Clinical Trials Network

Trial Progress – Over 13,000!
Trial enrollment numbers reflect study information as of June 22nd.

Open Studies
- CTN 0037 – Randomized 148 (N=330)
- CTN 0044 – Randomized 415 (N=500)
- CTN 0046 – Randomized 376 (N=528)
- CTN 0047 – Randomized 598 (N=1,285)
Total Randomized All Studies: 13,155

CTN GO Grant Study (AWARE) – Randomized 5,013

NIDA has launched its second annual MusiCares® and GRAMMY Foundation's® Teen Substance Abuse Awareness through Music Contest—with winners to be announced during National Drug Facts Week in November. Teens are asked to write an original music composition or music video promoting healthy living or telling a story about drug abuse. The winner gets to go backstage at a GRAMMY rehearsal, and the top three winners will receive a small cash prize. More information can be found at http://drugfactsweek.drugabuse.gov/contest.php.

Who’s Looking at the CTN Data Sets?
A preliminary review of the requestors for CTN trial data on the data share web site (http://www.ctndatashare.org/) shows an interesting mix of countries and people.

- Number of files downloaded – 934
- Number of studies available on data share – 24 (5 using Buprenorphine/Naloxone, 13 behavioral treatments, 3 surveys, 2 on smoking cessation, and 1 on adolescents with ADHD)
- Number of countries – 16 (USA, Pakistan, France, India, Canada, Spain, Malaysia, Egypt, China, United Kingdom, Turkey, Poland, Nepal, Bangladesh, South Korea, and Mexico)
- CTN 0030 - Prescription Opiate Abuse Treatment Study (POATS) data and accompanying study documentation are now available on the CTN Data Share website. The data are formatted by CRF level. It is hoped that this will be an easier format for researchers to use. CTN 0032 (HIV Rapid Testing and Counseling) will be the next trial posted at the end of the summer.

Reaching Teens through Music

CTN Bulletin
June 23, 2011
Volume 11 - 9

News from the Greater NY Node
An abstract from the Infections and Substance Abuse Study (CTN 0012) has been accepted for poster presentation at the 139th American Public Health Association Annual Meeting. It is entitled, Relationships between HIV Disease Knowledge, Opinions, Training, Experience; and Service Availability at Substance Abuse Programs. Co-authors, all from ARTC, are Lawrence S. Brown, Jr., MD, MPH, FASAM, Study Lead Investigator, Steven Kritz, MD, Study Project Manager, Melissa Chu, MS, and Roberto Zavala, MD. Principal Investigator for the study for the Greater NY Node was John Rotrosen, MD, Professor, Dept of Psychiatry, NYU School of Medicine.

In the June 2nd CTN Bulletin, we announced that Kathleen Tracy, PhD of the NYU School of Medicine had been invited to orally present data from one of the Infections and Substance Abuse Study (CTN 0012) papers at the Global International Forum on Neuroscience in Nanjing, Jiangsu, China. Subsequent investigation revealed that this forum was likely a scam. Fortunately, this was discovered prior to any exchange of funds, but we want to alert everyone to be aware of this kind of activity.

2011 Steering Committee (SC) Meeting
The Fall Steering Committee Meeting will be held in Bethesda, Maryland, on September 26-28, 2011. The hotel is the Bethesda North Marriott, one block from NIDA Headquarters. Registration and sign up information will be available at the end of the summer.

There will be a Design and Analysis Workshop on Monday, September 26, from 3 to 5 p.m. before the SC meeting. The workshop is titled Determining Stimulant Drug Use by Combining Results from Timeline Follow-Back and Urine Drug Screening. Many CTN trials collect self-reports on drug use via the Timeline Follow-Back (TLFB) as well as urine samples for drug screening (UDS). The primary outcome is based on UDS results alone, on TLFB alone, or on a combination of results from both methods. This workshop will compare several algorithms for combining TLFB reports and UDS results, and will offer a recommended approach for future CTN trials. All are welcome!

