

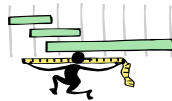
# Clinical Trials Network

CTN Bulletin  
November 4, 2005  
Volume 05 – 18

## Open Studies – 5 Enrolling, 5 in Follow Up

- CTN 0003 – randomized 516, **reached target**
- CTN 0010 – randomized 145, 69% of target
- CTN 0013 – randomized 163, 82% of target
- CTN 0014 – randomized 193, 40% of target
- CTN 0015 – randomized 352, **reached target**
- CTN 0017 – randomized 530, 75% of target
- CTN 0018 – randomized 594, **reached target**
- CTN 0019 – randomized 509, **reached target**
- CTN 0020 – randomized 540, 86% of target
- CTN 0021 – randomized 463, **reached target**

**Total Randomized All Studies: 6,688**  
**Total Screened All Studies: 11,133**



## Dallas SC Meeting in March 2006



The first CTN Steering Committee Meeting in 2006 has been scheduled at the Westin Galleria in Dallas, Texas, from March 20-23, 2006. Information and registration for this meeting will be available on the CTN website in December.

## Methamphetamine Meeting in Hawaii



The Center for the Clinical Trials Network) will sponsor an all day pre-conference brainstorming session entitled “*The Methamphetamine Menace: Treatment Approaches for a National Problem*” at the American College of Neuropsychopharmacology (ACNP) Annual Conference on December 10, 2005, in Waikoloa, Hawaii. Dr. Nora Volkow, Director of NIDA, will chair the session. Presenters will discuss possible treatment interventions and implications for methamphetamine addiction. Topics will range from behavioral interventions, psychiatric manifestations, neurotoxicity associated with methamphetamine use, treating addicts with HIV co-morbidity, and possible directions for NIDA and the CTN. For further information on the session and/or questions regarding registration, please contact Katia Delrahim at (301) 496-9004 or via e-mail at [kdelrahi@nida.nih.gov](mailto:kdelrahi@nida.nih.gov).

*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.*

## Wilma Visits Florida Node



The Florida Node is grateful for the outpouring of concern and support from their friends throughout the CTN in the aftermath of Hurricane Wilma. While many staff in South Florida still remain without electricity, spirits are high and they are well on the way to recovery. Two CTPs in the area were heavily impacted by the storm. Spectrum Programs/Miami Behavioral Health Centers lost whatever foliage had not been blown away during Katrina. Some staff suffered serious personal home damage, but no one had any personal injuries, and for that all are grateful. Their clients, for the most part, stayed within the treatment programs. Spirits remain high and will get better once full electrical power is restored.

The Village, another South Florida CTP, weathered the storm well. They had minor building and tree damage, with electrical power lost from Monday until Sunday. During this period Dr. Hansen, Clinical Coordinator, drove in and picked up information concerning the operational windows, as well as materials to conduct assessments from her home should the power not return. One week after the Hurricane, they randomized another BSFT (CTN-0014) participant. Staff at these treatment programs put their personal needs aside in going the extra mile to work with their clients. The RRTC at the University of Miami is proud to have such courageous and dedicated partners in the Florida Node.

## CTN 0029 ADHD in Adult Smokers



The CTN-0029 team has continued to meet their aggressive timeline for study start-up. The team is working around the delay caused by study medication expiration through use of a two-stage endorsement process. The first stage will allow sites to begin advertising, prescreening, and screening participants. All three wave 1 sites are on target to receive this endorsement by November 11th. The second stage will allow sites to begin randomization of patients. This will occur once the study medication is onsite and the EMMES initiation visit has taken place, currently targeted for early December.

## Topics for CTN Column in NIDA Notes

Please forward ideas for CTN related articles to Jeff Selzer (Long Island Node) at [selzer@lij.edu](mailto:selzer@lij.edu).

