



# Clinical Trials Network

## CTN Bulletin

June 25, 2010

Volume 10 - 10

### Trial Progress – Over 11,000!



Trial enrollment numbers reflect information as of June 25th.

#### Open Studies

- CTN 0027 – Randomized 1,269 (completed new enrollment, in follow up phase)
- CTN 0027A (Genetics) – Randomized 815
- CTN 0044 – Randomized **9 (New)**
- CTN 0046 – Randomized **55 (New)**

**Total Randomized All Studies: 11,513**

### CTN 0031 STAGE-12 Locks!

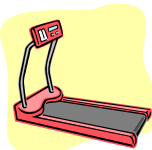


The STAGE-12 ((Stimulant Abuser Groups to Engage in 12 Step) protocol (CTN 0031 and 0031A) locked the trial database on June 14<sup>th</sup>, thanks to the good work of many people.

They include the clinical and research staff at RCKC, ChangePoint, Maryhaven, Gateway, Willamette Valley, CPCDS, Evergreen Manor, Dorchester, Nexus Recovery, and Hina Mauka, as well as the Pacific Northwest, Oregon/Hawaii, Ohio Valley, Florida, Appalachian Tri-State, Southern Consortium, Texas, and Pacific Nodes. Also major thanks go to the hard-working staff at DCRI and EMMES.

The STAGE-12 study was carried out at 10 sites across 8 CTN Nodes. The first participant was enrolled in February 2008. A total of 471 participants were randomized in all. Keep an eye out for many exciting papers to follow soon!

### CTN 0037 STRIDE Opens for Enrollment!



The CTN 0037 STRIDE (Stimulant Reduction Intervention using Dosed Exercise) study is now open for enrollment. The Lead Team recognizes Arapahoe House in Denver, Colorado, as the first site to

be endorsed for the STRIDE trial and to screen someone for study participation. Congratulations to Dr. Meredith Silverstein and her team: Nicole Berg, Michelle Deland, Brianna Gass, Marie Gurrola, and Jimmy Warne. The Lead Team also thanks all of the members of the Florida Node, Clinical Coordinating Center at EMMES, Data and Statistics Center 2 at EMMES, and NIDA for all of their hard work towards accomplishing this goal. The remaining Wave 1 sites are in the process of finalizing their initiation site visits from the CCC.

### CTN 0044 Web-delivery Starts Recruitment!



CTN-0044 Web-delivery of Evidence-based, Psychosocial Treatment for Substance Use Disorders is now enrolling participants. Three sites were endorsed to begin recruitment the second week of June: Project Outreach (Long Island), Homeward Bound, Inc. (Texas), and Midtown Community Mental Health Center (Ohio Valley). Congratulations to Homeward Bound for having the first randomized participant! As of June 25th, 9 participants have been randomized across the three sites. The study will randomize 500 participants over the next year. The remaining seven sites will be asked to begin the endorsement process over the next several weeks – all are eager to get underway! Thanks to everyone for their hard work and commitment to the study!

### Pacific Node PI Honored at CPDD



Dr. Walter Ling, Principal Investigator of the Pacific Region Node, received the 2010 NIDA International Program Award of Excellence in Mentoring at the recent College on Problems of Drug Dependency (CPDD) 72<sup>nd</sup> annual meeting in Scottsdale, Arizona. Dr. Ling is a productive researcher whose clinical trials helped pave the way for U.S. approval of naltrexone, buprenorphine, and LAAM. Dr. Ling also has trained a generation of drug abuse researchers. Directing the Integrated Substance Abuse Programs at the University of California Los Angeles, he has helped prepare young scientists to significantly improve drug abuse research around the globe—from Australia to Europe, the Middle East, Asia, and the United States.

As Principal Investigator for the NIDA Clinical Trials Network Pacific Region Node, Dr. Ling has trained researchers and treatment providers while conducting research on psychosocial and pharmacological treatments for opiate, cocaine, methamphetamine, alcohol, and nicotine abuse. His protégés include successful NIDA grantees and former NIDA International Program fellows who were inspired by Dr. Ling: many of them have followed his example by building productive research and training centers, particularly in China and Thailand. Congratulations!

*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 Results at the American Pain Society Meeting



The American Pain Society 29th Annual Scientific Meeting was held in Baltimore, Maryland, in May 2010. Patients with chronic pain and prescription opioid addiction are at risk

of receiving inadequate care, say experts. Specialists outlined how to strike the delicate balance between treating symptoms without fanning the flames of addiction in patients who are struggling.

Jennifer Sharpe Potter, PhD, from the University of Texas Health Sciences Center at San Antonio, presented data on patient characteristics from the Prescription Opiate Addiction Treatment Study (POATS CTN 0030). The analysis included 274 patients with chronic pain. The trial involved a 1-month drug taper followed by a 3-month stabilization period for those who did poorly during the initial taper.

