Clinical Trials Network

CTN Bulletin
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Trial Progress –Nearing 14,000!

Trial enrollment numbers reflect study information as of October 11th.

Open Studies

- CTN 0037 – Enrolled 205 (N=330)
- CTN 0044 – Enrolled 507 (N=500) (enrollment completed – in follow up phase)
- CTN 0046 – Enrolled 472 (N=528)
- CTN 0047 – Enrolled 1,014 (N=1,285)
- CTN 0048 – Enrolled 6 (N=300) New
- CTN 0050 – Enrolled 23 (N=1,269) New

Total Enrolled All Studies: 13,660

CTN GO Grant Study (AWARE) –Enrolled **5,012**

CTN 0048 – CURB

The CURB (Cocaine Use Reduction with Buprenorphine) study has begun recruiting participants! As of yesterday, six participants have been enrolled into the study. The aim of this study is to investigate the safety and effectiveness of buprenorphine in the presence of naltrexone for the treatment of cocaine dependence in a sample of individuals meeting diagnostic criteria for both cocaine dependence and, either past-year opioid dependence, or past-year opioid abuse, or past-year opioid use with a history of opioid dependence during the lifetime.

The sites for this trial are:

- Albert Einstein College of Medicine, Greater New York Node
- Atlanta VA Medical Center, Southern Consortium
- Addiction Research & Treatment Services (ARTS), Western States Node
- Bay Area Addiction Research and Treatment (BAART), Pacific Region Node
- Bellevue Hospital Center, Greater New York Node
- CODA, Inc., Western States Node
- Howard University, Mid-Atlantic Node
- Maryhaven, Ohio Valley Node
- Recovery Centers of King County (RCKC), Pacific Northwest Node
- South Texas Veterans Health Care System, Texas Node
- UCLA ISAP Outpatient Clinical Research Center, Pacific Region Node

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 0050 – Long Term Follow-up to the CTN 0027 (START) Study Begins

This study has begun re-enrolling the participants from the START study, which ended in 2010. This project will assess the longer-term outcomes of the large sample of opioid-dependent patients randomly assigned, in the START Study (CTN 0027), to receive Suboxone or methadone for a (planned) six to eight months of treatment. The study team will conduct personal interviews of START participants, approximately 3 to 5 years post-admission, supplemented by (electronic) medical and other records as available.

NIH Grant Guidance

After several years of experience with the multiple PD/PI model, NIH has determined that there are legitimate circumstances under which it would be in the best interest of an active project to change either from a multiple-PD/PI model to a single PD/PI model, or from a single PD/PI model to a multiple PD/PI model, and that peer review of the new leadership team and Leadership Plan may not be essential in these cases (NOT-OD-11-118). Accordingly, NIH has amended policy to allow post award PD/PI changes with the prior approval of the Grants Management Officer (GMO). It is anticipated that such requests will be rare, and requested changes must be accompanied by a strong scientific justification related to the funded project.

For further information, please contact Ron Dobbins at rdobbins@nida.nih.gov.

News from the Greater NY Node

An 8th paper from the "Infections and Substance Abuse Study" (NIDA CTN 0012) has been accepted for publication by the Journal of Substance Abuse Treatment (JSAT). It is titled “Hepatitis B Virus and Hepatitis C Virus Services Offered by Substance Abuse Treatment Programs in the United States.”

Lead author was Edmund Bini, MD, MPH (deceased). Co-authors were Steven Kritz, MD (study Project Manager), Lawrence S. Brown, Jr., MD, MPH (study originator and Lead Investigator), Jim Robinson, MEd, Donald Calsyn, PhD, Don Alderson, MS, Kathlene Tracy, PhD, Patrick McAuliffe, MBA, LADC (deceased), Cheryl Smith, MD, and John Rotrosen, MD (Greater NY Node Principal Investigator).

News from the Southern Consortium Node

Community engagement is an important aspect of the Clinical Trials Network, and three members of the Southern Consortium Node at the Medical University of South Carolina (MUSC) have developed a growing involvement in this aspect of research. Since 2009, Dr. Jeffrey Korte has served as Co-Director of the Research Core for the MUSC Center for Community Health Partnerships. This year, the Center is merging with the Community Engagement Program of the South Carolina Clinical and Translational Research Institute (SCTR). Dr. Korte has agreed to continue his involvement as a member of the steering committee.