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.
**Publications Committee (PC) Update**

**AJDAA Special Issue Update:** The American Journal of Drug and Alcohol Abuse CTN special issue entitled, "Methodology of Multisite Effectiveness Trials,” guest edited by Ned Nunes, anticipates a publication date of mid-August 2011.

**Acceptances for Publication:**
1. The Prescription Opioid Abuse Treatment (POATS; CTN 0030) main outcome paper, “A Two-Phase Randomized Controlled Trial of Adjunctive Counseling during Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence,” has received final acceptance in the Archives of General Psychiatry.

2. "Subjective Effects, Misuse, and Adverse Effects of Osmotic-Release Methylphenidate Treatment in Adolescent Substance Abusers with Attention Deficit Hyperactivity Disorder (ADHD)" is accepted in the Journal of Child and Adolescent Psychopharmacology.

3. "Is monogamy or committed relationship status a marker for low sexual risk among men in substance abuse treatment? Clinical and methodological considerations" is accepted for publication in the American Journal of Drug and Alcohol Abuse.


Several additional papers, posters, and abstracts have been reviewed by the PC. The posters include:

1. A Comparison of Buprenorphine Taper Outcomes between Prescription Opioid and Heroin Users
2. Predictors of Relationship Power among Drug-involved Women
3. Variations in Outcomes and Patient Characteristics Associated with Methadone and Buprenorphine Dose
4. The Relationship between Therapist and Patient Gender/Race Matching and Substance Use Outcomes across Two Motivational Enhancement Therapy Trials
5. CTN 0032 Counselor Training

**Pacific Northwest News**

The deadline for submitting a proposal to the 1st Seattle Implementation Research Conference (SIRC) is July 1, 2011. If you haven't yet and are planning to attend the conference in October, we hope you will consider giving a talk or poster presentation of implementation research or other related projects. Please visit their website for more information or contact the staff below: [http://www.chammp.org/SIRC/Registration.aspx](http://www.chammp.org/SIRC/Registration.aspx).

Conference Director: Kate Comtois, PhD, MPH  
comtois@uw.edu (office) 206-897-4225

Conference Coordinator: Karin Janis  
(office) 206-744-1753

**Update from the Southern Consortium Node**

On June 6-7, 2011, 35 members of the Southern Consortium Node (SCN) met at the Duke Clinical Research Institute (DCRI) in Durham, North Carolina, for the Node's bi-annual meeting. The meeting provided an opportunity for members to meet face to face, learn of the latest happenings from all corners of the Node, and to get to know each other during presentations and discussions of current activities and policies.

Drs. Kathleen Brady and John March, co-PIs, facilitated the meeting which consisted of: a) updates on the current CTN protocols in which SCN sites are participating (S-CAST, STRIDE, AWARE, CURB, and T-REMAS); b) discussion of protocols under development (BRAC, Vivitrol, and HOPE); c) presentations by LRADAC’s Leslie Wilson and Camille Peay on “Implementation of HIV Rapid Testing” and on “Telehealth” by Coastal Horizons’ Kenny House; d) NIDA and CTN updates by Dr. Brady; e) a discussion on dissemination led by Dr. Therese Killeen; f) a demonstration of the newly updated SCN website (http://academicdepartments.musc.edu/ctn) by Alisha Brice, Webmaster; g) a report on the ATTC by Ed Johnson, Webmaster; h) reports from the CTP directors, and j) an extensive discussion on protocol concepts under development within the Node.

