.D., Massachusetts General Hospital</td>
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<tr>
<td>11:00 am – 11:15 am</td>
<td>rTMS in Treatment Resistant Depression: A Systematic Review</td>
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<td>Bradley N. Gaynes, M.D., UNC School of Medicine</td>
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<td>11:15 am – 11:30 am</td>
<td>D-Cycloserine Augmentation of CBT for Social Anxiety Disorder: Results from an RCT</td>
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<td>Mark H. Pollack, M.D., Rush University Medical Center</td>
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<td>11:30 am – 11:45 am</td>
<td>A High-throughput Clinical Assay for Testing Drug Facilitation of Learning-based Psychotherapy</td>
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<td>Eric J. Lenze, M.D., Washington University</td>
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**Special Issues in Patient Grouping: Biomarkers, Medical Comorbidity and Attitudes**

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<tr>
<td>10:45 am – 11:00 am</td>
<td>Decreased Occipital Glutathione Levels in Tourette’s Disorder</td>
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<td>Vilma Gabbay, M.D., M.S., New York University Child Study Center, Nathan S. Kline Institute</td>
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<tr>
<td>11:00 am – 11:15 am</td>
<td>Cardiovascular Risk Factors in Individuals with Bipolar II Disorder</td>
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<td>Holly A. Swartz, M.D., University of Pittsburgh School of Medicine</td>
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<td>11:15 am – 11:30 am</td>
<td>Why Do Some Depressed Outpatients Who are in Remission According to the Hamilton Depression Rating Scale not Consider Themselves to be in Remission?</td>
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<td>Mark Zimmerman, M.D., Rhode Island Hospital</td>
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<td>11:30 am – 11:45 am</td>
<td>How Similar are Patients Who Participate in Randomized Controlled Trials from those Who Don't?</td>
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<td>Alisa B. Busch, M.D., McLean Hospital/Harvard Medical School</td>
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<tr>
<td>11:45 am – 1:00 pm</td>
<td>Lunch on own</td>
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*of special interest to clinicians
Pharmaceutical Pipeline Session

1:00 pm – 3:00 pm  *Pharmaceutical Pipeline Session

Frank Lloyd Wright Salon E-F

Chair:  Carlos Zarate, M.D., National Institute of Mental Health
2012 Program Committee Co-Chair

1:00 pm – 1:15 pm  PNB02: A Beneficial Treatment for Insufficient Response with Single Agent Treatment in Schizophrenia?
Erik Buntinx, Ph.D., PharmaNeuroBoost NV

1:15 pm – 1:30 pm  Novel Dopamine Stabilizer
Marc Cantillon, M.D., Reviva

1:30 pm – 1:45 pm  NOP Agonism: A Novel Mechanism for the Treatment of Anxiety and Depression
Carla M. Canuso, M.D., Janssen Research & Development, LLC

1:45 pm – 2:00 pm  Early Clinical Development of the Opioid Modulator ALKS 5461 in the Treatment of Depression and Addiction
Elliot W. Ehrich, M.D., Alkermes

2:00 pm – 2:15 pm  Clinical Development of the Norepinephrine Reuptake Inhibitor Edivoxetine (LY2216684 HCl) for the Treatment of Major Depressive Disorder: Use of Pharmacokinetics, Pharmacodynamics and Biomarkers
William Kielbasa, Ph.D., Eli Lilly and Company

2:15 pm – 2:30 pm  Merck Neuroscience Pharmaceutical Pipeline: June 2012
Armin Szegedi, M.D., Ph.D., Merck Research Laboratories

2:30 pm – 2:45 pm  A Novel V1a Receptor Antagonist and Potential Antidepressant, SRX246, Blocks Vasopressin Mediated Effects on Stress & Fear: An fMRI Study
Neal G. Simon, Ph.D., Azevan Pharmaceuticals, Lehigh University

*of special interest to clinicians
1:00 pm – 3:00 pm  *Pharmaceutical Pipeline Session
*Frank Lloyd Wright Salon E-F

2:45 pm – 3:00 pm  Translational Evaluation of JNJ-18038683, A Selective 5-HT7 Receptor Antagonist in Depression
Jaskaran Singh, M.D., Janssen R&D

3:00 pm – 3:15 pm  Coffee Break
*Frank Lloyd Wright Ballroom Foyer

Panel Sessions

3:15 pm – 4:45 pm  Identifying Common Targets in Treating Impulse Control Disorders
*Frank Lloyd Wright Salon I-J

Chair:  Lorrin M. Koran, M.D., Stanford University

3:15 pm – 3:40 pm  Pharmacotherapy Targets in Pathological Gambling
Jon E. Grant, M.D., University of Minnesota

3:40 pm – 4:05 pm  Pharmacotherapy Targets in Intermittent Explosive Disorder
Emil F. Coccaro, M.D., University of Chicago

4:05 pm – 4:30 pm  Pharmacotherapy Targets in Trichotillomania and Skin Picking Disorder
Lorrin M. Koran, M.D., Stanford University

4:30 pm – 4:45 pm  General Discussion
Susan L. McElroy, M.D., University of Cincinnati

*of special interest to clinicians
3:15 pm – 4:45 pm  
**NIDA & NIAAA Panel - Neuroimmune Targets for Treatment of Substance and Alcohol Use Disorders**  
*Frank Lloyd Wright Salon A-B*

**Chairs:** Phil Skolnick, Ph.D., D. Sc., National Institute on Drug Abuse  
Raye Z. Litten, Ph.D., National Institute on Alcohol Abuse and Alcoholism

3:15 pm – 3:40 pm  
**Activation of Immune Signaling Pathways is Implicated in some of the Pharmacological Effects of Ethanol**  
Peter M. Grace, Ph.D., University of Adelaide

3:40 pm – 4:05 pm  
**Immune Signaling, Neuroimmune Gene Expression and Regulation of Alcohol Consumption**  
Robert A. Harris, Ph.D., University of Texas at Austin

4:05 pm – 4:30 pm  
**Activation of TLR4 Pathways by Opiates and Cocaine: Implications for Abuse and Treatment**  
Linda R. Watkins, Ph.D., University of Colorado-Boulder

4:30 pm – 4:45 pm  
**General Discussion**  
David J. McCann, Ph.D., National Institute on Drug Abuse

3:15 pm – 4:45 pm  
*Rapidly-Acting Antidepressant Therapies: The NIMH-Sponsored RAPID Network*  
*Frank Lloyd Wright Salon C-D*

**Chairs:** Maurizio Fava, M.D., Massachusetts General Hospital  
Carlos Zarate, M.D., National Institute of Mental Health

3:15 pm – 3:35 pm  
**The Design and Implementation of the RAPID Network Studies**  
Maurizio Fava, M.D., Massachusetts General Hospital

3:35 pm – 3:55 pm  
**Low Field Magnetic Stimulation and its Rapid Effects on Mood**  
Michael Rohan, Ph.D., McLean Hospital

3:55 pm – 4:15 pm  
**Ketamine as a Rapidly Acting Antidepressant**  
Carlos Zarate, M.D., National Institute of Mental Health

*of special interest to clinicians*
3:15 pm – 4:45 pm  (continued)  *Rapidly-Acting Antidepressant Therapies: The NIMH-Sponsored RAPID Network
Frank Lloyd Wright Salon C-D

4:15 pm – 4:35 pm  The Role of Non-Ketamine, Non-Competitive NMDA-Receptor Antagonists in the Treatment of Depression
Mark A. Smith, M.D., AstraZeneca

4:35 pm – 4:45 pm  General Discussion
Carlos Zarate, M.D., National Institute of Mental Health

3:15 pm – 4:45 pm  *Emerging Clinical Evidence on Oxytocin in Schizophrenia
Frank Lloyd Wright Salon G-H

Chair:  Deanna L. Kelly, PharmD, University of Maryland Baltimore

3:15 pm – 3:35 pm  Oxytocin Improves Emotion Recognition in Patients with Schizophrenia
Bruno Averbeck, Ph.D., National Institute of Health

3:35 pm – 3:55 pm  Intranasal Oxytocin Reduces Core Symptoms of Schizophrenia
David Feifel, M.D., University of California, San Diego

Cort Pedersen, M.D., University of North Carolina at Chapel Hill

4:15 pm – 4:35 pm  Sex-Specific Associations between Peripheral Oxytocin, Symptoms, and Emotion Perception in Schizophrenia
Leah H. Rubin, Ph.D., University of Illinois at Chicago

4:35 pm – 4:45 pm  General Discussion
Deanna Kelly, PharmD, Maryland Psychiatric Research Center

6:00 pm – 7:30 pm  New Investigator Award Ceremony & Reception (Invitation Only)
Aztec

*of special interest to clinicians
Wednesday, May 30th

7:15 am  NCDEU 13th Annual Fun Run/Walk
          Conference Center Entrance

7:30 am – 8:30 am  New Investigator Awardee Roundtable
                   (Invitation Only)
                   Aztec

7:30 am – 9:30 am  Continental Breakfast
                   Frank Lloyd Wright Ballroom Foyer

8:30 am – 9:30 am  Plenary - Institute Directors’ Report
                   Frank Lloyd Wright Salon E-F

9:30 am – 10:30 am  Plenary - A New NIH Focus on Research to
                    Facilitate Clinical Research
                    Frank Lloyd Wright Salon E-F

10:30 am – 10:45 am  Coffee Break
                      Frank Lloyd Wright Ballroom Foyer

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

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<thead>
<tr>
<th>Panel Session</th>
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<tr>
<td>Gamma-Aminobutyric Acid</td>
<td>Frank Lloyd Wright Salon A-B</td>
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<td>Alterations across</td>
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<td>Psychiatric Disorders</td>
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<td>*Developing the Next</td>
<td>Frank Lloyd Wright Salon C-D</td>
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<td>*Trajectory-based Disease</td>
<td>Frank Lloyd Wright Salon E-F</td>
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<td>Pediatric Psychiatry</td>
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<td>Neuroendocrine Changes</td>
<td>Frank Lloyd Wright Salon G-H</td>
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<td>and Biological Markers</td>
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<td>DSM-5 and Psychopathology</td>
<td>Frank Lloyd Wright Salon I-J</td>
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<td>Domains as Therapeutic</td>
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<td>Indications</td>
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12:30 pm – 2:30 pm  Special Session - Improving the Teaching-Learning Process in Psychopharmacology: A Demonstration of New Teaching Formats from the ASCP Psychopharmacology Curriculum
                   Frank Lloyd Wright Salon C-D

*of special interest to clinicians
12:30 pm – 2:30 pm  **Poster Session I with Lunch**  McArthur Ballroom

2:45 pm – 5:45 pm  **Concurrent Workshop Sessions**

<table>
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<tr>
<th><em>Fatigue Across the CNS Spectrum: Symptom or Side Effect</em></th>
<th><em>Psychosocial Treatment Platforms in Psychopharmacology RCTs</em></th>
<th><em>Moderators and Mediators of Treatment Outcome in Late Life Depression</em></th>
<th>Comparative Effectiveness Trials in Bipolar Disorder: What Have We Learned and Where Do We Need To Go From Here?</th>
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<td>Location: Frank Lloyd Wright Salon I-J</td>
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4:10 pm – 4:25 pm  **Coffee Break**  
Frank Lloyd Wright Pre Function Central

6:30 pm – 8:00 pm  **NCDEU Reception**  
Gold Room, Patio, & Aztec Lawn

*of special interest to clinicians*
7:15 am  NCDEU 13th Annual Fun Run/Walk  
*Conference Center Entrance*

7:30 am – 8:30 am  New Investigator Awardee Roundtable  
*(Invitation Only)*  
*Aztec*

7:30 am – 9:30 am  Continental Breakfast  
*Frank Lloyd Wright Ballroom Foyer*

**Plenary Sessions**

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<th>Time</th>
<th>Event Description</th>
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| 8:30 am – 9:30 am | Plenary - *Institute Directors’ Report*  
*Frank Lloyd Wright Salon E-F* |

**Chair:** David J. Kupfer, M.D., University of Pittsburgh School of Medicine  
NCDEU 2012 Program Committee Chair

8:30 am – 9:00 am  **NIMH Update**  
Phillip S. Wang, M.D., National Institute of Mental Health

Although the enormous burdens from mental illness continue, pharmaceutical and biotech companies have been deterred from investing in CNS drug development due in part to some costly late-stage failures. Reversing these trends will require identifying new therapeutic targets and de-risking them. This presentation will provide an overview of some recent research findings illustrating potential disease mechanisms and new therapeutic targets. Findings such as these may offer translational opportunities to develop the next generation of treatments for mental illness.
Common Targets across Brain Diseases: New Opportunities to Treat Substance Use Disorders (SUDs)
Phil Skolnick, Ph.D., D.Sc., National Institute on Drug Abuse

Currently, there are no medications approved to treat either stimulant (e.g. cocaine, methamphetamine) or cannabis dependence, and approved pharmacotherapies to treat other SUDs (e.g., opiates, tobacco) are far from ideal. For example, no more than 20% of smokers are able to sustain “long term” (12 month) abstinence, despite the availability of therapeutic options to treat tobacco dependence (nicotine replacement therapies, bupropion, and varenicline). The pharmaceutical industry has largely neglected the development of medications to treat SUDs. The result of this indifference is that significant therapeutic advances are most likely to emerge from an understanding of the neurobiological processes common to SUDs and other neuropsychiatric disorders. Successful translation of this knowledge relies predominantly on the use of repurposed molecules. Based on this principle, molecules currently in either mid or late-stage clinical development that may represent new pharmacotherapies to treat SUDs will be described.