In addition, Louise Haynes, MSW, Co-Chair of the CTN Steering Committee and Dr. Korte have both agreed to serve as members of the Community Engagement Academic Board. The SCTR Community Engagement Program is part of the larger funded CTSA grant, with Dr. Kathleen Brady serving as Principal Investigator of both the CTSA grant and the CTN grant for the Southern Consortium Node. The Node anticipates that their ongoing efforts to create and foster links between academic researchers and community stakeholders will continue to help them ensure the relevance of their research efforts to the needs of the community.

Texas Node News

NIDA Avant-Garde Medications Development Award winners have been announced. Scientists proposing to develop vaccines against methamphetamine and nicotine have been selected to receive NIDA's second Avant-Garde Awards for Innovative Medication Development Research. Congratulations go to Thomas Kosten, M.D., Baylor College of Medicine, of the Texas Node.

Dr. Kosten's group will accelerate the development of a methamphetamine vaccine, which is expected to undergo initial clinical trials within the next five years. At present there is no FDA-approved medication for metham-phetamine addiction, so a vaccine could have substantial impact on the treatment of methamphetamine addiction.

This research competition is an extension of NIDA's successful Avant-Garde Award for Innovative HIV/AIDS Research, now in its fourth year. For further information about the Avant-Garde Award, please visit http://drugabuse.gov/avgp.html. Information about applications for the 2012 Avant-Garde Awards will be posted on this site soon.

Team Taskforce Recommendations for CTN Studies

Here is a brief summary of the recommendations from the CTN Taskforce last year:

Primary Outcome Measure

The primary outcome measure should be the number of days of drug use during the last 30 days of the active treatment phase, based on self-report corroborated with qualitative urine drug screening tests. If a Lead Investigator (LI) wants to use an alternative primary outcome on drug use that is more suitable for that trial's specific goal, the LI must submit to the CCTN (or include in the protocol) a brief description of the proposed primary outcome and a justification as to why it is more appropriate.

CTN Common Assessments

All CTN trials should use the following questions and instruments:

1. A standardized demographics form
2. Timeline Follow-back
3. A standardized qualitative Urine Drug Screening test
4. The CTN Addiction Severity Index (ASI) Lite (version 10/24/2000)
5. A question on primary drug of use
6. A question on age of first use (onset)
7. The World Health Organization's Quality of Life BREF instrument

Where to Find CTN Policies and Procedures?

The NIDA CTN Policies and Procedures guide was recently updated. The guide has been divided into three sections: 1) By-Laws, 2) Policies and Procedures, and 3) Investigator Toolbox. The Steering Committee will review and update the By-Laws as necessary and the CCTN will review and update the Policies and Procedures as necessary or at least every three years. The Investigator Toolbox, which is currently under development, will contain detailed procedures and will be updated frequently by the coordinating centers. The new versions of these documents are posted on the CTN's Clinical Trials Reports website (www.ctndsc2.com). The documents can be accessed by selecting the "CTN Documents" link in the menu bar. The website is password-protected. These documents have been removed from Livelink. If you need access, please contact the NIDA CTN DSC 2 Help Desk at nidadsc2help@emmes.com.

What's New in the CTN Dissemination Library?

Social Media Tools were the topic of two recent presentations by members of the RUC's Social Media Workgroup**.** In August, Gloria Miele (Greater New York Node) and colleagues presented a poster entitled "Innovative Use of Social Media Tools to Enhance Retention in Community-Based Research" at the National CTSA Community Engagement Conference in Bethesda. The poster describes how 3 sites participating in CTN 0044 used Facebook for locating and contacting patients who were enrolled in outpatient substance abuse treatment, for potential enrollment in the study. The poster touches on technology issues, confidentiality concerns, and recommendations for establishing systematic guidelines for use of these tools in the future.

Secondly, at the September CTN Steering Committee Meeting, Erin Winstanley (Ohio Valley Node) and Meg Brunner **(**CTN Dissemination Library) presented "We Are Not Alone: A Guide to Using Social Media" to both the RUC and PI Caucuses. This presentation, along with an accompanying Resource Guide, provided an overview of Facebook, Twitter, LinkedIn, and blogs, focusing on practical examples from the CTN and beyond. The presentations generated many helpful examples and suggestions about using social media tools in CTN research and dissemination. Also showcased was the new Facebook page for the CTN Library – take a look and "like" the page here: http://facebook.com/ctnlibrary.

In this article, Madhukar Trivedi, Tracy Greer, Bruce Grannemann, and colleagues present the rationale, design considerations, and study design of CTN Protocol 0037: Stimulant Reduction Intervention Using Dosed Exercise (STRIDE). STRIDE is a multisite randomized clinical trial that compares exercise to health education as potential treatments for stimulant abuse or dependence**.** STRIDE is one of the first studies conducted within the CTN that is specifically designed as a first test of a new intervention in a specific disorder. As such, it will not only test the efficacy and effectiveness of this intervention for stimulant abuse and dependence, but also provide information about conducting this type of study in the context of a network of community treatment programs.

