



NCDEU 52nd Annual Meeting

*An annual meeting sponsored by the American
Society of Clinical Psychopharmacology (ASCP)*

*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



ASCP
AMERICAN SOCIETY OF
CLINICAL PSYCHOPHARMACOLOGY

Welcome to the 52nd Meeting of NCDEU – the New NCDEU



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CLINICAL PSYCHOPHARMACOLOGY

On behalf of the American Society of Clinical Psychopharmacology we are pleased to welcome you to this year's NCDEU meeting. The ASCP is proud to sponsor the meeting, now in its 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.

A handwritten signature in black ink that reads "John M. Kane, M.D." in a cursive style.

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
 - o The meeting is now formally sponsored by the ASCP.
 - o A Steering Committee is responsible for organization of the meeting, and a Program Committee is responsible for evaluating submitted proposals and developing program innovations.
 - o 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).
 - o Regulatory agency collaborations include both the Food and Drug Administration (FDA) and the European Medicines Authority (EMA).
 - o Parthenon Management Group is organizing the NCDEU Meeting.
- Program Innovations
 - o Asterisks in the program identify sessions that will be of particular interest to clinicians because they highlight treatment advances of immediate clinical relevance.
 - o The meeting starts on Tuesday, May 29th with Panel Presentations, New Research Reports and the popular new feature, Pharma Pipeline Session.
 - o The Wednesday Plenary Session will feature leaders of NIMH, NIDA and NIAAA to update attendees on the latest news from the NIH institutes.
 - o 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.
 - o 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.
 - o NIMH, NIDA and NIAAA have organized panel sessions.
 - o 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
 - o The New Investigator Program includes a workshop for the 20 New Investigators and informal breakfast sessions.
 - o NCDEU Workshops – three hour intensive and interactive sessions focused on problems and solutions on Wednesday & Thursday afternoon.
 - o NCDEU Reception from 6:30 pm – 8:00 pm on Wednesday the 30th.
 - o 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 Schooler, 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**

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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 Interventional 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 performed clinical and research work at hospitals of the Universities of Bonn, Halle/Saale and Philadelphia (PennU) (Board certifications in Neurology, Psychiatry, Behavioural Psychotherapy). He served as Head of the Section Neurology/Psychiatry from 2000 to 2005 and became the department head from 2005 to 2009. Since 2009, Dr. Broich has been the deputy head (Vice-President) at the Federal Institute for Drugs and Medical Devices (BfArM). 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.

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.

Steering Committee Chairs



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



Nina R. Schooler, Ph.D.

Program Chairs



David J. Kupfer, M.D.



Carlos A. Zarate, M.D.

New Investigator Award Program Chairs



Lauren D. Hill, Ph.D.



Mark H. Rapaport, M.D.

Steering Committee Members

- Karl Broich, M.D.
Federal Institute of Drugs and Medical Devices, BfArM, Germany
- Maurizio Fava, M.D.
The Massachusetts General Hospital (ASCP Board Member)
- Marlene Freeman, M.D.
The Massachusetts General Hospital (ASCP Board Member)
- Donald Goff, M.D.
The Massachusetts General Hospital
- Robert K. Heinssen, Ph.D., A.B.P.P.
National Institute of Mental Health
- John M. Kane, M.D.*
The Zucker Hillside Hospital and Albert Einstein College of Medicine
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- Bruce Kinon, M.D.
Eli Lilly & Company
- David J. Kupfer, M.D.
University of Pittsburgh School of Medicine
- Thomas P. Laughren, M.D.
Food and Drug Administration
- Raye Litten, Ph.D.
National Institute of Alcohol Abuse and Alcoholism
- Husseini K. Manji, M.D., F.R.C.P.C
Johnson & Johnson Pharmaceutical Research & Development
- David Michelson
Merck & Company, Inc.
- John Newcomer, M.D.
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- William Z. Potter, M.D., Ph.D.
Neuroscience Steering Committee, FINH (ASCP Board Member)
- Nina R. Schooler, Ph.D.
State University of New York, Downstate Medical Center
- Philip Skolnick, Ph.D., D.Sc.
National Institute on Drug Abuse
- ★ Carlos A. Zarate, M.D.
National Institute of Mental Health

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

New Investigator Award Program Committee

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

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

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

Mark H. Rapaport, M.D.*
Emory University School of Medicine (ASCP Board Member)

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

Nina R. Schooler, Ph.D.
State University of New York, Downstate Medical Center
- ★ Holly A. Swartz, M.D.
University of Pittsburgh School of Medicine

Program Committee

- Katherine Beebe, Ph.D.
Titan Pharmaceuticals, Inc.