Medications Development for Alcohol Dependence: A Vision for the Next Decade
Kenneth R. Warren, Ph.D., National Institute on Alcohol Abuse and Alcoholism

Alcohol Use Disorders (alcohol abuse and dependence) are among the most prevalent mental health disorders found in the world today. More than 76 million people worldwide are estimated to have diagnosable alcohol use disorders. Pharmacotherapy offers promising means for treating alcohol dependence, and significant progress has been made
in the past 20 years. Currently, four medications have been approved by the U.S. Food and Drug Administration for alcoholism, the last three within the past two decades. Unfortunately, these medications do not work for everyone; as a result, active research continues to search for effective medications to treat an even wider range of patients. National Institute on Alcohol Abuse and Alcoholism (NIAAA) is committed to the vision of ensuring the development and delivery of new and more effective alcohol medications over the coming decade. To facilitate this, the NIAAA has identified 7 key objectives: 1) to discover and validate new molecular targets for the treatment of AUDs. This effort holds the promise of identifying novel therapeutics as well as more favorable side-effect profiles; 2) to develop and implement animal and human laboratory paradigms as screening models for drug development; 3) to bridge the often-discussed gaps in the drug development process (referred to as the “Valley of Death”) through a fully translational therapeutics development program; 4) to develop methodological approaches for conducting AUD clinical trials that are more efficient, both in terms of their economic and time costs; 5) to advance personalized medicine in the pursuit of new compounds, as a means of increasing the effect size in adequately selected patients; 6) to identify and remove barriers to the implementation and adoption of alcohol medications in real-world treatment settings; and 7) to facilitate the development of collaborative networks and partnerships among pertinent stakeholders seeking new therapeutics for addictive disorders, such as the federal government, the pharmaceutical industry, academia, healthcare organizations, as well as patient and advocacy groups. Successful implementation of these objectives will result in the development of more efficacious and safe medications, provide a greater selection of therapy options, and ultimately lessen the impact of this devastating disorder.
Plenary - A New NIH Focus on Research to Facilitate Clinical Research
Frank Lloyd Wright Salon E-F

Chair: William Z. Potter, M.D., Ph.D., Neuroscience Steering Committee, FNIH

Translational Therapeutics Development at NIH
Christopher P. Austin, M.D., National Center for Advancing Translational Science

The explosion in mechanistic understanding of human physiology in health and disease, exemplified by the Human Genome Project and its successors, has provided a deluge of potential new targets for therapeutic development. At the same time, evolution of technologies and operational systems for drug discovery has allowed investigators and institutions in the public sector to contribute directly to new therapeutics discovery in a more vigorous way, particularly for rare and neglected diseases. Over the last decade, the NIH has built a variety of programs which complement drug discovery efforts in the biopharmaceutical sector, principally in two areas: (a) science, technology, tool, and paradigm development to improve scientific understanding and efficiency of the therapeutics discovery process, and (b) early stage drug development programs to de-risk projects particularly for rare and neglected diseases, making them more amenable to biopharmaceutical adoption despite their low expected return on investment. The mission and accomplishments of these programs will be discussed.

Coffee Break
Frank Lloyd Wright Ballroom Foyer
Panel Sessions

10:45 am – 12:15 pm  Gamma-Aminobutyric Acid Alterations across Psychiatric Disorders  
*Frank Lloyd Wright Salon A-B*

**Chair:** Vilma Gabbay, M.D., New York University Child Study Center

10:45 am – 11:05 am  **Neurochemical Alterations in Adolescent Marijuana Abusers**  
Andrew P. Prescott, Ph.D., Brain Institute, University of Utah

11:05 am – 11:25 am  **GABAergic and Dopaminergic Changes in Schizophrenia**  
Lawrence S. Kegeles, M.D., Columbia University

11:25 am – 11:45 am  **Decreased Occipital GABA in Adults with Treatment-Resistant Depression**  
Sanjay Mathew, M.D., Baylor College of Medicine

11:45 am – 12:05 pm  **GABA Deficits in Adolescent Depression: Relationship to Anhedonia**  
Vilma Gabbay, M.D., New York University Child Study Center

12:05 pm – 12:15 pm  **General Discussion**  
Vilma Gabbay, M.D., New York University Child Study Center

10:45 am – 12:15 pm  *Developing the Next Generation of Antidepressants*

**Frank Lloyd Wright Salon C-D**

**Chairs:** Philip T. Ninan, M.D., Pfizer  
Steven J. Romano, M.D., Global Primary Care Business Unit

10:45 am – 11:05 am  **Targets for Pharmacological Intervention in MDD**  
Douglas E. Feltner, M.D., Douglas E. Feltner, LLC

11:05 am – 11:25 am  **Precision in Outcome Measures**  
Philip T. Ninan, M.D., Pfizer

*of special interest to clinicians*
**Wednesday, May 30, 2012**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Location</th>
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</thead>
</table>
| 10:45 am – 12:15 pm (continued) | *Developing the Next Generation of Antidepressants*  
*Frank Lloyd Wright Salon C-D* |                                |
| 11:25 am – 11:45 am | Pathways to Regulatory Approval in MDD  
Brendon Binneman, M.D., Pfizer |                                |
| 11:45 am – 12:05 pm | Competing Drivers Influencing Executive Decisions  
Steven J. Romano, M.D., Global Primary Care Business Unit |                                |
| 12:05 pm – 12:15 pm | General Discussion  
Robert Levin, M.D., Food and Drug Administration |                                |
| 10:45 am – 12:15 pm | *Trajectory-based Disease - Modifying Treatments in Pediatric Psychiatry*  
*Frank Lloyd Wright Salon E-F* |                                |

**Chair:**  
John March, M.D., Duke Clinical Research Institute

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Location</th>
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</table>
| 10:45 am – 11:05 am | Developing Disease Modifying Treatments in Mentally Ill Youth  
John March, M.D., Duke Clinical Research Institute |                                |
| 11:05 am – 11:25 am | Prevention of Psychosis: Current Approaches and Future Directions  
Christoph Correll, M.D., Hofstra North Shore LIJ School of Medicine |                                |
| 11:25 am – 11:45 am | Targeted Treatment Development in Autism Spectrum Disorders  
Craig A. Erickson, M.D., Indiana University School of Medicine |                                |
| 11:45 am – 12:05 pm | Disease Modifying Treatments in Marijuana Dependence  
Kevin M. Gray, M.D., Medical University of South Carolina |                                |
| 12:05 pm – 12:15 pm | General Discussion  
Benedetto Vitiello, M.D., National Institute of Mental Health |                                |

*of special interest to clinicians*
10:45 am – 12:15 pm  Neuroendocrine Changes in MDD and BD: Clinical and Biological Markers
Frank Lloyd Wright Salon G-H

Chair: Dorothy Sit, M.D., University of Pittsburgh

10:45 am – 11:05 am  Insulin Sensitizers as Modulators of Mood: Rationale and Preliminary Evidence for the use of Pioglitazone in the Treatment of Major Depressive Episodes
David Kemp, M.D., Case Western Reserve University

11:05 am – 11:25 am  Gestational Diabetes and Obesity in Pregnant Women with Major Depressive Disorder or Bipolar Disorder vs Healthy Controls: Effects on Adverse Neonatal Outcomes (Preterm Birth, Birth Weight and Peripartum Events)
Dorothy Sit, M.D., University of Pittsburgh

11:25 am – 11:45 am  Circadian and Hormonal Characteristics of Menopausal Women with Major Depression vs Normal Controls
Barbara L. Parry, M.D., University of California, San Diego

11:45 am – 12:05 pm  The Menopausal Transition: Risk of Mood Episodes and the Clinical Biomarker of Reproductive Hormones
Claudio Soares, M.D., McMaster University

12:05 pm – 12:15 pm  General Discussion
Claudio Soares, M.D., McMaster University
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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>10:45 am – 12:15 pm</td>
<td>DSM-5 and Psychopathology Domains as Therapeutic Indications</td>
<td>Frank Lloyd Wright Salon I-J</td>
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<tr>
<td><strong>Chair:</strong></td>
<td>Rajiv Tandon, M.D., State of Florida Program of Mental Health</td>
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<tr>
<td>10:45 am – 11:05 am</td>
<td>Psychotic Disorders and Psychopathology Domains in DSM-5</td>
<td>Rajiv Tandon, M.D., State of Florida Program of Mental Health</td>
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<tr>
<td>11:05 am – 11:25 am</td>
<td>Implications of Cross-cutting Dimensions for Clinical Trials Methodology</td>
<td>Stephen Marder, M.D., UCLA</td>
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<tr>
<td>11:25 am – 11:45 am</td>
<td>Industry Perspective on Psychotic Disorders and Symptom Dimensions</td>
<td>Ellen B. Dennehy, Ph.D., Eli Lilly and Company</td>
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<tr>
<td>11:45 am – 12:05 pm</td>
<td>Relating Symptom Dimensions to RDoC Behaviors and Neural Circuits</td>
<td>Gregory Strauss, Ph.D., University of Maryland School of Medicine</td>
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<tr>
<td>12:05 pm – 12:15 pm</td>
<td>General Discussion</td>
<td>Carlos Zarate, M.D., National Institute of Mental Health</td>
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</tbody>
</table>
**Special Session**

**12:30 pm – 2:30 pm**  
*Special Session*  
*Frank Lloyd Wright Salon C-D*

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

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**Improving the Teaching-Learning Process in Psychopharmacology: A Demonstration of New Teaching Formats from the ASCP Psychopharmacology Curriculum**

Ira Glick, M.D., Stanford University School of Medicine  
Sidney Zisook, M.D., University of California, San Diego  
Mark H. Rapaport, M.D., Emory University School of Medicine

This year’s teaching session will focus on the revised ASCP Psychopharmacology curriculum for psychiatric residents. Presenters will demonstrate 1) Dynamic and interactive lecturing, 2) making learning fun; e.g. using games, such as psychiatric Jeopardy, and 3) modernizing teaching by incorporating digital teaching tools. Each format each will be demonstrated – the aim is to have the audience-teachers leave with something new in their repertoire to bring back to their home institutions for teaching clinicians, residents, medical students and/or industry scientists.

