

Clinical Trials Network

CTN Bulletin

March 29, 2012

Volume 12 - 06

Trial Progress –Nearing 15,000!



Trial enrollment numbers reflect study information as of March 29, 2012. A recap of the active CTN trials follows.

Total Enrolled All Studies: 14,740

Brief Status of Active CTN Studies

CTN 0037 – STRIDE (Stimulant Reduction



Intervention using Dosed Exercise): The study is a 2-group, randomized controlled trial to test the effectiveness of the addition of exercise in improving drug treatment outcomes in approximately 330 stimulant and cocaine abusing individuals.

Projected Date Last Randomization – July 1, 2012
Randomization – 80% of target
Projected Trial Completion – March 26, 2013
Projected Database Lock – May 27, 2013

CTN 0044 – Web-delivery of Evidence-Based



Psychosocial Treatment for Substance Use Disorders: The purpose of this study is to evaluate the effectiveness of including an interactive, web-based version of the

Community Reinforcement Approach intervention plus incentives targeting drug abstinence and treatment participation as part of community-based, outpatient substance abuse treatment.

Actual Date Last Randomization – August 31, 2011
Randomization –101% of target
Projected Trial Completion –July 10, 2012
Projected Database Lock –September 10, 2012

CTN 0046 – Smoking-Cessation and Stimulant



Treatment (S-CAST): The primary objective of this study is to evaluate the impact of substance abuse treatment as usual plus smoking cessation treatment, relative to substance abuse treatment as usual on drug abuse outcomes.

Actual Date Last Randomization – December 14, 2011
Randomization – 102% of target
Projected Trial Completion – July 18, 2012
Projected Database Lock –September 18, 2012

CTN 0047 – SMART-ED (Screening, Motivational



Assessment, Referral, and Treatment in Emergency Departments): The present study builds on the knowledge base in developing and implementing screening and brief interventions for

harmful and hazardous alcohol use delivered in emergency departments and trauma centers, by transferring and evaluating these procedures when applied to drug use.

Actual Date Last Randomization – February 14, 2012
Randomization – 100% of target
Projected Trial Completion – March 16, 2013
Projected Database Lock – May 17, 2013

CTN 0048 – CURB (Cocaine Use Reduction with



Buprenorphine): 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.

Eleven CTP study sites will enroll 300 cocaine-dependent participants.

Projected Date Last Randomization – October 1, 2012
Randomization – 41% of target
Projected Trial Completion –March 4, 2013
Projected Database Lock – May 5, 2013

CTN 0049 - Project HOPE (Hospital Visit as



Opportunity for Prevention and Engagement for HIV-Infected Drug

Users): Project HOPE will evaluate the effectiveness of a brief intervention delivered to HIV-

infected drug users recruited from the hospital setting in achieving viral suppression. Approximately 800 study participants will be enrolled in this study.

This study is in the pre-implementation stage; the team expects to begin recruitment in summer 2012.

CTN 0050 – Long Term Follow-up to the CTN 0027



(START) study: This project will assess the longer-term outcomes of the large sample of opioid-dependent patients randomly assigned, in the START Study (CTN-0027), who received Suboxone or methadone for six to eight months of treatment. The study team is conducting personal interviews of START participants, approximately 3 to 5 years post-admission, supplemented by (electronic) medical and other records as available.

Follow-up Enrollment – 386 to date

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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 0051 – X-BOT (Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment):



This study will assess the comparative effectiveness of extended release injectable naltrexone (XR-NTX, Vivitrol®) versus buprenorphine-naloxone (BUP-NX, Suboxone®) as pharmacotherapeutic aids to recovery amongst treatment-seeking heroin- and/or prescription opioid-dependent participants.

This study is in the protocol development stage.

CTN 0052 – BRAC (Buspirone for Relapse-Prevention in Adults with Cocaine Dependence):



The primary objective of this study is to evaluate the efficacy of buspirone, relative to placebo, in preventing relapse in cocaine-dependent adults in inpatient/residential treatment who are planning to enter outpatient treatment upon inpatient/residential discharge.

This study is in the protocol development and approval stage. Recruitment is expected to start in summer 2012.

CTN 0053 – ACCENT (Achieving Cannabis Cessation-Evaluating N-Acetylcysteine Treatment)



The primary objective of this study is to evaluate the impact of N-Acetylcysteine (NAC) 1200 mg versus matched placebo (PBO) twice daily, added to compliance enhancement (CE) and contingency management (CM) interventions, on cannabis use among treatment-seeking cannabis-dependent adults.

This study is in the protocol development and approval stage. Recruitment is expected to begin in early 2013.

