



# Clinical Trials Network

CTN Bulletin  
February 21, 2008  
Volume 08 – 04

### Trial Progress –



Trial enrollment is taken from the official Trial Progress Report prepared by the Data and Statistics Center (DCRI) each month. These enrollment numbers reflect information in the database through January 31, 2008.

### Open Studies (4)

- CTN 0027 – Randomized 611
- CTN 0028 – Randomized 240
- CTN 0030 – Randomized 386
- CTN 0031 – NEW

**Total Randomized All Studies: 8,710**

### CTN 0031 STAGE –12 Is Randomizing!



The STAGE-12 (Stimulant Abuser Groups to Engage in 12-Step) study is underway! Two of the three Wave 1 sites began enrollment on February 11th, 2008, with the third site set to begin by early March. **RCKC (Pacific Northwest Node) and Maryhaven (Ohio Valley Node)**

**have both randomized their first patients in this study.** The STAGE-12 Executive Committee (EC) is grateful to the staff at all of the participating CTPs for their hard work and training! The EC also thanks the coordinating centers and NIDA liaison, without whom none of this would have been possible.

For CTPs interested in participating in Wave 2 of STAGE-12, surveys have been distributed through the Node RRTCs. Surveys are due to Amanda Moore [amoore@emmes.com](mailto:amoore@emmes.com) by February 29, 2008. Questions about the surveys can be sent to Anthony Floyd [asfloyd@u.washington.edu](mailto:asfloyd@u.washington.edu).

### Blending CD Set: The Science of Treatment

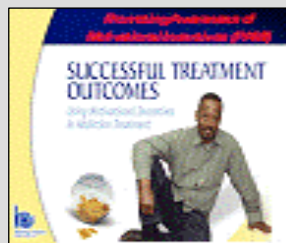


Since 2004, a total of 5 Blending Team products have been developed and are available at: <http://www.nida.nih.gov/blending/>. NIDA designed “*The Science of Treatment*” to

have all the completed Blending products accessible in one easy-to-use package. A limited number of Blending CD Sets will be distributed to every attendee at the June 2-3, 2008, Blending Conference. Also, NIDA is working with the National Office ATTC to reproduce and disseminate these Blending CD Sets by Spring of 2008. Contact NIDA’s Blending Project Officer, Denny Pintello [dpintell@nida.nih.gov](mailto:dpintell@nida.nih.gov) for additional information and Mary Beth Johnson ([no@nattc.org](mailto:no@nattc.org)) to submit your 2008 request for the Blending CD Set.

### Two Blending TOTs in Cincinnati, June 2008

NIDA and SAMHSA are co-sponsoring two Blending Training of Trainers (TOTs) sessions in Cincinnati following the June 2-3, 2008 Blending Conference. Each CTN node is encouraged to nominate one eligible individual to participate in each TOT. Details regarding participant eligibility are currently being fine-tuned. Interested parties are invited to contact their RUC representative or Denny Pintello ([dpintell@nida.nih.gov](mailto:dpintell@nida.nih.gov)) for additional information.



### **PAMI**

June 4, 2008  
1 Full Day  
Registration Cost: None  
Trainers: Lonetta Albright, Candace Peters, Amy Shanahan  
Location: Duke Energy Ctr.



### **MIA: STEP**

June 4, 5, & 6, 2008  
2.5 Days  
Registration Cost: None  
Trainers: Steve Martino, Denise Hall, Chris Farentinos  
Location: Duke Energy Ctr.

### CTN 0031A Launches 1<sup>st</sup> Site!



CTN 0031-A is a CTN-funded ancillary study to the CTN 0031 (STAGE-12 Stimulant Abusers Group to Engage in 12 Step) trial. Six of the nine CTN 0031 study sites will participate. Dr. Theresa Winhusen and Dr. Eugene Somoza and their Lead Team are pleased to announce the launching of the first Wave 1 site for this ancillary study “An Evaluation of Neurocognitive Function, Oxidative Damage, and Their Association with Treatment Outcomes in Methamphetamine and Cocaine Abusers.” Maryhaven, Inc. (OVN) in Columbus, Ohio, was endorsed to begin the study on February 19, 2008. Congratulations and good luck to Maryhaven! In all, approximately 164 patients will participate in CTN 0031-A.