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**12:30 pm – 2:30 pm**  
*Poster Session I with Lunch*  
(See page 71 for listing of posters)  
*McArthur Ballroom*
## Workshops

**2:45 pm – 5:45 pm**  
*Fatigue Across the CNS Spectrum: Symptom or Side Effect*  
*Frank Lloyd Wright Salon A-B*

**Chair:** Steven D. Targum, M.D., Clintara LLC.

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<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>2:45 pm</td>
<td>Introduction: The Many Faces of Fatigue</td>
<td>Steven D. Targum, M.D., Clintara LLC.</td>
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<tr>
<td>2:50 pm</td>
<td>Fatigue Associated with Major Depressive Disorder</td>
<td>Maurizio Fava, M.D., Massachusetts General Hospital</td>
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<tr>
<td>3:00 pm</td>
<td>Discussion</td>
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<tr>
<td>3:10 pm</td>
<td>Fatigue Associated with Neurological Disorders: Focus on Multiple Sclerosis</td>
<td>Thomas Wessel, M.D., Berkshire Drug Development Consulting LLC</td>
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<tr>
<td>3:20 pm</td>
<td>Discussion</td>
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<tr>
<td>3:30 pm</td>
<td>Differentiating Negative Symptoms from Fatigue and other Comorbid Conditions in Schizophrenia</td>
<td>Larry Alphs, M.D., Janssen Scientific Affairs LLC.</td>
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<tr>
<td>3:40 pm</td>
<td>Discussion</td>
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<tr>
<td>3:50 pm</td>
<td>ADHD and Fatigue</td>
<td>Lynn Starr, M.D., Janssen Scientific Affairs LLC.</td>
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<tr>
<td>4:00 pm</td>
<td>Discussion</td>
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<tr>
<td>4:10 pm</td>
<td>Break</td>
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<tr>
<td>4:25 pm</td>
<td>Fatigue and Alzheimer’s Disease</td>
<td>Dana Hilt, M.D., Envivo Pharmaceuticals</td>
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<tr>
<td>4:35 pm</td>
<td>Discussion</td>
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<tr>
<td>4:45 pm</td>
<td>Health Outcome Issues Related to Residual Fatigue</td>
<td>Michael F. Murphy, M.D., Worldwide Clinical Trials</td>
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<tr>
<td>4:55 pm</td>
<td>Discussion</td>
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<tr>
<td>5:05 pm</td>
<td>General Audience Discussion</td>
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</tbody>
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*of special interest to clinicians*
2:45 pm – 5:45 pm  Psychosocial Treatment Platforms in Psychopharmacology RCTs
Frank Lloyd Wright Salon C-D

Chair: Nina R. Schooler, Ph.D., SUNY Downstate Medical Center

2:45 pm – 2:55 pm  Introduction
Nina R. Schooler, Ph.D., SUNY Downstate Medical Center

2:55 pm – 3:15 pm  Psychosocial Treatments in RCTS for Alcohol Disorders
Stephanie S. O’Malley, Ph.D., Yale University School of Medicine

3:15 pm – 3:20 pm  Discussion

3:20 pm – 3:40 pm  Psychosocial Treatment in RCTs of Medications for Smoking Cessation
Michele Levine, Ph.D., University of Pittsburgh School of Medicine

3:40 pm – 3:45 pm  Discussion

3:45 pm – 4:05 pm  Characteristics of Psychosocial Treatment Platforms for RCT’s in Mood Disorders
Ellen Frank, Ph.D., University of Pittsburgh School of Medicine

4:05 pm – 4:10 pm  Discussion

4:10 pm – 4:25 pm  Break

4:25 pm – 4:45 pm  Adherence Enhancement as a Psychosocial Platform for Psychopharmacology RCTs
Dawn Velligan, Ph.D., University of Texas Health Science Center

4:45 pm – 4:50 pm  Discussion

4:50 pm – 5:45 pm  General Audience Discussion
Nina R. Schooler, Ph.D., SUNY Downstate Medical Center
<table>
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<tr>
<th>Time</th>
<th>Event</th>
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<tr>
<td>2:45 pm – 5:45 pm</td>
<td><em>Moderators and Mediators of Treatment Outcome in Late Life Depression</em></td>
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<td>Frank Lloyd Wright Salon G-H</td>
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**Chair:** Craig Nelson, M.D., UCSF

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<th>Time</th>
<th>Event</th>
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<tr>
<td>2:45 pm – 2:55 pm</td>
<td>Introduction</td>
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<tr>
<td>2:55 pm – 3:10 pm</td>
<td><strong>Efficacy of Antidepressants in Late Life Depression and Moderators of Response</strong></td>
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<tr>
<td></td>
<td>Craig Nelson, M.D., UCSF</td>
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<tr>
<td>3:10 pm – 3:20 pm</td>
<td>Discussion</td>
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<tr>
<td>3:20 pm – 3:35 pm</td>
<td><strong>Efficacy of Antidepressants in Older Depressed Patients with Vascular Depression and/or Executive Dysfunction or Vascular Depression</strong></td>
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<td>Warren D. Taylor, M.D., MHSc, Duke University School of Medicine</td>
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<tr>
<td>3:35 pm – 3:45 pm</td>
<td>Discussion</td>
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<tr>
<td>3:45 pm – 4:00 pm</td>
<td><strong>Efficacy of Antidepressants in Older Depressed Patients with Alzheimer’s Disease and the Potential for Augmentation with Cognitive Enhancers in Depressed Patients with Cognitive Impairment</strong></td>
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<td>D. P. Devanand, M.D., Columbia University</td>
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<td>4:00 pm – 4:10 pm</td>
<td>Discussion</td>
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<td>4:10 pm – 4:25 pm</td>
<td>Break</td>
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<tr>
<td>4:25 pm – 4:40 pm</td>
<td><strong>White Matter Abnormalities, Activation of Cognitive and Emotional Control Networks, and Late Life Depression</strong></td>
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<td>Faith Gunning-Dixon, Ph.D., Weill Cornell Medical College</td>
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<tr>
<td>4:40 pm – 4:50 pm</td>
<td>Discussion</td>
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<td>4:50 pm – 5:05 pm</td>
<td><strong>Cerebral Perfusion and Cognitive Functioning in Late Life Depression</strong></td>
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<td>R. Scott Mackin, Ph.D., UCSF</td>
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<td>5:05 pm – 5:15 pm</td>
<td>Discussion</td>
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<tr>
<td>5:15 pm – 5:45 pm</td>
<td><strong>General Audience Discussion</strong></td>
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</table>

*of special interest to clinicians*
Comparative Effectiveness Trials in Bipolar Disorder: What Have We Learned and Where Do We Need To Go From Here?

*Frank Lloyd Wright Salon I-J*

**Chairs:** Terence A. Ketter, M.D., Stanford University
Andrew A. Nierenberg, M.D., Massachusetts General Hospital

**2:45 pm – 3:00 pm**
*Welcome and Introductions*
Terence A. Ketter, M.D., Stanford University

**3:00 pm – 3:20 pm**
*Design Considerations in Bipolar Disorder Comparative Effectiveness Research*
Michael E. Thase, M.D., University of Pennsylvania

**3:20 pm – 3:30 pm**
*Discussion*

**3:30 pm – 3:50 pm**
*Balancing Generalizability and Assay Sensitivity Needs in Bipolar Disorder Comparative Effectiveness Research*
Joseph Calabrese, M.D., University Hospitals Case Medical Center

**4:00 pm – 4:10 pm**
*Discussion*

**4:10 pm – 4:25 pm**
*Break*

**4:25 pm – 4:45 pm**
*Outcome Measure Strengths and Limitations in Bipolar Disorder Comparative Effectiveness Research*
Terence A. Ketter, M.D., Stanford University

**4:45 pm – 4:55 pm**
*Discussion*

**4:55 pm – 5:45 pm**
*General Audience Discussion*
Andrew A. Nierenberg, M.D., Massachusetts General Hospital

**4:10 pm – 4:25 pm**
*Coffee Break*
*Frank Lloyd Wright Pre Function Central*

**6:30 pm – 8:00 pm**
*NCDEU Reception*
*Gold Room, Patio, & Aztec Lawn*
Thursday, May 31st

7:00 am - 8:30 am  NCDEU Steering Committee Meeting
Kaibab

7:30 am – 8:30 am  New Investigator Awardee Roundtable
(Invitation Only)
Aztec

7:30 am – 9:30 am  Continental Breakfast
Frank Lloyd Wright Ballroom Foyer

8:30 am – 10:00 am  Regulatory Plenary - New FDA and EMA Initiatives
in Depression and Schizophrenia
Frank Lloyd Wright Salon E-F

10:00 am – 10:35 am  Coffee Break
Frank Lloyd Wright Ballroom Foyer

10:30 am – 12:00 pm  Concurrent Panel Sessions

<table>
<thead>
<tr>
<th>Biologics for Addictions Treatment: Vaccines and Enzymes</th>
<th>*Novel Methods for Evaluating the Harm-Benefit Balance in Outcomes of Randomized Clinical Trials: Demonstration of a New Approach</th>
<th>“Food “Addiction”: Conceptualization, Assessment and Applications to Obesity</th>
<th>Long Term Outcome of Childhood Disorders and Its Predictors</th>
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<tbody>
<tr>
<td>Location: Frank Lloyd Wright Salon A-B</td>
<td>Location: Frank Lloyd Wright Salon C-D</td>
<td>Location: Frank Lloyd Wright Salon G-H</td>
<td>Location: Frank Lloyd Wright Salon I-J</td>
</tr>
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12:15 pm - 2:15 pm  Poster Session II with Lunch
McArthur Ballroom

*of special interest to clinicians
### Thursday, May 31, 2012

**Concurrent Workshop Sessions**

<table>
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<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>2:30 pm - 5:30 pm</td>
<td><strong>The Alcohol Clinical Trials Initiative (ACTIVE): Progress and Future Directions</strong></td>
<td>Frank Lloyd Wright Salon A-B</td>
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<td><strong>Dealing with Cross Cultural Differences in Standard Rating Scales in Psychiatric Research</strong></td>
<td>Frank Lloyd Wright Salon C-D</td>
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<td><strong>“Keeping it Real: Quantifying Clinical Relevance in Treatments for Psychiatric Disorders</strong></td>
<td>Frank Lloyd Wright Salon G-H</td>
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<td><strong>Strategies for Incomplete Data in Randomized Clinical Trials</strong></td>
<td>Frank Lloyd Wright Salon I-J</td>
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</table>

**Coffee Break**
Frank Lloyd Wright Pre Function Central

*of special interest to clinicians*
7:00 am - 8:30 am  NCDEU Steering Committee Meeting  
*Kaibab*

7:30 am – 8:30 am  New Investigator Awardee Roundtable  
(Invitation Only)  
*Aztec*

7:30 am – 9:30 am  Continental Breakfast  
*Frank Lloyd Wright Ballroom Foyer*

8:30 am – 10:00 am  Regulatory Plenary - *New FDA and EMA Initiatives in Depression and Schizophrenia*  
*Frank Lloyd Wright Salon E-F*

**Co-Chairs:**  
Thomas Laughren, M.D., Food & Drug Administration  
Karl Broich, M.D., Federal Institute for Drugs and Medical Devices (BfArM, Germany)

8:30 am – 8:50 am  Clinical Trials for Major Depression (MDD): Current Views from EU  
Karl Broich, M.D., Federal Institute for Drugs and Medical Devices (BfArM, Germany)

MDD is one of the most common psychiatric disorders, which is the fourth leading cause of global disease burden. Despite the many treatment options currently approved for MDD, a relevant proportion of patients up to one third does not adequately respond to treatment, even if there is good compliance and the treatment has been taken long enough with an adequate dosage. So there is a clear unmet medical need for patients, in whom even “state of the art”-antidepressant therapy fails to elicit a sufficient treatment response. Following a public consultation period the revision of the “Note for guidance on Clinical Investigation of Medicinal Products in the Treatment of Depression” gets now finalized. The regulatory requirements for development programs of antidepressant medicinal products are reviewed, special emphasis is given to issues regarding studied patient population (e.g. partial response, treatment resistance) and study designs (short-term and maintenance, active comparator).
US Food and Drug Administration (FDA) approves antidepressants for marketing based on short-term clinical trials. The maintenance effectiveness of antidepressants is also of considerable interest. We have compiled efficacy data from a total of 14 antidepressant maintenance trials with a randomized withdrawal design submitted to FDA since the approval of the first second-generation antidepressant in 1987. In these trials, responders to active drug during an open-label phase were randomized to active drug or placebo, and observed for relapse over a period of 6-12 months. Subjects on active drug had significantly lower relapse rates than those on placebo in every study. We will discuss the characteristics of open-label and double-blind phases, relapse rates in drug and placebo arms, and time-course of the treatment effect.

