



Clinical Trials Network

CTN Bulletin

June 18, 2008

Volume 08 – 10

Trial Progress – Over 9,000!



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 May 31, 2008.

Open Studies (3)

- CTN 0027 – Randomized 759
- CTN 0028 – Randomized 303 (*Now closed*)
- CTN 0030 – Randomized 512
- CTN 0031 – Randomized 42
- **Total Randomized All Studies: 9,089**

CTN 0030 POATS



Congratulations to all the participating sites in the Prescription Opiate Addiction Treatment Study (POATS) for achieving a recruitment milestone. As of May 19th, over 500 participants have been randomized into Phase 1! Overall recruitment continues to progress well. Currently, the study is at 98% of expected randomizations. Meanwhile, health services researchers from Brandeis University continue to collect data for an ancillary study to assess the cost effectiveness of study treatments.

CTN 0014 BSFT Locks on June 5



The Brief Strategic Family Therapy for Adolescent Drug Abusers (BSFT™) trial has come to a close. The Lead Team reports that the database was officially locked on June 5! This is great news for this family therapy study which enrolled a total of 481 adolescent participants. The next step is evaluating the data and writing outcome papers. Great job team!

SC and EC Elections

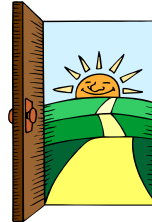


Both the Steering Committee (SC) and Executive Committee (EC) will have elections for new Chairs this summer. The EC will also elect half of its membership.

Start thinking of which position you may be interested in! The new members will take over their assignments with the October SC and EC meetings. Carol Cushing will send out a request for self-nominations before the elections are held.

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.

Looking for an Opportunity for Publication? Secondary Analysis of CTN Studies - Call for Concepts-Deadline June 30!



The accumulated data from completed CTN studies is a rich source of information about our study participants, our approach to care and our research endeavors. This wealth of information is waiting for investigators from the CTN to mine, extract and evaluate...and publish! Recognizing the importance of this opportunity, the CTN strongly encourages the design, conduct, and publication of secondary analyses.

To this end, CTN's Data and Statistics Center (DCRI) will support a total of 3 to 4 secondary analyses that involve multiple CTN studies. The service offered is comprehensive, with DCRI programmers and statisticians providing support from planning and executing the analyses through writing of the final article.

This is a great opportunity, and many important secondary questions have yet to be explored.

Don't delay! The last day to submit a concept for this round of proposals is June 30th.

To submit a concept, send a one to two page proposal to either Michele Straus or Paul Wakim and include the following information:

- Name of the primary investigator, with contact information
- Collaborators and co-authors to be included on the final paper
- Name of Node PI sponsoring the project
- Working title of the project
- Research question(s)/hypothesis(es) and its (their) importance
- CTN trials to be included
- Brief description of proposed analytic method(s)
- Preliminary timeline

For further information or to submit your proposal, contact Michele Straus (mstraus@nida.nih.gov) or Paul Wakim (pwakim@nida.nih.gov).

CTP Caucus – New Chair



The CTP (Community Treatment Program) Caucus met before the recent Steering Committee in Cincinnati, Ohio. John Hamilton (New England Node CTP – Regional Network of Programs) was elected to take over as the new Chair. Many thanks were given to outgoing Chair Michael Levy (Northern New England CTP – CAB Health and Recovery Services) for his service and dedication to this group. John will take over as Chair at the October meeting in Bethesda.

CTN 0032 Update



Site selection for the HIV Rapid Testing & Counseling (CTN 0032) protocol has been finalized. The CTN 0032 Investigative Team thanks all of the CTPs that participated in the multi-phase site selection process! The process is complete and a total of 12 geographically diverse CTPs representing a variety of treatment modalities, including methadone (or other narcotic replacement), residential, IOP and outpatient/ psychosocial counseling, were identified and invited to participate in the study on May 30, 2008. All CTPs accepted the invitation. We congratulate and welcome them aboard!

