



Clinical Trials Network

CTN Bulletin

March 28, 2013

Volume 13 - 05

Trial Progress – Over 15,000!



Trial enrollment numbers reflect study information as of March 27, 2013.

Open Studies

- **CTN 0047 – SMART-ED** (Screening, Motivational Assessment, Referral, and Treatment in Emergency Departments) Enrolled 1,285 (N=1,285). Enrollment completed – in follow up phase.
- **CTN 0048 – CURB** (Cocaine Use Reduction with Buprenorphine). Enrolled 302 (N=300). Enrollment completed – in follow up phase.
- **CTN 0049 – Project HOPE** (Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users). Enrolled 379 (N=800).
- **CTN 0050** – Long Term Follow-up to the CTN 0027 (START) Study. Enrolled 791 (N=1,267).
- **CTN 0052 – BRAC** (Buspirone for Relapse-Prevention in Adults with Cocaine Dependence). Enrolled 62 (N=60). Enrollment completed – in follow up phase.

Total Enrolled All Studies: 15,787

Status of Current CTN Studies



CTN 0037 – STRIDE (Stimulant Reduction Intervention using Dosed Exercise):

Actual Date Last Randomization – June 20, 2012
Actual Trial Completion – February 26, 2013
Projected Database Lock – May 15, 2013



CTN 0044 – Web-delivery of Evidence-Based Psychosocial Treatment for Substance Use Disorders:

Actual Date Last Randomization – August 31, 2011
Actual Trial Completion – June 24, 2012
Actual Database Lock – September 7, 2012



CTN 0046 – Smoking-Cessation and Stimulant Treatment (**S-CAST**): Evaluation of the Impact of Concurrent Outpatient Smoking-Cessation and Stimulant Treatment on Stimulant-Dependence:

Actual Date Last Randomization – December 14, 2011
Actual Trial Completion – July 11, 2012
Actual Database Lock – September 21, 2012



CTN 0047 – SMART-ED (Screening, Motivational Assessment, Referral, and Treatment in Emergency Departments):

Actual Date Last Randomization – February 14, 2012
Actual Trial Completion – February 12, 2013
Projected Database Lock – May 17, 2013



CTN 0048 – CURB (Cocaine Use Reduction with Buprenorphine):

Actual Date Last Randomization – November 1, 2012
Actual Trial Completion – March 19, 2013
Projected Database Lock – June 5, 2013



CTN 0049 - Project HOPE (Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users):

Actual Date First Randomization – July 10, 2012
Projected Date Last Randomization – December 1, 2013
Projected Trial Completion – February 1, 2015
Projected Database Lock – April 4, 2015

CTN 0050 – Long Term Follow Up to CTN 0027 (START):

Actual Date First Enrollment – August 18, 2011
Projected Date Last Enrollment – June 19, 2016
Projected Database Lock – August 19, 2016

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

This study is in the protocol development stage. Enrollment expected in early 2014.



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

Actual Date First Randomization – August 2, 2012
Actual Date Last Randomization – March 4, 2013
Projected Trial Completion – June 24, 2013
Projected Database Lock – August 25, 2013

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 0053 – ACCENT (Achieving Cannabis Cessation: Evaluating N-Acetylcysteine Tx):

This study is in the protocol development and approval stage. Enrollment expected to begin in fall 2013.



CTN 0054 – ADAPT-MD (Combo Pharmacotherapy for Methamphetamine Dependence: Extended Release Depot Naltrexone+Bupropion vs. Matched Placebos):

This protocol is in the final development and approval stage. Enrollment expected to begin in fall 2013.



CTN 0055 – CHOICES (Comparing Treatments for HIV Positive Users in an Integrated Care Effectiveness Study):

This protocol is in the development and approval stage. Enrollment expected to begin in spring 2014.



CTN 0056Ot – Testing and Linkage to HIV Care in China: a Cluster Randomized Trial.

The goal of this study is to determine whether implementation of two structural interventions will increase the proportion of HIV-positive, treatment-eligible patients, who are linked to antiretroviral treatment (ART) and who achieve VL suppression, thereby reducing mortality. The study consists of two interrelated cluster randomized trials at 24 county hospitals in Guangxi, China, to assess the effectiveness of two interventions: 1) a new testing algorithm, consisting of rapid point-of-care HIV and CD4 testing, with viral load testing in parallel, designed to ensure completeness of diagnostic assessment and accelerate time to ART initiation for patients deemed ART eligible; and 2) an innovative provider and patient incentives program designed to enhance linkage and retention in HIV care, achieve sustained viral suppression, and reduce mortality.

This protocol is in the development and approval stage. Enrollment expected to begin in fall 2013.



