Clinical Trials Network

CTN Bulletin
July 14, 2010
Volume 10 - 11

Trial Progress – Over 11,000!

Trial enrollment numbers reflect information as of July 14th.

Open Studies
- CTN 0037 – Randomized 1 (New)
- CTN 0044 – Randomized 19 (New)
- CTN 0046 – Randomized 68

Total Randomized All Studies: 11,537

CTN 0037 STRIDE Opens for Enrollment!
The CTN 0037 STRIDE (Stimulant Reduction Intervention using Dosed Exercise) study is now open for enrollment. Dr. Trivedi and the Lead Team at the Texas Node for STRIDE are proud to announce that on Friday, July 2nd, 2010, Arapahoe House in the Florida Node randomized the first participant for this study. The study plans to enroll 330 participants, and the CTPs are entering in 2 waves. The Wave 2 training is scheduled for early this November.

We would also like to congratulate Gateway Community Services (Dr. Candy Hodgkins, Dr. Chris Neuenfeldt, Sarah Kim, Cyndi Thomas, Kristin Staggs, Erika Jimenez, Stephanie Curtis, and Amy Tindell), Gibson Recovery Center (Andy Johnson, Eric Kohler, Sarah Essex, Ashley Naeger, Rebecca Tillman, and Tara Calkins), and Nexus Recovery Center (Dr. Cindy Seamans, Jim Lindsey, Aubrey Hopkins, Blake Apple, Vita Jackson and Matt Tucker) on their recent site endorsements. Congratulations and thanks also to the supporting Nodes (Florida - Gateway; Ohio Valley - Gibson Recovery; and Texas - Nexus Recovery), EMMES, and NIDA for their many contributions to these milestones. All Wave 1 sites are now endorsed and open for enrollment!

Registration Opens for Steering Committee Meeting
The fall CTN Steering Committee Meeting will take place at the Bethesda North Marriott Hotel and Conference Center, in Bethesda, Maryland, on September 21-23, 2010. To register and to obtain logistical and program information, please visit (http://www.seiservices.com/NIDA/CTN/Meetings/1025039/index.asp).

While updating your calendars, please also save the date for the Spring 2011 CTN Steering Committee Meeting, which will take place in Bethesda, Maryland, on March 15-17, 2011.

CTN 0044 Web- Open for Enrollment!
CTN 0044 Web-delivery of Evidence-based, Psychosocial Treatment for Substance Use Disorders has all 10 Community Treatment Programs (CTPs) open and enrolling participants. Congratulations to newly endorsed CTPs: The Center for Drug Free Living (FL), Evergreen Manor (PNW), Harbel Prevention & Recovery (Mid-Atlantic), Hina Mauka – Waipahu (Pacific), Midwestern CT Council on Alcoholism – MCCA (NE), Willamette Family (OR/HI), and Stanley Street Treatment & Resources (NNE). The Lead Team thanks and recognizes the support and hard work of the Data & Statistics Center 2 and the Clinical Coordinating Center at the EMMES Corporation. Recruitment is scheduled to be completed in approximately one year.

CTN 0044-A2: Acceptability of a Web-delivered, Psychosocial Intervention among Individuals with Substance Use Disorders who Identify as American Indian / Alaska Native
An ancillary study to CTN 0044 was approved to examine the acceptability of a web-delivered community reinforcement approach intervention (Therapeutic Education System) among clients who identify as American Indian / Alaska Native in two CTPs within the CTN: City / County Alcohol & Drug Programs (CCADP) from the Ohio Valley Node and Native American Rehabilitation Association (NARA Northwest) from the Oregon/Hawaii Node. The Site PIs for the study are Laura Lewis (CCADP) and Roz Ringor-Carty (NARA Northwest). The Long Island Node, led by Ned Nunes (Lead Investigator), Aimee Campbell (Project Director), and Gloria Miele (Training Director), will coordinate the study. The study will recruit approximately 40 participants and collect both quantitative and qualitative acceptability data. The protocol is currently under review by Institutional Review Boards. The estimated start date for recruitment is Fall 2010.

CTN 0047 SMART-ED Status
Study CTN 0047 Screening, Motivational Assessment, Referral, and Treatment in Emergency Departments (SMART-ED) is holding the national training for the Wave 1 sites July 19-22 in Albuquerque, NM. For more information please contact Christine Sanchez csanch11@unm.edu.

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.
CTN 0046 S-CAST Wave 2 Training Completed

Study staff 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 attended the Wave 2 national training in Cincinnati, Ohio, on July 12-14. Dr. Theresa Winhusen and her team at the Ohio Valley Node welcomed trainees and provided an overview of the study. Staff then received training on performing study procedures, monitoring participant safety, and ensuring accurate data collection.

Trainers from the Mayo Clinic Nicotine Research Program provided instruction on the study smoking cessation intervention “Smoke Free and Living It.” Interventionists and Intervention Supervisors from each Wave 2 site received training on delivering the intervention and had the opportunity to be certified prior to leaving the training. Afterward, Intervention Supervisors learned how to train the intervention and perform the monthly supervision.