Dr. Potter reported that most patients first started taking opioids to treat pain and not to get high. Although some continued taking the medication for pain, most continued to take the drugs inappropriately to avoid withdrawal symptoms. Almost half of the patients had a successful treatment response at week 12, but this benefit decreased again once the medications were tapered. The researchers found that reducing opioid use, whether initially or after a period of substantial improvement, led to nearly universal relapse. "The take-home message is really that pain is a chronic relapsing disorder and must be treated as such," Dr. Potter said.

### NNP Website



The NIDA Networking Project (NNP) provides opportunities for information sharing and research collaboration among NIDA's networks across the country. The NNP gives researchers and clinicians access to networks' locations, people, expertise, and resources to help synergize efforts, improve efficiency, and accelerate scientific discovery.

NIDA is planning to undertake more public outreach this Fall to promote science-based facts about drug abuse for teens. NNP scientists are encouraged to consider volunteering to respond to questions from local school and community leaders who are developing teen drug awareness projects. If you are a member, please update your members' profile which includes a new section about NNP Volunteer Scientist efforts.

Check out the NNP website at: <http://nnp.drugabuse.gov>

### Next Steering Committee Meetings



The Fall Steering Committee Meeting will be held on September 21-23, 2010; the Spring meeting will be on March 15-17, 2011. Both meetings will be held at the Bethesda North Marriott, Bethesda, Maryland, one block from NIDA Headquarters. Hotel logistics and meeting information will be sent out later this summer.

### Synergy Enterprises Inc. (SEI) Update



We frequently acknowledge that the CTN is associated with some of the more prominent researchers in our field, but we are also fortunate to have the support services of another superstar. Prachee Devadas, President and CEO of Synergy Enterprises, Inc - our Logistics Support Contractor, was invited to be part of a focus group to consult with the President on small business programs. Ms. Devadas, along with representatives of another small business, met with President Obama for a 20-minute discussion on a series of proposals his administration has put forth to promote small business growth and hiring. Ms. Devadas was the only Federal government contractor selected to participate in this focus group. Prachee has been involved with the CTN since its inception 10 years ago and is worthy of this recognition. Congratulations Prachee and SEI!

### Research Opportunities

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



- Seek, Test, Treat, and Retain:  
Addressing HIV among Vulnerable Populations (R01) (RFA-DA-11-001) <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-11-001.html>
- The FOA for the NIDA Core "Center of Excellence" Grant program (P30) has just been published as PAR-10-220 <http://grants.nih.gov/grants/guide/pa-files/PAR-10-220.html>
- Just a reminder that the FOA for P50 is PAR -10-189 <http://grants.nih.gov/grants/guide/pa-files/PAR-10-189.html>

### Delaware Valley Node News



Dr. George Woody, PI of the Delaware Valley Node, gave a presentation at a meeting entitled "Traditions and Innovations in Psychiatry" held by the World Psychiatric Association in St. Petersburg, Russia on June 10-12. His talk was titled "Data Points the Way: Medication Assisted Therapy for Reducing Drug Use, HIV Risk and Managing HIV Infection in Opioid Addicted Patients."

## What's New in the CTN Dissemination Library?

Mid-Atlantic CTN  
Regional  
Dissemination  
Workshop

June 3-4, 2010  
Radisson Hotel  
Baltimore, MD

Cutting Edge Addiction  
Treatment Tools  
from NIDA's  
Clinical Trials Network

On June 3-4, the Mid-Atlantic Node sponsored a CTN Dissemination Workshop entitled, "Cutting Edge Addiction Treatment Tools from NIDA's Clinical Trials Network."

Presentations covered a variety of topics, including the emergence of medication assisted therapy in addiction, contingency management, and understanding and managing addiction as a chronic condition. If you missed the workshop, the slides from both the plenary sessions and the workshops are now available in the CTN Dissemination Library:

<http://ctndisseminationlibrary.org/display/485.htm>.

Also new in the Library are several new articles from peer-reviewed journals:



[Impact of Attention-Deficit/Hyperactivity Disorder \(ADHD\) Treatment on Smoking Cessation Intervention in ADHD Smokers: A Randomized, Double-Blind, Placebo-Controlled Trial](#) by Theresa Winhusen, Eugene Somozoa, Greg Brigham, et al.

Journal of Clinical Psychiatry 2010 (in press). This article reports on the **primary outcomes of protocol CTN 0029**, which evaluated whether or not using osmotic-release methylphenidate to treat ADHD enhances response to smoking cessation treatment in smokers with ADHD.



[Association of Race and Ethnicity with Withdrawal Symptoms, Attrition, Opioid Use, and Side-Effects During Buprenorphine Therapy](#) by E. Sherwood Brown, Carlos Tirado, Abu Minhajuddin, et al.

Journal of Ethnicity in Substance Abuse 2010;9(2):106-114. This ancillary investigation of data from protocol CTN 0003 (Bup/ Nx Taper) examined racial/ethnic differences before and during stabilization with buprenorphine and found that **race/ethnicity may not play a major role in buprenorphine response** and treatment retention.



