



Clinical Trials Network

CTN Bulletin
March 25, 2008
Volume 08 – 06

Trial Progress –



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 29, 2008.

Open Studies (4)

- CTN 0027 – Randomized 648
- CTN 0028 – Randomized 259
- CTN 0030 – Randomized 421
- CTN 0031 – 5 (NEW)

Total Randomized All Studies: 8,801

CTN 0031 STAGE –12 Is Randomizing!



The STAGE-12 (Stimulant Abuser Groups to Engage in 12-Step) began enrolling patients on February 11. Three Wave 1 sites will be active in this first phase. At the end of February, 5 participants had been enrolled in the study, 3 at Maryhaven in the Ohio Valley Node and 2 at RCKC in the Pacific Northwest Node. The study will be carried out at 9 sites with a planned enrollment of 400 participants.

CTN 0027 START Protocol



The START (Starting Treatment with Agonist Replacement Therapies) study compares changes in liver enzymes related to treatment with Buprenorphine/Naloxone (Suboxone) to changes in liver enzymes related to treatment with methadone. The protocol was recently amended to allow for 2:1 randomization of Suboxone to methadone and for more flexible Suboxone dosing parameters. Last week there were 10 new consents and 8 new randomizations (all of which went to the Suboxone group). Kudos to both BAART and CODA, who each reached their 100th site randomization!!

RDC Call for Concepts



The Research Development Committee (RDC) is seeking concept ideas for the CTN's first web-based protocol. The RDC is open to all ideas, from stand-alone web-based treatments to those that complement treatment as usual at Community Treatment Programs. Please submit your one page proposals to Raul Mandler (mandlerr@nida.nih.gov) by March 31.

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 0028 Adolescent ADHD Protocol



The Lead Team of CTN 0028 (Randomized Controlled Trial of OROS-MPH in Adolescents with ADHD and Substance Use Disorders (SUD)) sends its warmest

“Congratulations!” to the eleven participating sites. With 270 of the targeted 300 adolescents randomized, study enrollment is expected to be completed by June 1, 2008. Successful recruitment of adolescents with co-occurring disorders, coupled with excellent treatment compliance, retention and safety is a strong indication that important research gaps in dually-diagnosed adolescents can be addressed and that CTN can serve as a platform for such research. Moreover, broad implementation of reliable and comprehensive substance and psychiatric diagnostic evaluation procedures has not been previously demonstrated in “real world” community based adolescent treatment programs. CTN 0028 sites take a bow for your landmark achievements!

SSTAR Fall River – Northern New England
Synergy - ARTS – Colorado
LRADAC – Southern Consortium
MHMR of Tarrant County – Texas
Operation PAR – Florida
Gateway – Florida
Crittenton – Ohio Valley
Mountain Manor – Mid-Atlantic
Rehab After Work – Delaware Valley
St. Luke's Roosevelt– Long Island
Addiction Medicine Svc – Appalachian Tri-State



CTN 0032 Update



Site selection activities for the HIV Rapid Testing & Counseling (CTN 0032) protocol continue to progress. A total of 25 treatment units from 17 CTPs are potentially eligible to participate in the study. Nearly all sites have completed Phase 2B (client survey) of the site selection process to garner more information about their clients' potential eligibility for the study. Phase 3A of the site selection process, involving telephone interviews with CTP representatives and their respective Node Coordinators, continues. Site visits for Phase 3B are beginning. Subsequently, 12 sites will be selected to participate in CTN 0032 and notified of their status. While site selection activities are underway, the Investigative Team, various work groups and collaborators continue to develop SOPs, training materials, assessments and CRFs.

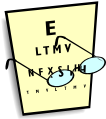
What is FISMA?



The Federal Information Security Management Act (FISMA) of 2002 applies to all Federal agencies and contractors.

FISMA is concerned with computer and network security. Computers and electronic systems which handle or house Federal information or data must follow specific guidelines to maintain the security and confidentiality of the information. How does this affect the Clinical Trials Network? The Act has broad consequences for all the clinical trial sites, our contractors, grantees, and staff who have access to any of the systems. The CTN's Data and Statistics Center at Duke Clinical Research Institute (DCRI) has set up the electronic clinical data systems (InForm and CRIS) to comply with federal standards. However, FISMA imposes additional requirements for all persons who may access the systems, no matter how infrequently this occurs. For the immediate future, all staff are reminded to keep their system passwords secure and confidential, and not to share their passwords with others. All computers and laptops which are used to access the data systems must have encryption software installed (compliant with FIPS 140-2). The CCTN is verifying some additional requirements and will address these at the upcoming Steering Committee in Cincinnati, Ohio. If you have any questions about this Act, contact your university grants and contracts office or Mary Ellen Michel at the CCTN for additional information.