Dr. Winhusen thanks all who traveled to Cincinnati to attend the training. Wave 2 sites are now encouraged to finish all remaining training elements and prepare for the Standardized Patient visits and EMMES pre-initiation visits, which should be completed by mid-August.

CTN INVEST Fellowships for 2010

Applications are due September 1st, 2010! NIDA is recruiting fellows for the 2010 INVEST/CTN research fellowship program. INVEST/CTN fellowships encourage postdoctoral fellows to conduct drug abuse and addiction research and promote collaboration with their U.S. mentors, creating an international network of scientists dedicated to exchanging information and collaborating on drug abuse research at a national, regional, and global level.

Qualified fellowship candidates must meet the standards posted on the website. Current CTN Node PIs can participate or encourage interested colleagues in their respective Nodes to mentor INVEST/CTN fellows. 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.

For additional information, see attached flyer, contact Carmen Rosa (erosa@nida.nih.gov) or visit the website at http://international.drugabuse.gov/research/fellowships_INVESTCTN.html

Research Opportunities

The following research opportunities may be of interest to those in the CTN:

- NIDA Core Center of Excellence Grant Program (P30) (PAR-10-220) http://grants.nih.gov/grants/guide/pa-files/PAR-10-220.html

Southwest Node – Recruiting Notice for R21 Grant

The Southwest Node is recruiting clinicians for a web-based informed consent study. Dr. Cynthia Geppert, along with Drs. Michael Bogenschutz, Scott Tonigan and Barbara McCrady, all of the Southwest Node, are conducting a NIDA funded R21 study entitled “A Survey Study of Informed Consent Processes in Addiction Treatment.” The research team is actively recruiting CTN clinicians to participate in this project investigating the knowledge, attitudes, and self-reporting practices of informed consent among addiction professionals. This is an area in which little previous research has been conducted, and the goal of the grant is to develop best practices that will improve the ethical and clinical quality of substance abuse treatment.

Participation will be open to both licensed and unlicensed CTN clinicians, including medical providers and non-medical providers such as psychologists, social workers, addiction therapists, and counselors. Those volunteering to participate will be provided access to a secure, web-based survey that will take less than 45 minutes to complete. The survey can be taken from any computer with on-line access, and no identifying information will be linked to participant responses. Participants will be compensated for their time.

If you are a CTN clinician who would like to participate or if you would like additional information, please e-mail the study Principal Investigator, Dr. Cynthia Geppert, at ethicdoc@comcast.net.
What's New in the CTN Dissemination Library?

Calling All Presenters!

Summer is a big time of year for conferences, and, as always, the CTN Dissemination Library wants to add your CTN-related posters and presentations to its digital collection. Several presentations from the recent meeting of the College on Problems of Drug Dependence (CPDD) have been added, thanks to those who sent the files — see them in What’s New? ctndisseminationlibrary.org/new.htm.

Do you have a recent CTN-related poster or presentation? If so, send the file attached to an email to info@disseminationlibrary.org!

New CE Opportunity in the Works

In the next few months, the CTN Dissemination Library, in partnership with the Research Utilization Committee (RUC) and the national Addiction Technology Transfer Centers (ATTC), will add a new CE opportunity for providers. The online training will focus on Reducing HIV/STD Risk Behaviors for Men & Women (CTN-0018/19), with a slide/audio segment and article(s) to read. NAADAC credit hours will be available for completing a short quiz based on the materials.

Currently, counselors and others can get CE credits based on the March 2009 Dissemination Workshop – view the video, take a quiz, and earn 3 NAADAC credit hours (free through the end of 2010!)

Watch the CTN Bulletin and the CTN Dissemination Library home page for updates on the new CE course and other new developments!

Listed below is recent activity on manuscripts.

- CTN 0018, Don Calsyn et al: Sexual Risk Behavior and Sex under the Influence: An Event Analysis of Men in Substance Abuse Treatment Who Have Sex with Women; accepted for publication in The American Journal on Addictions

- CTN 0017, its primary outcome paper, Robert Booth et al: Reducing HIV-related Risk Behaviors among Injection Drug Users in Residential Detoxification; accepted for publication in AIDS and Behavior

Recent PC reviews

- CTN 0028, Leanne Tamm et al: ADHD Subtypes in Adolescents with Co-morbid Substance Use Disorder

- CTN 0029, Lirio Covey et al: Attention-Deficit/Hyperactivity Disorder Subtypes: Differences in Smoking Cessation Response to OROS-methylphenidate

- CTN 0018/19, Aimee Campbell et al: Community Providers' Impression of HIV Prevention Intervention Research within NIDA's Clinical Trials Network

In PC review:

- CTN 0030, primary outcome paper, Roger Weiss et al: Treatment of Prescription Opioid Dependence: Results of a Multi-Site Randomized Controlled Trial

- CTN 0019, Aimee Campbell et al: Female Condom Skill and Attitude: Results from a NIDA Clinical Trials Network HIV Risk Reduction Study with Women in Substance Abuse Treatment

- CTN 0018, Don Calsyn et al: Are Recent Monogamy or Being in a Committed Relationship Markers for Low Sexual Risk in Men in Substance Abuse Treatment?