CTN 0057Ot – Screening, Brief Intervention, and Referral to Treatment in Primary Care (SBIRT-PC): An add-on project to “Duke University CMS Innovation Award Southeastern Diabetes Initiative.”

This study leverages the existing research resources of a funded parent project “Duke University Centers for Medicare and Medicaid Services (CMS) Innovation Award Southeastern Diabetes initiative (PI: Robert M. Califf, MD).” It explores the feasibility of implementing

Screening for substance use, Brief Intervention, and Referral to Treatment services (SBIRT) in diabetic patients in primary care, and examines the effects of substance use status on diabetes health care outcomes. It also assesses the feasibility of the CTN’s clinical decision support algorithm for SBIRT in the primary care setting. Adults aged 18 or older with type 2 diabetes and who meet the inclusion and exclusion criteria for the parent study at the Durham County, North Carolina sites will be screened and assessed for substance use at baseline and 6, 12, 18 and 24-month follow-up periods. The study will examine changes in substance use trajectories and explore the impact of substance use status on subsequent diabetes care and health outcomes.

This protocol is in the final development and approval stage. Enrollment expected to begin in summer of 2013.

Design and Analysis SIG Workshop



The Design and Analysis Special Interest Group (SIG) held a workshop on March 13, 2013, during the recent CTN Steering Committee meetings. The workshop title was “Matching Study Design to Existing Scientific Evidence.”

Dr. Edward Nunes (Greater New York Node) discussed how to pick winners, how to select new candidate treatments with pre-clinical and early stage clinical trials, and what evidence should be required before investing in a large definitive clinical trial. He argued that many of the research findings start serendipitously at bedside, then move to bench, then bedside.

Dr. George Woody (Delaware Valley Node) addressed the development of Naltrexone – bench to practice. He discussed the evolution of research on naltrexone from the first human studies at Lexington in 1971-73 to the Russian study on extended-release naltrexone in 2009-2010.

Dr. Andrew Saxon (Pacific Northwest Node) focused on study CTN 0027 (START) as a case study considering if the same questions could have been answered with an observational study rather than a randomized controlled trial (RCT). In this instance, the FDA had requested an RCT comparing buprenorphine/naloxone (BUP/NX) and methadone (MET) on indices of hepatic safety, with 300 “evaluable” participants in each treatment condition. The answer is not simple, and arguments on both sides were discussed.

The general discussion included pilot studies and if they provide useful information. Others argued for more evidence of efficacy and feasibility before conducting large multisite trials.

MIG Symposium



The Minority Interest Group (MIG) of the National Drug Abuse Treatment Clinical Trials Network (CTN) hosted a Race and Ethnic Minorities (REM) Research Symposium on March 12 and 13, 2013, in Bethesda, Maryland. The meeting started with opening remarks by Dr. Betty Tai, the Director of the Center for the Clinical Trials Network (CCTN) and Dr. David Shurtleff, the Acting Deputy Director of NIDA, followed by Dr. Derrick Tabor from the National Institute on Minority Health and Health Disparities (NIMHD). Next, the research presentations described CTN research on racial ethnic substance abusers across a wide range of topics including recruitment and retention into clinical trials, research on the efficacy of specific substance abuse interventions (e.g., HIV Rapid Testing, Seeking Safety, Motivational Enhancement Therapy, Brief Strategic Family Therapy, Real Men Are Safe), and HIV (i.e., risk behaviors, testing, and access to services). Other presenters described research on web-delivered treatment with ethnic minorities research, research on users of specific types of drugs (e.g., “cheese heroin”, methamphetamine) and barriers to enrollment in treatment (e.g., medical mistrust). Following the research presentations, representatives from the four NIDA workgroups described their activities. The meeting ended with a presentation on current training opportunities within NIDA and the CTN.

Gender Special Interest Group Symposium



The Gender Special Interest Group (GSIG) of the National Drug Abuse Treatment Clinical Trials Network (CTN) hosted a seminar titled “Gender Related Research in the Clinical Trials Network: What’s New?” on March 13, 2013, in Bethesda, Maryland. The seminar included an introduction presented by Dr. Shelly Greenfield (Harvard University) followed by presentations by: (1) Denise Hien (Columbia University) who discussed results from secondary analyses-beyond the main outcomes from CTN-0015, the Women and Trauma Study; (2) Dr. Audrey Brooks (University of Arizona) who presented her paper on gender differences in rates and correlates of HIV risk behaviors among drug dependent persons; (3) Drs. Susan Tross and Aimee Campbell (Columbia University) who presented data from the combined CTN 0018/0019 datasets, recent findings on sexual risk behaviors; and (4) Dr. Kate McHugh (Harvard University) who presented her paper “Gender differences in prescription opioid dependence: results from a secondary analysis of CTN 0030.” Dr. Greenfield provided conclusions and recommendations and also facilitated a panel discussion at the end of the seminar.