This presentation will give a brief overview of the FDA initiative to develop and implement standards to represent study data submitted in support of regulatory applications, including the latest information and resources for sponsors. Our recent experience in developing data standards specific to schizophrenia drug programs will then be discussed.
### Panel Sessions

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Venue</th>
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</table>
| 10:30 am – 12:00 pm | **Biologics for Addictions Treatment: Vaccines and Enzymes**  
*Panel A/B* | Frank Lloyd Wright Salon A-B |

**Chairs:** Thomas Kosten, M.D., Baylor College of Medicine  
Dave McCann, Ph.D., National Institute on Drug Abuse

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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker and Institution</th>
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</table>
| 10:30 am – 10:50 am | **Nicotine Vaccine Recent Developments**  
Marco Pravetoni, Ph.D., University of Minnesota | Marco Pravetoni, Ph.D., University of Minnesota |
| 10:50 am – 11:10 am | **A Vaccine Strategy against Heroin**  
Kim D. Janda, Ph.D., Scripps Research Institute | Kim D. Janda, Ph.D., Scripps Research Institute |
| 11:10 am – 11:30 am | **Cocaine Vaccine: Genetic and Immunological Response Predictors**  
Thomas Kosten, M.D., Baylor | Thomas Kosten, M.D., Baylor |
| 11:30 am – 11:50 am | **Rodent Studies of Cocaine Hydrolase Delivered by Gene Transfer as a Potential Future Treatment for Reducing Relapse in Recovering Cocaine Users**  
Stephen Brimijoin, Ph.D., Mayo Clinic | Stephen Brimijoin, Ph.D., Mayo Clinic |
| 11:50 am – 12:00 pm | **General Discussion**  
Dave McCann, Ph.D., National Institute on Drug Abuse | Dave McCann, Ph.D., National Institute on Drug Abuse |

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| 10:30 am – 12:00 pm | ** Novel Methods for Evaluating the Harm-Benefit Balance in Outcomes of Randomized Clinical Trials: Demonstration of a New Approach**  
*Panel C-D* | Frank Lloyd Wright Salon C-D |

**Chairs:** Ellen Frank, Ph.D., University of Pittsburgh School of Medicine  
Helena Kraemer, Ph.D., Stanford University

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<tr>
<th>Time</th>
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<th>Speaker and Institution</th>
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</table>
| 10:30 am – 10:55 am | **Rationale for an Integrated Harm-Benefit Measure**  
Helena Kraemer, Ph.D., Stanford University | Helena Kraemer, Ph.D., Stanford University |
| 10:55 am – 11:20 am | **A Pilot Study of the Integrated Preference Score (IPS) to Assess Harm-Benefit Balance in a Depression RCT**  
Ellen Frank, Ph.D., University of Pittsburgh School of Medicine | Ellen Frank, Ph.D., University of Pittsburgh School of Medicine |

*of special interest to clinicians*
10:30 am – 12:00 pm  *Novel Methods for Evaluating the Harm-Benefit Balance in Outcomes of Randomized Clinical Trials: Demonstration of a New Approach
Frank Lloyd Wright Salon C-D

11:20 am – 11:45 am  Novel Methods for Developing and Interpreting Moderator Profiles in Clinical Trials
Meredith L. Wallace, Ph.D., University of Pittsburgh

11:45 am – 12:00 pm  General Discussion
Nina Schooler, SUNY Downstate Medical Center

10:30 am – 12:00 pm  *Food “Addiction”: Conceptualization, Assessment and Applications to Obesity
Frank Lloyd Wright Salon G-H

Chair:  Nicole M. Avena, Ph.D., University of Florida

10:30 am – 10:55 am  Binge Eating Behavior in Rats shows results in Behavioral and Neurochemical Changes Suggesting Dependence
Miriam E. Bocarsly, Ph.D. Candidate, Princeton University

10:55 am – 11:20 am  Neuroimaging Reveals Overlaps between Feeding and Drug Addiction in Reward-related Brain Regions
Gene-Jack Wang, M.D., Brookhaven National Laboratory

11:20 am – 11:45 am  Predicting Unhealthy Weight Gain and Onset of Substance Use Based on fMRI Response
Eric Stice, Ph.D., Oregon Research Institute

11:45 am – 12:00 pm  General Discussion
Mark Gold, M.D., University of Florida

*of special interest to clinicians
10:30 am – 12:00 pm  Long-term Outcome of Childhood Disorders and its Predictors  
*Frank Lloyd Wright Salon I-J*

**Chair:**  Lily Hechtman, M.D., McGill University

10:30 am – 10:50 am  **Adolescent and Adult Outcome in Attention Deficit/Hyperactivity Disorder (ADHD) and its Predictors**  
Lily Hechtman, M.D., McGill University

10:50 am – 11:10 am  **Long-term Outcome of Bipolar Disorder**  
Gabrielle Carlson, M.D., Stony Brook University School of Medicine

11:10 am – 11:30 am  **Long-term Outcomes for Youth with Anxiety Disorders**  
Golda Ginsburg, Ph.D., Johns Hopkins University School of Medicine

11:30 am – 11:50 am  **Long-term Outcome of Depressive Disorders**  
Gabrielle Carlson, M.D., Stony Brook University School of Medicine

11:50 am – 12:00 pm  **General Discussion**  
Benedetto Vitiello, M.D., National Institute of Mental Health

12:15 pm - 2:15 pm  **Poster Session II with Lunch**  
*McArthur Ballroom*
### Workshops

**2:30 pm - 5:30 pm**  
**The Alcohol Clinical Trials Initiative (ACTIVE): Progress and Future Directions**  
*Frank Lloyd Wright Salon A-B*

**Chairs:** Raymond F. Anton, M.D. Medical University of South Carolina  
Raye Litten, Ph.D. National Institute of Alcohol Abuse and Alcoholism

<table>
<thead>
<tr>
<th>Time</th>
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| 2:30 pm – 2:40 pm | Welcome and Introductions  
Raymond F. Anton, M.D. Medical University of South Carolina |
| 2:40 pm – 3:00 pm | The Impact and Management of Missing Data in an Alcohol Pharmacotherapy Trial  
Henry Kranzler, M.D., University of Pennsylvania Perelman School of Medicine |
| 3:00 pm – 3:10 pm | Discussion                                                                                   |
| 3:10 pm – 3:30 pm | How Large is the Placebo Response in Alcohol Clinical Trials: Effect of Baseline Drinking and Patient Characteristics  
Stephanie O’Malley, Ph.D., Yale University School of Medicine |
| 3:30 pm – 3:40 pm | Discussion                                                                                   |
| 3:40 pm – 4:00 pm | Using Cumulative Proportion of Responders Analysis (CPRA) to Assess Treatment Outcome in Alcohol Clinical Trials  
Raye Litten, Ph.D., National Institute of Alcohol Abuse and Alcoholism |
| 4:00 pm – 4:10 pm | Discussion                                                                                   |
| 4:10 pm – 4:25 pm | Break                                                                                       |
| 4:25 pm – 4:45 pm | Alcohol Biomarkers as Outcome Measures Alone or in Conjunction with Drinking as Outcomes in Alcohol Clinical Trials  
Raymond F. Anton, M.D. Medical University of South Carolina |
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<td>The Alcohol Clinical Trials Initiative (ACTIVE): Progress and Future Directions&lt;br&gt;Frank Lloyd Wright Salon A-B</td>
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<td>4:45 pm – 4:55 pm</td>
<td>Discussion</td>
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<tr>
<td>4:55 pm – 5:30 pm</td>
<td>General Audience Discussion&lt;br&gt;Raye Litten, Ph.D. National Institute of Alcohol Abuse and Alcoholism</td>
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<td>2:30 pm - 5:30 pm</td>
<td>Dealing with Cross Cultural Differences in Standard Rating Scales in Psychiatric Research&lt;br&gt;Frank Lloyd Wright Salon C-D</td>
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<td>Lawrence H. Yang, Ph.D., Columbia University, Mailman School of Public Health</td>
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<td>2:40 pm – 3:00 pm</td>
<td>Validation Methods and Implementation&lt;br&gt;Considerations for International Use of Cognitive and Functional Outcomes&lt;br&gt;Richard Keefe, Ph.D., Duke University</td>
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<td>3:10 pm – 3:30 pm</td>
<td>Cross-cultural Differences in the Diagnosis and Assessment of Schizoaffective Disorder&lt;br&gt;Carla Canuso, M.D., Janssen Pharmaceutica, Inc.</td>
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2:30 pm - 5:30 pm (continued)  Dealing with Cross Cultural Differences in Standard Rating Scales in Psychiatric Research
*Frank Lloyd Wright Salon C-D*

3:40 pm – 4:00 pm  Preliminary Findings of Cross Cultural Differences with the Positive and Negative Syndrome Scale (Across 6 Geographical Regions) using Rasch Analysis
Lawrence H. Yang, Ph.D., Columbia University, Mailman School of Public Health

4:00 pm – 4:10 pm  Discussion

4:10 pm – 4:25 pm  Break

4:25 pm – 4:45 pm  Lost in Translation: Cross Cultural Differences in Depression, Anxiety, Functional Impairment and Suicidality Scales and Structured Diagnostic Interviews
David V. Sheehan, M.D., M.B.A., Depression & Anxiety Disorders Research Institute, University of South Florida College of Medicine

4:45 pm – 4:55 pm  Discussion

4:55 pm – 5:30 pm  General Audience Discussion

---

2:30 pm - 5:30 pm  *Keeping it Real: Quantifying Clinical Relevance in Treatments for Psychiatric Disorders
*Frank Lloyd Wright Salon G-H*

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

2:30 pm – 2:50 pm  Welcome and Introduction
Leslie Citrome, M.D., M.P.H., New York Medical College

2:50 pm – 3:00 pm  Teaching the Philosophy, Process, and Tools of Evidence-Based Medicine
Jamie Karagianis, M.D., Memorial University, Newfoundland

*of special interest to clinicians*
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<td><strong>Clinical Relevance in Treatments for Acute Bipolar Disorder</strong>&lt;br&gt;Terence Ketter, M.D., Stanford University School of Medicine</td>
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<td><strong>Clinical Relevance of Treatments for Schizophrenia</strong>&lt;br&gt;Taishiro Kishimoto, M.D., Ph.D., The Zucker Hillside Hospital</td>
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<td><strong>Communicating Benefits and Harms to Patients and Payors</strong>&lt;br&gt;Keming Gao, M.D., Ph.D., Case Western Reserve University School of Medicine</td>
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<td><strong>Circling Back: What Do Patients Really Care About?</strong>&lt;br&gt;Leslie Citrome, M.D., M.P.H., New York Medical College</td>
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*of special interest to clinicians*
## Strategies for Incomplete Data in Randomized Clinical Trials

**Chair:** David Sheehan, M.D., M.B.A., University of South Florida College of Medicine

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| 2:30 pm – 2:40 pm | **Introduction**  
David Sheehan, M.D., M.B.A., University of South Florida College of Medicine |
| 2:40 pm – 3:00 pm | **Clinically Practical Ways of Handling Incomplete Data: Experience from the Clinical Research Trenches**  
David Sheehan, M.D., MBA, University of South Florida College of Medicine |
| 3:00 pm – 3:10 pm | **Audience Discussion of Prevention Strategies** |
| 3:10 pm – 3:30 pm | **Sensible Approaches for Analyses of Incomplete Clinical Trial Data**  
Craig Mallinckrodt, Ph.D., Eli Lilly and Company |
| 3:30 pm – 3:40 pm | **Discussion** |
| 3:40 pm – 4:00 pm | **Analysis and Sensitivity Analysis for Incomplete Data from Clinical Studies**  
Geert Mohlenberghs, Ph.D., Hasselt University |
| 4:00 pm – 4:10 pm | **Audience Discussion on Analyses of Incomplete Data** |
| 4:10 pm – 4:25 pm | **Break** |
| 4:25 pm – 4:45 pm | **Application of ETRANK and Other Non-parametric Methods to handling Missing Data Analysis when Parametric Assumptions Fail**  
A. Richard Entsuah, Ph.D., Merck & Co, Inc. |
| 4:45 pm – 4:55 pm | **Audience Discussion of Regulatory Issues Regarding Incomplete Data** |
| 4:55 pm – 5:30 pm | **General Discussion** |
| 4:10 pm - 4:25 pm | **Coffee Break**  
*Frank Lloyd Wright Pre Function Central* |
**Friday, June 1, 2012**

**AT-A-GLANCE**

**Friday, June 1st**

7:30 am – 8:30 am  **New Investigator Awardee Roundtable**  
(Invitation Only)  
Aztec

7:30 am – 9:30 am  **Continental Breakfast**  
Frank Lloyd Wright Ballroom Foyer

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

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<thead>
<tr>
<th>Schedule</th>
<th>Session Title</th>
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<tr>
<td>NIAAA Panel - Targets to Treat Alcohol Dependence: New Human Studies</td>
<td><strong>Field Trial Testing of Proposed Revisions to DSM-5</strong></td>
<td>Frank Lloyd Wright Salon A-B</td>
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<td><strong>Identifying Biomarkers for Personalizing the Treatment of Depression – Implementation of Study Design and Initial Results in Subtype, Mechanism and Psychological Fields: An iSPOT-D Report</strong></td>
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<td><strong>Reaping the Benefits of Data Pooling and Sharing to Address Questions in Designing RCT’s and Predicting Outcomes of Antipsychotic and Antidepressant Drugs</strong></td>
<td>Frank Lloyd Wright Salon G-H</td>
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10:00 am – 10:15 am  **Coffee Break**  
Frank Lloyd Wright Ballroom Foyer

10:15 am – 11:45 am  **Regulatory Wrap-Up Session**  
Frank Lloyd Wright Salon E-F

12:00 pm  Meeting Adjourns

*of special interest to clinicians*
### New Investigator Awardee Roundtable
*Invitation Only*

7:30 am – 8:30 am

**Aztec**

### Continental Breakfast

7:30 am – 9:30 am

*Frank Lloyd Wright Ballroom Foyer*

### Panel Sessions

#### NIAAA Panel - Targets to Treat Alcohol Dependence: New Human Studies

**Frank Lloyd Wright Salon A-B**

- **Chair:** Raye Z. Litten, Ph.D., National Institute on Alcohol Abuse and Alcoholism