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

Lori Davis, M.D.
Tuscaloosa VA Medical Center

Michael Egan, M.D.
Merck & Company

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

★New Investigator Alumnae *Representing ASCP CME Committee

Program Committee (continued)

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

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

John Greist, M.D.
Healthcare Technology Systems, Inc.

Richard Keefe, Ph.D.
Duke University Medical Center

Terence Ketter, M.D.
Stanford University School of Medicine

Helena Kraemer, Ph.D.
Stanford University

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

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

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

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

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

Stephen Marder, M.D.
Semel Institute, UCLA

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

Thomas Newton, M.D.
Baylor College of Medicine

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

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

Program Committee (continued)

Jerrold Rosenbaum, M.D.
Massachusetts General Hospital

Neil Ryan, M.D.
University of Pittsburgh School of Medicine

Martha Sajatoric, M.D.
University Hospitals Case Medical Center

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

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

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

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

Karen Wagner, M.D.
University of Texas, Galveston (ASCP Board Member)

★ Janet Williams, D.S.W.
MedAvante

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

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

★New Investigator Alumnae *Representing ASCP CME Committee

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Meeting Services

Registration Desk Hours:

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

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



ASCP
AMERICAN SOCIETY OF
CLINICAL PSYCHOPHARMACOLOGY

The American Society for Clinical Psychopharmacology (ASCP) designates this live meeting for a maximum of 23.5 *AMA PRA Category 1*

*Credit(s)*TM. 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.

NCDEU 2013 – The 53rd meeting of NCDEU will take place May 28 – 31, 2013 at the Westin Diplomat in Hollywood Beach, Florida. Details regarding abstract submission for the 2013 will be released in September, 2012.

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AT-A-GLANCE

Monday, May 28th

8:30 am – 4:30 pm	New Investigator Workshop (Invitation Only) Aztec
12:00 pm – 5:00 pm	Registration Open Frank Lloyd Wright Ballroom Foyer
4:00 pm	ASCP Board Meeting Kaibab

[illegible]

8:30 am – 4:30 pm

Aztec Room

New Investigator Workshop (INVITATION ONLY)

Co-Chairs: Mark H. Rapaport, M.D., Emory University School of Medicine
Lauren D. Hill, Ph.D., National Institute of Mental Health

The NCDEU meeting offers a special program for new investigators in an effort to promote the education and training of junior investigators in psychopharmacology. Established investigators were asked to nominate individuals who may be interested in a research career in psychopharmacology for this special program. These nominees submitted an abstract describing their current research or area of research interest, a letter of recommendation from their chair or mentor, a career statement and a curriculum vitae. The selection of awardees was based upon the scientific merit of the abstract, the level of training of the nominee and a committee of internal and external reviewers' assessment of the relative value of the specialized program to each applicant at this time in his/her career. The awardees will participate in this special educational workshop and present their posters during the scheduled poster sessions. In addition, they will receive a travel expense award and a certificate acknowledging their participation in the program at an award ceremony on Tuesday evening, May 29. This year's 20 New Investigator awardees are indicated with a ribbon in the poster section of this program.

Faculty

Mark T. Bunker, PharmD, B.C.P.P.
Cyberonics, Inc.