The sites are: Center for Psychiatric and Chemical Dependency Services (CPCDS) of the Appalachian Tri-State Node, La Frontera Center, Inc. of the California/Arizona Node, Daymark Recovery Services of the Florida Node, Chesterfield Adult Substance Abuse Services and Glenwood Life Counseling Center of the Mid-Atlantic Node, Midwestern Connecticut Council on Alcoholism (MCCA) and Wheeler Clinic Inc. of the New England Node, Gibson Recovery Center, Inc. of the Ohio Valley Node, CODA, Inc. of the Oregon/Hawaii Node, Lexington/Richland Alcohol and Drug Council (LRADAC) and Morris Village Alcohol & Drug Addiction Treatment Center of the Southern Consortium Node and Life Link of the Southwest Node.

All CTPs are currently working on submitting their budget requests to NIDA and preparing their IRB submissions. The initial protocol is currently being reviewed by the central IRB, Western IRB. After being approved, site-specific protocols will be submitted and reviewed on a rolling basis. The Investigative Team, various work groups and collaborators continue to develop the manual of operations, intervention materials and training materials with the goal of holding the Investigators Meeting during the second week of September 2008.

The NIDA Networking Project (NNP)



The NIDA Networking Project (NNP) is expanding. Three new networks have been added:

- Research Training & Career Development Program
- Medications Development Centers
- Maternal Opioid Treatment: Human Experimental Research (MOTHER) Project

Use of the NNP Website is growing, as well—thanks to links on network websites. The website is located at http://nnp.drugabuse.gov//index.php?option=com_content&task=view&id=93&Itemid=57 in PDF; or you can request printed copies by e-mailing Susan David at davids2@nida.nih.gov. For more information, please contact: Susan David at 301-435-0640 or davids2@nida.nih.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

CTN Data Share Web Site



Data from CTN 0003 and CTN 0013 are now available to the public on the CTN Public Data Share website (www.ctndatashare.org). The website also contains data from the following studies: CTN 0001, 0002, 0004-9, 0011, 0012 and 0016. The next protocols to post will be CTN 0021 in July and CTN 0018 in September.

The website is also undergoing some major improvements over the summer to enhance the user experience, including a more dynamic design, additional protocol descriptions, a searchable list of validated instruments, and more documentation to help download data and navigate the web site's content.

Check the website periodically to access recently posted data, study documentation and other new study information. The website will be updated with additional "data release dates" as more timelines become available. If you have suggestions about what you would like to see on the website or any questions about the website contents, please contact Cindy Green at cindy.green@duke.edu or Carol Cushing at ccushing@nida.nih.gov.

Grants Tidbit Corner – New Grants



The following grant opportunities may be of interest to researchers in the CTN:
Notice of Intent to Publish a Request for Applications for Effects of Physical

Activity and Exercise on Drug Use and Abuse
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-018.html>

Notice of Availability of Set-aside Funds for FY 2009 for PAS-08-061
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-019.html>

Notice of Intent to Publish a Request for Applications for Research Centers to participate in the Criminal Justice Drug Abuse Treatment Studies 2 (U01)
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-017.html>

Quantitation of Drugs of Abuse and Related Substances in Biological Specimens
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-029.html>

Economics of Treatment and Prevention Services for Drug & Alcohol Abuse (R21)
<http://grants.nih.gov/grants/guide/pa-files/PA-08-172.html>

Economics of Treatment and Prevention Services for Drug & Alcohol Abuse (R21)
<http://grants.nih.gov/grants/guide/pa-files/PA-08-173.html>

Economics of Treatment and Prevention Services for Drug & Alcohol Abuse (R01)
<http://grants.nih.gov/grants/guide/pa-files/PA-08-174.html>

Please note the anticipated dates for conversion to e-applications for training and career mechanisms.
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-08-073.html>

February 12, 2009 - Research Career Development (all Ks except K12)

April 8, 2009 - Individual National Research Service Awards (F)

September 25, 2009 - Institutional National Research Service Awards and Other Training Grants (T, D), D43, D71/U2R and K12

NIDA Blending and CTN SC Presentations



If you missed the recent NIDA Blending Meeting in Cincinnati or want to learn more about the sessions, PowerPoint presentations for which presenter permission has been given are now available at

