Tramway Ride and Dinner in Albuquerque

The Southwest Node is hosting a Tramway Ride and Dinner during the CTN Steering Committee Meeting in Albuquerque. The event is scheduled for Tuesday, April 20 at 5:30 p.m. Please visit http://casaa.unm.edu/download/ctn/SWNodeTramRideandDinner.pdf for more information.

CTN INVEST Fellow at the SC

Please welcome Dr. Leonardo Estacio, Jr. at the upcoming CTN Steering Committee. He has been working with Dr. Dennis Donovan of the Pacific Northwest Node. Dr. Estacio is a CTN INVEST Fellow from the Philippines. He will give a lunchtime presentation, April 20 at 12:30 PM, on “Community-Based Randomized Clinical Trial Using Behavioral Therapies to Reduce Methamphetamine Use among Adolescent Filipinos.” For information about NIDA’s international program, go to http://international.drugabuse.gov/

Register Now for CTN 10th Anniversary Meeting

The spring CTN Steering Committee will be held April 19-20, followed by the CTN 10th Anniversary event on April 21st. Are you wondering what to do in Albuquerque after the April Steering Committee ends and before the Blending Conference begins? Join us on Wednesday, April 21, 2010 for the “Celebration and Symposium in Honor of the 10th Anniversary of the National Drug Abuse Treatment Clinical Trials Network”! The Symposium runs from 8:30 a.m. to 6:00 p.m. A reception for all attendees will follow immediately. Registration for the Steering Committee and 10th Anniversary Meetings is at: http://www.seiservices.com/NIDA/CTN/Meetings/

NIDA Blending Conference Sold Out!

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. Registration was capped at 1,300 participants, which will be the highest attendance yet for a Blending Conference! If you have not yet registered, please visit http://www.seiservices.com/blendingalbuquerque/onliner egistration.aspx to add your name on the waiting list. Contact Denny Pintello dpintello@nida.nih.gov for more information.

Trial Progress — Over 11,000!

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 February 28, 2010.

Open Studies (5)

- CTN 0027 – Randomized 1,269 (completed new enrollment, in follow up phase)
- CTN 0027A (Genetics) – Randomized 815
- CTN 0031 – Randomized 471 (completed new enrollment, in follow up phase)
- CTN 0031A – Randomized 217 (completed new enrollment, in follow up phase)
- CTN 0046 – Randomized 1 (New)

Total Randomized All Studies: 11,450

CTN 0046 Wave 1 Sites Complete Endorsement

All six Wave 1 sites in 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 have been endorsed for enrollment, and are now actively recruiting for the study.

Addiction Medicine Services (Appalachian Tri-State) was approved for endorsement on March 3rd and La Frontera (California/Arizona) was approved on March 9th. The Lead Team wishes to thank everyone who was involved in assisting the sites during the initiation process. Best of luck to all the Wave 1 sites as they proceed with participant recruitment!

SITE (Site Influences on Treatment Effectiveness)

A new approved ancillary study called SITE will be collecting program and counselor data prior to the start of the S-CAST (CTN 0046), Web- Based (CTN 0044), and STRIDE (CTN 0037) studies to assess the influence of provider characteristics on patient outcomes. Dennis McCarty is the Lead Investigator for this project.

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!

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.
Dr. George Woody, Node PI, was recently interviewed for an article in Alcoholism Drug Abuse Weekly. In addressing prescription drug abuse and anti-drug messages to young people, Dr. Woody noted that scare tactics are effective when they are true. He says that the prevention message has to be credible to targeted youth.

2010 ACNP Travel Information Online

The American College of Neuropsychopharmacology (ACNP) annually selects over 40 exceptional young scientists in the field of neuropsychopharmacology as Travel Awardees. These awards allow recipients to have exposure to the College and its members for the week of the Annual Meeting, and beyond. For 2010, the group is working on a program to bring the most talented young researchers to the best scientific meeting in neuropsychopharmacology. For 2010, all candidates will complete one common application; however, there are three types of awards that an individual may be considered for: The ACNP Young Investigator Memorial Travel Awards, The Travel Award for Minorities and Women, and The Early Career Travel Award. In addition to these three awards, the College will continue to offer the Faculty Research Fellowship. Please see additional information regarding these awards at: http://www.acnp.org/annualmeeting/travelawards.aspx.

