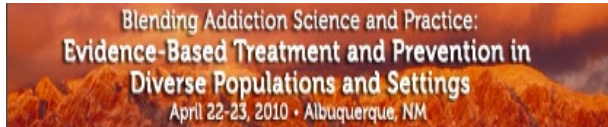




Clinical Trials Network

CTN Bulletin
February 17, 2010
Volume 10 - 03

Blending Conference and Call for Posters



The NIDA Blending Conference entitled *Blending Addiction Science and Practice: Evidence-Based Treatment and Prevention in Diverse Populations and Settings* will be held April 22-23, 2010, in Albuquerque, New Mexico. The information and registration web site is www.NIDABlendingConference.info

Designed to narrow the "translational gap," the 2010 NIDA Blending Conference will highlight the utilization of scientific evidence to support clinical practice with diverse populations and settings. Over 30 presentations are scheduled and include:

- Promising New Treatments Including Vaccines
- Substance Use Among High Risk Adolescents: Related Risks and Treatment Challenges
- Veteran Issues and Substance Use Disorders
- Treatment Through the Criminal Justice System
- Evidence-Based Practices for Women
- Smoking Prevention and Early Intervention

Hotel Rooms Going Fast

You are strongly encouraged to make your room reservations early. At this time, only a few hotel rooms remain available at the Hyatt Regency Albuquerque. To ensure lodging at the Doubletree Hotel, [Click here to make your reservation today.](#)

Poster Session

This year will highlight scientific posters each day of the conference. We are inviting two groups to submit posters: Individuals involved in NIDA's Clinical Trials Network (CTN) and professionals who are not affiliated with the CTN (General submission).

Community treatment providers, researchers, public health professionals, doctoral students and others are invited to submit a poster abstract for consideration as a poster presenter. Although original reports are preferred, posters displayed at a meeting within the past 12 months may also be accepted. Please [click here](#) to download and submit an application form. The application must be completed in full and submitted **by February 20, 2010.**

CTN is a program of the National Institute on Drug Abuse, part of the National Institutes of Health within the Department of Health and Human Services.

Blending Posters Do Not Need Prior PC Approval!



The Publications Committee (PC) reviews CTN posters and papers prior to their going public, but for the upcoming Blending Conference, the PC will accept submissions for review CONCURRENT with submission to the Conference. *PC review prior to submission is not required for these posters.* Some posters may already have received prior PC review, and that suffices. PC reviewers may request or require changes to posters' summary text that will be printed in the conference program. Thanks to PC Chair, Dr. George Bigelow, for clarification on this review!

Register Now for CTN Meeting



The spring CTN Steering Committee will be held April 19-20, followed by the CTN 10th Anniversary event on April 21 and the NIDA Blending Conference on April 23-24. All events will take place in Albuquerque. Registration is at: <http://www.seiservices.com/NIDA/CTN/Meetings/>

Special CTN 10th Anniversary Edition of JSAT



A special edition of the Journal of Substance Abuse Treatment (JSAT) will focus on the 10th anniversary of the CTN. The special issue is on schedule for publication at the end of March and will greet attendees at the upcoming Steering Committee and 10th Anniversary Meetings in Albuquerque in April. A lot of hard work went into putting this edition together. The unanimous support from all of the Node PIs made this possible. Deep appreciation goes to all the contributing authors for their tenacity in submitting great manuscripts. We look forward to reading it in April!

CTN 0046 S-CAST Open For Business!



Dr. Theresa Winhusen, Lead Investigator for the CTN 0046 study *Smoking-Cessation and Stimulant Treatment (S-CAST): Evaluation of the Impact of Concurrent Outpatient Smoking-Cessation and Stimulant Treatment on Stimulant-Dependence Outcomes*, is pleased to announce that the first study site received endorsement and the study is now "open for business." The staff at Maryhaven, Inc. (Ohio Valley) received endorsement on Tuesday, February 16th, and are eagerly awaiting their first randomization. At press time, the study staff at Dorchester (Southern Consortium) were awaiting finalization of the endorsement process, and were anticipating launching later the same week. Congratulations to all the staff at each of those sites, and the Lead Node looks forward to having all Wave 1 sites on board soon!