<http://www.sei2003.com/nida/blendingcinci/topics.htm>. Additional presentations will be added over the coming weeks as soon as presenters' permission is granted. The presentations given at the Steering Committee (SC) Meeting in Cincinnati are now available on LiveLink at: <https://livelink.nida.nih.gov/livelink/llisapi.dll?func=ll&objId=8772207&objAction=browse&sort=name&viewType=1>

UCLA CALDAR Summer Institute on Longitudinal Research



NIDA (National Institute on Drug Abuse) and CSAT (Center for Substance Abuse Treatment SAMHSA) are two of the sponsors of the UCLA CALDAR Summer Institute on Longitudinal Research. The three-day event will be held August 13-15, 2008, on the UCLA campus in Los Angeles. This conference will address current findings and future directions in longitudinal research on drug and alcohol abuse, HIV, mental health, and criminal justice. Longitudinal statistical/research methods and clinical workshops will also be offered.

The deadline to submit a poster abstract and to apply for a travel award (all investigators and substance abuse treatment provider staff can now apply) has been extended to Monday, June 30. For details and instructions on registration and submission of abstracts and travel award applications, please visit their website at www.caldar.org or e-mail Liz Evans (laevans@ucla.edu) or Cheryl Teruya (cteruya@ucla.edu).

News from the Northern New England Node

Shelly Greenfield, M.D., M.P.H. (Co-PI of the Northern New England Node) recently received the



Massachusetts Psychiatric Society 2008 Outstanding Psychiatrist Award for Research. Dr. Greenfield received the honor in recognition of her contributions to the field of substance abuse research, with a particular focus on gender differences in the prevention and treatment of substance use disorders. Congratulations Shelly!

RWJ Health & Society Scholars



The 2008-2009 Call for Applications for the Robert Wood Johnson (RWJ) Foundation Health & Society Scholars program has been released and is available at the following link:

http://www.rwjf.org/files/applications/cfp/HSS0809_cfp.pdf

The goal of the RWJ Foundation Health & Society Scholars program is to improve health by training scholars to:

- Investigate rigorously the connections among biological, genetic, behavioral, environmental, economic and social determinants of health; and
- Develop, evaluate and disseminate knowledge and interventions that integrate and act on these determinants to improve health.

Tips on Referencing NIDA and CTN



The CTN “snowflake” is not considered an official logo and may be used on any materials you develop. Some groups and Nodes have created their own logos to use on documents and web sites. Remember, the NIDA name and logo are only for official government documents and can not be used by others. Please review all materials and websites to ensure that you keep within guidelines. Contact Carol Cushing if you need clarification on this issue. Thanks!

Delaware Valley News



Drs. George Woody (Node PI) and Dmitry Lioznov, Infectious Disease specialist at Pavlov State Medical University in St. Petersburg, Russia, presented results of studies on the spread of HIV in St. Petersburg and the Leningrad Region, and

on naltrexone for preventing relapse to heroin addiction and HIV risk behavior. The meeting was held in Kiev, Ukraine during the week of April 17 and was sponsored by NIDA and the U.S. Civilian Research & Development Foundation. The conference was attended by physicians from a number of former Soviet States. The focus was on developing studies and interventions to reduce the spread of HIV and other infectious diseases by expanding and improving current approaches to drug abuse treatment. The meeting was timely in that after a very long series of delays, the import license for methadone was signed. A consignment of methadone that is sufficient to treat about 3000 patients over the next year cleared Ukrainian customs. It is now available to be used in the medication assisted treatment infrastructure that is being put in place in Ukraine.

Florida Node News



In keeping with the NIDA Clinical Trial Network’s mission to use science as the vehicle for improving the public’s health, Dr. José Szapocznik recently joined University of Miami

President Donna Shalala in efforts to create public consciousness of the drug abuse/HIV epidemic and its public health consequences for both the English and Spanish speaking communities in Miami, Florida. Drs. Szapocznik and Shalala co-contributed to an article which appeared in both the Spanish and English versions of Miami’s premier newspapers, El Nuevo Herald and The Miami Herald, respectively, intended to stimulate public debate about the link between injection drug use, health policy and the spread of HIV/AIDS in communities. President Shalala commented on noted CDC and NIH studies. Dr Szapocznik, Principal Investigator of the Florida Node and Chair of the University Of Miami Miller School Of Medicine’s Department of Epidemiology and Public Health, also addressed the topic of needle exchange programs.