Citation: Trivedi M, Greer TL, Grannemann BD, Church TS, et al. Stimulant Reduction Intervention Using Dosed Exercise (STRIDE) – CTN 0037: Study Protocol for a Randomized Controlled Trial. *Trials* 2011;12:206. This article is free online!

Request & read about these items and more in the CTN Dissemination Library! The web site is maintained by the Pacific Northwest Node of the Clinical Trials Network.
http://ctndisseminationlibrary.org.

Delaware Valley News

Dr. George Woody, Node Principal Investigator, provided an in-service training for staff at NETSteps, a local program with a large methadone census as well as non-agonist treatment programs, on the topic of medication-assisted therapy with a focus on opioid addiction and approaching it as a chronic relapsing disorder that requires long-term treatment. In attendance were two members of the Philadelphia Police Force who had become tired of arresting addicts again and again, and were now focusing on community education, responding to overdoses, and trying to get problematic substance users into treatment.

Project Engage Expands to Christiana Hospital; DelVal Node to Collaborate on Program Evaluation Study

From 2008-2010, Dr. Terry Horton and Wilmington Hospital successfully piloted Project Engage, an SBIRT program for hospitalized medical inpatients and presented results at the 2011 conference of the College on Problems of Drug Dependence in Hollywood, Florida. Due to the success of the program, an anonymous donor has provided 3 years of funding to expand and extend the project at Christiana Hospital, a 913-bed hospital in Christiana, Delaware. Together with Wilmington Hospital, Christiana Hospital treats 80% of all patients in the state. Drs. Woody and Pecoraro are collaborating with Dr. Horton and Christiana Care Health System to evaluate this project. The success of this project, and its potential to reduce health care costs by identifying patients on medical units with substance use disorders, get them into treatment, and reduce costly readmissions and emergency room visits, has attracted interest from the White House Office of National Drug Control Policy, and Deputy Director Mineta visited Christiana on September 20th to obtain more information about the project.

Sergey Dvoryak, a NIDA/INVEST/CTN fellow from Kiev, Ukraine, who is with the Delaware Valley Node for a year, was just selected as a representative to the International AIDS Society for a term that ends in 2014. In this role he will participate in decisions about HIV treatment and prevention policies and resources in developing countries, with a focus on persons with substance use disorders.

Publications Committee (PC)

The Publications Committee reports that the primary outcome papers of the following CTN studies have been accepted for publication in the journals listed below:

- Brief Strategic Family Therapy (CTN 0014) *Journal of Consulting & Clinical Psychology*
- Job Seekers Workshop (CTN 0020) *Drug & Alcohol Dependence*
- OROS MPH in Adolescent ADHD Substance Abusers (CTN 0028) *Journal of the American Academy of Child & Adolescent Psychiatry*
- Prescription Opioid Abuse Treatment (CTN 0030) *Archives of General Psychiatry*
- HIV Rapid Testing (CTN 0032) *American Journal of Public Health*

Two additional publications have resulted from secondary analysis of CTN trial results:

- Pilowsky DJ, Wu LT, Burchett B, Blazer DG, Woody GE, Ling W. Co-occurring amphetamine use and associated medical and psychiatric comorbidity among opioid-dependent adults: results from the Clinical Trials Network. Subst Abuse. Rehabil. 2011 Jan 1;2:133-144. PubMed PMID: 21886430; PubMed Central PMCID: PMC3163455. Free available here: http://www.dovepress.com/co-occurring-amphetamine-use-and-associated-medical-and-psychiatric-co-peer-reviewed-article-SAR
- Wu LT, Ling W, Burchett B, Blazer DG, Yang C, Pan JJ, Reeve BB, Woody GE. Use of item response theory and latent class analysis to link poly-substance use disorders with addiction severity, HIV risk, and quality of life among opioid-dependent patients in the Clinical Trials Network. Drug Alcohol Depend. 2011 November 1; 2-3; 186-193 PubMed PMID: 21501933; PubMed Central PMCID: PMC3170493.

Useful Sites for CTNers!