Wilson Compton, M.D.
National Institute on Drug Abuse

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

Mark H. Rapaport, M.D.
Emory University School of Medicine

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

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

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

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

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

New Investigator Awardees

Anthony Ahmed, Ph.D.
Georgia Health Sciences University

Alfredo Bellon, M.D., Ph.D.
University of Miami

Daniel Blumberger, M.D., M.S.
Centre for Addiction and Mental
Health

Crystal Clark, M.D.
VA Pittsburgh Healthcare System

Tobias Gerhard, Ph.D.
Rutgers University Institute for Health

Ayana Gibbs, B.S., M.D., Ph.D.
University of Sussex

Michelle Hilgeman, B.S., Ph.D.
Tuscaloosa VA Medical Center

Felipe Jain, M.D.
UCLA Semel Institute for
Neuroscience
and Resnick Neuropsychiatric
Hospital

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

Obiora Onwuameze, M.D., Ph.D., M.S.
Carver College of Medicine University
of Iowa

Sungwon Roh, M.D., Ph.D.
Center for Addiction Medicine,
Massachusetts General Hospital

Colin Sauder, M.S.
Stony Brook University

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

*Gregory Strauss, Ph.D.
University of Maryland School of
Medicine

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

*Andrew Leon Memorial Travel Awardee

AT-A-GLANCE

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**

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

- 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**

<i>Trial Design and Methodology</i>	<i>*New Treatments in Depression & Anxiety</i>	<i>Special Issues in Patient Grouping: Biomarkers, Medical Comorbidity and Attitudes</i>
Location: Frank Lloyd Wright Salon A-B	Location: Frank Lloyd Wright Salon C-D	Location: Frank Lloyd Wright Salon G-H

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**

<i>NIDA & NIAAA Panel - Neuroimmune Targets for Treatment of Substance and Alcohol Use Disorders</i>	<i>*Rapidly-Acting Antidepressant Therapies: The NIMH-Sponsored RAPID Network</i>	<i>*Emerging Clinical Evidence on Oxytocin in Schizophrenia</i>	<i>Identifying Common Targets in Treating Impulse Control Disorders</i>
Location: Frank Lloyd Wright Salon A-B	Location: Frank Lloyd Wright Salon C-D	Location: Frank Lloyd Wright Salon G-H	Location: Frank Lloyd Wright Salon I-J

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

- 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

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*

9:00 am – 10:30 am (continued) ***The Clinical Implications of Chronic Hyponatremia in Mental Health and Aging: New Findings**
Frank Lloyd Wright Salon G-H

10:00 am – 10:20 am **Hyponatremia in Psychosis and Depression: Treatment Guidelines and Future Directions**
Richard C. Josiassen, Ph.D., Drexel University College of Medicine

10:20 am – 10:30 am **General Discussion**
Joseph Verbalis, M.D., Georgetown University Medical Center

9:00 am – 10:30 am **New Opportunities and Strategies for NIMH Funding**
Frank Lloyd Wright Salon I-J

Chair: Christopher Sarampote, Ph.D., National Institute of Mental Health

9:00 am – 9:15 am **Demystifying Review at NIMH**
Aileen Schulte, Ph.D., National Institute of Mental Health

9:15 am – 9:30 am **Dimensional Approaches to Research Classification in Psychiatric Disorders (RDoC)**
Michael Kozak, Ph.D., National Institute of Mental Health

9:30 am – 9:45 am **Innovative Pilot Studies of Novel Mechanism of Action Compounds for Treating Psychiatric Disorders**
Christopher Sarampote, Ph.D., National Institute of Mental Health

9:45 am – 10:00 am **Late Breaking News from NIMH**
Tracy Waldeck, Ph.D., National Institute of Mental Health

10:00 am – 10:15 am **Catching and Shepherding Your Application**
Jean G. Noronha, Ph.D., National Institute of Mental Health

10:15 am – 10:30 am **General Discussion**
Tracy Waldeck, Ph.D., National Institute of Mental Health

**of special interest to clinicians*

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

Individual Research Reports

10:45 am – 11:45 am **Trial Design and Methodology**
Frank Lloyd Wright Salon A-B

Chair: Alan Breier, M.D., Indiana University

10:45 am – 11:00 am **A Research Tool to Assess Age-related Declines in Cognitive Function**
Keith A. Wesnes, B.S., Ph.D., Bracket, Swinburne University