At the conclusion of the general Node meeting, the Scientific Advisory Board and Executive Board met. These meetings generated several practical concepts and focused on emerging issues within the field. These discussions will help focus the activities over the coming year for the SCN, including dissemination, training, protocol development and involvement, and data analysis and publication.
Dr. George Woody, Node PI, participated in the kickoff meeting of ALICE RAP (Addictions and Lifestyles in Contemporary Europe Reframing Addictions Project), a new trans-disciplinary 5-year research project that is funded by a grant from the European Union with additional funding from several participating countries. ALICE RAP aims to help scientists, policy makers and society rethink and reshape current and future approaches to addictions and lifestyles in Europe. It is a unique project that will weave the work of over 100 scientists from 67 institutions in 25 countries into an integrated evidence base for informed policy action. The research program includes quantitative and qualitative disciplines and will critically examine and analyze currently fragmented research and strengthen scientific evidence to inform a platform for public and political debate on current and alternative approaches to addictions.

**Dr. Tom McLellan Returns to Create the Penn Center for Substance Abuse Solutions**

The breadth and depth of the DV Node will be enhanced by the return of Dr. McLellan to the University of Pennsylvania. He will create the Penn Center for Substance Abuse Solutions whose purpose is to develop and disseminate effective, practical, research-derived methods to address the problems of cigarette, alcohol and other drugs of abuse. The Solutions Center will work with faculty and students from the Medical School, the Wharton School, and the Annenberg School for Communication to translate findings from the 60+ Penn substance abuse researchers into practical, effective products, services and policies for schools, businesses, healthcare, and government agencies. Key features of the Solutions Center’s work will be consultation, training and implementation support, and evaluation of results to improve effectiveness and public value.

**Western States Node**

Dr. Dennis McCarty, Co-PI of the Western States Node, has been selected to receive the National Association of State Alcohol and Drug Abuse Directors, Inc. (NASADAD) Bob Anderson Research Award. The award was given at the annual NASADAD meeting in June. NASADAD is a private, not-for-profit educational, scientific, and informational organization. Its basic purpose is to foster and support the development of effective alcohol and other drug abuse prevention and treatment programs throughout every State. Congratulations!

**New Funding Opportunities**

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

- Notice of Correction to PAR-11-206 - National Cooperative Drug Discovery/Development Groups (NCDDG) for the Treatment of Mental Disorders, Drug or Alcohol Addiction (UM1) *(NOT-MH-11-010)*
- Notice of Correction to PAR-11-207 - National Cooperative Drug Discovery/Development Groups (NCDDG) for the Treatment of Mental Disorders, Drug or Alcohol Addiction (U19) *(NOT-MH-11-011)*
- Guidance for International Applicants Blocked from Registration Websites *(NOT-OD-11-090)*
- Epidemiology of Drug Abuse (R01) *(PA-11-230)*
  Epidemiology of Drug Abuse (R21) *(PA-11-231)*
  Epidemiology of Drug Abuse (R03) *(PA-11-232)*

**OHRP News**

On Monday, June 20, 2011, the Office for Human Research Protections (OHRP) announced the availability of the revised Federalwide Assurance (FWA) form, Terms of Assurance and related documents. The Terms of Assurance document is shortened and simplified. Key changes include:

- Only internal IRBs must be specifically designated or, if an institution does not have an internal IRB, only one external IRB must be specifically designated. All IRBs must be registered with OHRP before they can be designated on an OHRP-approved FWA;
- The revised FWA form allows the FWA to be signed electronically by the institution’s signatory official;
- OHRP now requires that institutions submit all FWAs (including new submissions, updates, and renewals) using the electronic submission system available through the OHRP website at [http://ohrp.cit.nih.gov/efile/](http://ohrp.cit.nih.gov/efile/), unless an institution lacks the ability to do so electronically; and
- The standard period of approval for an FWA is increased from a 3-year period to a 5-year period.
Clinical Coordinating Center (CCC) at EMMES

The 2011 Web Seminar Series!

Non-CTN members have been welcomed to our webinars since 2010. Please share the webinar information with colleagues near and far! Those interested in registering may contact ctntraining@emmes.com or Liz Buttrey at ebuttrey@emmes.com.