The CTN GSIG dedicated this seminar in memory of our dear friend and well-loved colleague, Don Calsyn, who passed away on February 3, 2013. Don was an extremely productive psychology researcher working in the area of treatment and interventions for people with substance use disorders and persons with HIV and AIDS. He was Professor in the Department of Psychiatry and Behavioral Sciences at University of Washington, a member of the Pacific Northwest Node and active participant in the CTN GSIG. The GSIG seminar was followed by a warm memorial to Don, where several CTN colleagues provided memories and remarks about Don’s career and life. Thanks to all and especially to Dr. Susan Tross for organizing the memorial!

Western States Node News



Congratulations to Dr. James Sorensen, Co-Principal Investigator of the Western States Node and Professor of Psychiatry at the University of California, San Francisco. The College on Problems of Drug Dependence (CPDD) has announced that he is the recipient of the CPDD Mentorship Award for 2013. CPDD has been in existence since 1929 and is the longest-standing group in the United States addressing problems of drug dependence and abuse. With over 700 members, the organization serves as an interface among governmental, industrial, and academic communities, maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.

The Mentorship Award, established in 2000, is given annually to a member of CPDD who has been an exemplary mentor to developing researchers in the field of drug dependence. Dr. Sorensen was nominated by several of his current and former fellows, one of whom stated, “I came to UCSF due to the strong mentorship I knew I would receive from Dr. Sorensen. I am glad that I did, because I have learned a lot from him and it’s been a pleasure having him as a mentor.” Dr. Sorensen has trained 15 faculty members, 28 post-doctoral fellows, and 22 pre-doctoral fellows. He is the director of a T32 training grant funded by the National Institute on Drug Abuse, the Research Training Core director in UCSF’s Drug Abuse Treatment and Services Research Center, cluster leader of the Clinical Psychology Training Program for pre-doctoral and post-doctoral fellows, and co-director of the Visiting Professors Program at the Center for AIDS Prevention Studies (CAPS) at UCSF. Jim will receive the award at CPDD’s 75th Annual Meeting in San Diego, June 15-20, 2013.

Congratulations on this prestigious award!

Delaware Valley Node Update



Dr. George Woody, Principal Investigator of the Delaware Valley Node, has been selected for the John P. McGovern award given annually by AMERSA (Association for Medical Education and Substance Abuse--www.amersa.org). The John P. McGovern award is given to an individual who has played a significant role in substance abuse research and education.

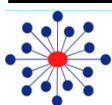
AMERSA is a national organization of researchers and educators in the field of substance abuse. Dr. Woody was nominated by one of his peers. He is scheduled to give the McGovern Lecture on Friday, November 8, 2013, at the AMERSA annual meeting in Bethesda, MD.

News from the Greater New York Node



At the recent CTN Steering Committee Meeting's Race and Ethnic Minorities Research Symposium, a presentation derived from a paper published in the *Journal of Addiction Medicine* from the Infections and Substance Abuse Study (CTN-0012) was given by Lawrence S. Brown, Jr., MD, MPH, FASAM, Chief Executive Officer at Addiction Research and Treatment Corporation. The presentation was entitled, *Disparities in Infection-Related Services in Substance Abuse Treatment Programs for Underserved Populations*. Co-authors of the publication included, among others, Steven Kritz, MD from ARTC and John Rotrosen, MD, co-Principal Investigator of the Greater NY Node.

Where to Get Useful Information



The NIDA CTN website includes information on the CTN Nodes, CTPs, and studies. For more information go to: <http://www.nida.nih.gov/CTN/>

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

Good Clinical Practice training is available via on-line self-study for all CTN members at: www.nihtraining.com/ctn.

CTN Data Share – download public data sets, and study information at www.ctndatashare.org.

CTN Dissemination Library – The CTN Library is web-based, publicly available, and includes a catalog with descriptive records for each item in the Library. The CTN Dissemination Library is maintained by the Pacific Northwest Node of the Clinical Trials Network. Their website is at: <http://ctndisseminationlibrary.org>

CTN International Workshop Recap



The CTN organized an international grant writing workshop and a symposium on March 14, 2013. At the grant writing workshop: (1) Dr. Rogers (NIDA) presented an overview of NIH grant application and review; (2) Drs. Gust, Montoya and Erinoff presented funding opportunities within NIDA; (3) Dr. Levintova (Fogarty International - NIH) presented opportunities within NIH Fogarty Center; and (4) Drs. Ling (UCLA) and Woody (University of Pennsylvania) discussed their experiences with international projects.