Project AWARE Gets GO Grant



Dr. Lisa Metsch from the Florida Node and Dr. Grant Colfax from the California/Arizona Node are pleased to announce that they have received

ARRA funding for a two year study that builds on the CTN 0032: HIV Rapid Testing and Counseling in Drug Abuse Treatment Study in the U.S. This new study, **Project AWARE: HIV Rapid Testing & Counseling in STD Clinics in the U.S.**, will evaluate whether receiving a rapid HIV test and counseling is more effective and more cost effective than rapid testing alone in reducing STI incidence among individuals receiving health care in sexually transmitted diseases clinics in the United States. This issue was identified as a top priority for comparative effectiveness by the Institute of Medicine. The study will randomize 5,000 patients in 9 clinics, and the sample size will be large enough to allow meaningful subgroup analyses including racial/ethnic groups, age groups, sexual orientation, gender and substance abusers. Collaborating with Drs. Metsch and Colfax are teams from four of the CTN 0032 sites and Nodes, and all new locations, each based in STD clinics in the U.S.; as well as Dr. Bruce Schackman from Weill Cornell Medical College in New York City who is leading the cost-effectiveness analysis.

Associated CTN Nodes

Appalachian Tri-State
California/Arizona
Florida
Long Island
Oregon/Hawaii
Southern Consortium
Long Island

From Skilled Counselors to Skilled Trainers of Counselors

Project AWARE, a NIDA funded study being conducted at nine STD clinics across the country, held its national training from February 16th through February 19th. An intense and packed counselor training was held for three days in Miami. The feedback from the new counselors attending the training was uniform: the hands-on, role-play filled training was great, the trainers were wonderfully supportive and helpful, and the training should have lasted an additional day! Instrumental to the success of Project AWARE's national counselor training were the seven CTN 0032 counselors (RAs/study coordinators) who became members of Project AWARE's counselor training team: Anna Amberg, Beverly Holmes, Beatrice Koon, and Kim Pressley from Columbia, SC; Walitta Abdullah and Josh Heffren from Pittsburgh, PA; and Rachael Baker from Portland.

In preparation for the counselor training, these seven CTN 0032 staff members attended several two-hour train-the-trainer conference calls and provided crucial input into Project AWARE's training format and process. During the national training, in the large group format, these seven key trainers were crucial in providing important "lessons learned" by sharing their own personal counselor stories in CTN 0032 and how what they learned from those experiences could be translated to Project AWARE counseling. Also in the large group setting, these seven CTN 0032 counselors role-played various portions of the counseling protocol so that new Project AWARE counselors could see exactly how the material was to be covered. Additionally, after each training day, the CTN seven, along with the other co-trainers, debriefed and provided important feedback to the Intervention Director and Coordinator about each new counselor's progress and struggles. At the close of the training, the CTN seven and other training team members provided written feedback on each of their new counselors to which the director and coordinator could refer during post national training sessions.

Congratulations (and thank you!) go to Anna, Beverly, Beatrice, Kim, Walitta, Josh, and Rachael for their outstanding work as counselor trainers and for making the Project AWARE National Counselor Training such a success. We look forward to your great work on Project AWARE!

Southern Consortium Node PI Is Recognized



On February 11, 2010, the Medical University of South Carolina (MUSC) Board of Trustees awarded Dr. Kathleen Brady the title of MUSC Distinguished University Professor. In awarding this honor, the MUSC Trustees stated that it, "...has been bestowed upon fewer than thirty individuals in the history of the university. This designation is reserved for individuals who have contributed in substantial ways to their own field of scholarship, and have enriched or enhanced the institution or society in areas outside of their own primary area of scholarship." Dr. Brady's distinguished contributions to the field of clinical psychiatry and to clinical and translational science at MUSC plus her remarkable leadership in obtaining the CTSA award have earned her this well-deserved honor. Dr. Brady has been a member of the Clinical Trials Network since September 2000 as the PI for the Southern Consortium Node. Her staff said that they are fortunate to have her not only as their leader, but also as a day-to-day mentor of kindness, hard work, and achievement. Congratulations!

News from the California/Arizona (CA/AZ) Node



An interview with **James Sorensen, Ph.D.**, PI of the CA-AZ Node, appeared in the Fall/Winter 2009 edition of *The Addictions Newsletter*, which is the APA

Division 50 Newsletter. The interview, conducted by Nancy Piotrowski of Capella University, is titled “Bridging the Gap: A Conversation on the NIDA Clinical Trials Network with James L. Sorensen,” and it offers a good introduction to and firsthand look at the issues of communication between researchers and clinicians. The interview can be accessed at http://www.apa.org/divisions/div50/publications_newsletters.html

Patricia Penn, Ph.D. of the CA/AZ Node is co-author with Emmett Velten Ph.D. of a newly released book titled *REBT for People with Co-occurring Problems: Albert Ellis in the Wilds of Arizona*. The authors have created a model based on Ellis’ REBT (Rational Emotive Behavioral Therapy), which they call Rational Assessment and Personalized Treatment (RAPT). In this new book, they present a conceptual framework; a strategy for cognitive, emotional, behavioral, and philosophical change; an explanation of RAPT techniques; and pertinent clinical examples, which are interspersed with explanations of what is going on in the sessions. There are also presentations on counselor burnout, discussion of the terms “dual diagnosis” and “co-morbidity,” best practices for working with co-occurring problems, and SMART Recovery. The book is aimed at professionals in the public treatment system and CBT therapists, and is available from Professional Resource Press (<http://www.prpress.com/index.htm>) either paperbound or in PDF form on CD-ROM.