11:00 am – 11:15 am **Adverse Events in Regulatory Clinical Trials of Second Generation Antipsychotics: Changes Over Time during the Past Two Decades**
Laszlo Tombor, M.D., Semmelweis University

11:15 am – 11:30 am **Are Large Numbers of Investigative Sites Associated with Symptom Improvement on Placebo in Antipsychotic Randomized Controlled Trials (RCTs)? A Meta-Analytic Review**
Robert Litman, M.D., CBH Health, LLC

11:30 am – 11:45 am **Prediction of Suicide in Clinical Trials using the C-SSRS**
Kelly Posner, M.D., Columbia University

10:45 am – 11:45 am ***New Treatments in Depression & Anxiety**
Frank Lloyd Wright Salon C-D

Chair: Richard Keefe, Ph.D., Duke University

10:45 am – 11:00 am **Personalized Therapy with Adjunctive L-methylfolate in Patients with SSRI-Resistant Depression**
Maurizio Fava, M.D., Massachusetts General Hospital

**of special interest to clinicians*

**10:45 am – 11:45 am
(continued)**

***New Treatments in Depression & Anxiety**
Frank Lloyd Wright Salon C-D

11:00 am – 11:15 am

rTMS in Treatment Resistant Depression: A Systematic Review

Bradley N. Gaynes, M.D., UNC School of Medicine

11:15 am – 11:30 am

D-Cycloserine Augmentation of CBT for Social Anxiety Disorder: Results from an RCT

Mark H. Pollack, M.D., Rush University Medical Center

11:30 am – 11:45 am

A High-throughput Clinical Assay for Testing Drug Facilitation of Learning-based Psychotherapy

Eric J. Lenze, M.D., Washington University

10:45 am – 11:45 am

Special Issues in Patient Grouping: Biomarkers, Medical Comorbidity and Attitudes
Frank Lloyd Wright Salon G-H

Chair: Tiffany Farchione, M.D., Food and Drug Administration

10:45 am – 11:00 am

Decreased Occipital Glutathione Levels in Tourette's Disorder

Vilma Gabbay, M.D., M.S., New York University Child Study Center, Nathan S. Kline Institute

11:00 am – 11:15 am

Cardiovascular Risk Factors in Individuals with Bipolar II Disorder

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

11:15 am – 11:30 am

Why Do Some Depressed Outpatients Who are in Remission According to the Hamilton Depression Rating Scale not Consider Themselves to be in Remission?

Mark Zimmerman, M.D., Rhode Island Hospital

11:30 am – 11:45 am

How Similar are Patients Who Participate in Randomized Controlled Trials from those Who Don't?

Alisa B. Busch, M.D., McLean Hospital/Harvard Medical School

11:45 am – 1:00 pm

Lunch on own

**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
(continued)**

***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

3:55 pm – 4:15 pm

**Intranasal Oxytocin Treatment in Schizophrenia:
Improvement in Social Cognition, PANSS Social
Item Scores and Verbal Learning**
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*

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AT-A-GLANCE

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**

<i>Gamma-Aminobutyric Acid Alterations across Psychiatric Disorders</i>	<i>*Developing the Next Generation of Antidepressants</i>	<i>*Trajectory-based Disease - Modifying Treatments in Pediatric Psychiatry</i>	<i>Neuroendocrine Changes in MDD and BD: Clinical and Biological Markers</i>	<i>DSM-5 and Psychopathology Domains as Therapeutic Indications</i>
Location: Frank Lloyd Wright Salon A-B	Location: Frank Lloyd Wright Salon C-D	Location: Frank Lloyd Wright Salon E-F	Location: Frank Lloyd Wright Salon G-H	Location: Frank Lloyd Wright Salon I-J

- 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**

<i>*Fatigue Across the CNS Spectrum: Symptom or Side Effect</i>	<i>Psychosocial Treatment Platforms in Psychopharmacology RCTs</i>	<i>*Moderators and Mediators of Treatment Outcome in Late Life Depression</i>	<i>Comparative Effectiveness Trials in Bipolar Disorder: What Have We Learned and Where Do We Need To Go From Here?</i>
Location: Frank Lloyd Wright Salon A-B	Location: Frank Lloyd Wright Salon C-D	Location: Frank Lloyd Wright Salon G-H	Location: Frank Lloyd Wright Salon I-J

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

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

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.