To access both the English and Spanish language news stories, click on these links:

http://www.miamiherald.com/news/miami_dade/story/542386.html

http://www6.miami.edu/UMH/CDA/UMH_Main/1,1770,39370-1;62450-3,00.html

APA Meeting Highlights



The American Psychiatric Association (APA) Annual Meeting was held May 5-7, 2008. On May 5, Drs. Petra Jacobs (NIDA CCTN) and George Woody (Delaware Valley) co-chaired

a symposium entitled "Diagnosis and Treatment of Adolescents/Young Adults with Substance Use Disorder." Presentations were made by Drs. Oscar Bukstein from the Appalachian-Tri-State Node, Geetha Subramaniam from the Mid-Atlantic Node, Ramon Solhkhah from the Long Island Regional Node, Michael Robbins from the Florida Node, and Dr. Woody from the Delaware Valley Node. The symposium was well-attended and the audience asked many questions, which is usually an expression of interest in the topic. Great job everyone!

Topics for CTN Articles in NIDA Notes

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

Attention CPDD Conference Presenters!



It's conference season again, so if you making presentations about the CTN at CPDD, NIATx, or other conferences this summer, please send your CTN-related presentations and posters to the **CTN Dissemination Library**. You may want to give out the URL or include a slide for the CTN Dissemination Library so your audience (and others) will be able to view your presentation later -- download the slide here: <http://ctndisseminationslibrary.org/ctnsubmit.htm>.

We're currently linking presentations from the recent NIDA Blending Conference to the CTN Library, where they'll be cross-referenced with articles and other materials from related CTN research. View the [What's New page](#) (or [subscribe to the RSS feed](#)) for updates about the Blending presentations in the Library.

New in the Library are two articles from the *Journal of Substance Abuse Treatment*:

- [Measurement and Data Analysis in Research Addressing Health Disparities in Substance Abuse](#), by Ann Kathleen Burley, Daniel Feaster, Mary-Lynn Brecht, and Robert Hubbard, describes concrete strategies for conducting substance abuse research with ethnic minorities, addressing two major issues associated with valid analysis: measurement and data analysis.
- [Using a Standardized Patient Walk-Through to Improve Implementation of Clinical Trials](#), by Holly Fussell, Lynn Kunkel, Colleen Lewy, Bentson McFarland, and Dennis McCarty, describes the use of a standardized patient (an actor trained to portray a set of symptoms) in facilitating the implementation of protocol CTN-0030 (Prescription Opiate Addiction Treatment Study (POATS)).

Add your posters, presentations, articles, and other CTN-related documents to the Library by e-mailing them to: info@ctndisseminationslibrary.org. If you have questions or comments, please ask! The library web site is <http://ctndisseminationslibrary.org>.

Sites to Remember!

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

Federal PerDiem Rates and GSA Forms

<http://www.gsa.gov/Portal/gsa/ep/home.do?tabId=0>

CRISP Data base

<http://crisp.cit.nih.gov/>

Three Students Win First-Ever NIDA Scholastic Addiction Science Award at ISEF



For the first time ever, three students received awards for exemplary projects in Addiction Science at the world's largest science competition for high school students - the Intel International Science and Engineering Fair (ISEF). The new Addiction Science award is co-sponsored by NIDA and its education partner Scholastic, the global children's publishing, education and media company. This is the first series of Intel awards given exclusively for projects that advance addiction science.