*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 0032 Update**



Site selection activities for the HIV Rapid Testing & Counseling (CTN 0032) protocol continue to move forward. As of January 29, 2008, CTP representatives and Node Coordinators of sites that were not selected to move forward in the site selection process were notified. In addition, Node Coordinators of sites that are still potentially eligible to participate in the study and who had not previously supplied client-level data were asked to move forward with Phase 2-B (client survey) to garner more information about their clients' potential eligibility for the study. Phase 3-A of the site selection process, involving telephone interviews with CTP representatives and their respective Node Coordinators, is currently underway. Phase 3-B, involving site visits, is scheduled to begin in late February and last through March 2008. Subsequently, 12 sites will be selected to participate in CTN 0032 and notified of their status. While site selection activities are underway, the Investigative Team, various work groups and collaborators continue to develop SOPs, training materials, assessments and CRFs.



Congratulations to Tiffany Kyle, Director of Research at the Center for Drug Free Living and Lead Team Member on CTN 0032, on the birth of her baby girl, Vivien Grace Kyle! Mom and baby are both doing very well.

### **Congratulations Traci Rieckmann!**



The Oregon/Hawaii Node is pleased to report that Traci Rieckmann, Ph.D., has received a K23 award for a CTN platform study – Adoption of Evidence-Based Practices in Substance Abuse Treatment. The award supports four years of training and career development activities plus research on adoption of evidence-based treatments. The research plan has three specific aims: 1) use qualitative interviews to identify counselor and organizational variables that influence the implementation of evidence-based practices, 2) complete chart reviews to document and describe strategies to maintain fidelity in the use of evidence-based practices, and 3) conduct a secondary analysis of data from the National Treatment Center Study to test the influence of organizational and counselor variables on adoption of evidence-based practices. Community treatment programs located in the Oregon/Hawaii, California/Arizona, and Pacific Nodes will participate in the investigation.

### **Topics for CTN Articles in NIDA Notes**

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

### **Grants Tidbit Corner- New Grants**



The following grant opportunities may be of interest to researchers in the CTN:

Research Education Grants for Statistical Training in the Genetics of Addiction (R25) (PAR-08-081) Application Receipt/Submission Date(s): March 18, 2008, March 17, 2009, March 17, 2010 <http://grants.nih.gov/grants/guide/pa-files/PAR-08-081.html>

NIDA Comprehensive Research “Center of Excellence” Grant Program (P60) (PAR-08-086) Multiple receipt dates. <http://grants.nih.gov/grants/guide/pa-files/PAR-08-086.html>

PHS 2008-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (**Parent SBIR [R43/R44]**) (PA-08-050) Multiple dates. <http://grants.nih.gov/grants/guide/pa-files/PA-08-050.html>

### **CTN Data Share Update**



Data from completed CTN studies are available to the public on the CTN Public Data Share web site approximately 18 months after completion of the study or after acceptance of publication of the primary manuscript, whichever occurs first. Currently, the website contains data from the following studies: CTN 0001, 0002, 0004-0009, 0011, 0012 and 0016. Within the next six months, the web site will also include data from CTN 0003 and CTN 0013.

On September 5, a web site user survey consisting of nine questions related to user experience was circulated to anyone who had downloaded data from the web site prior to that date. The overall user response was “Excellent” with the one common request being access to data in flat-file formats. Based on those responses, DCRI will now start posting data in both CDISC SDTM and flat-file data structures. CTN 0001 will be the first study to have flat-file datasets added in both SAS and ASCII formats. A timeline will be provided shortly, but we expect the first flat-files to appear on the web site by June 30, 2008.

Check the web site ([www.ctndatashare.org](http://www.ctndatashare.org)) periodically to access recently posted data, study documentation and other new study information. The web site will be updated with additional “data release dates” as more time lines become available. To date, 80 researchers have requested 104 data sets from the data share web site.