**8:30 am – 9:30 am
(continued)**

Plenary - Institute Directors' Report
Frank Lloyd Wright Salon E-F

9:00 am – 9:30 am

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.

9:30 am – 10:00 am

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

9:30 am – 10:00 am
(continued)

Medications Development for Alcohol Dependence: A Vision for the Next Decade

Kenneth R. Warren, Ph.D.

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.

9:30 am – 10:30 am **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.

10:30 am – 10:45 am **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*

**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

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

10:45 am – 12:15 pm **DSM-5 and Psychopathology Domains as Therapeutic Indications**
Frank Lloyd Wright Salon I-J

Chair: Rajiv Tandon, M.D., State of Florida Program of Mental Health

10:45 am – 11:05 am **Psychotic Disorders and Psychopathology Domains in DSM-5**
Rajiv Tandon, M.D., State of Florida Program of Mental Health

11:05 am – 11:25 am **Implications of Cross-cutting Dimensions for Clinical Trials Methodology**
Stephen Marder, M.D., UCLA

11:25 am – 11:45 am **Industry Perspective on Psychotic Disorders and Symptom Dimensions**
Ellen B. Dennehy, Ph.D., Eli Lilly and Company

11:45 am – 12:05 pm **Relating Symptom Dimensions to RDoC Behaviors and Neural Circuits**
Gregory Strauss, Ph.D., University of Maryland School of Medicine Maryland Psychiatric Research Center

12:05 pm – 12:15 pm **General Discussion**
Carlos Zarate, M.D., National Institute of Mental Health

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

**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.

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.

2:45 pm – 2:50 pm

Introduction: The Many Faces of Fatigue

Steven D. Targum, M.D., Clintara LLC.

2:50 pm – 3:00 pm

Fatigue Associated with Major Depressive Disorder

Maurizio Fava, M.D., Massachusetts General Hospital

3:00 pm – 3:10 pm

Discussion

3:10 pm – 3:20 pm

**Fatigue Associated with Neurological Disorders:
Focus on Multiple Sclerosis**

Thomas Wessel, M.D., Berkshire Drug Development Consulting LLC

3:20 pm – 3:30 pm

Discussion

3:30 pm – 3:40 pm

**Differentiating Negative Symptoms from Fatigue
and other Comorbid Conditions in Schizophrenia**

Larry Alphs, M.D., Janssen Scientific Affairs LLC.

3:40 pm – 3:50 pm

Discussion

3:50 pm – 4:00 pm

ADHD and Fatigue

Lynn Starr, M.D., Janssen Scientific Affairs LLC

4:00 pm – 4:10 pm

Discussion

4:10 pm – 4:25 pm

Break

4:25 pm – 4:35 pm

Fatigue and Alzheimer's Disease

Dana Hilt, M.D., Envivo Pharmaceuticals

4:35 pm – 4:45 pm

Discussion

4:45 pm – 4:55 pm

Health Outcome Issues Related to Residual Fatigue

Michael F. Murphy, M.D., Worldwide Clinical Trials

4:55 pm – 5:05 pm

Discussion

5:05 pm – 5:45 pm

General Audience Discussion

**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

2:45 pm – 5:45 pm

***Moderators and Mediators of Treatment Outcome
in Late Life Depression**
Frank Lloyd Wright Salon G-H

Chair: Craig Nelson, M.D., UCSF

2:45 pm – 2:55 pm

Introduction

2:55 pm – 3:10 pm

**Efficacy of Antidepressants in Late Life Depression
and Moderators of Response**
Craig Nelson, M.D., UCSF

3:10 pm – 3:20 pm

Discussion

3:20 pm – 3:35 pm

**Efficacy of Antidepressants in Older Depressed
Patients with Vascular Depression and/or
Executive Dysfunction or Vascular Depression**
Warren D. Taylor, M.D., MHSc, Duke University School
of Medicine