- CTN 0019, Dennis Donovan et al: How Practice and Science are Balanced and Blended in the NIDA Clinical Trials Network: The Bidirectional Process in the Development of the STAGE-12 Protocol as an Example

- From multiple CTN trials, Brian Hartzler et al: Rates and Influences of Alcohol Use Disorder Comorbidity Among Stimulant-Primary Treatment-Seekers: Meta-Analytic Findings Across Eight NIDA CTN Trials

Publications Committee (PC)

The PC reviewers continue to make useful suggestions to authors for improvements to their manuscripts.

Ned Nunes is serving as Guest Editor of a CTN special issue of the American Journal of Drug and Alcohol Abuse, with manuscripts targeted for journal submission in July and August 2010. The focus is on methodological lessons learned from CTN trials. The PC and the journal and guest editor are arranging that PC reviews will be accepted and utilized by the journal as part of its peer-review process. It is expected that this will be an effective way to expedite publication.

The CTN’s Minority Interest Group is working on a CTN special edition of Cultural Diversity in Ethnic Minority Psychology (CDEMP), targeted for journal submission in October 2010. Kathy Burlew is coordinating this effort.
The CTN RUC (Research Utilization Committee) are beginning to plan the CTN Pre-Steering Committee Dissemination Workshop on September 21 at the fall meeting in Bethesda (see page 1). This workshop aims to highlight the efforts community treatment programs (CTPs) have made to promote the implementation of empirically supported substance abuse treatments. The first workshops, held at our March and October 2009 CTN Steering Committee meetings, were very well received.

At this time, the RUC is gathering proposals from CTPs to present some aspect of their dissemination activities at the CTN Steering Committee Dissemination Workshop. The workshop will be held on September 21, 2010. It will be 2.5 hours in length and occur prior to the CTP Caucus. Please inform your CTP Directors about this opportunity and encourage them to submit proposals.

Presentations may cover effective evidence-based treatment (EBT) dissemination efforts or lessons learned from less successful, though very informative attempts. Inclusion of data about these dissemination efforts is highly encouraged. Please note that the group has a particular interest in proposals that describe efforts CTPs have made to establish: 1) smoking cessation interventions within their programs, or 2) supervision systems or other methods to promote counselor fidelity when implementing specific treatments.

All proposals are due by August 6, 2010. Before submitting them, please discuss the proposal with your Node PI to determine if the Node can fund your participation. Please send your proposal to Steve Martino at steve.martino@yale.edu.

Examples of Exculpatory (Unacceptable) Language:

- By agreeing to this use, you should understand that you will give up all claims to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language Include:

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

It is important to note that the regulations state that the informed consent is not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for consent to be legally effective (45 CFR 46.116(e)).

For more guidance on this issue, please contact your local IRB or EMMES at Regulatory documentation requests - ctnregdocs@emmes.com. Other CCC related questions and topics- Robert Lindblad at 301-251-1161, rlindblad@emmes.com.

NIDA Project Officer, Steve Sparenborg, at: sparenborgs@nida.nih.gov, telephone (301) 496-4844.
DSC 2 – EMMES Data and Statistics Center 2

DSC2 Web Site

The CTN DSC 2 has launched its web site at www.ctndsc2.com. The web site currently provides daily updates of the CTN Trial Progress Reports for Protocols CTN 0044 and CTN 0037. A username and password are required for access. Currently access is limited to NIDA CCTN staff and members of the CTN 0044 and CTN 0037 teams. Over the next few months, access will be granted to wider CTN audiences as the site is populated with more trial information. The trial reports will be similar in format to the reports generated by DCRI for their monthly trial updates. The DSC 2 will be communicating soon to CTN members the process by which access to the web site will be granted.

If you have any questions for the DSC 2, please feel free to contact them at nidadsc2@emmes.com or telephone (301) 251-1161.

DSC 2 Project Director, Colleen Allen, at: Callen@emmes.com

DSC 2 PI, Paul Van Veldhuisen, at: pvanveldhuisen@emmes.com

NIDA Project Officer, Carol Cushing, at: ccushing@nida.nih.gov, telephone (301)443-9815.

Late News from Florida Node!

Dr. Lisa Metsch, Florida Node Co-PI, has been appointed as the Chair of the NIH/CSR study section, Behavioral and Social Science Approaches to Preventing HIV/AIDS Study Section (BSPH). The BSPH Study Section reviews studies of risk factors and antecedents of HIV infection as well as basic behavioral, epidemiologic, and social science studies of mechanisms and factors at the individual and community levels. Congratulations!

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