### Texas News



The Robert Wood Johnson Foundation has named Homeward Bound, Inc, a Texas not-for-profit substance abuse treatment agency, as one of six awardees under its Advancing Recovery program. A \$2.2

million dollar award will go to selected programs that work to improve addiction treatment outcomes through the use of evidence-based practices. Each winning program funded in the second round of grant making will receive up to \$360,000. Advancing Recovery is co-directed by David Gustafson of the Network for the Improvement of Addiction Treatment (NIATx) at the University of Wisconsin-Madison and A. Thomas McLellan from the Treatment Research Institute (TRI) in Philadelphia.

Homeward Bound, Inc. is the lead agency for a group of Dallas agencies that will participate in the Advancing Recovery project. All of the participating agencies are provider members of the Texas Node of the National Institute on Drug Abuse's Clinical Trials Network. The Texas Node CTP agencies included in the Texas Advancing Recovery project are the Dallas County Juvenile Department, Homeward Bound, Inc., Nexus Recovery Center, and Phoenix House. Facilitated by the Advancing Recovery project, the CTPs will bring science to practice by implementing aspects of two CTN protocols, CTN 0005 Motivational Interviewing and CTN 0010 Buprenorphine/Naloxone-Facilitated Rehabilitation for Opioid Dependent Adolescents/Young Adults. By implementing these evidence-based practices, the CTPs hope to improve access, retention, and outcomes in treatment of adolescent and young adult heroin users in the Dallas area. Congratulations!

### OHRP – Spanish Language Pamphlet



The Office for Human Research Protections (OHRP) has announced that its pamphlet "Becoming a Research Volunteer: It's Your Decision" is now available in Spanish, "Ser Voluntario en Estudios Clínicos: Es Su Decisión."

You may order up to 50 (fifty) free copies by calling OHRP's toll-free number, (866) 447-4777. You may also download at no charge an electronic copy at <http://www.hhs.gov/ohrp/espanol/OHRP3PanelSpanish.pdf> for your own reprinting and distribution.

OHRP would like to hear about your experiences with the Spanish pamphlet. Please send them your feedback at: [ohrp@hhs.gov](mailto:ohrp@hhs.gov).

### APA Conference

The American Psychological Association (APA) has announced a conference on ***Culturally Informed Evidence-Based Practices: Translating Research and Policy for the Real World***. It will be held March 13-14 at the Double Tree Hotel in Bethesda, Maryland.

The purpose of this two-day conference is to inform and stimulate interest in generating research and evaluation efforts in the development of evidence-based practices for ethnic minority populations. The target audience is researchers and program evaluators who are interested in conducting intervention research with ethnic minorities.

The conference has the following objectives:

- 1) To review the current state of evidence-based practices designed for ethnic minority populations and for children and adults within these populations;
- 2) To examine the methodological issues faced when conducting intervention research with ethnic minority groups;
- 3) To examine the strengths and weaknesses of adaptations of existing evidence-based practices for ethnic minorities;
- 4) To make recommendations for increasing the pace and activity of generating research in this area; and
- 5) To identify mental health system, community, family and other extra-therapeutic factors that affect the extent to which evidence-based practices are applied and adopted in the treatment of ethnic minority clientele.

For more information and further inquiries you can contact Eduardo Morales, Ph.D. at [DrEMorales@aol.com](mailto:DrEMorales@aol.com) or call 415-519-4086.

### Congratulations Dr. Kathleen Carroll



Dr. Kathleen Carroll, PI of the New England Node at Yale University, has been selected to appear on ISIHighlyCited.com because of her exceptional citation count in the field of Social Sciences. Less than one percent of all publishing authors meet the criteria for inclusion on this website. Thomson Scientific's website is a free, publicly available site intended to highlight the most cited authors and create a network across diverse disciplines. Congratulations!

### How to Order Brochures, Conference Calls, etc.



To order materials or set up a call, please contact SEI (Synergy Enterprises Inc.) at: [CTNSupport@sei2003.com](mailto:CTNSupport@sei2003.com)

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