New Concepts Under Development



Look for information on two new concepts which have been approved for further consideration:

- Bupropion and Extended Release Depot Naltrexone in Methamphetamine Users: Lead Investigator, Dr. Walter Ling, Pacific Region Node
- Comparative Effectiveness of Implantable Buprenorphine and Extended Release Depot Naltrexone in HIV Opioid Users: Lead Investigator, Dr. Todd Korthuis, Western States Node

EMMES Offices Closed



The offices at the CCC and DSC 2 (EMMES) will be closed on Friday, April 6, 2012. The Help Desk staff will not be available that day but will respond to your requests upon their return on Monday, April 9.

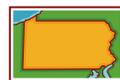
News from the Western States Node



Grant Colfax, MD, of the Western States Node, has just been appointed by President Obama as Director of the Office of National AIDS Policy (ONAP). "Grant Colfax will lead my Administration's continued progress in providing care and treatment to people living with HIV/AIDS," said President Obama. "Grant's expertise will be key as we continue to face serious challenges and take bold steps to meet them. I look forward to his leadership in the months and years to come."

Dr. Colfax, assistant clinical professor of medicine at the UCSF Division of HIV/AIDS at San Francisco General Hospital and director of the HIV Prevention and Research Section in the San Francisco Department of Public Health AIDS Office, has been Co-PI on Protocols CTN 0032 (HIV Rapid Testing) and CTN 0049 (Project HOPE). The Western States Node, as well as the CTN, is proud to have Dr. Colfax conducting these vital activities and wishes him the best in his new role.

Delaware Valley News



The Treatment Research Institute (TRI) announces that A. Thomas McLellan, Ph.D. has returned to continue his leadership role as CEO. Dr. McLellan appointed David Metzger as the Director of Research at TRI.

Terry Horton, M.D., Addiction Medicine, Wilmington Hospital, Christiana Care Health System (CCHS), has joined a national Hospital SBIRT Initiative headed by Drs. Eric Goplerud, Senior Vice President Substance Abuse, Mental Health and Criminal Justice Studies, NORC at the University of Chicago and Larry Gentilello, MD, Professor of Surgery, UT Southwestern Medical Center. Their mission is to change hospital practices nationally within two years so that hospitalized patients with substance use disorders and high risk behavioral health issues are universally screened, treated and followed. The researchers are working within the group to facilitate health economic studies to assess the benefits of referral to treatment of dependent hospitalized medical and surgical patients.

Harold Perl Moves On



Dr. Harold Perl has joined NIDA's DESPR (Division of Epidemiology, Services and Prevention Research) as Acting Branch Chief for the Prevention Research Branch. Dr. Perl has been with CCTN as Lead for Behavioral Research, Dissemination and Training since 2005. We wish him well in his new position!

News from the Mid-Atlantic Node



The Mid-Atlantic Node held its 12th Annual Symposium on March 9, 2012. The meeting drew the largest audience to date with over 200

attendees participating in Common Ground: Integrated Services of Mental Health and Substance Abuse. The day-long symposium began with a morning plenary presented by Dr. Alexandre Laudet, a social psychologist who leads the Center for the Study of Addictions at NDRI (National Development and Research Institutes, Inc.), who spoke about the science of recovery. Her talk was followed by a joint presentation by Dr. Yngvild Olsen and Dr. Lisa Hovermale, each presenting the philosophy of addiction and mental health services respectively. Finally, Elaine Carroll, from On Our Own Maryland added her personal experience as a consumer of both services and the challenges she has faced. For afternoon workshops, the Node's own Dr. Marc Fishman presented on current psychiatric medications and assessments. The other two workshops were designed with an eye toward the future: Sharing Philosophies and The Medical Model Home. This year the Node collaborated with Maryland Alcohol and Drug Administration, Mental Hygiene Administration, and Central East ATTC. The CEATTC provided CEU credits to the participants.



See the CTN Stars on the Mid-Atlantic Node's Motivational Incentives website (www.motivationalincentives.org). Seven

CTNers who have expertise in real world applications of incentives were videotaped at the last CTN Steering Committee Meeting. Each one speaks to a different element of implementation, both the challenges and the rewards. Click on their Hollywood Square on the website's opening page and hear what they have to say: Ray Anderson (Southwest Node), John Hamilton (New England Consortium), Christine Higgins (Mid-Atlantic Node) Candace Hodgkins (Florida Node Alliance), Tom Kelly (Appalachian Tri-State Node), Therese Killeen (Southern Consortium), and Michael Levy (New England Consortium). Thanks again to these CTNers for all their help!

Pacific Region News



The CALDAR Summer Institute will take place on August 13-15, 2012, in Los Angeles, California. This is the fourth Summer Institute on Longitudinal Research. The title of the conference is Promoting Substance Abuse Recovery within the Changing Health Services System.