### **AATOD National Conference**

The Center for the Clinical Trials Network (CCTN) is sponsoring an all day pre-conference session entitled “*Treating People with Dignity and Evidenced Based Medicine – Emerging Research Findings on Buprenorphine, Hepatitis C and Prescription Drug Addiction*” at the American Association for the Treatment of Opioid Dependence (AATOD) conference on Sunday, April 23, 2006, in Atlanta, Georgia. Dr. Betty Tai, Director of CCTN, will chair the session. Presenters will discuss the results of several recent CTN trials and their implications in the clinical setting. Topics will include:

- How to use Buprenorphine in clinical settings including rapid detoxification, stabilization, and tapering from opioid addiction.
- The nature and extent of the problem of infectious diseases, especially Hepatitis C, and innovative treatment approaches now being used in community treatment programs.
- Using Buprenorphine and individual drug counseling to treat prescription opioid addicts including those with chronic pain.
- The availability of prescription drugs over the internet.

The conference will be 8:30 AM to 5 PM on Sunday, April 23<sup>rd</sup>. Registration can be made online at: <http://www.aatod.org/> and clicking on AATOD National Conference. For additional information, please contact Dr. Petra Jacobs at (301) 496-8974 or e-mail at: [pjacobs@nida.nih.gov](mailto:pjacobs@nida.nih.gov).

### **Update from Rocky Mountain**

CTN-0017 (*HIV and HCV Intervention in Drug Treatment Settings*) Recovery Centers of King County, Seattle, Washington Node, has officially reached its recruitment goal! Congratulations for the hard work! This site will continue to enroll per a previously approved agreement. Enrollment is continuing at a steady pace for all other sites.

CTN-0028 (*ADHD in Adolescents*) Protocol Specific Training for the three Wave 1 sites was Nov. 1-4 in Denver. Training for the standard background treatment for this study, manualized Cognitive Behavioral Therapy will occur Nov. 7-11.

### **Upcoming RBS Training**



The Clinical Coordinating Center (CCC) has arranged for National Risk Behaviors Survey (RBS) training for interviewers on November 16 from 12- 3:00 PM. Gloria Miele of the Long Island Node will administer this web conference. To sign up, please send a registration form to [CTNSupport@EMMES.com](mailto:CTNSupport@EMMES.com) or fax to (301) 576-3924. For additional information, contact the CCC team at (301) 251-1161.

### **Publications Subcommittee (PSC)**



On October 18, the PSC approved the following papers and publications for submission, with minor revisions:

- Baseline Study: Treatment Programs (Dennis McCarty)
- Baseline Study: Direct Care Workforce (Dennis McCarty)
- Treatment Outcomes for Bup 0001 and 0002 (Douglas Ziedonis)
- AAAP Symposium (Ned Nunes)
- Minority and Hispanic Health Disparities Sessions (Carmen Rosa)
- Health Disparities Hispanic Session (Lourdes Suarez)
- Comparison of Minority Participation in CTN Studies (Kathryn Magruder)

### **From the California-Arizona Node**



Varda Shoham and Michael Rohrbaugh gave an invited presentation on Brief Strategic Family Therapy (CTN 0014 BSFT)

at the Universidad de la Coruna (Spain), September 8, 2005. The talk – entitled *Terapia Familiar Estratégica Breve para adolescentes que abusan de drogas* (BSFT for Adolescent Drug Abuse) – focused on understanding how and for whom these interventions are hypothesized to work.

Dr. Peter Banys, Director of Substance Programs at the SF VA Medical Center, has been elected to the Executive Council of the American Society of Addiction Medicine, and has an ex officio position on the Executive Board of the California Society of Addiction Medicine. Congratulations!

### **2006 CPDD URPOP Travel Award**



The Under-Represented Populations Committee (URPOP) of the College on Problems of Drug Dependence (CPDD) is soliciting applications for a limited number of travel awards to the 68th CPDD Scientific Meeting to be held in Scottsdale, Arizona, June 17-22, 2006. The URPOP travel award provides financial support to attend the CPDD Meeting and present current research related to drug abuse and dependence. Submissions must be postmarked by December 1, 2005. Eligibility requirements are:

- Current graduate or medical student who has not received a terminal degree;
- Member of an under-represented population;
- Must not have received a previous URPOP award

For further information, contact **Carl Hart, PhD**, ([clh42@columbia.edu](mailto:clh42@columbia.edu)) Chair, CPDD URPOP Committee.