Join the CCC on the following, upcoming webinars! Mark your calendar:

- July 20  Relapse Prevention
- August 10  Certificate of Confidentiality
- September 14  Integrated Treatment of Co-Occurring Disorders
- October 12  Informed Consent
- December 7  A New Look at Manual of Procedure (MOP) Development

FDA has Finalized New Consent Language Requirement

All sites who participate in developing and updating informed consent materials for clinical trials sponsored by the NIDA Clinical Trials Network should be aware that on January 4, 2011, FDA published a Final Rule modifying 21 CFR Part 50.25 requiring that specific statements be included in informed consent forms beginning next year. This is required of all studies that are registered with ClinicalTrials.gov, and all NIH funded studies fall into this category.

The following is a 4-sentence paragraph that must be included in all study informed consents:

"A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov), as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

This requirement for inclusion in consent forms is not mandatory until next year (the “effective date” is March 7, 2011, the “compliance date” is March 7, 2012). But as the Final Rule has been formally published, NIDA’s Clinical Coordinating Center (CCC) recommends that any consents currently being drafted or revised to incorporate the new required language for applicable registered trials as soon as this is practical before the compliance date.

Any consent templates should also be revised to include this language. This would not apply to trials (like certain pilot/phase I trials) that are not required to be listed on a registry.


Other CCC related questions and topics - Principal Investigator, Robert Lindblad, at 301-251-1161, rlindblad@emmes.com, or Eve Jelstrom, Project Director, at 301-251-1161, ejelstrom@emmes.com.

Mid-Atlantic Node News

The Mid-Atlantic Node announces a new website devoted to Motivational Incentives.

The Motivational Incentives (MI) website ([www.motivationalincentives.org](http://www.motivationalincentives.org)) aspires to reach an audience who are somewhat savvy about technology and use the internet as an expedient resource for gathering and sharing information. Most users look for easy downloads, quick definitions, ideas about how to do something. The concept for the website originated in the CTN Research Utilization Committee MI Workgroup. Christine Higgins, who chaired the MI Workgroup, took on the leadership task of developing a user friendly site. With Maxine Stitzer as the Principal Investigator, the Mid-Atlantic Node was a natural fit for hosting a site about all things having to do with the use of incentives.

The purpose of the website is to provide both practical information and sound research for successful implementation to three different audiences:

1. Users new to incentives, thinking about implementation
2. Users currently implementing incentives, looking for some guidance
3. Users who have already set up programs and are looking to modify or enhance their programs and/or share their success.

Some of the site features are:

- **About Us**—highlighting current researchers in the field, with contact information and links to their research.
- **Practical Resources**—resources for administrators and clinicians from available sources such as NIDA/SAMHSA Blending Products, CTN Mid-Atlantic Node, and NATTC. (continued on page 5)
• **Tools for Success**—directed toward implementers at the 3 stages of implementation offering encouragement and guidance.

• **News & Updates**—features current use of incentives, specifically in the health care industry and in general, features profiles and descriptions by Program Administrators and Clinicians who are successfully using incentives along with their contact information.

• **Research Resources**—a Glossary and Bibliography that provide an understanding of terms and scientific materials to the newcomer.

Please visit and share your own stories about implementation under Administrator or Clinician Spotlight. If you have other interests, comments or questions, you can contact Christine Higgins at chiggin2@jhmi.edu.

**APA Award**

Congratulations go to Dr. Harold Perl, NIDA CCTN, for being selected as one of this year’s recipients of the American Psychological Association (APA) Meritorious Research Service Commendation. This Commendation was initiated by the APA Board of Scientific Affairs to recognize individuals who have made outstanding contributions to psychological science by enhancing opportunities and resources for the field through their service as employees of the federal government or other organizations. He is being honored for his significant leadership contributions at the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse. Congratulations!

**Offices Closed**

The CCTN office, NIDA and The EMMES Corporation will be closed on Monday, July 4, 2011, for the Independence Day holiday observance.

**CTN Website:**


**CTN Dissemination Library:**

[http://ctndisseminationlibrary.org](http://ctndisseminationlibrary.org)

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