[Gender Differences in the Rates and Correlates of HIV Risk Behaviors Among Drug Abusers](#) by Audrey Brooks, Christina Meade, Jennifer Sharpe Potter, et al.

Substance Use & Misuse 2010 (in press). This ancillary investigation of data from protocols CTN 0001, 2, 5, 6, and 7, examined gender differences in the rates and correlates of HIV risk behaviors, finding distinct differences between men and women, which highlights the need for more gender-specific risk-reduction interventions.



[The Role of Alcohol Misuse in PTSD Outcomes for Women in Community Treatment: A Secondary Analysis of NIDA's Women and Trauma Study](#) by Denise Hien,

Aimee Campbell, Lesia Ruglass, et al. Drug and Alcohol Dependence 2010 (in press). This secondary analysis of data from the Women & Trauma protocol (CTN 0015) examined individuals with co-morbid substance use and PTSD and found that **the Seeking Safety treatment model may be a sound first-line clinical approach to managing PTSD among women with active alcohol misuse**.



**CPDD Posters and Presentations Coming Soon in the CTN Dissemination Library:**

Posters and presentations from this year's CPDD conference. If you attended and presented about the CTN, please submit your posters and presentations to us at [info@ctndisseminationlibrary.org](mailto:info@ctndisseminationlibrary.org).

The CTN Library is web-based and is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: <http://ctndisseminationlibrary.org>.

## Publications Committee (PC) Reminder



The Publications Committee reminds CTN members that posters and slide presentations need PC review and approval prior to public presentation. Please submit your items for review one month prior to the meeting. Send to the PC via Jack Blaine ([jblaine@nida.nih.gov](mailto:jblaine@nida.nih.gov)). Thanks!

## Clinical Coordinating Center (CCC) at EMMES



*The 2010 Web Seminar Series Catalog*

Now that most of the protocols are launching, the CCC is introducing the 2010 Web Seminar Series and Catalog. Production was completed in May and **seminars began in June**. The CTN certainly made a great showing during the 2009 series; we had a remarkable 700 attendees join these seminars! We thank the members of the CTN for this series' success; it is your input, feedback and participation that assures relevancy, presents new seminar ideas each year, and provides more subject matter experts than you can shake a stick at!

**The 2010 Web Seminar Series - Mark your calendar for the upcoming webinars:**

- **June 23** – Dr. Betty Tai, Director of the CCTN, kicked off the 2010 webinar series discussing the **Importance of the CTN. A record 141 registrants signed up to hear her presentation.**

- **June 30** – Laurel Hall presents recommendations for **Recruitment and Retention Success**
- **July 27** – Ron Jackson, Sabrina Poole, and Charlotte Royer-Malvestuto offer an **Addiction Severity Index Booster** webinar
- **August 10** - Aimee Campbell teaches the **Timeline Follow Back Method**
- **September 9** – Gloria Miele presents **Clinical Interviewing Guidelines**

Look for e-mailed invitations in the coming months.

**Methods for Disseminating Evidence-Based Treatments from the Frontlines of Community Treatment Programs** – this is a two hour workshop highlighting different methods CTPs have used to disseminate evidence-based treatment into their practice. The National Office of the ATTC will provide 3 NAADAC credit hours FREE until December 31, 2010 for this online workshop.

***Can Prisoners be paid for study participation? If so, how much?***



In non-prison settings, paying subjects to participate in research is considered ethically acceptable, so long as it is commensurate with the discomfort and/or inconvenience involved. Paying "prisoners" (defined as individuals who are incarcerated in a penal facility) who are enrolled in a study the same amount that


would be paid to non-prisoners may, however, be seen as unduly influential in a setting where inmates can earn only a small fraction of that amount for any other "work" activity.

However, paying "prisoners" as defined above, a fraction of what would be paid to non-prisoners can be seen as exploitative. One suggestion that has been offered is to require that investigators pay "prisoners" at the same rate as they would pay non-prisoners, but that individuals would receive an amount comparable to that paid for other prison-based tasks. The difference would be paid into a general prison fund, to be used, for instance, to subsidize the wages paid to all prisoners, or to be used for educational or recreational purposes (to be determined by the prison population, not the administrators). Alternatively, the difference could be paid into an escrow account, to be distributed to the "prisoner" upon release from the penal facility or to be paid to the prisoner's family.

Keep in mind, however, individuals who are not incarcerated in a penal facility and who may be court mandated to therapy or other type of restriction outside of a penal facility may be paid to participate in research and this payment can be considered ethically acceptable.

For more guidance on this issue, please contact your local IRB or EMMES at **Regulatory documentation requests** - [ctnregdocs@emmes.com](mailto:ctnregdocs@emmes.com).

**Other CCC related questions and topics**- Robert Lindblad at 301-251-1161, [rlindblad@emmes.com](mailto:rlindblad@emmes.com).

<b>Federal Offices Closed</b>	
	The CCTN office and NIDA will be closed on Monday, July 5, for the Independence Day holiday observance.

***Updates for this Bulletin should be sent to Carol Cushing at: [ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov)***