3:35 pm – 3:45 pm

Discussion

3:45 pm – 4:00 pm

**Efficacy of Antidepressants in Older Depressed
Patients with Alzheimer's Disease and the Potent-
tial for Augmentation with Cognitive Enhancers in
Depressed Patients with Cognitive Impairment**
D. P. Devanand, M.D., Columbia University

4:00 pm – 4:10 pm

Discussion

4:10 pm – 4:25 pm

Break

4:25 pm – 4:40 pm

**White Matter Abnormalities, Activation of
Cognitive and Emotional Control Networks, and
Late Life Depression**
Faith Gunning-Dixon, Ph.D., Weill Cornell Medical
College

4:40 pm – 4:50 pm

Discussion

4:50 pm – 5:05 pm

**Cerebral Perfusion and Cognitive Functioning in
Late Life Depression**
R. Scott Mackin, Ph.D., UCSF

5:05 pm – 5:15 pm

Discussion

5:15 pm – 5:45 pm

General Audience Discussion

**of special interest to clinicians*

2:45 pm – 5:45 pm **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

[illegible]

AT-A-GLANCE

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**

<i>Biologics for Addictions Treatment: Vaccines and Enzymes</i>	<i>*Novel Methods for Evaluating the Harm-Benefit Balance in Outcomes of Randomized Clinical Trials: Demonstration of a New Approach</i>	<i>*Food “Addiction”: Conceptualization, Assessment and Applications to Obesity</i>	<i>Long Term Outcome of Childhood Disorders and Its Predictors</i>
Location: Frank Lloyd Wright Salon A-B	Location: Frank Lloyd Wright Salon C-D	Location: Frank Lloyd Wright Salon G-H	Location: Frank Lloyd Wright Salon I-J

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

**of special interest to clinicians*

2:30 pm - 5:30 pm

Concurrent Workshop Sessions

<i>The Alcohol Clinical Trials Initiative (ACTIVE): Progress and Future Directions</i> Location: Frank Lloyd Wright Salon A-B	<i>Dealing with Cross Cultural Differences in Standard Rating Scales in Psychiatric Research</i> Location: Frank Lloyd Wright Salon C-D	<i>*Keeping it Real: Quantifying Clinical Relevance in Treatments for Psychiatric Disorders</i> Location: Frank Lloyd Wright Salon G-H	<i>Strategies for Incomplete Data in Randomized Clinical Trials</i> Location: Frank Lloyd Wright Salon I-J
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4:10 pm - 4:25 pm

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).

**8:30 am – 10:00 am
(continued)**

**Regulatory Plenary - New FDA and EMA Initiatives
in Depression and Schizophrenia**
Frank Lloyd Wright Salon E-F

8:50 am – 9:10 am

**FDA Review of Maintenance Trials for Major
Depressive Disorder: A 25-Year Perspective**
Silvana Borges, M.D., Food & Drug Administration

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.

9:10 am – 9:40 am

**FDA Initiative to Establish Data Standards in
Schizophrenia Drug Development**
Phillip Kronstein, M.D., Food & Drug Administration

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.

9:40 am – 10:00 am

Discussion

10:00 am – 10:30 am

Coffee Break
Frank Lloyd Wright Ballroom Foyer

Panel Sessions

10:30 am – 12:00 pm **Biologics for Addictions Treatment: Vaccines and Enzymes**
Frank Lloyd Wright Salon A-B

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

10:30 am – 10:50 am **Nicotine Vaccine Recent Developments**
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

11:10 am – 11:30 am **Cocaine Vaccine: Genetic and Immunological Response Predictors**
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

11:50 am – 12:00 pm **General Discussion**
Dave McCann, Ph.D., National Institute on Drug Abuse

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

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

10:30 am – 10:55 am **Rationale for an Integrated Harm-Benefit Measure**
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

**of special interest to clinicians*

**10:30 am – 12:00 pm
(continued)**

***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 <i>Frank Lloyd Wright Salon A-B</i>
Chairs:	Raymond F. Anton, M.D. Medical University of South Carolina Raye Litten, Ph.D. National Institute of Alcohol Abuse and Alcoholism
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