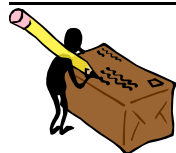
### Congrats to Southern Consortium (SC) PI



Dr. Kathleen Brady, PI of the SC Node, was recently appointed as the Director of the Medical University of South Carolina's General Clinical Research Center (GCRC) and Associate Dean for

Clinical Research. Dr. Brady will be working very hard in the next few months to bring together a strong team of individuals to assist her in optimizing and expanding the GCRC resources with a focus on conducting translational research. The CTN will provide a model for other clinical research networks to be developed by the Medical University of South Carolina.

### New Grants Tidbit Corner



*Dissemination and Implementation Research in Health:* This program announcement encourages investigators to submit research grant applications that will identify,

develop, and refine effective and efficient methods to disseminate and implement research-tested health behavior change interventions and evidence-based prevention, treatment, and quality of life improvement services into public health and clinical practice settings.

<http://grants.nih.gov/grants/guide/pa-files/PA-06-039.html>

*International Research Collaboration on Drug Addiction:* This program announcement solicits collaborative research proposals on drug abuse and addiction that take advantage of special opportunities that exist outside the United States. Special opportunities include access to unusual talent, resources, populations, or environmental conditions in other countries that will speed scientific discovery.  
<http://grants.nih.gov/grants/guide/pa-files/PA-06-050.html>

### Where to Get Information on the CTN



The NIDA CTN website is being revised to include current information on the new Appalachian-Tri State Node and Texas Node. Plus, some additions are for new

Community Treatment Providers and staffing changes. For more information on the CTN as well as summaries of all the protocols, please go to the website at: <http://www.nida.nih.gov/CTN/Index.htm>

### CTN Dissemination Library



The CTN Library is web-based, and includes a catalog with descriptive records for each item in the Library. The site is: <http://ctndisseminationlibrary.org>. It can be searched by author, subject keyword, source, date, CTN Protocol, Node, CTP, and other indices.

### News to Use and Share



*Livelihood Q and A*

- 1. Can I use someone else's protocol documents in my own study?** The study documents on Livelihood are the intellectual property of the investigators who developed them. CTN members are advised to contact the Lead Investigators or the person who posted the information before using Livelihood documents in research or publications.
- 2. Why doesn't my Livelihood password work?** Your access to Livelihood is disabled if you do not log into the system for at least 90 days. To have your password reinstated, please contact Jelena Fay-Lukic at: [jfaylukic@nida.nih.gov](mailto:jfaylukic@nida.nih.gov).
- 3. Can I change my password to one that is easier to remember?** Yes, once you've logged into the system, go to Tools, Settings, and Password. You may change your password as often as you wish.
- 4. Why do files seem skewed when I click on them to open?** By clicking on the document, you are downloading it in html format. This is a quick way to read a file, but it is not opened in its original format (Word, Excel, PowerPoint, etc). To download a document in its original format, click on the Function menu icon for that particular document, and then select "fetch".

### *HIPAA Policy*

An NIH web site has been developed to provide the research community with information about the HIPAA Privacy. Go to:

<http://privacyruleandresearch.nih.gov/>

### *The Research Assistant*

The Research Assistant was developed by Danya International, Inc., through the Small Business Innovation Research Program funded by the National Institute on Drug Abuse. This site is a source of tips, tools, and information to navigate the world of behavioral science research from formulating your question to getting your proposal funded.

<http://www.theresearchassistant.com/index.asp>

### *Tips for Writing Grant Applications*

Several NIH institutes have provided "tips" on how to present applications. The following web site contains links to some of these guidelines:

<http://www.nida.nih.gov/Funding/Grantapps.html>

### *NIH Forms to Download*

The following NIH web site contains forms that can be downloaded and filled out. This includes the PHS 398 (for new and competing renewal applications) and PHS 2590 (for non-competing renewals).