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<td><strong>A Double-blind, Placebo-Controlled Trial Assessing the Efficacy of Levetiracetam Extended-Release in Very Heavy Drinking Alcohol-Dependent Patients</strong></td>
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<td>8:55 am</td>
<td><strong>Effects of the Alpha-1 Noradrenergic Antagonist, Prazosin on Stress-induced Alcohol Craving, Anxiety and Brain Stress Dysregulation in Alcohol Dependent Individuals</strong></td>
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<td>8:55 am</td>
<td>Rajita Sinha, Ph.D., Foundations Fund Professor of Psychiatry</td>
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<td>9:20 am</td>
<td><strong>Pharmacogenetic Approach to Optimize Treatment Response to Ondansetron in Alcohol-Dependent Patients</strong></td>
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<td>9:20 am</td>
<td>Bankole Johnson, M.D., Ph.D., University of Virginia</td>
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<td><strong>General Discussion</strong></td>
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<td><strong>Chair:</strong> Darrel A. Regier, M.D., American Psychiatric Association</td>
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<td>8:30 am – 8:55 am</td>
<td>DSM-5 Field Trials in Academic or Large Clinical Settings</td>
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<td>Dimensional Measures in Psychiatric Diagnosis: Results from the DSM-5 Field Trials</td>
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<td>Testing DSM-5 in Routine Clinical Practice Settings</td>
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<td><strong>Chair:</strong> Evian Gordon, Ph.D., Brain Resource Ltd.</td>
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<td>8:30 am – 8:50 am</td>
<td>Protocol Design and Initial Results from the International Study to Predict Optimized Treatment in Depression: The iSPOT-D Study</td>
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<td>8:50 am – 9:10 am</td>
<td>Understanding Anxiety and its Relationship to Treatment Response in Depression: An iSPOT-D Report</td>
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*Frank Lloyd Wright Salon G-H* |
| 9:10 am – 9:30 am | **Prefrontal Dysfunction in Major Depression: Preliminary Functional Magnetic Resonance Imaging Results**  
Leanne Williams, Ph.D., University of Sydney |
| 9:30 am – 9:50 am | **Emotion Regulation Strategies and Treatment Response in Major Depressive Disorder: An iSPOT-D Report**  
Kateri McRae, Ph.D., University of Denver |
| 9:50 am – 10:00 am | **General Discussion**  
Evian Gordon, Ph.D., Brain Resource Ltd. |
| 8:30 am – 10:00 am | **Reaping the Benefits of Data Pooling and Sharing to Address Questions in Designing RCT's and Predicting Outcomes of Antipsychotic and Antidepressant Drugs**  
*Frank Lloyd Wright Salon I-J* |

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

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| 8:30 am – 8:55 am | **Improving Efficiency of RCT's of Antipsychotic Trials: Lessons Learned from the NewMeds Repository of RCT Data from AstraZeneca, Janssen, Eli Lilly, Lundbeck, and Pfizer**  
Jonathan Rabinowitz, Ph.D., Bar Ilan University |
| 8:55 am – 9:20 am | **Can Genome-wide Pharmacogenetics Help Predict Response of Antidepressant Treatment for Major Depressive Disorder: NewMeds Consortium of Academic and Industry-led Studies**  
Rudolf Uher, M.D., King’s College London |
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| 9:20 am – 9:45 am | Findings on Placebo Response and Treatment Effect from Pooled Analysis of Antipsychotic and Antidepressant Drugs Submitted to the FDA | Ni A. Khin, M.D., Food and Drug Administration                                                                                       |
| 9:45 am – 10:00 am | General Discussion | Bruce Kinon, M.D., Eli Lilly                                                                                                           |
| 10:00 am – 10:15 am | Coffee Break | *Frank Lloyd Wright Ballroom Foyer*                                                                                                   |
| 10:15 am – 11:45 am | Regulatory Wrap-Up Session | *Frank Lloyd Wright Salon E-F*  
Thomas Laughren, M.D., Food and Drug Administration  
Manuel Haas, PharmD, MSc, European Medicines Agency  
Karl Broich, M.D., Federal Institute of Drugs and Medical Devices                                                                 |
| 12:00 pm | Meeting Adjourns |                                                                                                                                          |
Wednesday, May 30th

12:30 pm – 2:30 pm  Poster Session I
McArthur Ballroom

1. The Alpha7 Neuronal Nicotinic Receptor (NNR) Modulator TC-5619 showed Efficacy Signals and was Generally Well Tolerated in a Phase 2 Trial in Adults with Attention-Deficit / Hyperactivity Disorder (ADHD)
   David Hosford, Targacept
   Paul Newhouse, Alexandra Potter, Geoffrey Dunbar, Jessica Beaver, Anthony Segreti

2. Reliability and Reliable Change of the CAARS Self-Report Short Version (CAARS-S:S) and Observer Screening Version (CAARS-O:SV) Scales in Adult ADHD
   Beth Friedmann, Worldwide Clinical Trials
   Lisle Kingery, Erin Kornsey, Cordelia Zakrajsek, Neal Cutler, Hank Riordan

3. Role of Patient Characteristics and Research Design Features in Clinical Trial Outcome of FDA Approved Medications for Attention-Deficit Hyperactivity Disorder: A Review of Publication Bias Free Data for 3,843 Patients
   Shirin Khan, Northwest Clinical Research Center
   James Faucett, Arif Khan

   J. Fowler, Duke Clinical Research Institute
   Steven Szabo, Ashwin Patkar, Barry Magnum, Wayne Beyer, Lan-Yan Yang, Shein-Chung Chow, Bruce Burnett, Brett Froeliger, Tong Lee

5. 5-HTT and DRD4 Genetic Polymorphisms and Family History as Moderators of Baclofen’s Effects on Drinking and Effects of Alcohol: A Preliminary Double-Blind Controlled Randomized Human Laboratory Study
   Lorenzo Leggio, Brown University
   George Kenna, William Zywiak, John McGeary, Steven Edwards, Samuel Fricchione, Tonya Tavares, Jessica Shoaff, Christine Goodwin, Eugenia Gurvich, Robert Swift

= New Investigator  ★ Pharmaceutical Pipeline
6. **NOP Agonism: A Novel Mechanism for the Treatment of Anxiety and Depression**
   Carla Canuso, Janssen Research & Development, LLC
   James Hutchison, Prasarn Manitpisitkul, John Moyer

7. **Trigeminal Nerve Stimulation in Post-traumatic Stress Disorder and Major Depression: A Novel Neuromodulation Approach**
   Ian Cook, UCLA Depression Research & Clinic Program, UCLA
   Department of Psychiatry
   Christopher DeGiorgio, Andrew Leuchter

8. **Mixed Depression: A Study of its Phenomenology and Relation to Treatment Response**
   Prakash Masand, Duke University Medical Center
   Chi-Un Pae, Paul Vöhringer, Niki Holtzman, Sairah Thommi, William Gilmer, Ashwin Patkar, S. Nassir Ghaemi

9. **The Efficacy of Memantine For Cognitive Deficits in Euthymic Subjects with Bipolar Disorder**
   Dan Iosifescu, Mount Sinai School of Medicine, Massachusetts General Hospital
   William Gilmer, Alexander Fan, Atilla Gonenc, Constance Moore, Christopher Randolph, Mark Rapaport, Thilo Deckersbach, Andrew Nierenberg

10. **Uridine Alters Frontal Lobe Phospholipid Metabolism and Reduces Depressive Symptoms in Adolescent Bipolar Depression: a Phosphorus-31 Magnetic Resonance Spectroscopy Study**
    Douglas Kondo, University of Utah Brain Institute
    Kristen Fiedler, Tracy Hellem, Xianfeng Shi, Young-Hoon Sung, Rebekah Huber, Perry Renshaw

11. **Cariprazine in the Treatment of Acute Mania in Bipolar Disorder: A Double-Blind, Placebo-Controlled, Phase III Trial**
    Anjana Bose, Forest Research Institute
    Anju Starace, Qing Wang, Elizabeth Diaz, Jennifer Goodman, Adam Ruth, György Németh, István Laszlovszky

12. **Carbamazepine Monotherapy Maintenance Treatment**
    Seville Gamer, RUMSC
    Eric Peselow

= New Investigator    * Pharmaceutical Pipeline
13. Six-Month Outcomes of Customized Adherence Enhancement (CAE) Therapy in Bipolar Disorder
Martha Sajatovic, Department of Psychiatry and Neurological Outcomes Center, Case Western Reserve University
Jennifer Levin, Curtis Tatsuoka, Weronika Micula-Gondek, Edna Fuentes-Casiano, Christopher Bialko, Kristin Cassidy

14. Relationship of Change in Adiposity to Psychiatric Symptom Change during Randomized Initial Antipsychotic Treatment in Pediatric Disruptive Behavior Disorders
Ginger Nicol, Washington University School of Medicine
Michael Yingling, Karen Flavin, Julia Schweiger, John Newcomer

15. The Lithium Archives Project: The Role of Lithium in the Protection of Neurodegenerative and Cardiovascular Disease
Monica Gilbert, Foundation for Mood Disorders
Ronald Fieve, Barbara Orlowski, Michael Oliva

Jessica Hellings, Kansas University Medical Center
Irfan Bhatti, Shumaila Younas

17. Depression in Mild Dementia: Preliminary Outcomes of a Pilot Intervention
Michelle Hilgeman, Tuscaloosa VA Medical Center, Tuscaloosa Research Education and Advancement Corporation (TREAC)

*18. Merck Neuroscience Pharmaceutical Pipeline: June 2012
Armin Szegedi, Merck & Company

19. The Effect of Desvenlafaxine 50 mg/d on a Subpopulation of Anxious/Depressed Patients: A Pooled Analysis of 7 Randomized, Placebo-Controlled Studies
Susan Kornstein, Virginia Commonwealth University School of Medicine
Christine Guico-Pabia, Rana Fayyad

20. Analysis of the Impact of Family History Subgroups on Drug Placebo Separation and Placebo Response on Tandem Rater and Computer Outcomes in RCTs
Gary Sachs, Bracket Global, Massachusetts General Hospital
Daniel DeBonis, Jean Dries

= New Investigator  Pharmaceutical Pipeline
21. **Biomarker Hypermapping as an Aid to the Stratification of Patients with Depression**
   Linda Thurmond, Ridge Diagnostics
   John Bilello, Bo Pi

22. **Predictors of Response & Remission with Desvenlafaxine 50 mg/d: A Pooled Analysis of Randomized, Placebo-Controlled Studies in Patients with Major Depressive Disorder**
   Claudio Soares, McMaster University & St. Joseph’s Healthcare
   Rana Fayyad, Cedric O’Gorman, Christine Guico-Pabia

23. **Early Clinical Development of the Opioid Modulator ALKS 5461 in the Treatment of Depression and Addiction**
   Elliot Ehrich, Alkermes, PLC
   Ryan Turncliff, Edward Sellers, Reese Jones, Maurizio Fava

24. **Lower Cronbach’s Alpha at Baseline than Next Visit in MDD Studies with and without Separate Inclusionary Scales**
   Joan Busner, Penn State College of Medicine, and Bracket
   David Daniel, Stuart Montgomery, John Bartko

25. **Lisdexamfetamine Dimesylate Augmentation in Escitalopram-Treated Adults with Major Depressive Disorder: Item Analyses of Depressive Symptom Scales**
   Brooke Geibel, Shire Development Inc., Ltd
   Robert Lasser, Cynthia Richards, Andrew Cutler, Ben Adeyi, Brian Scheckner, Angelo Sambunaris, Ashwin Patkar, Madhukar Trivedi

26. **Effects of the D-Amphetamine Prodrug, Lisdexamfetamine Dimesylate, and Antidepressant Medications on the Porsolt Behavioral Despair Test in Mice**
   Peter Hutson, Shire Development Inc., Ltd
   Jann Nielsen, Vincent Castagné, David Hackett

27. **Augmentation with the D-Amphetamine Prodrug, Lisdexamfetamine Dimesylate, of Antidepressant Medications: Effect on the Porsolt Behavioral Despair Test in Mice**
   Peter Hutson, Shire Development Inc., Ltd
   Vincent Castagné, David Hackett

= New Investigator  ⭐ Pharmaceutical Pipeline
28. **Efficacy of Right Unilateral Ultrabrief Pulse Electroconvulsive Therapy (ECT): Data from Phase 1 of the PRIDE Study**
Charles Kellner, Mount Sinai School of Medicine