RePORT Now Available to Public



The data base made available through the RePORT (Research Portfolio Online Reporting Tools) Expenditures and Results (RePORTER) system is now available for download by the public at

<http://projectreporter.nih.gov/exporter>, and has been added to the Tools catalog on data.gov at <http://www.data.gov/details/1563>. ExPORTER was created to provide raw data for those who would like to conduct detailed analyses of the research projects, publications, and patent information found in RePORTER or load these records into their own data systems. These data are drawn from multiple sources and are provided to the public. The information in these files has been gathered from multiple systems and databases.

CTN INVEST Fellowships for 2009



The National Institute on Drug Abuse (NIDA) awards fellowships to researchers through the INVEST/CTN research fellowship program. Clinical trial researchers from all non-U.S. countries including “developing” and “developed” nations apply for an opportunity to work with a research mentor at one of the sixteen CTN Nodes. During the fellowship year, fellows and mentors are encouraged to jointly develop and seek funding for a collaborative research project to be completed in the Fellow’s home country.

Two CTN INVEST fellows visited NIDA on January 29, 2010 and presented their current work. Dr. Mario A. Zapata, from the University of Medellin, Colombia, presented his planned work to conduct a study using Brief Strategic Family Therapy for Adolescent Drug Abusers (BSFT™) in a clinic in Colombia. Mario has been working with Michael Robbins (University of Miami, Florida Node) during the past year and plans to return to Colombia in the summer and continue his work with BSFT.

Dr. Leonardo Estacio, Jr., from the University of the Philippines presented an overview of the history and drug use problems in his country. He has been working with Dr. Dennis Donovan (University of Washington, Pacific Northwest Node) since October 2009 and will be selecting a project to work on the next year. He plans to present a summary of his work at the upcoming Steering Committee on April 21, 2010.

For additional information on the CTN INVEST project, please contact Carmen Rosa, M.S., at crosa@nida.nih.gov or visit the website at http://international.drugabuse.gov/research/fellowships_investCTN.html

Learn about Genetics



The University of Utah has developed a web site for teaching genetics: <http://learn.genetics.utah.edu/>. This site won the *Science* Prize for Online Resources in Education (SPORE). There is a module on addiction and genetics.

Reminder – Fall CTN Steering Committee



The fall CTN Steering Committee Meeting will be held in Bethesda, Maryland, from September 21-23, 2010. Registration and information will be made available on the Synergy meeting website this summer. Mark your calendars!

New Grants



The following grant opportunities may be of interest to researchers:

- 2010 NIDA Translational Avant-Garde Award for Medication Development for Diseases of Addiction (DP1) (RFA-DA-10-013) <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-10-013.html>
- Medications Development for Substance Related Disorders (R01) (RFA-DA-10-018) <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-10-018.html>
- Deep Sequencing and Analysis of Pharmacogenomic Regions: Discovery and Analysis of Genetic Variants Contributing to Drug Abuse and Addiction (R01) (RFA-DA-10-019) <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-10-019.html>
- Technology-Based Adherence Interventions for Substance Abusing Populations with HIV (R01) (PAS-10-097) <http://grants.nih.gov/grants/guide/pa-files/PAS-10-097.html>
- Technology-Based Adherence Interventions for Substance Abusing Populations with HIV (R34) (PAS-10-098) <http://grants.nih.gov/grants/guide/pa-files/PAS-10-098.html>

CTN Dissemination Library Update



What's New in the CTN Dissemination Library?

Are you planning a conference presentation or poster about CTN work this spring? The CTN Library would love to add your presentation to its digital collection, where it can reach a wide audience: info@ctndisseminationlibrary.org. Send them the slides in advance, and they'll give you a unique URL that you can show to your audience so they can view your presentation again. Of course, they won't post your presentation until after the event!

Recently added to the Library's digital collection:



[Methodological Innovation to Increase the Utility and Efficiency of Psychotherapy Research for Patients with Co-Occurring Mental Health and Substance Use Disorders](#) by Denise Hien, Lisa Cohen, Aimee

Campbell. *Professional Psychology: Research and Practice* 2009;40(5):502-509. This paper uses the CTN 0015 study to illustrate the application of hybrid model study design, while illuminating the inefficiency of the traditional linear stage model of behavioral therapy.