**2:30 pm - 5:30 pm
(continued)**

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

4:45 pm – 4:55 pm

Discussion

4:55 pm – 5:30 pm

General Audience Discussion

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

2:30 pm - 5:30 pm

**Dealing with Cross Cultural Differences in
Standard Rating Scales in Psychiatric Research**
Frank Lloyd Wright Salon C-D

Chair: Lawrence H. Yang, Ph.D., Columbia University, Mailman School of
Public Health

2:30 pm – 2:40 pm

Welcome and Introductions

Lawrence H. Yang, Ph.D., Columbia University,
Mailman School of Public Health

2:40 pm – 3:00 pm

**Validation Methods and Implementation
Considerations for International Use of Cognitive
and Functional Outcomes**

Richard Keefe, Ph.D., Duke University

3:00 pm – 3:10 pm

Discussion

3:10 pm – 3:30 pm

**Cross-cultural Differences in the Diagnosis and
Assessment of Schizoaffective Disorder**

Carla Canuso, M.D., Janssen Pharmaceutica, Inc.

3:30 pm – 3:40 pm

Discussion

**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*

**2:30 pm - 5:30 pm
(continued)**

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

3:00 pm – 3:10 pm

Discussion

3:10 pm – 3:20 pm

**Clinical Relevance in Treatments for Acute Bipolar
Disorder**

Terence Ketter, M.D., Stanford University School of
Medicine

3:20 pm – 3:30 pm

Discussion

3:30 pm – 3:40 pm

Clinical Relevance of Treatments for Schizophrenia

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

3:40 pm – 3:50 pm

Discussion

3:50 pm – 4:00 pm

**Communicating Benefits and Harms to Patients
and Payors**

Keming Gao, M.D., Ph.D., Case Western Reserve
University School of Medicine

4:00 pm – 4:10 pm

Discussion

4:10 pm – 4:25 pm

Break

4:25 pm – 4:35 pm

**Circling Back: What Do Patients Really Care
About?**

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

4:35 pm – 4:45 pm

Discussion

4:45 pm – 5:30 pm

General Audience Discussion

**of special interest to clinicians*

2:30 pm - 5:30 pm

Strategies for Incomplete Data in Randomized Clinical Trials

Frank Lloyd Wright Salon I-J

Chair:

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

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 Entsuaah, 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

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**

<i>NIAAA Panel - Targets to Treat Alcohol Dependence: New Human Studies</i>	<i>*Field Trial Testing of Proposed Revisions to DSM-5</i>	<i>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</i>	<i>Reaping the Benefits of Data Pooling and Sharing to Address Questions in Designing RCT's and Predicting Outcomes of Antipsychotic and Antidepressant Drugs</i>
Location: Frank Lloyd Wright Salon A-B	Location: Frank Lloyd Wright Salon C-D	Location: Frank Lloyd Wright Salon G-H	Location: Frank Lloyd Wright Salon I-J

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*

[illegible]

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

Panel Sessions

8:30 am – 10:00 am **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

8:30 am – 8:55 am **A Double-blind, Placebo-Controlled Trial Assessing**
the Efficacy of Levetiracetam Extended-Release in
Very Heavy Drinking Alcohol-Dependent Patients
Raye Litten, Ph.D., National Institute on Alcohol Abuse
and Alcoholism

8:55 am – 9:20 am **Effects of the Alpha-1 Noradrenergic Antagonist,**
Prazosin on Stress-induced Alcohol Craving,
Anxiety and Brain Stress Dysregulation in Alcohol
Dependent Individuals
Rajita Sinha, Ph.D., Foundations Fund Professor of
Psychiatry

9:20 am – 9:45 am **Pharmacogenetic Approach to Optimize Treatment**
Response to Ondansetron in Alcohol-Dependent
Patients
Bankole Johnson, M.D., Ph.D., University of Virginia

9:45 am – 10:00 am **General Discussion**
Raye Z. Litten, Ph.D., National Institute on Alcohol
Abuse and Alcoholism