29. **Item Analyses of Lisdexamfetamine Dimesylate Augmentation Effects on Depressive Symptoms in Adults with Major Depressive Disorder**
Manisha Madhoo, Shire Development, Inc.
Richard Keefe, Robert Roth, Angelo Sambunaris, James Wu, Madhukar Trivedi, Colleen Anderson, Robert Lasser

30. **A Novel V1a Receptor Antagonist and Potential Antidepressant, SRX246, Blocks Vasopressin Mediated Effects on Stress & Fear: an fMRI Study**
Neal Simon, Azevan Pharmaceuticals, Inc., Lehigh University
Royce Lee, Michael Brownstein, Emil Coccaro

31. **Functional Connectivity of the Default Mode Network in Person with Dysthymic Disorder: A Resting State FMRI Study**
Jonathan Posner, Columbia University
Bradley Peterson, Inbal Gat, Anna Mechling, David Hellerstein

32. **Sexual Satisfaction in Major Depressive Disorder before and after Treatment with SSRI in the STAR*D Study**
Waguih IsHak, Cedars-Sinai Medical Center and UCLA
Scott Christensen

33. **Symptomatic and Cognitive Response to Treatment in Depression**
Paul Maruff, University of Melbourne
Peter Snyder, Robert Pietrzak

34. **Vasopressinergic Modulation of Emotion: A Pilot fMRI Study**
Royce Lee, The University of Chicago
Emil Coccaro, Shi Fang Lu, Christophe Guillon, Karine Fabio, Brownstein Michael, Neal Simon

= New Investigator  * Pharmaceutical Pipeline
35. **Clinical Development of the Norepinephrine Reuptake Inhibitor Edivoxetine (LY2216684 HCl) for the Treatment of Major Depressive Disorder: Use of Pharmacokinetics, Pharmacodynamics and Biomarkers**
   William Kielbasa, Eli Lilly and Company
   Tonya Quinlan, Debra Luffer-Atlas, Malcolm Mitchell, Eshetu Wondmagegnehu, Michael Turik, Mary Anne Dellva, Sanjay Dube, Celine Goldberger

36. **A Pooled Analysis of Vilazodone in the Treatment of Major Depressive Disorder: Efficacy Across Symptoms**
   Arif Khan, Duke University School of Medicine, Northwest Clinical Research Center
   Wenjie Song, John Edwards, Adam Ruth

37. **Cytochrome P-450 2D6 Poor versus Extensive Phenotypes: Comparing Clinical Characteristics on an Inpatient Psychiatry Mood Disorders Unit**
   Simon Kung, Mayo Clinic
   Maria Lapid, Emily Johnson, Michael Govrik, Manuel Fuentes Salgado

38. **Predictors of Response and Remission during an Open-label 10-week Trial with Selegiline Transdermal System (STS)**
   Kimberly Portland, Dey Pharma, LP
   Sungwon Jung, Saeheon Jang, Chiun Pae, Prakash Masand, Paul Mastoridis, Ashwin Patkar

39. **Statistical Evaluation of the Power of the Arc Sine Test against the CMH test for Stratified Data for Smaller Proportions**
   Hewa Saranadasa, Symbiance
   Shawki Salem

40. **Translational Evaluation of JNJ-18038683, A Selective 5-HT7 Receptor Antagonist in Depression**
   Jaskaran Singh, Janssen R&D
   Michelle Kramer, Christine Dugovic, Nicholas Carruthers, De Boer Peter, Pascal Bonaventure, Timothy Lovenberg, Maurizio Fava

41. **Crossover Studies in Clinical Research: Experience with Carryover Effects**
   David Luckenbaugh, National Institute of Mental Health
   Carlos Zarate

= New Investigator  ★ Pharmaceutical Pipeline
42. **Genetic Predictors of Response to Antidepressant Treatment in Geriatric Depression using GWAS: A Pilot Study**  
Helen Lavretsky, UCLA  
Ascia Askin, Stan Nelson

43. **Clinical Trial Site Experiences & Attitudes Towards Prospective Assessments of Suicidal Ideation and Behavior (SIB): Results of a Global Internet-based Survey**  
Michelle Stewart, Pfizer, Inc.  
Adam Butler, Larry Alphs, Phil Chappell, Douglas Feltner, William Lenderking, Atul Mahableshwarkar, Clare Makumi, Sarah DuBrava

44. **7 Deadly Sins: Guidelines for Reporting Clinical Trial Methodology Research**  
Michael Detke, MedAvante, Inc., Indiana University School of Medicine  
Danielle Popp, Janet Williams

45. **Vilazodone is not a Substrate but may be a Weak Inhibitor of P-glycoprotein**  
Tobie Escher, Forest Research Institute  
Haijian (Jim) Zhu, Venugopal Marasanapalle, Patricia Gonzalez, Muhammad Ahasan, Haodan Yuan, Daksha Desai-Krieger, Ramesh Boinpally, Andreas Grill, Fuxing Tang

46. **Gender Contrasts and Similarities in Neural Underpinnings of Eating Behavior and BMI**  
Lawrence Maayan, Nathan S. Kline Institute for Psychiatric Research, New York University Medical Center  
Allison Larr, Melissa Benedict, Alexis Moreno, Laura Panek, Jay Nierenberg, Matthew Hoptman, Daniel Javitt, Francisco Castellanos, Michael Milham, Bennett Leventhal

47. **Bayesian Predictive Power for Adaptive Designs**  
Cynthia Siu, Data Power (DP), Inc.  
Carla Brambilla, Fabrizio Ruggeri

48. **5 Urban Legends of CNS Clinical Trial Methodology: Unsuccessful Solutions to the Problem of Failed Trials**  
Janet Williams, MedAvante, Inc., Department of Psychiatry, Columbia University  
Danielle Popp, Scott Reines, Michael Detke

= New Investigator  ★ Pharmaceutical Pipeline
49. **Paliperidone Palmitate (PP) for Maintenance Treatment of Schizoaffective Disorder (SCA): Baseline Data**  
Dong-Jing Fu, Janssen Scientific Affairs, LLC  
Ibrahim Turkoz, Richard Simonson, David Walling, Nina Schooler, Jean-Pierre Lindenmayer, Larry Alphs

50. **Patterns of Medication Adherence and Resource Utilization Among Patients with Schizoaffective Disorder (SCA)**  
Michael Markowitz, Janssen Scientific Affairs, LLC  
Sudeep Karve, Dong-Jing Fu, Jean-Pierre Lindenmayer, Chi-Chuan Wang, Sean Candrilli, Larry Alphs

51. **The Incidence of Tardive Dyskinesia in the Study of Pharmacotherapy for Psychotic Depression (STOP-PD)**  
Daniel Blumberger, Centre for Addiction and Mental Health  
Benoit Mulsant, Dora Kanellopoulos, Ellen Whyte, Anthony Rothschild, Alastair Flint, Barnett Meyers

52. **Development of a Rule Switching Test Designed to Assess Executive Control**  
Keith Wesnes, Bracket, Swinburne University  
Chris Edgar, Richard Wojciak, Howard Hassman, Maria Pinho, David Kreftez, Daniel Gruener, Lawrence Brownstein, Jean Dries

53. **Convergent Functional Genomics of Schizophrenia: From Comprehensive Understanding to Genetic Risk Prediction**  
Alexander Niculescu, Indiana University School of Medicine

54. **RP 5063 Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) in Schizophrenia**  
Marc Cantillon, Reviva  
Sarath Kanekal, Mike Li, Grace Li, Robert Ings, Kouacou Adiey, Laxminaran Bhat

55. **Cognitive Effects of Mecamylamine and Varenicline on Schizophrenia**  
Sungwon Roh, Center for Addiction Medicine, Massachusetts General Hospital  
Luke Stoeckel, A. Eden Evins

56. **Comparison of Outcomes in Patients with Early Phase versus Later Phase Schizophrenia**  
Peter Feldman, Lilly Research Laboratories  
Holland Detke, Christoph Correll, Chunxu Liu, John Landry, David McDonnell

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57. **Incidence and Time Course of Extrapyramidal Symptoms (EPS): Oral vs. Long-Acting Injectable (LAI) Paliperidone**
   David Hough, Janssen Research & Development
   Srihari Gopal, Yanning Liu, Larry Alphs, Adam Savitz, Isaac Nuamah

58. **Within-Drug Benefit/Risk of Olanzapine LAI at 1 and 2 Years of Treatment**
   Michael Shepherd, Eli Lilly Canada, Inc.
   Holland Detke, John Lauriello, Susan Watson, David McDonnell, John Landry

59. **Examining Methods for Computing “Clinical Response” in Placebo Controlled Trials of Antipsychotics in the NEWMEDS Repository**
   Jonathan Rabinowitz, Bar Ilan University
   Nomi Werbeloff, François Menard, Judith Jaeger, Bruce Kinon, Virginia Stauffer, Francine Mandel, Shitij Kapur

60. **A Chemical Biology Approach to Identify Disease Signatures in Schizophrenia and Bipolar Disorder using iPSC-derived Neuronal Cells: Implications for High-throughput Screening**
   Rakesh Karmacharya, Massachusetts General Hospital, McLean Hospital
   Steven Sheridan, Sabine Bavamian, Jennifer Wang, Kraig Theriault, Elizabeth O’Brien, Sigrun Gustafsdottir, Katherine Madden, Donna McPhie, Roy Perlis, Dost Ongur, Alykhan Shamji, Anne Carpenter, Bruce Cohen, Stuart Schreiber, Stephen Haggarty

61. **PNB02: A Beneficial Treatment for Insufficient Response with Single Agent Treatment in Schizophrenia?**
   Erik Buntinx, PharmaNeuroBoost NV
   Ludo Haazen, Didier de Chaffoy, Philip Harvey

62. **Lurasidone for the Acute Treatment of Adults with Schizophrenia: What is the Number Needed to Treat, Number Needed to Harm, and Likelihood to be Helped or Harmed?**
   Leslie Citrome, Nathan S. Kline Institute for Psychiatric Research

63. **Bleak House: A Study of Schizophrenia in the Era of Deinstitutionalization**
   Reuven Ferziger, Janssen Scientific Affairs, LLC
   Lian Mao, Cynthia Bossie, Larry Alphs

= New Investigator  ★ Pharmaceutical Pipeline
64. Cognitive Performance in Patients with Schizophrenia Treated with Lurasidone: Results from a 6-week Core Study and 6-month Double-blind Extension
Philip Harvey, University of Miami Miller School of Medicine
Cynthia Siu, Josephine Cucchiaro, Antony Loebel

65. A Pilot Study of Cognitive Remediation in a Forensic Setting
Anthony Ahmed, Georgia Health Sciences University

66. The Impact of Study Design in Comparative Effectiveness Research in Schizophrenia
Bruce Wong, Bruce Wong Consulting
Noam Kirson, Yermakov Sander, Wayne Huang, Thomas Samuelson, Steve Offord, Greenberg Paul

67. Switching to Lurasidone in Schizophrenia: Tolerability and Effectiveness of Three Strategies
Josephine Cucchiaro, Sunovion Pharmaceuticals Inc.
Joseph McEvoy, Leslie Citrome, David Hernandez, Joseph Severs, Antony Loebel

68. Evaluation of the Accuracy of Applying Item Response Theory (IRT) Linking to an Abbreviated Version of the Positive and Negative Syndrome Scale (PANSS) for Evaluation and Refinement
Anzalee Khan, Nathan S. Kline Institute for Psychiatric Research
Jean-Pierre Lindenmayer, Charles Lewis, Saurabh Kaushik

69. Safety and Tolerability of Cariprazine in the Long-Term Treatment of Schizophrenia: Results From a 48-Week Extension Study
Andrew Cutler, Florida Clinical Research Center, LLC
Anjana Bose, Suresh Durgam, Raffaele Migliore, Qing Wang, Adam Ruth, György Németh, István Laszlovszky

70. The Effect of the α2-adrenergic Receptor Antagonist Fluparoxan on a COMT-Val-tg Mouse Model of Cognitive Dysfunction
Ayana Gibbs, University of Sussex

Taishiro Kishimoto, The Zucker Hillside Hospital
Alfred Robenzadeh, Claudia Leucht, Stefan Leucht, Koichiro Watanabe, Masaru Mimura, John Kane, Christoph Correll

= New Investigator  Pharmaceutical Pipeline
72. **Effect of 12 Months of Treatment with Lurasidone on Weight in Subjects With Schizophrenia**  
Jonathan Meyer, Department of Psychiatry, University of California, San Diego  
Yongcai Mao, Andrei Pikalov, Josephine Cucchiaro, Antony Loebel