<http://grants1.nih.gov/grants/forms.htm>

## Grant Training Requirements



*Thanks to Deborah Wertz, Grants Management Officer, who provided the following clarification on grant training requirements.*

1. **Who needs human subjects training?**  
Individuals who will be involved in the design and conduct of the NIH-funded human subjects research must fulfill the education requirement.
2. **What if new people are added after the grant is awarded?** If Key Personnel are added to an award in a non-competing year, documentation that they have received the required education should be included in the non-competing Progress Report.
3. **Who needs to certify the training?** An institutional official must sign the documentation.
4. **How often is this training needed?** Key Personnel need to provide this documentation once for each competing award. The intent of the education requirement is for investigators to keep abreast of development in human subjects protection. We believe that institutions and investigators are in the best position to determine when additional education is warranted.
5. **Which courses fulfill the education requirement?** The NIH does not endorse any specific educational programs. We believe that institutions are in the best position to determine what programs are appropriate for fulfilling the education requirement.
6. **Are any other refresher courses required?** No – neither NIH nor the CTN requires refresher training. The Protocol Training Plan for each study dictates the training needed for those involved in the actual study. There are no CTN global requirements for additional training beyond the protocol requirements.

The WEB site for the Frequently Asked Questions on NIH training policy is:

[http://grants2.nih.gov/grants/policy/hs\\_educ\\_faq.htm](http://grants2.nih.gov/grants/policy/hs_educ_faq.htm)

## CTN Office Closed for Veterans Day



Reminder--- The federal government is closed Friday, November 11, for the Veterans Day holiday.

**The Clinical Coordinating Center at EMMES will have an update on their activities in the next edition of the CTN Bulletin Board. An ASI Interviewer Training session is planned for the end of November- early December in Dallas, Texas. Details to be sent out shortly. An ASI Train-the-Trainer program is planned for early Spring.**

## News from the Washington Node



Congratulations to Dennis Donovan (PI) and his staff for receiving a grant award "The Healing of the Canoe", a National Center on Minority Health and Health Disparities initiative.

This three year grant will use community-based participatory research methods to work with the Suquamish Tribe, located across Elliot Bay from Seattle on the Kitsap Peninsula. It will work in collaboration with the Tribe to identify high priority areas of health disparity, particularly related to alcohol and drug abuse by youth, and to develop culturally relevant prevention and intervention strategies that focus on the traditional "canoe journey" as a metaphor for the healing process. The funding provides for community development activities, needs assessment, and the development and piloting of an intervention. This is the first component of a potential three phase funding mechanism. An additional 5-year grant may be obtained through a competitive application to fund a more extensive efficacy trial of the previously developed intervention. The third phase, also through a competitive application, would provide three years of funding for dissemination work.

## Data and Statistics Center (DSC) at DCRI



The DSC Site Support Help Desk (SSHD) is championing three new roles! The SSHD is now responsible for granting access to CIDI and the CIDI training protocol. Though the

Oregon Node will still be the owners of the CIDI on-line system, the SSHD staff will perform the administrative tasks. Please direct requests for access to the CIDI On-line System to the SSHD in addition to any questions or need for assistance regarding the CIDI On-line System. Many thanks to the to the Oregon Node for hosting the on-line system.

The SSHD will also be maintaining the Training Tracking Database for CTN related training. Information regarding completed training should be sent to them starting in December. The DSC thanks the Ohio Valley Node for continuing to host the system during this transition period.

Lastly, ID numbers for CTPs, Sub-Sites, and their staff will be assigned and tracked by DCRI. For additional information please contact the Site Support Help Desk at 1-888-DSC-SSHD (1-888-372-7743) or e-mail at [nidadsc-help@mc.duke.edu](mailto:nidadsc-help@mc.duke.edu). The CCTN Project Officer is Jeng-Jong (JJ) Pan. He may be reached at (301) 443-8888 or [jpan@nida.nih.gov](mailto:jpan@nida.nih.gov).

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