8:30 am – 10:00 am ***Field Trial Testing of Proposed Revisions to DSM-5**
Frank Lloyd Wright Salon C-D

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

8:30 am – 8:55 am **DSM-5 Field Trials in Academic or Large Clinical Settings**
Darrel A. Regier, M.D., American Psychiatric Association

8:55 am – 9:20 am **Dimensional Measures in Psychiatric Diagnosis: Results from the DSM-5 Field Trials**
William E. Narrow, M.D., American Psychiatric Association

9:20 am – 9:45 am **Testing DSM-5 in Routine Clinical Practice Settings**
Eve K. Moscicki, Sc.D., M.P.H., American Psychiatric Institute for Research and Education

9:45 am – 10:00 am **General Discussion**
David J. Kupfer, M.D., University of Pittsburgh Medical Center

8:30 am – 10:00 am **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**
Frank Lloyd Wright Salon G-H

Chair: Evian Gordon, Ph.D., Brain Resource Ltd.

8:30 am – 8:50 am **Protocol Design and Initial Results from the International Study to Predict Optimized Treatment in Depression: The iSPOT-D Study**
Evian Gordon, Ph.D., Brain Resource Ltd.

8:50 am – 9:10 am **Understanding Anxiety and its Relationship to Treatment Response in Depression: An iSPOT-D Report**
Amit Etkin, M.D., University of Stanford

**of special interest to clinicians*

**8:30 am – 10:00 am
(continued)** **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**
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


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

8:30 am – 10:00 am (continued)	Reaping the Benefits of Data Pooling and Sharing to Address Questions in Designing RCT's and Predicting Outcomes of Antipsychotic and Antidepressant Drugs <i>Frank Lloyd Wright Salon I-J</i>
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 <i>Frank Lloyd Wright Ballroom Foyer</i>
10:15 am – 11:45 am	Regulatory Wrap-Up Session <i>Frank Lloyd Wright Salon E-F</i> 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
4. **Development and Pharmacokinetic Characterization of Delayed, Pulsatile-release Ondansetron Formulation**
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



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- ✱ 6. **NOP Agonism: A Novel Mechanism for the Treatment of Anxiety and Depression**
Carla Canuso, Janssen Research & Development, LLC
James Hutchison, Prasarn Manitsitkul, 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



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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 Orłowski, Michael Oliva
16. **Noradrenergic Contributors to Aggression and Self-Injury in Autism Spectrum Disorders: Atomoxetine Treatment Outcomes in a Case Series**
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



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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



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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
Mustafa Husain, Rebecca Knapp, W. Vaughn McCall, Georgios Petrides, Shirlene Sampson, Robert Young, Robert Greenberg, Shawn McClintock, Martina Mueller, Kristen Tobias, Richard Weiner, Mimi Briggs, Rosa Pasculli, Sarah Lisanby
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



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- * 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



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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



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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 Kreftz, 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



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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 $\alpha 2$ -adrenergic Receptor Antagonist Fluparoxan on a COMT-Val-tg Mouse Model of Cognitive Dysfunction**
Ayana Gibbs, University of Sussex

71. **New Results Alter Balance of Evidence of Long-Acting Injectable vs. Oral Antipsychotics Regarding Relapse Prevention in Schizophrenia: A Systematic Review and Meta-Analysis**

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



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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-amphetamine 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



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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 Riesenber
- 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
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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



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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



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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



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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



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-  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




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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 Touns, 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



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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



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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



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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**



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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
Joel Ray, Tara Gomes, Valerie Taylor



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FUTURE NCDEU ANNUAL MEETING DATES

- **May 28 - 31, 2013** - *Westin Diplomat, Hollywood, Florida*
 - **June 16 - 19, 2014** - *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

<u>Nearest Urgent Care Facility:</u> Urgent Care: 2301 North 44th Street Phoenix, AZ 85008 602.808.8786	<u>Nearest Hospital & Emergency Room:</u> St. Joseph's Thomas and 3rd 350 West Thomas Road Phoenix, AZ 85013 602.406.3000
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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



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