73. **Impact Of Antipsychotic Drug Adherence on the Management of Schizophrenia Among US Medicare Patients**  
Dario Mirski, Otsuka America Pharmaceutical, Inc.  
Steve Offord, Bruce Wong, Jay Lin, Ross Baker

74. **Age at Antipsychotic Drug Initiation and Hospitalization Risk: A US Health Claims Database Analysis**  
John Newcomer, Leonard M. Miller School of Medicine, University of Miami  
Krithika Rajagopalan, Andrei Pikalov, Masaaki Ogasa, Cynthia Siu, Antony Loebel

75. **NSA-16 Revisited: Identifying Latent Factors of Negative Symptoms in Schizophrenia**  
Danielle Popp, MedAvante, Inc.  
Janet Williams, Elan Cohen, Michael Detke

76. **Efficacy and Safety/Tolerability of 2 Approaches for Switching to Iloperidone in Patients With Schizophrenia**  
Peter Weiden, University of Illinois at Chicago  
Gus Alva, Matthew Brams, Leslie Citrome, Ira Glick, Richard Jackson, Greg Mattingly, Carrie Guindon, Farid Kianifard, Linda Pestreich, Adam Winseck, Marla Hochfeld

77. **Transdifferentiation of Macrophages into Neuronal-Like-Cells as a Potential Model for Treatment Prediction in Schizophrenia**  
Alfredo Bellon, University of Miami, INSERM

78. **Bayesian Modeling to Predict Placebo Responders in a Schizophrenia Trial using the Positive and Negative Syndrome (PANSS) Subscale Scores, in the Initial Weeks of Treatment**  
Christian Yavorsky, Cronos CCS  
Anzalee Khan, Guillermo DiClemente, Mark Opler, Ashleigh DeFries, Brian Rothman, Sofija Jovic

79. **Daytime Sleepiness as a Mediator of Treatment Outcome in a Placebo- and Quetiapine XR- controlled Trial of Lurasidone in Patients with Schizophrenia**  
Henry Nasrallah, University of Cincinnati College of Medicine  
Robert Silva, Andrei Pikalov, Josephine Cucchiaro, Jane Xu, Cynthia Siu, Anthony Loebel

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Thursday, May 31st

12:15 pm – 2:15 pm  Poster Session II
McArthur Ballroom

1. **Relationship of ADHD Symptom and Global Severity Assessments in Adults with ADHD and Executive Function Deficits Treated with Lisdexamfetamine Dimesylate**
   Thomas Babcock, Shire Development, Inc.
   Lenard Adler, Joel Young, Bryan Dirks, Patrick Deas, Ben Adeyi, Richard Weisler

2. **Lisdexamfetamine Dimesylate Effects on Self-Reported Executive Function and Quality of Life in Adults with Attention-Deficit/Hyperactivity Disorder: Focus on Emotional and Social Domains**
   Bryan Dirks, Shire Development, Inc.
   Ann Childress, Richard Weisler, Patrick Deas, Ben Adeyi, Lenard Adler

3. **Profiles of Lisdexamfetamine and Methylphenidate in Rats Trained to Discriminate d-amfetamine from Saline**
   David Heal, RenaSci, Ltd
   Jane Gosden, Nigel Slater, David Hackett

4. **A Microdialysis and Behavioural Comparison of Lisdexamfetamine and Methylphenidate in Freely-moving Rats**
   Helen Rowley, RenaSci, Ltd
   David Hackett, Rajiv Kulkarni, David Heal

5. **Comparing Participant-reported Memory Problems with Memory Performance Tests in Chronic Marijuana Users**
   Alan Boyd, CNS Vital Signs
   Bryan Porterfield, Scott Goddard, Kevin Gray

6. **The Alpha-1 Adrenergic Antagonist Doxazosin for Treatment of Cocaine Dependence**
   Daryl Shorter, Houston VAMC/Baylor College of Medicine
   Jan Lindsay, Thomas Kosten

7. **General Medical Burden in Bipolar Disorders: Findings from the LiTMUS Comparative Effectiveness Trial**
   David Kemp, Case Western Reserve University
   Louisa Sylvia, Joseph Calabrese, Andrew Nierenberg, Michael Thase, Noreen Reilly-Harrington, Michael Ostacher, Andrew Leon, Terence Ketter, Edward Friedman, Charles Bowden, Michael Pencina, Dan Iosifescu

= New Investigator Awardee
8. Diminished P300 Amplitude in Bipolar Men with a History of Suicide in a Visual Go/NoGo Event Related Potential Study
Masoud Kamali, University of Michigan Health Systems, Department of Psychiatry
Jinsoo Chun, Lisa O’Donnell, Patricia Deldin, Melvin McInnis

9. Sedation Intensity during Dose Escalation of Quetiapine XR or IR in Bipolar Depression: A Multicenter, Double-Blind, Randomized, Phase IV Study
Catherine Datto, AstraZeneca Pharmaceuticals, LP
Irina Baldycheva, Robert Riesenberg

10. Higher Open Stabilization Rate with Adjunctive Aripiprazole in Acute Manic Compared with Mixed Episodes in Bipolar I Patients
Terence Ketter, Stanford University
Elizabeth Bellocchio, James Eudicone, Robert Forbes, Zia Rahman, Berit Carlson

11. The Embla: An Innovative Device for Monitoring Sleep in Bipolar Disorder
Anna Urdahl, Massachusetts General Hospital
Louisa Sylvia, Matt Bianchi, Leah Shesler, Stephanie McMurrich, Andrew Nierenberg, Thilo Deckersbach

12. A Novel Tool for Tracking Changes in Prescribed Medication and its use in Comparative Effectiveness Research
Leah Shesler, Massachusetts General Hospital
Noreen Reilly-Harrington, Louisa Sylvia, Anna Urdahl, Andrew Leon, Dan Iosifesco, Michael Ostacher, Thilo Deckersbach, Andrew Nierenberg

13. Sleep Disturbance Predicts the Frequency of Clinically Significant Depressive Symptoms in Women with Bipolar Disorder
Erika Saunders, Penn State College of Medicine, University of Michigan
Julio Fernandez-Mendoza, Masoud Kamali, Scott Langenecker, Kelly Ryan, Melvin McInnis, Alan Gelenberg

14. Change in Glucose and Lipid Metabolism using Stable Isotope Tracing during Euglycemic Clamp Conditions during Initial Antipsychotic Treatment for Disruptive Behavior in Youth
Ginger Nicol, Washington University School of Medicine, Pfizer, Inc.
John Newcomer, Michael Yingling, Julia Schweiger, Karen Flavin, Martha Hessler
15. **The US and EU Pediatric Initiatives: A Rising Opportunity for Pediatric Psychopharmacology**  
Jeffrey Apter, Princeton Medical Institute  
Philippe Auby

16. **Second Generation Antipsychotics and Risk of Type 2 Diabetes in Publicly Insured Children and Adolescents**  
Tobias Gerhard, Rutgers University Institute for Health, Rutgers University Ernest Mario School of Pharmacy  
William Bobo, Stephen Crystal, Mark Olfson

17. **A Cognitive Task Sensitive to Dentate Gyrus Activity which has Implications for Assessing Neurogenesis Status in Aging and Various Clinical Conditions**  
Keith Wesnes, Bracket, Swinburne University

18. **Speech as a Marker of Prodromal Huntington’s Disease**  
Adam Vogel, University of Melbourne  
Andrew Churchyard, Chris Shirbin, Julie Stout

19. **Differential Association of Cognitive Function with Stress and Depressive Symptoms by BDNF val66met Genotype in Patients with Coronary Artery Disease**  
Walter Swardfager, Sunnybrook Health Sciences Centre, Toronto Rehabilitation Institute  
Nathan Herrmann, Mahwesh Saleem, Paul Oh, Paul Albert, Krista Lanctôt

20. **Regional Patterns in Baseline Efficacy Scale Internal Consistency in an International MDD Clinical Trial – Can Poor Ratings Patterns Improve?**  
Joan Busner, Penn State College of Medicine and Bracket  
David Daniel, Stuart Montgomery, John Bartko

21. **Trajectories of Symptom Changes in Depression Clinical Trials**  
Craig Mallinckrodt, Eli Lilly and Company  
Ralitza Gueorguieva, John H. Krystal

22. **Gaze Bias for Negative Emotion Stimuli as a Marker for Symptomatic Change in Dysphoric Individuals: A Preliminary Method Validation for the Empirical Study of Placebo Response**  
Kari Nations, University of Texas  
Seth Disner, Christopher Beevers

= New Investigator Awardee
23. Relapse Rates in Psychotic Depression are Lower than in Non-psychotic Depression after a Successful Course of Electroconvulsive Therapy (ECT)
Georgios Petrides, The Zucker Hillside Hospital, Northshore-LIJ Health System
Rebecca Knapp, Mustafa Husain, Teresa Rummans, Max Fink, Martina Mueller, Samuel Bailine, Charles Kellner

24. Surveillance Strategies to Improve Study Outcomes in a Depression Study
Manny Asgharnejad, CeNeRx
Steven Targum, Daniel Burch, Michael Gibertini, Maurizio Fava

25. Levomilnacipran in the Treatment of Major Depressive Disorder: Functional Health and Well-being Efficacy Results From a Phase III Clinical Trial
Steven Blum, Forest Research Institute
Stavros Tourkodimitris, Adam Ruth

26. Levomilnacipran in the Treatment of Major Depressive Disorder: An Analysis of Efficacy Data From 2 Phase III Studies
Anjana Bose, Forest Research Institute
Carl Gommoll, Hua Li, Adam Ruth, Tobie Escher

27. Early and Sustained Response Achieved Across Multiple Measures with Adjunctive Aripiprazole in MDD Patients with an Inadequate Response to Antidepressant Monotherapy
Daniel Casey, Oregon Health and Science University
Kimberly Laubmeier, James Eudicone, Ronald Marcus, Robert Berman, Ross Baker, Jack Sheehan

28. Selegiline Transdermal System (STS) for Major Depressive Disorder (MDD): Use Pattern, Adherence, and Effect on Health Service Expenditures
Lawrence Cohen, Washington State University
David Sclar, Kimberly Portland

29. The Efficacy of Levomilnacipran in the Treatment of Major Depressive Disorder: Results from a Phase III Clinical Trial
Tobie Escher, Forest Research Institute
Carl Gommoll, Anjana Bose, Changzheng Chen, Adam Ruth

= New Investigator Awardee
30. **Efficacy and Tolerability of Vilazodone in Patients with Moderate, Moderately Severe, and Severe Depression - Pooled Analyses From 2 Phase III Trials**
   Tobie Escher, Forest Research Institute
   Donald Robinson, Wenjie Song, John Edwards, Adam Ruth

31. **A Pilot Study of ALKS 5461 (Buprenorphine Combined with ALKS 33) in Treatment Resistant Depression**
   Maurizio Fava, Massachusetts General Hospital
   J. Alexander Bodkin, Michael Thase, Madhukar Trivedi, Richard Leigh-Pemberton, Yangchun Du, Elliot Ehrich

32. **The Clinical Impact of an Antidepressant Pharmacogenomic Algorithm**
   Kevin Furmaga, Pine Rest Christian Mental Health Services, Michigan State University College of Human Medicine
   LeAnn Smart, Eric Achtyes

33. **Relationships between GABA Levels and Functional Connectivity are Disrupted in Adolescent Major Depressive Disorder**
   Vilma Gabbay, New York University Child Study Center, Nathan S. Kline Institute
   Benjamin Ely, Chuqing Kang, Barbara Coffey, Francisco Castellanos, Dikoma Shungu, Michael Milham

34. **Levomilnacipran in the Treatment of Major Depressive Disorder: An Analysis of Safety and Tolerability Data from 2 Randomized Placebo-Controlled Trials**
   William Greenberg, Forest Research Institute
   Hua Li, Carl Gommoll, Adam Ruth, Tobie Escher

35. **Effects of Citalopram and Escitalopram on fMRI Response to Affective Stimuli in Healthy Volunteers Selected by 5-HTTLPR Genotype**
   Michael Henry, Steward St. Elizabeth’s Medical Center, McLean Hospital
   Tara Lauriat, Steven Lowen, Jeffrey Churchill, Colin Hodgkinson, David Goldman

36. **Does Prior Antidepressant Treatment of Major Depression Impact Brain Function During Current Treatment?**
   Aimee Hunter, UCLA Department of Psychiatry
   Ian Cook, Andrew Leuchter

= New Investigator Awardee
37. **Clinical Profiles of Response and Remission in STAR*D**
Felipe Jain, UCLA Semel Institute for Neuroscience and Resnick Neuropsychiatric Hospital
Aimee Hunter, John Brooks, Andrew Leuchter