- ***Medication and lab supply orders*** - ctnsupport@emmes.com
- ***Safety related issues/adverse event follow-up*** - ctnsafety@emmes.com
- ***Training information, comments or requests*** - ctntraining@emmes.com

2012 CPDD Primm-Singleton Minority Travel Awards Program

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 attend the 74th Annual Scientific Meeting of CPDD to be held in Palm Springs, California, June 9-14, 2012. The preferred candidate for this award is a graduate student with a demonstrated commitment to research and/or teaching in substance abuse. Applicants are required to be enrolled in a graduate program. In addition, applicants must be members of an ethnic minority group under-represented in substance abuse research, including but not limited to African Americans, Hispanics, Native Americans, and Pacific Islanders. Previous awardees and individuals currently supported by NIDA/NIH training grants or individual Predoctoral National Research Service Awards (F31) are not eligible. Citizenship of the United States or a permanent visa is required.

To apply, applicants should submit the following information in a single attachment:

1. A cover letter (<1 page) indicating your eligibility and interest in pursuing research on drug addiction, and how attending this conference will advance your career in research and education;
2. Complete contact information (e.g. name, title, mailing address, telephone number, and e-mail address);
3. Academic curriculum vitae;
4. Letter of recommendation from your mentor, advisor or an individual who is familiar with your work;
5. Copy of abstract (<250 words) for presentation at the CPDD Annual Scientific Meeting.

Incomplete applications will not be considered. Applications must be postmarked on or before **November 1st, 2011**.

Applications will be scored according to scientific relevance, methodological strength, and the candidate's involvement in the field. Applicants are required to submit their abstracts to be considered for presentation at the 2012 CPDD Annual Scientific Meeting. Application materials should be sent via e-mail to: carmen.masson@ucsf.edu.

Additional information can found on their website at http://www.cpdd.vcu.edu/Pages/Index/Awards/TravelDescrip.html.

NIDA's Women & Sex/Gender Differences Junior Investigator Travel Award Program for 2012 College on Problems of Drug Dependence (CPDD)

Special NIDA travel awards of $750 will be available to up to 30 junior investigators whose CPDD abstract on women or sex/gender differences is accepted for either a poster or oral session at the 2012 annual meeting in Palm Springs, California, June 9-14, 2012.

Eligibility:

- Graduate and medical students, post-doctoral students, medical residents, and investigators who are no more than five years past the doctoral degree or residency are eligible.
- Applicant MUST be first author on the CPDD abstract.
- Minority investigators and male investigators are especially encouraged to apply.
- Priority may be given to those who have not previously received this award or held an R01.
- Federal employees are ineligible.

To apply, follow the CPDD instructions (available on CPDD's website: **http://www.cpdd.vcu.edu/**) for abstract submission. Then, send an e-mail to Dr. Samia Noursi at snoursi@mail.nih.gov in the following format and with the required attachments:

- E-mail subject line: NIDA's 2012 Women & Sex/Gender Differences Junior Investigator Travel Award
- Attach a copy of the abstract that you submitted to CPDD, including title and authors.
- Attach your curriculum vitae (list all NIH grant support if applicable). Please include your mailing address, telephone number and e-mail address.
- Attach a cover letter stating (1) your eligibility, (2) your interest in continuing to pursue research on women and/or sex/gender differences, and (3) your career goals.

The deadline for applications is the same as the deadline for CPDD abstracts - December 1, 2011.

For additional information about this annual award, please contact
Dr. Samia Noursi - telephone 301-594-5622; snoursi@mail.nih.gov, or
Dr. Cora Lee Wetherington - telephone 301-435-1319; cwetheri@nida.nih.gov.

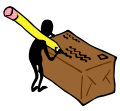
Reminder from the RDC

The CTN Research Development Committee (RDC) reminds Node PIs, Node Coordinators, and Node-level investigators of the process for requesting and approving an ancillary study. The RDC requires that Node PIs be made aware of applications for ancillary study concepts that will be submitted to the RDC by their respective investigators. The Node PI will be responsible for allocating funds and staff for the study if it goes forward and, as such, should support any proposals.

This is in addition to the requirement that investigators proposing an ancillary study have written documentation that the Lead Investigator of the parent protocol to which the ancillary study will be attached has reviewed and approves/supports the proposed ancillary study. Please share this with your Node personnel.

New Funding Opportunities

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



- Clinical Research Education and Career Development (CRECD) in Minority Institutions (R25) (PAR-11-325)
- Interventions for Health Promotion and Disease Prevention in Native American Populations (R01) (PAR-11-346)

Clinical Coordinating Center (CCC) at EMMES

2011 Web Seminar Series –
December 7 A New Look at Manual of Procedure (MOP) Development

Those interested in registering may contact ctntraining@emmes.com or Liz Buttrey at ebuttrey@emmes.com

All webinars are available online on the CTN Dissemination Library at the following site: http://ctndisseminationlibrary.org/ctntraining.htm

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