If you know of anyone within your institution who might be interested in applying for this program, please forward this information. Many past Travel Awardees are now ACNP members. The deadline to apply is April 30th. Should you have questions, please contact Nicole Greer at the ACNP office: ngreer@acnp.org.

Southwest (SW) Node Update

Please join the Southwest Node in congratulating Ray Daw, Director of Totah, a SW Node Community Treatment Program. Ray has taken a new position with the Navajo Nation as the Director of the Navajo Nation’s Department of Behavioral Health Services (DBHS). As the Health Systems Administrator for Navajo DBHS, he will continue to have a strong collaboration with the SW Node. Congratulations Ray!

PRB vs. DSMB?

There have been questions on the roles of the various review boards. Currently the CTN appoints a Protocol Review Board (PRB) and a Data and Safety Monitoring Board (DSMB) on a protocol by protocol basis.

For the PRB, independent experts are appointed to review the protocol and provide recommendations to NIDA. The selected experts are researchers (5 or 6) with expertise in the intervention, biostatistics, substance abuse and clinical trials. They usually meet face to face to review the study science, trial design, relevance of the intervention, feasibility, etc. The PRB may need to meet once or twice after the original meeting to provide further recommendations to NIDA; NIDA communicates the next steps to the study team.

A DSMB is appointed for all multi-site clinical trials conducted in the CTN, per NIH policy. Once the protocol is approved, a DSMB is appointed for each trial. This is usually the same group of experts that constituted the protocol PRB, plus a bioethicist. The DSMB reviews the protocol and the Data and Safety Monitoring Plan (DSMP). This review could happen face to face, via conference call or electronically. The DSMB provides recommendations to NIDA; NIDA communicates these to the investigators.

The DSMB for each study meets once or twice a year to monitor the study progress, based on the DSMP and trial enrollment. At the end of the study when the database is locked, the Lead Investigator team presents the final study report to the DSMB and NIDA.

The CTN currently has one DSMB that monitors the studies CTN 0027 and 0031 (pending final study report), one DSMB for study CTN 0032 (pending final study report), and one for each of the trials – CTN 0037, 0044, 0046 and 0047. There is a PRB for CTN 0048 (CURB), which is still in the development stage.

For details about the DSMB procedures, please refer to the CTN Policy and Procedure manual available in Livelink at: https://livelink.nida.nih.gov/livelink/llisapi.dll?func=ll&objId=7130119&objAction=viewheader. The CCTN contact for PRB/DSMB is Carmen Rosa at crosa@nida.nih.gov or Steve Sparenborg at sparenborgs@nida.nih.gov.
What’s New in the CTN Dissemination Library?

The latest issue of Counselor: The Magazine for Addiction Professionals features a must-read article by NIDA Deputy Director, Dr. Timothy Condon, and colleagues, describing the development and progress of NIDA’s Blending Initiative.

The Blending Initiative is a wide-ranging effort that combines the knowledge and skills of researchers, treatment providers, policy makers, and technology dissemination programs, with the goal of removing many of the obstacles that commonly impede technology transfer. This article, which can be found in the CTN Dissemination Library, describes the Blending Initiative process, as well as the five Blending Team Products that have been launched to date, offering training in the use of buprenorphine, the Addiction Severity Index, motivational interviewing, and motivational incentives. Read more about the article here:


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

The Relationship Between Depression and Smoking Cessation Outcomes in Treatment-Seeking Substance Abusers by Susan Sonne, Edward Nunes, Huiping Jiang, et al. American Journal on Addictions 2010;19(2):111-118. This article reports on a secondary analysis of data from CTN 0009 evaluating the effect of depressive symptomatology or history of depression on smoking cessation outcomes.