The grant writing workshop was followed by a research symposium with presentations from the current CTN INVEST fellows: Dr. Vivi Lubis (Indonesia) and Dr. Jan Klimas (Ireland), then by presentations from (1) Dr. Mathew Young, Canadian Centre on Substance Abuse, Ottawa, Ontario; (2) Dr. Fiestas, Centro Nacional de Salud Pública, Instituto Nacional de Salud, Lima-Perú; (3) Dr. Evan Wood, University of British Columbia, BC Centre for Excellence in HIV/AIDS, Vancouver, BC; (4) Dr. Roberto Mollica, Dipartimento Politiche Antidroga, Roma, Italy; and (5) Dr. Rodrigo Marin, Instituto de Psiquiatria Ramon de la Fuente, Mexico. The meeting was attended by visitors from Canada, Norway and China, as well as several Humphrey fellows.

New Funding Opportunities

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



- Notice of Participation of the NIH Common Fund in PA-12-149 Research Supplements to Promote Diversity in Health-Related Research (Admin Supp) ([NOT-RM-13-012](#))
- Limited Competition - Multicenter AIDS Cohort Study: Center for the Coordination, Analysis, and Management of the MACS (CAMACS)(UM1) ([RFA-AI-13-010](#))
- Limited Competition Multicenter AIDS Cohort Study (MACS) Clinical Research Sites (U01) ([RFA-AI-13-011](#))
- Research on Marijuana Legalization in the US (Admin Supp) ([PA-13-138](#))
- Advancing Exceptional Research on HIV/AIDS (R01) ([RFA-DA-14-003](#))

Western States Node – Free Training Offered



The Western States Node and MARC (Methamphetamine Abuse Research Center) are collaborating with three ATTCs (Addiction Technology Transfer Centers) to present a webinar on impulsivity and addiction. This FREE training event is brought to you by the Central Rockies ATTC, Northwest ATTC, Pacific Southwest ATTC, and the Western States Node of the NIDA Clinical Trials Network and MARC at Oregon Health and Science University.

About the Training:

Individuals with addictive disorders often make rash decisions and behave impulsively, which can impact their treatment. The webinar will critically examine different ways to measure impulsivity and how performance on these measures can predict changes in addictive behaviors. The discussion will highlight the important ways clinical research and basic science research can inform each other. It will also examine various factors that impact impulsivity, including genetics, environmental history of adversity and stress, emotional state including distress due to substance withdrawal symptoms, and other psychosocial factors. The final part of this webinar will outline studies that show how these factors alter the neural functions that govern impulsivity.

This webinar has been approved for a total of 1.5 contact hours through the National Association of Alcoholism and Drug Abuse Counselors (NAADAC).

For more information on ATTCs, please visit the website: <http://www.attcnetwork.org/index.asp>

For more information on the Western States Node of the NIDA Clinical Trials Network, please visit the website: <http://www.drugabuse.gov/about-nida/organization/cctn/ctn/network-organization/nodes/western-states>

To register, go to:
<https://casatunr.wufoo.com/forms/neuroscience-of-impulsivity-addictive-disorders/>

DSC and CCC Closed



The NIDA CCC (Clinical Coordinating Center) and DSC (Data and Statistics Center) offices at EMMES will also be closed Friday, March 29, 2013. The DSC 2 Help Desk will not be available that day, but staff will respond to your requests when the office reopens on Monday, April 1st. Please notify your sites.

RFI Issued – Feedback Requested



The HHS Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) jointly issued a Request for Information (RFI) to seek public input on policies and programs which would accelerate health information exchange (HIE) across providers to support more coordinated person-centered, value-driven care. There are several potential policy options within this RFI which could positively impact the behavioral health community.

The ONC and CMS will be accepting comments until 5:00 pm ET on April 22, 2013. Please send comments to: <http://www.gpo.gov/fdsys/pkg/FR-2013-03-07/pdf/2013-05266.pdf>.

Clinical Coordinating Center (CCC) at EMMES



General Update. The CCC will be contacting the various Node staff to conduct an annual update of the CCC's Distribution List for Monitoring correspondence. Please provide your updates accordingly.

Training Update. Webinar Invitation: The NIDA CCC will host a webinar entitled, "IRB and Regulatory Documentation," on **Wednesday, April 24th from 1:00 – 2:00 pm (ET)**. Ms. Emily Dorer and Dr. Ro Shauna Rothwell will address IRB requirements and requirements for site regulatory document management in the conduct of clinical trials.

An e-mail invitation with registration and webinar access information will be circulated to all those included in the CTN mailing list. If you have not been added to the mailing list and would like to participate in this or future training sessions, please send an email request to CTNtraining@emmes.com.

NIDA Project Officer, Steve Sparenborg, at: sparenborgs@nida.nih.gov, telephone (301) 496-4844.

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.

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

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