38. **The Clinical Relevance of Results Achieved with Vilazodone in the Treatment of Major Depressive Disorder**
Arif Khan, Duke University School of Medicine, Northwest Clinical Research Center
John Edwards, Wenjie Song, Adam Ruth

39. **Adjunctive Aripiprazole Doubles the Rate of Early and Sustained Response in MDD Patients with an Inadequate Response to Antidepressant Monotherapy**
Kimberly Laubmeier, Bristol-Myers Squibb
Daniel Casey, James Eudicone, Ronald Marcus, Robert Berman, Ross Baker, Jack Sheehan

40. **Development of a New Depression Rating Scale, The Rosenberg Mood Scale**
Leon Rosenberg, Center for Emotional Fitness
Howard Hassman

41. **Repeated Administrations of Ketamine in Treatment-Resistant Major Depression: Rapid Antidepressant Effects and Durability of Response**
James Murrough, Mount Sinai School of Medicine
Andrew Perez, Sarah Pillemer, Jessica Stern, Kyle Lapidus, Laili Soleimani, Diogo Alves, Dennis Charney, Dan Iosifescu

42. **Selegiline Transdermal System (STS) for Major Depressive Disorder (MDD) with Atypical Features: A Post-hoc Analysis of Data from an Open-label, 10-week Trial**
Terry Painter, Dey Pharma, LP
Saeheon Jang, Sungwon Jung, Chiun Pae, Kimberly Portland, Rob Mariani, Paul Mastoridis, Ashwin Patkar

43. **L-methylfolate Produces a Robust Effect on Core Symptoms using Maier Subscale Scores in a Randomized Clinical Trial of Patients with Major Depression**
George Papakostas, Massachusetts General Hospital
Stephen Stahl

= New Investigator Awardee
44. **Predictors of Relapse in a Fixed-dose, Randomized, Double-blind, 52-week Relapse Prevention Trial of Selegiline Transdermal System (STS)**
   Kimberly Portland, Dey Pharma, LP
   Saeheon Jang, Sungwon Jung, Chiun Pae, Paul Mastoridis, Ashwin Patkar

45. **Pooled Analysis of Three Trials of Adjunctive Aripiprazole in Major Depressive Disorder Patients: What CGI-S Score is a Logical Definition of Response in Depression?**
   Jack Sheehan, Bristol-Myers Squibb
   Daniel Casey, Kimberly Laubmeier, James Eudicone, Ronald Marcus, Robert Berman, Ross Baker

46. **Vilazodone in the Treatment of Major Depressive Disorder: Effects on Weight and Laboratory Values**
   Michael Thase, University of Pennsylvania School of Medicine
   Wenjie Song, John Edwards, Adam Ruth

47. **Interaction of Antidepressant Medications and Non-Steroidal Anti-Inflammatory Drugs Differentially Affects Outcome of Treatment**
   Marisa Toups, UT Southwestern
   Madhukar Trivedi, Jennifer Warner-Schmidt, Thomas Carmody, Benji Kurian, Maurizio Fava

48. **The Impact(s) of Family Psychiatric History on Signal Detection and Placebo-Response: Meta-Analysis**
   Charles Wilcox, Pharmacology Research Institute [PRI]
   Nader Oskooilar, Judy Morrissey, Daniel Grosz, Mellissa Henry, Kimberly Guevarra, Don De Francisco

49. **Psychometric Evaluation of the Brown Assessment of Beliefs Scale**
   Katharine Phillips, Rhode Island Hospital, Warren Alpert Medical School of Brown University
   Ashley Hart, William Menard, Jane Eisen

50. **Attitudes of Investigators and Site Staff Toward Placebo Response in International CNS Clinical Trials**
    David Daniel, United BioSource Corporation
    Antony Loebel, Josephine Cucchiaro, Jean Dries

= New Investigator Awardee
51. **Influence of 3 Protocol-Specific Eligibility Criteria on Signal Detection**  
Gary Sachs, Bracket  
Douglas Vanderburg, Suzanne Edman

52. **Scientific and Economic Benefits of Sequential Parallel Comparative Design (SPCD), a Cost Efficient Approach to the Problem of Placebo Response**  
Matt Bowman, RCT Logic  
Ilan Fogel, Michael Knable

53. **Going Electronic: Moving Data and Discovery to Pharmacology Teachers**  
Ira Glick, Stanford University School of Medicine

54. **Psychiatry on YouTube: Information or Misinformation?**  
Rajnish Mago, Thomas Jefferson University  
Aashna Mago, Rahul Gupta

55. **A Structured Interview for Assessing Global Impressions**  
David Walling, Collaborative Neuroscience Network  
Celine Houser, Joanne Northcutt, Ira Glick, Andrew Cutler, Donald Garcia, Michael Downing, Jessica Little, Steven Targum

56. **Olanzapine, Melatonin Suppression and Weight Gain**  
Nael Kilzieh, VAPSHCS, University of Washington  
Dennis Rasmussen, Murray Raskind, Annette Kennedy, Amanda Wood, Andre Tapp

57. **The Impact of Patient Recruitment Methods on Data Quality**  
Brian Hunter, Clinical Neuroscience Solutions, Inc.  
Patricia Brown, Linda Harper, John Joyce, Susan Angel, Leann Carmichael, Lora McGill

58. **Test-Retest Reliability of fMRI Measures of Amygdala Activation Elicited by Emotional Stimuli Among Healthy Adults**  
Colin Sauder, Stony Brook University  
Joseph Blader, Greg Hajcak, Mike Angstadt, K. Luan Phan

59. **Health Economic Modeling Schizophrenia Outcomes Using Time to Event Simulation**  
Nicolas Furiak, Medical Decision Modeling Inc.  
Harry Smolen, James Gahn, Megha Bansal

= New Investigator Awardee
60. **MAPK14 and CNR1 Gene Variant Interactions: Effects on Brain Volume Deficits in Schizophrenia Patients with Marijuana Misuse**
Obiora Onwuameze, Carver College of Medicine University of Iowa

61. **Which Schizophrenia Patients Relapse Despite Adherence to Long-Acting Antipsychotic Therapy?**
David Hough, Janssen Pharmaceutical Research and Development, LLC
Henry Nasrallah, Ibrahim Turkoz, Cynthia Bossie, Srihari Gopal, Larry Alphs

62. **Efficacy of Lurasidone in Schizophrenia: Factor Analysis Of Short-term Trials**
Josephine Cucchiaro, Sunovion Pharmaceuticals, Inc.
Robert Silva, Yongcai Mao, Antony Loebel, Stephen Marder

63. **Long-term Safety and Tolerability of Once-monthly Aripiprazole Intramuscular Depot (ARI-IM-depot) for Maintenance Treatment in Schizophrenia**
Robert Forbes, Otsuka Pharmaceutical Development and Commercialization, Inc.
Wolfgang Fleischhacker, Raymond Sanchez, Pam Perry, Na Jin, Brian Johnson, Robert McQuade, William Carson, John Kane

64. **Factors Affecting Placebo Separation in a Clinical Trial for Cognitive Impairment in Schizophrenia**
Michael Hufford, NeuroCog Trials
Maria Gawryl, Nancy Dgetluck, Vicki Davis, Stephen Murray, Richard Keefe, Dana Hilt

65. **Patient-reported Outcomes with Aripiprazole Intramuscular Depot (ARI-IM-Depot) for Long-term Maintenance Treatment in Schizophrenia**
Brian Johnson, Otsuka Pharmaceutical Development and Commercialization, Inc.
Raymond Sanchez, Na Jin, Robert Forbes, William Carson, Robert McQuade, John Cane, Wolfgang Fleischhacker

66. **Efficacy of Aripiprazole Intramuscular Depot (ARI-IM-Depot) for the Long-Term Maintenance Treatment of Schizophrenia**
John Kane, The Zucker Hillside Hospital and The Hofstra North Shore-LIJ School of Medicine
Raymond Sanchez, Pam Perry, Na Jin, Brian Johnson, Robert Forbes, Robert McQuade, William Carson, Wolfgang Fleischhacker

= New Investigator Awardee
67. **Adjunctive Lisdexamfetamine Dimesylate Treatment of Predominant Negative Symptoms of Schizophrenia: Post-hoc Analysis by Global Improvement Criteria**
Jean-Pierre Lindenmayer, New York University School of Medicine
Bryan Dirks, Henry Nasrallah, Courtney Kirsch, Ben Adeyi, Brian Scheckner, Robert Lasser

68. **Lurasidone vs. Quetiapine XR For Relapse Prevention In Schizophrenia: A 12-Month, Double-Blind Study**
Anthony Loebel, Sunovion Pharmaceuticals, Inc.
Josephine Cucchiaro, Jane Xu, Kaushik Sarma, Andrei Pikalov, John Kane

69. **Open Board**

70. **Effects of a Long-acting Injectable Formulation of Aripiprazole on Secondary Efficacy Outcomes in Maintenance Treatment of Schizophrenia**
Pam Perry, Otsuka Pharmaceutical Development and Commercialization, Inc.
William Carson, Raymond Sanchez, Na Jin, Robert Forbes, Robert McQuade, Wolfgang Fleischhacker, John Kane

71. **Assessment of Change in Body Weight after Antipsychotic Treatment is Confounded by Regression to the Mean**
Cynthia Siu, Data Power (DP), Inc.
Jane Xu, Josephine Cucchiaro, Andrei Pikalov, Antony Loebel

72. **An Evaluation of the Psychometric Properties of the Brief Negative Symptom Scale (BNSS) in Individuals with Schizophrenia**
Gregory Strauss, University of Maryland School of Medicine
Lauren Catalano, James Gold, William Keller, Robert Buchanan, William Carpenter, Brian Kirkpatrick

73. **The Evaluation of Negative Symptoms by Videoconferencing in a Clinical Trial**
Janet Williams, MedAvante, Inc., Department of Psychiatry, Columbia University
Danielle Popp, Douglas Osman, Elan Cohen, Michael Detke

74. **Open Board**
75. **Reliability of the Global Assessment of Functioning Scale in Patients with Excessive Sleepiness associated with Shift Work Disorder**  
Christian Yavorsky, Cronos Clinical Consulting Services  
Anzalee Khan, Mark Opler, Guillermo DiClemente, Brian Rothman, Ashleigh DeFries, Sofija Jovic

76. **Lamotrigine Dosing for Pregnant Patients with Bipolar Disorder**  
Crystal Clark, VA Pittsburgh Healthcare System, Western Psychiatric Institute and Clinic, University of Pittsburgh  
Autumn Klein, Katherine Wisner

77. **Cognitive-Behavioral Therapy in Women Discontinuing Antidepressant in Anticipation of Pregnancy**  
Lee Cohen, Massachusetts General Hospital, Center for Women’s Mental Health  
Christina Psaros, Marlene Freeman, Steven Safren, Maria Barsky

78. **Pregnancy Outcomes Among Women using Antipsychotic Drugs**  
Simone Vigod, Women’s College Hospital and University of Toronto, Institute for Clinical Evaluative Sciences  
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FUTURE NCDEU ANNUAL MEETING DATES

- **May 28 - 31, 2013** - Westin Diplomat, Hollywood, Florida

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**EMERGENCY INFORMATION SHEET**

The ASCP Executive Office has developed the following information to assist you in case of an emergency. Please ensure that someone not attending the meeting with you has the following information:

**Meeting Name:** 52nd Annual NCEDU Meeting

**Meeting Location:** Arizona Biltmore Resort, 2400 East Missouri Ave, Phoenix, AZ 85016

**Hotel Phone Number:** +1-602-955-6600

**ASCP Executive Office Number:** +1-615-324-2365

Additionally, your contact should have the following:

- Your cell phone number (if applicable)
- Your lodging information including room number
- Your transportation information

**LOCAL INFORMATION**

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<tr>
<td>Phoenix, AZ 85008</td>
<td>350 West Thomas Road</td>
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<tr>
<td>602.808.8786</td>
<td>Phoenix, AZ 85013</td>
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**EMERGENCY PROCEDURES**

The Arizona Biltmore is fully prepared to handle different types of situations to assist our guests. The following is information on our emergency procedures:

- The hotel internal emergency number is 11. Please dial 11 to be connected to our emergency line.
- The hotel has an emergency response team 24 hours a day. In the event of an emergency, calling the emergency number 11 will initiate the appropriate response.
- Paramedics, Fire Department, and the Police Department are all located approximately 3 minutes from the hotel.
- Our Security Department, as well as a small number of other employees, are trained in CPR and First Aid.
- Emergency evacuation routes and procedures are located on the inside of all guest room doors.
Save the Date: NCDEU 2013
May 28-31, 2013
Westin Diplomat • Hollywood, Florida