[A Multi-Site, Two-Phase, Prescription Opioid Addiction Treatment Study \(POATS\): Rationale, Design, and Methodology](#)

by Roger Weiss, Jennifer Potter, Scott Provost, et al.

Contemporary Clinical Trials 2010 (in press). The CTN POATS study was launched in response to rising rates of prescription opioid dependence and gaps in understanding the optimal course of treatment for this population. Read about the rationale and design of POATS in this article from CTN 0030 researchers.



[The Adoption of Alcohol Pharmacotherapies in the Clinical Trials Network: The Influence of Research Network Participation](#)

by Amanda Abraham, Hannah Knudsen, Tanja Rothrauff, and Paul Roman.

Journal of Substance Abuse Treatment 2010 (in press). This article from University of Georgia researchers looks at the CTN as a platform for considering the ways organizational participation in clinical research may led to adoption of greater innovativeness beyond specific interventions tested.



[Sex Under the Influence of Drugs or Alcohol: Common for Men in Substance Abuse Treatment and Associated with High Risk Sexual Behavior](#)

by Don Calsyn, Sarah Cousins, Mary Hatch-Maillette, et al.

American Journal on Addictions 2010 (in press). This article about CTN 0018 finds that sex is a strong relapse trigger for a variety of substances and that, therefore, patients might benefit from interventions targeting sexual behavior and substance use as mutual triggers.

Visit the CTN Dissemination Library online at: <http://ctndisseminationlibrary.org> The CTN Dissemination Library is managed by the Pacific Northwest Node of the Clinical Trials Network.

Clinical Data Systems Help Desks



For DSC 1 (DCRI), you may contact the Site Support Help Desk at 1-888-DSC-SSHD (1-888-372-7743) from 8:00 a.m. to 8:00 p.m. Monday through Friday or send an e-mail to: nidadsc-help@mc.duke.edu.

For DSC 2 (EMMES), you may contact the DSC 2 Help Desk from 8:00 a.m. to 8:00 p.m. Monday through Friday at (888) 337-7071 or send an e-mail to: nidadsc2help@emmes.com

Clinical Coordinating Center (CCC) at EMMES



Regulatory Updates:

The CTN has had some new studies which have had the question posed about whether an IND (Investigational New Drug) Exemption would be needed. The following information provides the regulations which affect decision making regarding the granting of IND Exemptions.

Generally, regulations in part 312 (21 CFR part 312) require sponsors who wish to study a drug or biological product in humans to submit an IND to the Agency (Food and Drug Administration - FDA). However, these regulations also provide for the exemption of some studies from the requirement to submit an IND if they meet certain criteria.

Regulations in 21 CFR 312.2(b)(1) provide for the exemption of certain studies for some drugs from IND regulations if the studies meet the following five criteria:

1. The study is not intended to support FDA approval of a new indication or a significant change in the product labeling.
2. The study is not intended to support a significant change in the advertising for the product.
3. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that *significantly increases the risks* (or decreases the acceptability of the risks) associated with the use of the study product.
4. The study is conducted in compliance with institutional review board (IRB) and informed consent regulations set forth in parts 56 and 50 (21 CFR parts 56 and 50).
5. The study is conducted in compliance with § 312.7 (promotion and charging for investigational drugs).

The FDA has explained in the past that exemptions were intended to permit deviations from the approved labeling to the extent that such changes are supported by the scientific literature and generally known clinical experience.

For more information, contact Rajesh Venugopal at rvenugopal@emmes.com with questions for any proposed studies or study concepts.

Other CCC related questions and topics- Bob Lindblad



at 301-251-1161, rlindblad@emmes.com,
ctnsupport@emmes.com for laboratory and/or medication supplies, and
ctnsafety@emmes.com for safety related issues/adverse event follow-up.

New CTN RFP Just released!

RFP N01DA-10-2221, Clinical Coordinating Center for NIDA CCTN, was issued February 5, 2010. Proposals are due March 23, 2010. This is a recompetition for the Clinical Coordinating Center. For information, go to: <http://www.drugabuse.gov/funding/rfplist.html>

CTN 0030 A3 POATS LTFU Update



The Prescription Opioid Addiction Treatment Long-Term Follow-Up study (POATS LTFU) is progressing well at the Northern New England Node. The original POATS study enrolled 653 participants and was completed in July 2009. This LTFU study is a 42- month followup with the original participants. This extension study examines substance use outcomes of POATS participants at 18, 30 and 42 months post-randomization. To date, 372 POATS participants have been enrolled in the LTFU, and we have completed 176 month-18 assessments, 71 month-30 assessments and 6 month-42 assessments. The study is currently on pace to meet all projected data collection targets.

Updates for this Bulletin should be sent to Carol Cushing at: ccushing@nida.nih.gov