Health Services Research Group Update



The CTN Health Services Research (HSR) interest group has changed their monthly call to every other month, 2:30 EST, the second Tuesday of odd-numbered months. The group's activities include: (1) discussion of

current HSR ancillary studies, (2) discussion of future potential HSR ancillary studies with new CTN studies, and (3) sharing of opportunities for external funding for HSR ideas and for presentation at scientific meetings. Interested individuals can contact Carmen Rosa (CCTN) at crosa@nida.nih.gov or Jim Sorensen (CA/AZ) at james.sorensen@ucsf.edu. The next call is May 13.

Minority Interest Group Update



The Minority Interest Group meets the first Monday of the month at 3 pm EST. The members are currently working on two major activities: (1)

literature search for a possible review paper on ethnic minorities and SUD treatment and (2) review of the current CTN publications to summarize what has been published about ethnic minorities so far (in the CTN). Interested individuals should contact Carmen Rosa at crosa@nida.nih.gov.

Public Access Law Now Mandatory



The NIH voluntary Public Access Law is mandatory effective April 7, 2008. Investigators are now required to send to PubMed Central an electronic version of their final,

peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.

Specifically:

1. The Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.
2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements fully comply with this Policy.
3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible (<http://www.pubmedcentral.nih.gov/>).
4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.
5. Beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH funded research.

For more information, click on this web site:

[NIH Guide Notice for Public Access](#)

Gender Special Interest Group

The Gender Special Interest Group meets the first Wednesday of the month at 1 pm EST. The group is involved in the following activities: (1) reviewing current and completed protocols for possible gender related secondary analyses, (2) reviewing

activities with current gender related multi study secondary analysis (*Gender Differences in the Prevalence and Predictors of HIV Risk Behaviors*), and (3) following up possible publications of gender related ancillary studies and other single study secondary analyses. There will be a symposium at the upcoming American Psychiatric Association annual meeting (*Women and Substance Abuse Treatment: Exploring Women-Focused Treatments and Services*) that was coordinated by Shelly Greenfield and Carmen Rosa. Shelly Greenfield, Susan Tross, Denise Hien and Susan Gordon will present results, and Kathleen Brady will be the discussant. Interested individuals should contact Carmen Rosa at crosa@nida.nih.gov.

Retention Tips from the 0027 Team



In an effort to improve participant retention in the START study (CTN 0027), the Lead Team asked the participating Community Treatment Programs (CTPs) what their best strategies have been. Here are a few

successful tips to share from those CTPs:

- ✓ Dosing more aggressively on Day One and Two
- ✓ Bonding with clients at induction, building a stronger rapport during treatment
- ✓ Increasing the frequency of phone calls to see how the patients are doing between visits
- ✓ Lengthening the clinic's operating hours
- ✓ Linking new patients with their counselor on induction day
- ✓ Adding more staff training in dosing for the patient population and on the protocol itself
- ✓ Integrating the START study into the clinic operations more effectively

Thanks to the Team for sharing these great tips!

CTN Data Share Web Site



Study data from completed CTN studies are available to the public on the CTN Public Data Share web site (www.ctndatashare.org) approximately 18 months after completion of the study or after acceptance of publication

of the primary manuscript, whichever occurs first. Currently, the web site contains data from the following studies: CTN 0001, 0002, 0004-0009, 0011, 0012 and 0016. Within the next 4-6 months, the web site will also include new data from CTN 0003 (Bup/Nx Taper Study) and CTN 0013 (MET in Pregnant Substance Abusers), as well as flat-file datasets for CTN 0001 and CTN 0002

The web site will be undergoing some improvements over the new few months. An updated design along with documentation to help navigate the web site's content are expected. Our overall user response to date is "Excellent" based on the survey response of active users; however, we are always looking for ways to improve upon what we have already accomplished. If you have suggestions about what you would like to see on the web site or any questions about the web site contents, please contact Cindy Green at cindy.green@duke.edu.

Check the web site periodically to access recently posted data, study documentation and other new study information.