Effects of Buprenorphine and Hepatitis C on Liver Enzymes in Adolescents and Young Adults by Michael Bogenschutz, Patrick Abbott, Robert Kushner, et al. Journal of Addiction Medicine 2010 (in press). This article explores changes in transaminase values associated with buprenorphine treatment and hepatitis C status among opioid dependent subjects aged 15-21 participating in protocol CTN 0010.

A Method to Diagnose Opioid Dependence Resulting from Heroin Versus Prescription Opioids Using the Composite International Diagnostic Interview by Jennifer Sharpe Potter, Kristi Prather, et al. Contemporary Clinical Trials 2010 (in press). This article describes an innovative method used by the Prescription Opioid Addiction Treatment Study (POATS, protocol CTN 0030) to identify potential participants with DSM-IV opioid dependence resulting from prescription opioid use and not heroin use.

Conducting Clinical Research with Prescription Opioid Dependence: Defining the Population by Roger Weiss, Jennifer Sharpe Potter, Marc L. Copersino, et al. American Journal on Addictions 2010;19(2):141-146. A key methodological challenge for research on prescription opioid use involves defining the population. This paper describes various inclusion criteria considered by the CTN 0030 study team related to heroin use and pain management.

Read about these articles and more online at the CTN Dissemination Library! http://ctndisseminationlibrary.org

Calling all Counselors!

Are you interested in earning FREE CEUs? Do you want to learn how your peers are using CTN research in their clinical programs? Watch the 2-hour online video, “Methods for Disseminating Evidence-Based Treatments from the Frontlines of Community Treatment Programs,” highlighting methods used by CTN substance abuse treatment providers to disseminate evidence-based treatment into their practice settings. The video can be viewed online in the CTN Dissemination Library.

From a substance abuse counselor: “The web information was easy to access and I like the variety in the workshop discussions . . . it was designed with me in mind. If I can do it anyone can!”

Watch the video, take a quick ten-item quiz, and then apply to receive three NAADAC contact credit hours from the National Office of the Addiction Technology Transfer Center (ATTC). It’s easy! These credits are being offered FREE for a limited time by the NATTC, so don’t delay! Get started here: http://ctndisseminationlibrary.org/display/402.htm

An informational flyer is attached -- please distribute to anyone you think might be interested! This training is not limited to CTN members.

The CTN Dissemination Library is web-based, and includes a catalog with descriptive records for each item in the Library. The web site is maintained by the Pacific Northwest Node of the Clinical Trials Network.
Ohio Valley Node - IN MEMORIAM

The Ohio Valley Node is very sad to announce that Dr. Duane Mackey passed away on Thursday, March 11, 2010, in Lincoln, Nebraska. Dr. Mackey was instrumental as a guide and mentor to the Ohio Valley Node in developing working relationships with several tribes in the Northern Plains, and he was a co-PI in the implementation of CTN 0033 in South Dakota. Dr. Mackey was the Regional Coordinator of Native American Programs for the Prairielands Addiction Technology Transfer Center (PATTC), as well as a faculty member at the University of South Dakota. He was a published author in the field of Indian Education, Native American parenting, counseling Native people, mental health and alcoholism. He helped develop wellness centers on several reservations in Nebraska, and was instrumental in focusing on the relationship between the co-occurring diseases of diabetes and alcoholism in the Native American community. Dr. Mackey also collaborated on the film "Nagi Kicopi: Calling Back the Spirit," which was nominated for an award at the 2001 Annual American Indian Film Festival.

He conceived and co-developed "The Heart Room Concept," a culturally sensitive alcohol and substance abuse outreach prevention/intervention model focusing on the psycho-social, emotional and cultural "unmet needs" of Native youth within the school setting. In his role with PATTC, Dr. Mackey developed and disseminated a curriculum on Native American culture for non-Native substance abuse treatment providers in the state of South Dakota, for which he earned several awards.

Dr. Mackey was the guiding force behind the Ohio Valley Node’s efforts to develop relationships and establish research collaborations with Native Tribes in the Northern Plains. He was a gentle spirit, a wise counselor, and a good friend. The Ohio Valley Node and the CTN will miss him dearly.