A16-year-old senior, Kapil Vishveshwar Ramachandran, from Westwood High School in Austin, Texas, received top honors and a cash award of \$2500 for his project, *The Novel Role of the GluCl α ; Ion Channel and Diazepam Binding Genes in Alcohol Addiction*, an ambitious exploration of the basic mechanisms underlying addiction. The winning young scientist determined that when a specific protein (Diazepam binding inhibitor) is deleted in fruit flies, the flies may lose their tolerance to alcohol. Although the protein had been previously identified, these findings are a strong indication that it may play a role in addiction.

Winning second place distinction and \$1500 was Ethan Garrett Guinn, from Moore High School in Moore, Oklahoma, for his project, *Video Games: The Next Generation's Addiction*. The 17-year-old senior chose the topic based on his own observation that video games are often used as babysitting tools, yet can lead to obsessive use.

The third place \$1000 cash award was given to freshman Shelby Marie Raye from Manatee High School in Bradenton, Florida. Her project, *What's In and What's Out: High Schoolers' Perceptions of Coolness*, identified unique parameters that affect life trajectories, and may help scientists better understand peer pressure, a factor in initiation of substance abuse.

Plan for October SC



The fall Steering Committee will be held October 21-23, 2008, in Bethesda, Maryland. Mark your calendars now! Hotel and meeting information will be sent out later this summer.

Federal Offices Closed



The CCTN office and NIDA will be closed on Friday, July 4, 2008, for the Independence Day holiday observance.

Clinical Coordinating Center (CCC) at EMMES

Regulatory Facts & Tidbits – How do you obtain informed consent from someone who speaks and understands but cannot read English?



Illiterate persons who understand English may have the consent read to them and "make their mark," if appropriate under applicable state law. The 21 CFR

50.27(b)(2) requirements for signature of a witness to the consent process and signature of the person conducting consent interview must be followed, if a "short form" is used. Clinical investigators should be cautious when enrolling subjects who may not truly understand what they have agreed to do. The IRB should consider illiterate persons as likely to be vulnerable to coercion and undue influence and should determine that appropriate additional safeguards are in place when enrollment of such persons is anticipated, see 21 CFR 56.111(b).

Training - The table below provides the status of attendees for the recent Web Seminar Series 2008. The CCC would like to thank Carol Cushing, Debbie Drosdick, Anthony Floyd, and Katharina Wiest for their contribution to the Site Management Overview held on June 12, 2008.



Training ideas requests and comments are welcome and may be addressed to

cntraining@emmes.com or ebuttrey@emmes.com.

CCC Webinar Series			
	Time Line Follow Back	Site Management	Recruitment and Retention
Dates	May 15	June 12	June 18
Number of Participants	32	40	38
Number of Nodes	11	9	9

A new contact list of all EMMES personnel has been added as an attachment to this Bulletin.

Other CCC related questions and topics- Bob Lindblad at 301-251-1161, rlindblad@emmes.com, ctnsupport@emmes.com for laboratory and/or medication supplies, and ctnsafety@emmes.com for safety related issues/adverse event follow-up.

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

Data and Statistics Center (DSC) at DCRI



The DSC is planning to launch a new utility of the Clinical Research Information System (CRIS) in June 2008. This utility will include enhancements for CRIS v1.7.1 and v1.8.1. Features of the two versions are as follows:

- CRIS v1.7.1 includes:
 - Codified reasons for use when a participant misses a visit.
 - Partially Complete (Versus Missed) - a new status used when a participant does not complete all of the assessments within a visit window.
- CRIS v1.8.1 includes:
 - Skip Visit functionality - used to move past an assessment that has not been completed in a visit in order to administer assessments in the next visit.
 - Auto Complete Feature - used to write data to the analysis table when an assessment is partially completed.

If your project uses CRIS, the DSC issued a training URL to allow the Research Assistants to become familiar with the system and the new functions. Training slides were also released for the system. If you do not have access to the training URL, please contact the DSC Helpdesk toll free at 1-888-372-7743.

The DSC reminds users that CRIS is intended to capture electronic Patient Reported Outcome (ePRO) data. Participants should complete the assessments or ePRO data at the time of their visit in the CRIS system and not on paper source. A paper source is only appropriate when the CRIS system is not functioning.

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@dcric.duke.edu

Lead Statistician:

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

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

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