CTN Policies and Procedures:



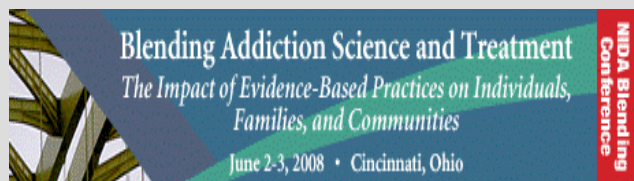
The CCTN has updated the Policy and Procedures Guide (first released on May 2006). To access the revised Policy and Procedures Guide, please go to

<https://livelink.nida.nih.gov/livelink/lisapi.dll?func=UniteAtlas.ToggleTreeDisplay&TreeName=LL> (1.1, dated March 20, 2008).

Revisions include:

1. **Section 1.1: CTN Bylaws** – The Bylaws were amended on February 2008 by the SC.
2. **Section 1.3: CTN as a Platform** – This section was revised to delete the ancillary studies.
3. **Section 1.8: Research Conducted in the CTN** – This section was added to detail procedures for ancillary studies and secondary analyses. This is a new document and should be disseminated widely to Lead Investigators and others considering ancillary studies in the CTN. The new definition of an ancillary study is any type of study that is "attached" to a main, parent CTN study (regardless of funding). It is important to consider this document when considering collaborations.
4. **Section 2.3: Protocol Development and Approval** – This section was revised to indicate a new process for protocol review. Effective immediately, investigators will need to submit a 12-15 page document for initial review by an independent group. Once (or if) this study plan is approved, the study team can proceed to develop a complete protocol with data and safety plan for DSMB review. This is a new process for protocol review and should be disseminated to all staff at the Nodes.
5. **Section 3.5: Release of Data Prior to Data Lock** – This is a new section that indicates that (1) no outcome data will be released prior to data lock, and (2) if requested by the LI, a one time data set with pre-randomization data (baseline data) will be prepared soon after all participants are randomized. This is a new document and should be widely disseminated to all staff in the CTN and outside, especially for those considering ancillary studies.
6. **Section 3.6: Public Access Policy** – See box on page 2 of this Bulletin.
7. **Appendix III: DSMB Procedures** – The initial protocol review criteria were simplified.
8. **Appendix V: Guidance of Final Study Report Preparation** – This section was revised to clarify requirements for the final study report. The Lead Investigator should submit a final study report with nine sections plus appendices.

NIDA Blending Conference



Don't miss out on this state-of-the-art conference highlighting the science of addiction treatment, *Blending Science and Treatment: The Impact of Evidence-Based Practices on Individuals, Families and Communities*, June 2-3, 2008 in Cincinnati, Ohio. For additional information go to www.NIDABlendingConference.info

The Early Bird Conference Fee (\$79) is available through April 15, 2008. After this date the Regular Fee (\$99) will apply. The room block at the Cincinnati Hyatt is set up for travelers to make a single reservation to stay for the Blending Conference as well as the Steering Committee Meetings which follow June 4-6. You may make your reservation on-line by [clicking here](#) or you may call reservations (888) 421-1442 or the hotel at (513) 579-1234. Be sure to ask for the "NIDA" room block to receive the negotiated rate when you call.

The NIDA Networking Project (NNP)



The National Institute on Drug Abuse (NIDA) has a new website to reach drug abuse researchers, practitioners, and policy makers. The NIDA Networking Project (NNP) website provides opportunities for information sharing among those interested in addiction research and the potential for research collaboration among scientists across the country. The NNP Website gives users access to the locations, people, expertise, and resources of NIDA's research networks to help create synergies, improve efficiency, and accelerate scientific discovery. The NNP Website is located at: <http://nnp.drugabuse.gov>.

This one-stop portal to drug abuse resources includes the following information:

- Map locations and contacts for about 200 NIDA-supported network sites across the U.S.
- Links to scientific protocols and papers, as well as procedural policies and manuals
- The NNP Colleagues Directory—a searchable database of network members' expertise and research interests.

For more information, please contact:
Susan David at 301-435-0640 or davids2@nida.nih.gov.

CTN Dissemination Library Update



Three new papers have recently been added to the CTN Dissemination Library featuring study outcomes from protocols CTN 0011 (TELE), CTN 0013 (MET in Pregnant Substance Users), and CTN 0015 (Women & Trauma):

- [Improving the Transition from Residential to Outpatient Addiction Treatment: Gender Differences in Response to Supportive Telephone Calls](#) [CTN-0011] by Rickey E. Carter, et al. *American Journal of Drug and Alcohol Abuse* 2008;34(1):47-59.
- [Motivational Enhancement Therapy to Improve Treatment Utilization and Outcome in Pregnant Substance Users](#) [CTN-0013] by Theresa Winhusen, et al. *Journal of Substance Abuse Treatment* 2008 (in press).
- [Adverse Events in an Integrated Trauma-Focused Intervention for Women in Community Substance Abuse Treatment](#) [CTN-0015] by Therese Killeen, et al. *Journal of Substance Abuse Treatment* 2008 (in press).