Registration and travel award details are available at <http://www.caldar.org/>

New Funding Opportunities

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



- The NLM Information Resource Grants to Reduce Health Disparities (G08) <http://grants.nih.gov/grants/guide/rfa-files/RFA-LM-12-001.html>. The National Library of Medicine (NLM) solicits resource grant applications for projects that will bring useful, usable health information to health disparity populations and the health care providers who care for those populations. For help on preparing a G08 application using the SF424 (R&R) Application forms package, go to <http://www.nlm.nih.gov/ep/GrantInfoInstruct.html>
- Use-Oriented Basic Research: Change Mechanisms of Behavioral Social Interventions (Admin Supp) (PA-12-119). This FOA solicits administrative supplement applications to study possible mechanisms of action of behavioral or social interventions.
- Data, Statistics, and Clinical Trial Support for NIDA, N01DA-12-2229 is available at <https://www.fbo.gov/index?s=opportunity&mode=form&id=41e2c1669c171a29f6bb91324a665a38&tab=core&cvview=0>
- Notice Announcing the National Institute on Drug Abuse Interest in Studies on Nicotine/Tobacco and HIV/AIDS (NOT-DA-12-009)
- RFP Notice: Pharmacokinetic and Pharmacodynamic Studies for Medications Development (NOT-DA-12-030)
- Strategic Alliances for Medications Development to Treat Substance Use Disorders (R01) (PAS-12-122)
- Health Services and Economic Research on the Prevention and Treatment of Drug, Alcohol, and Tobacco Abuse (R01) (PA-12-127), (R21) (PA-12-128), and (R03) (PA-12-129)
- Pilot Health Services and Economic Research on the Treatment of Drug, Alcohol, and Tobacco Abuse (R34) (PA-12-130)
- Technology-Based Interventions to Promote Engagement in Care and Treatment Adherence for Substance Abusing Populations with HIV (R01) (PA-12-117) and (R34) (PA-12-118)

Design and Analysis (D & A) Group Forming



Recently within the CTN, there has been an interest in discussing clinical trial design and analysis (D&A) issues. Some members have suggested organizing a face-to-face meeting to discuss issues around primary outcomes. Others have suggested starting a special interest group (SIG) to discuss D&A issues in clinical trials on substance abuse treatments.

An e-mail was sent out on March 20th, to see if there is enough interest among the CTN community in meeting by conference call on a monthly basis to:

- 1) Address common D&A issues that come up during protocol development of CTN trials;
- 2) Discuss journal articles, such as the one by McCann and Li on primary outcome that has been discussed via e-mail; and,
- 3) Offer assistance to investigators who are in the process of protocol development of a CTN trial. (This would be only if the investigator requests assistance; this SIG would not be another CTN protocol review group.)

The group will meet monthly beginning on Friday, April 13th, from 2-3 P.M. (EDT), and will have their regular conference calls on the second Friday of every month. If, after several months, the enthusiasm is still there and some value emerges, the D&A group will continue; otherwise, we will sunset the group. Please contact Paul Wakim if you are interested in joining at pwakim@nida.nih.gov.

More from Western States Node



The University of Amsterdam hosts the two-week Summer Institute on Alcohol, Drugs, and Addiction July 8 to July 20. Dr. Dennis McCarty serves as the academic director for the Institute.

The Institute provides a multi-disciplinary approach to the study of alcohol and drug use disorders. Classes provide overviews of the neuroscience and genetics of addiction, prevention and early intervention strategies, international drug control policy, and treatment improvement and health services research. Field trips to a coffee shop and a heroin-assisted treatment program expose students to Dutch pragmatism and how it shapes drug use and drug treatment. See the website for details:

<http://www.graduateschoolofsocialsciences.uva.nl/sia/introduction.cfm>

Last year, 17 students from 13 countries participated in the Institute.

The Institute is accepting students for the 2012 class (deadline for applications is April 15). The National Institute on Drug Abuse provides one tuition scholarship (\$1600 euros) to a U.S. student interested in a career in drug abuse research. The scholarship does not include travel, housing and per diem expenses. Individuals must be in graduate school or have completed graduate studies. See the NIDA website for details.

<http://international.drugabuse.gov/about-us/news/2012/02/applications-open-intensive-summer-training-addiction>

This is an excellent opportunity for new investigators who seek a broad perspective on drug abuse research to meet Dutch, U.S., English, and other investigators and learn more about international drug control and drug treatment policies. Please encourage and support participation from new investigators.

Clinical Coordinating Center (CCC) at EMMES



2012 Web Seminar Series

The recorded session and handouts are available on the CTN Dissemination Library

<http://ctndisseminationlibrary.org/ctntraining.htm>

Upcoming webinars:

May 9	Managing Emotions in Recovery
June 13	Biological Measures and Specimen Handling
July 18	Co-occurring Disorders: Integrated Treatment of Addiction and Mood and Anxiety Disorders

Don't forget to follow [CTN Training](#) on Facebook, and while you're there, be sure to check out the Facebook page for the [CTN Dissemination Library](#).

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

NIDA Project Officer, Steve Sparenborg, at:
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Updates for this Bulletin should be sent to Carol Cushing at
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