New Funding Opportunities

The following grant opportunities may be of interest to researchers:

- Drug Abuse Aspects of HIV/AIDS (R01) (PA-10-129)

- Drug Abuse Aspects of HIV/AIDS (R21) (PA-10-130)

- Drug Abuse Aspects of HIV/AIDS (R03) (PA-10-131)

- Collaborative Clinical Trials in Drug Abuse (Collaborative R01)(PAR-10-099)

- SHIFT Award: Small Businesses Helping Investigators to Fuel the Translation of Scientific Discoveries [SBIR: R43/R44](PA-10-122)

Mid-Atlantic Node Regional Dissemination Workshop

The Mid-Atlantic Node is co-sponsoring a two day workshop on dissemination of evidence-based practices, June 3-4, in Baltimore, Maryland. The workshop is titled “Cutting Edge Addiction Treatment Tools from NIDA’s Clinical Trials Network.” The program will benefit treatment administrators, policy makers, and clinicians. Researchers will present the scientific basis for selected evidence-based practices. In the workshops, attendees will receive concrete examples, the wisdom of lessons learned, and practical implementation guidance.

Conference sessions will take place at the Radisson Plaza Lord Baltimore in the heart of downtown Baltimore. There is a $50 conference fee for the two-day workshop which includes two continental breakfasts, two lunches, and snacks. To register for the workshop, go to [www.ceattc.org](http://www.ceattc.org). For directions and room reservations, please go to [www.radisson.com/ctnworkshop](http://www.radisson.com/ctnworkshop).

Clinical Data Systems Help Desks

For DSC 1 (DCRI), you may contact the Site Support Help Desk at 1-888-DSC-SSHID (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 Requirements when Using a Laboratory for Your Study

All facilities that test human specimens for the purpose of diagnosis, treatment or monitoring are subject to Clinical Laboratory Improvement Amendments (CLIA) regulations. Each site where testing is performed, regardless of ownership of the specimen, must have a valid CLIA certificate. If testing is done under the same roof or on the same campus of a medical facility, then one CLIA certificate would be enough. If the clinic study site is not testing the specimen but merely collecting it, then it wouldn't need a CLIA certificate.

Differences between CLIA waived vs. CLIA certification:

CLIA requirements are based on the complexity of the test being performed and the categories include: waived, PPMP, moderate, and high, which are detailed below.

1. **Waived** – meaning the CLIA certification is waived or not necessary because the test conducted employs methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly. **Types of tests for CLIA waived**: urine dip strip, fecal occult blood, Strep A kits, pregnancy tests, small instruments for urinalysis, blood chemistry.

2. **Provider Performed Microscopy Procedures (PPMP)** – waived tests as well as moderate complexity tests performed by physician, mid-level practitioner, or dentist with primary instrument being a microscope to perform PPMP procedures. **Types of tests are**: Microscopic: urinalysis KOH preps, semen detection.

3. **Moderate complexity** – moderate complexity tests and the CLIA certification is needed. **Types of tests include**: Creatinine in EZ chem, CBC, large chemistry, immunoassay analyzers.

4. **High Complexity** – higher complexity tests and CLIA certification is needed. **Types of tests**: cultures and sensitivities, pathology, histology.

A Certificate of Waiver is only for facilities that perform CLIA waived tests.

If you have questions regarding CLIA certifications please contact Rajesh Venugopal at the Clinical Coordinating Center at rvenugopal@emmes.com or 301-251-1161 ext. 2948.

Other CCC related questions and topics- Bob Lindblad at 301-251-1161, rlindblad@emmes.com, contact ctnsupport@emmes.com for laboratory and/or medication supplies, and ctmsafety@emmes.com for safety related issues/adverse event follow-up.

Where to Get Information on the CTN and NIDA

The NIDA CTN website is being revised to include information on the new protocols and new sites. For more information on the CTN as well as summaries of all the protocols, please go to: [http://www.nida.nih.gov/CTN/Index.htm](http://www.nida.nih.gov/CTN/Index.htm)

For information on NIDA (National Institute on Drug Abuse), please go to: [http://www.drugabuse.gov/](http://www.drugabuse.gov/)

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