Conference season is now approaching -- don't forget to submit your CTN-related presentations and posters to the Library! If you send your slides before the conference, we can give you the direct URL where your audience members and others can find your slides after the conference (we will wait to actually post your presentation/poster until after the conference is over, of course). Get your slide for the CTN Dissemination Library at the end of your presentation here:

<http://ctndisseminationslibrary.org/ctnsubmit.htm>

Submit your posters, presentations and other CTN-related documents to the Library by e-mailing them to: info@ctndisseminationslibrary.org. If you have any questions or comments about the Library, please don't hesitate to ask! The web site is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: <http://ctndisseminationslibrary.org>.

Where to Get Information on the CTN and NIDA



The NIDA CTN website includes information on the CTN Nodes, CTPs, and studies. For more information on the CTN go to: <http://www.nida.nih.gov/CTN/Index.htm> For information on NIDA (National Institute on Drug Abuse), please go to: <http://www.drugabuse.gov/>

How to Order Brochures, Conference Calls, etc.



To order materials or set up a call, please contact SEI (Synergy Enterprises Inc.) at: CTNSupport@sei2003.com

Data and Statistics Center (DSC) at DCRI



A new data audit process for the CTN was completed on February 8, 2008. All sites that are participating in the DSC data audits will continue to receive a 20-30% (of total expected enrollment) data audit as before.

A second audit at 70-80% of total expected enrollment will occur in only two instances. The first instance is if a site has an error rate that exceeds 50 errors per 10,000 fields on the first audit. The second instance is if the site is randomly selected for a second audit. Two sites from each protocol will be randomly selected for a follow-up audit. The new process went into effect March 18, 2008.

Who to Contact:



You may contact the Site Support Help Desk at 1-888-DSC-SSHD (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

Data Management Lead:

Lori Poole, B.A., Phone (919) 668-8238
lori.poole@dcri.duke.edu

Lead Statistician:

Jeff Leimberger, Ph.D., Phone (919) 668-8758
leimb001@dcri.duke.edu

NIDA Project Officer, Carol Cushing, at:
ccushing@nida.nih.gov, telephone (301) 443-9815.

Clinical Coordinating Center (CCC) at EMMES



Michele Straus, R.Ph., M.S., the CCC's Principal Investigator, has announced that she will be leaving the project in April. Her involvement and dedication to the network have been greatly appreciated. Robert Lindblad, M.D., the current CCC medical consultant, will assume leadership of the project on an interim basis and will represent the CCC on the Steering and the Executive Committees. He can be reached at: 301-251-1161 or rlindblad@emmes.com.

Federal Per Diem Rates



The General Services Administration (GSA) publishes guidance on domestic and international per diem rates for travelers.

The link for federal reimbursement for travel (specifically the per diem rates for each city) is at: <http://www.gsa.gov/Portal/gsa/ep/home.do?tabId=0>

Click on Per Diem Rates under Travel Resources.

Reminder to Grantees



All grantees must acknowledge funding received from the National Institute on Drug Abuse at the National Institutes of Health when

issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects funded in whole or in part with NIDA money. Advance notice should be given to NIDA when research findings are about to be published so that NIDA may coordinate accurate and timely release to the media. Any press notification should be coordinated with the NIDA Press Officer at (301) 443-6245.

Topics for CTN Articles in NIDA Notes

Please forward ideas for CTN related articles to Jeff Selzer (Long Island Node) at selzer@lij.edu

CTN Repository Data



The following information is taken from all studies that have reported data to the NIDA repository through February 29, 2008.

Pooled Ethnic Demographics: All Studies					
Hispanic	Non-Hispanic	No Answer or Missing Information			
19%	80%	1%			
Pooled Racial Demographics: All Studies					
Caucasian	African - American	Native American	Asian - Pacific Islander	Multiple Race	Unknown-Missing-Other
54%	22%	1.3%	0.5%	7%	15%
Pooled Gender Demographics: All Studies					
Male	Female	Msg - No Report			
59%	41%	0%			
Age Breakdown: All Studies					
< 25	25-35	35-45	45-55	55-65	>65
23%	26%	29%	19%	3%	0.2%

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